**Risk Factors Comparison 2024-03-13 to 2023-03-06 Form: 10-K**

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In evaluating the Company and our business, careful consideration should be given to the following risk factors, in addition to the other information set forth in this Annual Report on Form 10- K (Annual Report) and in other documents that we file with the Securities and Exchange Commission (SEC). Investing in our common stock involves a high degree of risk. If any of the following risks are realized, our business, financial condition, results of operations and prospects could be materially and adversely affected. In that event, the trading price of our common stock could decline and you could lose part or all of your investment. Unless otherwise indicated, reference in this section and elsewhere in this Annual Report to our business being adversely affected, negatively impacted or harmed will include an adverse effect on, or a negative impact or harm to, the business, reputation, financial condition, results of operations, revenue and our future prospects. The material and other risks and uncertainties summarized above and described below are not intended to be exhaustive and are not the only ones we face. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also impair our business operations. This Annual Report also contains forward- looking statements that involve risks and uncertainties. Our actual results could differ materially from those anticipated in the forward- looking statements as a result of a number of factors, including the risks described below. See the section titled " Cautionary Note Regarding Forward- Looking Statements. " Risks Related to Our Limited Operating History, Financial Position and Capital Requirements We have a limited operating history, have incurred significant operating losses since our inception and expect to incur significant losses for the foreseeable future. We may never generate any revenue from product sales or become profitable or, if we achieve profitability, we may not be able to sustain it. Biopharmaceutical product development is a highly speculative undertaking and involves a substantial degree of risk. We are a ~~preclinical- stage~~ biopharmaceutical company with a limited operating history upon which our stockholders can evaluate our business and prospects. ~~All~~ **Most** of our development programs, **with the exception of** ~~including our lead therapeutic candidates,~~ ENTR- 601- 44 ~~, ENTR- 601- 45~~ and our partnered candidate **VX- 670, but including** ENTR- ~~701~~ **601- 45 and ENTR- 601- 50** , are in preclinical development or in the drug discovery stage. We commenced operations in 2016, and to date, we have focused primarily on organizing and staffing our company, business planning, raising capital, developing our proprietary, highly versatile and modular **Endosomal Escape Vehicle (** EEV **)** platform (EEV Platform), identifying EEV therapeutic candidates, establishing our intellectual property portfolio and conducting research and preclinical studies. Our approach to the discovery and development of therapeutic candidates based on our EEV Platform is unproven, and we do not know whether we will be able to conduct clinical studies on **any of** our therapeutic candidates **beyond ENTR- 601- 44** , develop any therapeutic candidates that succeed in clinical development or produce products of commercial value. As an organization, we have not yet ~~initiated or~~ completed any clinical trials, obtained regulatory approvals, manufactured a clinical- or commercial- scale product, or arranged for a third party to do so on our behalf, or conducted sales and marketing activities necessary for successful product commercialization. Consequently, any predictions made about our future success or viability may not be as accurate as they could be if we had a history of successfully developing and commercializing biopharmaceutical products. We have incurred significant operating losses since our inception. We do not have any products approved for sale and have not generated any product revenue since our inception. If our therapeutic candidates are not successfully developed and approved, we may never generate any significant revenue from product sales. ~~Our~~ **We have incurred significant** net losses **since inception** ~~were $ 94~~ **As of** ~~6 million and $ 51. 2 million for the years ended~~ December 31, ~~2022~~ **2023** ~~and 2021, respectively. As of December 31, 2022~~ , we had an accumulated deficit of **195** ~~$ 188~~ . ~~3~~ **0** million. Substantially all of our losses have resulted from expenses incurred in connection with our research and development programs and from general and administrative costs associated with our operations. All of our therapeutic candidates will require substantial additional development time and resources before we would be able to apply for or receive regulatory approvals and begin generating revenue from product sales. We expect to continue to incur losses for the foreseeable future, and we anticipate these losses will increase substantially as we continue our development of, seek regulatory approval for and potentially commercialize any of our therapeutic candidates. To become and remain profitable, we must succeed in developing and eventually commercializing products that generate significant revenue. This will require us to be successful in a range of challenging activities, including completing preclinical studies and clinical trials of our therapeutic candidates, identifying lead therapeutic candidates, discovering additional therapeutic candidates, conducting preclinical studies prior to submitting an **Investigational new Drug (** IND **)** application, obtaining clearance for INDs, obtaining regulatory approval for these therapeutic candidates and manufacturing, marketing and selling any products for which we may obtain regulatory approval. We are only in the preliminary stages of most of these activities. We may ~~never~~ **not** succeed in ~~these~~ **completing necessary** activities **and regulatory approvals necessary to bring a product to market** and, even if we do, may never generate revenues that are significant enough to achieve profitability. In addition, we have not yet demonstrated an ability to successfully overcome many of the risks and uncertainties frequently encountered by companies in new and rapidly evolving fields, particularly in the biopharmaceutical industry. Because of the numerous risks and uncertainties associated with biopharmaceutical product development, we are unable to accurately predict the timing or amount of increased expenses or when, or if, we will be able to achieve profitability. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable may have an adverse effect on the value of our company and could impair our ability to raise capital, expand our business, maintain our research and development efforts, diversify our therapeutic candidates or even continue our operations. A decline in the value of our company could also cause our stockholders to lose all or part of their investment. Our limited operating history may make it

difficult to evaluate our technology and industry and predict our future performance. Though several groups have conducted or are conducting studies involving the intracellular delivery of therapeutic molecules, the relevance of those studies to the evaluation of therapeutic candidates developed using our EEV Platform may be difficult to ascertain. Our short history as an operating company and novel therapeutic approach make any assessment of our future success or viability subject to significant uncertainty. We will encounter risks and difficulties frequently experienced by **earlier** ~~early-~~ stage companies in rapidly evolving fields. Failure to address these risks successfully will cause our business to suffer. Similarly, we expect that our financial condition and operating results will fluctuate significantly from quarter to quarter and year to year due to a variety of factors, many of which are beyond our control. As a result, our stockholders should not rely upon the results of any quarterly or annual period as an indicator of future operating performance. In addition, as an early **clinical** - stage company, we have encountered unforeseen expenses, difficulties, complications, delays and other known and unknown circumstances. As we advance our EEV therapeutic candidates, we will need to **continue our** transition from a company with a research focus to a company ~~capable of~~ supporting clinical development and if successful, **capable of supporting** commercial activities. We may not **continue to** be successful in **our** ~~such a~~ transition. We will require additional financing to achieve our goals, and a failure to obtain this necessary capital when needed on acceptable terms, or at all, could force us to delay, limit, reduce or terminate our development programs, commercialization efforts or other operations. The development of biopharmaceutical therapeutic candidates is capital- intensive. We expect our expenses to increase in connection with our ongoing activities, particularly as we conduct our ongoing and planned preclinical studies of our development programs, **continue to** initiate clinical trials for our therapeutic candidates and seek regulatory approval for our current therapeutic candidates and any future therapeutic candidates we may develop. If we obtain regulatory approval for any of our therapeutic candidates, we also expect to incur significant commercialization expenses related to product manufacturing, marketing, sales and distribution. Because the outcome of any preclinical study or clinical trial is highly uncertain, we cannot reasonably estimate the actual amounts necessary to successfully complete the development and commercialization of our therapeutic candidates. Furthermore, we expect to incur additional costs associated with operating as a public company. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations. Failing to raise capital when needed or on attractive terms could force us to delay, reduce or eliminate our research and development programs or any future commercialization efforts. We believe that our ~~existing~~ cash, cash equivalents and marketable securities ~~of $ 188. 7 million~~ as of December 31, ~~2022~~ **2023** , together with ~~the proceeds received under the Vertex Agreement,~~ ongoing research support and the anticipated achievement of certain ~~near- term~~ milestones under the Vertex Agreement will be sufficient to extend our cash runway ~~into~~ **through** the second ~~half~~ **quarter** of ~~2025~~ **2026** , supporting the Company' s expansion and continued development of EEV therapeutic candidates targeting Duchenne muscular dystrophy and advance EEV- therapeutic candidates in indications beyond neuromuscular disease. We have based this estimate on assumptions that may prove to be wrong, and we could use our capital resources sooner than we currently expect. Our operating plans and other demands on our cash resources may change as a result of many factors currently unknown to us, and we may need to seek additional funds sooner than planned, through public or private equity or debt financings or other capital sources, including potentially additional collaborations, licenses and other similar arrangements. In addition, we may seek additional capital due to favorable market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans **. For example, in September 2023, we entered into a sales agreement (the Sales Agreement) with Cowen and Company, LLC acting as our agent and / or principal (the Sales Agent), with respect to an" at the market offering" program under which we may offer and sell, from time to time, at our sole discretion, shares of common stock having an aggregate offering price of up to $ 150. 0 million through the Sales Agent. However, there can be no assurance that the Sales Agent will be successful in consummating future sales based on prevailing market conditions or in the quantities or at the prices that we deem appropriate** . Attempting to secure additional financing may divert our management from our day- to- day activities, which may adversely affect our ability to develop our therapeutic candidates. Our future capital requirements will depend on many factors, including, but not limited to: • the type, number, scope, progress, expansions, results, costs and timing of our preclinical studies and any clinical trials of the therapeutic candidates that we are pursuing or may choose to pursue in the future; • the clinical development plans we establish for our EEV therapeutic candidates; • the costs and timing of manufacturing for our therapeutic candidates and commercial manufacturing if any therapeutic candidate is approved; • the costs of establishing and maintaining clinical and commercial supply for the development and manufacture of our therapeutic candidates; • the costs, timing and outcome of regulatory review of our therapeutic candidates; • the terms and timing of establishing and maintaining collaborations, licenses and other similar arrangements; • the costs of obtaining, maintaining and enforcing our patents and other intellectual property rights; • our efforts to enhance operational systems and hire additional personnel to satisfy our obligations as a public company, including enhanced internal controls over financial reporting; • the costs associated with hiring additional personnel and consultants as our preclinical and clinical activities increase; • the achievement of milestones or occurrence of other developments that trigger payments under any collaboration agreements, if any; • the costs and timing of establishing or securing sales and marketing capabilities if any therapeutic candidate is approved; • subject to receipt of regulatory approval, revenue, if any, received from commercial sales of our therapeutic candidates; • our ability to achieve sufficient market acceptance, coverage and adequate reimbursement from third- party payors and adequate market share and revenue for any approved products; • the costs of preparing, filing and prosecuting patent applications, maintaining and protecting our intellectual property rights, including enforcing and defending intellectual property related claims; and • the ongoing costs of operating as a public company. Identifying potential therapeutic candidates and conducting preclinical studies and clinical trials is a time- consuming, expensive and uncertain process that takes years to complete, and we may never generate the necessary data or results required to obtain regulatory approval and commercialize our therapeutic candidates. In addition, our therapeutic candidates, if approved, may not achieve commercial success. Our commercial revenues, if any, will be derived from sales of products that we do not expect to be

commercially available for many years, if at all. Accordingly, we will need to continue to rely on additional financing to achieve our business objectives. Adequate additional financing may not be available to us on acceptable terms, or at all. Our operating results may fluctuate significantly, which makes our future operating results difficult to predict and could cause our operating results to fall below expectations or our guidance. Our quarterly and annual operating results may fluctuate significantly in the future, which makes it difficult for us to predict our future operating results. From time to time, we may enter into license or collaboration agreements or strategic partnerships with other companies that include development funding and significant upfront and milestone payments and / or royalties, which may become an important source of our revenue. These upfront and milestone payments may vary significantly from period to period and any such variance could cause a significant fluctuation in our operating results from one period to the next. In addition, we measure compensation cost for stock- based awards made to employees at the grant date of the award, based on the fair value of the award as determined by our board of directors, and recognize the cost as an expense over the employee' s requisite service period. As the variables that we use as a basis for valuing these awards change over time, including our underlying stock price and stock price volatility, the magnitude of the expense that we must recognize may vary significantly. Furthermore, our operating results may fluctuate due to a variety of other factors, many of which are outside of our control and may be difficult to predict, including the following: • the timing and cost of, and level of investment in, research and development activities relating to our programs, which will change from time to time; • our ability to enroll patients in clinical trials and the timing of enrollment; • the cost of manufacturing our current therapeutic candidates and any future therapeutic candidates, which may vary depending on **the U. S. Food and Drug Administration (** FDA **)** , **the European Medicines Agency (** EMA **)** or other comparable foreign regulatory authority guidelines and requirements, the quantity of production and the terms of our agreements with manufacturers; • expenditures that we will or may incur to acquire or develop additional therapeutic candidates and technologies or other assets; • the timing and outcomes of preclinical studies and clinical trials for ENTR- 601- 44, ENTR- 601- 45, ENTR- ~~701-~~ **601- 50, our partnered candidate VX- 670** and any therapeutic candidates from our discovery programs, or competing therapeutic candidates; • the need to conduct unanticipated clinical trials or trials that are larger or more complex than anticipated; • competition from existing and potential future products that compete with ENTR- 601- 44, ENTR- 601- 45, ENTR- ~~701-~~ **601- 50, our partnered candidate VX- 670** or any of our discovery programs, and changes in the competitive landscape of our industry, including consolidation among our competitors or partners; • any delays in regulatory review or approval of ENTR- 601- 44, ENTR- 601- 45, ENTR- ~~701-~~ **601- 50, our partnered candidate VX- 670** or therapeutic candidates from any of our discovery programs; • the level of demand for any of our therapeutic candidates, if approved, which may fluctuate significantly and be difficult to predict; • the risk / benefit profile, cost and reimbursement policies with respect to our therapeutic candidates, if approved, and existing and potential future products that compete with ENTR- 601- 44, ENTR- 601- 45, ENTR- ~~701-~~ **601- 50, our partnered candidate VX- 670** or any of our discovery programs; • our or our partners' ability to commercialize ENTR- 601- 44, ENTR- 601- 45, ENTR- ~~701-~~ **601- 50, our partnered candidate VX- 670** or therapeutic candidates from any of our discovery programs, if approved, inside and outside of the U. S., either independently or working with third parties; • our ability to establish and maintain collaborations, licensing or other arrangements; • our ability to adequately support future growth; • potential unforeseen business disruptions that increase our costs or expenses; • future accounting pronouncements or changes in our accounting policies; and • the changing and volatile **United States** ~~U. S.~~ and global economic and political environment. The cumulative effect of these factors could result in large fluctuations and unpredictability in our quarterly and annual operating results. As a result, comparing our operating results on a period- to- period basis may not be meaningful. Investors should not rely on our past results as an indication of our future performance. This variability and unpredictability could also result in our failing to meet the expectations of industry or financial analysts or investors for any period. If our revenue or operating results fall below the expectations of analysts or investors or below any forecasts we may provide to the market, or if the forecasts we provide to the market are below the expectations of analysts or investors, the price of our common stock could decline substantially. Such a stock price decline could occur even when we have met any previously publicly stated guidance we may provide. Risks Related to the Discovery, Development and Regulatory Approval of Our Therapeutic Candidates We are early in our development efforts ~~. We have not initiated clinical studies,~~ and as a result it will be years before we commercialize a therapeutic candidate, if ever. If we are unable to identify and advance therapeutic candidates through preclinical studies and **/ or** clinical trials, obtain marketing approval and ultimately commercialize them, or experience significant delays in doing so, our business will be materially harmed. We are early in our development efforts and all our development programs, including our lead therapeutic candidates ENTR- 601- 44 ~~, ENTR- 601- 45~~ and our partnered candidate **VX- 670, which are in the early clinical stage, and** ENTR- ~~701-~~ **601- 45 and ENTR- 601- 50** , **which** are in the preclinical or drug discovery stage. We have invested substantially all of our research efforts to date in developing our EEV Platform, identifying potential therapeutic candidates ~~and ,~~ conducting preclinical studies **, and initiating early clinical studies** . As an organization, we have never ~~conducted~~ **completed** any clinical trials or submitted an application for regulatory approval, and we may be unable to do so for our therapeutic candidates. ~~Our~~ **The** ~~IND~~ **INDs** for ENTR- 601- 44 ~~has~~ **and VX- 670 have** not yet been allowed to proceed **in the United States** , and we have not completed IND- enabling studies for our other candidates. We **, or our partner as applicable,** will need to complete these steps to support the progression of ENTR- 601- 44, ENTR- 601- 45 ~~and ,~~ ENTR- ~~701~~ **601- 50, and VX- 670** into and **/ or** through clinical studies **in the United States** . In addition, we have a development portfolio of programs that are in earlier stages of development and have not yet initiated or completed IND- enabling studies. We may never advance any therapeutic candidates through IND- enabling studies and receive authorization from the FDA, to proceed under an IND prior to initiating their clinical- stage development. Our ability to generate product revenue, which we do not expect will occur for many years, if ever, will depend heavily on the successful development and eventual commercialization of our therapeutic candidates, which may never occur. We currently generate no revenue from sales of any product, and we may never be able to develop or commercialize a marketable product. Commencing clinical trials in the United States is subject to

acceptance by the FDA of an IND and finalizing the trial design based on discussions with the FDA and other regulatory authorities. For the FDA to accept an IND, we must complete Good Laboratory Practices (GLP) studies, which may not be successful or may take longer than we expect. The FDA may require us to complete additional preclinical studies or we may be required to satisfy other FDA requests prior to commencing clinical trials, and such requests may not currently be known or anticipated, which may cause the start of our first clinical trials to be delayed or prevent us from conducting clinical trials. For example, the FDA has placed ENTR- 601- 44 on clinical hold and requested that we gather and submit additional information regarding ENTR- 601- 44. Even after we receive and incorporate guidance from these regulatory authorities, the FDA or other regulatory authorities could disagree that we have satisfied their requirements to commence any clinical trial or change their position on the acceptability of our trial design or the clinical endpoints selected, including with respect to ENTR- 601- 44, which may require us to complete additional preclinical studies or clinical trials, impose stricter approval conditions than we currently expect or may prevent us from conducting clinical trials. There are equivalent processes and risks applicable to clinical trial applications in other countries, including countries in the European Union (EU). Commercialization of any therapeutic candidates we may develop will require preclinical and clinical development; regulatory and marketing approval in multiple jurisdictions, including by the FDA and the EMA; manufacturing supply, capacity and expertise; a commercial organization; and significant marketing efforts. The success of therapeutic candidates we may identify and develop will depend on many factors, including: • timely and successful completion of preclinical studies, including toxicology studies, biodistribution studies and minimally efficacious dose studies in animals, where applicable; • sufficiency of our financial and other resources to complete the necessary preclinical studies and clinical trials; • effective INDs or comparable foreign applications that allow commencement of our planned clinical trials or future clinical trials for any therapeutic candidates we may develop; • successful enrollment and completion of clinical trials, including under the FDA' s ~~eGCPs~~ **current Good Clinical Practices** , GLPs and any additional regulatory requirements from foreign regulatory authorities; • positive results from our **current and** future clinical trials that support a finding of safety and effectiveness and an acceptable risk- benefit profile in the intended populations; • receipt of regulatory marketing approvals from applicable regulatory authorities; • establishment of arrangements with third- party manufacturers for clinical supply and, where applicable, commercial manufacturing capabilities; • establishment, maintenance, defense and enforcement of patent, trademark, trade secret and other intellectual property protection or regulatory exclusivity for any therapeutic candidates we may develop; • patient recruitment and enrollment; • commercial launch of any therapeutic candidates we may develop, if approved, whether alone or in collaboration with others; • acceptance of the benefits and use of our therapeutic candidates we may develop, including method of administration, if and when approved, by patients, the medical community and third- party payors; • our ability to compete effectively with other therapies and treatment options; • maintenance of a continued acceptable safety, tolerability and efficacy profile of any therapeutic candidates we may develop following approval; and • establishment and maintenance of healthcare coverage and adequate reimbursement by payors. If we do not succeed in one or more of these factors in a timely manner or at all, we could experience significant delays or an inability to successfully commercialize any therapeutic candidates we may develop, which would materially harm our business. If we are unable to advance our therapeutic candidates to clinical development, obtain regulatory approval and ultimately commercialize our therapeutic candidates, or experience significant delays in doing so, our business will be materially harmed. The FDA has placed the IND application for ENTR- 601- 44 for the potential treatment of **DMD** ~~Duchenne muscular dystrophy~~ on clinical hold. Should **our** ~~we be delayed in submitting a~~ response to the clinical hold in the United States ~~or our response is~~ not **be** satisfactory to the FDA, the clinical hold may not be lifted on a timely basis, or at all. The FDA has placed the IND application for ENTR- 601- 44 for the potential treatment of **DMD** ~~Duchenne muscular dystrophy~~ on clinical hold and requested that we gather and submit additional information regarding ENTR- 601- 44. We are actively working to resolve the clinical hold in the United States ~~as quickly as possible~~ . Should we be delayed in submitting a response to the clinical hold in the United States or our response is not satisfactory to the FDA, the clinical hold may not be lifted on a timely basis, or at all. **In addition, we received authorization from** ~~We are exploring a range of options globally with~~ the ~~goal of~~ **MHRA to** ~~initiating~~ **initiate** a healthy volunteer trial in **the United Kingdom in** 2023. However, if our efforts in the United States ~~and elsewhere~~ **or the United Kingdom** are not successful, we may not be able to initiate ~~our~~ **or** ~~healthy volunteer~~ **complete a** clinical ~~trial for~~ **development program that enables the approval and marketing of** ENTR- 601- 44 as planned, or at all. Our business is highly dependent on the clinical advancement of our programs and modalities and is especially dependent on the success of our lead EEV therapeutic **candidates, ENTR- 601- 44, ENTR- 601- 45, ENTR- 601- 50 and our partnered** candidate **VX** ~~, ENTR - 670 601- 44~~ . Delay or failure to advance programs or modalities, including ENTR- 601- 44 **, ENTR- 601- 45, ENTR- 601- 50 and VX- 670** could adversely impact our business. Using our platform, we are developing product features for medicines based on EEVs. Over time, our platform work led to commonalities, where a specific combination of EEV technologies, delivery technologies, and manufacturing processes generated a set of product features shared by multiple programs, for example, oligonucleotide- ~~conjugated EEVs~~ **, enzyme-,** and antibody- conjugated EEVs. This is what we call a " modality. " We are utilizing early programs in a modality, such as ENTR- 601- 44 for oligonucleotide- conjugated EEVs, to understand the technology risks within the modality, including manufacturing and pharmaceutical properties. Our lead therapeutic candidate, ENTR- 601- 44, is being developed to address ~~Duchenne muscular dystrophy (~~DMD ~~)~~ and we are highly dependent on the success of the future clinical trials of ENTR- 601- 44, the outcomes of which are uncertain, to further develop ENTR- 601- 45, ~~a~~ **our** lead therapeutic candidate for patients with DMD with exon 45 skipping amenable mutations **as well as ENTR- 601- 50, our therapeutic candidate for patients with DMD who are exon 50 skipping amenable** . Because ENTR- 601- 44 is our first EEV therapeutic candidate, if ENTR- 601- 44 encounters safety, efficacy, supply or manufacturing problems, developmental delays, regulatory or commercialization issues or other problems, the value of our EEV Platform, including our other therapeutic candidates such as ENTR- 601- 45 **, ENTR- 601- 50,** and our partnered candidate ~~ENTR~~ **VX** ~~701~~ **670** , could be greatly diminished and our development plans and business would be significantly harmed. Even if our earlier programs in a modality

are successful in any phase of development any of such earlier programs may fail at a later phase of development, and other programs within the same modality may still fail at any phase of development including at phases where earlier programs in that modality were successful. This may be a result of technical challenges unique to that program or due to biology risk, which is unique to every program. As we progress our programs through clinical development, there may be new technical challenges that arise that cause an entire modality to fail. Our EEV therapeutic candidates are based on a novel therapeutic approach, which makes it difficult to predict the time and cost of development and of subsequently obtaining regulatory approval, if at all. Using EEV technology to develop therapeutic candidates is a new therapeutic approach and no products based on EEVs have been approved to date in the United States ~~, the United Kingdom~~ or the ~~EU~~ **rest of the world** . As such, it is difficult to accurately predict the developmental challenges we may face for our EEV therapeutic candidates as they proceed through development. In addition, because we have not yet ~~commenced~~ **completed** any clinical trials with our EEV therapeutic candidates, we have not yet been able to assess safety in humans and there may be short- term or long- term effects from treatment with any therapeutic candidates that we develop that we cannot predict at this time. Also, animal models may not exist for some of the diseases we choose to pursue in our programs. As a result of these factors, it is more difficult for us to predict the time and cost of therapeutic candidate development and we cannot predict whether our EEV Platform, or any similar or competitive intracellular delivery technologies, will enable the identification, development and regulatory approval of any products. There can be no assurance that any development problems we experience in the future related to our EEV Platform or any of our research programs will not cause significant delays or unanticipated costs or that such development problems can be solved. Any of these factors may prevent us from completing our preclinical studies or any clinical trials that we may initiate or commercializing any therapeutic candidates we may develop on a timely or profitable basis, if at all. The clinical trial requirements of the FDA and other regulatory authorities and the criteria these regulators use to determine the safety and efficacy of a therapeutic candidate vary substantially according to the type, complexity, novelty and intended use and market of the therapeutic candidate. No products based on EEVs have been approved to date by regulators. As a result, the regulatory approval process for therapeutic candidates such as ours is uncertain and may be more expensive and take longer than the approval process for therapeutic candidates based on other, better known or more extensively studied technologies. For example, the general approach for FDA approval of a new biologic or drug is for sponsors to seek licensure or approval based on dispositive data from well- controlled, Phase 3 clinical trials of the relevant therapeutic candidate in the relevant patient population. Phase 3 clinical trials typically involve hundreds of patients, have significant costs and take years to complete. It is difficult to determine how long it will take or how much it will cost to obtain regulatory approvals for our therapeutic candidates in the U. S., the UK, ~~the EU~~ or other regions of the world or how long it will take to commercialize our therapeutic candidates. Delay or failure to obtain or unexpected costs in obtaining the regulatory approvals necessary to bring a potential therapeutic candidate to market could decrease our ability to generate sufficient product revenue and our business, financial condition, results of operations and prospects may be harmed. Preclinical and clinical development involves a lengthy and expensive process with an uncertain outcome, and the results of preclinical studies are not necessarily predictive of the results of later preclinical studies and any clinical trials of our therapeutic candidates. We have not ~~tested~~ **yet completed the testing of** any of our therapeutic candidates in clinical trials and our therapeutic candidates may not have favorable results in clinical trials ~~, if any,~~ or receive regulatory approval on a timely basis, if at all. Preclinical and clinical development is expensive and can take many years to complete, and its outcome is inherently uncertain. We cannot guarantee that any preclinical studies or clinical trials will be conducted as planned or completed on schedule, if at all, and failure can occur at any time during the preclinical study or clinical trial process. Any positive results from our preclinical studies of our EEV therapeutic candidates may not necessarily be predictive of the results in later preclinical studies and clinical trials. Similarly, even if we are able to complete our **current or** planned preclinical studies or clinical trials of our therapeutic candidates according to our current development timeline, the positive results from such preclinical studies and clinical trials may not be replicated in our subsequent preclinical studies or later- stage clinical trials. Despite promising preclinical or clinical results, any therapeutic candidate can unexpectedly fail at any stage of preclinical or clinical development. The historical failure rate for therapeutic candidates in our industry is high. The results from preclinical studies or clinical trials of a therapeutic candidate may not predict the results of later clinical trials of the therapeutic candidate, and interim, topline, or preliminary results of a clinical trial are not necessarily indicative of final results. Therapeutic candidates in later stages of clinical trials may fail to show the desired safety and efficacy characteristics despite having progressed through preclinical studies and initial clinical trials. In particular, while we have conducted certain preclinical studies of ENTR- 601- 44, ENTR- 601- 45, ENTR- ~~701~~ **601- 50, our partnered candidate VX- 670** and other potential therapeutic candidates, we do not know whether ENTR- 601- 44, ENTR- 601- 45, ENTR- ~~701~~ **601- 50, VX- 670** or the other potential therapeutic candidates will perform in future clinical trials as they have performed in these prior studies. The positive results we have observed for our therapeutic candidates in early, non- GLP preclinical studies and animal models may not be predictive of our future clinical trials in humans. Furthermore, for some indications that we are pursuing there are no animal models that adequately mirror the human disease to predict any level of positive results. It is not uncommon to observe results in clinical trials that are unexpected based on preclinical studies and early clinical trials, and many therapeutic candidates fail in clinical trials despite very promising early results. Unexpected observations or toxicities observed in our IND- enabling studies for example, could delay clinical trials for ENTR- 601- 44, ENTR- 601- 45, ENTR- ~~701~~ **601- 50, VX- 670** or our other development programs. Moreover, preclinical and clinical data may be susceptible to varying interpretations and analyses. A number of companies in the biopharmaceutical and biotechnology industries have suffered significant setbacks in clinical development even after achieving promising results in earlier studies, and companies that have believed their therapeutic candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain FDA approval. Additionally, we may conduct clinical trials that utilize an " open- label " trial design. An " open- label " clinical trial is one where both the patient and investigator know whether the patient is receiving the investigational therapeutic candidate or either

an existing approved drug or placebo. Most typically, open- label clinical trials test only the investigational therapeutic candidate and sometimes may do so at different dose levels. Open- label clinical trials are subject to various limitations that may exaggerate any therapeutic effect as patients in open- label clinical trials are aware when they are receiving treatment. Open- label clinical trials may be subject to a " patient bias " where patients perceive their symptoms to have improved merely due to their awareness of receiving an experimental treatment. In addition, open- label clinical trials may be subject to an " investigator bias " where those assessing and reviewing the physiological outcomes of the clinical trials are aware of which patients have received treatment and may interpret the information of the treated group more favorably given this knowledge. The results from an open- label trial may not be predictive of future clinical trial results with any of our therapeutic candidates for which we include an open- label clinical trial when studied in a controlled environment with a placebo or active control. For the foregoing reasons, we cannot be certain that our ongoing and planned preclinical studies and planned clinical trials will be successful. Any safety concerns observed in any one of our clinical trials in our targeted indications could limit the prospects for regulatory approval of our therapeutic candidates in those and other indications, which could have a material adverse effect on our business, financial condition and results of operations. Substantial delays in the commencement ~~, enrollment or completion~~ of our planned clinical trials **or the enrollment or completion of our current or planned clinical trials,** or failure to demonstrate safety and efficacy to the satisfaction of applicable regulatory authorities could prevent us from commercializing any therapeutic candidates we determine to develop on a timely basis, if at all. The risk of failure in developing therapeutic candidates is high. It is impossible to predict when or if any therapeutic candidate would prove effective or safe in humans or will receive regulatory approval. Before obtaining marketing approval from regulatory authorities for the sale of any therapeutic candidate, we must complete preclinical development, submit an IND or foreign equivalent to permit initiation of clinical studies, and then conduct extensive clinical trials to demonstrate the safety and efficacy of therapeutic candidates in humans. As an organization, we submitted an IND for ENTR- 601- 44 in the fourth quarter of 2022, which was subsequently placed on clinical hold. We **are advancing this program in a single ascending dose clinical trial in healthy volunteers in the United Kingdom and have completed dosing in three cohorts of our Phase 1 clinical trial. In parallel we are committed to resolving the clinical hold in the United States. We** plan to advance ENTR- 601- 45, our EEV therapeutic candidate targeting exon 45, to **CTA /** IND submission in the fourth quarter of 2024 **and ENTR- 601- 50 to CTA / IND submission in 2025** . We ~~have not previously conducted any clinical trials of any therapeutic candidates,~~ have limited experience as a company in preparing, submitting and prosecuting regulatory filings and have not previously submitted an IND, NDA or BLA or other comparable foreign regulatory submission for any therapeutic candidate. In addition, we have had limited interactions with the FDA and cannot be certain how many clinical trials of ENTR- 601- 44, ENTR- 601- 45, ENTR- ~~701~~ **601- 50, our partnered candidate VX- 670** or any other therapeutic candidates will be required or how such trials should be designed. Consequently, we may be unable to successfully and efficiently execute and complete necessary clinical trials in a way that leads to regulatory submission and approval of any of our therapeutic candidates. Clinical trials may fail to demonstrate that our therapeutic candidates are safe for humans and effective for indicated uses. Even if the clinical trials are successful, changes in marketing approval policies during the development period, changes in or the enactment or promulgation of additional statutes, regulations or guidance or changes in regulatory review for each submitted product application may cause delays in the approval or rejection of an application. Before we can commence clinical trials for a therapeutic candidate, we must complete extensive preclinical testing and studies that support our INDs and other regulatory filings. We cannot be certain of the timely identification of a therapeutic candidate or the completion or outcome of our preclinical testing and studies and cannot predict whether the FDA will accept our proposed clinical programs or whether the outcome of our preclinical testing and studies will ultimately support the further development of any therapeutic candidates. Conducting preclinical testing is a lengthy, time- consuming and expensive process. The length of time may vary substantially according to the type, complexity and novelty of the program, and often can be several years or more per program. As a result, we cannot be sure that we will be able to submit INDs for our preclinical programs on the timelines we expect, if at all, and we cannot be sure that submission of INDs will result in the FDA allowing clinical trials to begin. For example, the FDA has placed the IND application for ENTR- 601- 44 for the potential treatment of Duchenne muscular dystrophy on clinical hold and requested that we gather and submit additional information regarding ENTR- 601- 44. We are actively working to resolve the clinical hold in the United States ~~as quickly as possible~~ . Should **our** ~~we be delayed in submitting a~~ response to the clinical hold in the United States ~~or our response is~~ not **be** satisfactory to the FDA, the clinical hold may not be lifted on a timely basis, or at all. In addition, given the extraordinary unmet need, we **initiated** ~~are exploring a range of options globally with the goal of initiating~~ a healthy volunteer trial in ~~2023~~ **the United Kingdom and have completed dosing in three cohorts in our Phase 1 clinical trial evaluating ENTR- 601- 44 for the potential treatment of individuals with DMD who are exon 44 skipping amenable** . However, if our efforts in the United States and elsewhere are not successful, we may not be able to **complete a** ~~initiate our healthy volunteer~~ clinical ~~trial for~~ **development program that enables the approval and marketing of** ENTR- 601- 44 as planned, or at all. Furthermore, therapeutic candidates are subject to continued preclinical safety studies, which may be conducted concurrently with our clinical testing. The outcomes of these safety studies may delay the launch of or enrollment in future clinical trials and could impact our ability to continue to conduct our clinical trials. Clinical testing is expensive, is difficult to design and implement, can take many years to complete and is uncertain as to outcome. We cannot guarantee that any clinical trials will be conducted as planned or completed on schedule, or at all. A failure of one or more clinical trials can occur at any stage of testing, which may result from a multitude of factors, including, but not limited to, flaws in trial design, dose selection issues, patient enrollment criteria and failure to demonstrate favorable safety or efficacy traits. Other events that may prevent successful enrollment, initiation or timely completion of clinical development include: • we may be unable to generate sufficient preclinical, toxicology or other in vivo or in vitro data to support the initiation of clinical trials; • delays in reaching a consensus with regulatory authorities on trial design; • delays in reaching agreement on acceptable terms with prospective clinical research organizations (CROs) and clinical trial sites; • delays

in opening clinical trial sites or obtaining required institutional review board (IRB) or independent ethics committee approval, or the equivalent review groups for sites outside the United States, at each clinical trial site; • we may need to add new or additional clinical trial sites; • imposition of a clinical hold by regulatory authorities as a result of a serious adverse event or after an inspection of our clinical trial operations or trial sites; • negative or inconclusive results observed in clinical trials, including failure to demonstrate statistical significance, safety, purity or potency, which could lead us, or cause regulators to require us, to conduct additional clinical trials or abandon product development programs; • positive results from our preclinical studies of our therapeutic candidates may not necessarily be predictive of the results from required later preclinical studies and clinical trials and positive results from such preclinical studies and clinical trials of our therapeutic candidates may not be replicated in subsequent preclinical studies or clinical trial results; • failure by us, any CROs we engage or any other third parties to adhere to clinical trial requirements; • failure to perform in accordance with applicable GCPs; • failure by investigators to adhere to clinical trial protocols leading to variable results; • delays in the testing, validation, manufacturing and delivery of any therapeutic candidates we may develop to the clinical sites, including delays by third parties with whom we have contracted to perform certain of those functions; • failure of our third- party contractors to comply with regulatory requirements or to meet their contractual obligations to us in a timely manner, or at all; • delays in having patients complete participation in a trial or return for post- treatment follow- up; • clinical trial sites or patients dropping out of a trial; • selection of clinical endpoints that require prolonged periods of clinical observation or analysis of the resulting data; • occurrence of serious adverse events associated with the therapeutic candidate that are viewed to outweigh its potential benefits; • occurrence of serious adverse events associated with a therapeutic candidate in development by another company, which are viewed to outweigh its potential benefits, and which may negatively impact the perception of our product due to a similarity in technology or approach; • changes in regulatory requirements and guidance that require amending or submitting new clinical protocols; • the FDA or other regulatory authorities may require us to submit additional data such as long- term toxicology studies or impose other requirements before permitting us to initiate a clinical trial; • changes in the legal or regulatory regimes domestically or internationally related to patient rights and privacy; or • lack of adequate funding to continue the clinical trial. After initiating a clinical trial, we could also encounter delays if the clinical trial is suspended, placed on clinical hold or terminated by us, the IRBs of the institutions in which such trials are being conducted, or the FDA or other regulatory authorities or recommended for suspension or termination by the Data Safety Monitoring Board (DSMB) for such trial. A suspension or termination may be imposed due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a product or treatment, failure to establish or achieve clinically meaningful trial endpoints, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. Many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our therapeutic candidates. Further, the FDA or other regulatory authorities may disagree with our clinical trial design and our interpretation of data from preclinical studies, clinical trials, or may change the requirements for approval even after they have reviewed and commented on the design for our clinical trials. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses and many companies that believed their therapeutic candidates performed satisfactorily in preclinical studies and clinical trials nonetheless failed to obtain ~~FDA~~ **regulatory** approval. Any inability to successfully complete preclinical studies and clinical trials could result in additional costs to us or impair our ability to generate revenues from product sales, regulatory and commercialization milestones and royalties. In addition, manufacturing or formulation changes to any therapeutic candidates we may develop may require us to conduct additional studies or trials to bridge our modified therapeutic candidates to earlier versions. Clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize any therapeutic candidates we may develop or allow our competitors to bring products to market before we do, which could impair our ability to successfully commercialize any therapeutic candidates we may develop and may harm our business, financial condition, results of operations and prospects. Additionally, if the results of future clinical trials are inconclusive or if there are safety concerns or serious adverse events associated with any therapeutic candidates we may develop, we may: • be delayed in obtaining marketing approval for therapeutic candidates, if at all; • obtain approval for indications or patient populations that are not as broad as intended or desired; • obtain approval with labeling that includes significant use or distribution restrictions or safety warnings; • be subject to changes in the way the product is administered; • be required to perform additional clinical trials to support approval or be subject to additional post- marketing testing requirements; • have regulatory authorities withdraw, or suspend, their approval of the product or impose restrictions on its distribution in the form of a modified risk evaluation and mitigation strategy; • be subject to the addition of labeling statements, such as warnings or contraindications; • be sued; or • experience damage to our reputation. Delays or difficulties in the enrollment of patients in clinical trials could delay or prevent our receipt of necessary regulatory approvals. Failure to locate and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA or similar regulatory authorities outside the U. S. may delay or prevent us from initiating or continuing clinical trials for our therapeutic candidates. Because the target patient populations for some of our therapeutic candidates are relatively small, it may be difficult to successfully identify patients. Although we may enter into agreements with third parties to develop companion diagnostic tests for use in some of our future clinical trials in order to help identify eligible patients in certain indications, we may experience delays in reaching, or fail to reach, agreement on acceptable terms to develop such companion diagnostic tests. Any third parties whom we engage to develop companion diagnostic tests may experience delays or may not be successful in developing such companion diagnostic tests, furthering the difficulty in identifying patients for our clinical trials. In addition, current commercially available diagnostic tests to identify appropriate patients for our clinical trials or any approved therapeutic candidates may become unavailable in the future. Furthermore, some of our competitors have ongoing clinical trials for

therapeutic candidates that treat the same indications as our therapeutic candidates, and patients who would otherwise be eligible for our clinical trials may instead enroll in clinical trials of our competitors' therapeutic candidates. In addition, the pediatric population is an important patient population for certain of the indications we are targeting, including DMD, and our addressable patient population estimates include pediatric populations. However, it may be more challenging to conduct studies in this population, and to locate and enroll pediatric patients. Additionally, it may be challenging to ensure that pediatric or adolescent patients adhere to clinical trial protocols. Patient enrollment and trial competition may be affected by other factors including: • clinicians' and patients' perceived risks and benefits of the therapeutic candidate under trial, particularly therapeutic candidates developed using a novel and unproven therapeutic approach, like our EEV therapeutic candidates in relation to available or investigational drugs; • size of the patient population, in particular for rare diseases such as the diseases on which we are initially focused, and process for identifying patients; • design of the trial protocol; • efforts to facilitate timely enrollment in clinical trials; • eligibility and exclusion criteria; • availability of competing therapies and clinical trials; • severity of the disease or disorder under investigation; • proximity and availability of clinical trial sites for prospective patients; • ability to obtain and maintain patient consent; • risk that enrolled patients will drop out before completion of the trial; • patient referral practices of physicians; and • ability to monitor patients adequately during and after treatment. Our inability to identify patients appropriate for enrollment in our clinical trials, or to enroll a sufficient number of patients in our clinical trials, would result in significant delays and could require us to abandon one or more clinical trials altogether. Enrollment delays in our clinical trials may result in increased development costs for our therapeutic candidates, which would cause the value of our company to decline and limit our ability to obtain additional financing. If we are unable to include patients with the driver of the disease, including the applicable genomic alteration for diseases in genomically defined patient populations, this could limit our ability to seek participation in the FDA' s expedited development programs, including Breakthrough Therapy Designation and Fast Track Designation, or otherwise to seek to accelerate clinical development and regulatory timelines. Even if we are able to enroll a sufficient number of patients for our clinical trials, we may have difficulty maintaining patients in our clinical trials. In our planned clinical trials that will include a placebo group, some of the patients who end up receiving placebo may perceive that they are not receiving the therapeutic candidate being tested, and they may decide to withdraw from our clinical trials to pursue other alternative therapies rather than continue the trial with the perception that they are receiving placebo. Difficulty enrolling or maintaining a sufficient number of patients to conduct our clinical trials, may require us to delay, limit or terminate clinical trials, any of which would harm our business, financial condition, results of operations and prospects. Use of our therapeutic candidates could be associated with side effects, adverse events or other properties or safety risks, which could delay or preclude approval, cause us to suspend or discontinue clinical trials, abandon a therapeutic candidate, limit the commercial profile of an approved label or result in other significant negative consequences that could severely harm our business, prospects, operating results and financial condition. ~~We have not evaluated any therapeutic candidates in human clinical trials.~~ Although other oligonucleotide therapeutics, enzyme replacement therapies and gene therapies have received regulatory approval, our EEV- based therapeutics are a novel approach to the delivery of biological therapeutics, which may present enhanced uncertainty associated with the safety profile of ENTR- 601- 44, ENTR- 601- 45, ENTR- ~~701~~ **601- 50, our partnered candidate VX- 670** and other EEV- based therapeutics compared to more well- established classes of therapies. Moreover, it is impossible to predict when or if any therapeutic candidates we may develop will prove safe in humans. As is the case with biopharmaceuticals generally, it is likely that there may be side effects and adverse events associated with our therapeutic candidates' use. Results of our clinical trials could reveal a high and unacceptable severity and prevalence of side effects or unexpected characteristics. Undesirable side effects caused by our therapeutic candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or comparable foreign regulatory authorities. The drug- related side effects could affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. Any of these occurrences may harm our business, financial condition and prospects significantly. Further, clinical trials by their nature utilize a sample of the potential patient population. With a limited number of patients and limited duration of exposure, rare and severe side effects of our therapeutic candidates may only be uncovered with a significantly larger number of patients exposed to the therapeutic candidate. Any undesirable side effects or unexpected characteristics associated with our therapeutic candidates in clinical trials may lead us to elect to abandon their development or limit their development to more narrow uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk- benefit perspective, which may limit the commercial expectations for the therapeutic candidate if approved. We may also be required to modify our study plans based on findings after we commence our clinical trials. Many compounds that initially showed promise in early- stage testing have later been found to cause side effects that prevented further development of the compound. In addition, regulatory authorities may draw different conclusions or require additional testing to confirm these determinations. It is possible that as we test our therapeutic candidates in larger, longer and more extensive clinical trials, or as the use of these therapeutic candidates becomes more widespread if they receive regulatory approval, illnesses, injuries, discomforts and other adverse events that were observed in earlier trials, as well as conditions that did not occur or went undetected in previous trials, may be reported by subjects. Any findings of such side effects later in development or upon approval, if any, may harm our business, financial condition and prospects significantly. Patients treated with our therapeutics, if approved, may experience previously unreported adverse reactions, and it is possible that the FDA or other regulatory authorities may ask for additional safety data as a condition of, or in connection with, our efforts to obtain approval of our therapeutic candidates. If safety problems occur or are identified after our therapeutics, if any, reach the market, we may make the decision or be required by regulatory authorities to amend the labeling of our therapeutics, recall our therapeutics or even withdraw approval for our therapeutics. Our therapeutic candidates are subject to extensive regulation and compliance, which is costly and time- consuming, and such regulation may cause unanticipated delays or prevent the receipt of the required approvals

to commercialize our therapeutic candidates. The clinical development, manufacturing, labeling, packaging, storage, record-keeping, advertising, promotion, import, export, marketing, distribution and adverse event reporting, including the submission of safety and other information, of our therapeutic candidates are subject to extensive regulation by the FDA in the United States and by comparable foreign regulatory authorities in foreign markets. In the United States, we are not permitted to market our therapeutic candidates until we receive regulatory approval from the FDA. The process of obtaining regulatory approval is expensive, often takes many years following the commencement of clinical trials and can vary substantially based upon the type, complexity and novelty of the therapeutic candidates involved, as well as the target indications and patient population. Approval policies or regulations may change, and the FDA has substantial discretion in the drug approval process, including the ability to delay, limit or deny approval of a therapeutic candidate for many reasons. Despite the time and expense invested in clinical development of therapeutic candidates, regulatory approval is never guaranteed. Neither we nor any current or future collaborator is permitted to market any of our therapeutic candidates in the United States until we receive approval from the FDA. Prior to obtaining approval to commercialize a therapeutic candidate in the United States or abroad, we or our collaborators must demonstrate with substantial evidence from adequate and well- controlled clinical trials, and to the satisfaction of the FDA or comparable foreign regulatory authorities, that such therapeutic candidates are safe and effective for their intended uses. Results from preclinical studies and clinical trials can be interpreted in different ways. Even if we believe the preclinical or clinical data for our therapeutic candidates are promising, such data may not be sufficient to support approval by the FDA and comparable foreign regulatory authorities. The FDA or comparable foreign regulatory authorities, as the case may be, may also require us to conduct additional preclinical studies or clinical trials for our therapeutic candidates either prior to or post- approval, or may object to elements of our clinical development program. The FDA or comparable foreign regulatory authorities can delay, limit or deny approval of a therapeutic candidate for many reasons, including: • such authorities may disagree with the design or implementation of our or our current or future collaborators' clinical trials; • negative or ambiguous results from our clinical trials or results may not meet the level of statistical significance required by the FDA or comparable foreign regulatory agencies for approval; • serious and unexpected drug- related side effects may be experienced by participants in our clinical trials or by individuals using drugs similar to our therapeutic candidates; • such authorities may not accept clinical data from trials which are conducted at clinical facilities or in countries where the standard of care is potentially different from that of the United States; • we or any of our current or future collaborators may be unable to demonstrate that a therapeutic candidate is safe and effective, and that therapeutic candidate' s clinical and other benefits outweigh its safety risks; • such authorities may disagree with our interpretation of data from preclinical studies or clinical trials; • such authorities may not agree that the data collected from clinical trials of our therapeutic candidates are acceptable or sufficient to support the submission of an NDA or BLA or other submission or to obtain regulatory approval in the United States or elsewhere, and such authorities may impose requirements for additional preclinical studies or clinical trials; • such authorities may disagree regarding the formulation, labeling and / or the specifications of our therapeutic candidates; • approval may be granted only for indications that are significantly more limited than what we apply for and / or with other significant restrictions on distribution and use; • such authorities may find deficiencies in the manufacturing processes, approval policies or facilities of our third- party manufacturers with which we or any of our current or future collaborators contract for clinical and commercial supplies; • regulations of such authorities may significantly change in a manner rendering our or any of our potential future collaborators' clinical data insufficient for approval; or • such authorities may not accept a submission due to, among other reasons, the content or formatting of the submission. With respect to foreign markets, approval procedures vary among countries and, in addition to the foregoing risks, may involve additional product testing, administrative review periods and agreements with pricing authorities. In addition, events raising questions about the safety of certain marketed biopharmaceuticals may result in increased cautiousness by the FDA and comparable foreign regulatory authorities in reviewing new drugs based on safety, efficacy or other regulatory considerations and may result in significant delays in obtaining regulatory approvals. Any delay in obtaining, or inability to obtain, applicable regulatory approvals would prevent us or any of our potential future collaborators from commercializing our therapeutic candidates. Our approach to the discovery and development of therapeutic candidates based on our EEV Platform is unproven, and we do not know whether we will be able to develop any products of commercial value, or if competing technological approaches will limit the commercial value of our therapeutic candidates or render our EEV Platform obsolete. The success of our business depends primarily upon our ability to identify, develop and commercialize products based on our proprietary EEV Platform, which leverages a novel and unproven approach. While we have observed favorable preclinical study results based on our EEV Platform, we have not yet succeeded and may not succeed in demonstrating efficacy and safety for any therapeutic candidates in clinical trials or in obtaining marketing approval thereafter. Our lead therapeutic candidates, **with the exception of** ENTR- 601- 44 ~~, ENTR- 601- 45~~ and our partnered candidate **VX- 670, but including** ENTR- ~~701~~ **601- 45 and ENTR- 601- 50** , are in preclinical development ~~and we have not yet initiated any clinical trials for any therapeutic candidate~~ . Our research methodology and novel approach to intracellular therapeutics may be unsuccessful in identifying additional therapeutic candidates, and any therapeutic candidates based on our EEV Platform may be shown to have harmful side effects or may have other characteristics that may necessitate additional clinical testing, or make the therapeutic candidates unmarketable or unlikely to receive marketing approval. Further, because all of our therapeutic candidates and development programs are based on our EEV Platform, adverse developments with respect to one of our programs may have a significant adverse impact on the actual or perceived likelihood of success and value of our other programs. In addition, the biotechnology and biopharmaceutical industries are characterized by rapidly advancing technologies. Our future success will depend in part on our ability to maintain a competitive position with our EEV approach. Failure to stay at the forefront of technological change in utilizing our EEV Platform to create and develop therapeutic candidates may prevent us from competing effectively. Our competitors may render our EEV approach obsolete, or limit the commercial value of our therapeutic candidates, by advances in existing technological approaches or the development of new or different approaches, potentially

eliminating the advantages in our drug discovery process that we believe we derive from our research approach and proprietary technologies. By contrast, adverse developments with respect to other companies that attempt to use a similar approach to our approach may adversely impact the actual or perceived value of our EEV Platform and potential of our therapeutic candidates. The occurrence of any of these events may force us to abandon our development efforts for a program or programs, which would have a material adverse effect on our business and could potentially cause us to cease operations. Interim, topline and preliminary data from our preclinical studies and planned clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data. From time to time, we may publicly disclose interim, preliminary or topline data from our preclinical studies and planned clinical trials, which are based on a preliminary analysis of then- available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular trial. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. Topline data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, topline data should be viewed with caution until the final data are available. From time to time, we may also disclose interim, preliminary or topline data from our clinical studies. Interim, topline or preliminary data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Adverse differences between preliminary, topline or interim data and final data could significantly harm our business prospects. Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular therapeutic candidate or product and the value of our company in general. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial will be based on what is typically extensive information, and our stockholders or others may not agree with what we determine is the material or otherwise appropriate information to include in our disclosure, and any information we determine not to disclose may ultimately be deemed significant with respect to future decisions, conclusions, views, activities or otherwise regarding a particular product, therapeutic candidate or our business. If the topline data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, our therapeutic candidates may be harmed, which could harm our business, operating results, prospects or financial condition. We may expend our limited resources to pursue a particular therapeutic candidate or indication, such as our initial focus on developing ENTR- 601- 44, and fail to capitalize on therapeutic candidates or indications that may be more profitable or for which there is a greater likelihood of success. Because we have limited human capital and financial resources, we focus on research programs and therapeutic candidates that we identify for specific indications. As a result, we may forego or delay pursuit of opportunities with other therapeutic candidates or for other indications that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs and therapeutic candidates for specific indications may not yield any commercially viable therapeutic candidates. If we do not accurately evaluate the commercial potential or target market for a particular therapeutic candidate, we may relinquish valuable rights to that therapeutic candidate through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such therapeutic candidate. At any time and for any reason, we may determine that one or more of our discovery programs or ~~pre- clinical~~ **preclinical** or clinical therapeutic candidates or programs does not have sufficient potential to warrant the allocation of resources toward such program or therapeutic candidate. Accordingly, we may choose not to develop a potential therapeutic candidate or elect to suspend, deprioritize or terminate one or more of our discovery programs or ~~pre- clinical~~ **preclinical** or clinical therapeutic candidates or programs. Suspending, deprioritizing or terminating a program or therapeutic candidate in which we have invested significant resources, we will have expended resources on a program that will not provide a full return on our investment and may have missed the opportunity to have allocated those resources to potentially more productive uses, including existing or future programs or therapeutic candidates. For example, in 2020, we made the strategic decision to focus the majority of our immediate efforts on EEV- oligonucleotide opportunities ~~. In order to support~~ **while pausing development on an existing program,** ENTR- 501 ~~progress, we are exploring partnership opportunities~~ **which is an EEV- conjugated protein designed to treat patients** with **a rare disease known as mitochondrial neurogastrointestinal encephalomyopathy (MNGIE). We have since partnered with an** ~~organizations~~ **organization** that ~~have~~ **has** the resources and expertise to continue the development of ENTR- 501 ~~into and through clinical development~~ . We continue to believe that the program will have an important role **to play** in the future treatment of patients with MNGIE. We may not be successful in our efforts to expand our development portfolio of therapeutic candidates. A key element of our strategy is to use our novel EEV Platform to address intracellular targets that are drivers of diseases in genomically defined patient populations with high unmet medical need in order to build a development portfolio of therapeutic candidates. Although our research and development efforts to date have resulted in a development portfolio of potential programs and therapeutic candidates, we may not be able to continue to identify intracellular disease targets and develop therapeutic candidates. We may also pursue opportunities to acquire or in- license additional businesses, technologies or products, form strategic alliances or create joint ventures with third parties to complement or augment our existing business. However, we may not be able to identify any therapeutic candidates for our development portfolio through such acquisition or in- license. Even if we are successful in continuing to build and expand our development portfolio, the potential therapeutic candidates that we identify may not be suitable for clinical development. For example, they may be shown to have harmful side effects or other characteristics that indicate that they are unlikely to be drugs that will be successful in clinical trials or receive marketing approval and achieve market acceptance. If we do not successfully develop and

commercialize therapeutic candidates, we will not be able to obtain drug revenues in future periods, which likely would result in significant harm to our financial position and adversely affect our stock price. Where appropriate, we plan to secure approval from the FDA, EMA or comparable foreign regulatory authorities through the use of accelerated approval pathways. If we are unable to obtain such approval, we may be required to conduct additional preclinical studies or clinical trials beyond those that we contemplate, which could increase the expense of obtaining, and delay the receipt of, necessary marketing approvals. Even if we receive accelerated approval from the FDA, EMA or comparable regulatory authorities, if our confirmatory trials do not verify clinical benefit, or if we do not comply with rigorous post- marketing requirements, the FDA, EMA or such other regulatory authorities may seek to withdraw accelerated approval. Where possible, we plan to pursue accelerated development strategies in areas of high unmet need. We may seek an accelerated approval pathway for our one or more of our therapeutic candidates from the FDA, EMA or comparable foreign regulatory authorities. Under the accelerated approval provisions in the Federal Food, Drug, and Cosmetic Act, and the FDA' s implementing regulations, the FDA may grant accelerated approval to a therapeutic candidate designed to treat a serious or life- threatening condition that provides meaningful therapeutic benefit over available therapies upon a determination that the therapeutic candidate has 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, such as irreversible morbidity or mortality. For the purposes of accelerated approval, a surrogate endpoint is a marker, such as a laboratory measurement, radiographic image, physical sign, or other measure that is thought to predict clinical benefit, but is not itself a measure of clinical benefit. An intermediate clinical endpoint is a clinical endpoint that can be measured earlier than an effect on irreversible morbidity or mortality that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit. The accelerated approval pathway may be used in cases in which the advantage of a new drug over available therapy may not be a direct therapeutic advantage, but is a clinically important improvement from a patient and public health perspective. If granted, accelerated approval is usually contingent on the sponsor' s agreement to conduct, in a diligent manner, additional post-approval confirmatory studies to verify and describe the drug' s clinical benefit, and the FDA is permitted to require, as appropriate, that such studies be underway prior to approval or within a specified period after the date of approval. Sponsors must also update the FDA on the status of these studies, and under FDORA, the FDA has increased authority to withdraw approval of a drug granted accelerated approval on an expedited basis if the sponsor fails to conduct such studies in a timely manner, send the necessary updates to the FDA, or if such post- approval studies fail to verify the drug' s predicted clinical benefit. Prior to seeking accelerated approval, we will seek feedback from the FDA, EMA or comparable foreign regulatory authorities and will otherwise evaluate our ability to seek and receive such accelerated approval. There can be no assurance that after our evaluation of the feedback and other factors we will decide to pursue or submit an NDA or BLA for accelerated approval or any other form of expedited development, review or approval. Similarly, there can be no assurance that after subsequent feedback from the FDA, EMA or comparable foreign regulatory authorities, we will continue to pursue or apply for accelerated approval or any other form of expedited development, review or approval, even if we initially decide to do so. Furthermore, if we decide to submit an application for accelerated approval, there can be no assurance that such application will be accepted or that any approval will be granted on a timely basis, or at all. The FDA, EMA or other comparable foreign regulatory authorities could also require us to conduct further studies prior to considering our application or granting approval of any type, including, for example, if other products are approved via the accelerated pathway and subsequently converted by FDA to full approval. In addition, the FDA currently requires, unless otherwise informed by the agency, pre- approval of promotional materials for products receiving accelerated approval, which could adversely impact the timing of the commercial launch of any of our products. A failure to obtain accelerated approval or any other form of expedited development, review or approval for our therapeutic candidate would result in a longer time period to commercialization of such therapeutic candidate, could increase the cost of development of such therapeutic candidate and could harm our competitive position in the marketplace. Thus, even if we seek to utilize the accelerated approval pathway, we may not be able to obtain accelerated approval and, even if we do, we may not experience a faster development, regulatory review or approval process for that product. In addition, receiving accelerated approval does not assure that the product' s accelerated approval will eventually be converted to a traditional approval. We may seek Fast Track designation, Breakthrough Therapy designation and / or orphan drug designation from the FDA or similar designations from other regulatory authorities for one or more of our therapeutic candidates. Even if one or more of our therapeutic candidates receive any of these designations, we may be unable to obtain or maintain the benefits associated with such designation. The FDA has established various designations to facilitate more rapid and efficient development and approval of certain types of drugs. Such designations include Fast Track designation, Breakthrough Therapy designation, and orphan drug designation. Fast Track designation is designed to facilitate the development and expedite the review of therapies for serious conditions that fill an unmet medical need. Programs with Fast Track designation may benefit from early and frequent communications with the FDA, potential priority review and the ability to submit a rolling application for regulatory review. Fast Track designation applies to both the therapeutic candidate and the specific indication for which it is being studied. If any of our therapeutic candidates receive Fast Track designation but do not continue to meet the criteria for Fast Track designation, or if our clinical trials are delayed, suspended or terminated, or put on clinical hold due to unexpected adverse events or issues with clinical supply, we will not receive the benefits associated with the Fast Track program. Fast Track designation alone does not guarantee qualification for the FDA' s priority review procedures. A Breakthrough Therapy, on the other hand, is defined as a drug or biologic that is intended, alone or in combination with one or more other drugs or biologics, to treat a serious or life- threatening disease or condition and preliminary clinical evidence indicates that the drug or biologic may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints. For therapeutic candidates that have been designated as Breakthrough Therapies, interaction and communication between the FDA and the sponsor of the trial can help to identify the most efficient path for clinical

development while minimizing the number of patients placed in ineffective control regimens. Designation as a Breakthrough Therapy is within the discretion of the FDA, and drugs designated as Breakthrough Therapies by the FDA may also be eligible for other expedited approval programs, including accelerated approval. Even if one or more of our therapeutic candidates qualify as Breakthrough Therapies pursuant to FDA standards, the FDA may later decide that the product no longer meets the conditions for qualification. Thus, even though we may seek Breakthrough Therapy designation for one or more of our current or future therapeutic candidates, there can be no assurance that we will receive Breakthrough Therapy designation. Regulatory authorities in some jurisdictions, including the United States and the EU, may also designate drugs for relatively small patient populations as orphan drugs. Under the Orphan Drug Act, the FDA may designate a therapeutic candidate as an orphan drug if it is a drug intended to treat a rare condition, which is generally defined as a patient population of fewer than 200, 000 individuals annually in the United States, or a patient population greater than 200, 000 in the United States where there is no reasonable expectation that the cost of developing the drug will be recovered from sales in the United States. In the EU, the EMA' s Committee for Orphan Medicinal Products (COMP) evaluates orphan designation in respect of a product if its sponsor can establish that: (1) the product is intended for the diagnosis, prevention or treatment of a life- threatening or chronically debilitating condition; (2) either (i) such condition affects no more than five (5) in ten thousand (10, 000) persons in the EU when the application is made, or (ii) it is unlikely that the product, without the benefits derived from orphan status, would generate sufficient return in the EU to justify the necessary investment in its development; and (3) there is no satisfactory method of diagnosis, prevention or treatment of such condition authorized for marketing in the EU, or, if such a method exists, the product would be of significant benefit to those affected by that condition. In the United States, orphan drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages and user- fee waivers, and it may entitle the therapeutic to exclusivity in the United States and the EU. Even if we obtain orphan drug designation for a therapeutic candidate, we may not be able to obtain or maintain orphan drug exclusivity for that therapeutic candidate. If any of our programs or therapeutic candidates receive Fast Track, Breakthrough Therapy or orphan drug designation by the FDA or similar designations by other regulatory authorities, there is no assurance that we will receive any benefits from such programs or that we will continue to meet the criteria to maintain such designation. Even if we obtain such designations, we may not experience a faster development process, review or approval compared to conventional FDA procedures. A Fast Track, Breakthrough Therapy, or orphan drug designation does not ensure that a therapeutic candidate will receive marketing approval or that approval will be granted within any particular timeframe. Obtaining and maintaining marketing approval or commercialization of our therapeutic candidates in the United States does not mean that we will be successful in obtaining marketing approval of our therapeutic candidates in other jurisdictions. Failure to obtain marketing approval in foreign jurisdictions would prevent any therapeutic candidates we may develop from being marketed in such jurisdictions, which, in turn, would materially impair our ability to generate revenue. In order to market and sell any therapeutic candidates we may develop in the EU and many other foreign jurisdictions, **including the United Kingdom,** we or our collaborators must obtain separate marketing approvals and comply with numerous and varying regulatory requirements. The approval procedure varies among countries and can involve additional testing. The time required to obtain approval may differ substantially from that required to obtain FDA approval. The regulatory approval process outside the United States generally includes all of the risks associated with obtaining FDA approval. In addition, in many countries outside the United States, it is required that the product be approved for reimbursement before the product can be approved for sale in that country. We or these third parties may not obtain approvals from regulatory authorities outside the United States on a timely basis, if at all. Approval by the FDA does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one regulatory authority outside the United States does not ensure approval by regulatory authorities in other countries or jurisdictions or by the FDA. We may not be able to file for marketing approvals and may not receive necessary approvals to commercialize our medicines in any jurisdiction, which would materially impair our ability to generate revenue. Additionally, now that the UK is no longer part of the EU, separate applications and procedures will be required to obtain regulatory approval for our products in the UK and EU. In particular, Great Britain is no longer covered by the centralized procedure for obtaining EU- wide marketing authorizations from the EMA for medicinal products (under the Northern Ireland Protocol, the EU regulatory framework continues to apply in Northern Ireland ~~and centralized~~ **until January 1, 2025, following which medicinal products must obtain a UK- wide marketing authorization to be marketed throughout the** EU ~~authorizations continue to be recognized~~ **, under the Windsor Framework** ) and a separate process for authorization of drug products will be required in Great Britain. ~~Until December 31, 2023, the Medicines and Healthcare Products Regulatory Agency may rely on a decision taken by the European Commission on the approval of a new marketing authorization in the centralized procedure, in order to more quickly grant a new Great Britain marketing authorization, however~~ **However** ~~a separate application will still be required. On January 24~~ , **under** ~~2023, the MHRA announced that~~ a new international recognition ~~framework will be~~ **procedure which was** put in place ~~from~~ **by the MHRA on** January 1, 2024, ~~which will have regard to~~ **the MHRA may take into account** decisions on the approval of **a** marketing ~~authorizations~~ - **authorization from** ~~made by~~ the EMA **(** and certain other regulators **)** when ~~determining~~ **considering** an application for a **UK** ~~new Great Britain~~ marketing authorization. In addition, the regulatory regime in Great Britain at present broadly aligns with EU regulations, however, longer term, Great Britain is likely to develop its own legislation that diverges from that in the EU now that its regulatory system is independent from the EU and the Trade and Cooperation Agreement entered into by the EU and UK does not provide for mutual recognition of UK and EU pharmaceutical legislation. It is possible therefore, that there will be increased regulatory complexities in the UK and EU, which could disrupt the timing of any regulatory approvals that we may determine to pursue in these jurisdictions. The FDA, EMA and other comparable foreign regulatory authorities may not accept data from trials conducted in locations outside of their jurisdiction. We anticipate we will initially conduct clinical trials of our therapeutic candidates in the United States and we may choose to conduct our clinical trials internationally as well. The acceptance of study data by the FDA, EMA or other

comparable foreign regulatory authority from clinical trials conducted outside of their respective jurisdictions may be subject to certain conditions. In cases where data from United States clinical trials are intended to serve as the basis for marketing approval in the foreign countries outside the United States, the standards for clinical trials and approval may be different. There can be no assurance that any United States or foreign regulatory authority would accept data from trials conducted outside of its applicable jurisdiction. If the FDA, EMA or any applicable foreign regulatory authority does not accept such data, it would result in the need for additional trials, which would be costly and time- consuming and delay aspects of our business plan, and which may result in our therapeutic candidates not receiving approval or clearance for commercialization in the applicable jurisdiction. Changes in methods of therapeutic candidate manufacturing or formulation may result in additional costs or delay, which could adversely affect our business, results of operations and financial condition. As therapeutic candidates progress through preclinical and clinical trials to marketing approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods and formulation, are altered along the way in an effort to optimize yield and manufacturing batch size, minimize costs and achieve consistent quality and results. For example, we may introduce an alternative formulation of one or more of our therapeutic candidates during the course of our planned clinical trials. Such changes carry the risk that they will not achieve these intended objectives. Any of these changes could cause our therapeutic candidates to perform differently and affect the results of planned clinical trials or other future clinical trials conducted with the altered materials. This could delay completion of clinical trials, require the conduct of bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay approval of our therapeutic candidates and jeopardize our ability to commercialize our therapeutic candidates, if approved, and generate revenue. Even if we, or any collaborators we may have, obtain marketing approvals for any therapeutic candidates we may develop, the terms of approvals and ongoing regulation of our therapeutics could require the substantial expenditure of resources and may limit how we, or they, manufacture and market our therapeutics, which could materially impair our ability to generate revenue. Any therapeutic candidate for which we obtain marketing approval, if ever, along with the manufacturing processes, post- approval clinical data, labeling, advertising and promotional activities for such medicine, will be subject to continual requirements of and review by the FDA and other regulatory authorities. These requirements include submissions of safety and other post- marketing information and reports, registration and listing requirements, cGMP requirements relating to quality control, quality assurance and corresponding maintenance of records and documents, compliance with applicable product tracking and tracing requirements, and requirements regarding the distribution of samples to physicians and recordkeeping. For example, the holder of an approved BLA is obligated to monitor and report adverse events and any failure of a product to meet the specifications in the BLA. The FDA typically advises that patients treated with genetic medicine undergo follow- up observations for potential adverse events for a 15- year period. The holder of an approved BLA must also submit new or supplemental applications and obtain FDA approval for certain changes to the approved product, product labeling or manufacturing process. Even if marketing approval of a therapeutic candidate is granted, the approval may be subject to limitations on the indicated uses for which the medicine may be marketed or to the conditions of approval, or contain requirements for costly post- marketing testing and surveillance to monitor the safety or efficacy of the medicine. Accordingly, assuming we, or any third parties we may collaborate with, receive marketing approval for one or more therapeutic candidates we may develop, we, and such collaborators, and our and their contract manufacturers will continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production, product surveillance and quality control. If we and such collaborators are not able to comply with post- approval regulatory requirements, we and such collaborators could have the marketing approvals for our therapeutics withdrawn by regulatory authorities and our, or such collaborators', ability to market any future products could be limited, which could adversely affect our ability to achieve or sustain profitability. Further, the cost of compliance with post- approval regulations may have a negative effect on our business, operating results, financial condition and prospects. If we fail to comply with applicable regulatory requirements following approval of any therapeutic candidates we may develop, a regulatory agency may: • issue a warning letter asserting that we are in violation of the law; • seek an injunction or impose civil or criminal penalties or monetary fines; • suspend or withdraw regulatory approval; • suspend any ongoing clinical trials; • refuse to approve a pending BLA or supplements to a BLA submitted by us; • seize product; or • refuse to allow us to enter into supply contracts, including government contracts. Any government investigation of alleged violations of law could require us to expend significant time and resources in response and could generate negative publicity. The occurrence of any event or penalty described above may inhibit our ability to commercialize any therapeutic candidates we may develop and generate revenues. Clinical trial and product liability lawsuits against us could divert our resources, could cause us to incur substantial liabilities and could limit commercialization of any therapeutic candidates we may develop. We will face an inherent risk of clinical trial and product liability exposure related to the testing of any therapeutic candidates we may develop in clinical trials, and we will face an even greater risk if we commercially sell any products that we may develop. While we currently have no therapeutic candidates in clinical trials or that have been approved for commercial sale, the future use of therapeutic candidates by us in clinical trials, and the sale of any approved products in the future, may expose us to liability claims. These claims might be made by patients that use the product, healthcare providers, pharmaceutical companies or others selling such products. If we cannot successfully defend ourselves against claims that our therapeutic candidates or products caused injuries, we will incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in: • decreased demand for any therapeutic candidates we may develop; • injury to our reputation and significant negative media attention; • withdrawal of clinical trial participants and inability to continue clinical trials; • initiation of investigations by regulators; • significant costs to defend any related litigation; • substantial monetary awards to trial participants or patients; • product recalls, withdrawals or labeling, marketing or promotional restrictions; • loss of revenue; • exhaustion of any available insurance and our capital resources; • decline in our stock price; • reduced resources of our management to pursue our business strategy; and • the inability to commercialize any therapeutic candidates we may develop. We will need to increase our insurance coverage if we **continue to** commence clinical trials or if

we commence commercialization of any therapeutic candidates. Insurance coverage is increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise. If and when coverage is secured, our insurance policies may also have various exclusions and we may be subject to a product liability claim for which we have no coverage. Even if our agreements with any future corporate collaborators entitle us to indemnification against losses, such indemnification may not be available or adequate should any claim arise. If a successful clinical trial or product liability claim or series of claims is brought against us for uninsured liabilities or in excess of insured liabilities, our assets may not be sufficient to cover such claims and our business operations could be impaired. We may develop our current or future therapeutic candidates in combination with other therapies, which would expose us to additional risks. We may develop our current or potential future therapeutic candidates in combination with one or more currently approved therapies or therapies in development. Even if any of our current or future therapeutic candidates were to receive marketing approval or be commercialized for use in combination with other existing therapies, we would continue to be subject to the risks that the FDA, EMA or other comparable foreign regulatory authorities could revoke approval of the therapy used in combination with any of our therapeutic candidates, or safety, efficacy, manufacturing or supply issues could arise with these existing therapies. In addition, it is possible that existing therapies with which our therapeutic candidates are approved for use could themselves fall out of favor or be relegated to later lines of treatment. This could result in the need to identify other combination therapies for our therapeutic candidates or our own products being removed from the market or being less successful commercially. We may also evaluate our current or future therapeutic candidates in combination with one or more other therapies that have not yet been approved for marketing by the FDA, EMA or comparable foreign regulatory authorities. We will not be able to market and sell any therapeutic candidate in combination with any such unapproved therapies that do not ultimately obtain marketing approval. Furthermore, we cannot be certain that we will be able to obtain a steady supply of such therapies for use in developing combinations with our therapeutic candidates on commercially reasonable terms or at all. Any failure to obtain such therapies for use in clinical development and the expense of purchasing therapies in the market may delay our development timelines, increase our costs and jeopardize our ability to develop our therapeutic candidates as commercially viable therapies. If the FDA, EMA or other comparable foreign regulatory authorities do not approve or withdraw their approval of these other therapies, or if safety, efficacy, commercial adoption, manufacturing or supply issues arise with the therapies we choose to evaluate in combination with any of our current or future therapeutic candidates, we may be unable to obtain approval of or successfully market any one or all of the current or future therapeutic candidates we develop. Additionally, if the third- party providers of therapies or therapies in development used in combination with our current or future therapeutic candidates are unable to produce sufficient quantities for clinical trials or for commercialization of our current or future therapeutic candidates, or if the cost of combination therapies are prohibitive, our development and commercialization efforts would be impaired, which would have an adverse effect on our business, financial condition, results of operations and growth prospects. Risks Related to Our Reliance on Third Parties We rely, and expect to continue to rely, on third parties to conduct some or all aspects of our product manufacturing, research and preclinical and clinical testing, and these third parties may not perform satisfactorily. We do not expect to independently conduct all aspects of our product manufacturing, research and preclinical and clinical testing. We currently rely, and expect to continue to rely, on third parties with respect to many of these items, including contract manufacturing organizations (CMOs) for the manufacturing of any therapeutic candidates we test in preclinical or clinical development, as well as CROs for the conduct of our animal testing and research and CROs for the conduct of our planned clinical trials. Any of these third parties may terminate their engagements with us at any time. A need to enter into alternative arrangements could delay our product development activities, and we may not be able to enter into alternative arrangements on reasonable terms, if at all. Our reliance on these third parties for research and development activities will reduce our control over these activities but will not relieve us of our responsibility to ensure compliance with all required regulations and study protocols. For example, for therapeutic candidates that we develop and commercialize on our own, we will remain responsible for ensuring that each of our **CTA /** IND- enabling studies and clinical trials are conducted in accordance with the study plan and protocols. Moreover, the FDA **and similar foreign regulatory bodies** ~~requires~~ **require** us to comply with GCPs for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected. We also are required to register ongoing clinical trials and post the results of completed clinical trials on ~~a~~ government- sponsored ~~database~~ **databases** , **such as** clinicaltrials. gov, within specified timeframes. Failure to do so can result in fines, adverse publicity and civil and criminal sanctions. If we or any of our CROs or other third parties, including trial sites, fail to comply with applicable GCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA, EMA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure our stockholders that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials complies with GCP regulations. In addition, our clinical trials must be conducted with product produced under conditions that comply with ~~the FDA' s~~ GMPs. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process. Although we intend to design the clinical trials for any therapeutic candidates we may develop, CROs will conduct some or all of the clinical trials. As a result, many important aspects of our development programs, including their conduct and timing, will be outside of our direct control. Our reliance on third parties to conduct future preclinical studies and clinical trials will also result in less direct control over the management of data developed through preclinical studies and clinical trials than would be the case if we were relying entirely upon our own staff. Communicating with outside parties can also be challenging, potentially leading to mistakes as well as difficulties in coordinating activities. Outside parties may: • have staffing difficulties; • be unable to acquire the necessary supplies to perform successfully; • fail to comply with contractual obligations; • experience regulatory compliance issues; • undergo changes in priorities or become financially distressed; or • form relationships with other entities, some of which may be our competitors.

These factors may materially adversely affect the willingness or ability of third parties to conduct our preclinical studies and clinical trials and may subject us to unexpected cost increases that are beyond our control. We expect to have to negotiate budgets and contracts with CROs and trial sites, which may result in delays to our development timelines and increased costs. In addition, any third parties conducting our clinical trials will not be our employees, and except for remedies available to us under our agreements with such third parties, we cannot control whether or not they devote sufficient time and resources to our clinical programs. If these CROs, and any other third parties we engage do not perform preclinical studies and future clinical trials in a satisfactory manner, if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols, or if they breach their obligations to us or fail to comply with regulatory requirements, the development, regulatory approval and commercialization of any therapeutic candidates we may develop may be delayed, we may not be able to obtain regulatory approval and commercialize our therapeutic candidates or our development programs may be materially and irreversibly harmed. If we are unable to rely on preclinical and clinical data collected by our CROs and other third parties, we could be required to repeat, extend the duration of or increase the size of any preclinical studies or clinical trials we conduct and this could significantly delay commercialization and require greater expenditures. Nevertheless, we are responsible for ensuring that each of our clinical trials is conducted in accordance with the applicable protocol, legal and regulatory requirements and scientific standards and our reliance on third parties does not relieve us of our regulatory responsibilities. We and these third parties are required to comply with GCP requirements, which are regulations and guidelines enforced by the FDA and other regulatory authorities for therapeutic candidates in clinical development. Regulatory authorities enforce these GCP requirements through periodic inspections of trial sponsors, clinical investigators and trial sites. If we or any of these third parties fail to comply with applicable GCP requirements, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or other regulatory authorities may require us to suspend, place on clinical hold or terminate these trials or perform additional preclinical studies or clinical trials before approving our marketing applications. We cannot be certain that, upon inspection, such regulatory authorities will determine that any of our clinical trials comply with the GCP requirements. In addition, our clinical trials must be conducted with biologic product produced under cGMP requirements and may require a large number of patients. In the U. S., we also are required to register ongoing clinical trials and post the results of completed clinical trials on a government- sponsored database, clinicaltrials. gov, within certain timeframes. Failure to do so can result in fines, adverse publicity and civil and criminal sanctions. These third parties may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials or other product development activities, which could affect their performance on our behalf. If these third parties do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to complete development of, obtain regulatory approval of or successfully commercialize our therapeutic candidates. As a result, our financial results and the commercial prospects for our therapeutic candidates would be harmed, our costs could increase and our ability to generate revenue could be delayed. Our failure or any failure by these third parties to comply with these regulations or to recruit a sufficient number of patients may require us to repeat clinical trials, which would delay the regulatory approval process. Moreover, our business may be implicated if any of these third parties violates federal or state fraud and abuse or false claims laws and regulations or healthcare privacy and security laws. For any violations of laws and regulations during the conduct of our preclinical studies and clinical trials, we could be subject to warning letters or enforcement action that may include civil penalties up to and including criminal prosecution. If any of our relationships with these third- party CROs or others terminate, we may not be able to enter into arrangements with alternative CROs or other third parties or to do so on commercially reasonable terms. Switching or adding additional CROs involves additional cost and requires management time and focus. In addition, there is a natural transition period when a new CRO begins work. As a result, delays may occur, which can materially impact our ability to meet our desired clinical development timelines. Though we carefully manage our relationships with our CROs, there can be no assurance that we will not encounter similar challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition and prospects. If third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct our studies in accordance with regulatory requirements or our stated study plans and protocols, we will not be able to complete, or may be delayed in completing, the preclinical studies and clinical trials required to support future IND submissions and approval of any therapeutic candidates we may develop. We are dependent on third- party vendors to provide certain licenses, products and services and our business and operations, including clinical trials, could be disrupted by any problems with our significant third- party vendors. We engage a number of third- party suppliers and service providers to supply critical goods and services, such as contract research services, contract manufacturing services and IT services. Disruptions to the business, financial stability or operations of these suppliers and service providers, including due to strikes, labor disputes or other disruptions to the workforce, for instance, if employees are not able to come to work, or to their willingness and ability to produce or deliver such products or provide such services in a manner that satisfies the requirements put forth by the authorities, or in a manner that satisfies our own requirements, could affect our ability to develop and market our future therapeutic candidates on a timely basis. If these suppliers and service providers were unable or unwilling to continue to provide their products or services in the manner expected, or at all, we could encounter difficulty finding alternative suppliers. Even if we are able to secure appropriate alternative suppliers in a timely manner, costs for such products or services could increase significantly. Any of these events could adversely affect our results of operations and our business. Our EEV- based therapeutic candidates are based on novel technologies and any therapeutic candidates we develop may be complex and difficult to manufacture. We may encounter difficulties in manufacturing, product release, shelf life, testing, storage, supply chain management or shipping. If we or any of our third- party manufacturers encounter such difficulties, our ability to supply material for clinical trials or any approved product could be delayed or stopped. The

manufacturing processes for our therapeutic candidates are novel. There are no medicines incorporating or utilizing our EEV Platform that have been commercialized to date ~~or manufactured at such scale~~. Due to the novel nature of this technology and limited experience at larger scale production, we may encounter difficulties in manufacturing, product release, shelf life, testing, storage and supply chain management, or shipping. These difficulties could be due to any number of reasons including, but not limited to, complexities of producing batches at larger scale, equipment failure, choice and quality of raw materials and excipients, analytical testing technology, and product instability. In an effort to optimize product features, we have in the past and may in the future make changes to our therapeutic candidates in their manufacturing and stability formulation and conditions. This has in the past resulted in and may in the future result in our having to resupply batches for preclinical or clinical activities when there is insufficient product stability during storage and insufficient supply. Insufficient stability or shelf life of our therapeutic candidates could materially delay our or our strategic collaborators' ability to continue the clinical trial for that therapeutic candidate or require us to begin a new clinical trial with a newly formulated drug product, due to the need to manufacture additional preclinical or clinical supply. Our rate of innovation is high, which has resulted in and will continue to cause a high degree of technology change that can negatively impact product comparability during and after clinical development. Furthermore, technology changes may drive the need for changes in, modification to, or the sourcing of new manufacturing infrastructure or may adversely affect third- party relationships. The process to generate our EEV- based therapeutics is complex and, if not developed and manufactured under well- controlled conditions, can adversely impact pharmacological activity. Furthermore, we have not manufactured our EEV- based therapeutics at commercial scale. We may encounter difficulties in scaling up our manufacturing process, thereby potentially impacting clinical and commercial supply. During clinical development of our EEV- based therapeutics, in many cases, we may have to utilize multiple batches of drug substance and drug product to meet the clinical supply requirement of a single clinical trial. Failure in our ability to scale up batch size or failure in any batch may lead to a substantial delay in our clinical trials. As we continue developing new manufacturing processes for our drug substance and drug product, the changes we implement to manufacturing process may in turn impact specification and stability of the drug product. Changes in our manufacturing processes may lead to failure of lots and this could lead to a substantial delay in our clinical trials. Our EEV- based therapeutic candidates may prove to have a stability profile that leads to a lower than desired shelf life of our final approved EEV- based product. This poses risk in supply requirements, wasted stock, and higher cost of goods. Due to the number of different programs, we may have cross contamination of products inside of our factories, CROs, suppliers, or in the clinic that affect the integrity of our therapeutics. As we scale the manufacturing output for particular programs, we plan to continuously improve yield, purity, and the pharmaceutical properties of our development candidates from IND- enabling studies through commercial launch, including shelf life stability, and solubility properties of drug product and drug substance. Because of continuous improvement in manufacturing processes, we may switch processes for a particular program during development. However, after the change in process, more time is required for pharmaceutical property testing, such as 6 or 12 month stability testing. That may require resupplying clinical material, or making additional cGMP batches to keep up with clinical trial demand before such pharmaceutical property testing is completed. We are utilizing a number of raw materials and excipients that are either new to the pharmaceutical industry or are being employed in a novel manner. Some of these raw materials and excipients have not been scaled to a level to support commercial supply and could experience unexpected manufacturing or testing failures, or supply shortages. Such issues with raw materials and excipients could cause delays or interruptions to clinical and commercial supply of our therapeutic candidates. Further, now and in the future one or more of our programs may have a single source of supply for raw materials and excipients. We may establish a number of analytical assays to assess the quality of our EEV- based therapeutic candidates. We may identify gaps in our analytical testing strategy that might prevent release of product or could require product withdrawal or recall. For example, we may discover new impurities that have an impact on product safety, efficacy, or stability. This may lead to an inability to release our therapeutic candidates until the manufacturing or testing process is rectified. We may find that our therapeutic candidates are extremely temperature sensitive, and we may learn that any or all of our therapeutics are less stable than desired. We may also find that transportation conditions negatively impact product quality. This may require changes to the formulation or manufacturing process for one or more of our therapeutic candidates and result in delays or interruptions to clinical or commercial supply. In addition, the cost associated with such transportation services and the limited pool of vendors may also add additional risks of supply disruptions. Our reliance on third parties requires us to share our trade secrets, which increases the possibility that a competitor will discover them or that our trade secrets will be misappropriated or disclosed. Because we currently rely on third parties to manufacture our therapeutic candidates and to perform quality testing, we must, at times, share our proprietary technology and confidential information, including trade secrets, with them. We seek to protect our proprietary technology, in part, by entering into confidentiality agreements, and, if applicable, material transfer agreements, collaborative research agreements, consulting agreements or other similar agreements with our collaborators, advisors, employees and consultants prior to beginning research or disclosing proprietary information. These agreements typically limit the rights of the third parties to use or disclose our confidential information. Despite the contractual provisions employed when working with third parties, the need to share trade secrets and other confidential information increases the risk that such trade secrets become known by our competitors, are intentionally or inadvertently incorporated into the technology of others or are disclosed or used in violation of these agreements. Given that our proprietary position is based, in part, on our know- how and trade secrets and despite our efforts to protect our trade secrets, a competitor' s discovery of our proprietary technology and confidential information or other unauthorized use or disclosure would impair our competitive position and may have a material adverse effect on our business, financial condition, results of operations and prospects. We may from time to time be dependent on single- source suppliers for some of the components and materials used in the therapeutic candidates we may develop. We may from time to time depend on single- source suppliers for some of the components and materials used in any therapeutic candidates we may develop. We cannot ensure that these suppliers or service

providers will remain in business, have sufficient capacity or supply to meet our needs or that they will not be purchased by one of our competitors or another company that is not interested in continuing to work with us. Our use of single- source suppliers of raw materials, components, key processes and finished goods could expose us to several risks, including disruptions in supply, price increases or late deliveries. There are, in general, relatively few alternative sources of supply for substitute components. These vendors may be unable or unwilling to meet our future demands for our clinical trials or commercial sale. Establishing additional or replacement suppliers for these components, materials and processes could take a substantial amount of time and it may be difficult to establish replacement suppliers who meet regulatory requirements. Any disruption in supply from any single- source supplier or service provider could lead to supply delays or interruptions which would damage our business, financial condition, results of operations and prospects. If we have to switch to a replacement supplier, the manufacture and delivery of any therapeutic candidates we may develop could be interrupted for an extended period, which could adversely affect our business. Establishing additional or replacement suppliers, if required, may not be accomplished quickly. If we are able to find a replacement supplier, the replacement supplier would need to be qualified and may require additional regulatory authority approval, which could result in further delay. While we seek to maintain adequate inventory of the single source components and materials used in our therapeutics, any interruption or delay in the supply of components or materials, or our inability to obtain components or materials from alternate sources at acceptable prices in a timely manner, could impair our ability to meet the demand for our investigational medicines. We have and may in the future enter into collaborations, licenses and other similar arrangements with third parties for the research, development and commercialization of certain of the therapeutic candidates we may develop, including our collaboration with Vertex. If any such arrangements are not successful, we may not be able to capitalize on the market potential of those therapeutic candidates. We may seek third- party collaborators for the research, development and commercialization of certain of the therapeutic candidates we may develop. If we enter into any such arrangements with any third parties, we will likely have limited control over the amount and timing of resources that our partners dedicate to the development or commercialization of any therapeutic candidates we may seek to develop with them. Our ability to generate revenues from these arrangements will depend on our abilities to successfully perform the functions assigned to them in these arrangements. We cannot predict the success of any arrangement that we enter into. Collaborations involving our research programs or any therapeutic candidates we may develop pose numerous risks to us, including the following: • collaborators would have significant discretion in determining the efforts and resources that they will apply to these collaborations; • collaborators may not perform their obligations as expected; • collaborators may not pursue development and commercialization of any therapeutic candidates we may develop or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in the collaborator' s strategic focus or available funding or external factors such as an acquisition that diverts resources or creates competing priorities; • collaborators may delay programs, preclinical studies or clinical trials, provide insufficient funding for programs, preclinical studies or clinical trials, stop a preclinical study or clinical trial or abandon a therapeutic candidate, repeat or conduct new clinical trials or require a new formulation of a therapeutic candidate for clinical testing; • collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with any therapeutic candidates we may develop if the collaborators believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours; • collaborators may be acquired by a third party having competitive products or different priorities, causing the emphasis on our product development or commercialization program under such collaboration to be delayed, diminished or terminated; • collaborators with marketing and distribution rights to one or more products may not commit sufficient resources to the marketing and distribution of such product or products; • collaborators may not properly obtain, maintain, enforce or defend our intellectual property or proprietary rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our proprietary information or expose us to potential litigation; • if a collaborator of ours is involved in a business combination, the collaborator might de- emphasize or terminate the development or commercialization of any therapeutic candidate licensed to it by us; • **disputes may arise between the collaborators and us that result in the delay or termination of the research, development, or commercialization of any therapeutic candidates we may develop or that result in costly litigation or arbitration that diverts management attention and resources; • we may lose certain valuable rights under certain circumstances, including if we undergo a change of control; • collaborations may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable therapeutic candidates we may develop; and •** our collaborators' business or operations could be disrupted due to ~~the ongoing COVID- 19 pandemic or other~~ reasons outside of our control **, such as global health crises** , which could have an adverse impact on their development and commercialization efforts or the prospects of our collaboration; • ~~disputes may arise between the collaborators and us that result in the delay or termination of the research, development, or commercialization of any therapeutic candidates we may develop or that result in costly litigation or arbitration that diverts management attention and resources; • we may lose certain valuable rights under certain circumstances, including if we undergo a change of control; • collaborations may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable therapeutic candidates we may develop; and •~~ collaboration agreements may not lead to development or commercialization of therapeutic candidates in the most efficient manner or at all. If our collaborations do not result in the successful development and commercialization of therapeutic candidates, or if one of our collaborators terminates its agreement with us, we may not receive any future research funding or milestone or royalty payments under the collaboration. If we do not receive the funding we expect under these agreements, our development of therapeutic candidates could be delayed, and we may need additional resources to develop therapeutic candidates. In addition, if one of our collaborators terminates its agreement with us, we may find it more difficult to find a suitable replacement collaborator or attract new collaborators, and our development programs may be delayed or the perception of us in the business and financial communities could be adversely affected. All of the risks relating

to product development, regulatory approval and commercialization described in this Annual Report apply to the activities of our collaborators. For example, we will have limited influence and control over the development and commercialization activities of Vertex ~~Pharmaceuticals Incorporated (Vertex)~~ in the development and commercialization of ~~ENTR~~ **VX** - ~~701~~ **670** or certain other product candidates. **On January 7, 2024, Vertex announced that they received clearances from Health Canada and the Medicines and Healthcare Products Regulatory Agency (MHRA – UK) for CTAs for VX- 670 for patients with DM1. Vertex initiated the Phase 1 / 2 clinical trial in patients with DM1 in Canada and will initiate the study in the UK near- term. However, Vertex also announced that the FDA requested additional information related to their VX- 670 IND, which resulted in a clinical hold. Vertex is working to address FDA comments and initiate the study in the U. S. Should Vertex be delayed in submitting a response to the clinical hold in the United States or their response is not satisfactory to the FDA, the clinical hold may not be lifted on a timely basis, or at all.** Vertex' s development and commercialization activities may adversely impact our own efforts. Failure by Vertex to meet its obligations under the ~~Strategic Collaboration and License Agreement (the~~ Vertex Agreement ~~)~~, to apply sufficient efforts at developing and commercializing collaboration products, or to comply with applicable legal or regulatory requirements, may materially adversely affect our business and our results of operations. In addition, to the extent we rely on Vertex to commercialize any products upon obtaining regulatory approval, we may receive less revenues than if we commercialized these products ourselves, which could materially harm our prospects. These relationships, or those like them, may require us to incur non- recurring and other charges, increase our near- and long- term expenditures, issue securities that dilute our existing stockholders, or disrupt our management and business. In addition, we could face significant competition in seeking appropriate collaborators, and the negotiation process is time- consuming and complex. Our ability to reach definitive collaboration agreements will depend, among other things, upon our assessment of the collaborator' s resources and expertise, the terms and conditions of the proposed collaboration, and the proposed collaborator' s evaluation of several factors. If we license rights to any therapeutic candidates we or our collaborators may develop, we may not be able to realize the benefit of such transactions if we are unable to successfully integrate them with our existing operations and company culture. If conflicts arise between us and our current or potential collaborators, these parties may act in a manner adverse to us and could limit our ability to implement our strategies. If conflicts arise between us and our current or potential collaborators, the other party may act in a manner adverse to us and could limit our ability to implement our strategies. Our collaborators may develop, either alone or with others, products in related fields that are competitive with the therapeutic candidates we may develop that are the subject of these collaborations with us. Competing products, either developed by the collaborators or to which the collaborators have rights, may result in the withdrawal of support for our therapeutic candidates. Some of our future collaborators could also become our competitors. Our collaborators could develop competing products, preclude us from entering into collaborations with their competitors, fail to obtain timely regulatory approvals, terminate their agreements with us prematurely, fail to devote sufficient resources to the development and commercialization of products, or merge with or be acquired by a third party who may do any of these things. Any of these developments could harm our product development efforts. If we are not able to establish collaborations on commercially reasonable terms, we may have to alter our development and commercialization plans. Our product development and research programs and the potential commercialization of any therapeutic candidates we may develop will require substantial additional cash to fund expenses. For some of the therapeutic candidates we may develop, we may decide to collaborate with other pharmaceutical and biotechnology companies for the development and potential commercialization of those therapeutic candidates. We face significant competition in seeking appropriate collaborators. Whether we reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator' s resources and expertise, the terms and conditions of the proposed collaboration, and the proposed collaborator' s evaluation of a number of factors. Those factors may include the design or results of clinical trials, the likelihood of approval by the FDA, the EMA or similar regulatory authorities outside the United States, the potential market for the subject therapeutic candidate, the costs and complexities of manufacturing and delivering such therapeutic candidate to patients, the potential of competing products, the existence of uncertainty with respect to our ownership of technology, which can exist if there is a challenge to such ownership without regard to the merits of the challenge, and industry and market conditions generally. The collaborator may also consider alternative therapeutic candidates or technologies for similar indications that may be available to collaborate on and whether such a collaboration could be more attractive than the one with us. Collaborations are complex and time- consuming to negotiate and document. In addition, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators. We may not be able to negotiate collaborations on a timely basis, on acceptable terms, or at all. If we are unable to do so, we may have to curtail the development of the therapeutic candidate for which we are seeking to collaborate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization, reduce the scope of any sales or marketing activities, or increase our own expenditures on the development of the therapeutic candidate. Risks Related to Commercialization of Our Therapeutic Candidates The commercial success of our therapeutic candidates will depend upon the degree of market acceptance of such therapeutic candidates by physicians, patients, healthcare payors and others in the medical community. Our therapeutic candidates may not be commercially successful. Even if any of our therapeutic candidates receive regulatory approval, they may not gain market acceptance among physicians, patients, healthcare payors or the medical community. The commercial success of any of our current or future therapeutic candidates will depend significantly on the broad adoption and use of the resulting product by physicians and patients for approved indications. The degree of market acceptance of our therapeutics will depend on a number of factors, including: • **the** demonstration of clinical efficacy and safety compared to other more- established products; • the indications for which our therapeutic candidates are approved; • the limitation of our targeted patient population and other limitations or warnings contained in any FDA- approved labeling; • **the** acceptance of a new drug for the relevant indication by healthcare providers and their patients; • the pricing and cost- effectiveness of our therapeutics, as well as the cost of treatment

with our therapeutics in relation to alternative treatments and therapies; • our ability to obtain and maintain sufficient third- party coverage and adequate reimbursement from government healthcare programs, including Medicare and Medicaid, private health insurers and other third- party payors; • the willingness of patients to pay all, or a portion of, out- of- pocket costs associated with our therapeutics in the absence of sufficient third- party coverage and adequate reimbursement; • any restrictions on the use of our therapeutics, and the prevalence and severity of any adverse effects; • potential product liability claims; • the timing of market introduction of our therapeutics as well as competitive drugs; • the effectiveness of our or any of our current or potential future collaborators' sales and marketing strategies; and • unfavorable publicity relating to the product. If any therapeutic candidate is approved but does not achieve an adequate level of acceptance by physicians, hospitals, healthcare payors or patients, we may not generate sufficient revenue from that product and may not become or remain profitable. Our efforts to educate the medical community and third- party payors regarding the benefits of our therapeutics may require significant resources and may never be successful. Even if we are able to commercialize any of our therapeutic candidates, if approved, such therapeutic candidate may become subject to unfavorable pricing regulations or third- party coverage and reimbursement policies, which would harm our business. The regulations that govern regulatory approvals, pricing and reimbursement for new products vary widely from country to country. Some countries require approval of the sale price of a product before it can be marketed. In many countries, the pricing review period begins after marketing approval is granted. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain marketing approval for a therapeutic candidate in a particular country, but then be subject to price regulations that delay our commercial launch of the therapeutic candidate, possibly for lengthy time periods, and negatively impact the revenues we are able to generate from the sale of the therapeutic candidate in that country. Adverse pricing limitations may hinder our ability to recoup our investment in one or more therapeutic candidates, even if our therapeutic candidates obtain marketing approval. Our ability to commercialize any therapeutic candidates successfully also will depend in part on the extent to which coverage and reimbursement for these therapeutic candidates and related treatments will be available from government authorities, private health insurers and other organizations. In the U. S. and markets in other countries, patients generally rely on third- party payors to reimburse all or part of the costs associated with their treatment. Adequate coverage and reimbursement from governmental healthcare programs, such as Medicare and Medicaid, and commercial payors is critical to new product acceptance. In the United States, the principal decisions about reimbursement for new medicines are typically made by the Centers for Medicare & Medicaid Services (CMS), an agency within the U. S. Department of Health and Human Services (HHS). CMS decides whether and to what extent a new medicine will be covered and reimbursed under Medicare and private payors tend to follow CMS to a substantial degree. The availability of coverage and extent of reimbursement by governmental and private payors is essential for most patients to be able to afford treatments. Sales of these or other products that we may identify will depend substantially, both domestically and abroad, on the extent to which the costs of our therapeutics will be paid by health maintenance, managed care, pharmacy benefit and similar healthcare management organizations, or reimbursed by government health administration authorities, private health coverage insurers and other third-party payors. If coverage and adequate reimbursement is not available, or is available only to limited levels, we may not be able to successfully commercialize our therapeutics. Even if coverage is provided, the approved reimbursement amount may not be high enough to allow us to establish or maintain pricing sufficient to realize a sufficient return on our investment. Factors payors consider in determining reimbursement are based on whether the product is: • a covered benefit under its health plan; • safe, effective and medically necessary; • appropriate for the specific patient; • cost- effective; and • neither experimental nor investigational. A primary trend in the U. S. healthcare industry and elsewhere is cost containment. Government authorities and third- party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular products. Increasingly, third- party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for products. We cannot be sure that coverage will be available for any therapeutic candidate that we commercialize and, if coverage is available, the level of reimbursement. Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States. Increasingly, third- party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. We cannot be sure that reimbursement will be available for any therapeutic candidate that we commercialize and, if reimbursement is available, the level of reimbursement. In addition, many pharmaceutical manufacturers must calculate and report certain price reporting metrics to the government, such as average sales price (ASP) and best price. Penalties may apply in some cases when such metrics are not submitted accurately and timely. Further, these prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs. In addition, in some foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing vary widely from country to country. For example, the EU provides options for its Member States to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. To obtain reimbursement or pricing approval, some of these countries may require the completion of clinical trials that compare the cost effectiveness of a particular therapeutic candidate to currently available therapies. A Member State may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our therapeutic candidates. Historically, products launched in the EU do not follow price structures of the U. S. and generally prices tend to be significantly lower. We face significant competition, and if our competitors develop technologies or therapeutic candidates more rapidly than we do or their technologies are more effective, our business and our ability to develop and successfully commercialize products

may be adversely affected. The biotechnology and biopharmaceutical industries are characterized by rapid advancing technologies, intense competition and a strong emphasis on proprietary and novel products and therapeutic candidates. Our competitors have developed, are developing or may develop products, therapeutic candidates and processes competitive with our therapeutic candidates. Any therapeutic candidates that we successfully develop and commercialize will compete with existing therapies and new therapies that may become available in the future. We believe that a significant number of products are currently under development, and may become commercially available in the future, for the treatment of conditions for which we may attempt to develop therapeutic candidates. Our competitors include larger and better funded pharmaceutical, biopharmaceutical, biotechnological and therapeutics companies. Moreover, we may also compete with universities and other research institutions who may be active in the indications we are targeting and could be in direct competition with us. We also compete with these organizations to recruit management, scientists and clinical development personnel, which could negatively affect our level of expertise and our ability to execute our business plan. We will also face competition in establishing clinical trial sites, enrolling subjects for clinical trials and in identifying and in- licensing new therapeutic candidates. Smaller or early stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. Currently, patients with DMD are treated with corticosteroids to manage the inflammatory component of the disease. EMFLAZA (deflazacort) is an FDA- approved corticosteroid marketed by PTC Therapeutics, Inc. (PTC). In addition, there are four FDA- approved exon skipping drugs: EXONDYS 51 (eteplirsen), VYONDYS 53 (golodirsen), and AMONDYS 45 (casimersen), which are PMOs approved for the treatment of patients with DMD who are amenable to exon 51, exon 53 and exon 45 skipping, respectively, and are marketed by Sarepta Therapeutics, Inc. (Sarepta), and VILTEPSO (vitolarsen), a PMO approved for the treatment of patients with DMD who are amenable to exon 53 skipping, which is marketed by Nippon Shinyaku Co. Ltd. Companies focused on developing treatments for DMD that target dystrophin mechanisms, as does our DMD program, include Sarepta with SRP- 5051, a peptide- linked PMO currently being evaluated following a Phase 2 clinical trial for patients amenable to exon 51 skipping along with **additional exons** ~~SRP- 5053, SRP- 5045, SRP- 5050 and SRP- 5044~~ in preclinical development, Nippon Shinyaku Co. Ltd., which recently completed a Phase 1 / 2 clinical trial for patients amenable to exon 44 skipping in Japan, PTC with ataluren, a small molecule targeting nonsense mutations in a Phase 3 clinical trial, Avidity Biosciences, Inc. (Avidity), which announced the ~~initiation of~~ **preliminary data from** its **ongoing** Phase 1 / 2 clinical trial with antibody oligonucleotide conjugates for exon 44 (AOC- 1044), and has similar programs for patients amenable to exon 45, and exon 51 skipping in preclinical development, Wave Life Sciences Ltd., which is clinically evaluating WVE- N531, a splicing clinical candidate that is designed to target exon 53 within the dystrophin gene, Dyne Therapeutics, Inc. (Dyne), which is pursuing antibody fragment- oligonucleotide conjugates for exons 44, 45, 51 (clinical candidate DYNE- 251), and 53, PepGen, Inc. with PGN- EDO51, a clinical candidate designed to address exon 51, along with discovery programs targeting exons 53, 44, and 45, and BioMarin Pharmaceutical Inc., which is in preclinical development with BMN 351, an antisense oligonucleotide therapy for exon 51. In addition, several companies are developing gene therapies to treat DMD, including Pfizer Inc. (PF- 06939926), Sarepta (SRP- 9001 ~~and Galgt2 gene therapy program~~ **; delandistrogene moxeparvovec- rokl approved for ambulatory 4- 5 year old patients** ), Solid Biosciences Inc. (SGT- 003), and REGENXBIO (RGX- 202). Gene editing treatments that are in preclinical development are also being pursued by Vertex and Sarepta. We are also aware of several companies targeting non- dystrophin mechanisms for the treatment of DMD. We expect to face competition from existing products and products in development for each of our ~~wholly owned and partnered~~ therapeutic candidates. There are currently no approved therapies to treat the underlying cause of DM1. Therapeutic candidates currently in development to treat DM1 include: tideglusib, a GSK3- ß inhibitor in late- stage clinical development by AMO Pharma Ltd. for the congenital phenotype of DM1; AOC- 1001, an antibody linked siRNA in clinical development by Avidity; DYNE- 101, an antibody fragment conjugated to an ASO targeting DM1 protein kinase knockdown in clinical development by Dyne; EDODM1, a linear peptide conjugated to a PMO targeting CUG repeats in ~~preclinical~~ --- **clinical** development by PepGen, Inc. ~~, in preclinical development~~ ; a small molecule targeting GTG repeats in preclinical development by Design Therapeutics, Inc. ~~; gene editing treatments in preclinical development by Vertex~~ ; an RNA- targeting gene therapy in preclinical development by Locana, Inc.; and small molecules interacting with RNA in preclinical development by Expansion Therapeutics, Inc. The only currently- approved therapies for Pompe disease are alglucosidase alfa (Lumizyme in the United States, Myozyme in other geographies) ~~and~~ **,** avalglucosidase alfa- ngpt (Nexviazyme in the United States) **and cipaglucosidase alfa- atga miglustat** , which **rely on the** ~~are both forms of ERT delivered~~ **delivery of GAA** via IV infusions. There is one **GYS1 inhibitor** ~~next- generation GAA enzyme~~ in ~~registration~~ **clinical development** from ~~Amicus~~ **Maze** Therapeutics Inc. ~~(Amicus),~~ and **another from Aro Biotherapeutics.** ~~there~~ **There** are four gene therapies in the early stages of clinical development from Astellas Pharma Inc., Bayer AG, Roche Holding AG and Lacerta Therapeutics, Inc. There are ~~five~~ gene therapies in preclinical development from AVROBIO, Inc. ~~,~~ **and** Amicus ~~, Provention Bio Inc., Selecta Biosciences, Inc. and Sarepta. There is one GYS1 inhibitor in Phase l development form Maze~~ Therapeutics ~~Inc. and two preclinical therapies targeting GYS1 inhibition from Aro Biotherapeutics, and Avidity, respectively~~ . Many of our competitors have significantly greater financial, technical, manufacturing, marketing, sales and supply resources or experience than we do. If we successfully obtain approval for any therapeutic candidate, we will face competition based on many different factors, including the safety and effectiveness of our therapeutics, the ease with which our therapeutics can be administered and the extent to which patients accept relatively new routes of administration, the timing and scope of regulatory approvals for these products, the availability and cost of manufacturing, marketing and sales capabilities, price, reimbursement coverage and patent position. Competing products could present superior treatment alternatives, including by being more effective, safer, more convenient, less expensive or marketed and sold more effectively than any products we may develop. Competitive products or technological approaches may make any products we develop, or our EEV Platform, obsolete or noncompetitive before we recover the expense of developing and commercializing our therapeutic candidates. If we are unable to compete effectively, our opportunity to generate revenue from

the sale of our therapeutics we may develop, if approved, could be adversely affected. Risks Related to Our Business Operations and Industry Our future success depends on our ability to retain key employees and to attract, retain and motivate qualified personnel. We are highly dependent on the research expertise of Natarajan Sethuraman, Ph. D., our Chief Scientific Officer, and the development and management expertise of Dipal Doshi, our ~~President and~~ Chief Executive Officer, as well as the other principal members of our management, scientific and clinical team. Although we have entered into employment agreements and / or offer letters with our executive officers, each of them may terminate their employment with us at any time. Our industry has experienced a high rate of turnover in recent years. Our ability to compete in the highly competitive pharmaceuticals industry depends upon our ability to attract, retain and motivate highly skilled and experienced personnel with scientific, clinical, regulatory, manufacturing and management skills and experience. We conduct our operations in the Boston area, a region that is home to many other pharmaceutical companies as well as many academic and research institutions, resulting in fierce competition for qualified personnel. We may not be able to attract or retain qualified personnel in the future due to the intense competition for a limited number of qualified personnel among pharmaceutical companies. Many of the other pharmaceutical companies against which we compete have greater financial and other resources, different risk profiles and a longer history in the industry than we do. Our competitors may provide higher compensation, more diverse opportunities and / or better opportunities for career advancement. Any or all of these competing factors may limit our ability to continue to attract and retain high quality personnel, which could negatively affect our ability to successfully develop and commercialize our therapeutic candidates and to grow our business and operations as currently contemplated. To induce valuable employees to remain at our company, in addition to salary and cash incentives, we have provided stock options that vest over time. The value to employees of stock options that vest over time may be significantly affected by movements in our stock price that are beyond our control and may at any time be insufficient to counteract more lucrative offers from other companies. Despite our efforts to retain valuable employees, members of our management, scientific and development teams may terminate their employment with us on short notice. For example, employment of our key employees is at- will, which means that any of our employees could leave our employment at any time, with or without notice. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development and commercialization strategy. Our consultants and advisors may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. Our success also depends on our ability to continue to attract, retain and motivate highly skilled junior, mid- level and senior managers as well as junior, mid- level and senior scientific and medical personnel. Failure to succeed in clinical trials may make it more challenging to recruit and retain qualified scientific personnel. We expect to expand our development and regulatory capabilities, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations. As of ~~February 28~~ **March 6** , ~~2023~~ **2024** , we had ~~130~~ **159** full- time employees. We expect to experience significant growth in the number of our employees and the scope of our operations, particularly in the areas of clinical development, clinical operations, manufacturing, regulatory affairs and, if any of our therapeutic candidates receives marketing approval, sales, marketing and distribution. To manage our anticipated future growth, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. Due to our limited financial resources and the limited experience of our management team in managing a company with such anticipated growth and with developing sales, marketing and distribution infrastructure, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. The expansion of our operations may lead to significant costs and may divert our management and business development resources. Further, we currently rely, and for the foreseeable future will continue to rely, in substantial part on certain third- party contract organizations, advisors and consultants to provide certain services, including assuming substantial responsibilities for the conduct of our clinical trials and the manufacture of ENTR- 601- 44, ENTR- 601- 45, **ENTR- 601- 50,** our partnered candidate ~~ENTR-~~ **VX** - ~~701-~~ **670** or any future therapeutic candidates. We cannot assure our stockholders that the services of such third- party contract organizations, advisors and consultants will continue to be available to us on a timely basis when needed, or that we can find qualified replacements. In addition, if we are unable to effectively manage our outsourced activities or if the quality or accuracy of the services provided by our vendors or consultants is compromised for any reason, our clinical trials may be extended, delayed or terminated, and we or our partners may not be able to obtain marketing approval of ENTR- 601- 44, ENTR- 601- 45, ENTR- ~~701-~~ **601- 50, VX- 670** or any future therapeutic candidates or otherwise advance our business. We cannot assure our stockholders that we will be able to properly manage our existing vendors or consultants or find other competent outside vendors and consultants on economically reasonable terms, or at all. If we are not able to effectively manage growth and expand our organization, we may not be able to successfully implement the tasks necessary to further develop and commercialize ENTR- 601- 44, ENTR- 601- 45, **ENTR- 601- 50,** our partnered candidate ~~ENTR-~~ **VX** - ~~701-~~ **670** , our other development portfolio therapeutic candidates or any future therapeutic candidates and, accordingly, may not achieve our research, development and commercialization goals. Recently enacted and future legislation may increase the difficulty and cost for us to obtain marketing approval of and commercialize our therapeutic candidates and decrease the prices we may obtain. In the United States and some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of our therapeutic candidates, restrict or regulate post- approval activities and affect our ability to profitably sell any therapeutic candidates for which we obtain marketing approval. For example, the ACA was passed in 2010 and substantially changed the way healthcare is financed by both governmental and private insurers, and continues to significantly impact the U. S. pharmaceutical industry. Among the provisions of the ACA of importance to our potential therapeutic candidates are the following: • annual fees and taxes on manufacturers of certain branded prescription drugs; • an annual, nondeductible fee on any entity that manufactures or imports specified branded prescription drugs and biologic products; • a Medicare Part D coverage gap discount program, in which manufacturers must ~~now~~ agree to offer 70 % point- of- sale discounts off negotiated prices of applicable brand drugs to eligible

beneficiaries during their coverage gap period, as a condition for the manufacturer' s outpatient drugs to be covered under Medicare Part D; • an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program and extended the rebate program to individuals enrolled in Medicaid managed care organizations; • expansion of healthcare fraud and abuse laws, including the False Claims Act and the federal Anti- Kickback Statute, new government investigative powers, and enhanced penalties for noncompliance; • extension of manufacturers' Medicaid rebate liability; • expansion of eligibility criteria for Medicaid programs; • expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program; • requirements to report financial arrangements with physicians and teaching hospitals; • a requirement to annually report drug samples that manufacturers and distributors provide to physicians; and • a Patient- Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research. Other legislative changes have been proposed and adopted since the ACA was enacted. The Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. These changes include aggregate reductions to Medicare payments to providers of up to 2 % per fiscal year. Subsequent legislation extended the 2 % payment reduction which remains in effect through ~~2030~~ **2031** . The American Taxpayer Relief Act of 2012 further reduced Medicare payments to several providers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years **. On March 11, 2021, President Biden signed the American Rescue Plan Act of 2021 into law, which eliminates the statutory Medicaid drug rebate cap, currently set at 100 % of a drug' s average manufacturer price, for single source and innovator multiple source drugs, beginning January 1, 2024. Due to the Statutory Pay- As- You- Go Act of 2010, estimated budget deficit increases resulting from the American Rescue Plan Act of 2021, and subsequent legislation, Medicare payments to providers will be further reduced starting in 2025 absent further legislation. On May 30, 2018, the Right to Try Act, was signed into law. The law, among other things, provides a federal framework for certain patients to access certain investigational new drug products that have completed a Phase 1 clinical trial and that are undergoing investigation for FDA approval. Under certain circumstances, eligible patients can seek treatment without enrolling in clinical trials and without obtaining FDA permission under the FDA expanded access program. There is no obligation for a pharmaceutical manufacturer to make its drug products available to eligible patients as a result of the Right to Try Act** . The Inflation Reduction Act of 2022 (the IRA) includes several provisions that may impact our business to varying degrees, including provisions that create a $ 2, 000 out- of- pocket cap for Medicare Part D beneficiaries, impose new manufacturer financial liability on all drugs in Medicare Part D, allow the U. S. government to negotiate Medicare Part B and Part D pricing for certain high- cost drugs and biologics without generic or biosimilar competition, require companies to pay rebates to Medicare for drug prices that increase faster than inflation, and delay the rebate rule that would limit the fees that pharmacy benefit managers can charge. Further, under the IRA, orphan drugs are exempted from the Medicare drug price negotiation program, but only if they have **orphan** ~~one rare disease~~ designation and for which the only approved indication is for that disease or condition. If a product receives multiple **orphan** ~~rare disease~~ designations or has multiple approved indications, it may not qualify for the orphan drug exemption **. The implementation of the IRA is currently subject to ongoing litigation challenging the constitutionality of the IRA' s Medicare drug price negotiation program** . The effect of the IRA on our business and the healthcare industry in general is not yet known. Further, there has been heightened governmental scrutiny recently over the manner in which drug manufacturers set prices for their marketed products, which has resulted in several 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 drug products. President Biden has issued multiple executive orders that have sought to reduce prescription drug costs. **In February 2023, HHS also issued a proposal in response to an October 2022 executive order from President Biden that includes a proposed prescription drug pricing model that will test whether targeted Medicare payment adjustments will sufficiently incentivize manufacturers to complete confirmatory trials for drugs approved through FDA' s accelerated approval pathway.** Although a number of these and other proposed measures may require authorization through additional legislation to become effective, and the Biden administration may reverse or otherwise change these measures, both the Biden administration and Congress have indicated that it will continue to seek new legislative measures to control drug costs. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. We expect that the ACA, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any approved product. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our therapeutics. Legislative and regulatory proposals have been made to expand post- approval requirements and restrict sales and promotional activities for pharmaceutical products. Legally mandated price controls on payment amounts by third- party payors or other restrictions could harm our business, financial condition, results of operations and prospects. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. We cannot be sure whether additional legislative changes will be enacted, or whether the FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of our therapeutic candidates, if any, may be. It is also possible that additional governmental action is taken in response to ~~the ongoing COVID- 19 pandemic~~ **pandemics or global health crises** . Failure or ~~security~~ **cybersecurity** ~~breaches~~ **incidents** , loss or leakage of data and other disruptions of our internal information technology systems, or those of our third- party CROs or other vendors, contractors or consultants could result in material disruption of our development programs, compromise sensitive information related to our

business or prevent us from accessing critical information, potentially exposing us to liability or otherwise adversely affecting our business. We are increasingly dependent upon information technology systems, infrastructure and data to operate our business. In the ordinary course of business, we collect, store and transmit confidential information (including but not limited to intellectual property, proprietary business information and personal information). It is critical that we do so in a secure manner to maintain the confidentiality and integrity of such confidential information. We also have outsourced elements of our operations to third parties, and as a result we manage a number of third- party CROs, vendors, and other contractors and consultants who have access to our confidential information. Despite the implementation of security measures, given their size and complexity and the increasing amounts of confidential information that they maintain, our internal information technology systems and those of our third- party CROs, vendors and other contractors and consultants are potentially vulnerable to breakdown or other damage or interruption from service interruptions, system malfunction, natural disasters, terrorism, war and telecommunication and electrical failures, as well as ~~security~~ **cybersecurity** ~~breaches~~ **incidents** from inadvertent or intentional actions by our employees, third- party CROs, vendors, contractors, consultants, business partners and / or other third parties, or from cyber- attacks by malicious third parties (including the deployment of harmful malware, ransomware, denial- of- service attacks, social engineering and other means to affect service reliability and threaten the confidentiality, integrity and availability of information), which may compromise our system infrastructure, or that of our third- party CROs, vendors and other contractors and consultants, or lead to data leakage. The risk of a ~~security~~ **cybersecurity** ~~breach~~ **incident** or disruption, particularly through cyber- attacks or cyber intrusion, including by computer hackers, foreign governments, and cyber terrorists, has generally increased as the number, intensity and sophistication of attempted attacks and intrusions from around the world have increased. We may not be able to anticipate all types of security threats, nor may we be able to implement preventive measures effective against all such security threats. The techniques used by cyber criminals change frequently, may not be recognized until launched and can originate from a wide variety of sources, including outside groups such as external service providers, organized crime affiliates, terrorist organizations or hostile foreign governments or agencies. To the extent that any disruption or ~~security~~ **cybersecurity** ~~breach~~ **incident** were to result in a loss of, or damage to, our data or applications, or those of our third- party CROs, vendors and other contractors and consultants, or inappropriate disclosure of confidential or proprietary information, we could incur liability and reputational damage and the further development and commercialization of ENTR- 601- 44, ENTR- 601- 45, ENTR- ~~701~~ **601- 50, our partnered candidate VX- 670** or any future therapeutic candidates could be delayed. The costs related to significant ~~security~~ **cybersecurity** ~~breaches~~ **incidents** or disruptions could be material and exceed the limits of the cybersecurity insurance we maintain against such risks. If the information technology systems of our third- party CROs, vendors and other contractors and consultants become subject to disruptions or ~~security~~ **cybersecurity** ~~breaches~~ **incidents** , we may have insufficient recourse against such third parties and we may have to expend significant resources to mitigate the impact of such an event, and to develop and implement protections to prevent future events of this nature from occurring. ~~Our data protection efforts and our investment in information technology will prevent significant~~ **Significant** breakdowns, data leakages, ~~breaches~~ **cybersecurity incidents** in our systems, or those of our third- party CROs, vendors and other contractors and consultants, or other cyber incidents that ~~could~~ **may** have a material adverse effect upon our reputation, business, operations or financial condition. For example, if such an event were to occur and cause interruptions in our operations, or those of our third- party CROs, vendors and other contractors and consultants, it could result in a material disruption of our programs and the development of our therapeutic candidates could be delayed. In addition, the loss of clinical trial data for ENTR- 601- 44, ENTR- 601- 45, ENTR- ~~701~~ **601- 50, our partnered candidate VX- 670** or any other therapeutic candidates could result in delays in our marketing approval efforts and significantly increase our costs to recover or reproduce the data. Furthermore, significant disruptions of our internal information technology systems or those of our third- party CROs, vendors and other contractors and consultants, or ~~security~~ **cybersecurity** ~~breaches~~ **incidents** could result in the loss, misappropriation and / or unauthorized access, use, or disclosure of, or the prevention of access to, confidential information (including trade secrets or other intellectual property, proprietary business information and personal information), which could result in financial, legal, business and reputational harm to us. For example, any such event that leads to unauthorized access, use, or disclosure of personal information, including personal information regarding our clinical trial subjects or employees, could harm our reputation directly, compel us to comply with federal and / or state ~~breach~~ **cybersecurity incident** notification laws and foreign law equivalents, subject us to mandatory corrective action, and otherwise subject us to liability under laws and regulations that protect the privacy and security of personal information, which could result in significant legal and financial exposure and reputational damages that could potentially have an adverse effect on our business. A pandemic, epidemic or outbreak of an infectious disease ~~, such as COVID- 19,~~ may materially and adversely affect our business and could cause a disruption to the development of our therapeutic candidates. **Public health crises could adversely impact** ~~The ongoing COVID- 19 pandemic has broadly affected~~ the global economy and ~~has~~ **financial markets, and** put a significant strain on healthcare resources. **Worldwide** ~~In the United States, President Biden' s administration announced that it will end COVID- 19 emergency declarations on May 11, 2023. The ultimate extent of the impact of the COVID- 19 pandemic~~ **pandemics** ~~on our business, preclinical studies and planned clinical trials, financial condition and results of operations is uncertain and will depend on future developments. The continuation of the worldwide COVID- 19 or another pandemic~~ may affect our ability to initiate and complete preclinical studies, delay the initiation of our planned clinical trials, disrupt regulatory activities or have other adverse effects on our business, results of operations, financial condition and prospects. ~~In addition, the ongoing COVID- 19 pandemic has adversely impacted economies worldwide and may cause substantial disruption in the financial markets, both of which could adversely affect our business, operations and ability to raise funds to support our operations.~~ To date, we have not experienced a material financial impact or significant business disruptions, including with our vendors, or impairments of any of our assets as a result of the ~~ongoing~~ **post-** COVID ~~- 19 pandemic. While most COVID- 19 restrictions have been lifted, we plan to continue to follow, recommendations from federal, state and local governments regarding workplace policies, practices and~~

~~procedures. We have taken precautionary measures intended to help minimize the risk of the virus to our employees, including embracing a hybrid work~~ environment ~~where permissible and appropriate, providing for social distancing, increased sanitization of our facilities and providing personal protective equipment for our employees. We expect to continue to take actions as may be required or recommended by government authorities or as we determine are in the best interests of our employees and other business partners. We are continuing to monitor the potential impact of the ongoing COVID- 19 pandemic, but we cannot be certain what the overall impact of the COVID- 19 pandemic will be on our business, financial condition, results of operations and prospects~~ . Failure to comply with environmental, health and safety laws and regulations could subject us to fines or penalties or incur costs that could harm our business. We are subject to numerous foreign, federal, state and local environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our operations involve the use of hazardous and flammable materials, including chemicals and biological materials. Our operations also produce hazardous waste products. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources, including any available insurance. In addition, our leasing and operation of real property may subject us to liability pursuant to certain of these laws or regulations. Under existing U. S. environmental laws and regulations, current or previous owners or operators of real property and entities that disposed or arranged for the disposal of hazardous substances may be held strictly, jointly and severally liable for the cost of investigating or remediating contamination caused by hazardous substance releases, even if they did not know of and were not responsible for the releases. We could incur significant costs and liabilities which may adversely affect our financial condition and operating results for failure to comply with such laws and regulations, including, among other things, civil or criminal fines and penalties, property damage and personal injury claims, costs associated with upgrades to our facilities or changes to our operating procedures, or injunctions limiting or altering our operations. Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage or disposal of biological, hazardous or radioactive materials. In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations, which are becoming increasingly more stringent, may impair our research, development or production efforts. Our failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions. Our relationships with customers, third- party payors, physicians and healthcare providers will be subject to applicable anti- kickback, fraud and abuse, and other laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm, and diminished profits. Healthcare providers, physicians and third- party payors will play a primary role in the recommendation and prescription of any therapeutic candidates for which we obtain regulatory approval. Our current and future arrangements with third- party payors and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we conduct research and would market, sell and distribute our therapeutics. As a pharmaceutical company, even though we do not and will not control referrals of healthcare services or bill directly to Medicare, Medicaid or other third- party payors, federal and state healthcare laws and regulations pertaining to fraud and abuse and patients' rights are and will be applicable to our business. Restrictions under applicable federal and state healthcare laws and regulations that may affect our ability to operate include the following: • the federal Anti- Kickback Statute, which prohibits, among other things, persons or entities from knowingly and willfully soliciting, receiving, offering or paying any remuneration (including any kickback, bribe or rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce, or in return for, the purchase, lease, order, arrangement, or recommendation of any good, facility, item or service for which payment may be made, in whole or in part, under a federal healthcare program, such as the Medicare and Medicaid programs. A person or entity does not need to have actual knowledge of the federal Anti- Kickback Statute or specific intent to violate it to have committed a violation. Violations are subject to civil and criminal fines and penalties for each violation, plus up to three times the remuneration involved, imprisonment, and exclusion from government healthcare programs. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti- Kickback Statute constitutes a false or fraudulent claim for purposes of the federal False Claims Act or federal civil money penalties; • the federal civil and criminal false claims laws and civil monetary penalty laws, such as the federal False Claims Act, which impose criminal and civil penalties and authorize civil whistleblower or qui tam actions, against individuals or entities for, among other things: knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent; knowingly making, using or causing to be made or used, a false statement of record material to a false or fraudulent claim or obligation to pay or transmit money or property to the federal government or knowingly concealing or knowingly and improperly avoiding or decreasing an obligation to pay money to the federal government. Manufacturers can be held liable under the federal False Claims Act even when they do not submit claims directly to government payors if they are deemed to " cause " the submission of false or fraudulent claims. The federal False Claims Act also permits a private individual acting as a " whistleblower " to bring actions on behalf of the federal government alleging violations of the federal False Claims Act and to share in any monetary recovery; • the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA), which created new federal criminal statutes that prohibit a person from knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (e. g., public or private) and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false, fictitious, or fraudulent statements or representations in connection with the

delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters; similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation; • HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 (HITECH) and their respective implementing regulations, including the Final Omnibus Rule published in January 2013, which impose requirements on certain covered healthcare providers, health plans, and healthcare clearinghouses as well as their respective business associates, independent contractors or agents of covered entities, that perform services for them that involve the creation, maintenance, receipt, use, or disclosure of, individually identifiable health information relating to the privacy, security and transmission of individually identifiable health information. HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions. In addition, there may be additional federal, state and non- U. S. laws which govern the privacy and security of health and other personal information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts; • the U. S. federal transparency requirements under the ACA, including the provision commonly referred to as the Physician Payments Sunshine Act, and its implementing regulations, which requires applicable manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children' s Health Insurance Program to report annually to CMS, information related to payments or other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain other licensed health care practitioners (defined to include physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists and anesthesiologist assistants, and certified- nurse midwives) and teaching hospitals, as well as ownership and investment interests held by the physicians described above and their immediate family members; • federal government price reporting laws, which require us to calculate and report complex pricing metrics in an accurate and timely manner to government programs; and • federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers. Additionally, we are subject to state and foreign equivalents of each of the healthcare laws and regulations described above, among others, some of which may be broader in scope and may apply regardless of the payor. Many U. S. states have adopted laws similar to the federal Anti- Kickback Statute and False Claims Act, and may apply to our business practices, including, but not limited to, research, distribution, sales or marketing arrangements and claims involving healthcare items or services reimbursed by non- governmental payors, including private insurers. In addition, some states have passed laws that require pharmaceutical companies to comply with the April 2003 Office of Inspector General Compliance Program Guidance for Pharmaceutical Manufacturers and / or the Pharmaceutical Research and Manufacturers of America' s Code on Interactions with Healthcare Professionals. Several states also impose other marketing restrictions or require pharmaceutical companies to make marketing or price disclosures to the state and require the registration of pharmaceutical sales representatives. State and foreign laws, including for example the European Union (EU) General Data Protection Regulation (which became effective on May 25, 2018) and the United Kingdom (UK) General Data Protection Regulation (which became effective following UK withdrawal from the EU as of January 2021) also govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts. There are ambiguities as to what is required to comply with these state requirements and if we fail to comply with an applicable state law requirement we could be subject to penalties. Finally, there are state and foreign laws governing the privacy and security of health information, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts. Federal and state enforcement bodies have recently increased their scrutiny of interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry. Ensuring business arrangements comply with applicable healthcare laws, as well as responding to possible investigations by government authorities, can be time and resource consuming and can divert a company' s attention from the business. Ensuring that our internal operations and future business arrangements with third parties comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations, agency guidance or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of the laws described above or any other governmental laws and regulations that may apply to us, we may be subject to significant penalties, including administrative, civil and criminal penalties, damages, fines, disgorgement, the exclusion from participation in federal and state healthcare programs, individual imprisonment, reputational harm, and the curtailment or restructuring of our operations, as well as additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non- compliance with these laws. Further, defending against any such actions can be costly and time-consuming, and may require significant financial and personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired. If any of the physicians or other providers or entities with whom we expect to do business is found to not be in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs and imprisonment. If any of the above occur, our ability to operate our business and our results of operations could be adversely affected. Our employees and independent contractors, including principal investigators, CROs, consultants and vendors, may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements. We are exposed to the risk that our employees and independent contractors, including principal investigators, CROs, consultants and vendors may engage in misconduct or other illegal activity. Misconduct by these parties could include intentional, reckless and / or negligent conduct or disclosure of unauthorized activities to us that violate: (i) the laws and regulations of the FDA and other

similar regulatory requirements, including those laws that require the reporting of true, complete and accurate information to such authorities, (ii) manufacturing standards, including cGMP requirements, (iii) federal and state data privacy, security, fraud and abuse and other healthcare laws and regulations in the United States and abroad or (iv) laws that require the true, complete and accurate reporting of financial information or data. Activities subject to these laws also involve the improper use or misrepresentation of information obtained in the course of clinical trials, the creation of fraudulent data in our preclinical studies or clinical trials or illegal misappropriation of drug product, which could result in regulatory sanctions and cause serious harm to our reputation. It is not always possible to identify and deter misconduct by employees and other third parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. In addition, we are subject to the risk that a person or government could allege such fraud or other misconduct, even if none occurred. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business and financial results, including, without limitation, the imposition of significant civil, criminal and administrative penalties, damages, monetary fines, disgorgements, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, imprisonment, contractual damages, reputational harm, diminished profits and future earnings, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non- compliance with these laws and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations. We are subject to certain U. S. and certain foreign anti- corruption, anti- money laundering, export control, sanctions and other trade laws and regulations. We can face serious consequences for violations. U. S. and foreign anti- corruption, anti- money laundering, export control, sanctions and other trade laws and regulations prohibit, among other things, companies and their employees, agents, CROs, legal counsel, accountants, consultants, contractors and other partners from authorizing, promising, offering, providing, soliciting, or receiving directly or indirectly, corrupt or improper payments or anything else of value to or from recipients in the public or private sector. Violations of these laws can result in substantial criminal fines and civil penalties, imprisonment, the loss of trade privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm and other consequences. We have direct or indirect interactions with officials and employees of government agencies or government- affiliated hospitals, universities and other organizations. We also expect our non- U. S. activities to increase over time. We expect to rely on third parties for research, preclinical studies and clinical trials and / or to obtain necessary permits, licenses, patent registrations and other marketing approvals. We can be held liable for the corrupt or other illegal activities of our personnel, agents, or partners, even if we do not explicitly authorize or have prior knowledge of such activities. Any violations of the laws and regulations described above may result in substantial civil and criminal fines and penalties, imprisonment, the loss of export or import privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm and other consequences. We may engage in strategic transactions that could impact our liquidity, increase our expenses and present significant distractions to our management. From time to time, we may consider strategic transactions, such as acquisitions of companies, asset purchases and out- licensing or in- licensing of intellectual property, products or technologies. Additional potential transactions that we may consider in the future include a variety of business arrangements, including spin- offs, strategic partnerships, joint ventures, restructurings, divestitures, business combinations and investments. Any future transactions could increase our near and long- term expenditures, result in potentially dilutive issuances of our equity securities, including our common stock, or the incurrence of debt, contingent liabilities, amortization expenses or acquired in- process research and development expenses, any of which could affect our financial condition, liquidity and results of operations. Future acquisitions may also require us to obtain additional financing, which may not be available on favorable terms or at all. These transactions may never be successful and may require significant time and attention of our management. In addition, the integration of any business that we may acquire in the future may disrupt our existing business and may be a complex, risky and costly endeavor for which we may never realize the full benefits of the acquisition. Moreover, we may not be able to locate suitable acquisition opportunities and this inability could impair our ability to grow or obtain access to technology or products that may be important to the development of our business. Accordingly, although there can be no assurance that we will undertake or successfully complete any additional transactions of the nature described above, any additional transactions that we do complete could have a material adverse effect on our business, results of operations, financial condition and prospects. Legislation or other changes in U. S. tax law could adversely affect our business and financial condition. The rules dealing with U. S. federal, state, and local income taxation are constantly under review by persons involved in the legislative process and by the Internal Revenue Service and the U. S. Treasury Department. Changes to tax laws (which changes may have retroactive application) could adversely affect us or holders of our common stock. In recent years, many changes have been made to applicable tax laws and changes are likely to continue to occur in the future. For example, under Section 174 of the Internal Revenue Code of 1986, as amended (the Code), in taxable years beginning after December 31, 2021, expenses that are incurred for research and development in the U. S. will be capitalized and amortized, which may have an adverse effect on our cash flow. Future changes in tax laws could have a material adverse effect on our business, cash flow, financial condition or results of operations. **For example, under Section 174 of the Code, in taxable year beginning after December 31, 2023, expenses that are incurred for research and development in the U. S. will be capitalized and amortized, which may have an adverse effect on our cash flow.** It cannot be predicted whether, when, in what form, or with what effective dates, new tax laws may be enacted, or regulations and rulings may be enacted, promulgated or issued under existing or new tax laws, which could result in an increase in our or our stockholders' tax liability or require changes in the manner in which we operate in order to minimize or mitigate any adverse effects of changes in tax law or in the interpretation thereof. We urge investors to consult with their legal and tax advisers regarding the implications of potential changes in tax laws on an investment in our common stock. Our ability to use our U. S. net operating loss carryforwards and certain other U. S. tax

attributes may be limited. Our ability to use our U. S. federal and state net operating losses to offset potential future taxable income and related income taxes that would otherwise be due is dependent upon our generation of future taxable income, and we cannot predict with certainty when, or whether, we will generate sufficient taxable income to use all of our net operating losses. Under current law, unused U. S. federal net operating losses generated for tax years beginning after December 31, 2017 are not subject to expiration and may be carried forward indefinitely. Such U. S. federal net operating losses generally may not be carried back to prior taxable years, except that, net operating losses generated in 2018, 2019 and 2020 may be carried back to each of the five tax years preceding the tax years of such losses. Additionally, for taxable years beginning after December 31, 2020, the deductibility of such U. S. federal net operating losses is limited to 80 % of our taxable income in any future taxable year. In addition, both our current and our future unused U. S. federal net operating losses and tax credits may be subject to limitation under Sections 382 and 383 of the Code, if we undergo an " ownership change, " generally defined as a greater than 50 percentage point change (by value) in its equity ownership by certain stockholders over a rolling three- year period. We ~~may~~ have ~~experienced~~ **determined that** such ownership changes **have occurred** in the past, and we may experience **additional** ownership changes in the future as a result of shifts in our stock ownership, some of which are outside our control. Our net operating losses and tax credits may also be impaired or restricted under state law. As of December 31, ~~2022~~ **2023**, we had U. S. federal net operating loss carryforwards of approximately $ ~~119~~ **14**. ~~3~~ **6** million, and our ability to utilize those net operating loss carryforwards could be limited by an " ownership change " as described above, which could result in increased tax liability to us. We plan to distribute our technology, biology, execution and financing risks across a wide variety of therapeutic areas, disease states, programs, and technologies. However, our assessment of, and approach to, risk may not be comprehensive or effectively avoid delays or failures in one or more of our programs or modalities. Failures in one or more of our programs or modalities could adversely impact other programs or modalities in our development portfolio and have a material adverse impact on our business, results of operations and ability to fund our business. We are creating a new category of potential therapeutics based on EEVs to improve the lives of patients. We have designed our strategy and operations to realize the full potential value and impact of EEVs over a long time horizon across a broad array of human diseases. We have made investments in our platform, infrastructure, and clinical capabilities that have enabled us to establish a development portfolio of several programs in development. As our therapeutic candidates and discovery programs progress, we or others may determine: that certain of our risk allocation decisions were incorrect or insufficient; that we made platform level technology mistakes; that individual programs or our EEV science in general has technology or biology risks that were unknown or underappreciated; that our choices on how to develop our infrastructure to support our scale will result in an inability to manufacture our therapeutics for clinical trials or otherwise impair our manufacturing; or that we have allocated resources in such a way that large investments are not recovered and capital allocation is not subject to rapid re- direction. All of these risks may relate to our current and future programs sharing similar science (including EEV science) and infrastructure, and in the event material decisions in any of these areas turn out to have been incorrect or under- optimized, we may experience a material adverse impact on our business and ability to fund our operations and we may never realize what we believe is the potential of EEVs. While we will attempt to diversify our risks by developing one or more programs in each modality, there are risks that are unique to each modality and risks that are applicable across modalities. These risks may impair our ability to advance one or more of our programs in clinical development, obtain regulatory approval, or ultimately commercialize our programs, or cause us to experience significant delays in doing so, any of which may materially harm our business. Certain features in our therapeutic candidates, including those related to large enzymes, antibodies and oligonucleotides, and their components, may result in foreseen and unforeseen risks that are active across some or all of our modalities. In addition, the biology risk across much of our development portfolio represents targets and pathways not clinically validated by one or more approved drugs. While we believe we have made progress in seeking to reduce biology risk in certain settings, the risk that the targets or pathways that we have selected may not be effective could continue to apply across our current and future programs. Any such portfolio spanning risks, whether known or unknown, if realized in any one of our programs would have a material and adverse effect on our other programs and on our business as a whole. Successful development of intracellular therapeutics is highly uncertain and is dependent on numerous factors, many of which are beyond our control. Intracellular therapeutics that appear promising in the early phases of development may fail to reach the market for several reasons, including: • nonclinical or preclinical testing or study results may show our EEV- therapeutics to be less effective than desired or to have harmful or problematic side effects or toxicities; • clinical trial results may show our oligonucleotides to be less effective than expected (e. g., a clinical trial could fail to meet its primary endpoint (s)) or to have unacceptable side effects or toxicities; • failure to receive the necessary regulatory approvals or a delay in receiving such approvals. Among other things, such delays may be caused by slow enrollment in clinical trials, patients dropping out of trials, length of time to achieve trial endpoints, additional time requirements for data analysis, NDA or BLA preparation, discussions with the FDA, a failure to align with the FDA regarding clinical trial endpoints and related approval criteria, an FDA request for additional nonclinical or clinical data, or unexpected safety or manufacturing issues; • manufacturing costs, formulation issues, pricing or reimbursement issues, or other factors that make our EEV- therapeutics uneconomical; and • proprietary rights of others and their competing products and technologies that may prevent our EEV- therapeutics from being commercialized **. Adverse developments affecting the financial services industry, such as actual events or concerns involving liquidity, defaults, or non- performance by financial institutions or transactional counterparties, could adversely affect the Company' s current and projected business operations and its financial condition and results of operations. Actual events involving limited liquidity, defaults, non- performance or other adverse developments that affect financial institutions, transactional counterparties or other companies in the financial services industry or the financial services industry generally, or concerns or rumors about any events of these kinds or other similar risks, have in the past and may in the future lead to market- wide liquidity problems. Although we assess our banking and customer relationships as we believe necessary or appropriate, our access to funding sources and other**

**credit arrangements in amounts adequate to finance or capitalize our current and projected future business operations could be significantly impaired by factors that affect the Company, the financial institutions with which the Company has credit agreements or arrangements directly, or the financial services industry or economy in general. These factors could include, among others, events such as liquidity constraints or failures, the ability to perform obligations under various types of financial, credit or liquidity agreements or arrangements, disruptions or instability in the financial services industry or financial markets, or concerns or negative expectations about the prospects for companies in the financial services industry. These factors could involve financial institutions or financial services industry companies with which the Company has financial or business relationships, but could also include factors involving financial markets or the financial services industry generally. The results of events or concerns that involve one or more of these factors could include a variety of material and adverse impacts on our current and projected business operations and our financial condition and results of operations. These could include, but may not be limited to, the following: • Delayed access to deposits or other financial assets or the uninsured loss of deposits or other financial assets; • Potential or actual breach of statutory, regulatory or contractual obligations, including obligations that require the Company to maintain letters of credit or other credit support arrangements; • Termination of cash management arrangements and / or delays in accessing or actual loss of funds subject to cash management arrangements. In addition, investor concerns regarding the U. S. or international financial systems could result in less favorable commercial financing terms, including higher interest rates or costs and tighter financial and operating covenants, or systemic limitations on access to credit and liquidity sources, thereby making it more difficult for us to acquire financing on acceptable terms or at all. Any decline in available funding or access to our cash and liquidity resources could, among other risks, adversely impact our ability to meet our operating expenses, financial obligations or fulfill our other obligations, result in breaches of our financial and / or contractual obligations or result in violations of federal or state wage and hour laws. Any of these impacts, or any other impacts resulting from the factors described above or other related or similar factors not described above, could have material adverse impacts on our liquidity, our current and / or planned business operations, and our current or projected financial condition and results of operations. In addition, any further deterioration in the macroeconomic economy or financial services industry could lead to losses or defaults by our suppliers, which in turn, could have a material adverse effect on our current and / or planned business operations and our current or projected results of operations and financial condition. For example, a customer may fail to make payments when due, default under their agreements with us, become insolvent or declare bankruptcy, or a supplier may determine that it will no longer deal with us as a customer. In addition, a customer or supplier could be adversely affected by any of the liquidity or other risks that are described above as factors that could result in material adverse impacts on the Company, including but not limited to delayed access or loss of access to uninsured deposits or loss of the ability to draw on existing credit facilities involving a troubled or failed financial institution. Any customer, collaborator or supplier bankruptcy or insolvency, or the failure of any customer or collaborator to make payments when due, or any breach or default by a customer, collaborator or supplier, or the loss of any significant supplier or collaborator relationships, could result in material losses to the Company and may have a material adverse impact on our business** . Risks Related to Our Intellectual Property If we or our collaborators are unable to obtain and maintain patent protection for our therapeutic programs and other proprietary technologies we develop, or if the scope of the patent protection obtained is not sufficiently broad, our competitors could develop and commercialize products and technology similar or identical to ours, and our ability to successfully commercialize our therapeutic programs and other proprietary technologies we may develop may be adversely affected. Our success depends in large part on our ability and the abilities of our collaborators to obtain and maintain patent protection in the United States and other countries with respect to our therapeutic programs and other proprietary technologies we may develop. In order to protect our proprietary position, we have filed or intend to file patent applications in the United States and abroad relating to our therapeutic programs and other proprietary technologies we may develop; however, there can be no assurance that any such patent applications will issue as granted patents. If we are unable to obtain or maintain patent protection with respect to our therapeutic programs and other proprietary technologies we may develop, our business, financial condition, results of operations and prospects could be materially harmed. Changes in either the patent laws or their interpretation in the United States and other countries may diminish our ability to protect our inventions, obtain, maintain and enforce our intellectual property rights and, more generally, could affect the value of our intellectual property or narrow the scope of our protection. In addition, we may rely on third- party collaborators or licensors to file patent applications relating to therapeutic programs or proprietary technology that may be developed or in- licensed. We cannot predict whether the patent applications we are currently pursuing, or that we or our third- party collaborators or licensors may pursue, will issue as patents in any particular jurisdiction or whether the claims of any issued patents will provide sufficient protection against competitors or other third parties. The patent prosecution process is expensive, time- consuming, and complex, and we may not be able to file, prosecute, maintain, enforce, or license 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 in time to obtain patent protection. Although we enter into non- disclosure and confidentiality agreements with parties who have access to confidential or patentable aspects of our research and development output, such as our employees, corporate collaborators, outside scientific collaborators, CROs, contract manufacturers, consultants, advisors and other third parties, any of these parties may breach the agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to seek patent protection. In addition, our ability to obtain and maintain valid and enforceable patents depends on whether the differences between our inventions and the prior art allow our inventions to be patentable over the prior art. Furthermore, publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot be certain that we or our licensors were the first to

make the inventions claimed in any of our owned or licensed patents or pending patent applications, or that we or our licensors were the first to file for patent protection of such inventions. No consistent policy regarding the scope of claims allowable in patents in the biotechnology field has emerged in the United States, and the patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has been the subject of much litigation in recent years. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Our patent applications may not result in patents being issued which protect our therapeutic programs and other proprietary technologies we may develop or which effectively prevent others from commercializing competitive technologies and products. In particular, our ability to stop third parties from making, using, selling, offering to sell, or importing products that infringe our intellectual property will depend in part on our success in obtaining and enforcing patent claims that cover our technology, inventions and improvements. We do not currently have issued patents that cover all of our technology or therapeutic candidates. With respect to both licensed and company- owned intellectual property, we cannot be sure that patents will be granted with respect to any of our pending patent applications or with respect to any patent applications filed by us in the future. Moreover, even issued patents do not provide us with the right to practice our technology in relation to the commercialization of our therapeutics. The area of patent and other intellectual property rights in biotechnology is an evolving one with many risks and uncertainties, and third parties may have blocking patents that could be used to prevent us from commercializing our patented therapeutic candidates and practicing our proprietary technology. Our issued patents, those that may issue in the future and those that we in- license may be challenged, invalidated, or circumvented, which could limit our ability to stop competitors from marketing related products or limit the length of the term of patent protection that we may have for our therapeutic candidates. Furthermore, our competitors may independently develop similar technologies. Moreover, the claim coverage in a patent application can be significantly reduced before the patent is granted. Even if our patent applications issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors or other third parties from competing with us or otherwise provide us with any competitive advantage. Any patents issuing from our patent applications may be challenged, narrowed, circumvented or invalidated by third parties. Consequently, we do not know whether our therapeutic programs and other proprietary technology will be protectable or remain protected by valid and enforceable patents. For example, we do not currently have any issued patents covering any of our oligonucleotide therapeutic candidates. The extent to which any patents, if and when granted, will cover our therapeutic candidates is uncertain. Even if a patent is granted, our competitors or other third parties may be able to circumvent the patent by developing similar or alternative technologies or products in a non- infringing manner which could materially adversely affect our business, financial condition, results of operations and prospects. In addition, given the amount of time required for the development, testing and regulatory review of our therapeutic programs and eventual therapeutic candidates, patents protecting the therapeutic candidates might expire before or shortly after such therapeutic candidates are commercialized. As a result, our intellectual property may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours. The issuance of a patent is not conclusive as to its inventorship, scope, validity, or enforceability and our patents may be challenged in the courts or patent offices in the United States and abroad. We may be subject to a third- party pre- issuance submission of prior art to the United States Patent and Trademark Office (USPTO) or in other jurisdictions, or become involved in opposition, derivation, revocation, reexamination, post- grant and inter partes review, or other similar proceedings challenging our patent rights. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate or render unenforceable, our patent rights, allow third parties to commercialize our therapeutic programs and other proprietary technologies we may develop and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third- party patent rights. Such proceedings also may result in substantial cost and require significant time from our scientists and management, even if the eventual outcome is favorable to us. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, regardless of the outcome, it could dissuade companies from collaborating with us to license, develop or commercialize current or future therapeutic candidates. Our rights to develop and commercialize any therapeutic candidates are subject and may in the future be subject, in part, to the terms and conditions of licenses granted to us by third parties. If we fail to comply with our obligations under our current or future intellectual property license agreements or otherwise experience disruptions to our business relationships with our current or any future licensors, we could lose intellectual property rights that are important to our business. We are and expect to continue to be reliant upon third- party licensors for certain patent and other intellectual property rights that are important or necessary to the development of our therapeutic programs, eventual therapeutic candidates, and proprietary technologies. For example, we rely on a license from Ohio State Innovation Foundation (OSIF), an affiliate of The Ohio State University (OSU) to certain patent rights and know- how of OSU. Our license agreement with OSIF imposes, and we expect that any future license agreement will impose, specified diligence, milestone payments, royalty payments, commercialization, development and other obligations on us and require us to meet development timelines, or to exercise diligent or commercially reasonable efforts to develop and commercialize licensed products, in order to maintain the licenses. These milestone payments, and other payments associated with the license, will make it less profitable for us to develop and potentially commercialize our therapeutic candidate. If this agreement is terminated, we could lose intellectual property rights that may be important to our business, potentially be liable for damages to the licensor or potentially be prevented from developing and commercializing our therapeutic candidate. Termination of the agreement or reduction or elimination of our rights under the agreement may also potentially result in us being required to negotiate a new or reinstated agreement with less favorable terms, and it is possible that we may be unable to obtain any such additional license at a reasonable cost or on reasonable terms, if at all. In that event, we may be required to spend significant time and resources to redesign our therapeutic candidate or the method for manufacturing it or to develop or license replacement technology, all of which may not be feasible on a technical or commercial basis. For more information on the terms of the license agreement with OSIF, see " Business - — Intellectual ~~Property~~ **property** - — License

~~Agreement~~ **agreement** with The Ohio State University " **and Note 10** ~~in our final prospectus filed with the SEC pursuant to Rule 424 (b) (4) under the Securities Act on November 1~~ , ~~2021~~ **Commitments and Contingencies, to our consolidated financial statements included elsewhere in this Annual Report** . Furthermore, our licensors have, or may in the future have, the right to terminate a license if we materially breach the agreement and fail to cure such breach within a specified period or in the event we undergo certain bankruptcy events. In spite of our best efforts, our current or any future licensors might conclude that we have materially breached our license agreements and might therefore terminate the license agreements. If our license agreements are terminated, we may lose our rights to develop and commercialize therapeutic candidates and technology, lose patent protection, experience significant delays in the development and commercialization of our therapeutic candidates and technology, and incur liability for damages. If these in- licenses are terminated, or if the underlying intellectual property fails to provide the intended exclusivity, our competitors or other third parties could have the freedom to seek regulatory approval of, and to market, products and technologies identical or competitive to ours and we may be required to cease our development and commercialization of certain of our therapeutic candidates and technology. In addition, we may seek to obtain additional licenses from our licensors and, in connection with obtaining such licenses, we may agree to amend our existing licenses in a manner that may be more favorable to the licensors, including by agreeing to terms that could enable third parties, including our competitors, to receive licenses to a portion of the intellectual property that is subject to our existing licenses and to compete with any therapeutic candidates we may develop and our technology. Any of the foregoing could have a material adverse effect on our competitive position, business, financial condition, results of operations and prospects. Disputes may arise regarding intellectual property subject to a licensing agreement, including: • the scope of rights granted and obligations imposed under the license agreement and other interpretation- related issues; • our or our licensors' ability to obtain, maintain and defend intellectual property and to enforce intellectual property rights against third parties; • the extent to which our technology, therapeutic candidates and processes infringe, misappropriate or otherwise violate the intellectual property of the licensor that is not subject to the license agreement; • the sublicensing of patent and other intellectual property rights under our license agreements; • our diligence, development, regulatory, commercialization, financial or other obligations under the license agreement and what activities satisfy those diligence obligations; • the inventorship and ownership of inventions and know- how resulting from the joint creation or use of intellectual property by our current or future licensors and us and our partners; and • the priority of invention of patented technology. In addition, any current or future license agreements to which we are a party, including our license agreement with OSIF, are likely to be, complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology, or increase what we believe to be our diligence, development, regulatory, commercialization, financial or other obligations under the relevant agreement. In addition, if disputes over intellectual property that we have licensed or any other dispute related to our license agreements prevent or impair our ability to maintain our current license agreements on commercially acceptable terms, we may be unable to successfully develop and commercialize the affected therapeutic candidates and technology. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects. License agreements we may enter into in the future may be non- exclusive. Accordingly, third parties may also obtain non- exclusive licenses from such licensors with respect to the intellectual property licensed to us under such license agreements. Accordingly, these license agreements may not provide us with exclusive rights to use such licensed patent and other intellectual property rights, or may not provide us with exclusive rights to use such patent and other intellectual property rights in all relevant fields of use and in all territories in which we may wish to develop or commercialize our technology and any therapeutic candidates we may develop in the future. Moreover, some of our in- licensed patent and other intellectual property rights may in the future be subject to third party interests such as co- ownership. If we are unable to obtain an exclusive license to such third- party co- owners' interest, in such patent and other intellectual property rights, such third- party co- owners may be able to license their rights to other third parties, including our competitors, and our competitors could market competing products and technology. We or our licensors may need the cooperation of any such co- owners of our licensed patent and other intellectual property rights in order to enforce them against third parties, and such cooperation may not be provided to us or our licensors. Additionally, we may not have complete control over the preparation, filing, prosecution, maintenance, enforcement and defense of patents and patent applications that we license from third parties. It is possible that our licensors' filing, prosecution and maintenance of the licensed patents and patent applications, enforcement of patents against infringers or defense of such patents against challenges of validity or claims of enforceability may be less vigorous than if we had conducted them ourselves, and accordingly, we cannot be certain that these patents and patent applications will be prepared, filed, prosecuted, maintained, enforced and defended in a manner consistent with the best interests of our business. If our licensors fail to file, prosecute, maintain, enforce and defend such patents and patent applications, or lose rights to those patents or patent applications, the rights we have licensed may be reduced or eliminated, our right to develop and commercialize any of our technology and any therapeutic candidates we may develop that are the subject of such licensed rights could be adversely affected and we may not be able to prevent competitors or other third parties from making, using and selling competing products. Furthermore, our owned and in- licensed patent rights may be subject to a reservation of rights by one or more third parties, including the U. S. government. Pursuant to the Bayh- Dole Act of 1980, the U. S. government has certain rights in inventions developed with government funding. These U. S. government rights include a non- exclusive, non- transferable, irrevocable worldwide license to use inventions for any governmental purpose. When new technologies are developed with government funding, in order to secure ownership of patent rights related to the technologies, the recipient of such funding is required to comply with certain government regulations, including timely disclosing the inventions claimed in such patent rights to the U. S. government and timely electing title to such inventions. A failure to meet these obligations may lead to a loss of rights or the unenforceability of relevant patents or patent applications. In addition, the U. S. government has the right, under certain limited circumstances, to require us to grant

exclusive, partially exclusive, or non- exclusive licenses to any of these inventions to a third party if it determines that: (1) adequate steps have not been taken to commercialize the invention; (2) government action is necessary to meet public health or safety needs; or (3) government action is necessary to meet requirements for public use under federal regulations (also referred to as "march- in rights"). If the U. S. government exercised its march- in rights in our current or future intellectual property rights that are generated through the use of U. S. government funding or grants, we could be forced to license or sublicense intellectual property developed by us or that we license on terms unfavorable to us, and there can be no assurance that we would receive compensation from the U. S. government for the exercise of such rights. If the U. S. government decides to exercise these rights, it is not required to engage us as its contractor in connection with doing so. The U. S. government' s rights may also permit it to disclose the funded inventions and technology, which may include our confidential information, to third parties and to exercise march- in rights to use or allow third parties to use the technology that was developed using U. S. government funding. Intellectual property generated under a government funded program is also subject to certain reporting requirements, compliance with which may require us to expend substantial resources. In addition, the U. S. government requires that any products embodying any of these inventions or produced through the use of any of these inventions be manufactured substantially in the United States. This preference for U. S. industry may be waived by the federal agency that provided the funding if the owner or assignee of the intellectual property can show that reasonable but unsuccessful efforts have been made to grant licenses on similar terms to potential licensees that would be likely to manufacture substantially in the United States or that under the circumstances domestic manufacture is not commercially feasible. This preference for U. S. industry may limit our ability to contract with non- U. S. product manufacturers for products covered by such intellectual property. Any of the foregoing could harm our business, financial condition, results of operations and prospects significantly. We may not be able to protect our intellectual property rights throughout the world. Filing, prosecuting, maintaining, enforcing and defending patents and other intellectual property rights on our technology and any therapeutic candidates we may develop in all jurisdictions throughout the world would be prohibitively expensive, and accordingly, our intellectual property rights in some jurisdictions outside the United States could be less extensive than those in the United States. In some cases, we or our licensors may not be able to obtain patent or other intellectual property protection for certain technology and therapeutic candidates outside the United States. In addition, the laws of some foreign jurisdictions do not protect intellectual property rights to the same extent as federal and state laws in the United States. Consequently, we and our licensors may not be able to obtain issued patents or other intellectual property rights covering any therapeutic candidates we may develop and our technology in all jurisdictions outside the United States and, as a result, may not be able to prevent third parties from practicing our and our licensors' inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Third parties may use our technologies in jurisdictions where we and our licensors have not pursued and obtained patent or other intellectual property protection to develop their own products and, further, may export otherwise infringing, misappropriating or violating products to territories where we have patent or other intellectual property protection, but enforcement is not as strong as that in the United States. These products may compete with any therapeutic candidates we may develop and our technology and our or our licensors' patents or other intellectual property rights may not be effective or sufficient to prevent them from competing. Additionally, many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain jurisdictions, particularly certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property protection, particularly those relating to biotechnology and pharmaceutical products, which could make it difficult for us to stop the infringement, misappropriation or other violation of our patent and other intellectual property rights or marketing of competing products in violation of our intellectual property rights generally. For example, an April 2019 report from the Office of the United States Trade Representative identified a number of countries, including China, Russia, Argentina, Chile and India, where challenges to the procurement and enforcement of patent rights have been reported. Proceedings to enforce our or our licensors' patent and other intellectual property rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patent and other intellectual property rights 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 or our licensors may not prevail in any lawsuits that we or our licensors initiate and, if we or our licensors prevail, 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. Many jurisdictions have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, many jurisdictions limit the enforceability of patents against government agencies or government contractors. In these jurisdictions, the patent owner may have limited remedies, which could materially diminish the value of such patents. If we or any of our licensors is forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired, and our business, financial condition, results of operations and prospects may be adversely affected. Patent protection must ultimately be sought on a country- by- country basis, which is an expensive and time- consuming process with uncertain outcomes. Accordingly, we may choose not to seek patent protection in certain countries, and we will not have the benefit of patent protection in such countries. Issued patents covering any therapeutic candidates we may develop could be found invalid or unenforceable if challenged in court or before administrative bodies in the United States or abroad. Our owned and licensed patent rights may be subject to priority, validity, inventorship and enforceability disputes. If we or our licensors are unsuccessful in any of these proceedings, such patent rights may be narrowed, invalidated or held unenforceable, we may be required to obtain licenses from third parties, which may not be available on commercially reasonable terms or at all, or we may be required to cease the development, manufacture and commercialization of one or more of our therapeutic candidates. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects. If we or one of our licensors initiate legal

proceedings against a third party to enforce a patent covering any of any therapeutic candidates we may develop or our technology, the defendant could counterclaim that the patent covering the therapeutic candidate or technology is invalid or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, lack of written description or non- enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld information material to patentability from the USPTO, or made a misleading statement, during prosecution. Third parties also may raise similar claims before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include re-examination, interference proceedings, derivation proceedings, post grant review, inter partes review and equivalent proceedings such as opposition, invalidation and revocation proceedings in foreign jurisdictions. Such proceedings could result in the revocation or cancellation of or amendment to our patents in such a way that they no longer cover any therapeutic candidates we may develop or our technology or no longer prevent third parties from competing with any therapeutic candidates we may develop or our technology. The outcome following legal assertions of invalidity and unenforceability is unpredictable. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a distraction to management and other employees. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which the patent examiner and we or our licensing partners were unaware during prosecution. If a third party were to prevail on a legal assertion of invalidity or unenforceability, we could lose at least part, and perhaps all, of the patent protection on one or more of our therapeutic candidates or technology. Such a loss of patent protection could have a material adverse effect on our business, financial condition, results of operations and prospects. Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment, and other requirements imposed by government patent agencies, and our patent protection could be reduced or eliminated for non- compliance with these requirements. Periodic maintenance fees, renewal fees, annuity fees, and various other government fees on patents and applications will be due to be paid to the USPTO and various government patent agencies outside of the United States over the lifetime of our owned or licensed patents and applications. In certain circumstances, we rely on our licensing partners to pay these fees due to U. S. and non- U. S. patent agencies. The USPTO and various non- U. S. government agencies require compliance with several procedural, documentary, fee payment and other similar provisions during the patent application process. We are also dependent on our licensors to take the necessary action to comply with these requirements with respect to our licensed intellectual property. In some cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. There are situations, however, in which non- compliance can result in abandonment or lapse of the patent or patent application, resulting in a partial or complete loss of patent rights in the relevant jurisdiction. In such an event, potential competitors might be able to enter the market with similar or identical products or technology, which could have a material adverse effect on our business, financial condition, results of operations, and prospects. Changes in patent law in the United States or worldwide could diminish the value of patents in general, thereby impairing our ability to protect any therapeutic candidates we may develop and our technology. Changes in either the patent laws or interpretation of patent laws in the United States and worldwide, including patent reform legislation such as the Leahy- Smith America Invents Act (the Leahy-Smith Act), could increase the uncertainties and costs surrounding the prosecution of any owned or in- licensed patent applications and the maintenance, enforcement or defense of any current in- licensed issued patents and issued patents we may own or in- license in the future. The Leahy- Smith Act includes a number of significant changes to U. S. patent law. These changes include provisions that affect the way patent applications are prosecuted, redefine prior art, provide more efficient and cost- effective avenues for competitors to challenge the validity of patents, and enable third- party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent at USPTO- administered post-grant proceedings, including post- grant review, inter partes review, and derivation proceedings. Assuming that other requirements for patentability are met, prior to March 2013, in the United States, the first to invent the claimed invention was entitled to the patent, while outside the United States, the first to file a patent application was entitled to the patent. After March 2013, under the Leahy- Smith Act, the United States transitioned to a first- to- file system in which, assuming that the other statutory requirements for patentability are met, the first inventor to file a patent application will be entitled to the patent on an invention regardless of whether a third party was the first to invent the claimed invention. As such, 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 in- licensed issued patents and issued patents we may own or in- license in the future, all of which could have a material adverse effect on our business, financial condition, results of operations and prospects. Since patent applications in the United States and most other countries are confidential for a period of time after filing or until issuance, we cannot be certain that we or our licensors were the first to either (i) file any patent application related to our therapeutic candidates or (ii) invent any of the inventions claimed in our or our licensor' s patents or patent applications. The Leahy- Smith Act also includes a number of significant changes that affect the way patent applications will be prosecuted and also may affect patent litigation. These include allowing third party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by USPTO administered post- grant proceedings, including post- grant review, inter partes review, and derivation proceedings. Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in United States federal courts 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 unpatentable even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. Accordingly, a third party may attempt to use the USPTO procedures to review patentability of our patent claims that would not have been invalidated if first challenged by the third party as a defendant in a district court action. Therefore, the Leahy- Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our owned or in- licensed patent

applications and the enforcement or defense of our owned or in- licensed issued patents, all of which could have a material adverse effect on our business, financial condition, results of operations, and prospects. In addition, the patent positions of companies in the development and commercialization of biologics and pharmaceuticals are particularly uncertain. Recent U. S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. As one example, in the case Assoc. for Molecular Pathology v. Myriad Genetics, Inc., the U. S. Supreme Court held that certain claims to DNA molecules are not patentable simply because they have been isolated from surrounding material. Moreover, in 2012, the USPTO issued a guidance memo to patent examiners indicating that process claims directed to a law of nature, a natural phenomenon or a naturally occurring relation or correlation that do not include additional elements or steps that integrate the natural principle into the claimed invention such that the natural principle is practically applied and the claim amounts to significantly more than the natural principle itself should be rejected as directed to patent- ineligible subject matter. Accordingly, in view of the guidance memo, there can be no assurance that claims in our patent rights covering any therapeutic candidates we may develop or our technology will be held by the USPTO or equivalent foreign patent offices or by courts in the United States or in foreign jurisdictions to cover patentable subject matter. This combination of events has created uncertainty with respect to the validity and enforceability of patents once obtained. Depending on future actions by the U. S. Congress, the federal courts and the USPTO, the laws and regulations governing patents could change in unpredictable ways that could have a material adverse effect on our patent rights and our ability to protect, defend and enforce our patent rights in the future. If we do not obtain patent term extension and data exclusivity for any therapeutic candidates we may develop, our business may be harmed. Depending upon the timing, duration and specifics of any FDA marketing approval of any therapeutic candidates we may develop and our technology, one or more of our U. S. patents that we license or may own in the future may be eligible for limited patent term extension under Hatch- Waxman Amendments. The Hatch- Waxman Amendments permit a patent extension term of up to five years as compensation for patent term lost during the FDA regulatory review process. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, only one patent may be extended and only those claims covering the approved product, a method for using it or a method for manufacturing it may be extended. The application for the extension must be submitted prior to the expiration of the patent for which extension is sought and within 60 days of FDA approval. A patent that covers multiple products for which approval is sought can only be extended in connection with one of the approvals. However, we may not be granted an extension because of, for example, failing to exercise due diligence during the testing phase or regulatory review process, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents or otherwise failing to satisfy applicable requirements. Moreover, the applicable time period or the scope of patent protection afforded could be less than we request. In addition, to the extent we wish to pursue patent term extension based on a patent that we in- license from a third party, we would need the cooperation of that third party. If we are unable to obtain patent term extension or the term of any such extension is less than we request, our competitors may obtain approval of competing products following our patent expiration, and our revenue could be reduced. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects. We may be subject to claims challenging the inventorship or ownership of our patent and other intellectual property rights. We or our licensors may be subject to claims that former employees, collaborators or other third parties have an interest in our owned or in- licensed patent rights, trade secrets or other intellectual property as an inventor or co-inventor. For example, we or our licensors may have inventorship disputes arise from conflicting obligations of employees, consultants or others who are involved in developing our therapeutic candidates or technology. Litigation may be necessary to defend against these and other claims challenging inventorship or our or our licensors' ownership of our owned or in- licensed patent rights, trade secrets or other intellectual property. If we or our licensors fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of or right to use intellectual property that is important to any therapeutic candidates we may develop or our technology. 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. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects. If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed. In addition to seeking patent protection for our therapeutic programs and other proprietary technologies we may develop, we also rely on trade secrets and confidentiality agreements to protect our unpatented know-how, technology, and other proprietary information and to maintain our competitive position. With respect to our EEV Platform and development programs, we consider trade secrets and know- how to be one of our important sources of intellectual property, including our extensive knowledge of oligonucleotide drug delivery techniques and antibody conjugation. Trade secrets and know- how can be difficult to protect. In particular, the trade secrets and know- how in connection with our EEV Platform, development programs and other proprietary technology we may develop may over time be disseminated within the industry through independent development, the publication of journal articles describing the methodology and the movement of personnel with scientific positions in academic and industry. We seek to protect these trade secrets and other proprietary technology, in part, by entering into non- disclosure and confidentiality agreements with parties who have access to them, such as our employees, corporate collaborators, outside scientific collaborators, CROs, contract manufacturers, consultants, advisors and other third parties. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants. We cannot guarantee that we have entered into such agreements with each party that may have or have had access to our trade secrets or proprietary technology and processes. Despite these efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time- consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets. If any of our trade secrets were to be lawfully obtained or independently

developed by a competitor or other third party, we would have no right to prevent them from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor or other third party, our competitive position would be materially and adversely harmed. We may be subject to claims that third parties have an ownership interest in our trade secrets. For example, we may have disputes arise from conflicting obligations of our employees, consultants or others who are involved in developing our therapeutic candidate. Litigation may be necessary to defend against these and other claims challenging ownership of our trade secrets. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable trade secret rights, such as exclusive ownership of, or right to use, trade secrets that are important to our therapeutic programs and other proprietary technologies we may develop. Such an outcome could have a material adverse effect on our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to our management and other employees. We may not be successful in obtaining necessary rights to any therapeutic candidate we may develop through acquisitions and in- licenses. We currently own or exclusively license intellectual property rights covering certain aspects of our therapeutic programs. Other pharmaceutical companies and academic institutions may also have filed or are planning to file patent applications potentially relevant to our business. In order to avoid infringing these third- party patents, we may find it necessary or prudent to obtain licenses to such patents from such third- party intellectual property holders. However, we may be unable to secure such licenses or otherwise acquire or in- license any compositions, methods of use, processes or other intellectual property rights from third parties that we identify as necessary for our therapeutic programs and other proprietary technologies we may develop. The licensing or acquisition of third- party intellectual property rights is a competitive area, and several more established companies may pursue strategies to license or acquire third party intellectual property rights that we may consider attractive or necessary. These established companies may have a competitive advantage over us due to their size, capital resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to license or acquire third party intellectual property rights on terms that would allow us to make an appropriate return on our investment or at all. If we are unable to successfully obtain rights to required third party intellectual property rights or maintain the existing intellectual property rights we have, we may have to abandon development of the relevant program or therapeutic candidate, which could have a material adverse effect on our business, financial condition, results of operations and prospects. We may be subject to claims that our employees, consultants or advisors have wrongfully used or disclosed alleged trade secrets of their current or former employers or claims asserting ownership of what we regard as our own intellectual property. Some of our employees, consultants and advisors are currently or were previously employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees, consultants and advisors do not use the proprietary information or know- how of others in their work for us, we may be subject to claims that we or these individuals have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such individual' s current or former employer. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to our management. In addition, while it is our policy to require our employees and contractors who may be involved in the conception or development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who, in fact, conceives or develops intellectual property that we regard as our own. The assignment of intellectual property rights may not be self- executing, or the assignment agreements may be breached, and we may be forced to bring claims against third parties, or defend claims that they may bring against us, to determine the ownership of what we regard as our intellectual property. Such claims could have a material adverse effect on our business, financial condition, results of operations and prospects. Third- party claims of intellectual property infringement, misappropriation or other violations against us or our collaborators may prevent or delay the development and commercialization of our therapeutic programs and other proprietary technologies we may develop. Our commercial success depends in part on our ability to avoid infringing, misappropriating and otherwise violating the patents and other intellectual property rights of third parties. There is a substantial amount of complex litigation involving patents and other intellectual property rights in the biotechnology and pharmaceutical industries, as well as administrative proceedings for challenging patents, including interference, derivation and reexamination proceedings before the USPTO or oppositions and other comparable proceedings in foreign jurisdictions. As discussed above, recently, due to changes in U. S. law referred to as patent reform, new procedures including inter partes review and post- grant review have also been implemented. As stated above, this reform adds uncertainty to the possibility of challenge to our patents in the future. Numerous U. S. and foreign issued patents and pending patent applications owned by third parties exist in the fields in which we are commercializing or plan to commercialize our therapeutic programs and in which we are developing other proprietary technologies. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our therapeutic programs and commercializing activities may give rise to claims of infringement of the patent rights of others. We are aware of third party patents that may cover certain aspects of therapeutic candidates that we are developing or may develop. We cannot assure our stockholders that our therapeutic programs and other proprietary technologies we may develop will not infringe existing or future patents owned by third parties. We may not be aware of patents that have already been issued and that a third party, for example, a competitor in the fields in which we are developing our therapeutic programs, might assert as infringed by us. It is also possible that patents owned by third parties of which we are aware, but which we do not believe we infringe or that we believe we have valid defenses to any claims of patent infringement, could be found to be infringed by us. It is not unusual that corresponding patents issued in different countries have different scopes of coverage, such that in one country a third- party patent does not pose a material risk, but in another country, the corresponding third- party patent may pose a material risk to our planned products. As such, we review third- party patents in

the relevant pharmaceutical markets. In addition, because patent applications can take many years to issue, there may be currently pending patent applications that may later result in issued patents that we may infringe. In the event that any third party claims that we infringe their patents or that we are otherwise employing their proprietary technology without authorization and initiates litigation against us, even if we believe such claims are without merit, a court of competent jurisdiction could hold that such patents are valid, enforceable and infringed by us. In this case, the holders of such patents may be able to block our ability to commercialize the infringing products or technologies unless we obtain a license under the applicable patents, or until such patents expire or are finally determined to be held invalid or unenforceable. Such a license may not be available on commercially reasonable terms or at all. Even if we are able to obtain a license, the license would likely obligate us to pay license fees or royalties or both, and the rights granted to us might be nonexclusive, which could result in our competitors gaining access to the same intellectual property. If we are unable to obtain a necessary license to a third- party patent on commercially reasonable terms, we may be unable to commercialize the infringing products or technologies or such commercialization efforts may be significantly delayed, which could in turn significantly harm our business. Defense of infringement claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of management and other employee resources from our business, and may impact our reputation. In the event of a successful claim of infringement against us, we may be enjoined from further developing or commercializing the infringing products or technologies. In addition, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, obtain one or more licenses from third parties, pay royalties and / or redesign our infringing products or technologies, which may be impossible or require substantial time and monetary expenditure. In that event, we would be unable to further develop and commercialize our therapeutic candidate or technologies, which could harm our business significantly. Further, we cannot predict whether any required license would be available at all or whether it would be available on commercially reasonable terms. In the event that we could not obtain a license, we may be unable to further develop our therapeutic candidate and commercialize our product, if approved, which could harm our business significantly. Even if we are able to obtain a license, the license would likely obligate us to pay license fees or royalties or both, and the rights granted to us might be nonexclusive, which could result in our competitors gaining access to the same intellectual property. Ultimately, we could be prevented from commercializing a product, or be forced to cease some aspect of our business operations, if, as a result of actual or threatened patent infringement claims, we are unable to enter into licenses on acceptable terms. Engaging in litigation defending against third parties alleging infringement of patent and other intellectual property rights is very expensive, particularly for a company of our size, and time- consuming. Some of our competitors may be able to sustain the costs of litigation or administrative proceedings more effectively than we can because of greater financial resources. Patent litigation and other proceedings may also absorb significant management time. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could impair our ability to compete in the marketplace. The occurrence of any of the foregoing could have a material adverse effect on our business, financial condition or results of operations. We may in the future pursue invalidity proceedings with respect to third- party patents. The outcome following legal assertions of invalidity is unpredictable. Even if resolved in our favor, these legal proceedings may cause us to incur significant expenses, and could distract our technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. Such proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. We may not have sufficient financial or other resources to conduct such proceedings adequately. Some of these third parties may be able to sustain the costs of such proceedings more effectively than we can because of their greater financial resources. If we do not prevail in the patent proceedings the third parties may assert a claim of patent infringement directed at our therapeutic candidates. We may become involved in lawsuits to protect or enforce our patents and other intellectual property rights, which could be expensive, time- consuming and unsuccessful. Third parties, such as a competitor, may infringe our patent rights. In an infringement proceeding, a court may decide that a patent owned by us is invalid or unenforceable or may refuse to stop the other party from using the invention at issue on the grounds that the patent does not cover the technology in question. In addition, our patent rights may become involved in inventorship, priority or validity disputes. To counter or defend against such claims can be expensive and time- consuming. An adverse result in any litigation proceeding could put our patent rights at risk of being invalidated or interpreted narrowly. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses and could distract our personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments, and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources and more mature and developed intellectual property portfolios. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace. If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected. Our registered or unregistered trademarks or trade names may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. During trademark registration proceedings, we may receive rejections of

our applications by the USPTO or in other foreign jurisdictions. Although we are given an opportunity to respond to those rejections, we may be unable to overcome such rejections. In addition, in the USPTO and in comparable agencies in many foreign jurisdictions, third parties are given an opportunity to oppose pending trademark applications and to seek to cancel registered trademarks. Opposition or cancellation proceedings may be filed against our trademarks, which may not survive such proceedings. Moreover, any name we have proposed to use with our therapeutic candidate in the United States must be approved by the FDA, regardless of whether we have registered it, or applied to register it, as a trademark. Similar requirements exist in Europe. The FDA typically conducts a review of proposed product names, including an evaluation of potential for confusion with other product names. If the FDA or an equivalent administrative body in a foreign jurisdiction objects to any of our proposed proprietary product names, we may be required to expend significant additional resources in an effort to identify a suitable substitute name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the FDA or equivalent body. Furthermore, in many countries, owning and maintaining a trademark registration may not provide an adequate defense against a subsequent infringement claim asserted by the owner of a senior trademark. We may not be able to protect our rights to these trademarks and trade names, which we need to build name recognition among potential partners or customers in our markets of interest. At times, competitors or other third parties may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement claims brought by owners of other registered trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names. Furthermore, assertions of potential trademark infringement or possible market confusion may lead to coexistence agreements in order to avoid costly disputes related to our trademarks. As a consequence, we may be forced to amend the list of goods and services covered by our trademarks more narrowly than as originally filed and intended, which could adversely affect our ability to establish name recognition. For example, the description of goods and services for our Entrada trademark was amended twice to settle potential disputes with two other biopharmaceutical companies as part of coexistence agreements. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively and our business may be adversely affected. Our efforts to enforce or protect our proprietary rights related to trademarks, trade names, domain name or other intellectual property may be ineffective and could result in substantial costs and diversion of resources and could adversely affect our business, financial condition, results of operations and prospects. Intellectual property rights do not necessarily address all potential threats. The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations and may not adequately protect our business or permit us to maintain our competitive advantage. For example: • others may be able to make products that are similar to our therapeutic candidate or utilize similar technology but that are not covered by the claims of the patents that we license or may own; • we might not have been the first to make the inventions covered by our current or future patent applications; • we might not have been the first to file patent applications covering our inventions; • others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights; • it is possible that our current or future patent applications will not lead to issued patents; • any patent issuing from our current or future patent applications may be held invalid or unenforceable, including as a result of legal challenges by our competitors or other third parties; • our competitors or other third parties might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets; • we have engaged in scientific collaborations in the past and will continue to do so in the future and our collaborators may develop adjacent or competing products that are outside the scope of our patents; • we may not develop additional proprietary technologies that are patentable; • the patents of others may harm our business; and • we may choose not to file for patent protection in order to maintain certain trade secrets or know- how, and a third party may subsequently file a patent application covering such intellectual property. The occurrence of any of these events would have a material adverse effect on our business, financial condition, results of operations and prospects. We partially depend on intellectual property licensed from third parties, and our licensors may not always act in our best interest. If we fail to comply with our obligations under our intellectual property licenses, if the licenses are terminated or if disputes regarding these licenses arise, we could lose significant rights that are important to our business. We are dependent, in part, on patents, know-how and proprietary technology licensed from others. Our licenses to such patents, know- how and proprietary technology may not provide exclusive rights in all relevant fields of use and in all territories in which we may wish to develop or commercialize our therapeutics in the future. The agreements under which we license patents, know- how and proprietary technology from others are complex, and certain provisions in such agreements may be susceptible to multiple interpretations. If we fail to comply with obligations under any license agreements, our licensors may have the right to terminate our license, in which event we would not be able to develop or market technology or therapeutic candidates covered by the intellectual property licensed under these agreements. In addition, we may need to obtain additional licenses from our existing licensors and others to advance our research or allow commercialization of therapeutic candidates we may develop. It is possible that we may be unable to obtain any additional licenses at a reasonable cost or on reasonable terms, if at all. In either event, we may be required to expend significant time and resources to redesign our technology, therapeutic candidates, or the methods for manufacturing them or to develop or license replacement technology, all of which may not be feasible on a technical or commercial basis. If we are unable to do so, we may be unable to develop or commercialize the affected technology or therapeutic candidates. If we or our licensors fail to adequately protect our licensed intellectual property, our ability to commercialize therapeutic candidates could suffer. We do not have complete control over the maintenance, prosecution and litigation of our in- licensed patents and patent applications and may have limited control over future intellectual property that may be in- licensed. For example, we cannot be certain that activities such as the maintenance and prosecution by our licensors have been or will be conducted in compliance with applicable laws and regulations or will result in valid and enforceable patents and other intellectual property rights. It is possible

that our licensors' infringement proceedings or defense activities may be less vigorous than had we conducted them ourselves, or may not be conducted in accordance with our best interests. In addition, the resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant patents, know- how and proprietary technology, or increase what we believe to be our financial or other obligations under the relevant agreement. Disputes that may arise between us and our licensors regarding intellectual property subject to a license agreement could include disputes regarding: • the scope of rights granted under the license agreement and other interpretation- related issues; • whether and the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement; • our right to sublicense patent and other rights to third parties under collaborative development relationships; • our diligence obligations with respect to the use of the licensed technology in relation to our development and commercialization of our therapeutic candidates and what activities satisfy those diligence obligations; and • the ownership of inventions and know- how resulting from the joint creation or use of intellectual property by our licensors and us. If disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on acceptable terms, we may be unable to successfully develop and commercialize the affected technology or therapeutic candidates. As a result, any termination of or disputes over our intellectual property licenses could result in the loss of our ability to develop and commercialize our EEV Platform, or EEV products, or we could lose other significant rights, any of which could have a material adverse effect on our business, financial condition, results of operations and prospects. For example, our agreements with certain of our third- party research partners provide that improvements developed in the course of our relationship may be owned solely by either us or our third- party research partner, or jointly between us and the third party. If we determine that rights to such improvements owned solely by a research partner or other third party with whom we collaborate are necessary to commercialize our therapeutic candidates or maintain our competitive advantage, we may need to obtain a license from such third party in order to use the improvements and continue developing, manufacturing or marketing our therapeutic candidates. We may not be able to obtain such a license on an exclusive basis, on commercially reasonable terms, or at all, which could prevent us from commercializing our therapeutic candidates or allow our competitors or others the chance to access technology that is important to our business. We also may need the cooperation of any co- owners of our intellectual property in order to enforce such intellectual property against third parties, and such cooperation may not be provided to us. We may not be successful in obtaining or maintaining necessary rights to product components and processes for our development portfolio through acquisitions and in- licenses. The growth of our business may depend in part on our ability to acquire, in- license or use third- party proprietary rights. For example, our therapeutic candidates may require specific formulations to work effectively and efficiently, we may develop therapeutic candidates containing our compounds and pre- existing pharmaceutical compounds, or we may be required by the FDA or comparable foreign regulatory authorities to provide a companion diagnostic test or tests with our therapeutic candidates, any of which could require us to obtain rights to use intellectual property held by third parties. In addition, with respect to any patents we may co- own with third parties, we may require licenses to such co- owners interest to such patents. 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 or important to our business operations. In addition, we may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. Were that to happen, we may need to cease use of the compositions or methods covered by those third- party intellectual property rights, and may need to seek to develop alternative approaches that do not infringe on those intellectual property rights, which may entail additional costs and development delays, even if we were able to develop such alternatives, which may not be feasible. Even if we are able to obtain a license, it may be non- exclusive, which means that our competitors may also receive access to the same technologies licensed to us. In that event, we may be required to expend significant time and resources to develop or license replacement technology. Additionally, we sometimes collaborate with academic institutions to accelerate our preclinical research or development under written agreements with these institutions. In certain cases, these institutions provide us with an option to negotiate a license to any of the institution' s rights in technology resulting from the collaboration. Even if we hold such an option, we may be unable to negotiate a license from the institution within the specified timeframe or under terms that are acceptable to us. If we are unable to do so, the institution may offer the intellectual property rights to others, potentially blocking our ability to pursue our program. The licensing and acquisition of third- party intellectual property rights is a competitive area, and companies that may be more established or have greater resources than we do may also be pursuing strategies to license or acquire third- party intellectual property rights that we may consider necessary or attractive in order to commercialize our therapeutic candidates. More 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 rights to us. There can be no assurance that we will be able to successfully complete these types of negotiations and ultimately acquire the rights to the intellectual property surrounding the additional therapeutic candidates that we may seek to develop or market. If we are unable to successfully obtain rights to required third- party intellectual property or to maintain the existing intellectual property rights we have, we may have to abandon development of certain programs and our business financial condition, results of operations and prospects could suffer. We, our collaborators and our service providers may be subject to a variety of privacy and data security laws and contractual obligations, which could increase compliance costs and our failure to comply with them could subject us to potentially significant fines or penalties and otherwise harm our business. We maintain a large quantity of sensitive information, including confidential business and patient health information in connection with our preclinical studies, and are subject to laws and regulations governing the privacy and security of such information. The global data protection landscape is rapidly evolving, and we may be affected by or subject to new, amended or existing laws and regulations in the future, including as our operations continue to expand or if we operate in foreign jurisdictions. These laws and regulations may be subject to differing interpretations, which adds to the complexity of processing personal data. Guidance on implementation and compliance practices are often updated or otherwise revised. In the

United States, there are numerous federal and state privacy and data security laws and regulations governing the collection, use, disclosure and protection of personal information, including federal and state health information privacy laws, federal and state ~~security~~ **cybersecurity** ~~breach~~ **incident** notification laws and federal and state consumer protection laws. Each of these laws is subject to varying interpretations and constantly evolving. By way of example, HIPAA imposes privacy and security requirements and breach reporting obligations with respect to individually identifiable health information upon " covered entities " (health plans, health care clearinghouses and certain health care providers), and their respective business associates, individuals or entities that create, received, maintain or transmit protected health information in connection with providing a service for or on behalf of a covered entity. HIPAA mandates the reporting of certain breaches of health information to the U. S. Department of Health and Human Services (HHS), affected individuals and if the breach is large enough, the media. Entities that are found to be in violation of HIPAA may be subject to significant civil, criminal and administrative fines and penalties and / or additional reporting and oversight obligations. Even when HIPAA does not apply, failing to take appropriate steps to keep consumers' personal information secure may constitute unfair acts or practices in or affecting commerce in violation of Section 5 (a) of the Federal Trade Commission Act (FTCA), 15 U. S. C § 45 (a). The FTC expects a company' s data security measures to be reasonable and appropriate in light of the sensitivity and volume of consumer information it holds, the size and complexity of its business and the cost of available tools to improve security and reduce vulnerabilities. Individually identifiable health information is considered sensitive data that merits stronger safeguards. In addition, certain state laws govern the privacy and security of health information in certain circumstances, some of which are more stringent than HIPAA and many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts. By way of example, the California Consumer Privacy Act (CCPA), which went into effect on January 1, 2020, ~~gives California residents~~ **established a comprehensive privacy framework for covered businesses by creating an** expanded **definition of** ~~rights to access and delete their~~ personal information, **establishing new data privacy rights for consumers in** ~~opt out of certain personal information sharing, and receive detailed information about how their~~ -- **the** ~~personal information is used~~ **State of California, and imposing special rules on the collection of consumer data from minors** . The CCPA **also** ~~provides~~ **provided** for civil penalties for violations **of the act** , as well as a private right of action for data breaches ~~that~~ **, which** is expected to increase **the risk of future** data breach litigation. ~~The CCPA may increase our compliance costs and potential liability. Some observers have noted that the CCPA could mark the beginning of a trend toward more stringent privacy legislation in the United States, which could increase our potential liability and adversely affect our business.~~ Further, a ~~new California~~ ballot initiative, the California Privacy Rights Act (CPRA), was passed by California voters on November 3, 2020 **and as of January 1, 2023 has imposed additional obligations on companies covered by the legislation** . The CPRA **significantly modified the CCPA** ~~which became effective on January 1~~ , ~~2023 creates~~ **including by creating** additional obligations with respect to **the** processing and storing **of** personal information **and by expanding consumers' rights with respect to certain sensitive information** . **The** ~~Additionally, some observers have noted that the~~ CCPA and CPRA ~~could~~ mark the beginning of a trend toward more stringent privacy legislation in the U. S. **While** ~~, which could increase our potential liability and adversely affect our business. Already, in the~~ **these comprehensive consumer** ~~United States, we have witnessed significant developments at the~~ state ~~level. For example, on March 2, 2021, Virginia enacted the Consumer Data Protection Act (CDPA), which became effective on January 1, 2023 and, on July 8, 2021, Colorado' s governor signed the Colorado Privacy~~ **privacy** ~~Act (CPA), into law. This law will become effective on July 1, 2023. Moreover, on March 24, 2022, Utah' s governor signed the Utah Consumer Privacy Act (UCPA), into law. The UCPA will take effect on December 31, 2023. Most recently, on April 28, 2022, the Connecticut state legislature passed " An Act Concerning Personal Data Privacy and Online Monitoring ". Once signed, the Connecticut Act will take effect on July 1, 2023. While the new state~~ laws incorporate many similar concepts **as the CCPA** , there are also several key differences in the scope, application, and enforcement of ~~the~~ **these** ~~law~~ **laws** that will change the operational practices of regulated businesses. ~~The~~ **These** ~~new~~ **comprehensive privacy** laws will, among other things, impact how regulated businesses collect and process personal sensitive data, conduct data protection assessments, transfer personal data to affiliates, and respond to consumer rights requests. A number of other states have **also** proposed new **comprehensive** privacy laws, some of which are similar to the above discussed recently passed laws. Such proposed legislation, if enacted, may add additional complexity, variation in requirements, restrictions and potential legal risk, require additional investment of resources in compliance programs, impact strategies and the availability of previously useful data and could result in increased compliance costs and / or changes in business practices and policies. ~~The existence of~~ **Furthermore, in addition to** comprehensive privacy laws **, certain states have enacted laws which focus on certain specific types of information. For example, the state of Washington recently passed a health privacy law that will regulate the collection and sharing of health information. The Washington law also has a private right of action, which further increases the relevant compliance risk for covered businesses. Connecticut and Nevada have also passed similar laws regulating consumer health data. Further, a small number of states have passed laws that regulate biometric information. The existence of these laws as well as comprehensive privacy laws** in different states in the country ~~would~~ make our compliance obligations more complex and costly and may increase the likelihood that we may be subject to enforcement actions or otherwise incur liability for noncompliance **. State laws are changing rapidly and there is discussion in the U. S. Congress of a new comprehensive federal data privacy law to which we may likely become subject, if enacted** . We will be subject to the data protection laws of the European Union (EU) and United Kingdom (UK) in relation to personal data we collect from these territories. These laws impose additional obligations and risk upon our business, including substantial expenses and changes to business operations that are required to comply with these laws. The withdrawal of the UK from the EU (Brexit) and the subsequent separation of the data protection regimes of these territories means we are required to comply with separate data protection laws in the EU and UK which may lead to additional compliance costs and could increase our overall risk. The collection, use, storage, disclosure, transfer, and other processing of personal data in the EU is governed by the provisions of the General Data Protection Regulation, or the EU

GDPR. ~~Further to Brexit~~ **Following the withdrawal of the UK from the EU** , the EU GDPR ceased to apply in the UK ~~at the end of the transition period on December 31, 2020~~ . As of January 1, 2021, the UK' s European Union (Withdrawal) Act 2018 incorporated the EU GDPR into UK law along with the UK Data Protection Act 2018, referred to as the UK GDPR and together with the EU GDPR, referred to as the GDPR. Failure to comply with the GDPR, and any supplemental European Economic Area, or EEA, country' s national data protection laws which may apply by virtue of the location of the individuals whose personal data we collect, may result in fines and other administrative penalties, including monetary penalties of up to € 20 / £ 17. 5 million or 4 % of worldwide revenue (whichever is higher). The GDPR also confers a private right of action on data subjects and consumer associations to lodge complaints with supervisory authorities, seek judicial remedies, and obtain compensation for damages resulting from violations of the GDPR. The GDPR imposes several requirements relating to processing personal data, including the requirement to provide notice to individuals about personal data processing activities, ~~the~~ **ensure an appropriate** lawful basis **and /** ~~for~~ **or conditions applies to the** processing **of** personal data, having data processing agreements with third parties who process personal data, appointing data protection officers, conducting data protection impact assessments **for high risk processing** , record- keeping, responding to individuals' requests to exercise their rights in respect of their personal data, notification of data breaches to the competent national data protection authority, and the implementation of safeguards to protect the security and confidentiality of personal data. The GDPR also imposes several additional requirements relating to the processing of health and other sensitive data which may require us to obtain consent from the individuals to whom the personal data relates. The GDPR imposes strict rules on the transfer of personal data out of the EEA / UK to countries not regarded by the European Commission and the UK government as providing adequate protection, or third countries, including the United States. These transfers are prohibited unless an appropriate safeguard specified by data protection laws is implemented, such as the Standard Contractual Clauses, or SCCs, approved by the European Commission, or a derogation applies. ~~A~~ **Transfers made pursuant to the SCCs need to be assessed on a case- by- case basis to ensure the law in the recipient country provides " essentially equivalent " protections to safeguard the transferred data. If the standard is not met, businesses will be required to adopt supplementary measures. Further, the EU and United States have adopted its adequacy** decision ~~by the Court of Justice of the European Union, or~~ **for the EU** ~~CJEU, in 2020 Case C- 311 / 18 (~~ **U. S.** Data ~~Protection Commissioner v Facebook Ireland and Maximillian Schrems or Schrems II) invalidated the EU- U. S.~~ Privacy ~~Shield~~ Framework ( **Framework),** which ~~was~~ **entered into force** ~~one-~~ **on July 11, 2023** ~~of the primary mechanisms used by U- S. companies to import~~ **This Framework provides that the protection of** personal data ~~from~~ **transferred between** the ~~EEA~~ **EU and the United States is comparable to that offered** in ~~compliance~~ **the EU. This provides a further avenue to ensuring transfers to the United States are carried out in line** with ~~the~~ GDPR ~~' s cross- border data transfer restrictions) and introduced substantial new requirements to the use of the SCCs, including the requirement to assess the risk of the transfer taking into account the laws in the destination country. As a result of these developments, the European Commission published updated versions of the SCCs, with businesses required to have replaced all previous versions as of December 2022. Finalizing the implementation of the updated SCCs may continue to necessitate significant contractual overhaul of our data transfer arrangements with customers, sub- processors and vendors~~ . The UK is not subject to the European Commission' s ~~new~~ SCCs but the UK Information Commissioner' s Office has published the UK' s own transfer mechanisms for personal data originating from the UK (the International Data Transfer Agreement and International Data Transfer Addendum (each an IDTA)), which ~~are~~ **have been** in force **since** ~~as of~~ March 21, 2022. The IDTA requires the same case- by- case risk assessment of the transfer **. In addition, there has been an extension to the Framework to cover UK transfers to the United States. The Framework could be challenged like its predecessor frameworks** . The international transfer obligations under the EEA and UK data protection regimes will require significant effort and cost, and may result in us needing to make strategic considerations around where EEA / UK personal data is located and which service providers we can utilize for the processing of EEA / UK personal data, particularly as the enforcement around GDPR international transfer compliance obligations is currently unclear. The above transfer requirements and other future developments regarding the flow of data across borders could increase the cost and complexity of delivering our services in some markets and may lead to governmental enforcement actions, litigation, fines, and penalties or adverse publicity, which could adversely affect our business and financial position. Although the UK is regarded as a third country under the EU' s GDPR, the European Commission (EC) has now issued a decision recognizing the UK as providing adequate protection under the EU GDPR and, therefore, transfers of personal data originating in the EU to the UK remain unrestricted. Like the EU GDPR, the UK GDPR restricts personal data transfers outside the UK to countries not regarded by the UK as providing adequate protection. The UK Government has also now introduced a Data Protection and Digital Information Bill, or the UK Bill, into the UK legislative process with the intention for this bill to reform the UK' s data protection regime following Brexit. If passed, the final version of the UK Bill ~~may~~ **will** have the effect of further altering the similarities between the UK and EU data protection regime ~~and threaten the UK Adequacy Decision from the EU Commission~~ . This may lead to additional compliance costs and could increase our overall risk **. All of these evolving compliance and operational requirements impose significant costs, such as costs related to organizational changes, implementing additional protection technologies, training employees and engaging consultants and legal advisors, which are likely to increase over time** . Compliance with these and any other applicable privacy and data security laws and regulations is a rigorous and time- intensive process **. We** ~~, and we~~ may be required to **modify our data processing practices and policies,** put in place additional **compliance** mechanisms ~~ensuring~~ **, and utilize management' s time and / or divert resources from other initiatives and projects to ensure** compliance with ~~the~~ new data protection rules. ~~If we fail~~ **Any failure or perceived failure by us** to comply with any ~~such~~ **applicable federal, state or foreign** laws ~~or~~ **and** regulations **relating to data privacy and security could result in damage to our reputation** , ~~we may face~~ **as well as proceedings or litigation by governmental agencies or other third parties, including class action privacy litigation in certain jurisdictions, which would subject us to** significant fines ~~and~~ **, sanctions, awards, injunctions,** penalties **or judgments. Any of the foregoing could have a material**

**adverse effect on our business, financial condition and results of operations. The use of new and evolving technologies, such as artificial intelligence, in our offerings may result in spending material resources and presents risks and challenges that can impact our business including by posing security and other risks to our confidential information, proprietary information and personal information, and as a result we may be exposed to reputational harm and liability. We continue to build and integrate artificial intelligence into our offerings, and this innovation presents risks and challenges** that could **affect its adoption, and therefore our business. If we enable or offer solutions that draw controversy due to perceived or actual negative societal impact, we may experience brand or reputational harm, competitive harm or legal liability. The use of certain artificial intelligence technology can give rise to intellectual property risks, including compromises to proprietary intellectual property and intellectual property infringement. Additionally, we expect to see increasing government and supranational regulation related to artificial intelligence use and ethics, which may also significantly increase the burden and cost of research, development and compliance in this area. For example, the EU' s Artificial Intelligence Act (AI Act) — the world' s first comprehensive AI law — is anticipated to enter into force in Spring 2024 and, with some exceptions, become effective 24 months thereafter. This legislation imposes significant obligations on providers and deployers of high risk artificial intelligence systems, and encourages providers and deployers of artificial intelligence systems to account for EU ethical principles in their development and use of these systems. If we develop or use AI systems that are governed by the AI Act, it may necessitate ensuring higher standards of data quality, transparency, and human oversight, as well as adhering to specific and potentially burdensome and costly ethical, accountability, and administrative requirements. The rapid evolution of artificial intelligence will require the application of significant resources to design, develop, test and maintain our products and services to help ensure that artificial intelligence is implemented in accordance with applicable law and regulation and in a socially responsible manner and to minimize any real or perceived unintended harmful impacts. Our vendors may in turn incorporate artificial intelligence tools into their own offerings, and the providers of these artificial intelligence tools may not meet existing or rapidly evolving regulatory or industry standards, including with respect to privacy and data security. Further, bad actors around the world use increasingly sophisticated methods, including the use of artificial intelligence, to engage in illegal activities involving the theft and misuse of personal information, confidential information and intellectual property. Any of these effects could damage our reputation, result in the loss of valuable property and information, cause us to breach applicable laws and regulations, and** adversely ~~affect~~ **impact** our business ~~, financial condition and results of operations~~ . Use of open source software could impose limitations on us that may adversely affect our business. Should use of open source software be necessary for commercialization of our therapeutic candidates, such use could impose limitations on our ability to commercialize. As a result, as we seek to use our platform in connection with commercially available products, we may be required to license software under different license terms, which may not be possible on commercially reasonable terms, if at all. If we are unable to license software components on terms that permit its use for commercial purposes, we may be required to replace those software components, which could result in delays, additional cost and additional regulatory approvals. Use and distribution of open source software may entail greater risks than use of third-party commercial software, as open source licensors generally do not provide warranties or other contractual protections regarding infringement claims or the quality of the software code. Some open source licenses contain requirements that we make available source code for modifications or derivative works we create based upon the type of open source software we use. If we combine our proprietary software with open source software in a certain manner, we could, under certain of the open source licenses, be required to release the source code of our proprietary software to the public. This could allow our competitors to create similar products with lower development effort and time, and ultimately could result in a loss of product sales for us. Although we monitor our use of open source software, the terms of many open source licenses have not been interpreted by U. S. courts, and there is a risk that those licenses could be construed in a manner that could impose unanticipated conditions or restrictions on our ability to commercialize our therapeutic candidates. We could be required to seek licenses from third parties in order to continue offering our therapeutic candidates, to re- engineer our therapeutic candidates or to discontinue the sale of our therapeutic candidates in the event re- engineering cannot be accomplished on a timely basis, any of which could materially and adversely affect our business, financial condition, results of operations and prospects. Should any of these events occur, they could have a material adverse effect on our business, financial condition, results of operations, and prospects. Our reliance on third parties requires us to share our trade secrets, which increases the possibility that a competitor or other third party will discover our trade secrets or that our trade secrets will be misappropriated or disclosed. Because we currently rely on certain third parties to manufacture all or part of our drug product and to perform quality testing, and because we collaborate with various organizations and academic institutions for the advancement of our product engine and development portfolio, we must, at times, share our proprietary technology and confidential information, including trade secrets, with them. We seek to protect our proprietary technology, in part, by entering into confidentiality agreements and, if applicable, material transfer agreements, collaborative research agreements, consulting agreements and other similar agreements with our collaborators, advisors, employees, consultants and contractors prior to beginning research or disclosing any proprietary information. These agreements typically limit the rights of the third parties to use or disclose our confidential information, including our trade secrets. Despite the contractual provisions employed when working with third parties, the need to share trade secrets and other confidential information increases the risk that such trade secrets become known by our competitors or other third parties, are inadvertently incorporated into the technology of others or are disclosed or used in violation of these agreements. Despite our efforts to protect our trade secrets, our competitors may discover our trade secrets, either through breach of these agreements, independent development or publication of information including our trade secrets by third parties. Given that our proprietary position is based, in part, on our know- how and trade secrets, a competitor' s or other third party' s discovery of our proprietary technology and confidential information or other unauthorized use or disclosure would impair our competitive position and may

harm our business, financial condition, results of operations and prospects. Rights to improvements to our therapeutic candidates may be held by third parties. In the course of testing our therapeutic candidates, we may enter into agreements with third parties to conduct clinical testing, which may provide that improvements to our therapeutic candidates may be owned solely by a party or jointly between the parties. If we determine that rights to such improvements owned solely by a third party are necessary to commercialize our therapeutic candidates or maintain our competitive advantage, we may need to obtain a license from such third party in order to use the improvements and continue developing, manufacturing or marketing the therapeutic candidates. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain such a license, it could be granted on non- exclusive terms, thereby giving our competitors and other third parties access to the same technologies licensed to us. Failure to obtain a license on commercially reasonable terms or at all, or to obtain an exclusive license, could prevent us from commercializing our therapeutic candidates or force us to cease some of our business operations, which could materially harm our business. If we determine that rights to improvements jointly owned between us and a third party are necessary to commercialize our therapeutic candidates or maintain our competitive advantage, we may need to obtain an exclusive license from such third party. If we are unable to obtain an exclusive license to any such third- party co-owners' interest in such improvements, such co- owners may be able to license their rights to other third parties, including our competitors, and our competitors could market competing products and technology. In addition, we may need the cooperation of any such co- owners of our intellectual property in order to enforce such intellectual property against third parties, and such cooperation may not be provided to us. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects. We may be subject to claims that we have wrongfully hired an employee from a competitor or that we or our employees have wrongfully used or disclosed alleged confidential information or trade secrets of their former employers. As is common in the biotechnology and pharmaceutical industries, in addition to our employees, we engage the services of consultants to assist us in the development of our therapeutic candidate, and other proprietary technologies. Many of these consultants, and many of our employees, were previously employed at, or may have previously provided or may be currently providing consulting services to, other pharmaceutical companies including our competitors or potential competitors. We may become subject to claims that we, our employees or a consultant inadvertently or otherwise used or disclosed trade secrets or other information proprietary to their former employers or their former or current clients. 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 affect our business. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to our management team and other employees. Risks Related to Ownership of Our Common Stock We do not know whether an active, liquid and orderly trading market will develop for our common stock and as a result it may be difficult for our stockholders to sell their shares of our common stock. Prior to our initial public offering, no market for shares of our common stock existed and an active trading market for our shares may never develop or be sustained. The lack of an active market may impair our stockholders' ability to sell their shares at the time they wish to sell them or at a price that they consider reasonable. The lack of an active market may also reduce the fair market value of our stockholders' shares. Furthermore, an inactive market may also impair our ability to raise capital by selling shares of our common stock and may impair our ability to enter into strategic collaborations or acquire companies, technologies or other assets by using our shares of common stock as consideration. Recent volatility in capital markets and lower market prices for many securities may affect our ability to access new capital through sales of shares of our common stock or issuance of indebtedness, which may harm our liquidity, limit our ability to grow our business, pursue acquisitions or improve our operating infrastructure and restrict our ability to compete in our markets. Our operations consume substantial amounts of cash, and we intend to continue to make significant investments to support our business growth, respond to business challenges or opportunities, develop new solutions, retain or expand our current levels of personnel, improve our existing solutions, enhance our operating infrastructure, and potentially acquire complementary businesses and technologies. Our future capital requirements may be significantly different from our current estimates and will depend on many factors, including the need to: • finance unanticipated working capital requirements; • develop or enhance our technological infrastructure and our existing solutions; • pursue acquisitions or other strategic relationships; and • respond to competitive pressures. Accordingly, we may need to pursue equity or debt financings to meet our capital needs. With uncertainty in the capital markets and other factors, such financing may not be available on terms favorable to us or at all. If we raise additional funds through further issuances of equity or convertible debt securities, our existing stockholders could suffer significant dilution, and any new equity securities we issue could have rights, preferences, and privileges superior to those of holders of our common stock. Any debt financing secured by us in the future could involve additional restrictive covenants relating to our capital- raising activities and other financial and operational matters, which may make it more difficult for us to obtain additional capital and to pursue business opportunities, including potential acquisitions. If we are unable to obtain adequate financing or financing on terms satisfactory to us, we could face significant limitations on our ability to invest in our operations and otherwise suffer harm to our business. The market price of our common stock may be volatile, and investors could lose all or part of their investment. The trading price of our common stock is likely to be highly volatile and subject to wide fluctuations in response to various factors, some of which we cannot control. The stock market in general, and pharmaceutical and biotechnology companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance. In addition to the factors discussed in this " Risk Factors " section and elsewhere in this Annual Report, these factors include: • the timing and results of INDs, preclinical studies and clinical trials of our therapeutic candidates or those of our competitors; • the success of competitive products or announcements by potential competitors of their product development efforts; • our decision to initiate a clinical trial, not to initiate a clinical trial or to terminate an existing clinical trial; • any delay in our regulatory filings for our

therapeutic candidates and any adverse development or perceived adverse development with respect to the applicable regulatory authority' s review of such filings; • adverse developments concerning our potential future in- house manufacturing facilities or CMOs; • regulatory actions with respect to our therapeutics or therapeutic candidates or our competitors' products or therapeutic candidates; • actual or anticipated changes in our growth rate relative to our competitors; • the size and growth of our initial target markets; • unanticipated serious safety concerns related to the use of our therapeutic candidates; • regulatory or legal developments in the U. S. and other countries; • developments or disputes concerning patent applications, issued patents or other proprietary rights; • significant lawsuits, including patent or stockholder litigation; • publication of research reports about us or our industry, or positive or negative recommendations or withdrawal of research coverage by securities analysts; • the recruitment or departure of key personnel; • announcements by us or our competitors of significant acquisitions, strategic collaborations, joint ventures, collaborations or capital commitments; • actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts; • fluctuations in the valuation of companies perceived by investors to be comparable to us; • market conditions in the pharmaceutical and biotechnology sector; • changes in the structure of healthcare payment systems; • share price and volume fluctuations attributable to inconsistent trading volume levels of our shares; • our failure to meet the estimates and projections of the investment community or that we may otherwise provide to the public; • announcement or expectation of additional financing efforts; • sales of our common stock by us, our insiders or our other stockholders; • expiration of market stand- off or lock- up agreements; • the impact of any natural disasters or public health emergencies, such as the ~~ongoing~~ COVID- 19 pandemic; • general economic, political, industry and market conditions such as recessions, interest rates, fuel prices, foreign currency fluctuations, international tariffs, social, political and economic risks and acts of war (such as the **ongoing** conflict between ~~Russian~~ **Russia** and Ukraine **and the conflict in the Middle East** ) or terrorism; and • other events or factors, many of which are beyond our control. The realization of any of the above risks or any of a broad range of other risks, including those described in this " Risk factors " section, could have a dramatic and adverse impact on the market price of our common stock. If securities or industry analysts do not publish research or reports, or if they publish adverse or misleading research or reports, regarding us, our business or our market, our stock price and trading volume could decline. The trading market for our common stock will be influenced by the research and reports that securities or industry analysts publish about us, our business or our market. In the event that one or more of the analysts who covers us issues adverse or misleading research or reports regarding us, our business model, our intellectual property, our stock performance or our market, or if our operating results fail to meet the expectations of analysts, our stock price would likely decline. If one or more of these analysts cease coverage of us or fail to publish reports on us regularly, we could lose visibility in the financial markets, which in turn could cause our stock price or trading volume to decline. **Increased attention to, and evolving expectations for, environmental, climate change, social, and governance (ESG) initiatives could increase our costs, harm our reputation, or otherwise adversely impact our business. Companies across industries are facing increasing scrutiny from a variety of stakeholders related to their ESG and sustainability practices. Expectations regarding voluntary ESG initiatives and disclosures may result in increased costs (including but not limited to increased costs related to compliance, stakeholder engagement, contracting and insurance), enhanced compliance or disclosure obligations, or other adverse impacts to our business, financial condition, or results of operations. While we may at times engage in voluntary initiatives (such as voluntary disclosures, certifications, or goals, among others) to improve the ESG profile of the Company, such initiatives may be costly and may not have the desired effect. Moreover, we may not be able to successfully complete such initiatives due to factors that are within or outside of our control. Even if this is not the case, our actions may subsequently be determined to be insufficient by various stakeholders, and we may be subject to investor or regulator engagement on our ESG efforts, even if such initiatives are currently voluntary. Certain market participants, including major institutional investors and capital providers, use third- party benchmarks and scores to assess companies' ESG profiles in making investment or voting decisions. Unfavorable ESG ratings could lead to increased negative investor sentiment towards us, which could negatively impact our share price as well as our access to and cost of capital. To the extent ESG matters negatively impact our reputation, it may also impede our ability to compete as effectively to attract and retain employees, which may adversely impact our operations. In addition, we expect there will likely be increasing levels of regulation, disclosure- related and otherwise, with respect to ESG matters. For example, the SEC has published propose rules that would require companies to provide significantly expanded climate- related disclosures in their periodic reporting, which may require us to incur significant additional costs to comply, including the implementation of significant additional internal controls processes and procedures regarding matters that have not been subject to such controls in the past, and impose increased oversight obligations on our management and board of directors. These and other changes in stakeholder expectations will likely lead to increased costs as well as scrutiny that could heighten all of the risks identified in this risk factor. Additionally, our business partners may be subject to similar expectations, which may augment or create additional risks, including risks that may not be known to us.** Unstable market and economic conditions may have serious adverse consequences on our business, financial condition and stock price. As widely reported, global credit and financial markets have experienced extreme volatility and disruptions in the past several years, ~~most recently due to the evolving ongoing COVID- 19 pandemic,~~ including severely diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, increases in unemployment rates and uncertainty about economic stability **. For example, inflation generally affects us by increasing our employee- related costs and clinical trial expenses, as well as other operating expenses** . There can be no assurance that further deterioration in credit and financial markets and confidence in economic conditions ~~, whether due to the evolving effects of the COVID- 19 pandemic or otherwise,~~ will not occur. Our general business strategy may be adversely affected by any such economic downturn, volatile business environment or continued unpredictable and unstable market conditions. **Further, changing circumstances, some of which may be beyond our control, could cause us to consume capital significantly faster than we currently anticipate, and we may need to seek**

**additional funds sooner than planned. Our business could also be impacted by volatility caused by geopolitical events, such as the ongoing conflicts in Ukraine and the Middle East.** If the current equity and credit markets deteriorate, or do not improve, it may make any necessary debt or equity financing more difficult, more costly, and more dilutive. Failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse event on our growth strategy, financial performance and stock price and could require us to delay or abandon clinical development plans. In addition, there is a risk that one or more of our current service providers, manufacturers and other partners may not survive these difficult economic times, which could directly affect our ability to attain our operating goals on schedule and on budget **. To the extent that our profitability and strategies are negatively affected by downturns or volatility in general economic conditions, our business and results of operations may be materially adversely affected** . Our stock price may decline due in part to the volatility of the stock market and the general economic downturn. Our business is affected by macroeconomic conditions, including rising inflation, interest rates and supply chain constraints. Various macroeconomic factors could adversely affect our business and the results of our operations and financial condition, including changes in inflation, interest rates and overall economic conditions and uncertainties such as those resulting from the current and future conditions in the global financial markets. Recent supply chain constraints have led to higher inflation, which if sustained could have a negative impact on **our** ~~the Company' s~~ product development and operations. If inflation or other factors were to significantly increase our business costs, our ability to develop our current pipeline and new therapeutic products may be negatively affected. Interest rates, the liquidity of the credit markets and the volatility of the capital markets could also affect the operation of our business and our ability to raise capital on favorable terms, or at all, in order to fund our operations. Similarly, these macroeconomic factors could affect the ability of our third- party suppliers and manufacturers to manufacture clinical trial materials for our product candidates. Our principal stockholders and management own a significant percentage of our stock and will be able to exert significant control over matters subject to stockholder approval. Our executive officers, directors, holders of 5 % or more of our capital stock and their respective affiliates beneficially owned approximately ~~80~~ **71** . ~~7~~ **0** % of our outstanding voting stock as of December 31, ~~2022~~ **2023** . These stockholders, acting together, may be able to impact matters requiring stockholder approval. For example, they may be able to impact elections of directors, amendments of our organizational documents or approval of any merger, sale of assets or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that investors may feel are in their best interest as one of our stockholders. The interests of this group of stockholders may not always coincide with each investor' s interests or the interests of other stockholders and they may act in a manner that advances their best interests and not necessarily those of other stockholders, including seeking a premium value for their common stock, and might affect the prevailing market price for our common stock. Future sales and issuances of our common stock or rights to purchase common stock, including pursuant to our 2021 Plan, could result in additional dilution of the percentage ownership of our stockholders and could cause our stock price to fall. We expect that significant additional capital may be needed in the future to continue our planned operations, including conducting clinical trials, commercialization efforts, expanded research and development activities and costs associated with operating a public company. 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. If we sell common stock, convertible securities or other equity securities, investors may be materially diluted by subsequent sales. Such sales may also result in material dilution to our existing stockholders, and new investors could gain rights, preferences and privileges senior to the holders of our common stock. Pursuant to our 2021 **Stock Option and Incentive** Plan **(2021 Plan)** , our management is authorized to grant stock options to our employees, directors and consultants. If the number of shares reserved under our 2021 Plan is increased pursuant to the terms of the 2021 Plan, our stockholders may experience additional dilution, which could cause our stock price to fall. Any of the above events could significantly harm our business, prospects, financial condition and results of operations and cause the price of our common stock to decline. Raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish rights to our technologies or therapeutic candidates. We do not have any committed external source of funds or other support for our development and commercialization efforts, and we cannot be certain that additional funding will be available on acceptable terms, or at all. Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through equity offerings, debt financings, or other capital sources, including potential collaborations, licenses and other similar arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, our stockholders' ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect our stockholders' rights. Any future 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, selling or licensing our assets, making capital expenditures, declaring dividends or encumbering our assets to secure future indebtedness. Such restrictions could adversely impact our ability to conduct our operations and execute our business plan. As a result of our recurring losses from operations and recurring negative cash flows from operations, there is uncertainty regarding our ability to maintain liquidity sufficient to operate our business effectively. If we raise additional funds through future collaborations, licenses and other similar arrangements, we may have to relinquish valuable rights to our future revenue streams, research programs, therapeutic candidates or EEV Platform, or grant licenses on terms that may not be favorable to us and / or that may reduce the value of our common stock. If we are unable to raise additional funds through equity or debt financings or other arrangements when needed or on terms acceptable to us, we would be required to delay, limit, reduce, or terminate our product development or future commercialization efforts or grant rights to develop and market therapeutic candidates that we would otherwise prefer to develop and market ourselves. Any of the above events could significantly harm our business, prospects, financial condition and results of operations and cause the price of our common stock to decline. We are an " emerging growth company " and a smaller reporting company, and we cannot be certain if the reduced reporting requirements applicable to emerging growth companies and smaller reporting companies will make our common stock less attractive to

investors. We are an " emerging growth company, " as defined in the Jumpstart Our Business Startups Act of 2012 (JOBS Act). For as long as we continue to be an emerging growth company, we intend to take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including: • being permitted to provide only two years of audited financial statements, in addition to any required unaudited interim financial statements, with correspondingly reduced " Management' s Discussion and Analysis of Financial Condition and Results of Operations " disclosure in our periodic reports; • not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes- Oxley Act of 2002, as amended (Sarbanes- Oxley Act); • not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor' s report providing additional information about the audit and the financial statements; • reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements; and • exemptions from the requirements of holding nonbinding advisory stockholder votes on executive compensation and stockholder approval of any golden parachute payments not previously approved. Under the JOBS Act, emerging growth companies can also delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have elected to avail ourselves of this exemption from new or revised accounting standards and, therefore, will not be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies. As a result, our financial statements may not be comparable to companies that comply with the new or revised accounting pronouncements as of public company effective dates. We will remain an emerging growth company until the earliest to occur of: (i) the last day of the fiscal year in which we have more than $ 1. 235 billion in annual revenue; (ii) the date we qualify as a " large accelerated filer, " with at least $ 700. 0 million of equity securities held by non- affiliates; (iii) the date on which we have issued more than $ 1. 0 billion in non- convertible debt securities during the prior three- year period; and (iv) the last day of the fiscal year ending after the fifth anniversary of our initial public offering. Even after we no longer qualify as an emerging growth company, we may still qualify as a " smaller reporting company, " which would allow us to continue to take advantage of many of the same exemptions from disclosure requirements, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes- Oxley Act and reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements. We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile. We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. We do not intend to pay dividends on our common stock so any returns will be limited to the value of our stock. We have never declared or paid any cash dividends on our common stock. We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. Any return to stockholders will therefore be limited to any appreciation in the value of their stock. Anti- takeover provisions in our certificate of incorporation, our bylaws and Delaware law might discourage, delay or prevent a change in control of our company or changes in our management and, therefore, depress the market price of our common stock. Our fourth amended and restated certificate of incorporation and amended and restated bylaws contain provisions that could depress the market price of our common stock by acting to discourage, delay or prevent a change in control of our company or changes in our management that the stockholders of our company may deem advantageous. These provisions include, among other things: • a board of directors divided into three classes serving staggered three- year terms, such that not all members of the board will be elected at one time; • a prohibition on stockholder actions through written consent, which requires that all stockholder actions be taken at a meeting of our stockholders; • a requirement that special meetings of stockholders be called only by the board of directors acting pursuant to a resolution approved by the affirmative vote of a majority of the directors then in office; • advance notice requirements for stockholder proposals and nominations for election to our board of directors; • a requirement that no member of our board of directors may be removed from office by our stockholders except for cause and, in addition to any other vote required by law, upon the approval of not less than two- thirds of all outstanding shares of our voting stock then entitled to vote in the election of directors; • a requirement of approval of not less than two- thirds of all outstanding shares of our voting stock to amend any bylaws by stockholder action; • a requirement of approval by the affirmative vote of a majority of the outstanding shares of our voting stock to amend or repeal specified provisions of our certificate of incorporation, and the affirmative vote of a majority of the outstanding shares of each class entitled to vote thereon as a class, at a duly constituted meeting of stockholders called expressly for such purpose; and • the authority of the board of directors to issue preferred stock on terms determined by the board of directors without stockholder approval and which preferred stock may include rights superior to the rights of the holders of common stock. In addition, Section 203 of the General Corporation Law of the State of Delaware (DGCL) prohibits a publicly- held Delaware corporation from engaging in a business combination with an interested stockholder, generally a person which together with its affiliates owns, or within the last three years has owned, 15 % of our voting stock, for a period of three years after the date of the transaction in which the person became an interested stockholder, unless the business combination is approved in a prescribed manner. Any provision of our fourth amended and restated certificate of incorporation, amended and restated bylaws or Delaware law that has the effect of delaying or preventing a change in control could limit the opportunity for our stockholders to receive a premium for their shares of our capital stock and could also affect the price that some investors are willing to pay for our common stock. Our bylaws designate certain courts as the sole and exclusive forum for certain types of actions and proceedings that may be initiated by our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers, or employees. Our amended and restated 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 state law claims for (i) any derivative action or proceeding brought on our behalf, (ii) any action asserting a claim of breach of, or a claim based on, fiduciary duty owed by any of our current or former directors, officers, and employees to us or our

stockholders, (iii) any action asserting a claim arising pursuant to any provision of the Delaware General Corporation Law, our certificate of incorporation or our bylaws or (iv) any action asserting a claim that is governed by the internal affairs doctrine, in each case subject to the Court of Chancery having personal jurisdiction over the indispensable parties named as defendants therein (Delaware Forum Provision). The Delaware Forum Provision will not apply to any causes of action arising under the Securities Act or the Exchange Act. Our amended and restated bylaws further provide that, unless we consent in writing to the selection of an alternative forum, the federal district courts of the U. S. shall be the sole and exclusive forum for resolving any complaint asserting a cause or causes of action arising under the Securities Act (Federal Forum Provision). In addition, our amended and restated bylaws provide that any person or entity purchasing or otherwise acquiring any interest in shares of our common stock is deemed to have notice of and consented to the foregoing provisions; provided, however, that stockholders cannot and will not be deemed to have waived our compliance with the federal securities laws and the rules and regulations thereunder. The Delaware Forum Provision and the Federal Forum Provision in our amended and restated bylaws may impose additional litigation costs on stockholders in pursuing any such claims. Additionally, the forum selection clauses in our amended and restated bylaws may limit our stockholders' ability to bring a claim in a forum that they find favorable for disputes with us or our directors, officers or employees, which may discourage such lawsuits against us and our directors, officers and employees even though an action, if successful, might benefit our stockholders. In addition, while the Delaware Supreme Court ruled in March 2020 that federal forum selection provisions purporting to require claims under the Securities Act be brought in federal court were " facially valid " under Delaware law, there is uncertainty as to whether other courts will enforce our Federal Forum Provision. If the Federal Forum Provision is found to be unenforceable, we may incur additional costs associated with resolving such matters. The Federal Forum Provision may also impose additional litigation costs on stockholders who assert that the provision is not enforceable or invalid. The Court of Chancery of the State of Delaware and the federal district courts of the U. S. may also reach different judgments or results than would other courts, including courts where a stockholder considering an action may be located or would otherwise choose to bring the action, and such judgments may be more or less favorable to us than our stockholders. ~~Our failure to meet Nasdaq' s continued listing requirements could result in a delisting of our common stock. If we fail to satisfy Nasdaq' s continued listing requirements, such as the corporate governance requirements or the minimum closing bid price requirement, Nasdaq may take steps to delist our common stock. Such a delisting would likely have a negative effect on the price of our common stock and would impair our stockholders' ability to sell or purchase our common stock when our stockholders wish to do so. In the event of a delisting, we can provide no assurance that any action taken by us to restore compliance with listing requirements would allow our common stock to become listed again, stabilize the market price or improve the liquidity of our common stock, prevent our common stock from dropping below the Nasdaq minimum bid price requirement or prevent future non- compliance with Nasdaq' s listing requirements.~~ General Risk Factors We **have incurred and** will **continue to** incur increased costs as a result of operating as a public company, and our management ~~will~~ **is required to** devote substantial time to related compliance initiatives. As a public company, we ~~will~~ incur significant legal, accounting and other expenses that we did not incur as a private company, and these expenses may increase even more after we are no longer an " emerging growth company. " We are subject to the reporting requirements of the Securities Exchange Act of 1934, as amended (Exchange Act), the Sarbanes- Oxley Act, the Dodd- Frank Wall Street Reform and Protection Act, as well as rules adopted, and to be adopted, by the SEC and Nasdaq. Our management and other personnel **devote and** will need **to continue** to devote a substantial amount of time to these compliance initiatives. Moreover, we expect these rules and regulations to substantially increase our legal and financial compliance costs and to make some activities more time- consuming and costly, which will increase our operating expenses. For example, we expect these rules and regulations to make it more difficult and more expensive for us to obtain director and officer liability insurance and we may be required to incur substantial costs to maintain sufficient coverage, particularly in light of recent cost increases related to coverage. We cannot accurately predict or estimate the amount or timing of additional costs we may incur to respond to these requirements. The impact of these requirements could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, our board committees or as executive officers. In addition, as a public company we **are** ~~will be~~ required to incur additional costs and obligations in order to comply with SEC rules that implement Section 404 of the Sarbanes- Oxley Act. Under these rules, beginning with our second annual report on Form 10- K after we become a public company, we **are** ~~will be~~ required to make a formal assessment of the effectiveness of our internal control over financial reporting, and once we cease to be an emerging growth company, we may be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. To achieve compliance with Section 404 ~~within the prescribed period~~, we **are engaged** ~~will be engaging~~ in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to continue to dedicate internal resources, potentially engage outside consultants and adopt a detailed work plan to assess and document the adequacy of our internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are designed and operating effectively, and implement a continuous reporting and improvement process for internal control over financial reporting. If we experience material weaknesses in the future or otherwise fail to maintain an effective system of internal controls in the future, we may not be able to accurately or timely report our financial condition or results of operations, which may adversely affect investor confidence in us and, as a result, the value of our common stock. We may in the future discover material 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 in a timely manner, or if

we are unable to maintain proper and effective internal controls over financial reporting, we may not be able to produce timely and accurate financial statements. If that were to happen, our investors could lose confidence in our reported financial information, the market price of our stock could decline, and we could be subject to sanctions or investigations by the stock exchange on which our common stock is listed, the SEC or other regulatory authorities. Our disclosure controls and procedures may not prevent or detect all errors or acts of fraud. We are subject to the periodic reporting requirements of the Exchange Act. We designed our disclosure controls and procedures to reasonably assure that information we must disclose in reports we file or submit under the Exchange Act is accumulated and communicated to management, and recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC. We believe that any disclosure controls and procedures or internal controls and procedures, no matter how well- conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. These inherent limitations include the facts that judgments in decision- making can be faulty and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements due to error or fraud may occur and not be detected. We may be subject to securities litigation, which is expensive and could divert management attention. The market price of our common stock may be volatile and, in the past, companies that have experienced volatility in the market price of their stock have been subject to securities class action litigation. We may be the target of this type of litigation in the future. Securities litigation against us could result in substantial costs and divert our management' s attention from other business concerns, which could seriously harm our business. Our insurance policies are expensive and only protect us from some business risks, which will leave us exposed to significant uninsured liabilities. We do not carry insurance for all categories of risk that our business may encounter. Some of the policies we currently maintain include property, general liability, employment benefits liability, business automobile, workers' compensation, and directors' and officers', employment practices and fiduciary liability insurance. We do not know, however, if we will be able to maintain insurance with adequate levels of coverage. Any significant uninsured liability may require us to pay substantial amounts, which would adversely affect our financial position and results of operations. Disruptions at the FDA and other government agencies caused by funding shortages or global health concerns could hinder their ability to hire, retain or deploy key leadership and other personnel, or otherwise prevent new or modified products from being developed, approved or commercialized in a timely manner or at all, which could negatively impact our business. The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, statutory, regulatory and policy changes, the FDA' s ability to hire and retain key personnel and accept the payment of user fees, and other events that may otherwise affect the FDA' s ability to perform routine functions. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable. Disruptions at the FDA and other agencies may also slow the time necessary for new drugs and biologics or modifications to approved drugs and biologics to be reviewed and / or approved by necessary government agencies, which would adversely affect our business. Since March 2020 when foreign and domestic inspections of facilities were largely placed on hold, the FDA has been working to resume pre- pandemic levels of inspection activities, including routine surveillance, bioresearch monitoring and pre- approval inspections. Should the FDA determine that an inspection is necessary for approval and an inspection cannot be completed during the review cycle due to restrictions on travel, and the FDA does not determine a remote interactive evaluation to be adequate, the agency has stated that it generally intends to issue, depending on the circumstances, a complete response letter or defer action on the application until an inspection can be completed. During the COVID- 19 pandemic, a number of companies announced receipt of complete response letters due to the FDA' s inability to complete required inspections for their applications. Regulatory authorities outside the United States may adopt similar restrictions or other policy measures in response to ~~the ongoing~~ **a worldwide pandemic, such as** COVID- 19 ~~pandemic~~ **,** and may experience delays in their regulatory activities. If a prolonged government shutdown occurs, or if global health concerns continue to prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, including formal and informal interactions with product developers, it could significantly impact the ability of the FDA or other regulatory authorities to timely review and process our future regulatory submissions, which could have a material adverse effect on our business.