Risk Factors Comparison 2024-02-27 to 2023-03-09 Form: 10-K

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Our business, financial condition, and operating results may be affected by a number of factors, whether currently known or unknown, including but not limited to those described below. Any one or more of such factors could directly or indirectly cause our actual results of operations and financial condition to vary materially from past or anticipated future results of operations and financial condition. Any of these factors, in whole or in part, could materially and adversely affect our business, financial condition, results of operations, and stock price. The following information should be read in conjunction with Part II, Item 7, " Management' s Discussion and Analysis of Financial Condition and Results of Operations " and the consolidated financial statements and related notes in Part II, Item 8, " Financial Statements and Supplementary Data " of this Annual Report. ~~Risk~~ **Risks Related** ~~Factor Summary Investing in our common stock involves a high degree of risk because our business is subject~~ to ~~numerous risks~~ **Our Financial Condition** and **Capital Requirements** ~~uncertainties, as fully described below. The principal factors and uncertainties that make investing in our common stock risky include, among others: •~~ We will need to raise additional capital, and if we are unable to do so when needed, we will not be able to continue as a going concern. ~~• We have historically incurred losses, have a limited operating history on which to assess our business, and anticipate that we will continue to incur significant losses for the foreseeable future. • We have never generated any revenue from product sales and may never be profitable. • Raising additional capital may cause dilution to our stockholders, restrict our operations, or require us to relinquish rights. • Clinical trials are costly, time consuming, and inherently risky, and we may fail to demonstrate safety and efficacy to the satisfaction of applicable regulatory authorities. • Our product candidates may cause undesirable side effects or have other properties that could delay or prevent their regulatory approval, limit the commercial viability of an approved label, or result in significant negative consequences following marketing approval, if any. • We are heavily dependent on the success of our product candidates, which are in the early stages of clinical development. Some of our product candidates have produced results only in non- clinical settings, or for other indications than those for which we contemplate conducting development and seeking FDA approval, and we cannot give any assurance that we will generate data for any of our product candidates sufficiently supportive to receive regulatory approval in our planned indications, which will be required before they can be commercialized. • Product development involves a lengthy and expensive process with an uncertain outcome, and results of earlier preclinical studies and clinical trials may not be predictive of future clinical trial results. Risks Related to Our Financial Condition and Capital Requirements~~ As of December 31, ~~2022~~ **2023** , we had $ ~~424~~ **477** . ~~6~~ **4** million of cash, cash equivalents, and short- term investments. **In January** ~~We believe that our current cash, cash equivalents and short- term investments, including the Term Loan, will be sufficient to fund our operations, including our clinical development plan described elsewhere in this Annual Report, into the second half~~ of ~~2025~~ **2024** ~~. We will need to raise additional capital to continue to fund our operations and service our obligations in the future. If we are unable to raise additional capital when needed~~ , we **sold** will not be able to continue as..... party payors, and adequate market share **shares** ~~for our product candidates in those markets. We expect to continue to incur significant expenses and increasing operating losses for the foreseeable future and our expenses will increase substantially if and as we: • continue the development~~ of ~~our product candidates; • continue efforts to discover and develop new product candidates; • continue the manufacturing of our product candidates or~~ **our common stock (i)** ~~increase volumes manufactured by third parties; • advance our programs into large expensive clinical trials; • initiate additional preclinical studies or clinical trials for our product candidates; • seek regulatory and marketing approvals and reimbursement for our product candidates; • establish a sales, marketing, and distribution infrastructure to commercialize any products for which we may obtain marketing approval and market for ourselves; • seek to identify, assess, acquire, and / or develop other product candidates; • make milestone, royalty, or other payments~~ under third- party license agreements; •..... or other preferences that adversely affect your - **our** rights as a stockholder. Debt financing..... including pursuant to any sales under the Open Market Sale AgreementSM entered into in September 2022 (the " September 2022 ATM Agreement ") with Jefferies LLC (" Jefferies ") rights as a stockholder.Debt financing and preferred equity 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 marketing,distribution,or licensing arrangements with third parties,we may be required to relinquish valuable rights to our 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 or other arrangements with third parties when needed,we may be required to delay,limit,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.To the extent that we raise additional capital through the sale of equity,including pursuant to any sales under ~~our~~ **the** , convertible debt, or other securities convertible into equity, the ownership interest of our stockholders will be diluted, and the terms of these new securities may include liquidation or other preferences that adversely affect the rights of our stockholders. ~~In December 2019, the Company entered into a common stock purchase agreement (the " Aspire Stock Purchase Agreement ") with Aspire Capital, LLC (" Aspire Capital "). Any~~ additional sales of our ~~common~~ **capital** stock **by us** ~~under the September 2022 ATM Agreement and the Aspire Common Stock Purchase Agreement~~ will dilute the ownership interest of our stockholders and may cause the price per share of our common stock to decrease. In addition, any exercise of outstanding warrants will dilute the ownership interest of our stockholders and may cause the price per share of our common stock to decrease. Debt financing, including under our Hercules Loan and Security Agreement, may include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt,

making capital expenditures, making additional product acquisitions, or declaring dividends. If we raise additional funds through strategic collaborations or licensing arrangements with third parties, we may have to relinquish valuable rights to our product candidates or future revenue streams or grant licenses on terms that are not favorable to us. We cannot be assured that we will be able to obtain additional funding if and when necessary to fund our entire portfolio of product candidates to meet our projected plans. If we are unable to obtain funding on a timely basis, we may be required to delay or discontinue one or more of our development programs or the commercialization of any product candidates or be unable to expand our operations or otherwise capitalize on potential business opportunities, which could materially harm our business, financial condition, and results of operations. Business disruptions could seriously harm our future revenue and financial condition and increase our costs and expenses. Our operations, and those of our third- party research institution collaborators, contract research organizations (" CROs "), contract manufacturing operations (" CMOs "), and other contractors and consultants, could be subject to acts of war, earthquakes, power shortages, telecommunications failures, water shortages, floods, hurricanes, typhoons, fires, extreme weather conditions, medical pandemics or epidemics, such as the novel coronavirus, and other natural or man-made disasters or business interruptions, for which we are partly uninsured. In addition, we rely on our third- party research institution collaborators for conducting research and development of our product candidates, and they may be affected by government shutdowns or withdrawn funding. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses. **We maintain our cash at financial institutions, often in balances that exceed federally- insured limits. The failure of financial institutions could adversely affect our ability to pay our operational expenses or make other payments. Our cash held in non- interest- bearing and interest- bearing accounts exceeds the Federal Deposit Insurance Corporation (" FDIC ") insurance limits. If such banking institutions were to fail, we could lose all or a portion of those amounts held in excess of such insurance limitations. For example, the FDIC took control of Silicon Valley Bank on March 10, 2023. The Federal Reserve subsequently announced that account holders would be made whole. However, the FDIC may not make all account holders whole in the event of future bank failures. In addition, even if account holders are ultimately made whole with respect to a future bank failure, account holders' access to their accounts and assets held in their accounts may be substantially delayed. Any material loss that we may experience in the future or inability for a material time period to access our cash and cash equivalents could have an adverse effect on our ability to pay our operational expenses or make other payments, which could adversely affect our business.** Risks Related to the Discovery and Development of Our Product Candidates **Clinical trials are costly, time consuming, and inherently risky, and we may fail to demonstrate safety and efficacy to the satisfaction of applicable regulatory authorities.** Clinical development is expensive, time consuming, and involves significant risk. We cannot guarantee that any clinical trials will be conducted as planned or completed on schedule, if at all. A failure of one or more clinical trials can occur at any stage of development. Events that may prevent successful or timely completion of clinical development include but are not limited to: • inability to generate satisfactory preclinical, toxicology, or other in vivo or in vitro data or diagnostics to support the initiation or continuation of clinical trials; • delays in reaching agreement on acceptable terms with CROs and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs, clinical trial sites, and in countries or regions where our trials are conducted; • delays in obtaining required approvals from institutional review boards or independent ethics committees at each clinical trial site; • failure to permit the conduct of a clinical trial by regulatory authorities; • delays in recruiting eligible patients and / or subjects in our clinical trials; • failure by clinical sites, CROs, or other third parties to adhere to clinical trial requirements; • failure by our clinical sites, CROs, or other third parties to perform in accordance with **current GCP** ~~the good clinical practices~~ requirements of the FDA or applicable foreign regulatory guidelines; • patients and / or subjects dropping out of our clinical trials; • adverse events or tolerability or animal toxicology issues significant enough **in our studies, in studies of third parties, or as reported for marketed products** for the FDA or other regulatory agencies to put any or all clinical trials on hold **, require us to change how we conduct our IND- enabling studies or our ongoing or future trials, including amending or submitting new clinical protocols or additional safety monitoring or measurements** ; • occurrence of adverse events associated with our product candidates; • changes in regulatory requirements and guidance that require amending or submitting new clinical protocols; • significant costs of clinical trials of our product candidates, including manufacturing activities; • negative or inconclusive results from our clinical trials **or the trials of third parties with related or similar product candidates** , which may result in our deciding, or regulators requiring us, to conduct additional clinical trials or abandon development programs in other ongoing or planned indications for a product candidate **, or change how we conduct our IND- enabling studies or our ongoing or future trials, including amending or submitting new clinical protocols or additional safety monitoring or measurements** ; and • delays in reaching agreement on acceptable terms with third- party manufacturers and the time to manufacture sufficient quantities of our product candidates acceptable for use in clinical trials. **We are expecting that that the THRIVE and THRIVE- 2 Phase 3 clinical trials, together with a safety database comprising 300 treated patients, will support global health authority registration for VRDN- 001 IV for marketing approval in both active and chronic TED, respectively. However, the FDA or other regulatory authorities may require additional patients in this safety database or may require us to take other additional steps. We are also intending in mid- 2024 to initiate what we expect to be a pivotal program for VRDN- 003, pending regulatory authority alignment. The FDA or other regulatory authorities may require us to take other additional steps in the course of development and regulatory interaction regarding our product candidates, including, without limitation, initiating new trials, conducting bridging studies or enrolling more patients, or requiring us to assess additional parameters related to safety or efficacy. Such additional requirements could increase the cost of development of our product candidates, negatively affect our anticipated timelines, delay our time to market with our product candidates, if approved, and could harm our business.** The FDA may withdraw approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of

previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of post- market studies or clinical studies to assess new safety risks; or imposition of distribution restrictions or other restrictions **, for example,** under a REMS program. Other potential consequences include, among other things: • restrictions on the marketing or manufacturing of a product, complete withdrawal of the product from the market, or product recalls; • fines, warning letters, or holds on post- approval clinical studies; • refusal of the FDA to approve pending applications or supplements to approved applications, or suspension or revocation of existing product approvals; • product seizure or detention, or refusal of the FDA to permit the import or export of products; or • injunctions or the imposition of civil or criminal penalties. Any inability to successfully complete clinical development and obtain regulatory approval for our product candidates could result in additional costs to us or impair our ability to generate revenue. In addition, if we make manufacturing or formulation changes to our product candidates, we may need to conduct additional **clinical or** nonclinical studies and the results obtained from studying such new formulation may not be consistent with previous results obtained. Clinical trial delays could also shorten any periods during which our products have patent protection and may allow competitors to develop and bring products to market before we do, which could impair our ability to successfully commercialize our product candidates and may harm our business and results of operations. **Our product candidates may cause undesirable side effects or have other properties that could delay or prevent their regulatory approval, limit the commercial viability of an approved label, or result in significant negative consequences following marketing approval, if any.** Undesirable side effects caused by our product candidates **, or other product candidates in the TED space,** could cause us or regulatory authorities to interrupt, delay, or terminate clinical trials. ~~They~~ **Such side effects** additionally may result in a delay of regulatory approval by the FDA **, EMA,** or comparable foreign authorities, or, even in the instance that an affected product candidate is approved, may result in a restrictive drug label **. For example, hearing impairment observed in Tepezza ®, or other negative side effects of other IGF- 1R antagonists in development, may negatively affect clinical trials for our product candidates, delay regulatory approval or result in a restrictive drug label, if approved** . Even if one or more of our product candidates receives marketing approval, and we or others later identify undesirable side effects caused by such products, potentially significant negative consequences could result, including but not limited to: • regulatory authorities may withdraw approvals of such products; • regulatory authorities may require additional warnings on the drug label; • we may be required to create a REMS, which could include a medication guide outlining the risks of such side effects for distribution to patients, a communication plan for healthcare providers, and / or other elements to assure safe use; • we could be sued and held liable for harm caused to patients or subjects; and • our reputation may suffer. Any of these events could prevent us from achieving or maintaining market acceptance of a product candidate, even if approved, and could significantly harm our business, results of operations, and prospects. **Additional time may be required to obtain marketing authorizations for certain of our product candidates because they are, or are anticipated to be, drug- device combination products. Some of our product candidates, including VRDN- 003, VRDN- 006 and VRDN- 008, are or are anticipated to be drug- device combination products that will require coordination within the FDA and similar foreign regulatory agencies for review of their device and drug components. Although the FDA and similar foreign regulatory agencies have systems in place for the review and approval of combination products, we may experience delays in the development and commercialization of our product candidates due to complexities arising from them being combination products and associated regulatory timing constraints and uncertainties in the product development and approval process. Of note, prior clearance or approval of one component of a combination product does not increase the likelihood that the FDA will approve a later product combining the previously cleared product or approved active ingredient with a novel active ingredient. See " Business — Government Regulation — Regulation of Combination Products. "** Our product development program may not uncover all possible adverse events that patients or subjects who take our product candidates may experience. The number of patients or subjects exposed to our product candidates and the average exposure time in the clinical development program may be inadequate to detect rare adverse events that may only be detected once the product is administered to more patients or subjects and for greater periods of time. Clinical trials by their nature utilize a sample of the potential patient population. However, with a limited number of subjects and limited duration of exposure, we cannot be fully assured that rare and severe side effects of our product candidates will be uncovered. Such rare and severe side effects may only be uncovered with a significantly larger number of patients or subjects exposed to the drug. If such safety problems occur or are identified after our product candidates reach the market, the FDA may require that we amend the labeling of the product or recall the product or may even withdraw approval for the product. We are heavily dependent on the success of our product candidates **,** and we cannot give any assurance that we will generate data for any of our product candidates sufficiently supportive to receive regulatory approval in our planned indications, which will be required before they can be commercialized. We have invested substantially all of our effort and financial resources to identify, acquire, and develop our portfolio of product candidates. Our future success is dependent on our ability to successfully develop, obtain regulatory approval for and commercialize one or more product candidates. We currently generate no revenue from sales of any products, and we may never be able to develop or commercialize a product candidate. We continue to evaluate and pursue additional opportunities to expand our product pipeline, either by discovering novel antibodies **or proteins** internally, or by acquiring rights to existing antibodies or antibody sequences **or proteins and protein sequences** . Our goal is to build a sustainable portfolio of ~~investigational monoclonal~~ **protein and** antibody therapies. We currently have a limited number of product candidates. There can be no assurance that the data that we may or may not develop for our product candidates in our planned indications will be sufficiently supportive to obtain regulatory approval. We are not permitted to market or promote any of our product candidates before they receive regulatory approval from the FDA **, EMA,** or comparable foreign regulatory authorities, and we may never receive such regulatory approval for any of our product candidates. We cannot be certain that any of our product candidates will be successful in clinical trials or receive regulatory approval. Further, our

product candidates may not receive regulatory approval even if they are successful in clinical trials. If we do not receive regulatory approvals for our product candidates, we may not be able to continue our operations. **Product development involves a lengthy and expensive process with an uncertain outcome, and results of earlier preclinical studies and clinical trials may not be predictive of future clinical trial results.** Clinical testing is expensive and generally takes many years to complete, and the outcome is inherently uncertain. Failure can occur at any time during the clinical trial process. The results of preclinical studies and early clinical trials of our product candidates may not be predictive of the results of larger, later- stage controlled clinical trials. Product candidates that have shown promising results in early- stage clinical trials may still suffer significant setbacks in subsequent clinical trials **. In addition, from time to time, we may publicly disclose interim, topline, or preliminary 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 as more patient data become available. The interim, topline, or preliminary results that we report may differ from final results upon study completion, or different conclusions or considerations may qualify such results** . We will have to conduct well- controlled trials in our proposed indications to support any regulatory submissions for further clinical development. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or adverse safety profiles despite promising results in earlier, smaller clinical trials. **Larger scale clinical trials for our product candidates may generate additional data that raise issues regarding the safety and efficacy of our product candidates that were not observed in smaller clinical trials. Certain approaches that we take in our clinical trials may differ in important respects as compared to the trials of our competitors, which may lead to negative regulatory and / or commercial outcomes.** Moreover, clinical data are often susceptible to varying interpretations and analyses. We do not know whether any clinical trials we may conduct will demonstrate consistent or adequate efficacy and safety of our product candidates, with respect to the proposed indication for use, sufficient to receive regulatory approval to market our drug candidates. **Additionally, differences in our clinical trial designs as compared to those of our competitors could render our product candidates less attractive. Preliminary data from our clinical trials that we announce or publish are subject to audit and verification procedures that could result in material changes in the final data. From time to time, we publish preliminary data from our clinical trials. On December 18, 2023, we reported clinical data from our Phase 1 clinical study in healthy volunteers and announced the selection of VRDN- 003 as our lead subcutaneous program for TED. This data set includes preliminary data which was not subject to the standard quality control measures typically associated with final clinical trial results. Based on the comparable pharmacology of VRDN- 003 to VRDN- 001, we believe VRDN-003 has the potential to maintain the clinical response of VRDN- 001 IV while significantly increasing patient convenience. If this preliminary clinical data on VRDN- 003 changes following audit and verification, it could negatively impact the development of VRDN- 003 and could harm our business prospects. However, the data from our Phase 2 trials for VRDN- 001 may also not be fully reflective of topline results for our Phase 3 THRIVE and THRIVE- 2 trials which are expected in the middle of 2024 and by year end 2024, respectively. If clinical data from VRDN- 001 is not positive, it could negatively impact the development of VRDN- 003 and could harm our business prospects. Topline or preliminary data from our clinical trials that we announce or publish from time to time, including the data from our Phase 1 study in healthy volunteers and the masked data for VRDN- 001 from our ongoing trials, may change as more patient data become available, and we become subject to audit and verification procedures that could result in material changes in the final data. This creates a risk that the final results could be materially different from the preliminary results reported to date. Additionally, differences in patient populations across our clinical trials may lead to inconsistent or unrepresentative data. Significant adverse differences between preliminary data and final, audited and verified data could negatively affect the prospect of regulatory approval for our product candidates and could materially harm our reputation and business prospects.** We may use our financial and human resources to pursue a particular research program or product candidate and fail to capitalize on programs or product candidates that may be more profitable or for which there is a greater likelihood of success. Because we have limited financial and human resources, we may forgo or delay **the** pursuit of opportunities with some programs or product candidates or for other indications **,** that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or more profitable market opportunities. Our spending on current and future research and development programs and future product candidates for specific indications may not yield any commercially viable products. We may also enter into additional strategic collaboration agreements to develop and commercialize some of our programs and potential product candidates in indications with potentially large commercial markets. 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 strategic collaborations, 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 **. We** ~~, or we~~ may allocate internal resources to a product candidate in a therapeutic area in which it would have been more advantageous to enter into a collaboration arrangement. We may find it difficult to enroll and maintain patients or subjects in our clinical trials, in part due to the limited number of patients or subjects who have the diseases for which our product candidates are being studied **or the availability of competing therapies and clinical trials** . We cannot predict if we will have difficulty enrolling and maintaining patients or subjects in our future clinical trials. Difficulty in enrolling and maintaining patients or subjects could delay or prevent clinical trials of our product candidates. Identifying and ~~qualifying~~ **enrolling** patients or subjects to participate in clinical trials of our product candidates is essential to our success. The timing of our clinical trials depends in part on the rate at which we can recruit patients or subjects to participate in clinical trials of our product candidates, and we may experience delays in our clinical trials if we encounter difficulties in enrollment. **Our current or future clinical trials may also face increased competition for eligible patients for enrollment, for example, as a result of additional therapies for TED being tested in clinical trials.** In addition, our enrollment has been

and may in the future be delayed due to supply chain delays and difficulties in site activation **. Delays in enrollment may delay the generation of clinical data and the completion of our clinical trials** . The eligibility criteria of our clinical trials may further limit the available eligible trial participants as we expect to require that patients or subjects have specific characteristics that we can measure or meet the criteria to assure their conditions are appropriate for inclusion in our clinical trials. Accordingly, we may not be able to identify, recruit, enroll ~~,~~ and maintain a sufficient number of patients or subjects to complete our ~~future~~ clinical trials in a timely manner because of the perceived risks and benefits of the product candidate under study, the availability and efficacy of competing therapies and clinical trials, the option for patients to choose alternate existing approved therapies ~~,~~ and the willingness of physicians to participate in our planned clinical trials. ~~Our~~ **Additional factors outside our control, such as pandemics or other public health crises, may also impact our** ability to enroll patients in our planned clinical trials ~~may be impacted by the COVID- 19 pandemic, or any future disease pandemic~~ . If patients or subjects are unwilling or unable to participate in our clinical trials for any reason, the timeline for conducting trials and obtaining regulatory approval of our product candidates may be delayed. If we experience delays in the completion of, or termination of, any clinical trials of our product candidates, the commercial prospects of our product candidates could be harmed, and our ability to generate product revenue from any of these product candidates could be delayed or prevented. In addition, any delays in completing our clinical trials would likely increase our overall costs, impair product candidate development, and jeopardize our ability to obtain regulatory approval relative to our current plans. Any of these occurrences may harm our business, financial condition, and prospects significantly. We may face ~~potential product~~ liability **for our products** , ~~and~~ **if approved** , **and for our product candidates, and** if successful claims are brought against us, we may incur substantial liability and costs. If the use or misuse of our approved products, if any, or product candidates harm patients or subjects, or is perceived to harm patients or subjects even when such harm is unrelated to our approved products, if any, or product candidates, our regulatory approvals, if any, could be revoked or otherwise negatively impacted, and we could be subject to costly and damaging product liability claims. If we are unable to obtain adequate insurance or are required to pay for liabilities resulting from a claim excluded from, or beyond the limits of, our insurance coverage, a material liability claim could adversely affect our financial condition. The use or misuse of our product candidates in clinical trials and the sale of any products for which we may obtain marketing approval exposes us to the risk of potential product liability claims. There is a risk that our product candidates may induce adverse events. If we cannot successfully defend against product liability claims, we could incur substantial liability and costs. Patients with the diseases targeted by our product candidates may already be in severe and advanced stages of disease and have both known and unknown significant preexisting and potentially life- threatening health risks. During the course of treatment, patients may suffer adverse events, including death, for reasons that may or may not be related to our product candidates. Such events could subject us to costly litigation, require us to pay substantial amounts of money to injured patients, delay, negatively impact, or end our opportunity to receive or maintain regulatory approval to market our products, or require us to suspend or abandon our commercialization efforts. Even in a circumstance in which an adverse event is unrelated to our product candidates, the investigation into the circumstance may be time- consuming or inconclusive. These investigations may delay our regulatory approval process or impact and limit the type of regulatory approvals our product candidates receive or maintain. As a result of these factors, a product liability claim, even if successfully defended, could have a material adverse effect on our business, financial condition, or results of operations. Although we have product liability insurance, which covers our historical clinical trials in the United States, for up to $ ~~5~~ **10** . 0 million per occurrence, up to an aggregate limit of $ ~~5~~ **10** . 0 million, our insurance may be insufficient to reimburse us for any expenses or losses we may suffer. We will also likely be required to increase our product liability insurance coverage for any future clinical trials that we may initiate. If we obtain marketing approval for any of our product candidates, we will need to expand our insurance coverage to include the sale of commercial products. There is no way to know if we will be able to continue to obtain product liability coverage and obtain expanded coverage, if we require it, in sufficient amounts to protect us against losses due to liability, on acceptable terms, or at all. We may not have sufficient resources to pay for any liabilities resulting from a claim excluded from, or beyond the limits of, our insurance coverage. Where we have provided indemnities in favor of third parties under our agreements with them, there is also a risk that these third parties could incur liability and bring a claim under such indemnities. An individual may bring a product liability claim against us alleging that one of our product candidates causes, or is claimed to have caused, an injury or is found to be unsuitable for consumer use. Any such product liability claims may include allegations of defects in manufacturing, defects in design, failure to warn of dangers inherent in the product, negligence, strict liability, and a breach of warranties. Claims could also be asserted under state consumer protection acts. Any product liability claim brought against us, with or without merit, could result in: • **inability to recruit clinical trial volunteers, investigators, patients or subjects, or trial sites; •** withdrawal of clinical trial volunteers, investigators, patients or subjects, or trial sites, or limitations on approved indications **; • delay in the development of product candidates** ; • the inability to commercialize, or if commercialized, decreased demand for, our product candidates; • if commercialized, product recalls, labeling, marketing or promotional restrictions, or the need for product modification; • initiation of investigations by regulators; • loss of revenue; • substantial costs of litigation, including monetary awards to patients or other claimants; • liabilities that substantially exceed our product liability insurance, which we would then be required to pay ourselves; • an increase in our product liability insurance rates or the inability to maintain insurance coverage in the future on acceptable terms, if at all; • the diversion of management' s attention from our business; and • damage to our reputation and the reputation of our products and our technology. Product liability claims may subject us to the foregoing and other risks, which could have a material adverse effect on our business, financial condition, or results of operations. Risks Related to Our Reliance on Third Parties We rely on third parties to conduct our preclinical development activities and clinical trials,manufacture our product candidates,and perform other services.If these third parties do not successfully perform and comply with regulatory requirements,we may not be able to successfully complete clinical development,obtain regulatory approval,or commercialize our product candidates and our business could be substantially harmed.We have relied upon and plan to continue to rely upon

third- party CROs to conduct,monitor,and manage preclinical and clinical programs. ~~Adding or changing CROs for our clinical programs carries implementation risk and may delay advancement of our clinical programs.~~ We rely on these parties for execution of clinical trials,and we manage and control only some aspects of their activities.We remain responsible for ensuring that each of our trials is conducted in accordance with the applicable protocol,legal,regulatory,and scientific standards,and our reliance on the CROs does not relieve us of our regulatory responsibilities.We and our CROs and other vendors are required to comply with all applicable laws,regulations,and guidelines,including those required by the FDA ~~,EMA,~~ and comparable foreign regulatory authorities for all of our product candidates in clinical development.If we or any of our CROs or vendors fail to comply with applicable ~~and evolving~~ laws,regulations,and guidelines,the results generated in our clinical trials may be deemed ~~insufficient or~~ unreliable,and the FDA ~~,EMA,~~ or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. **We** ~~For example,we are aware of certain instances of non-compliance with GCP protocols at our clinical sites,such as fully documenting informed consent protocols.While we believe that we have made significant progress in remediating these deficiencies,we~~ cannot be assured that our CROs ~~,clinical sites,~~ and other vendors ~~will fully remediate any deficiencies and~~ will meet these requirements ~~on an ongoing basis~~ ,or that upon inspection by any regulatory authority,such regulatory authority will determine that efforts,including any of our clinical trials,comply with applicable requirements.Our failure to comply with these laws,regulations **,** and guidelines ~~may negatively impact the integrity of the data collected in our clinical trials and~~ may require us to repeat ~~clinical trials or add patients to ongoing~~ clinical trials,which would be costly and delay the regulatory approval process.If any of our relationships with these third- party CROs terminate,we may not be able to enter into arrangements with alternative CROs in a timely manner or do so on commercially reasonable terms.In addition,our CROs may not prioritize our clinical trials relative to those of other customers,and any turnover in personnel or delays in the allocation of CRO employees by the CRO may negatively affect our clinical trials.If CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines,our clinical trials may be delayed or terminated,and we may not be able to meet our current plans with respect to our product candidates.Additionally,regional disruptions,including natural disasters or health emergencies (such as novel viruses or pandemics),could significantly disrupt the timing of clinical trials.CROs may also involve higher costs than anticipated,which could negatively affect our financial condition and operations.Shortages and governmental restrictions resulting from **the COVID- 19** ~~pandemics~~ **pandemic** ~~or other public health crises~~ may disrupt the ability of or increase the cost for our clinical trial sites and other CROs to procure items that are essential for our research and development activities,including animals that are used for preclinical studies.For example, ~~the~~ **there have been** ~~COVID- 19 pandemic and resulting disruptions to the global supply chain caused~~ shortages of various animals used in research studies,such as several types of monkeys,which are typically sourced from China **,due to the COVID- 19 pandemic and disruptions to the global supply chain** .In addition,we do not currently have,nor do we currently plan to establish,the capability to manufacture product candidates for use in the conduct of our clinical trials,and we lack the resources and the capability to manufacture any of our product candidates on a clinical or commercial scale without the use of third- party manufacturers.We plan to rely on third- party manufacturers and their responsibilities will include purchasing from third- party suppliers the materials necessary to produce our product candidates for our clinical trials and regulatory approval.There are expected to be a limited number of suppliers for the active ingredients and other materials ~~,including devices and device components,~~ that we expect to use to manufacture ~~and deliver~~ our ~~product candidates,including those of our product candidates that are anticipated to be drug- device combination products~~ **product** .~~We~~ **candidates,and we** may not be able to identify alternative suppliers to prevent a possible disruption of the manufacture of our product candidates for our clinical trials,and,if approved,ultimately for commercial sale.Although we generally do not expect to begin a clinical trial unless we believe we have a sufficient supply of a product candidate to complete the trial,any significant delay or discontinuity in the supply of a product candidate,or the active ingredient or other material components in the manufacture of the product candidate,could delay completion of our clinical trials and potential timing for regulatory approval of our product candidates,which would harm our business and results of operations.Our manufacturing process is complex ~~,~~ and we may encounter difficulties in production,which would delay or prevent our ability to provide a sufficient supply of our product candidates for future clinical trials or commercialization,if approved.The process of manufacturing our biologic product candidates is complex,highly regulated,variable,and subject to numerous risks.Our manufacturing process is susceptible to product loss or failure,or product variation that may negatively impact patient outcomes,due to logistical issues associated with preparing the product for administration,infusing the patient with the product,manufacturing issues,or different product characteristics resulting from the inherent differences in starting materials,variations between reagent lots,interruptions in the manufacturing process,contamination,equipment or reagent failure,improper installation or operation of equipment and / or programs,vendor or operator error ~~,loss of product during shipment or storage~~ and variability in product characteristics ~~.Some of our product candidates,including VRDN- 003,VRDN- 006 and VRDN- 008,are or are anticipated to be drug- device combination products.In particular,we anticipate using an autoinjector device in connection with our product candidate VRDN-003.Drug- device combination products are complex to manufacture,and this manufacturing complexity could lead to delays in manufacturing and product candidate availability for our clinical trials.In addition,drug- device combination products typically have a longer and more complex supply chain that increases the risk of supply interruptions and could negatively impact product candidate availability~~ .Even minor variations in starting reagents and materials,or deviations from normal manufacturing processes could result in reduced production yields,product ~~shortages,product~~ defects,manufacturing failure,and other supply disruptions.If microbial,viral,or other contaminations are discovered in our product candidates or in any of the manufacturing facilities in which products or other materials are made,such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination.Any failure in the foregoing processes could render a batch of product unusable,could affect the regulatory approval of such product candidate,could cause us to incur fines or penalties,or could harm our reputation and that of our product candidates.We may make changes to our manufacturing process for various

reasons,such as to control costs,increase yield or dose,achieve scale,decrease processing time,increase manufacturing success rate ~~,availability of raw materials~~ ,or for other reasons.Changes to our process made during the course of clinical development could require us to show the comparability of the product used in earlier clinical phases or at earlier portions of a trial to the product used in later clinical phases or later portions of the trial.Other changes to our manufacturing process made before or after commercialization could require us to show the comparability of the resulting product to the product candidate used in the clinical trials using earlier processes.Such showings could require us to collect additional nonclinical or clinical data from any modified process prior to obtaining marketing approval for the product candidate produced with such modified process.If such data are not ultimately comparable to that seen in the earlier trials or earlier in the same trial in terms of safety or efficacy,we may be required to make further changes to our process and / or undertake additional clinical testing,either of which could significantly delay the clinical development or commercialization of the associated product candidate,which would materially adversely affect our business,financial condition,results of operations and growth prospects.We rely and expect to continue to rely on third parties to manufacture our clinical product supplies ~~,including devices and device components~~ ,and we intend to rely on third parties to produce and process our product candidates,if approved,and our commercialization of any of our product candidates could be stopped,delayed,or made less profitable if those third parties fail to obtain approval of government regulators,fail to provide us with sufficient quantities of drug product, ~~devices,or device components,~~ or fail to do so at acceptable quality levels or prices.We do not currently have,nor do we currently plan to develop,the infrastructure or capability internally to manufacture our clinical supplies for use in the conduct of our clinical trials,and we lack the resources and the capability to manufacture any of our product candidates ~~,devices,or device components~~ on a clinical or commercial scale.We currently rely on outside vendors to manufacture our clinical supplies of our product candidates and plan to continue relying on third parties to manufacture our product candidates ~~,devices,or device components~~ on a commercial scale,if approved ~~.In particular,we rely upon single- sourced manufacturing with one CMO for our drug product~~ .We do not yet have sufficient information to reliably estimate the cost of the commercial manufacturing of our product candidates and our current cost to manufacture our drug products may not be commercially feasible.Additionally,the actual cost to manufacture our product candidates could materially and adversely affect the commercial viability of our product candidates.As a result,we may never be able to develop a commercially viable product.In addition,our reliance on third- party manufacturers exposes us to the following additional risks:• We may be unable to identify manufacturers of our product candidates on acceptable terms or at all.• Our third- party manufacturers might be unable to timely formulate and manufacture our product or produce the quantity and quality required to meet our clinical and commercial needs,if any.• Contract manufacturers may not be able to execute our manufacturing procedures appropriately.• Our future third- party manufacturers may not perform as agreed or may not remain in the contract manufacturing business for the time required to supply our clinical trials or to successfully produce,store,and distribute our ~~commercial~~ products ~~,if approved.• Our reliance on single- sourced manufacturing with one CMO increases the risk that any problems or delays with that CMO could materially,negatively affect the development of our product candidates~~ .• Manufacturers are subject to ongoing periodic unannounced inspection by the FDA and some state agencies to ensure strict compliance with cGMPs and other government regulations and corresponding foreign standards.We do not have control over third- party manufacturers' compliance with these regulations and standards.• We may not own,or may have to share,the intellectual property rights to any improvements made by our third- party manufacturers in the manufacturing process for our product candidates.• Our third- party manufacturers could breach or terminate their agreement with us.• ~~Our third- party manufacturers' performance,available capacity and ability to manufacture clinical or commercial products may be impacted by mergers and or acquisitions.•~~ We may experience labor disputes or ~~shortages,raw material shortages or manufacturing capacity~~ shortages,including from the effects of health emergencies (such as novel viruses or pandemics) and natural disasters.• **Our** ~~We and our~~ third- party manufacturers may be impacted by global conflicts,including any potential conflict involving China and Taiwan,and any resulting trade sanctions ~~.• We are heavily reliant on third- party manufacturing operations in China,and any disruption could negatively impact our clinical trials and development of our product candidates,which would harm our business.• Foreign third- party manufacturers may be subject to U.S.legislation or investigations,including the proposed BIOSECURE bill,trade restrictions and other foreign regulatory requirements,which could increase the cost or reduce the supply of material available to us,delay or prevent the procurement or supply of such material,delay clinical trials,or have an adverse effect on our ability to secure significant commitments from governments to purchase our potential therapies~~ .Each of these risks could delay our clinical trials,as well as the approval,if any,of our product candidates by the FDA,or the commercialization of our product candidates,or could result in higher costs,or could deprive us of potential product revenue.In addition,we rely on third parties to perform release testing on our product candidates prior to delivery to patients.If these tests are not appropriately conducted and test data are not reliable,patients could be put at risk of serious harm,and this could result in product liability suits. ~~In addition,we are currently undertaking a technology transfer of certain drug product related to our VRDN- 001 program from one manufacturer to another.If we encounter any material problems in connection with that process,we may be delayed in the development of our product candidates,including VRDN- 001,and our business could be harmed.~~ The manufacture of ~~drug~~ **medical** products ~~,including combination products that comprise a drug product and a device,~~ is complex and requires significant expertise and capital investment,including the development of advanced manufacturing techniques ~~,~~ **and** process controls ~~and product testing methods~~ .Manufacturers of medical products often encounter difficulties in production,particularly in scaling up and validating initial production and absence of contamination.These problems include difficulties with ~~raw material supply,~~ production costs and yields,quality control,stability of the product,quality assurance testing,operator error,shortages of qualified personnel ~~,logistical problems or delays encountered when using multiple sites for manufacturing and testing~~ ,as well as compliance with strictly enforced federal,state,and foreign regulations. ~~These problems may be more likely,or worse,in cases where the products candidates being manufactured are drug- device combination products,like certain of our product candidates,due to the increased complexity in their manufacture and associated supply chain.~~

Furthermore,if contaminants are discovered in our supply of our product candidates or in the manufacturing facilities,such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination.We cannot be assured that any stability issue or other issues relating to the manufacture of our product candidates will not occur in the future.Additionally,our manufacturers may experience manufacturing difficulties due to resource constraints or as a result of labor disputes,shortages,including from the effects of heath emergencies (such as novel viruses or pandemics) and natural disasters,or unstable political environments.If our manufacturers were to encounter any of these difficulties,or otherwise fail to comply with their contractual obligations,our ability to provide our product candidates to patients or subjects in clinical trials would be jeopardized.Any delay or interruption in the supply of clinical trial supplies could delay the completion of clinical trials,increase the costs associated with maintaining clinical trial programs and,depending upon the period of delay,require us to commence new clinical trials at additional expense or terminate clinical trials completely ~~.We currently rely on foreign CROs and CMOs,including WuXi,to manufacture our clinical materials,and will likely continue to rely on foreign CROs and CMOs in the future.Foreign CMOs may be subject to U.S.legislation or investigations,including the proposed BIOSECURE Act,sanctions,trade restrictions and other foreign regulatory requirements,which could increase the cost or reduce the supply of material available to us,delay the procurement or supply of such material,delay or impact clinical trials,have an adverse effect on our ability to secure significant commitments from governments to purchase our potential therapies and could adversely affect our financial condition and business prospects.The biopharmaceutical industry in China is strictly regulated by the Chinese government.Changes to Chinese regulations or government policies affecting biopharmaceutical companies are unpredictable and may have a material adverse effect on us or on our collaborators in China which could have an adverse effect on our business,financial condition,results of operations and prospects.Evolving changes in China' s public health,economic,political,and social conditions and the uncertainty around China' s relationship with other governments,such as the United States and the U.K.,could also negatively impact our ability to use Chinese companies to manufacture our product candidates for our clinical trials or have an adverse effect on our ability to secure commitments from governments to purchase our potential therapies,which could cause us to delay our clinical development programs or adversely affect our financial condition~~ .We may be unable to realize the potential benefits of any collaboration.Even if we are successful in entering into additional future collaborations with respect to the development and / or commercialization of one or more product candidates,there is no guarantee that the collaboration will be successful.Collaborations may pose a number of risks,including:• collaborators often have significant discretion in determining the efforts and resources that they will apply to the collaboration and may not commit sufficient resources to the development,marketing,or commercialization of the product or products that are subject to the collaboration;• collaborators may not perform their obligations as expected;• any such collaboration may significantly limit our share of potential future profits from the associated program and may require us to relinquish potentially valuable rights to our current product candidates,potential products,proprietary technologies,or grant licenses on terms that are not favorable to us;• collaborators may cease to devote resources to the development or commercialization of our product candidates if the collaborators view our product candidates as competitive with their own products or product candidates;• disagreements with collaborators,including disagreements over proprietary rights,contract interpretation,or the course of development,might cause delays or termination of the development or commercialization of product candidates,and might result in legal proceedings,which would be time consuming,distracting,and expensive;• collaborators may be impacted by changes in their strategic focus or available funding,or business combinations involving them,which could cause them to divert resources away from the collaboration;• collaborators may infringe the intellectual property rights of third parties,which may expose us to litigation and potential liability ~~,which would be time consuming,distracting,and expensive~~ ;• the collaborations may not result in us achieving revenue to justify such transactions;and • collaborations may be terminated and,if terminated,may result in a need for us to raise additional capital to pursue further development or commercialization of the applicable product candidate.As a result,a collaboration may not result in the successful development or commercialization of our product candidates.We enter into various contracts in the normal course of our business in which we indemnify the other party to the contract.In the event we have to perform under these indemnification provisions,we could have a material adverse effect on our business,financial condition,and results of operations.In the normal course of business,we periodically enter into commercial,service,licensing,consulting,and other agreements that contain indemnification provisions.With respect to our research agreements,we typically indemnify the party and related parties from losses arising from claims relating to the products,processes,or services made,used,sold,or performed pursuant to the agreements for which we have secured licenses,and from claims arising from our or our sublicensees' exercise of rights under the agreement.With respect to future collaboration agreements,we may indemnify our collaborators from any third- party product liability claims that could result from the production,use,or consumption of the product,as well as for alleged infringements of any patent or other intellectual property right by a third party.With respect to consultants,we indemnify them from claims arising from the good faith performance of their services.Should our obligation under an indemnification provision exceed applicable insurance coverage or if we were denied insurance coverage,our business,financial condition,and results of operations could be adversely affected.Similarly,if we are relying on a collaborator to indemnify us and the collaborator is denied insurance coverage or the indemnification obligation exceeds the applicable insurance coverage,and if the collaborator does not have other assets available to indemnify us,our business,financial condition,and results of operations could be adversely affected.Risks Related to Our Intellectual Property We **intend to** rely on patent rights,trade secret protections **,** and confidentiality agreements to protect the intellectual property related to our product candidates and any future product candidates.If we are unable to obtain or maintain exclusivity from the combination of these approaches,we may not be able to compete effectively in our markets.We rely or will rely upon a combination of patents,trade secret protection,and confidentiality agreements to protect the intellectual property related to our technologies and product candidates.Our success depends in large part on our **and our licensors'** ability to obtain regulatory exclusivity and ~~our and our licensors' ability to~~ maintain patent and other intellectual property protection in the United States

and in other countries with respect to our proprietary technologies and product candidates.We have sought to protect our proprietary position by filing and licensing the rights to patent applications in the United States and abroad related to our technologies and product candidates that are important to our business.This process is expensive and time consuming,and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner.It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection.The patent position of biotechnology and pharmaceutical companies generally is highly uncertain and involves complex legal and factual questions for which legal principles ~~continue to evolve and may~~ remain unresolved.The patent applications that we own or in- license may fail to result in issued patents with claims that cover our product candidates in the United States or in other foreign countries.There is no assurance that all potentially relevant prior art relating to our patents and patent applications has been found,which can invalidate a patent or prevent a patent from issuing from a pending patent application.Even if patents do successfully issue,and even if such patents cover our product candidates,third parties may challenge their validity,enforceability,or scope,which may result in such patents being narrowed,found unenforceable, ~~unpatentable,~~ or invalidated.Furthermore,even if they are unchallenged,our patents and patent applications may not adequately protect our intellectual property,provide exclusivity for our product candidates,or prevent others from designing around our claims.Any of these outcomes could impair our ability to prevent competition from third parties,which may have an adverse impact on our business.We,independently or together with our licensors,have filed patent applications covering various aspects of our product candidates ~~,including compositions of matter~~ and their methods of use.We cannot offer any assurances about which,if any,patents will issue,the breadth of any such patent,or whether any issued patents will be found invalid and unenforceable or **will be threatened** ~~unpatentable following a challenge~~ by third parties.Any successful **opposition** ~~post- grant review proceeding or litigation with respect~~ to these patents or any other patents owned by or licensed to us after patent issuance could deprive us of rights necessary for the successful commercialization of any product candidates that we may develop.Further,if we encounter delays in regulatory approvals,the period of time during which we could market a product candidate under patent protection could be reduced.If we cannot obtain and maintain effective protection of exclusivity from our regulatory efforts and intellectual property rights,including patent protection or data exclusivity,for our product candidates,we may not be able to compete effectively,and our business and results of operations would be harmed.We may not have sufficient patent term protections for our product candidates to effectively protect our business.Patents have a limited term.In the United States,the statutory expiration of a patent is generally 20 years after it is filed.Additional patent terms may be available through a patent term adjustment **(“ PTA ”)** process,resulting from the United States Patent and Trademark Office (“ USPTO ”) delays during prosecution.Although various extensions may be available,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 generic medications** .Patent term extensions (“ PTEs ”) under the Hatch- Waxman Act in the United States and under supplementary protection certificates in Europe may be available to extend the patent **or data** exclusivity terms of our product candidates.We will likely rely on ~~PTEs~~ **patent term extensions** ,and we cannot provide any assurances that any such ~~PTEs~~ **patent term extensions** will be obtained and,if so,for how long.As a result,we may not be able to maintain exclusivity for our product candidates for an extended period after regulatory approval,if any,which would negatively impact our business,financial condition,results of operations,and prospects.If we do not have sufficient patent terms or regulatory exclusivity to protect our product candidates,our business and results of operations will be adversely affected.Changes in ~~patent laws in the~~ U.S. **patent law** ~~and other jurisdictions~~ could diminish the value of patents in general,thereby impairing our ability to protect our products,and recent patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents.As is the case with other biotechnology and pharmaceutical companies,our success is heavily dependent on patents.Obtaining and enforcing patents in the biotechnology industry involve both technological and legal complexity,and is therefore costly,time- consuming,and inherently uncertain.In addition,in 2011 the **United States** ~~U.S.~~ enacted the Leahy- Smith America Invents Act (the “ Leahy- Smith Act ”) and is still currently implementing wide- ranging patent reform legislation.Recent rulings from the U.S.Supreme Court and the Court of Appeals for the Federal Circuit have narrowed the scope of patent protection available in specified circumstances and weakened the rights of patent owners in specified situations.In addition to increasing uncertainty with regard to our ability to obtain patents in the future,this combination of events has created uncertainty with respect to the value of patents,once obtained.Depending on decisions by the U.S.Congress,the federal courts,and the USPTO,the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future.The USPTO has issued subject matter eligibility guidance instructing USPTO examiners on the ramifications of the Supreme Court rulings in Mayo Collaborative Services v.Prometheus Laboratories,Inc.and Association for Molecular Pathology v.Myriad Genetics,Inc.,and applied the Myriad ruling to natural products and principles including all naturally occurring molecules.In addition,the USPTO continues to provide updates to its guidance continues to be a developing area.The USPTO guidance may make it impossible for us to obtain similar patent claims in future patent applications.Currently,our patent portfolio contains claims of various types and scope,including methods of medical treatment.The presence of varying types of claims in our patent portfolio significantly reduces,but may not eliminate,our exposure to potential validity challenges.For our U.S.patent applications,which contain claims entitled to priority after March 16,2013,there is a greater level of uncertainty due to the **the** Leahy- Smith Act mentioned above.The Leahy- Smith Act includes a number of significant changes to U.S.patent law.These include provisions that affect the way patent applications will be prosecuted and may also affect patent litigation.The USPTO has promulgated regulations and developed procedures to govern administration of the Leahy- Smith Act,and many of the substantive changes to patent law associated with the Leahy- Smith Act,and in particular,the first to file provisions,did not come into effect until March 16,2013. ~~The~~ **Accordingly,it is not yet 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 patent applications and the enforcement or defense of our issued patents,all of which could have a material adverse effect on our business,financial condition,or results of operations.An important change introduced by the Leahy- Smith Act is that,as of March 16,2013,the United States transitioned to a " first- to- file " system for deciding which party should be granted a patent when two or more patent applications are filed by different parties claiming the same invention.This will require us to be cognizant going forward of the time from invention to filing of a patent application.Furthermore,our ability to obtain and maintain valid and enforceable patents depends on whether the differences between our technology and the prior art allow our technology to be patentable over the prior art.Since patent applications in the United States and most other countries are confidential for a period of time after filing,we cannot be certain that we were the first to either:(i) file any patent application related to our product candidates or (ii) invent any of the inventions claimed in our patents or patent applications ~~until these filings are no longer confidential~~ .Among some of the other changes introduced by the Leahy- Smith Act are changes that limit where a patentee may file a patent infringement suit and new ~~post- grant review~~ procedures providing opportunities for third parties to challenge any issued patent in the USPTO.Included in these new procedures is a process known as Inter Partes Review (" IPR "),which has been generally used by many third parties since the enactment of the Leahy- Smith Act to ~~render~~ **invalidate** patents ~~unpatentable~~ . ~~These post- grant review~~ **Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in U.S.federal court necessary to invalidate a patent claim,a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action.Accordingly,a third party may attempt to use the USPTO** procedures ~~are and continue~~ to **invalidate** ~~be an evolving and developing area of law.Geopolitical actions in the U.S.and in foreign countries could increase the uncertainties and costs surrounding the prosecution or~~ **our** ~~maintenance of patent applications and the maintenance,enforcement or defense of issued patents~~ **patent claims** .~~For example,the U.S.and foreign government actions related to Russia' s invasion of Ukraine may limit or prevent filing,prosecution and maintenance of patent applications in Russia.Government actions may also prevent maintenance of issued patents in Russia.These actions could result in abandonment or lapse of patents or patent applications,resulting in partial or complete loss of patent rights in Russia.If such an event were to occur,it could have a material adverse effect on our business.In addition,a decree was adopted by the Russian government in March 2022,allowing Russian companies and individuals to exploit inventions owned by patentees~~ that ~~have citizenship or nationality in,are registered in,or have predominately primary place of business or profit- making activities in the United States and other countries that Russia has deemed unfriendly without consent or compensation.Consequently,we~~ would not ~~be able to prevent~~ **have been invalidated if first challenged by the** third **party as** ~~parties from practicing its inventions in Russia or from selling or importing products made using its inventions in and into Russia.Accordingly,our competitive position may be impaired,and our business,financial condition,operations and prospects may be adversely affected.In addition,~~ a **defendant in** ~~European Unified Patent Court (" UPC ") came into force on June 1,2023.The UPC will be~~ a **district** ~~common patent~~ court ~~to hear patent infringement~~ **action.Additionally,the rights of review** and **appeal** ~~revocation proceedings effective~~ for **IPR decisions** ~~member states of the European Union.This could enable third parties to seek revocation of a European patent in a single proceeding at the UPC rather than through multiple proceedings in each of the jurisdictions in which the European patent~~ is ~~validated.A revocation of any~~ **an area of law** ~~European patents and applications~~ that **is still** ~~we may own now or license or obtain in the future could have a material adverse impact on our business and our ability to commercialize or license our technology and products.Moreover,the controlling laws and regulations of the UPC will develop~~ **developing** ~~over time and may adversely affect our ability to enforce or defend the validity of any European patents obtained.We may decide to opt out from the UPC for any future European patent applications that we may file and any patents we may obtain.If certain formalities and requirements are not met,however,such European patents and patent applications could be challenged for non- compliance and brought under the jurisdiction of the UPC.We cannot be certain that future European patents and patent applications will avoid falling under the jurisdiction of the UPC,even if we are able to or decide to opt out of the UPC~~ .If we are unable to maintain effective proprietary rights for our product candidates or any future product candidates,we may not be able to compete effectively in our proposed markets.In addition to the protection afforded by patents,we rely on trade secret protection and confidentiality agreements to protect proprietary know- how that is not patentable or that we elect not to patent,such as processes for which patents are difficult to enforce ~~,~~ other elements of our product candidate discovery and / or development processes that involve proprietary know- how,information,or technology that is not covered by patents.However,trade secrets can be difficult to protect.We seek to protect our proprietary technology and processes,in part,by entering into confidentiality agreements with our employees,consultants,scientific advisors,and contractors.We also seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining physical security of our premises and physical and electronic security of our information technology systems.While we have confidence in these individuals,organizations,and systems, ~~the~~ agreements or security measures may be breached,and we may not have adequate remedies for such a breach.In addition,our trade secrets may otherwise become known or be independently discovered by competitors.Although we expect all of our employees and consultants to assign their inventions to us,and all of our employees,consultants,advisors,and any third parties who have access to our proprietary know- how,information,or technology to enter into confidentiality agreements,we cannot provide any assurances that all such agreements have been duly executed,or that our trade secrets and other confidential proprietary information will not be disclosed,or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques.Misappropriation or unauthorized disclosure of our trade secrets could impair our competitive position and may have a material adverse effect on our business,financial condition,or results of operations.Additionally,if the steps taken to maintain our trade secrets are deemed inadequate,we may have insufficient recourse against third parties for misappropriating the trade secret.Third- party claims of intellectual property infringement may prevent or delay our development and commercialization efforts.Our commercial success depends in part on our ability to

develop,manufacture,market,and sell our product candidates and use our proprietary technology without infringing the patent rights of third parties.Numerous third- party U.S.and non- U.S.issued patents and pending applications exist in the area of our product candidates.From time to time,we may also monitor these patents and patent applications.We may in the future pursue available proceedings in the U.S.and foreign patent offices to challenge **the validity of** these patents and patent applications.In addition,or alternatively,we may consider whether to seek to negotiate a license of rights to technology covered by one or more of such third- party patents and patent applications.If any patents or patent applications cover our product candidates or technologies,we may not be free to manufacture or market our product candidates as planned,absent such a license,which may not be available to us on commercially reasonable terms,or at all.It is also possible that we have failed to identify relevant third-party patents or applications.For example,applications filed before November 29,2000 remain confidential until patents issue,and applications filed after that date that will not be filed outside the United States can elect to remain confidential until patents issue.Moreover,it is difficult for industry participants,including us,to identify all third- party patent rights that may be relevant to our product candidates and technologies because patent searching is imperfect due to differences in terminology among patents,incomplete databases,and the difficulty in assessing the meaning of patent claims.We may fail to identify relevant patents or patent applications or may identify pending patent applications of potential interest but incorrectly predict the likelihood that such patent applications may issue with claims of relevance to our technology.In addition,we may be unaware of one or more issued patents that would be infringed by the manufacture,sale,or use of a current or future product candidate,or we may incorrectly conclude that a third- party patent is invalid,unenforceable, ~~unpatentable,~~ or not infringed by our activities.Additionally,pending patent applications that have been published can,subject to specified limitations,be later amended in a manner that could cover our technologies,our product candidates,or the use of our product candidates.There have been many lawsuits and other proceedings involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries,including patent infringement lawsuits in federal courts,and interferences,oppositions,inter partes reviews,post- grant reviews,and reexamination proceedings before the USPTO and corresponding foreign patent offices.Numerous U.S.and foreign- issued patents and pending patent applications,which are owned by third parties,exist in the fields in which we are developing product candidates.As the biotechnology and pharmaceutical industries expand and more patents are issued,the risk increases that our product candidates may be subject to claims of infringement of the patent rights of third parties.Parties making claims against us may obtain injunctive or other equitable relief,which could effectively block our ability to further develop and commercialize one or more of our product candidates.Defense of these claims,regardless of their merit,would involve substantial litigation expense and would be a substantial diversion of employee resources from our business.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,redesign our infringing products, ~~cease development or commercialization,~~ or obtain one or more licenses from third parties,which may be impossible or require substantial time and monetary expenditure.We may not be successful in meeting our obligations under our existing license agreements necessary to maintain our product candidate licenses in effect.In addition,if required in order to commercialize our product candidates,we may be unsuccessful in obtaining or maintaining necessary rights to our product candidates through acquisitions and in-licenses.We currently have rights to ~~certain~~ **the** intellectual property,through licenses from third parties and under ~~technology and~~ patents that we do not own,to develop and commercialize our product candidates.Because our programs may require the use of proprietary rights held by third parties,the growth of our business will likely depend in part on our ability to maintain in effect these proprietary ~~rights.Mergers and acquisitions involving the third parties from whom we license intellectual property may negatively impact our~~ rights.Any termination of license agreements with third parties with respect to our product candidates would be expected to negatively impact our business prospects.We may be unable to acquire or in- license any compositions,methods of use,processes,or other third- party intellectual property rights from third parties that we identify as necessary for our product candidates.The licensing and acquisition of third- party intellectual property rights is a competitive area,and a number of more established companies are also 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,cash resources,and greater clinical development and commercialization capabilities.In addition,companies that perceive us to be a competitor may be unwilling to assign or license their patent rights to us.Even if we are able to license or acquire third- party intellectual property rights that are necessary for our product candidates,there can be no assurance that they will be available on favorable terms.If we are unable to successfully obtain and maintain rights to required third- party intellectual property,we may have to abandon development ~~or commercialization~~ of that product candidate or pay additional amounts to the third party,and our business and financial condition could suffer.The patent protection and patent prosecution for some of our product candidates are **dependent on third parties.While we normally seek and gain the right to fully prosecute the patents relating to our product candidates,there may be times when patents relating to our product candidates are controlled by our licensors.If any of our licensors fail to appropriately follow our instructions with regard to the prosecution and maintenance of patent protection for patents covering any of our product candidates,our ability to develop and commercialize those product candidates may be adversely affected,and we may not be able to prevent competitors from making,using,importing,and selling competing products.In addition,even where we now have the right to control patent prosecution of patents and patent applications we have licensed from third parties,we may still be adversely affected or prejudiced by actions or inactions of our licensors in effect from actions prior to us assuming control over patent prosecution.If we fail to comply with obligations in the agreements under which we license intellectual property and other rights from third parties or otherwise experience disruptions to our business relationships with our licensors,we could lose license rights that are important to our business.We are a party to intellectual property licenses and supply agreements that are important to our business and expect to enter into additional license agreements in the future.Our existing agreements impose,and we expect that future license agreements**

will impose,various diligence,milestone payments,royalties,purchasing,and other obligations on us.If we fail to comply with our obligations under these agreements,or we are subject to a bankruptcy,our agreements may be subject to termination by the licensor,in which event we would not be able to develop,manufacture,or market products covered by the license or subject to supply commitments.We may be involved in lawsuits to protect or enforce our patents or the patents of our licensors,which could be expensive,time consuming,and unsuccessful.Competitors may infringe our patents or the patents of our licensors.If we,or one of our licensing partners,were to initiate legal proceedings against a third party to enforce a patent covering one of our product candidates,the defendant could counterclaim that the patent covering our product candidate is invalid and / or unenforceable.In patent litigation in the United States,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 lack of novelty,obviousness,written description,clarity,or non- enablement.Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld material information from the USPTO,or made a misleading statement,during prosecution.The outcome following legal assertions of invalidity and unenforceability is unpredictable.Interference proceedings provoked by third parties or brought by us or declared by the USPTO may be necessary to determine the priority of inventions with respect to our patents or patent applications or those of our licensors.An unfavorable outcome could require us to cease using the related technology or to attempt to license rights to us from the prevailing party.Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms.Our defense of litigation or interference proceedings may fail and,even if successful,may result in substantial costs and distract our management and other employees.In addition,the uncertainties associated with litigation could have a material adverse effect on our ability to raise the funds necessary to continue our clinical trials,continue our research programs,license necessary technology from third parties,or enter into development partnerships that would help us bring our product candidates to market.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.There could also be public announcements of the results of hearings,motions,or other interim proceedings or developments.If securities analysts or investors perceive these results to be negative,it could have a material adverse effect on the price of our common stock.We may be subject to claims that our employees,consultants,or independent contractors have wrongfully used or disclosed confidential information of third parties or that our employees have wrongfully used or disclosed alleged trade secrets of their former employers.We employ individuals who were previously employed at universities or other biotechnology or pharmaceutical companies,including our competitors or potential competitors.Although we have written agreements and make every effort to ensure that our employees,consultants,and independent contractors do not use the proprietary information or intellectual property rights of others in their work for us,we may in the future be subject to any claims that our employees,consultants,or independent contractors have wrongfully used or disclosed confidential information of third parties.Litigation may be necessary to defend against these claims.If we fail in defending any such claims,in addition to paying monetary damages,we may lose valuable intellectual property rights or personnel,which could adversely impact our business.Even if we are successful in defending against such claims,litigation could result in substantial costs and be a distraction to management and other employees.We may not be able to protect our intellectual property rights throughout the world.Filing,prosecuting,and defending patents on product candidates in all countries throughout the world would be prohibitively expensive,and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States.In addition,the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States.Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop our own products and may also export infringing products to territories where we have patent protection,but enforcement is not as strong as that in the United States.These products may compete with our products 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,particularly some developing countries,do not favor the enforcement of patents,trade secrets,and other intellectual property protection,particularly those relating to biotechnology and therapeutic products,which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally.Proceedings to enforce our patent rights in foreign jurisdictions,whether or not successful,could result in substantial costs and divert our efforts and attention from other aspects of our business,could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing,and could provoke third parties to assert claims against us.We may not prevail in any lawsuits that we initiate,and the damages or other remedies awarded,if any,may not be commercially meaningful.Accordingly,our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.Risks Related to Regulatory Approval of Our Product Candidates and Other Legal Compliance Matters We expect the product candidates we develop will be regulated as biologics, and therefore they may be subject to competition ~~sooner than anticipated~~ . The ~~Biologics Price Competition and Innovation Act of 2009 (" BPCIA ")~~ was enacted as part of the **ACA** ~~Affordable Care Act~~ to establish an abbreviated pathway for the approval of biosimilar and interchangeable biological products. The regulatory pathway establishes legal authority for the FDA to review and approve biosimilar biologics, including the possible designation of a biosimilar as " interchangeable " based on its similarity to an approved biologic. Under the BPCIA, an application for a biosimilar product cannot be approved by the FDA until 12 years after the reference product was approved under a ~~Biologics License Application (" BLA ")~~ . The law is complex and is still

being interpreted and implemented by the FDA. As a result, its ultimate impact, implementation, and meaning are subject to uncertainty. ~~While it is uncertain when processes intended to implement BPCIA may be fully adopted by the FDA, any of these processes could have a material adverse effect on the future commercial prospects for our biological products.~~ We believe that any of the product candidates we develop that is approved in the United States as a biological product under a BLA should qualify for the **current** 12- year period of exclusivity **provided law** . However, there is a risk that this exclusivity could be shortened **in the future** due to congressional action or otherwise, or that the FDA will not consider the subject product candidates to be reference products for competing products, potentially creating the opportunity for generic competition sooner than anticipated. Moreover, the extent to which a biosimilar, once approved, will be substituted for any one of the reference products in a way that is similar to traditional generic substitution for non- biological products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing. In addition, the **first biologic product submitted under the abbreviated approval pathway that is determined to be interchangeable with the reference product has exclusivity against other biologics submitted under the abbreviated approval pathway for the lesser of (i) one year after the first commercial marketing, (ii) 18 months after approval if there is no legal challenge, (iii) 18 months after the resolution in the applicant' s favor of a lawsuit challenging the biologics' patents if an application has been submitted, or (iv) 42 months after the application has been approved if a lawsuit is ongoing within the 42- month period. The** approval of a biologic product biosimilar to one of our product candidates could have a material adverse impact on our business as it may be significantly less costly to bring to market and may be priced significantly lower than our product candidates. We are seeking Orphan drug designation for VRDN- 001 from the FDA and may seek Orphan drug designation for future product candidates, but we might not receive such designation. In September 2022, we filed an amended application for Orphan drug designation for VRDN- 001 based on clinical data. In response, the FDA has indicated that further review of the application is suspended pending receipt of additional information. **We are currently reviewing our submission further.** There is no guarantee that upon submission of this additional data information the FDA will grant us Orphan drug designation. See " Business — Government Regulation ~~and Product Approvals~~ — Orphan Drug Designation. " **Even with an orphan drug designation for its current and potential future product candidates, we may not be the first to obtain marketing approval for any particular orphan indication due to the uncertainties associated with developing pharmaceutical products. Further, even if we obtain orphan drug exclusivity for an existing or future product candidate, that exclusivity may not effectively protect the product from competition because different drugs with different active moieties still can be approved for the same condition even with an orphan drug designation. Even after an orphan drug is approved, the FDA can subsequently approve the same drug with the same active moiety for the same condition if the FDA concludes that the later drug is clinically superior in that it is safer, more effective, or makes a major contribution to patient care. Orphan drug designation neither shortens the development time or regulatory review time of a drug or biologic nor gives the drug or biologic any advantage in the regulatory review or approval process. In addition, the FDA' s interpretation of the scope of orphan drug exclusivity may change. The FDA' s longstanding interpretation of the Orphan Drug Act is that exclusivity is specific to the orphan indication for which the drug was actually approved. As a result, the scope of exclusivity has been narrow and protected only against competition from the same " use or indication " rather than the broader " disease or condition. " Our ability to obtain and maintain orphan drug designation and the benefits thereof, including orphan drug exclusivity, may materially impact our financial performance.** We may seek Breakthrough Therapy designation for one or more of our product candidates from the FDA, but we might not receive such designation, and even if we do, such designation may not actually lead to a faster development or regulatory review or approval process. We may seek a breakthrough therapy designation from the FDA for some of our product candidates. Designation as a breakthrough therapy is within the discretion of the FDA. Accordingly, even if we believe that one of our product candidates meets the criteria for designation as a breakthrough therapy, the FDA may disagree and instead determine not to make such designation. In any event, the receipt of a breakthrough therapy designation for a product candidate may not result in a faster development process, review, or approval compared to drugs considered for approval under conventional FDA procedures and does not assure ultimate approval by the FDA. In addition, even if one of our product candidates is designated as a breakthrough therapy, the FDA may later decide that the product candidate no longer meets the conditions for designation and the designation may be rescinded. See " Business — Government Regulation ~~and Product Approvals~~ — Expedited Development and Review Programs. " We may seek Fast Track designation for one or more of our product candidates, but we might not receive such designation, and even if we do, such designation may not actually lead to a faster development or regulatory review or approval process. If a product candidate is intended for the treatment of a serious condition and nonclinical or clinical data demonstrate the potential to address unmet medical need for this condition, a product sponsor may apply for FDA Fast Track designation. If we seek Fast Track designation for a product candidate, we may not receive it from the FDA. However, even if we receive Fast Track designation, Fast Track designation does not ensure that we will receive marketing approval in any particular timeframe or at all. We may not experience a faster development or regulatory review or approval process with Fast Track designation compared to conventional FDA procedures. In addition, the FDA may withdraw Fast Track designation if it believes that the designation is no longer supported by data from our clinical development program. Fast Track designation alone does not guarantee qualification for the FDA' s priority review procedures. See " Business — Government Regulation ~~and Product Approvals~~ — Expedited Development and Review Programs. " We may attempt to obtain accelerated approval of our product candidates. If we are unable to obtain accelerated approval, we may be required to conduct clinical trials beyond those that we contemplate, or the size and duration of our pivotal clinical trials could be greater than currently planned, which could increase the expense of obtaining, reduce the likelihood of obtaining, and / or delay the timing of obtaining necessary marketing approvals. Even if we receive accelerated approval from the FDA, the FDA may require that we conduct confirmatory trials to verify clinical benefit. If our confirmatory trials do not verify clinical benefit, or if we do not comply with rigorous post- approval requirements, the

FDA may seek to withdraw accelerated approval. We may seek accelerated approval for our product candidates. The FDA may grant accelerated approval to a product designed to treat a serious or life- threatening condition that provides meaningful therapeutic advantage over available therapies and demonstrates an effect on a surrogate endpoint or intermediate clinical endpoint that is reasonably likely to predict clinical benefit. The FDA considers a clinical benefit to be a positive therapeutic effect that is clinically meaningful in the context of a given disease. If granted, accelerated approval may be contingent on the sponsor' s agreement to conduct, in a diligent manner, additional post- approval confirmatory studies to verify and describe the drug' s predicted effect on irreversible morbidity or mortality or other clinical benefit. **Under the Food and Drug Omnibus Reform Act of 2022, the FDA may require, as appropriate, that such studies be underway prior to approval or within a specific time period after the date of approval for a product granted accelerated approval.** The FDA may require that any such confirmatory study be initiated or substantially underway prior to the submission of an application for accelerated approval. If such post- approval studies fail to confirm the drug' s clinical benefits relative to its risks, the FDA may withdraw its approval of the drug. If we choose to pursue accelerated approval, there can be no assurance that the FDA will agree that our proposed primary endpoint is an appropriate surrogate endpoint. Similarly, there can be no assurance that after subsequent FDA feedback that we will continue to pursue accelerated approval or any other form of expedited development, review, or approval, even if we initially decide to do so. Furthermore, if we submit an application for accelerated approval, there can be no assurance that such application will be accepted or that approval will be granted on a timely basis, or at all. The FDA also could require us to conduct further studies or trials prior to considering our application or granting approval of any type. We might not be able to fulfill the FDA' s requirements in a timely manner, which would cause delays, or approval might not be granted because our submission is deemed incomplete by the FDA. Even if we receive accelerated approval from the FDA, we will be subject to rigorous post- approval requirements, including submission to the FDA of all promotional materials prior to their dissemination. The FDA may require us to conduct a confirmatory study to verify the predicted clinical benefit. The FDA could withdraw accelerated approval for multiple reasons, including our failure to conduct any required post- approval study with due diligence, or the inability of such study to confirm the predicted clinical benefit. A failure to obtain accelerated approval or any other form of expedited review or approval for a product candidate could result in a longer time period prior to commercializing such product candidate, increase the cost of development of such product candidate, and harm our competitive position in the marketplace. Even if we obtain regulatory approval for a product candidate, we will remain subject to ongoing regulatory requirements. If any of our product candidates are approved, we will be subject to ongoing regulatory requirements with respect to manufacturing, labeling, packaging, storage, advertising, promotion, sampling, record- keeping, conduct of post- marketing clinical trials, and submission of safety, efficacy, and other post- approval information, including both federal and state requirements in the United States, and requirements of **the EMA and** comparable foreign regulatory authorities. See " Business — Government Regulation ~~and Product Approvals — Expedited Development and Review Programs~~ **" and " Business — Government Regulation — Regulation in the European Union** . " Any regulatory approvals that we receive for our product candidates may be subject to limitations on the approved indicated uses for which the product may be marketed or to 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 marketed product. We will be required to report adverse reactions and production problems, if any, to the FDA **, EMA,** and comparable foreign regulatory authorities. Any new legislation could result in delays in product development or commercialization, or increased costs to assure compliance. If our original marketing approval for a product candidate was granted accelerated approval by the FDA, we could be required to conduct a successful post- marketing clinical trial in order to confirm the clinical benefit of our products. An unsuccessful post- marketing clinical trial or failure to complete such a trial could result in the withdrawal of marketing approval. Any government investigation of alleged violations of law would be expected to require us to expend significant time and resources in response and could generate adverse publicity. Any failure to comply with ongoing regulatory requirements may significantly and adversely affect our ability to develop and commercialize our products, and the value of the company and our operating results would be adversely affected. In addition, if we were able to obtain accelerated approval of any of our drug candidates, the FDA may require us to conduct a confirmatory study to verify the predicted clinical benefit. Other regulatory authorities outside of the United States may have similar requirements. The results from the confirmatory study may not support the clinical benefit, which could result in the approval being withdrawn. While operating under accelerated approval, we will be subject to certain restrictions that we would not be subject to upon receiving regular approval. Healthcare legislative reform measures may have a material adverse effect on our business, financial condition, or results of operations, and current and future legislation may increase the difficulty and cost for us, and any collaborators, to obtain marketing approval of and commercialize our drug candidates and affect the prices we, or they, may obtain. In the United States, there have been and continues to be a number of legislative initiatives to contain healthcare costs. For example, in March 2010, the **ACA** ~~Affordable Care Act~~ was passed, which was intended to substantially change the way healthcare is financed by both governmental and private insurers, and significantly impact the U. S. pharmaceutical industry. More recently, on August 16, 2022, President Biden signed into law the ~~Inflation Reduction Act of 2022 (" IRA ")~~, which, among other provisions, included several measures intended to lower the cost of prescription drugs and related healthcare reforms. See " Business — Health Reform. " Heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products has resulted in several recent Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for products. We expect that additional state and federal healthcare reform measures will be adopted in the future, particularly in light of the new presidential administration, any of which could limit the amounts that federal and state governments will pay for healthcare therapies, which could result in reduced demand for our product candidates or additional pricing pressures. We cannot be sure whether additional legislation or rulemaking related to the IRA

will be issued or enacted, or what impact, if any, such changes will have on the profitability of any of our drug candidates, if approved for commercial use, in the future. We may be subject, directly or indirectly, to foreign, federal, and state healthcare fraud and abuse laws, false claims laws, and health information privacy and security laws. If we are unable to comply, or have not fully complied, with such laws, we could face substantial penalties, sanctions, or other liability. Our operations may be subject to various foreign, federal, and state fraud and abuse laws, including, without limitation, the federal Anti- Kickback Statute, the federal False Claims Act, and Physician Payments Sunshine Act, the EU' s GDPR, and other regulations. These laws may impact, among other things, our relationships with healthcare professionals and our proposed sales, marketing, and education programs. In addition, we may be subject to patient privacy regulation by both the federal government and the states in which we conduct our business. See " Business — Other Regulations. " If our operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including significant civil, criminal, and administrative penalties, disgorgement, damages, fines, contractual damages, reputational harm, diminished profits and future earnings, exclusion from participation in government healthcare programs, such as Medicare and Medicaid, imprisonment, additional reporting requirements and / or oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of noncompliance with these laws, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations. If we fail to comply with environmental, health, and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on our business, financial condition, or results of operations. Our research and development activities and our third- party manufacturers' and suppliers' activities involve the controlled storage, use, and disposal of hazardous materials, including the components of our product candidates and other hazardous compounds. We and our manufacturers and suppliers are subject to laws and regulations governing the use, manufacture, storage, handling, and disposal of these hazardous materials. In some cases, these hazardous materials and various wastes resulting from their use are stored at our and our manufacturers' facilities pending their use and disposal. We cannot eliminate the risk of contamination, which could cause an interruption of our commercialization efforts, research and development efforts, and business operations, and cause environmental damage resulting in costly clean- up and liabilities under applicable laws and regulations governing the use, storage, handling, and disposal of these materials and specified waste products. Although we believe that the safety procedures utilized by us and our third- party manufacturers for handling and disposing of these materials generally comply with the standards prescribed by these laws and regulations, we cannot guarantee that this is the case or eliminate the risk of accidental contamination or injury from these materials. In such an event, we may be held liable for any resulting damages and such liability could exceed our resources, and state or federal or other applicable authorities may curtail our use of specified materials and / or interrupt our business operations. Furthermore, environmental laws and regulations are complex, change frequently, and have tended to become more stringent. We cannot predict the impact of such changes and cannot be certain of our future compliance. We do not currently carry biological or hazardous waste insurance coverage. Failure to comply with existing or future laws and regulations related to privacy or data security could lead to government enforcement actions (which could include civil or criminal fines or penalties), private litigation, other liabilities, and / or adverse publicity. Compliance or the failure to comply with such laws could increase the costs of our products and services, could limit their use or adoption, and could otherwise negatively affect our operating results and business. Regulation of personal data or personal information processing is evolving, as federal, state, and foreign governments continue to adopt new, or modify existing, laws and regulations addressing data privacy and security, and the collection, processing, storage, transfer, and use of such data. We, our collaborators, and our service providers may be subject to current, new, or modified federal, state, and foreign data protection laws and regulations (e. g., laws and regulations that address data privacy and data security, including, without limitation, health data). These new or proposed laws and regulations are subject to differing interpretations and may be inconsistent among jurisdictions, and guidance on implementation and compliance practices are often updated or otherwise revised, which adds to the complexity of processing personal data. These and other requirements could require us or our collaborators to incur additional costs to achieve compliance, limit our competitiveness, necessitate the acceptance of more onerous obligations in our contracts, restrict our ability to use, store, transfer, and process data, impact our or our collaborators' ability to process or use data in order to support the provision of our products or services, affect our or our collaborators' ability to offer our products and services or operate in certain locations, cause regulators to reject, limit, or disrupt our clinical trial activities, result in increased expenses, reduce overall demand for our products and services and make it more difficult to meet expectations of or commitments to customers or collaborators. See " Business — Other Regulations. " Failure to comply with U. S. and foreign data protection laws and regulations could result in government investigations and enforcement actions (which could include civil or criminal penalties, fines, or sanctions), private litigation, and / or adverse publicity and could negatively affect our operating results and business. Moreover, patients or subjects about whom we or our 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 or failed to comply with data protection laws or applicable privacy notices even if we are not found liable, could be expensive and time- consuming to defend and could result in adverse publicity that could harm our business. Any failure by our third- party collaborators, service providers, contractors, or consultants to comply with applicable law, regulations, or contractual obligations related to data privacy or security could result in proceedings against us by governmental entities or others. We may publish privacy policies and other documentation regarding our collection, processing, use, and disclosure of personal information and / or other confidential information. Although we endeavor to comply with our published policies and other documentation, we may at times fail to do so or may be perceived to have failed to do so. Moreover, despite our efforts, we may not be successful in achieving compliance if our employees or vendors fail to comply with our published policies and documentation. Such failures can subject us to potential foreign, local, state, and federal action if they are found to be deceptive, unfair, or misrepresentative of our actual practices. Moreover, subjects about whom we or our

partners 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 or failed to comply with data protection laws or applicable privacy notices even if we are not found liable, could be expensive and time- consuming to defend and could result in adverse publicity that could harm our business. Any of these matters could materially adversely affect our business, financial condition, or operational results. Risks Related to Our Reliance on Third Parties We rely..... develop or license. Risks Related to Commercialization of Our Product Candidates If we are unable to establish commercial manufacturing, sales and marketing capabilities or enter into agreements with third parties to commercially manufacture, market and sell our product candidates, we may be unable to generate any revenue. Although some of our employees may have been employed at companies that have launched pharmaceutical products in the past, we have no experience establishing commercial manufacturing relationships for or selling and marketing our product candidates and we currently have no commercial manufacturing relationships or marketing or sales organization. To successfully commercialize any products that may result from our development programs, we will need to find one or more collaborators to commercialize our products or invest in and develop these capabilities, either on our own or with others, which would be expensive, difficult, and time consuming. Any failure or delay in entering into agreements with third parties to market or sell our product candidates or in the timely development of our internal commercialization capabilities could adversely impact the potential for the launch and success of our products. If commercialization collaborators do not commit sufficient resources to commercialize our future products and we are unable to develop the necessary marketing and sales capabilities on our own, we will be unable to generate sufficient product revenue to sustain or grow our business. We may be competing with companies that currently have extensive and well-funded marketing and sales operations, particularly in the markets our product candidates are intended to address. Without appropriate capabilities, whether directly or through third- party collaborators, we may be unable to compete successfully against these more established companies. We may attempt to form collaborations in the future with respect to our product candidates, but we may not be able to do so, which may cause us to alter our development and commercialization plans. We may attempt to form strategic collaborations, create joint ventures, or enter into licensing arrangements with third parties with respect to our programs that we believe will complement or augment our existing business. We may face significant competition in seeking appropriate strategic collaborators, and the negotiation process to secure appropriate terms is time consuming and complex. We may not be successful in our efforts to establish such a strategic collaboration for any product candidates and programs on terms that are acceptable to us, or at all. This may be because our product candidates and programs may be deemed to be at too early of a stage of development for collaborative effort, our research and development pipeline may be viewed as insufficient, the competitive or intellectual property landscape may be viewed as too intense or risky, and / or third parties may not view our product candidates and programs as having sufficient potential for commercialization, including the likelihood of an adequate safety and efficacy profile. Even if we are able to successfully enter into a collaboration regarding the development or commercialization of our product candidates, we cannot guarantee that such a collaboration will be successful. Any delays in identifying suitable collaborators and entering into agreements to develop and / or commercialize our product candidates could delay the development or commercialization of our product candidates, which may reduce their competitiveness even if they reach the market. Absent a strategic collaborator, we would need to undertake development and / or commercialization activities at our own expense. If we elect to fund and undertake development and / or commercialization activities on our own, we may need to obtain additional expertise and additional capital, which may not be available to us on acceptable terms or at all. If we are unable to do so, we may not be able to develop our product candidates or bring them to market and our business may be materially and adversely affected. We face substantial competition **,** and our competitors may discover, develop, or commercialize products faster or more successfully than us. The development and commercialization of new drug products is highly competitive **, particularly in the treatment of TED** . We face competition from major pharmaceutical companies, specialty pharmaceutical companies, biotechnology companies, universities, and other research institutions worldwide with respect to our product candidates ~~that we may seek to develop or commercialize in the future~~ . We are aware that the following companies **, among others,** have therapeutics marketed or in development for TED: **Amgen,** ~~Horizon Therapeutics plc and~~ Immunovant, Inc., Harbour BioMed, **Acelyrin** ~~Valenza Bio~~ , Inc. and Sling Therapeutics, Inc. If approved, VRDN- 001 **and VRDN- 003** will also compete against generic medications, such as corticosteroids, that are prescribed for and surgical procedures for the treatment of TED **. We are also aware that the following companies, among others, may have anti- FcRn therapeutics marketed or in development: Argenx, UCB S. A., Janssen Pharmaceutical Companies of Johnson & Johnson, Immunovant, Inc. and AstraZeneca / Alexion Pharmaceuticals, Inc. Moreover, there are more than 20 indications announced or in development across the FcRn class. Depending on the indications in which we choose to develop VRDN- 006 and VRDN- 008, there may be further competition from marketed and in- development therapeutics targeting other mechanisms such as complement inhibition, T- cell inhibitors, anti- 1L- 6 and other mechanisms of action. Our product candidates may demonstrate inferior efficacy and safety profiles as compared to currently approved drugs, or product candidates currently in development by our competitors** . Our competitors may succeed in developing, acquiring, or licensing technologies and drug products that are more effective or less costly than our product candidates that we are currently developing or that we may develop, which could render our product candidates obsolete and noncompetitive. Our competitors may also adopt a similar licensing and development strategy as ours with regard to the development of an existing anti- IGF- 1R monoclonal antibody for the treatment of TED. If any competitor was able to effect this strategy in a more efficient manner, there may be less demand for our product candidates if any are approved. Many of our competitors have substantially greater financial, technical, and other resources, such as larger research and development staff and experienced marketing and manufacturing organizations. Third- party payors, including governmental and private insurers, may also encourage the use of generic products. For example, if VRDN- 001 is approved, it may be priced at a significant premium over other competitive products. This may make it difficult for VRDN- 001 or any other future products to

compete with these products. If our competitors obtain marketing approval from the FDA **, EMA,** or comparable foreign regulatory authorities for their product candidates more rapidly than us, it could result in our competitors establishing a strong market position before we are able to enter the market. Many of our competitors have materially greater name recognition and financial, manufacturing, marketing, research, and drug development resources than we do. Additional mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated in our competitors. For example, in ~~December~~ **October** ~~2022~~ **2023** , Amgen Inc. **completed** ~~announced that it~~ **its acquisition of** ~~intends to acquire~~ Horizon ~~Therapeutics plc~~ , which could have a significant impact on the competitive landscape for **clinical trials and** therapeutics for TED. Large pharmaceutical companies in particular have extensive expertise in preclinical and clinical testing and in obtaining regulatory approvals for drugs. In addition, academic institutions, government agencies, and other public and private organizations conducting research may seek patent protection with respect to potentially competitive products or technologies. These organizations may also establish exclusive collaborative or licensing relationships with our competitors. **If** ~~Failure of VRDN- 001, VRDN- 002 or~~ **our** ~~our other~~ product candidates **fail** to **compete** effectively ~~compete~~ against established treatment options or ~~in the~~ future ~~with new~~ products currently in development **, this** would harm our business, financial condition, results of operations ~~,~~ and prospects. The commercial success of any of our current or future product candidates will depend upon the degree of market acceptance by physicians, patients, third- party payors, and others in the medical community. Even with the approvals from the FDA **, EMA,** and comparable foreign regulatory authorities, the commercial success of our products will depend in part on the healthcare providers, patients, and third- party payors accepting our product candidates as medically useful, cost- effective, and safe. Any product that we bring to the market may not gain market acceptance by physicians, patients, and third- party payors. The degree of market acceptance of any of our products will depend on a number of factors, including but not limited to: • the efficacy **or safety** of the product as demonstrated in clinical trials and potential advantages over competing treatments; • the prevalence and severity of the disease and any side effects; • the clinical indications for which approval is granted, including any limitations or warnings contained in a product' s approved labeling; • the convenience and ease of administration; • the cost of treatment; • the willingness of the patients and physicians to accept these therapies; • the perceived ratio of risk and benefit of these therapies by physicians and the willingness of physicians to recommend these therapies to patients based on such risks and benefits; • the marketing, sales, and distribution support for the product; • the publicity concerning our products or competing products and treatments; and • the pricing and availability of third- party payor coverage and adequate reimbursement. Even if a product displays a favorable efficacy and safety profile upon approval, market acceptance of the product remains uncertain. **We may be unable to penetrate the existing TED market and successfully commercialize our product candidates, if approved.** Efforts to educate the medical community and third- party payors on the benefits of the products may require significant investment and resources and may never be successful. If our products fail to achieve an adequate level of acceptance by physicians, patients, third- party payors, and other healthcare providers, we will not be able to generate sufficient revenue to become or remain profitable **. In addition, the market for TED therapies may fail to continue its growth, or may shrink, which could affect the commercial viability of our product candidates and could negatively impact revenues from any approved products. For example, sales of Tepezza ® may fall, and this could cause our business to be negatively impacted** . We may not be successful in any efforts to identify, license, discover, develop, or commercialize additional product candidates. Although a substantial amount of our effort will focus on clinical testing, potential approval, and commercialization of our existing product candidates, the success of our business is also expected to depend in part upon our ability to identify, license, discover, develop, or commercialize additional product candidates. Research programs to identify new product candidates require substantial technical, financial, and human resources. We may focus our efforts and resources on potential programs or product candidates that ultimately prove to be unsuccessful. Our research programs or licensing efforts may fail to yield additional product candidates for clinical development and commercialization for a number of reasons, including but not limited to the following: • our research or business development methodology or search criteria and process may be unsuccessful in identifying potential product candidates; • we may not be able or willing to assemble sufficient resources to acquire or discover additional product candidates; • our product candidates may not succeed in preclinical or clinical testing; • our potential product candidates may be shown to have harmful side effects or may have other characteristics that may make the products unmarketable or unlikely to receive marketing approval; • competitors may develop alternatives that render our product candidates obsolete or less attractive; • product candidates we develop may be covered by third parties' patents or other exclusive rights; • the market for a product candidate may change during our program so that such a product may become unreasonable to continue to develop; • a product candidate may not be capable of being produced in commercial quantities at an acceptable cost, or at all; and • a product candidate may not be accepted as safe and effective by patients, the medical community, or third- party payors. If any of these events occur, we may be forced to abandon our development efforts for a program or programs, or we may not be able to identify, license, discover, develop, or commercialize additional product candidates, which would have a material adverse effect on our business, financial condition, or results of operations and could potentially cause us to cease operations. Failure to obtain or maintain adequate reimbursement or insurance coverage for our products, if any, could limit our ability to market those products and decrease our ability to generate revenue. The pricing, as well as the coverage, and reimbursement of our approved products, if any, must be sufficient to support our commercial efforts and other development programs, and the availability of coverage and adequacy of reimbursement by third- party payors, including government healthcare programs, health maintenance organizations, private insurers, and other healthcare management organizations, are essential for most patients to be able to afford expensive treatments. Sales of our approved products, if any, will depend substantially, both domestically and abroad, on the extent to which the costs of our approved products, if any, will be paid for or reimbursed by third- party payors. If coverage and reimbursement are not available, or are available only in limited amounts, we may have to subsidize or provide products for free, or we may not be able to successfully commercialize our products. See " Business — Coverage and Reimbursement. "

Outside the ~~United States~~ **U. S.** , international operations are generally subject to extensive governmental price controls and other price- restrictive regulations, and we believe the increasing emphasis on cost- containment initiatives in Europe, Canada, and other countries has and will continue to put pressure on the pricing and usage of products. In many countries, the prices of products are subject to varying price control mechanisms as part of national health systems. Price controls or other changes in pricing regulation could restrict the amount that we are able to charge for our products, if any. Accordingly, in markets outside the ~~United States~~ **U. S.** , the potential revenue may be insufficient to generate commercially reasonable revenue and profits. We expect to experience pricing pressures in connection with products due to the increasing trend toward managed healthcare, including the increasing influence of health maintenance organizations and additional legislative changes. The downward pressure on healthcare costs in general, particularly prescription drugs, has increased and is expected to continue to increase in the future. As a result, profitability of our products, if any, may be more difficult to achieve even if they receive regulatory approval. Risks Related to Our Business Operations Our future success depends in part on our ability to attract, retain, and motivate qualified personnel. ~~Recruiting~~ **If we lose key personnel, or if we fail to recruit additional highly skilled personnel, our ability to develop our product candidates will be impaired** and **our business may be harmed. Our ability to compete in the highly competitive biotechnology and pharmaceutical industries depends greatly upon our ability to attract and** ~~retaining~~ **retain highly qualified managerial, scientific and medical personnel with particular subject matter expertise. We are highly dependent on our management team. The loss of the services of key personnel, and our inability to find suitable replacements, could result in delays in the development of our product candidates and harm our business. Unless we are able to replace departed employees effectively, we may require current employees to fill additional roles, and this could overextend their responsibilities. As a result, we may experience increased turnover due to employees being overworked. Employees also may be unable to perform these multiple roles effectively due to time and resource constraints. Additionally, if we are unable to retain key personnel, we may be required to cover the roles previously performed by such employees with consultants. These consultants may lack the same skills and performance of departed employees and, as a result, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain regulatory approval of our product candidates or otherwise advance our business. We primarily conduct our business in Massachusetts. This region is headquarters to many** other **biopharmaceutical companies** ~~qualified employees, consultants,~~ and **many academic** ~~advisors for our business, including scientific~~ and **research institutions** ~~technical personnel, are critical to our success~~ . There is currently a shortage of highly qualified personnel in our industry, which is likely to continue. ~~As a result, competition~~ **Competition** for **skilled** personnel **in our market** is intense ~~,~~ and ~~the turnover rate can be high. We~~ may ~~not be able~~ **limit our ability** to ~~attract~~ **hire** and retain **highly qualified** personnel on acceptable terms ~~given~~ **or at all. To induce valuable employees to remain at our company, in addition to salary and cash incentives, we may grant equity awards that vest over time or vest upon the achievement of certain pre- established milestones. The value to employees of equity awards has been, and may continue to be, significantly affected by movements in our stock price that are beyond our control, and** ~~the~~ **these** ~~competition among numerous pharmaceutical and biotechnology~~ **equity awards may at any time be insufficient to counteract more lucrative offers from other** companies **. Despite our efforts to retain valuable employees, they may terminate their employment with us on short notice. Although we have employment agreements with our key employees, these agreements provide** for **at- will employment, which means that any of our employees could leave our employment at any time, with or without notice. We do not maintain " key man " insurance policies on the lives of these** individuals ~~with similar skill sets. In addition, failure to succeed in development and commercialization of our~~ **or the lives of any of our** ~~product candidates may make it more challenging to recruit and retain qualified personnel. The inability to recruit and retain qualified personnel may impede the~~ **other employees** ~~progress of our research, development, and commercialization objectives and would negatively impact our ability to succeed in our product development strategy~~ . We will need to expand our organization and we may experience difficulties in managing this growth, which could disrupt our operations. As our development and commercialization plans and strategies develop, we expect to need additional managerial, operational, sales, marketing, financial, legal, and other resources. Our management may need to divert a disproportionate amount of our attention away from our day- to- day activities and devote a substantial amount of time to managing these growth activities. We may not be able to effectively manage the expansion of our operations, which may result in weaknesses in our infrastructure, operational mistakes, loss of business opportunities, loss of employees, and reduced productivity among remaining employees. Our expected growth could require significant capital expenditures and may divert financial resources from other projects, such as the development of additional product candidates. If our management is unable to effectively manage our growth, our expenses may increase more than expected, our ability to generate and / or grow revenue could be reduced and we may not be able to implement our business strategy. Our future financial performance and our ability to commercialize product candidates and compete effectively will depend, in part, on our ability to effectively manage any future growth. Unstable market and economic conditions, inflation, increases in interest rates, natural disasters, public health crises such as the COVID- 19 pandemic, political crises, geopolitical events, such as the crisis in Ukraine, or other macroeconomic conditions, may have serious adverse consequences on our business and financial condition. The global economy, including credit and financial markets, have experienced extreme volatility and disruptions at various points over the last few decades, including, among other things, diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, supply chain shortages, increases in inflation rates, higher interest rates, and uncertainty about economic stability. For example, the COVID- 19 pandemic resulted in widespread unemployment, economic slowdown and extreme volatility in the capital markets. The Federal Reserve has raised interest rates multiple times in response to concerns about inflation and it may raise them again. Higher interest rates, coupled with reduced government spending and volatility in financial markets, may increase economic uncertainty and affect consumer spending. Similarly, the ongoing military conflict between Russia and Ukraine ~~and~~ **,** the rising tensions between China and Taiwan **, the conflict in Israel and surrounding area and domestic tensions within the U. S.**

(including the upcoming U. S. presidential election) have created ~~extreme~~ **significant** volatility in the ~~global~~ capital markets and may have further global economic consequences, including disruptions of the global supply chain. Any such volatility and disruptions may adversely affect our business or the third parties on whom we rely. If the equity and credit markets deteriorate, including as a result of political unrest or war, it may make any necessary debt or equity financing more difficult to complete, more costly, and more dilutive. Failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our growth strategy, financial performance and share price and could require us to delay or abandon development or commercialization plans. In addition, there is a risk that one or more of our service providers, manufacturers or other partners would not survive or be able to meet their commitments to us under such circumstances, which could directly affect our ability to attain our operating goals on schedule and on budget. We have experienced and may in the future experience disruptions as a result of such macroeconomic conditions, including delays or difficulties in initiating or expanding clinical trials and manufacturing sufficient quantities of materials. Any one or a combination of these events could have a material and adverse effect on our results of operations and financial condition. The Hercules Loan and Security Agreement contains certain covenants that could adversely affect our operations and, if an event of default were to occur, we could be forced to repay any outstanding indebtedness sooner than planned and possibly at a time when we do not have sufficient capital to meet this obligation. Pursuant to the Hercules Loan and Security Agreement, we have pledged substantially all of our assets, other than our intellectual property rights. Additionally, the Hercules Loan and Security Agreement contains certain affirmative and negative covenants that could prevent us from taking certain actions without the consent of our lenders. These covenants may limit our flexibility in operating our business and our ability to take actions that might be advantageous to us and our stockholders. The Hercules Loan and Security Agreement also contains customary affirmative and negative covenants that, among other things, limit our ability, subject to certain exceptions, to incur indebtedness, grant liens, enter into a merger or consolidation, enter into transactions with affiliates, or sell all or a portion of our property, business or assets. The Hercules Loan and Security Agreement contains customary events of default. Upon the occurrence and continuation of an event of default, all amounts due under the Hercules Loan and Security Agreement become (in the case of an insolvency or bankruptcy event), or may become (in the case of all other events of default and at the option of Hercules), immediately due and payable. If an event of default under the Hercules Loan and Security Agreement should occur, we could be required to immediately repay any outstanding indebtedness. If we are unable to repay such debt, the lenders would be able to foreclose on the secured collateral, including our cash accounts, and take other remedies permitted under the Hercules Loan and Security Agreement. Even if we are able to repay any indebtedness on an event of default, the repayment of these sums may significantly reduce our working capital and impair our ability to operate as planned. Failure in our information technology and storage systems **,** or those of third parties upon whom we rely **,** could significantly disrupt the operation of our business and adversely impact our financial condition. Our ability to execute our business plan and maintain operations depends on the continued and uninterrupted performance of our information technology (“ IT ”) systems or those of third parties upon whom we rely. IT systems are vulnerable to risks and damages from a variety of sources, including telecommunications or network failures, malicious human acts, and natural disasters (such as a tornado, an earthquake, or a fire). Moreover, despite network security and back- up measures, some of our and our vendors’ servers are potentially vulnerable to physical or electronic break- ins, including cyber-attacks, computer viruses, and similar disruptive problems. The techniques used by criminal elements to attack computer systems are sophisticated, change frequently, and may originate from less regulated and remote areas of the world. As a result, we may not be able to address these techniques proactively or implement adequate preventative measures. If the IT systems are compromised, we could be subject to fines, damages, litigation, and enforcement actions, and we could lose trade secrets, the occurrence of which could harm our business. Despite precautionary measures designed to prevent unanticipated problems that could affect the IT systems, sustained or repeated system failures that interrupt our ability to generate and maintain data could adversely affect our ability to operate our business. In addition, the failure of our systems, maintenance problems, upgrading or transitioning to new platforms, or a breach in security could result in delays and reduce efficiency in our operations. Remediation of such problems could result in significant, unplanned capital investments. Furthermore, parties in our supply chain may be operating from single sites, increasing their vulnerability to natural disasters or other sudden, unforeseen, and severe adverse events. If such an event were to affect our supply chain, it could have a material adverse effect on our business. A ~~network or~~ data **breach,** security incident **, or other unauthorized network intrusion or access** may allow unauthorized access to our network or data, which could result in a material disruption of our clinical trials, harm our reputation, harm our business, create additional liability and adversely impact our financial results or operational results. **Cybersecurity** ~~Increasingly, we are subject to a wide variety of~~ threats ~~on~~ **to** our information networks ~~,~~ and systems **,** and those of our service providers or collaborators **have generally increased in sophistication, scale, and frequency in recent years** . In addition to threats from natural disasters, telecommunications and electrical failures, traditional computer hackers, malicious code (such as malware, viruses, worms, and ransomware), employee error, theft or misuse, password spraying, phishing, and distributed denial- of-service ~~(“ DDOS ”)~~ attacks, we now also face threats from sophisticated nation- state and nation- state supported actors who engage in attacks (including advanced persistent threat intrusions) that add to the risks to our internal networks **and systems** , our third- party service providers, our collaborators and the information that they store and process. Despite **having implemented technical and organizational security measures and made other** significant efforts ~~to create security barriers~~ to safeguard against such threats, it is virtually impossible for us to entirely mitigate these risks. The security measures we have integrated into our internal networks and systems, which are designed to detect unauthorized activity and prevent or minimize security incidents or breaches, may not function as expected or may not be sufficient to protect our internal networks and platform against certain threats. In addition, techniques used to obtain unauthorized access to networks in which data is stored or through which data is transmitted change frequently and generally are not recognized until launched against a target. As a result, we may be unable to anticipate these techniques or implement adequate preventative measures to prevent **such** an **event**

~~electronic intrusion~~ . In addition, security incidents or breaches **affecting us** or ~~those of~~ our current or future collaborators or third- party service providers could result in **the** ~~a risk of loss or~~ unauthorized access to **,** or disclosure **or loss** of the information we process. This, in turn, could require notification under applicable data privacy regulations or contracts, and could lead to litigation, governmental audits, investigations, fines, penalties, and other possible liability, damage our relationships with our collaborators, trigger indemnification and other contractual obligations, cause us to incur investigation, mitigation and remediation expenses, ~~and~~ have a negative impact on our ability to conduct clinical trials **, and cause reputational damage** . For example, the loss of clinical trial data for our product candidates could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. We may not have adequate insurance coverage for security incidents or breaches or information system failures. The successful assertion of one or more large claims against us that exceeds our available insurance coverage or results in changes to our insurance policies (including premium increases or the imposition of large deductible or co- insurance requirements), could have an adverse effect on our business. In addition, we cannot be sure that any existing insurance coverage and coverage for errors and omissions will continue to be available on acceptable terms or that our insurers will not deny coverage as to any future claim. Any failure or perceived failure by us or ~~any~~ **our employees, representatives, contractors, consultants,** collaborators, **or other third- party** service providers ~~, or others~~ to comply with our **data** privacy, **security, protection, or** confidentiality, ~~data security~~ or ~~similar obligations~~ to **respond to** ~~third parties, or~~ any data security incidents **, breaches** or other ~~security breaches that result in the~~ unauthorized access, acquisition, or disclosure of sensitive information (including, without limitation ~~personally~~ -- **personal** ~~identifiable~~ information), may result in **additional cost and / or liability to us, including costs from** governmental investigations, enforcement actions, regulatory fines, litigation, **costs of doing business, or damage to** ~~or~~ **our reputation** ~~public statements against us, could cause third parties to lose trust in us or result in claims against us~~ . Any of these events could cause harm to our reputation, business, financial condition, or operational results. Our ability to use net operating loss carryforwards and certain other tax attributes to offset future taxable income or taxes may be limited. Our net operating loss (" NOL ") carryforwards could expire unused and be unavailable to offset future income tax liabilities because of their limited duration or because of restrictions under U. S. tax law. Our NOLs generated in tax years ending on or prior to December 31, 2017 are only permitted to be carried forward for 20 years under applicable U. S. tax law. Under the Tax Act, our federal NOLs generated in tax years ending after December 31, 2017 may be carried forward indefinitely, but the deductibility of federal NOLs generated in tax years beginning after December 31, 2017 is limited. It is uncertain if and to what extent various states will conform to the Tax Act. In addition, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended ~~(the " Code ")~~ , and corresponding provisions of state law, if a corporation undergoes an " ownership change, " which is generally 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 to offset its post- change income or taxes may be limited. Our most recent analysis of possible ownership changes was completed for certain tax periods ending through December 31, ~~2022~~ **2023** . It is possible that we have in the past undergone and may in the future undergo, additional ownership changes that could result in additional limitations on our NOL and tax credit carryforwards. In addition, at the state level, there may be periods during which the use of net operating losses is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed. Consequently, even if we achieve profitability, we may not be able to utilize a material portion of our NOL carryforwards and certain other tax attributes, which could have a material adverse effect on cash flow and results of operations. 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 adversely affect our business operations and financial performance. Further, existing tax laws, statutes, rules, regulations, or ordinances could be interpreted, changed, modified, or applied adversely to us. For example, the Tax Act enacted many significant changes to the U. S. tax laws. Future guidance from the Internal Revenue Service and other tax authorities with respect to the Tax Act may affect us, and certain aspects of the Tax Act could be repealed or modified in future legislation. In addition, it is uncertain if and to what extent various states will conform to the Tax Act or any newly enacted federal tax legislation. Changes in corporate tax rates, the realization of net deferred tax assets relating to our operations, the taxation of foreign earnings, and the deductibility of expenses under the Tax Act or future 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 effective tax rate may fluctuate, and we may incur obligations in tax jurisdictions in excess of accrued amounts. We are subject to taxation in numerous U. S. states and territories and non- U. S. jurisdictions. As a result, our effective tax rate is derived from a combination of applicable tax rates in the various places that we operate. In preparing our financial statements, we estimate the amount of tax that will become payable in each of such places. Nevertheless, our effective tax rate may be different than experienced in the past due to numerous factors including the results of examinations and audits of our tax filings, our inability to secure or sustain acceptable agreements with tax authorities, changes in accounting for income taxes, and changes in tax laws. Any of these factors could cause us to experience an effective tax rate significantly different from previous periods or our current expectations and may result in tax obligations in excess of amounts accrued in our financial statements. Risks Related to Ownership of our Common Stock Anti- takeover provisions in our charter documents and under Delaware law and the terms of some of our contracts could make an acquisition of us more difficult and may prevent attempts by our stockholders to replace or remove our management. Provisions in our Certificate of Incorporation and Bylaws may delay or prevent an acquisition or a change in management. These provisions include a prohibition on actions by written consent of our stockholders and the ability of our board of directors to issue Preferred Stock without stockholder approval. In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporate Law, which prohibits stockholders owning in excess of 15 % of our outstanding voting stock from merging or combining with us. Although we believe these provisions collectively will provide for an opportunity to receive higher bids by requiring potential

acquirers to negotiate with our board of directors, they would apply even if the offer may be considered beneficial by some stockholders. In addition, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove then current management by making it more difficult for stockholders to replace members of the board of directors, which is responsible for appointing the members of management. In addition, ~~he~~ **the** Certificate of Designation of our Series A Preferred Stock and the provisions of our warrants issued in 2020 may delay or prevent a change in control of our company. At any time while at least 30 % of the originally issued Series A Preferred Stock remains issued and outstanding, we may not consummate a Fundamental Transaction (as defined in the Certificate of Designation of the Series A Preferred Stock) or any merger or consolidation of the Company with or into another entity or any stock sale to, or other business combination in which the stockholders of the Company immediately before such transaction do not hold at least a majority of the capital stock of the Company immediately after such transaction, without the affirmative vote of the holders of a majority of the then outstanding shares of the Series A Preferred Stock. As of December 31, ~~2022~~ **2023** , a majority of the then outstanding shares of Series A Preferred Stock was held by entities affiliated with one stockholder. This provision of the Certificate of Designation may make it more difficult for us to enter into any of the aforementioned transactions. In addition, pursuant to such warrants, under certain circumstances each warrant holder has the right to demand that we redeem the warrant for a cash amount equal to the Black-Scholes value of a portion of the warrant upon the occurrence of specified events, including a merger, an asset sale or certain other change of control transactions. A takeover of us may trigger the requirement that we redeem the warrants, which could make it more costly for a potential acquirer to engage in a business combination transaction with us. Our Bylaws provide that the Court of Chancery of the State of Delaware is the exclusive forum for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers, or other employees. Our Bylaws provide that **, unless we consent in writing to an alternative forum,** the Court of Chancery of the State of Delaware is the sole and exclusive forum for any derivative action or proceeding brought on our behalf, any action asserting a breach of fiduciary duty owed by any of our directors, officers, or other employees to us or our stockholders, any action asserting a claim against us arising pursuant to any provisions of the Delaware General Corporation Law, our certificate of incorporation or our ~~bylaws~~ **Bylaws** , or any action asserting a claim against us that is governed by the internal affairs doctrine. **Our Bylaws further provide that, unless we consent in writing to an alternative forum, federal district courts of the United States will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act of 1933, as amended (the " Securities Act ").** While these choice of forum provisions do not apply to suits brought to enforce a duty or liability created by ~~the Securities Act of 1933, as amended (the " Securities Act "),~~ the Exchange Act, or any other claim for which the federal courts have exclusive jurisdiction, the choice of forum provision may limit a stockholder' s ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers, or other employees, which may discourage such lawsuits against our and our directors, officers, and other employees. If a court were to find the choice of forum provision contained in the bylaws to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions. We do not anticipate that we will pay any cash dividends in the foreseeable future. The current expectation is that we will retain our future earnings, if any, to fund the development and growth of our business. As a result, capital appreciation, if any, of our common stock will be your sole source of gain, if any, for the foreseeable future. Future sales of shares by existing stockholders could cause our stock price to decline. If our stockholders sell, or indicate an intention to sell, substantial amounts of our common stock in the public market after legal restrictions on resale lapse, the trading price of our common stock could decline. In addition, shares of our common stock that are subject to our outstanding options will become eligible for sale in the public market to the extent permitted by the provisions of various vesting agreements and Rules 144 and 701 under the Securities Act. Future sales and issuances of equity and debt could result in additional dilution to our stockholders. We expect that we will need significant additional capital to fund our current and future operations, including to complete potential clinical trials for our product candidates. To raise capital, we may sell common stock, convertible securities, or other equity securities in one or more transactions at prices and in a manner we determine from time to time. As a result, our stockholders may experience additional dilution, which could cause our stock price to fall. In addition, pursuant to our ~~Equity~~ **equity** ~~Incentive~~ **incentive** ~~Plans~~ **plans** , we may grant equity awards and issue additional shares of our common stock to our employees, directors, and consultants, and the number of shares of our common stock reserved for future issuance under certain of these plans will be subject to automatic annual increases in accordance with the terms of the plans. To the extent that new options are granted and exercised, or we issue additional shares of common stock in the future, our stockholders may experience additional dilution, which could cause our stock price to fall. Our principal stockholders own a significant percentage of our stock and will be able to exert significant control over matters subject to stockholder approval. Our directors, officers, 5 % stockholders, and their affiliates currently beneficially own a substantial portion of our outstanding voting stock. Therefore, these stockholders have the ability and may continue to have the ability to influence us through this ownership position. These stockholders may be able to determine some or all matters requiring stockholder approval. For example, these stockholders, acting together, may be able to control elections of directors, amendments of organizational documents, or approval of any merger, sale of assets, or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that you may believe are in your best interest as one of our stockholders. General Risk Factors The market price of our common stock has historically been volatile, and the market price of our common stock may drop in the future. The market price of our common stock has been, and may continue to be, subject to significant fluctuations. Market prices for securities of early- stage pharmaceutical, biotechnology, and other life sciences companies have historically been particularly volatile. In addition to the factors described elsewhere in this " Risk Factors, " some of the factors that may cause the market price of our common stock to fluctuate **greatly, and to decline significantly,** include: • failure to meet or exceed financial and development projections we may provide to the public and the investment community; • **negative outcomes, or perceived negative outcomes, from our interactions with**

regulatory authorities in connection with the development of our product candidates; • the perception of the pharmaceutical **and biotechnology** ~~industry~~ **industries** by the public, legislatures, regulators, and the investment community; • announcements of significant acquisitions, strategic collaborations, joint ventures, or capital commitments by us or our competitors; • significant lawsuits, including patent or stockholder litigation; • if securities or industry analysts do not publish research or reports about our business, or if they issue an adverse or misleading opinion regarding our business and stock; • changes in the market valuations of similar companies **; • changes in the possible market size, or perceived market size, for our product candidates** ; • announcements by commercial partners or competitors of new commercial products, clinical progress or the lack thereof, significant contracts, commercial relationships, or capital commitments; • the introduction of technological innovations or new therapies that compete with our potential products; • changes in the structure of health care payment systems; and • period- to- period fluctuations in our financial results. Moreover, the capital markets in general have experienced substantial volatility that has often been unrelated to the operating performance of individual companies, including volatility resulting from ~~the COVID- 19 pandemic and~~ general global macroeconomic conditions. These broad market fluctuations may also adversely affect the trading price of our common stock. In the past, following periods of volatility in the market price of a company' s securities, stockholders have often instituted class action securities litigation against those companies. Such litigation, if instituted, could result in substantial costs and diversion of management attention and resources, which could significantly harm our ~~profitability~~ **business** and reputation. We incur costs and demands upon management as a result of complying with the laws and regulations affecting public companies. We incur significant legal, accounting, and other expenses associated with public company reporting requirements. We also incur costs associated with corporate governance requirements, including requirements under the Sarbanes- Oxley Act **of 2002 (the " Sarbanes- Oxley Act ")** , as well as rules implemented by the SEC and The Nasdaq Stock Market LLC (" Nasdaq "). These rules and regulations increase our legal and financial compliance costs and make some activities more time- consuming and costly. These rules and regulations may also make it difficult and expensive for us to obtain directors' and officers' liability insurance. As a result, it may be more difficult for us to attract and retain qualified individuals to serve on our board of directors or as our executive officers, which may adversely affect investor confidence and could cause our business or stock price to suffer. If equity research analysts do not publish research or reports, or publish unfavorable research or reports, about us, our business, or our market, our stock price and trading volume could decline. The trading market for our common stock is influenced by the research and reports that equity research analysts publish about us and our business. Equity research analysts may elect not to provide research coverage of our common stock and such lack of research coverage may adversely affect the market price of our common stock. In the event we do have equity research analyst coverage, we will not have any control over the analysts or the content and opinions included in their reports. The price of our common 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 us or fails to publish reports on us regularly, demand for our common stock could decrease, which in turn could cause our stock price or trading volume to decline. If we fail to maintain proper and effective internal controls, our ability to produce accurate financial statements on a timely basis could be impaired, investors may lose confidence in the accuracy and completeness of our financial reports and the market price of our common stock may be negatively affected. We are subject to the reporting requirements of the Exchange Act, the Sarbanes- Oxley Act ~~,~~ and the rules and regulations of Nasdaq. The Sarbanes- Oxley Act requires, among other things, that we maintain effective disclosure controls and procedures and internal control over financial reporting. We must 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 controls over financial reporting in our annual report filing for that year, as required by Section 404 of the Sarbanes- Oxley Act. This requires that we incur substantial professional fees and internal costs to expand our accounting and finance functions and that we expend significant management efforts. We may experience difficulty in meeting these reporting requirements in a timely manner for each period. We may discover weaknesses in our system of internal financial and accounting controls and procedures that could result in a material misstatement of our financial statements. Our internal control over financial reporting will not prevent or detect all errors and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system' s objectives will be met. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud will be detected. If we are not able to comply with the requirements of Section 404 of the Sarbanes- Oxley Act, or if we are unable to maintain proper and effective internal controls, it could result in a material misstatement of our financial statements that would not be prevented or detected on a timely basis, which could require a restatement, cause us to be subject to sanctions or investigations by Nasdaq, the SEC, or other regulatory authorities, cause investors to lose confidence in our financial information, or cause our stock price to decline. As a public company, we incur significant legal, accounting, insurance, and other expenses, and our management and other personnel have and will need to continue to devote a substantial amount of time to compliance initiatives resulting from operating as a public company. We also anticipate that these costs and compliance initiatives will continue to increase as a result of ceasing to be ~~an~~ **a** " ~~emerging growth~~ **smaller reporting** company, " as defined in **Rule 12b- 2 of** the ~~in the Jumpstart~~ **Exchange Act.** Our ~~Business Startups~~ **transition to being a large accelerated filer and compliance with Section 404 of the Sarbanes- Oxley** Act of ~~2012~~ **2002 has been and will continue to be time consuming and costly . Our inability to maintain effective internal control over financial reporting in the future could result in investors losing confidence in the accuracy and completeness of our financial reports and negatively affect the market price of our common stock. As a public company, we are required to maintain internal control over financial reporting and to report any material weaknesses in such internal controls. We became a large accelerated filer effective December 31, 2023, and Section 404 of the Sarbanes- Oxley Act requires our independent registered public accounting firm to attest to the effectiveness of our internal control over financial reporting. Our transition to becoming subject to additional requirements of Section 404 of the Sarbanes-**

Oxley Act has been and will continue to be time- consuming, and there is a risk of noncompliance. Further, the costs associated with the compliance with and implementation of procedures under these and future laws and related rules could have a material impact on our results of operations. If we have a material weakness in our internal control over financial reporting, we may not detect errors on a timely basis and our financial statements may be materially misstated. If we identify material weaknesses in our internal control over financial reporting, if we are unable to comply with the requirements of Section 404 of the Sarbanes- Oxley Act in a timely manner, if we are unable to assert that our internal controls over financial reporting is effective or if our independent registered public accounting firm is unable to express an opinion as to the effectiveness of our internal control over financial reporting, investors may lose confidence in the accuracy and completeness of our financial reports, and the market price of our common stock could be negatively affected. In addition, we could become subject to investigations by any stock exchange on which our securities are listed, the SEC or other regulatory authorities, which could require additional financial and management resources, which could have an adverse impact on our business.