Risk Factors Comparison 2025-02-19 to 2024-02-26 Form: 10-K

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Our business involves significant risks, some of which are described below. You should carefully consider the risks and uncertainties described below, together with all of the other information contained in this Annual Report on Form 10- K, including " Management' s Discussion and Analysis of Financial Condition and Results of Operations " and the consolidated financial statements and the related notes **included in this Annual Report on Form 10- K** . If any of the following risks actually occur, it could harm our business, prospects, operating results ~~and~~ **,** financial condition **,** and future prospects. In such event, the market price of our common stock could decline, and you could lose all or part of your investment. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also impair our business operations. This Annual Report on Form 10- K 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 factors that are described below and elsewhere in this Annual Report on Form 10- K. Risks Related to Our Business and Industry We are substantially dependent on the commercial success of VYJUVEK To date, we have invested substantial efforts and financial resources in the research and development of **VYJUVEK and** our product candidates. Our near- term prospects, including our ability to develop our product candidates and generate revenue, and our future growth is substantially dependent on the commercial success of VYJUVEK. Although we received approval from the FDA for VYJUVEK for the treatment of DEB ~~on May 19, 2023~~ , we can provide no assurances that we will obtain regulatory approval in any other jurisdiction, which would have an adverse impact on our results of operations. In addition, the successful commercialization of VYJUVEK will depend on a number of factors **and involves risk** , including **some of** the risks identified in these " Risk Factors **.** " ~~.~~ One or more of these factors, many of which are beyond our control, could cause significant delays or an inability to successfully commercialize VYJUVEK. We may not be successful in our efforts to identify, develop and commercialize additional product candidates, which may impair our ability to expand our business and achieve our strategic objectives, and we may fail to capitalize on programs or product candidates that may be a greater commercial opportunity or for which there is a greater likelihood of success. Although a substantial amount of our efforts ~~focuses~~ -- **focus** on the commercialization of VYJUVEK and the development and potential approval of our current product candidates, a key component **of** our strategy is to identify, develop and potentially commercialize a portfolio of genetic medicines. Research programs to identify new product candidates require substantial technical, financial, and human resources and may not be successful in identifying potential product candidates. Even if we identify product candidates that initially show promise, we may fail to successfully develop and commercialize such product candidates for many reasons, including the following: • competitors may develop alternatives that render our product candidates obsolete; • product candidates we develop may be covered by third parties' patents or other exclusive rights; • a product candidate may, on further study, be shown to have harmful side effects or other characteristics that indicate it is unlikely to be effective or otherwise does not meet applicable regulatory criteria; • a product candidate may not be capable of being produced in commercial quantities at an acceptable cost, or at all; and • a product candidate may not be accepted as safe and effective by patients, the medical community, or third- party payors. If we are unsuccessful in identifying and developing additional product candidates, our potential for growth may be impaired. Additionally, because we have limited resources, we may forego or delay pursuit of opportunities with certain programs or product candidates or for indications that later prove to have commercial potential. Our resource allocation decisions may cause us to fail to timely capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs may not yield any commercially viable products. If we do not accurately evaluate the commercial potential for a particular product candidate, we may relinquish valuable rights to that product candidate through strategic collaboration, licensing, or other arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate. Alternatively, we may allocate internal resources to a product candidate in a therapeutic area in which it would have been more advantageous to enter into a partnering arrangement. If any of these events occur, we may be forced to abandon our development efforts with respect to a particular product candidate or fail to develop a potentially successful product candidate, which could have a material adverse effect on our business, financial condition, results of operations, and prospects. VYJUVEK and, if approved, our investigational product candidates regulated as biologics may face competition from biosimilars approved through an abbreviated regulatory pathway. The ~~Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively, the~~ ACA ~~,~~ includes a subtitle called the Biologics Price Competition and Innovation Act of 2009 ~~, or~~ **(“** BPCIA **”)** , which created an abbreviated approval pathway for biological products that are biosimilar to or interchangeable with an FDA- licensed reference biological product. Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date that the reference product was first licensed by the FDA. In addition, the approval of a biosimilar product may not be made effective by the FDA until 12 years from the date on which the reference product was first licensed. During this 12- year period of exclusivity, another company may still market a competing ~~version of the reference~~ product if the FDA approves a Biologics License Application, or BLA, for the competing product containing ~~the sponsor~~ **that company** ' s own preclinical data and data from adequate and well- controlled clinical trials to demonstrate the safety, purity, and potency of **that** ~~the other~~ company' s product. In addition, a competitor may choose to challenge our patent rights relating to the reference product by initiating litigation during the 12- year period of exclusivity. After the FDA approves the BLA for the competing product, the competitor may also bring a declaratory judgment action of non- infringement, invalidity, and / or unenforceability of our patent rights. The law is complex and is still being interpreted and

implemented by the FDA. As a result, its ultimate impact, implementation, and meaning are subject to uncertainty. We believe that any of our product candidates approved as a biological product under a BLA should qualify for the 12- year period of exclusivity. However, there is a risk that this exclusivity could be shortened due to congressional action or otherwise, or that the FDA will not consider our investigational **genetic** medicines to be reference products for competing products, potentially creating the opportunity for generic competition sooner than anticipated. Other aspects of the BPCIA, some of which may impact the BPCIA exclusivity provisions, have also been the subject of recent litigation. Moreover, the extent to which a biosimilar, once licensed, will be substituted for any one of our approved products in a way that is similar to traditional generic substitution for non- biological products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing. If competitors are able to obtain marketing approval for biosimilars referencing any of our approved products, our approved products may become subject to competition from such biosimilars, which would impair our ability to successfully commercialize and generate revenue from sales of such products. We face significant competition in an environment of rapid technological change and the possibility that our competitors may achieve regulatory approval before us or develop therapies that are more advanced or effective than ours, which may adversely affect our financial condition and our ability to successfully commercialize and market our product candidates. We are aware of several companies and institutions that **have developed, or** are currently developing **,** alternative autologous or palliative gene therapy **or other** approaches for our targeted indications, including DEB ~~and ,~~ cystic fibrosis **, solid tumors, and aesthetic skin conditions** . Many of our potential competitors, alone or with their strategic partners, have substantially greater financial, technical, and other resources, such as larger research and development, clinical, marketing, and manufacturing organizations. Mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated among a smaller number of competitors. Our commercial opportunities could be reduced or eliminated if competitors ~~develop and~~ commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient **,** or are less expensive than VYJUVEK or any product candidate that we may ~~develop~~ **commercialize** . Competitors also may obtain FDA or other regulatory approval for their products more rapidly or earlier than we may obtain approval for our product candidates, which could result in our competitors establishing a strong market position before we are able to enter the market. Additionally, technologies developed by our competitors may render VYJUVEK or any of our product candidates uneconomical or obsolete, and we may not be successful in marketing VYJUVEK or any of our product candidates that obtain regulatory approval against **such** competitors. ~~In the future, even~~ **Even** if we commercialize a product candidate faster than our competitors, we could also face competition from lower cost biosimilars. In addition, as a result of the expiration or successful challenge of our patent rights, we could face litigation with respect to the validity and / or scope of patents relating to our competitors' products. The availability of our competitors' products could limit the demand, and the price we are able to charge, for VYJUVEK or any product candidate that we may develop and commercialize. If any product liability lawsuits are successfully brought against us, we may incur substantial liabilities and may be required to limit commercialization of VYJUVEK or our product candidates. We face an inherent risk of product liability lawsuits related to the sale of VYJUVEK, use of VYJUVEK and our product candidates, and testing of our product candidates. Product liability claims may be brought against us by participants enrolled in our clinical trials, patients, health care providers **,** or others using ~~,~~ or administering VYJUVEK and our product candidates. If we cannot successfully defend ourselves against any such claims, we may incur substantial liabilities. Regardless of their merit or eventual outcome, liability claims may result in: • decreased demand for VYJUVEK **or any of our product candidates that are approved for commercial sale in the future** ; • injury to our reputation; • withdrawal of clinical trial participants; • termination of clinical trial sites or entire trial programs; • increased regulatory scrutiny; • significant litigation costs; • substantial monetary awards to or costly settlement with claimants; • product recalls for any approved products or a change in the indications for which they may be used; • loss of revenue; • diversion of management and scientific resources from our business operations; and • the inability to successfully commercialize VYJUVEK or our product candidates, if approved. With respect to VYJUVEK and any of our product candidates that are approved for commercial sale in the future, we are, and will be, highly dependent upon physician and patient perceptions of us and the safety and quality of our products. We could be adversely affected if we are subject to negative publicity. We could also be adversely affected if any of our products or any similar products distributed by other companies prove to be, or are asserted to be, harmful to patients. Because of our dependence upon consumer perceptions, any adverse publicity could have a material adverse impact on our financial condition or results of operations. Our product liability insurance coverage may not be adequate to cover all liabilities that we may incur. We may need to increase our insurance coverage ~~now that VYJUVEK has been approved by the FDA and~~ when we begin **commercialization of VYJUVEK outside of the United States or** the commercialization of our product candidates, if approved. Insurance coverage is becoming increasingly expensive. As a result, we may be unable to maintain or obtain sufficient insurance at a reasonable cost to protect us against losses that could have a material adverse effect on our business. A successful product liability claim, or series of claims brought against us, particularly if judgments exceed any insurance coverage we may have, could decrease our cash resources and adversely affect our business, financial condition, and results of operations. Negative public opinion and increased regulatory scrutiny of gene therapy may damage public perception of the safety of our gene therapy **product or** product candidates and adversely affect our ability to conduct our business or obtain regulatory approvals for our product candidates. Gene therapy remains a novel technology. Ethical, social, and legal concerns about gene therapy could result in additional regulations restricting or prohibiting VYJUVEK or our product candidates. Public perception may be influenced by claims that gene therapy is unsafe, and gene therapy may not gain the acceptance of the public or the medical community. In particular, our success ~~will depend~~ **depends** upon physicians who specialize in the treatment of **DEB or** genetic diseases targeted by our product candidates prescribing **VYJUVEK or** treatments that involve the use of our product candidates **that may be** in lieu of, or in addition to, existing treatments with which they are familiar and for which greater clinical data may be available. More restrictive government regulations or negative public opinion would have an adverse effect on our business, financial condition,

results of operations , and prospects and may delay or impair the ~~development and~~ commercialization of VYJUVEK ~~or~~ , **regulatory approval of** our product candidates , or demand for VYJUVEK or any product candidates ~~we may develop~~ **that are approved for commercial sale** . For example, earlier gene therapy trials led to several well- publicized adverse events, including cases of leukemia and death seen in trials using other vectors. Serious adverse events in our clinical trials ~~,~~ or other clinical trials involving gene therapy products ~~or our competitors' products~~ , even if not ultimately attributable to the relevant product candidates, and the resulting publicity, could result in increased government regulation, unfavorable public perception, potential regulatory delays in the testing or approval of our product candidates, stricter labeling requirements for those product candidates that are approved , and a decrease in demand for any such product candidates. Our business operations may subject us to disputes, claims and lawsuits, which may be costly and time- consuming and could materially and adversely impact our financial position and results of operations. From time to time, we may become involved in disputes, claims , and lawsuits relating to our business operations. For example, we may ~~, from time to time,~~ face or initiate claims related to intellectual property matters, employment matters, or commercial matters. Any dispute, claim , or lawsuit may divert management' s attention away from our business, we may incur significant expenses in addressing or defending any dispute, claim , or lawsuit, and we may be required to pay damage awards or settlements or become subject to equitable remedies that could **materially and** adversely affect our operations and financial results ~~. Litigation related to these disputes may be costly and time- consuming and could materially and adversely impact our financial position and results of operations if resolved against us~~ . In addition, the uncertainty associated with litigation could lead to increased volatility in our stock price. The increasing use of social media platforms presents new risks and challenges. Social media is increasingly being used by us, our employees, or others to communicate about our business, VYJUVEK, our clinical development programs, DEB, and the diseases our product candidates are being developed to treat. We use ~~appropriate~~ social media in connection with our commercialization efforts of VYJUVEK and intend to use it in connection with our commercialization efforts of our product candidates, if approved. Social media practices in the biotechnology and biopharmaceutical industries continue to evolve, and regulations and regulatory guidance relating to such use are evolving and not always clear. This evolution creates uncertainty and risk of noncompliance with regulations applicable to our business, resulting in potential regulatory actions against us, along with the potential for litigation and heightened scrutiny by the FDA, the Securities and Exchange Commission, or the SEC, and other regulators. For example, patients may use social media channels to comment on their experience in an ongoing clinical trial of our product candidates, or to report an alleged adverse event. If such disclosures occur, there is a risk that clinical trial enrollment may be adversely impacted, that we may fail to monitor and comply with applicable adverse event reporting obligations, or that we may not be able to defend our business or the public' s legitimate interests in the face of the political and market pressures generated by social media due to restrictions on what we may say about our product candidates. There is also a risk of inappropriate disclosure of sensitive information, loss of trade secrets or other intellectual property, public exposure of personal information of our employees, patients who use VYJUVEK, clinical trial patients, and others, or negative or inaccurate posts or comments about us on any social networking website. In addition, we may encounter attacks on social media regarding our company, management, VYJUVEK, or our product candidates that seriously damage our reputation, brand image, and goodwill. If any of these events were to occur or we otherwise fail to comply with applicable regulations, we could incur liability, face regulatory actions, or incur other harm to our business that could have a material adverse effect on our business, prospects, operating results, and financial condition , and could adversely affect the price of our common stock. We have experienced significant growth in the number of employees and infrastructure and may experience difficulties in managing this growth. If we are unable to manage expected growth in the scale and complexity of our operations, our performance may suffer. We have experienced a period of significant expansion in personnel and of our facilities, infrastructure and overhead as we developed our own manufacturing facilities, built our sales, marketing , and distribution infrastructure that we believe is necessary to commercialize VYJUVEK, and increased our research and development efforts. The commercialization of VYJUVEK and our ongoing development of other product candidates will continue to impose significant capital requirements, as well as added responsibilities on members of management, including the need to identify, recruit, maintain , and integrate new personnel **in the United States and abroad** . Our future ~~financial~~ performance and our ability to compete effectively will depend, in part, on our ability to manage our growth effectively. If we are successful in executing our business strategy, we will need to expand our managerial, operational, financial, and other systems and resources to manage our operations, continue our research and development activities and build a commercial infrastructure to support commercialization of any of our product candidates that are approved for sale **. Depending on demand, we may need to scale up the manufacturing process for any approved product, which is subject to risks and uncertainties** . Future growth would impose significant added responsibilities on members of management. Our management, finance, development personnel, **and** systems ~~,~~ **(including infrastructure such as IT** and facilities **)** currently in place may not be adequate to support this expected future growth. Our need to effectively manage our operations, growth , and product candidates requires that we continue to develop more robust business processes and improve our systems and procedures in each of these areas and to attract and retain enough numbers of talented employees. We may be unable to successfully implement these tasks on a larger scale and, accordingly, may not achieve our research, development, and growth goals. Our future success depends on our ability to retain key employees and scientific advisors and to attract, retain , and motivate qualified personnel. We are highly dependent on members of our management team, the loss of whose services may adversely impact the achievement of our objectives. Our employees and scientific advisors are at- will employees and consultants, and the loss of one or more of them might impede the achievement of our research, development, and commercialization objectives. Recruiting and retaining ~~other~~ qualified employees and scientific advisors for our business, including scientific and technical personnel, also will be critical to our success. Competition for skilled personnel, including in gene therapy research and vector manufacturing, is intense and the turnover rate can be high. We may not be able to attract and retain personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies and

academic institutions for individuals with similar skill sets. In addition, failure to succeed in preclinical or clinical trials or applications for marketing approval may make it more challenging to recruit and retain qualified personnel. The inability to recruit, or loss of services of certain executives, key employees, or advisors, may impede the progress of our research, development , and commercialization objectives and have a material adverse effect on our business, financial condition, results of operations , and prospects. Our employees, principal investigators and advisors may engage in misconduct or other improper activities, including non- compliance with regulatory standards and requirements. We are exposed to the risk of fraud or other misconduct by our employees, principal investigators, and advisors. Misconduct by these parties could include intentional failures to comply with FDA regulations or the regulations applicable in the ~~European Union, or~~ EU ~~,~~ and other jurisdictions, provide accurate information to the FDA, the ~~European Medicines Agency (“~~ EMA ~~,”)~~ and other regulatory authorities, comply with healthcare fraud and abuse laws and regulations in the United States and abroad, report financial information or data accurately or disclose unauthorized activities ~~to us~~ . Sales, marketing, and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self- dealing , and other abusive practices. These laws and regulations restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs , and other business arrangements. It is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from government investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. 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, financial condition, results of operations , and prospects, including the imposition of significant fines, criminal penalties, or other sanctions. In addition, principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and receive compensation in connection with such services. Under certain circumstances, we may be required to report some of these relationships to the FDA. The FDA may conclude that a financial relationship between us and a principal investigator has created a conflict of interest or otherwise affected interpretation of the clinical trial. The FDA may therefore question the integrity of the data generated at the applicable clinical trial site and the utility of the clinical trial itself may be jeopardized. This could result in a delay in approval, or rejection, of our marketing applications by the FDA and may ultimately lead to the denial of marketing approval of our current and future product candidates. Healthcare legislative reform measures may have a material adverse effect on our business and results of operations. In the United States and some foreign jurisdictions, there have been, and continue to be, several legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of our product candidates, restrict or regulate post- approval activities, and affect our ability to profitably sell VYJUVEK and any product candidates for which we obtain marketing approval. In the United States, there have been and continue to be a number of legislative efforts to contain healthcare costs. Any legislative changes that result in price controls, reduce access to and reimbursement for care , or add additional regulations may have an adverse effect on our financial condition and results of operations. Any changes that reduce, or impede the ability to obtain, reimbursement for VYJUVEK or our product candidates that we intend to commercialize in the United States could adversely affect successful commercialization of VYJUVEK and our plans to introduce our product candidates in the United States. **The** ~~For example, the Bipartisan Budget Act of 2018, among other things, amended the ACA, effective January 1, 2019, to increase from 50 percent to 70 percent the point- of- sale discount that is owed by pharmaceutical manufacturers who participate in Medicare Part D and to close the coverage gap in most Medicare drug plans, commonly referred to as the “ donut hole. ” Other legislative changes have been proposed and adopted in the United States since the ACA was enacted. For example, in August 2011, the~~ Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least $ 1. 2 trillion for the years 2012 through 2021, was unable to reach required goals, thereby triggering the legislation’ s automatic reduction to several government programs. This includes aggregate reductions of Medicare payments to providers of up to 2 % per fiscal year, which went into effect in April 2013 and will remain in effect through ~~2027~~ **2032** unless additional Congressional action is taken. In January 2013, the American Taxpayer Relief Act of 2012, among other things, further reduced Medicare payments to certain providers, and increased the time for Medicare contractors to recoup Medicare overpayments to providers from three to five years. In August 2022, the ~~Inflation Reduction Act of 2022 (“~~ IRA ~~”)~~ was signed into law. The IRA includes several provisions to lower prescription drug costs for people with Medicare and reduce drug spending by the federal government. In relevant part, the IRA allows Medicare to negotiate prices for certain prescription drugs, requires drug manufacturers to pay a rebate to the federal government if prices for single- source drugs and biologicals covered under Medicare Part B and nearly all covered drugs under Part D increase faster than the rate of inflation, caps out of pocket spending for Medicare Part D enrollees, and makes other benefit design changes to Medicare Part D intended to lower drug costs for enrollees and Medicare. Implementation of these changes began in 2023 ~~,~~ and will continue to be implemented over the next several years **. Beginning January 1, 2025, Medicare Part D enrollees now have a new annual out- of- pocket cap of $ 2, 000 on prescription drugs. Other 2025 Medicare Part D changes include the elimination of the coverage gap phase and the replacement of the Coverage Gap Discount Program with the Manufacturer Discount Program, which requires drug manufacturers to pay a 10 % discount for brand- name drugs and biologics during the initial coverage period and a 20 % discount during the catastrophic phase** . Multiple pharmaceutical manufacturers have challenged the law in court, largely on constitutional grounds. These suits will **likely** continue ~~through 2024~~ and the ultimate effects of such legal challenges are unclear. At this time, we continue to evaluate the effect of the IRA on our business operations and financial condition and results as the full impact of the IRA remains uncertain. Further, there has been heightened governmental scrutiny in recent years over the manner in which manufacturers set prices for their marketed products and the cost of prescription drugs to consumers and government healthcare programs, which have resulted in several recent Congressional inquiries and proposed and enacted bills designed to, among

other things, reduce the cost of prescription drugs, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for products. In addition, the United States government, state legislatures, and foreign governments have shown significant interest in implementing cost containment programs, including price- controls, restrictions on reimbursement and requirements for substitution of generic products for branded prescription drugs to limit the growth of government paid health care costs. For example, the United States government has passed legislation requiring pharmaceutical manufacturers to provide rebates and discounts to certain entities and governmental payors to participate in federal healthcare programs. Individual states in the United States have also been increasingly passing legislation and implementing 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. Additional changes may affect our business, including those governing enrollment in federal healthcare programs, reimbursement changes, fraud and abuse enforcement, and expansion of new programs, such as Medicare payment for performance initiatives. ~~In October 2022, President Biden signed Executive Order 14087 on " Lowering Prescription Drug Costs for Americans. " The Executive Order specifically requests that the Center for Medicare and Medicaid Innovation consider " models that may lead to lower cost sharing for commonly used drugs and support value- based payment that supports high- quality care. " The outcomes of the findings made under the Executive Order could lead to further drug pricing initiatives that could affect reimbursement for our product and product candidates. These initiatives, as well as other healthcare~~ **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. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms could result in reduced demand for our product and product candidates or additional pricing pressures and may adversely impact our ability to generate sufficient revenue, attain consistent profitability, or commercialize our product candidates, if approved. We are subject, directly or indirectly, to federal and state healthcare fraud and abuse laws, false claims laws **,** and health information privacy and security laws. If we are unable to comply, or have not fully complied, with such laws, we could face substantial penalties. With the FDA approval of VYJUVEK, our operations are directly, or indirectly through our prescribers, customers, and purchasers, subject to various federal and state fraud and abuse laws and regulations, including, without limitation, the federal Anti- Kickback Statute, federal civil and criminal false claims laws and the Physician Payments Sunshine Act and regulations. These laws impact, among other things, our sales, marketing, access assistance, sponsored genetic patient testing, and educational programs. In addition, we are subject to patient privacy laws by both the federal government and the states in which we conduct our business **,** as well as ~~other~~ **by foreign** jurisdictions. The laws that affect our operations include, but are not limited to: • 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, in return for the purchase, recommendation, leasing **,** or furnishing of an item or service reimbursable under a federal healthcare program, such as the Medicare and Medicaid programs. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand, and prescribers, purchasers, and formulary managers on the other. The ACA amended the intent requirement of the federal Anti- Kickback Statute to clarify that a person or entity does not have to have actual knowledge of this statute or specific intent to violate it; • federal civil and criminal false claims laws and civil monetary penalty laws which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment or approval from Medicare, Medicaid, or other government payors that are false or fraudulent. The ACA provides that a claim for items or services resulting from an Anti- Kickback Statute violation is a false claim under the ~~federal False Claims Act (" FCA ")~~. Cases against pharmaceutical manufacturers support the view that certain marketing practices, including off- label promotion, may implicate the FCA; • the federal Health Care Fraud statute imposes criminal and civil liability for executing **or attempting to execute** a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters; • the ~~Health Insurance Portability and Accountability Act of 1996 (" HIPAA "), as amended by the Health Information Technology for Economic and Clinical Health Act (" HITECH "), and its implementing regulations, and as amended again by the final HIPAA omnibus rule (the " Omnibus Rule " and together with HIPAA and HITECH, the~~ HIPAA Rules ~~)~~, which impose certain requirements relating to the privacy, security **,** and transmission of individually identifiable health information by certain entities subject to the HIPAA Rules, such as health plans, health care clearinghouses **,** and health care providers that engage in certain covered transactions **, known as covered entities, as well as their business associates that perform certain services that involve the use or disclosure of individually identifiable health information for or on behalf of covered entities** ; • federal transparency laws, including the federal Physician Payment Sunshine Act, that require certain manufacturers of drugs, devices, biologics **,** and medical supplies for which payment is available under Medicare, Medicaid **,** or the Children' s Health Insurance Program, with specific exceptions, to report annually to ~~the Centers for Medicare and Medicaid Services (" CMS ")~~ information related to: (i) payments or other " transfers of value " made to physicians and teaching hospitals, and (ii) ownership and investment interests held by physicians and their immediate family members; • state and foreign law equivalents of each of the above federal laws, state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures **;** and **•** state **and foreign** laws governing ~~the~~ **data** privacy and security of health information ~~in certain circumstances~~, many of which differ from each other ~~in significant ways~~ and ~~may not have the same effect~~ **require attention to frequently changing regulatory requirements** , thus complicating compliance efforts in certain circumstances ~~, such as specific disease states;~~ and **increasing exposure to liability** ~~• state and foreign laws that 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 the HIPAA Rules, thus complicating compliance efforts~~ .

Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available, it is possible that some of our business activities could be subject to challenge under one or more of such laws. If our operations are found to be in violation of any of the laws described above or any other government regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines, exclusion from participation in government health care programs, such as Medicare and Medicaid, imprisonment **,** and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations. Often, to avoid the threat of treble damages and penalties under the FCA, health care providers **and drug manufacturers** will resolve allegations in a settlement without admitting liability. Any such settlement could materially affect our business, financial operations, and reputation. Efforts to ensure that our business arrangements with third parties comply with applicable healthcare laws and regulations involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. The risk of our being found in violation of these laws is increased by the fact that many of them have not been fully interpreted by the regulatory authorities or the courts, and their provisions are open to a variety of interpretations. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management' s attention from the operation of our business. The shifting compliance environment and the need to build and maintain a robust and expandable systems to comply with multiple jurisdictions with different compliance and / or reporting requirements increases the possibility that we may run afoul of one or more of the requirements. If we fail to comply with environmental, health **,** and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on the success of our business. We are subject to numerous environmental, health **,** and safety laws and regulations, including those governing laboratory procedures and the generation, handling, use, storage, treatment, manufacture, transportation, and disposal of, and exposure to, hazardous materials and wastes, as well as laws and regulations relating to occupational health and safety. Our operations involve the use of hazardous and flammable materials, including chemicals and biologic 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. Moreover, certain environmental laws may impose liability without regard to fault or legality of the action at the time of its occurrence. We also could incur significant costs associated with civil or criminal fines and penalties. We do not carry specific biological or hazardous waste insurance coverage ~~, and our property, casualty and general liability insurance policies specifically exclude coverage for damages and fines arising from biological or hazardous waste exposure or contamination~~ . Accordingly, in the event of contamination or injury, we could be held liable for damages or be penalized with fines in an amount ~~exceeding~~ **that could have a material adverse effect on** our ~~resources~~ **business, financial condition, results of operations, and prospects** , and our clinical trials or regulatory approvals could be suspended. Although we maintain workers' compensation insurance for certain costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials or other work- related injuries, this insurance may not provide adequate coverage against potential liabilities. We ~~do not maintain insurance for toxic tort claims that may be asserted against us in connection with our storage or disposal of biologic or hazardous materials. We~~ also may incur substantial costs to comply with current or future environmental, health **,** and safety laws and regulations, which have tended to become more stringent over time. These current or future laws and regulations may impair our research, development, or production efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties **,** or other sanctions or liabilities, which could materially adversely affect our business, financial condition, results of operations **,** and prospects. We are subject to stringent and evolving U. S. and foreign laws, regulations and other obligations related to privacy and data security. Our actual or perceived failure to comply with such obligations could lead to regulatory inquiries or actions, litigation, fines and penalties, disruptions to our business operations, reputational harm, loss of revenue, and other adverse business consequences. Privacy and data security have become significant areas of legal and regulatory focus in the United States, European Union **,** and in many other jurisdictions where we conduct or may conduct our operations. In our ordinary course of business, we collect, receive, store, process, generate, use, transfer, disclose, make accessible, protect, secure, dispose of, transmit, and share (collectively, " process ") personal information and other sensitive information, including, but not limited to, health information, individuals' financial information, as well as proprietary and confidential business data, including trade secrets, intellectual property, and sensitive third- party data (collectively, " sensitive data "). **The legislative and regulatory landscape for privacy and data security continues to evolve, and there has been an increasing focus on privacy and data security issues, which may affect our business and is expected to increase our compliance costs and exposure to liability.** Our data processing activities may subject us to numerous privacy and data security obligations, including, but not limited to, domestic and international laws, regulations, guidance, industry standards, external and internal privacy and security policies, and contractual requirements. In the United States, federal, state, and local governments have enacted numerous data privacy and security laws, including data breach notification laws, personal information privacy laws, consumer protection laws, and other similar laws. Notably, HIPAA, as amended by HITECH, imposes requirements on ~~certain~~ **covered** entities **, as well as their business associates** regarding the privacy, security, and transmission of individually identifiable health information **. Further, states continue to adopt new laws or amend existing laws related to data privacy, requiring attention to frequently changing regulatory requirements. For example,** and the California Consumer Privacy Act of 2018 (" CCPA ") requires businesses to provide specific disclosures in their privacy notices and honor ~~California~~ residents' privacy rights. The CCPA provides for civil penalties of up to $ 7, 500 per violation and allows private litigants affected by certain data breaches to recover significant statutory damages. Although the CCPA does not apply to certain data that we process in the context of clinical trials, efforts to comply with the CCPA may increase our annual compliance costs and subject us to potential liability with respect to other personal information we may

maintain about California residents. In addition, the California Privacy Rights Act of 2020 (" CPRA "), which came into effect on January 1, 2023, expanded the CCPA' s requirements, extending it to cover personal information of business representatives and employees and the CPRA established a new regulatory agency to implement and enforce the law. Other states, such as Virginia, Nevada, **Connecticut, Utah, Texas,** and Colorado, have also passed comprehensive privacy laws, and similar laws are being considered in several other states, as well as at the federal and local levels **, which impose similar obligations to those in the CCPA** . ~~While~~ **Further, other states, such as Nevada and Washington, have enacted privacy laws specifically governing consumer health information, with Washington providing for a private right of action. Although many of** these ~~states'~~ laws **currently** ~~, like the CCPA, also~~ exempt ~~some~~ **certain health- related information, the laws may increase our potential liability related to our** data **processing activities** ~~processed in the context of clinical trials~~ , ~~these developments further~~ complicate our compliance efforts **,** and increase both legal risk and compliance costs for us and the third parties upon whom we rely. Outside of the United States, there are an increasing number of laws, regulations, and industry standards regarding privacy and data security. For example, the EU General Data Protection Regulation (" GDPR ") and UK GDPR impose strict requirements for processing personal information, and companies that violate the GDPR may face temporary or permanent bans on certain data processing activities and they may be subject to other penalties such as fines of up to 20 million Euros under the EU GDPR / 17. 5 million pounds sterling under the UK GDPR or 4 % of annual global revenue, whichever is greater; or private litigation related to processing of personal information brought by classes of data subjects or consumer protection organizations authorized to represent data subjects' interests. In some circumstances, we may be unable to transfer personal information between certain jurisdictions due to data localization requirements or other limitations on cross- border data flows. Europe and other jurisdictions have enacted laws requiring data to be localized or limiting the transfer of personal information to other countries. In particular, the European Economic Area (" EEA ") and the UK have significantly restricted the transfer of personal information to the United States and other countries whose privacy laws they consider inadequate. Although there are various mechanisms that may be used to transfer personal information from the EEA and UK to the United States in compliance with the law, such as the EEA and UK' s standard contractual clauses, these mechanisms are subject to legal challenges, and we may be unable to rely on these measures to lawfully transfer personal information to the United States in all cases. If there is no lawful manner for us to transfer personal information from the EEA, the UK, or other jurisdictions to the United States, or if the requirements for a legally compliant transfer are too onerous, we could face significant adverse consequences, including increased exposure to regulatory actions, substantial fines and penalties, the inability to transfer data and work with partners, vendors **,** and other third parties, and injunctions against our processing or transferring of personal information necessary to operate our business. Some European regulators have ordered certain companies to suspend or permanently cease certain transfers of personal information to recipients outside Europe for allegedly violating the EU GDPR' s cross- border data transfer limitations. Additionally, companies that transfer personal information to recipients outside of the EEA and / or UK to other jurisdictions, particularly to the United States, are subject to increased scrutiny from regulators, individual litigants, and activist groups. **Compliance with applicable privacy and data security laws and regulations is a rigorous and time- intensive process, and we may be required to put in place additional mechanisms ensuring compliance with new data protection rules. Failure to comply with any such laws or regulations puts us at risk of facing significant fines and penalties that could adversely affect our business, financial condition, reputation, and results of our operations. Furthermore, conflicting requirements across applicable privacy and data security laws would complicate our compliance efforts and increase both legal risk and compliance costs for us and the third parties upon whom we rely.** In addition to any applicable privacy and data security laws and regulations, we may be subject to industry standards adopted by industry groups or bound by other contractual obligations related to privacy and data security. We may publish privacy policies, marketing materials, and other statements, such as compliance with certain certifications or self- regulatory principles, regarding data privacy and security. If these policies, materials, or statements are found to be deficient, lacking in transparency, deceptive, unfair, or misrepresentative of our practices, we may be subject to regulatory inquiries, regulatory enforcement actions **,** and other adverse consequences. Our obligations related to privacy and data security are quickly changing, becoming increasingly stringent, and creating regulatory uncertainty. Additionally, these obligations may be subject to differing applications and interpretations, which may be inconsistent between jurisdictions. Preparing for and complying with these obligations requires us to devote significant resources and may necessitate changes to our information technologies, systems, and practices and to those of any third parties that process personal information or other sensitive data on our behalf. We may at times fail (or be perceived to have failed) in our efforts to comply with our privacy and data security obligations. Moreover, despite our efforts, our personnel or third parties on whom we rely on may fail to comply with such obligations, which could negatively impact our business operations. If we or the third parties that process personal information or other sensitive data our behalf fail, or are perceived to have failed, to address or comply with applicable privacy and data security obligations, we could face significant consequences, including but not limited to ~~:~~government enforcement actions (e. g., investigations, fines, penalties, audits, and inspections) ~~;~~**,** litigation (including class- action claims) ~~;~~**,** additional reporting requirements and / or oversight ~~;~~**,** bans on processing personal information ~~;~~**,** and orders to destroy or not use personal information. Any of these events could have a material adverse effect on our reputation, business, or financial condition, including but not limited to loss of customers ~~;~~**,** significant reputational harm ~~;~~**,** an inability to process personal information or to operate in certain jurisdictions ~~;~~**,** limited ability to commercialize VYJUVEK or develop and commercialize our product candidates ~~;~~**,** expenditures of time and resources to defend ourselves against claims or inquiries ~~;~~**,** adverse publicity ~~;~~**,** or substantial changes to our business model or operations. Unfavorable global economic conditions could adversely affect our business, financial condition **,** or results of operations. Our results of operations could be adversely affected by general conditions in the global economy and in the global financial markets, including ~~high~~ inflation and interest rates and concerns of a recession in the United States or other major markets due to a number of factors. ~~For example, inflation and rising interest rates have caused volatility and disruptions in the capital and~~

~~credit markets, and it is unclear how long such volatility will continue.~~ In addition, **the conflict between** Russia **and** ~~'s invasion of~~ Ukraine and ~~/ or~~ the ~~Israel- Hamas conflict~~ **conflicts in the Middle East** may lead to a prolonged, adverse impact on global economic, sociopolitical **,** and market conditions. A severe or prolonged economic downturn could result in a variety of risks to our business, including our ability to raise additional capital ~~when~~ **if** needed or on acceptable terms, if at all. A weak or declining economy, sanctions, trade restrictions **,** and other global conditions could also strain our suppliers, possibly resulting in supply delays or disruptions. Any of the foregoing could ~~harm~~ **materially and adversely affect** our business **,** and we cannot anticipate all the ways in which the current economic climate and financial market conditions could adversely impact our business, financial condition, results of operations, and prospects. Our internal computer systems, or those of ~~our collaborators or other contractors or consultants,~~ **any third- party with whom we do business** may fail or suffer a cyber- security incident, such as a data breach or computer virus, which could harm our business by damaging our reputation, exposing us to liability, **adversely impacting our revenue,** or materially disrupting our operations, including production of VYJUVEK or our product development programs. We **rely on our information technology systems and infrastructure to manage our business. In addition, we** receive, process, store, and transmit, often electronically, confidential data of others, including the participants in our clinical trials. Unauthorized access to our ~~or (our~~ **or** ~~collaborators'~~ **any third party with whom we do business, such as suppliers, distributors, manufacturers, or vendors)** computer systems or stored data could result in the theft or improper disclosure of personal or confidential information or other sensitive data, the deletion or modification of records, or could cause interruptions in our operations. Cybersecurity threats include, but are not limited to, ransomware attacks, phishing attempts, and the exploitation of software vulnerabilities to gain access to our information technology environment, and cyber- security risks increase when we transmit information from one location to another, including transmissions over the Internet or other electronic networks. Despite our robust security measures and our commitment to implementing and continually improving our cybersecurity posture to mitigate the risk of a cybersecurity incident, we cannot guarantee that such incidents will not occur **to us or any third- party with whom we do business** . ~~Any~~ **For example, in 2024, our specialty pharmacy provider was affected by a cybersecurity incident that delayed reimbursement approvals and had a negative impact on our product revenue. A** cybersecurity incident, even if promptly addressed, may harm our reputation, damage our brand, and erode trust. Our ~~facilities and~~ systems, and those of ~~our~~ **any** third- party ~~service providers~~ **with whom we do business** , may also be vulnerable to ~~acts of vandalism,~~ software viruses, **stolen,** misplaced **,** or lost data, programming and / or human errors, or other similar events which may disrupt our operations or expose personal and confidential information. Moreover, in the event of a cybersecurity incident, we may face investigations, legal actions, including class action litigation, regulatory inquiries, and regulatory enforcement actions. We may also be subject to fines, consent orders, or mandated corrective actions that could have a material adverse impact on our operations and financial position. Furthermore, cybersecurity incidents and their legal consequences may impact investor confidence, potentially leading to a decrease in our stock price or limitations on our access to capital markets. If such an event were to occur and cause material interruptions in our operations, it could result in a material disruption of our development programs and our business operations, whether due to a loss of our trade secrets or other proprietary information. For example, the loss of clinical trial data from completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability, our competitive position could be harmed, and the further development and commercialization of our product candidates could be delayed. Certain data breaches must be reported to affected individuals and various government and / or regulatory agencies, and in some cases to the media, under provisions of HIPAA, ~~as amended by HITECH,~~ other U. S. federal and state ~~law~~ **laws** , and requirements of non- U. S. jurisdictions, including the EU GDPR and relevant member state law in the European Union and other foreign laws ~~, and financial penalties may also apply~~ . ~~Our~~ **Although we maintain cyber- security and other customary insurance, our** insurance policies may not be adequate to compensate us for the potential losses arising from breaches, failures **,** or disruptions of our infrastructure ~~, catastrophic events and disasters or otherwise~~ . In addition, such insurance may not be available to us in the future on economically reasonable terms, or at all. Further, our insurance may not cover all claims made against us and defending a suit, regardless of its merit, could be costly and divert management' s attention. Any security breach involving the misappropriation, loss or other unauthorized disclosure or use of confidential information of others, whether by us or a third- party, could: (i) subject us to civil and criminal penalties; (ii) have a negative impact on our reputation; or (iii) expose us to liability to third parties or government authorities. **Notifications and follow- up actions related to a data security incident could impact our reputation and cause us to incur significant costs, including significant legal expenses and remediation costs. We expect to incur significant costs in an effort to detect and prevent security incidents, and we may face increased costs and requirements to expend substantial resources in the event of an actual or perceived security incident. However, we cannot guarantee that we will be able to detect or prevent any such incidents, or that we can remediate any such incidents in an effective or timely manner. Our efforts to improve security and protect data from compromise may also identify previously undiscovered instances of data breaches or other cybersecurity incidents. To the extent that any data breach, disruption or security incident were to result in any loss, destruction, or alteration of, damage, unauthorized access to or inappropriate or unauthorized disclosure or dissemination of, our data, including personal data, or other information that is processed or maintained on our behalf, we could be exposed to litigation and governmental investigations and inquiries, the further development and commercialization of our product candidates could be delayed, and we could be subject to significant fines or penalties for any noncompliance with applicable state, federal, and foreign privacy and security laws, rules, regulations, and standards. Artificial intelligence presents risks and challenges that could negatively impact our business. Artificial intelligence (" AI ")- based platforms and tools are increasingly being used in the biopharmaceutical industry, and we have adopted and integrated in limited situations artificial intelligence**

platforms for limited specific business uses and may adopt and integrate additional artificial intelligence platforms and / or tools into our business. As with many technological innovations, artificial intelligence presents opportunities, risks and challenges that could impact our business. Harnessing AI' s potential may enable us to speed up the discovery and development of new product candidates, optimize our manufacturing processes, and drive efficiencies. However, AI may exacerbate existing risks, including risks associated with data privacy, cybersecurity, intellectual property, healthcare fraud and abuse, product development and manufacturing, and risks to subjects in clinical trials. If the models underlying AI technologies that we may use are incorrectly designed or implemented, trained, or reliant on incomplete, inadequate, inaccurate, biased, or otherwise poor quality data, or on data to which we do not have sufficient rights or in relation to which we and / or the providers of such data have not implemented sufficient legal compliance measures, used without sufficient oversight and governance to ensure their responsible use, misused, or used outside of scope of applicable regulatory authorizations, and / or adversely impacted by unforeseen defects, technical challenges, cybersecurity threats, or material performance issues, the performance of our products and business, as well as our reputation, could suffer or we could incur liability resulting from the violation of laws or contracts to which we are a party, regulatory enforcement actions, or civil claims. Additionally, the use of AI solutions by us or third parties on which we rely could lead to (i) the public disclosure of confidential information (including personal data of our employees, clinical trial participants, or other third parties) in contravention of our internal policies, data protection laws, other applicable laws, or contractual requirements, and / or (ii) the loss of proprietary information, trade secrets, or other intellectual property. In addition to existing risks, AI also introduces new risks, due to the autonomous nature of the technology, which, in some cases, may be deployed to perform tasks, inform decisions, automate decisions, and make predictions. AI may amplify biased and discriminatory decision making, perform unreliably and malfunction, generate insights which are difficult to interpret and explain, and cause direct harm to individuals or groups. Our failure to use AI technologies in a way that maintains trust, quality and control in our business activities and to capitalize on opportunities presented by AI may place us at a competitive disadvantage. Furthermore, uncertainties regarding developing legal and regulatory requirements and standards may require significant resources to modify and maintain business practices to comply with such laws and regulations concerning the use of AI. Failure to address AI risks could reduce our ability to deliver on our strategic objectives, result in reputational harm, and have a material adverse effect on our business, prospects, operating results, and financial condition. The regulatory framework for AI is rapidly evolving as many federal, state, and foreign government bodies and agencies have introduced or are currently considering additional laws and regulations. Evolving AI- related regulations, particularly in the United States, may impact our ability to develop, use, and commercialize AI technologies in the future. It is possible that further new laws and regulations will be adopted in the United States and in other non- U. S. jurisdictions, or that existing laws and regulations may be interpreted in ways that would limit our ability to use AI for our business, or require us to change the way we use AI in a manner that negatively affects the performance of our system and business and the way in which we use AI. We may need to expend resources to adjust our system in certain jurisdictions if the laws, regulations, or decisions are not consistent across jurisdictions. Further, the cost to comply with such laws, regulations or decisions and / or guidance interpreting existing laws, could be significant and would increase our operating expenses (such as by imposing additional reporting obligations regarding our use of AI). Such an increase in operating expenses, as well as any actual or perceived failure to comply with such laws and regulations, could materially and adversely affect our business, financial condition, results of operations, and prospects. Our business continuity and disaster recovery plans may not adequately protect us from a serious disaster. Natural **or technological** disasters could severely disrupt our operations or the operations of third- party suppliers or service providers and have a material adverse effect on our business, financial condition, results of operations **,** and prospects. The **severity and frequency of information technology system failures and cyberattacks continue to increase. Additionally, the** severity and frequency of weather- related natural disasters have been amplified, and are expected to continue to be amplified by, global climate change. Such natural **and technological** disasters may cause damage to and / or disrupt our operations, which may result in a material adverse effect on our VYJUVEK sales, our other product candidates, business, and results of operations. Moreover, climate change may also result in various chronic physical changes, such as changes in temperature or precipitation patterns or sea- level rise, that **could** ~~may also~~ have an adverse impact on our operations. Our suppliers, vendors **,** and business partners also face similar risks, and any disruption to their operations could have an adverse effect on our supply ~~and~~ **chain,** manufacturing ~~chain~~ **operations, or our commercial operations** . If a natural disaster, power outage **,** or other event occurred that prevented us from using all or a significant portion of our headquarters, that damaged critical infrastructure, such as our manufacturing facilities **and IT systems** , or that otherwise disrupted operations, it may be difficult or, in certain cases, impossible for us to continue our business for a substantial period of time. The disaster recovery and business continuity plans that we have in place currently are limited and may not prove adequate in the event of a serious disaster or similar event. A significant portion of our current supply of ~~drug~~ **materials necessary for** ~~product~~ **production** ~~for~~ **of** VYJUVEK and our product candidates **, as well as finished VYJUVEK and product candidates,** is located at our manufacturing facilities in Pittsburgh, Pennsylvania. We may incur substantial expenses as a result of the limited nature of our disaster recovery and business continuity plans, which could have a material adverse effect on our business, financial condition, results of operations **,** and prospects. Increased attention to, and evolving expectations for, environmental, 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 **, including diversity, equity, and inclusion (" DEI "),** and sustainability practices **. Investor advocacy groups, certain institutional investors, investment funds, and other influential investors have increasingly focused on ESG practices and have placed increasing importance on the non- financial impacts of their investments** . 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 our company and / or ~~product~~ **VYJUVEK** and **our** product candidates, such initiatives may be costly and may not have the desired effect. Moreover, we may not be able to successfully complete such **voluntary** 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 or our industry, which could negatively impact **the** ~~our share~~ price ~~as well as our access to and cost~~ of ~~capital~~ **our common stock** . ~~Furthermore~~ **In addition** , ~~certain investors have been engaged~~ in **recent years** " anti- ESG " ~~campaigns~~ **sentiment has gained momentum across the United States** , **with several states and Congress having proposed or enacted " anti- ESG " policies, legislation, or initiatives or issued related legal opinions, and the President having recently issued** ~~and~~ **an executive order opposing DEI initiatives in the private sector. Such anti- ESG and anti- DEI- related policies, legislation, initiatives, litigation, legal opinions, and scrutiny could result in us facing additional compliance obligations, becoming the subject of investigations and enforcement actions, or sustaining reputational harm. Therefore** , to the extent we take actions that are seen as positive to some investors **,** other investors may take issue with such actions **or face regulatory pressure to refrain from investing in, or divest from, our business** . To the extent ESG matters negatively impact our reputation, it may also impede our ability to compete as effectively to attract and retain employees ~~or~~ **,** customers, **or business partners** which may adversely impact our operations. In addition, ~~we expect~~ there **may** ~~will likely~~ be increasing levels of regulation, disclosure- related and otherwise, with respect to ESG matters. For example, the SEC ~~has published proposed~~ **recently adopted new** rules that ~~would~~ require companies to provide significantly expanded climate- related disclosures in their periodic reporting **. The new climate disclosure rules were the subject of multiple legal challenges** , ~~which~~ **and the SEC voluntarily stayed the climate disclosure rules pending the completion of judicial review. Therefore, it is unknown whether the new rules will go into effect and if they do, whether there will be significant changes. If the new rules go into effect and are not substantially different than the rules adopted by the SEC, we** may **be** ~~require~~ **required** ~~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 **. Even if the SEC rules are not adopted, states or ex- U. S. jurisdictions in which we currently or may in the future operate may also have or adopt ESG or climate- related disclosure rules requiring similar or broader disclosure obligations** . 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 customers and suppliers may be subject to similar expectations, which may augment or create additional risks, including risks that may not be known to us. Our international operations may expose us to business, regulatory, political, operational, financial, pricing and reimbursement **,** and economic risks associated with doing business outside of the United States. We currently have operations and employees located outside the United States and our business strategy incorporates potential additional international expansion to target patient populations outside the United States. Doing business internationally involves a number of risks, including, but not limited to: • **compliance with** multiple, conflicting, and changing laws and regulations such as privacy regulations, tax laws, export and import restrictions, employment laws, regulatory requirements, and other governmental approvals, permits, and licenses; • failure by us to obtain and maintain regulatory approvals for the use of our product candidates in various countries; • **complexities and difficulties in obtaining protection and enforcing our intellectual property, and** additional potentially relevant third- party patent rights; • ~~complexities and difficulties in obtaining protection and enforcing our intellectual property; •~~ difficulties in staffing and managing foreign operations **, including language barriers and translation** ; • complexities associated with managing multiple payor reimbursement regimes, government payors, or patient self- pay systems; • limits in our ability to penetrate international markets; • financial risks, such as longer payment cycles, **increased expenses for travel, translation, and insurance,** difficulty collecting accounts receivable, the impact of local and regional financial crises on demand and payment for our products **that are approved for sale** , and exposure to foreign currency exchange rate fluctuations; • **risks from or relating to** natural disasters, political and economic instability, including wars, terrorism, and political unrest, outbreak of disease, boycotts, curtailment of trade, and other business restrictions ~~; • certain expenses including, among others, expenses for travel, translation, and insurance~~ ; and • regulatory and compliance risks that relate to maintaining accurate information and control over sales and activities that may fall within the purview of the U. S. Foreign Corrupt Practices Act, its books and records provisions, or its anti- bribery provisions. Any of these factors could significantly harm our potential international expansion and operations and, consequently, our results of operations. We are subject to U. S. and certain foreign export and import controls, anti- corruption laws and anti- money laundering laws and regulations. Compliance with these legal standards could impair our ability to compete in domestic and international markets. We can face criminal liability and other serious consequences for violations, which can harm our business. We are subject to export control and import laws and regulations, including the U. S. Export Administration Regulations, U. S. Customs regulations, and various economic and trade sanctions regulations administered by the U. S. Treasury Department' s Office of Foreign Assets Controls, and anti- corruption and anti- money laundering laws and regulations, including the U. S. Foreign Corrupt Practices Act of 1977, as amended, the U. S. domestic bribery statute contained in 18 U. S. C. § 201, the U. S. Travel Act, the USA PATRIOT Act, and other state and national anti- bribery and anti- money laundering laws in the countries in which we conduct activities. Anti- corruption laws are interpreted broadly and prohibit

companies and their employees, agents, contractors and other collaborators and partners from authorizing, promising, offering, providing, soliciting, or receiving, directly or indirectly, improper payments or anything else of value to recipients in the public or private sector. We ~~may~~ engage third parties to sell VYJUVEK ~~or~~ **and may engage third parties to sell** our product candidates, if approved, abroad and / or to obtain necessary marketing authorizations, permits, licenses, patent registrations **,** and other regulatory approvals. We may have direct or indirect interactions with officials and employees of government agencies or government- affiliated hospitals, universities, and other organizations. We can be held liable for the corrupt or other illegal activities of our employees, agents, contractors **,** and other collaborators and partners, even if we do not explicitly authorize or have actual 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 adverse consequences. Furthermore, U. S. export control laws and economic sanctions prohibit the provision of certain products and services to countries, governments, and persons targeted by U. S. sanctions. The effect of pandemics, epidemics, outbreaks of infectious diseases, or similar public health crises on our operations and the operations of our customers, suppliers, third- party partners, and regulators could have an adverse impact our business. Pandemics, epidemics, outbreaks of infectious diseases, or similar public health crises could adversely disrupt or impact our operations or those of our customers, suppliers, third- party partners, and regulators. In response to a pandemic or public health crisis, authorities may impose, and businesses and individuals may implement, numerous measures to try to contain the pandemic or public health crisis or treat its impact, such as travel bans and restrictions, quarantines, shelter- in- place / stay- at- home and social distancing orders, shutdowns, and vaccine requirements. In the event that such measures or similar measures or restrictions are implemented as a result of a pandemic or public health crisis, our employees conducting research and development or manufacturing activities may not be able to access our laboratory or manufacturing spaces, and our core activities may be significantly limited or curtailed, possibly for an extended period of time. In addition, the operations of our customers, suppliers, third- party partners, and regulators could be significantly limited or curtailed. Timely initiation and completion of clinical trials are essential to our business and clinical trials are dependent upon the availability of clinical trial sites, researchers and investigators, regulatory agency personnel, and materials, any of which may be adversely affected by public health crises, such as pandemics. The extent to which a health crisis may impact our business, results of operations **,** and future growth prospects will depend on a variety of factors and future developments, which are highly uncertain and cannot be predicted with confidence, including the duration, scope, and severity of the public health crisis. A future public health crisis may have a material adverse effect on our business and results of operations. Inadequate funding for the FDA and other government agencies, including from government shut downs, or other disruptions to these agencies' operations, could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, 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, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory and policy changes. Disruptions at the FDA and other agencies may also slow the time necessary for new product candidates to be reviewed and / or approved by necessary government agencies, which could adversely affect our business. For example, when the U. S. government has shut down in the past, certain regulatory agencies, such as the FDA and the United States Securities and Exchange Commission ~~, or the SEC,~~ have had to furlough critical employees and stop critical activities. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to review and process our regulatory submissions in a timely manner, which could have a material adverse effect on our business. Further, future government shutdowns could impact our ability to access the public markets and obtain necessary capital. In addition, government funding of government agencies on which our operations may rely is subject to the political process, which is inherently fluid and unpredictable. Risks Related to the Development, Regulatory Review and Approval of Our Product Candidates If we are unable to advance our product candidates through clinical trials, obtain regulatory approval and ultimately commercialize our product candidates, or if we experience significant delays in doing so, our business will be materially harmed. The development and commercialization of our product candidates are subject to many uncertainties, including the following: **• successful completion of preclinical studies, including animal studies, to determine the predicted safety and efficacy profile of our product candidates;** • successful enrollment and completion of clinical trials; • positive results from our current and planned clinical trials; • receipt of regulatory approvals from applicable regulatory authorities; • successful development of our internal manufacturing processes on an ongoing basis **, including any required or desired changes to our manufacturing processes,** and maintenance of our existing arrangements with third- party suppliers or manufacturers for clinical supply; • commercial launch of our product candidates, if and when approved, whether alone or in collaboration with others; and • acceptance of our product candidates, if and when approved, by patients, the medical community and third- party payors. If we fail 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 our product candidates, which would materially harm our business. If we do not receive regulatory approvals for our product candidates **or required changes to our manufacturing processes** , our business, financial condition, results of operations and prospects could be materially and adversely affected. Our gene therapy platform is based on a novel technology, which makes it difficult to predict the time and cost of obtaining regulatory approvals for our product candidates. The clinical trial requirements of the FDA, EMA and other regulatory authorities and the criteria these regulators use to determine the safety and efficacy of a product candidate vary substantially according to the type, complexity, novelty and intended use and market of such product candidates. The regulatory approval process for novel product candidates such as ours **, including approvals of or changes to manufacturing processes,** can be more expensive and take longer than for other, better known or more extensively studied product candidates. It is difficult to determine how long it will take or how much it will cost to obtain regulatory approvals for our product candidates in

the United States, the European Union, or elsewhere, or how long it will take to commercialize our product candidates. Approvals by the European Commission may not be indicative of what the FDA may require for approval and approval by the FDA may not be indicative of what the European Commission would require for approval. Regulatory requirements and policy governing gene and cell therapy products have changed frequently and may continue to change in the future. In 2016, the FDA established the Office of Tissues and Advanced Therapies (" OTAT ") within its Center for Biologics Evaluation and Research to consolidate the review of gene therapy and related products, and has established the Cellular, Tissue and Gene Therapies Advisory Committee, among others, to advise this review. In September 2022, the FDA announced retitling of OTAT to the Office of Therapeutic Products ~~(" ~~**, or** OTP **, ")~~ and elevation of OTP to a " Super Office " to meet its growing cell and gene therapy workload. If we engage a National Institutes of Health funded institution to conduct a clinical trial, that institution' s Institutional Biosafety Committee as well as its Institutional Review Board ~~(" IRB "),~~ would need to review the proposed clinical trial to assess the safety **and ethics** of the trial. Similarly, the EMA may issue new guidelines concerning the development and marketing authorization for gene therapy medicinal products and require that we comply with these new guidelines. These regulatory review committees and advisory groups and the new guidelines they promulgate may lengthen the regulatory review process, require us to perform additional studies, increase our development costs, lead to changes in regulatory positions and interpretations, delay or prevent approval and commercialization of our product candidates **,** or lead to significant post- approval limitations or restrictions. These additional processes may result in a review and approval process that ~~are~~ **is** longer than we otherwise would have expected. Delay or failure to obtain, or unexpected costs in obtaining, the regulatory approval necessary to bring a potential product to market could decrease our ability to generate sufficient product revenue, and our business, financial condition, results of operations **,** and prospects would be materially and adversely affected. Our product or product candidates may cause undesirable side effects or have other properties that could delay or prevent their regulatory approval, limit the commercial potential, or result in significant negative consequences before or following any potential marketing approval. There have been several significant adverse side effects in gene therapy trials using other vectors in the past. Gene therapy is still a relatively new approach to disease treatment and additional adverse side effects could develop. There also is the potential risk of delayed adverse events following exposure to gene therapy products due to persistent biologic activity of the genetic material or other components of products used to carry the genetic material. In addition to side effects caused by our product **or product** candidates, the administration process or related procedures also can cause adverse side effects. If any such adverse events occur, our clinical trials could be suspended or terminated. If ~~in the future~~ we are unable to demonstrate that such adverse events were caused by the administration process or related procedures and not by our product candidates, the FDA, the European Commission, the EMA, or other regulatory authorities could order us to cease further development of, or deny approval of, our product candidates for any or all targeted indications. Even if we can demonstrate that any serious adverse events are not product- related, such occurrences could affect patient recruitment or the ability of enrolled patients to complete the trial. Moreover, if we elect, or are required, to delay, suspend **,** or terminate any clinical trial of our product candidates, the commercial prospects of such product candidates may be harmed and our ability to generate product revenue from the product candidates may be delayed or eliminated. Any of these occurrences may harm our ability to develop product candidates, and may harm our business, financial condition, and prospects significantly. Additionally, if a product candidate receives marketing approval, the FDA **or a foreign regulatory authority** could require us to adopt a post- approval safety monitoring program to ensure that the benefits outweigh its risks, which may include, among other things, a medication guide outlining the risks of the product for distribution to patients and a communication plan to health care practitioners. Furthermore, if we or others later identify undesirable side effects caused by VYJUVEK or our product candidates, several potentially significant negative consequences could result, including: • regulatory authorities may suspend or withdraw approvals of ~~such~~ **VYJUVEK or our** product **candidates that may be approved** ; • regulatory authorities may require additional warnings on the label; • we may be required to change the way VYJUVEK or a product candidate is administered or conduct additional clinical trials; • we could be sued and held liable for harm caused to patients; and • our reputation may suffer. Any of these events could prevent us from achieving or maintaining market acceptance of VYJUVEK or our product candidates and could significantly harm our business, financial condition, results of operations **,** and prospects. ~~We~~ **Our product candidates that are in preclinical stages of development may never advance to clinical development and for those product candidates that do progress to clinical development, we** may encounter substantial delays in our clinical trials, or we may fail to demonstrate safety and efficacy to the satisfaction of applicable regulatory authorities **. Preclinical studies, which are also known as nonclinical studies, refer to a stage of research that begins before clinical trials (testing in humans) can begin, and during which important feasibility, iterative testing, and safety data are collected. Because of their early nature, preclinical product candidates tend to carry a higher risk of failure as compared with clinical- stage assets. Preclinical product candidates must generate sufficient safety and efficacy data through in vitro studies and a variety of tests before they can be considered appropriate for testing in humans. The development risks, timeline, and cost of preclinical assets can be high because of the unknowns and absence of data. It can be difficult to identify relevant tests and animal models for preclinical studies. If preclinical studies of our product candidates do not generate strong data, our preclinical stage programs may never progress to clinical development and may prove to be worthless. In addition, the results of preclinical studies may not be predictive of the results of clinical trials. For example, we utilize animal models to ascertain the predicted safety and efficacy profile of our product candidates, but animal models are imperfect predictors of a product candidate' s effect / interactions in humans. As such, positive data from animal models may not be predictive of positive human results, patients may have side effects that were not observed in animals, and a product candidate may pose significant and unexpected safety risks to humans** . Before obtaining marketing approval from regulatory authorities for the sale of our product candidates, we must conduct extensive clinical trials to demonstrate the safety and efficacy of the product candidate for its intended indications. Obtaining marketing approval is an extensive, lengthy,

expensive, and inherently uncertain process, and regulatory authorities may delay, limit, or deny approval of our product candidates for many reasons. We cannot guarantee that any clinical trials will be conducted as planned or completed on schedule, if at all. A failure of one or more clinical trials can occur at any stage of testing. Events that may prevent successful or timely completion of clinical ~~development~~ **trials** include: • delays in reaching a consensus with regulatory authorities on trial design; • delays in opening sites and recruiting a sufficient number and diversity of suitable ~~patients~~ **study subjects** to participate in our clinical trials; • imposition of a clinical hold by regulatory authorities as a result of a serious adverse event or concerns with a class of product candidates, or after an inspection of our clinical trial operations or trial sites; • delays in having ~~patients~~ **study subjects** complete participation in a trial or return for post- treatment follow- up; • occurrence of serious adverse events associated with the product candidate that are viewed to outweigh its potential benefits; or • changes in regulatory requirements and guidance that require amending or submitting new clinical protocols. The results of nonclinical ~~and preclinical~~ studies and early clinical trials may not be predictive of the results of later- stage clinical trials, and interim results of a clinical trial do not necessarily predict final results. In some instances, there can be significant variability in safety or efficacy results between different clinical trials of the same product candidate due to numerous factors, including changes in trial procedures set forth in protocols, differences in the size and type of the ~~patient~~ **study subject** populations, changes in and adherence to the dosing regimen and other clinical trial protocols and the rate of dropout among clinical trial participants. In addition, preclinical and clinical data are often susceptible to various interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy profile despite having progressed through nonclinical studies and initial clinical trials. If we make manufacturing **processes** or formulation changes to our product or product candidates, we may need to conduct additional studies to bridge our modified product or product candidate to earlier versions **and obtain regulatory approvals** . Clinical trial delays could also shorten any periods during which we may have the exclusive right to commercialize our **approved** products or allow our competitors to bring products to market before we do, which could limit our potential revenue or impair our ability to successfully commercialize our **approved** products and may harm our business, financial condition, results of operations **,** and prospects. Any delays, setbacks or failures in our clinical trials could materially and adversely affect our business, financial condition, results of operations **,** and prospects. Additionally, if the results of our clinical trials are inconclusive or if there are safety concerns or serious adverse events associated with our product candidates, we may: • be delayed in obtaining marketing approval, if at all, or be required to conduct additional confirmatory safety and / or efficacy studies; • 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 **, precautions, or contraindications** ; • obtain approval without labeling claims that are necessary or desirable for the successful commercialization of our product candidates; • be subject to additional and costly post- marketing testing requirements or clinical trials; • be required to perform additional clinical trials to support approval; • have regulatory authorities withdraw, or suspend, their approval of the product or impose restrictions on its distribution; • be ~~subject to the addition of labeling statements, such as warnings, precautions, or contraindications; • be~~ sued; or • experience damage to our reputation. Our product development costs will also increase if we experience delays in testing or obtaining marketing approvals. We do not know whether any of our preclinical studies or clinical trials will begin as planned, need to be restructured or be completed on schedule, if at all. Further, we, the FDA or an IRB, may suspend our clinical trials at any time if it appears that we or our collaborators are failing to conduct a trial in accordance with regulatory requirements, including the FDA' s Current Good Clinical Practice, or CGCP, regulations, that we are exposing participants to unacceptable health risks, or if the FDA finds deficiencies in our ~~Investigational~~ **investigational** ~~New~~ **new** ~~Drug~~ **drug** , or IND, applications or the conduct of these trials. Therefore, we cannot predict with any certainty the schedule for commencement and completion of future clinical trials. If we experience delays in the commencement or completion of our clinical trials, or if we terminate a clinical trial prior to completion, the commercial prospects of our product candidates could be negatively impacted, and our ability to generate revenue from our product candidates may be eliminated or delayed. We rely on third parties to conduct certain ~~aspects~~ of our preclinical studies and clinical trials. If these third parties do not successfully carry out their contractual duties, meet expected deadlines **,** or comply with regulatory requirements, we may not be able to obtain regulatory approval for, or commercialize, our product candidates. We depend upon third parties to conduct certain ~~aspects~~ of our preclinical studies and depend on third parties, including independent principal investigators, to conduct our clinical trials under agreements with universities, medical institutions, and others. We negotiate budgets and contracts with such third parties, which may result in delays to our development timelines and increased costs. We rely on third **party contract research organizations (" CROs ") to conduct our preclinical animal studies to support product candidate development and related regulatory submissions. Use of CROs for our animal studies subjects us to a number of risks, including a CRO going out of business, failing to meet deadlines or appropriately performing an animal study, or altering their internal practices that prevent future collaboration (e. g., change the types or biosafety levels of materials they are willing to handle). In addition, our use of CROs located outside of the United States is subject to changes in import / export regulations that could delay or prevent timely shipping / receiving of our product candidates for animal studies. If any such adverse events occur, the development of our product candidates or the acceptability of nonclinical data packages for regulatory agencies could be significantly and adversely impacted. We rely on third** parties over the course of our clinical trials, and, as a result, may have limited control over the clinical principal investigators and limited visibility into their day- to- day activities, including with respect to their compliance with the approved clinical protocol. 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 CGCP requirements, which are regulations and guidelines enforced by the FDA and comparable

foreign regulatory authorities for product candidates in clinical development. Regulatory authorities enforce these CGCP requirements through periodic inspections of clinical trial sponsors, clinical investigators, and clinical trial sites. If we or any of these third parties fail to comply with applicable CGCP requirements, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to suspend or terminate these clinical 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 CGCP requirements. In addition, our later- stage clinical trials must be conducted with product produced under **Current Good Manufacturing Practice, or** CGMP **,** requirements **(and comparable quality regulations in foreign countries)** and may require a large number of ~~patients~~ **study subjects** . Our failure or any failure by these third parties to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process. Moreover, our business may be adversely affected 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. Any third parties conducting ~~aspects of~~ our preclinical studies ~~,~~ or our clinical trials will not be our employees and, except for remedies that may be available to us under our agreements with such third parties, we cannot control whether or not they devote sufficient time and resources to our preclinical studies and clinical programs. 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 preclinical or clinical data they obtain is compromised due to the failure to adhere to our protocols or regulatory requirements or for other reasons, our development timelines, including clinical development timelines, may be extended, delayed or terminated, and we may not be able to complete development of, obtain regulatory approval of, or successfully commercialize our product candidates. As a result, our financial results and the commercial prospects for our product candidates would be harmed, our costs could increase **,** and our ability to generate revenue could be delayed or precluded entirely. Though we carefully manage our relationships with principal investigators and other third parties, there can be no assurance that we will not encounter challenges or delays or that these delays or challenges will not have a material adverse impact on our business, financial condition, and prospects. Interim, " top- line, " and preliminary data from our clinical trials that we announce or publish from time to time may change as more ~~patient~~ data ~~become~~ **becomes** available or as additional analyses are conducted, and as the data are subject to audit and verification procedures that could result in material changes in the final data. From time to time, we may publish interim, " top- line **,** " or preliminary data from our clinical trials. Interim data from clinical trials ~~that we may complete~~ are subject to the risk that one or more of the clinical outcomes may materially change as ~~patient~~ **study subject** enrollment continues and more ~~patient~~ data becomes available. Preliminary or " top- line " 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, interim and preliminary data should be viewed with caution until the final data are available. Material adverse changes between preliminary, " top- line **,** " or interim data and final data could significantly harm our business, financial condition, results of operations **,** and prospects. Even if we obtain and maintain approval for our product candidates from the FDA, we may never obtain approval for them outside of the United States, which would limit our market opportunities and adversely affect our business. Approval of a product candidate in the United States by the FDA does not ensure approval of such product candidate by regulatory authorities in other countries or jurisdictions, and approval by one foreign regulatory authority does not ensure approval by regulatory authorities in other foreign countries or by the FDA. Sales of VYJUVEK or our product candidates, if approved, outside of the United States will be subject to foreign regulatory requirements governing clinical trials and marketing approval. Even if the FDA grants marketing approval for a product candidate, comparable regulatory authorities of foreign countries also must approve the manufacturing and marketing of the product candidate in those countries and the process for obtaining such approval may be lengthy and expensive. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from, and more onerous than, those in the United States, including additional preclinical studies or clinical trials. In many countries outside the United States, a product candidate must be approved for reimbursement before it can be approved for sale in that country. In some cases, the price that we intend to charge for our product candidates, if approved, is also subject to approval. Obtaining a Marketing Authorization Application (" MAA ") from the European Commission following the opinion of the EMA is a lengthy and expensive process. Even if a product candidate is approved, the FDA or the European Commission, as the case may be, may limit the indications for which the product may be marketed, require extensive warnings on the product labeling or require expensive and time- consuming additional clinical trials or reporting as conditions of approval. Regulatory authorities in countries outside of the United States and the European Union also have requirements for approval of product candidates with which we must comply prior to marketing in those countries. Obtaining foreign regulatory approvals and compliance with foreign regulatory requirements could result in significant delays, difficulties, and costs for us and could delay or prevent the introduction of our product candidates in certain countries. Further, clinical trials conducted in one country may not be accepted by regulatory authorities in other countries. Also, regulatory approval for any of our product candidates may be withdrawn. If we fail to comply with the regulatory requirements, our target market will be reduced and our ability to realize the full market potential of our product candidates will be harmed and our business, financial condition, results of operations **,** and prospects will be adversely affected. VYJUVEK and our product candidates **that receive marketing approvals** remain subject to regulatory oversight even after regulatory approval. We will continue to incur costs related to regulatory compliance and are subject to risks related to non- compliance with or changes to applicable laws and regulations, which could cause VYJUVEK or any of our product candidates that obtain regulatory approval to lose that approval. VYJUVEK, our first FDA- approved product, and any other product candidates that obtain regulatory approval in the future, will remain subject to ongoing regulatory requirements for manufacturing, labeling, packaging, storage, advertising, promotion, sampling, record- keeping **,** and

submission of safety and other post- market information. Any regulatory approvals that we receive for our product candidates may also be subject to a post- approval safety monitoring program, limitations on the approved indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for potentially costly post- marketing testing, including Phase 4 clinical trials, and surveillance to monitor the quality, safety, and efficacy of the product. 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 holder of an approved BLA also must submit new or supplemental applications and obtain FDA approval for certain changes to the approved product, product labeling **,** or manufacturing process **. For example, if demand for an approved product increases more than we previously estimate, we may need or desire to scale up an existing FDA- approved manufacturing process and the scaled- up manufacturing process would be subject to FDA review and approval** . Advertising and promotional materials must comply with FDA rules and are subject to FDA review, in addition to other potentially applicable federal and state laws. In addition, product manufacturers and their facilities are subject to payment of user fees and continual review and periodic inspections by the FDA and other regulatory authorities for compliance with CGMP requirements and adherence to commitments made in the BLA or foreign marketing application. If we, or a regulatory authority, discover previously unknown problems with an approved product, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured or a regulatory authority disagrees with the promotion, marketing **,** or labeling of that product, a regulatory authority may impose restrictions relative to that product, the manufacturing facility or us, including requiring recall or withdrawal of the product from the market or suspension of manufacturing. If we fail to comply with applicable regulatory requirements, a regulatory authority may **, among other actions** : • issue a warning letter asserting that we are in violation of the law; • seek an injunction or impose administrative, civil, or criminal penalties or monetary fines; • suspend or withdraw regulatory approval; • suspend any ongoing clinical trials; • refuse to approve a pending BLA or comparable foreign marketing application (or any supplements thereto) submitted by us or our strategic partners, if any; • restrict the marketing or manufacturing of the product; • seize or detain the product or otherwise require the withdrawal of the product from the market; • refuse to permit the import or export of product candidates; or • refuse to allow us to enter into 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 our approved product **, VYJUVEK,** and **any** product candidates **that obtain regulatory approval** and adversely affect our business, financial condition, results of operations **,** and prospects. The FDA' s policies, and those of equivalent foreign regulatory agencies, may change and additional government regulations may be enacted that could negatively impact the existing marketing approval for VYJUVEK and prevent, limit, or delay regulatory approval of our product candidates. We cannot predict the likelihood, nature **,** or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained, which would materially and adversely affect our business, financial condition, results of operations **,** and prospects. While we have obtained orphan drug exclusivity for VYJUVEK **in the United States,** and orphan drug designation for ~~KB105, KB407,~~ **certain product candidates in the United States** and ~~KB408~~ **other jurisdictions** , it may not effectively protect us from competition, and we may be unable to obtain orphan drug designation for other product candidates. If our competitors are able to obtain orphan drug exclusivity before us, we may not be able to have competing products approved by the applicable regulatory authority for a significant period of time. Regulatory authorities in some jurisdictions, including the United States, the European Union, and Japan may designate drugs for relatively small patient populations as orphan drugs. Under the Orphan Drug Act of 1983, as amended, the FDA may designate a product candidate as an orphan drug if it is intended to treat a rare disease or condition, which is generally defined as having a patient population of fewer than 200, 000 individuals in the United States, or a patient population greater than 200, 000 in the United States where there is no reasonable expectation that the cost of developing the drug will be recovered from sales in the United States **of such drug** . Orphan drug designation **itself** does not convey any advantage in or shorten the duration of the regulatory review and approval process, but it can lead to financial incentives, such as opportunities for grant funding toward clinical trial costs, tax advantages **,** and user- fee waivers. In addition, if a product that has orphan designation subsequently receives the first FDA approval for the disease or condition for which it has such designation, the drug is entitled to orphan drug marketing exclusivity for a period of seven years. Orphan drug marketing exclusivity generally prevents the FDA from approving another application to market the same drug or biological product for the same disease or condition for seven years, except in limited circumstances, including if the FDA concludes that the later drug is safer, more effective **,** or makes a major contribution to patient care. A designated orphan drug may not receive orphan drug marketing exclusivity if it is approved for a use that is broader than the indication for which it received orphan designation. Orphan drug marketing exclusivity rights in the United States may be lost if the FDA later determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the drug to meet the needs of patients with the rare disease or condition. In the European Union, the European Commission, upon a recommendation from the EMA' s Committee for Orphan Medicinal Products, grants orphan drug designation to promote the development of products that are intended for the diagnosis, prevention, or treatment of a life- threatening or chronically debilitating condition affecting not more than 5 in 10, 000 persons in the EU. Additionally, orphan designation is granted for products intended for the diagnosis, prevention, or treatment of a life- threatening, seriously debilitating, or serious and chronic condition and when, without incentives, it is unlikely that sales of the drug in the European Union would be sufficient to justify the necessary investment in developing the drug or biologic product. In the European Union, orphan medicinal product designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process, but orphan drug designation may entitle an applicant to financial incentives such as reduction of fees or fee waivers, protocol assistance, and access to the centralized marketing authorization procedure. Upon

grant of a marketing authorization, orphan products are entitled to ten years of market exclusivity for the approved therapeutic indication, which means that the EMA and European Commission cannot accept another marketing authorization application, grant a marketing authorization, or accept an application to extend a marketing authorization for a similar product for the same indication for a period of ten years. The period of market exclusivity is extended by two years for orphan medicinal products that have also complied with an agreed Pediatric Investigation Plan ~~, or PIP~~. The ten- year market exclusivity in the European Union may be reduced to six years if, at the end of the fifth year, it is established that the product no longer meets the criteria for which it received orphan designation, including where it is shown that the product is sufficiently profitable not to justify maintenance of market exclusivity, or where the prevalence of the condition has increased above the threshold. Additionally granting of an authorization for another similar orphan medicinal product where another product has market exclusivity can happen at any time: (i) **that** the second applicant can establish that its product, although similar, is safer, more effective, or otherwise clinically superior ~~;~~ **,** (ii) **that** the applicant cannot supply enough orphan medicinal product, or (iii) where the applicant consents to a second orphan medicinal product application **. Additionally, a recent legislative initiative that is still under discussion in the European Parliament, may introduce a variable duration of market exclusivity based on the type of orphan medicinal product (between four and 11 years) in the upcoming years** . The orphan drug designation system in Japan aims to support the development of drugs for diseases that affect fewer than 50, 000 patients in Japan, for which significant unmet medical need exists. An investigational therapy is eligible to qualify for orphan drug designation in Japan if there is no approved alternative treatment option or if there is high efficacy or safety compared to existing treatment options expected. Specific measures to support the development of orphan drugs in Japan include subsidies for research and development expenditures, prioritized consultation regarding clinical development, reduced consultation fees, tax incentives, priority review of applications, reduced application fees, and extended registration validity period. Up to ~~10~~ **ten** years of orphan exclusivity, known as the re- examination period, is granted for the product after approval. The orphan drug exclusivity may be rescinded by the Japanese government in certain circumstances. Even though we have obtained orphan drug exclusivity for VYJUVEK in the United States; orphan drug designation for ~~VYJUVEK~~ **B- VEC** in the European Union and Japan; orphan drug designation for KB105 and KB407 in the United States and the European Union; and orphan drug designation for KB408 in the United States, we **may not** ~~cannot assure you that we will~~ be able to ~~obtain or~~ maintain orphan drug exclusivity **,** and if we are able to maintain the orphan drug exclusivity, the exclusivity may not effectively protect the product from competition because different drugs can be approved for the same condition. Further, we cannot assure you that any of our other product candidates will be approved for any orphan- designated use in any jurisdiction, in a timely manner **,** or at all, or that a competitor will not obtain orphan drug exclusivity that could block the regulatory approval of any of our ~~drug~~ **product** candidates for several years. If we are unable to maintain or obtain orphan drug exclusivity, our ability to generate sufficient revenue may be negatively affected. If a competitor is able to obtain orphan drug exclusivity that would block our product candidates' regulatory approval, our ability to generate revenue could be significantly reduced, which would harm our business prospects, financial condition **,** and results of operations. We do not know if, when, or how the FDA or other regulators may change the applicable orphan drug regulations and policies in the future, and it is uncertain how any changes might affect our business. Depending on what changes may be made to orphan drug regulations and policies, our business could be adversely impacted. Accelerated approval by the FDA, even if granted for any of our product candidates, may not lead to a faster development or regulatory review or approval process and it does not increase the likelihood that our product candidates will receive marketing approval. We may seek approval of our current or future product candidates using the FDA' s accelerated approval pathway. This pathway may not lead to a faster development, regulatory review **,** or approval process and does not increase the likelihood that our product candidates will receive marketing approval. A product may be eligible for accelerated approval if it treats a serious or life- threatening condition, generally provides a meaningful advantage over available therapies, and demonstrates an effect on a surrogate **endpoint or an intermediate clinical** endpoint that is reasonably likely to predict clinical benefit. As a condition of approval, the FDA may require that a sponsor of a product receiving accelerated approval perform adequate and well- controlled post- marketing confirmatory clinical trials. These confirmatory trials must be completed with due diligence. Under the Food and Drug Omnibus Reform Act of 2022, or FDORA, the FDA is permitted to require, as appropriate, that a post- approval confirmatory trial or trials be underway prior to approval or within a specified time after the date accelerated approval was granted. FDORA also requires sponsors to send updates to the FDA every 180 days on the status of such studies, including progress toward enrollment targets, and the FDA must promptly post this information publicly. Furthermore, under FDORA, the FDA is empowered to take action, such as issuing fines, against companies that fail to conduct with due diligence any post- approval confirmatory trial or submit timely reports to the agency on their progress. In addition, for products under consideration for accelerated approval, the FDA currently requires, unless otherwise requested by the agency, pre- approval of promotional materials intended for dissemination or publication within 120 days of marketing approval be submitted to the agency for review during the review period, which could adversely impact the timing of the commercial launch of the product. There can be no assurance that the FDA would allow any of our product candidates to proceed on an accelerated approval pathway, and even if the FDA did allow such pathway, there can be no assurance that any expedited development, review, or approval will be granted on a timely basis, or at all. Breakthrough Therapy Designation, Fast Track Designation, Regenerative Medicine Advanced Therapy Designation **,** or Priority Review by the FDA, or PRIME Scheme by the EMA, even if granted for any of our product candidates, may not lead to a faster development, regulatory review **,** or approval process, and such designations may not increase the likelihood that any of our product candidates will receive marketing approval. We may seek a Breakthrough Therapy Designation for some of our product candidates. A breakthrough therapy is defined as a therapy that is intended, alone or in combination with one or more other therapies, to treat a serious or life- threatening disease or condition, and preliminary clinical evidence indicates that the therapy may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. For therapies 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. Therapies designated as breakthrough therapies by the FDA may also be eligible for priority review and accelerated approval. Designation as a breakthrough therapy is within the discretion of the FDA. Accordingly, even if we believe one of our product candidates meets the criteria for designation as a breakthrough therapy, the FDA may disagree and instead determine not to make such designation. In any event, the receipt of a Breakthrough Therapy Designation for a product candidate may not result in a faster development process, review **,** or approval compared to therapies considered for approval under conventional FDA procedures and does not assure ultimate approval by the FDA. In addition, even if one or more of our product candidates qualify as breakthrough therapies, the FDA may later decide that such product candidates no longer meet the conditions for qualification or decide that the time for FDA review or approval will not be shortened. We have obtained and may seek Fast Track Designation for some of our product candidates. For instance, VYJUVEK, KB105, and KB707 **(intratumoral and inhaled)** were granted Fast Track Designation by the FDA. If a therapy is intended for the treatment of a serious or life- threatening condition and the therapy demonstrates the potential to address unmet medical needs for this condition, the sponsor may apply for Fast Track Designation. The FDA has broad discretion whether or not to grant this designation, so even if we believe a particular product candidate is eligible for this designation, we cannot assure you that the FDA would decide to grant it. Even if we do receive Fast Track Designation, we may not experience a faster development process, review **,** or approval compared to conventional FDA procedures. For products that receive Fast Track Designation, sponsors may have greater interactions with the FDA and the FDA may initiate review of sections of the marketing application before the application is complete. This rolling review may be available if the FDA determines, after preliminary evaluation of clinical data submitted by the sponsor, that a Fast Track product may be effective. The sponsor must also provide, and the FDA must approve, a schedule for the submission of the remaining information and the sponsor must pay applicable user fees. However, the FDA' s time period goal for reviewing an application does not begin until the last section of the application is submitted. The FDA may withdraw Fast Track Designation if it believes that the designation is no longer supported by data from clinical programs. Many biologics that have received Fast Track Designation have failed to obtain marketing approval. Fast Track Designation alone does not guarantee qualification for the FDA' s priority review procedures. We **were** ~~have obtained and may seek Regenerative Medicine Advanced Therapy, or RMAT, designation for some of our product candidates. For instance, VYJUVEK was~~ granted RMAT designation ~~by~~ **for B- VEC from** the FDA **, and we may seek RMAT designation for some of our product candidates** . In 2017, the FDA established the RMAT designation as part of its implementation of the 21st Century Cures Act to expedite review of any drug that meets the following criteria: it qualifies as a RMAT, which is defined as a cell therapy, therapeutic tissue engineering product, human cell and tissue product, or any combination product using such therapies or products, with limited exceptions; it is intended to treat, modify, reverse, or cure a serious or life- threatening disease or condition; and preliminary clinical evidence indicates that the drug has the potential to address unmet medical needs for such a disease or condition. Like Breakthrough Therapy Designation, RMAT designation provides potential benefits that include more frequent meetings with the FDA to discuss the development plan for the product candidate, and eligibility for rolling review and priority review. Products granted RMAT designation may also be eligible for accelerated approval **based** on ~~the basis of a~~ surrogate or intermediate ~~endpoint~~ **endpoints** reasonably likely to predict long- term clinical benefit, or reliance upon data obtained from a meaningful number of sites, including through expansion to additional sites. RMAT- designated products that receive accelerated approval may, as appropriate, fulfill their post- approval requirements through the submission of clinical evidence, clinical trials, patient registries, or other sources of real- world evidence, such as electronic health records; through the collection of larger confirmatory data sets; or via post- approval monitoring of all patients treated with such therapy prior to approval of the therapy. There is no assurance that we will be able to obtain RMAT designation for our product candidates. RMAT designation does not change the FDA' s standards for product approval, and there is no assurance that such designation will result in expedited review or approval or that the approved indication will not be narrower than the indication covered by the designation. Additionally, RMAT designation can be revoked if the criteria for eligibility cease to be met as clinical data emerges. If the FDA determines that a product candidate offers a treatment for a serious condition and, if approved, the product would provide a significant improvement in safety or effectiveness, the FDA may designate the product candidate for priority review. A priority review designation means that the goal for the FDA to review an application is six months, rather than the standard review period of ten months. The FDA has broad discretion with respect to whether or not to grant priority review status to a product candidate, so even if we believe a particular product candidate is eligible for such designation or status, the FDA may decide not to grant it. Moreover, a priority review designation does not necessarily result in an expedited regulatory review or approval process or necessarily confer any advantage with respect to approval compared to conventional FDA procedures. Receiving priority review from the FDA does not guarantee approval within the six- month review cycle, or at all. We have obtained and may seek to qualify our product candidates under the ~~PRIority MEdicines (“~~ PRIME ~~”)~~ scheme from the EMA. For instance, ~~VYJUVEK~~ **B- VEC** was granted PRIME designation. The PRIME scheme is open to medicines under development and for which the applicant intends to apply for an initial MAA through the centralized procedure. Eligible products must target conditions for which ~~where~~ **there** is an unmet medical need (there is no satisfactory method of diagnosis, prevention **,** or treatment in the European Union or, if there is, the new medicine will bring a major therapeutic advantage) and they must demonstrate the potential to address the unmet medical need by introducing new methods or therapy or improving existing ones. There is no assurance that we will be able to obtain PRIME qualification for our product candidates. PRIME does not change the standards for product approval, and there is no assurance that such qualification will result in expedited review or approval. Moreover, where, during the course of development, a product no longer meets the eligibility criteria, support under the PRIME scheme may be withdrawn. We have obtained a rare pediatric disease designation for certain of our product candidates; however, there is no guarantee that FDA

approval will result in issuance of a priority review voucher. In 2012, Congress authorized the FDA to award priority review vouchers to sponsors of certain rare pediatric disease product applications. This program is designed to encourage development of new drug and biological products for prevention and treatment of certain rare pediatric diseases. Specifically, under this program, a sponsor that receives an approval for a drug or biologic for a " rare pediatric disease " that meets certain criteria may qualify for a voucher that can be redeemed to receive a priority review of a subsequent marketing application for a different product. The sponsor of a rare pediatric disease drug product receiving a priority review voucher may transfer (including by sale) the voucher to another sponsor. The voucher may be further transferred any number of times before the voucher is used, as long as the sponsor making the transfer has not yet submitted the application. The FDA may also revoke any priority review voucher if the rare pediatric disease drug for which the voucher was awarded is not marketed in the United States within one year following the date of approval. We received rare pediatric disease designation for VYJUVEK and were awarded a priority review voucher following FDA approval of VYJUVEK in May 2023. The priority review voucher was sold in August 2023. We have also obtained a rare pediatric disease designation for KB105, KB104, and for KB407. **In addition, in May 2024, inhaled KB707 was granted rare pediatric disease designation by the FDA for the treatment of osteosarcoma, and in August 2024, intratumoral KB707 was granted rare pediatric disease designation by the FDA for the treatment of rhabdomyosarcoma.** However, there is no guarantee that we will be able to obtain a priority review voucher if these product candidates are approved by the FDA. Congress included a sunset provision in the statute authorizing the rare pediatric disease priority review voucher program. Under the current statutory sunset provisions, ~~after September 30~~ **since December 20** , 2024, the FDA ~~may~~ **is** only **able to** award a voucher for an approved rare pediatric disease product application if the sponsor has rare pediatric disease designation for the product candidate, and that designation was granted by September 30, ~~2024~~ **2026** . After September 30, 2026, the FDA may not award any rare pediatric disease priority review vouchers. We may seek designation for our platform technology as a designated platform technology, but we might not receive such designation, and even if we do, such designation may not lead to a faster development or regulatory review or approval process. We may seek designation for our platform technology as a designated platform technology. Under the Food and Drug Omnibus Reform Act of 2022, or FDORA, a platform technology incorporated within or utilized by a drug or biologic is eligible for designation as a designated platform technology if (1) the platform technology is incorporated in, or utilized by, a product approved under a New Drug Application, or NDA, or BLA; (2) preliminary evidence submitted by the sponsor of the approved product, or a sponsor that has been granted a right of reference to data submitted in the application for such product, demonstrates that the platform technology has the potential to be incorporated in, or utilized by, more than one product without an adverse effect on quality, manufacturing, or safety; and (3) data or information submitted by the sponsor indicates that incorporation or utilization of the platform technology has a reasonable likelihood to bring significant efficiencies to the product development or manufacturing process and to the review process. A sponsor may request the FDA to designate a platform technology as a designated platform technology concurrently with, or at any time after, submission of an IND application for a product that incorporates or utilizes the platform technology that is the subject of the request. If so designated, the FDA may expedite the development and review of any subsequent NDA or BLA for a product that uses or incorporates the platform technology. Even if we believe our platform technology meets the criteria for such designation, the FDA may disagree and instead determine not to grant such designation. In addition, the receipt of such designation for a platform technology does not ensure that our applicable product candidates will be developed more quickly or receive a faster FDA review process or ultimate FDA approval. Moreover, the FDA may revoke a designation if the FDA determines that a designated platform technology no longer meets the criteria for such designation. Risks Related to Manufacturing Delays in obtaining regulatory approvals of the process **, or changes to the process,** and facilities needed to manufacture **VYJUVEK or** our product candidates or disruptions in our manufacturing process may disrupt our production of VYJUVEK or delay or disrupt our development and commercialization efforts with respect to our product candidates. Before we can begin to commercially manufacture our product candidates, we must pass a pre- approval inspection of our manufacturing facilities by the FDA. A manufacturing authorization must also be obtained from the appropriate EU regulatory authorities. The timeframe required for us to obtain such approvals is uncertain. To obtain approval, we need to ensure that all our processes, methods **,** and equipment are compliant with CGMP, and perform extensive audits of vendors, contract laboratories, and suppliers. If any of our vendors, contract laboratories, or suppliers is found to be out of compliance with CGMP, we may experience delays or disruptions in manufacturing while we work with these third parties to remedy the violation or while we work to identify suitable replacement vendors, contract laboratories, or suppliers. The CGMP requirements govern quality control of the manufacturing process and documentation policies and procedures. In complying with CGMP, we are obligated to expend time, money **,** and effort in production, record keeping and quality control to assure that the product meets applicable specifications and other requirements. If we fail to comply with these requirements, we will be subject to possible regulatory action and may not be permitted to sell any approved product ~~that we may develop~~ . In addition, the manufacturing process used to produce VYJUVEK and our product candidates is complex and novel **and demand for an approved product may require us to change the manufacturing process, which may require regulatory approval before we are able to sell the product manufactured by the changed process** . The production of VYJUVEK and our product candidates require processing steps that are more complex than those required for most ~~chemical~~ pharmaceuticals. Moreover ~~,~~ ~~unlike chemical pharmaceuticals~~ , the physical and chemical properties of a biologic such as ours generally cannot be fully characterized. As a result, assays of the finished product may not be sufficient to ensure that the product will perform in the intended manner. Accordingly, we employ multiple steps to control our manufacturing process to assure that the process works and that VYJUVEK and our product candidates are made strictly and consistently in compliance with the process. Problems with ~~the~~ **an approved** manufacturing process, even minor deviations from the normal process, could result in product defects or manufacturing failures that result in lot failures, product recalls, product liability claims **,** or insufficient inventory **. In addition, changes to an approved manufacturing process may result in problems with the process design, process reproducibility,**

stability, or batch consistency, and may require regulatory approval before we are permitted to sell products manufactured with the changed manufacturing process, which could potentially delay commercial availability of an approved product . We may encounter problems achieving adequate quantities and quality of materials that meet FDA, EMA **,** or other applicable standards or specifications with consistent and acceptable production yields and costs **, which could materially and adversely affect our business, financial condition, results of operations, and prospects** . Although we have established our own manufacturing facilities for VYJUVEK and our product candidates, we may also utilize third parties to conduct our product manufacturing or components thereof **. We are also dependent on a limited number of third- party suppliers for some of the components and materials used in manufacturing VYJUVEK and our product candidates and in commercially supplying VYJUVEK** . Therefore, we are subject to the risk that these third parties may not perform satisfactorily. We may maintain third- party manufacturing capabilities in order to provide multiple sources of supply of VYJUVEK or a product candidate that is approved for sale. In addition, we may utilize third parties to manufacture components of **VYJUVEK** ~~our~~ **or our** ~~products~~ **product candidates** . For example, we use a third- party to manufacture the sterile gel that is mixed with our in- house produced vector for VYJUVEK. Our ability to commercially supply VYJUVEK depends, in part, on the ability of third parties to supply and manufacture the raw materials and other important components related to our manufacture of VYJUVEK **. For some materials and components related to our manufacture of VYJUVEK and our product candidates, there are, in general, relatively few alternative sources of supply. Our use of a limited number of suppliers for some of the components and materials used in manufacturing VYJUVEK and our product candidates and commercially supplying VYJUVEK exposes us to several risks, including disruptions in supply, price increases, late deliveries, and an inability to meet demand** . If we fail to develop and maintain supply relationships with these third parties, we may be unable to successfully commercialize VYJUVEK or any approved product candidate. Any of our existing suppliers may: • fail to supply us on a timely basis or in the requested amount due to unexpected damage to or destruction of facilities or equipment or otherwise; • fail to increase manufacturing capacity and at higher yields in a timely or cost- effective manner, or at all, to sufficiently meet our commercial needs; • be unable to meet our production demands due to issues related to their reliance on sole- source suppliers and manufacturers; • supply us with materials that fail to meet regulatory requirements; • become unavailable through business interruption or financial insolvency; • lose regulatory status as an approved supply source; • be unable or unwilling to (i) honor current supply agreements or (ii) renew current supply agreements when such agreements expire on a timely basis, on acceptable terms or at all; or • discontinue production or manufacturing of materials that we acquire through such third- party supplier. In the event of any of the foregoing, if we do not have an alternative supplier or manufacturer in place, we may not be able to manufacture our products for commercial, regulatory, or clinical purposes and would be required to expend substantial management time and expense to identify, qualify **,** and transfer to alternative suppliers or manufacturers. There can be no assurance that replacements would be available to us on a timely basis, on acceptable terms, or at all. Any need to find and qualify new suppliers or manufacturers could significantly delay production of VYJUVEK or any product candidate, if approved, adversely impact our ability to market VYJUVEK or any product candidate, if approved, and have a material adverse effect on our business, financial condition, results of operations **,** and prospects. If we or a third- party supplier or manufacturer fails to comply with applicable CGMP regulations, the FDA and foreign regulatory authorities can impose regulatory sanctions including, among other things, refusal to approve a pending application for a new product candidate or suspension or revocation of a pre- existing approval. Such an occurrence may cause our business, financial condition, results of operations **,** and prospects to be materially harmed. Any contamination in **, or changes to,** our manufacturing process, shortages of raw materials or failure of any of our key suppliers to deliver necessary components could result in delays in our ability to produce VYJUVEK **or any other approved product** for commercial supply or any product candidate for clinical development. Given the nature of biologics manufacturing, there is a risk of contamination. Any contamination could materially adversely affect our ability to produce VYJUVEK or our product candidates on schedule and could, therefore, harm our results of operations and cause reputational damage. Some of the raw materials required in our manufacturing process are derived from biologic sources. Such raw materials are difficult to procure and may be subject to contamination or recall. A material shortage, contamination, recall or restriction on the use of biologically derived substances in the manufacture of VYJUVEK or our product candidates could adversely impact or disrupt the commercial manufacturing or the production of clinical material, which could materially and adversely affect our development timelines and our business, financial condition, results of operations **,** and prospects **. Failure to increase manufacturing capacity and at higher yields in a timely or cost- effective manner, or at all, to sufficiently meet our commercial needs could result in delays in commercial availability of an approved product. If a manufacturing process is approved by the FDA, implementing a new or changed manufacturing processes is difficult, time consuming, and would require regulatory approvals, which could potentially delay commercial availability of an approved product, which, in turn, could harm our results of operations and cause reputational damage** . Our failure to maintain or continuously improve our quality management program could have an adverse effect upon our business, subject us to regulatory actions **,** and cause patients to lose confidence in us or our products, among other negative consequences. Quality management plays an essential role in the manufacturing of ~~drugs~~ **VYJUVEK and** ~~or~~ **our** ~~drug products~~ **product candidates** , conducting clinical trials, preventing defects, improving our product candidates, and assuring the safety and efficacy of **VYJUVEK** ~~our product~~ and **our** product candidates. We seek to maintain a robust quality management program which includes the following broad pillars of quality: • monitoring and assuring regulatory compliance for clinical trials, manufacturing, and testing of good applicable practice (“ GxP ”) **for regulated products** (e. g., CGCP and CGMP ~~regulated~~ ~~products~~ ; • monitoring and providing oversight of all GxP suppliers; • establishing and maintaining an integrated, robust quality management system for clinical, manufacturing, supply chain **,** and distribution operations; and • cultivating a proactive, preventative quality culture and employee and supplier training to ensure quality. Our success depends on our ability to maintain and continuously improve our quality management program. **Any change to an approved manufacturing process will put**

strain on our quality management program. A quality or safety issue may result in adverse inspection reports, warning letters, monetary sanctions, injunctions to halt manufacture and distribution of **VYJUVEK** ~~our~~ **or our** ~~products~~ **product candidates** , civil or criminal sanctions, costly litigation, refusal of a government to grant approvals and licenses, restrictions on operations, or withdrawal, suspension or variation of existing approvals and licenses. An inability to address a quality or safety issue in an effective and timely manner may also cause negative publicity, or a loss of patient confidence in us or **VYJUVEK** ~~our~~ **or** ~~product or~~ **our** product candidates, which may result in difficulty in successfully launching products and the loss of potential future sales, which could have an adverse effect on **our business, financial condition, and results of operations. If demand for VYJUVEK or any product for which we obtain marketing approval increases more than previously estimated or we wish to improve manufacturing efficiencies to lower cost of production, we may need or choose to scale up or change a current FDA- approved commercial manufacturing process, which is subject to risks and uncertainties and could require us to submit a Prior Approval Supplement (" PAS ") to the FDA and obtain the agency' s approval for the manufacturing process changes before they can be implemented. We may desire or need to make manufacturing process changes to scale- up manufacturing to meet increased demand, to improve efficiencies or costs, or otherwise. Scaling up a manufacturing process carries regulatory, financial, and operational risks, which could potentially impact product availability. For example, as a result of the strong and increasing commercial demand for VYJUVEK, we designed a revised commercial manufacturing process that should more than quadruple the output of each production batch. We validated the revised commercial manufacturing process and submitted a PAS to the FDA, which was approved by the FDA. Receipt of FDA approval was required before we could commercially sell VYJUVEK manufactured with the revised commercial manufacturing process. In addition to requiring FDA approval of a PAS, there are risks associated with scaling up a manufacturing process, including, among others, cost overruns, potential problems with the process scale- up design, process reproducibility, stability issues, and batch consistency. Furthermore, studies or tests to demonstrate comparability of product manufactured under an existing and under a revised manufacturing process, or any other studies on a revised process, such as validation studies, may uncover findings that result in the FDA delaying or refusing to approve a revised process. We cannot guarantee if or when the FDA may approve a PAS for any manufacturing process change (s), and failure to obtain FDA approval or other risks associated with manufacturing processes changes could impact commercial availability of VYJUVEK or an approved product candidate, which could result in the loss of sales and adversely affect our business, results of operations, and financial condition. We may need or desire to transfer VYJUVEK or an approved product candidate manufacturing from ANCORIS, our commercial scale CGMP- compliant manufacturing facility where VYJUVEK is currently manufactured to ASTRA, our recently completed and qualified state- of- the- art CGMP manufacturing facility, or transfer an approved product manufacturing from ASTRA to ANCORIS, and technical transfer of a manufacturing process is subject to risks and uncertainties and requires FDA inspection and approval of the facility where manufacturing is planned to be transferred. We plan to complete a technical transfer process to allow us to commercially manufacture VYJUVEK at ASTRA, our recently completed and qualified state- of- the- art CGMP manufacturing facility, in addition to ANCORIS, where VYJUVEK is currently manufactured. This process may be time consuming and will require an FDA inspection of ASTRA. We cannot provide any assurance of the timing of such FDA approval, or if the FDA will approve commercial manufacturing of VYJUVEK at ASTRA. We have never completed a technical transfer process to an in- house manufacturing facility, and there is no guarantee that we will be successful doing so. Failure or delay in technical transfer of VYJUVEK or another approved product from ANCORIS to ASTRA, or from ASTRA to ANCORIS, could impair our ability to supply sufficient product to meet commercial demand and successfully commercialize and generate revenue from sales of approved products, which could adversely affect** our business, financial condition, and results of operations. Risks Related to Commercialization of VYJUVEK and Our Product Candidates We have limited experience as a commercial company and the sales, marketing, and distribution of VYJUVEK or any future approved products may be unsuccessful or less successful than anticipated. We received FDA approval of VYJUVEK in May 2023 and initiated a commercial launch of VYJUVEK in the United States in the second quarter of 2023. As a company, we have no prior experience commercializing a biologic. The success of our commercialization efforts is difficult to predict and subject to the effective execution of our business plan, including, among other things, the continued development of our internal sales, marketing, **manufacturing,** and distribution capabilities and our ability to navigate the significant expenses and risks involved with the development and management of such capabilities. For example, our commercial launch of VYJUVEK may not develop as planned or anticipated, which may require us to, among others, adjust or amend our business plan and incur significant expenses. Further, given our lack of experience commercializing products, we do not have a track record of successfully executing a commercial launch **. There is a risk that we underestimate the level of demand for a product, which could require us to change a manufacturing process to increase production yields and changes to a manufacturing process are time consuming and subject to regulatory, financial, and operational risks** . If we are unsuccessful in accomplishing our objectives and executing on our business plan, or if our commercialization efforts do not develop as planned, we may not be able to successfully commercialize VYJUVEK and any future approved products, we may require significant additional capital and financial resources, we may not become profitable on a consistent basis, and we may not be able to compete against more established companies in our industry. If we are unable to maintain our agreements with third parties to distribute VYJUVEK to patients in the United States, our results of operations and business could be adversely affected. We rely on a small number of third parties to commercially distribute VYJUVEK to patients in the United States. We have contracted with a third- party packaging company to package VYJUVEK, a third- party logistics company to warehouse, process, and ship VYJUVEK to a limited number of specialty pharmacies that mix the medication and administer it to patients in the patient' s home by a healthcare professional and ~~a specialty distributor that distributes VYJUVEK~~ to **a limited number of** hospitals and

distributors ~~outpatient clinics~~ where patients are administered the medication ~~at~~ **in** a **hospital or clinic** ~~healthcare professional's office~~. This distribution network requires significant coordination with our sales and marketing and finance organizations. In addition, failure to coordinate financial systems could negatively impact our ability to accurately report product revenue from VYJUVEK. If we are unable to effectively manage the distribution process, the sales of VYJUVEK could be compromised and our results of operations may be harmed. If the third parties involved in the commercial distribution of VYJUVEK in the United States do not fulfill their contractual obligations to us or refuse or fail to adequately or to properly distribute VYJUVEK and serve patients, or the agreements with them are terminated without adequate notice, shipments of VYJUVEK, and associated revenue, could be adversely affected. In addition, if we were required to replace such third ~~-~~parties, it could take time to locate an appropriate replacement third- party on acceptable terms, which could cause delays in our distribution network and increased expenses, and thereby adversely impact our commercial sales of VYJUVEK in the United States and result in a material adverse effect on our business, financial condition, results of operations, and prospects. ~~We plan on using~~ **Using** ~~local~~ **specialty** distributors to market and sell VYJUVEK in certain jurisdictions outside of the **United States** ~~U. S.~~, the **United Kingdom** ~~U. K.~~, certain EU countries, and Japan ~~, which~~ subjects us to certain risks. ~~We plan on using local~~ **Outside of the United States, major European markets and Japan, we intend to and have started entering into distribution agreements with specialty** distributors to **commercialize** ~~market and sell~~ VYJUVEK ~~outside of the U. S., the U. K., certain EU countries, and Japan~~. We may be unable to enter into appropriate supply, marketing, and distribution arrangements on favorable terms, if at all. Our use of distributors in these ~~market~~ **markets** to market and sell VYJUVEK involves certain risks, including, but not limited to, risks that these organizations will not comply with applicable laws and regulations, not effectively sell or support VYJUVEK or reduce or discontinue their efforts to sell or support VYJUVEK, not devote the resources necessary to market and sell VYJUVEK in the volumes and within the time frame we expect, not be able to satisfy financial obligations to us or others, not provide us with accurate or timely information regarding their inventories of VYJUVEK or the number of patients who are using VYJUVEK, or not provide us with accurate or timely information regarding serious adverse events and / or product complaints. Any such events may result in regulatory actions that may include suspension or termination of the distribution and sale of our products in a certain country, loss of revenue, and / or reputational damage, which could harm our results of operations and business. In connection with the commercial launch of VYJUVEK in the United States, we recruited a sales force and established marketing, market access **,** and medical affairs teams and distribution capabilities and if the commercial launch of VYJUVEK is not successful for any reason, we could incur substantial costs and our investment would be lost if we cannot retain or reposition our sales, marketing, market access **,** and medical affairs personnel. To achieve commercial success for VYJUVEK, we have devoted and anticipate that we will continue to devote significant resources to support our sales force, marketing, market access, and medical affairs teams and distribution capabilities. There are risks involved with establishing our own sales, marketing, distribution, training, and support capabilities. For example, recruiting and training sales and marketing personnel is expensive and time- consuming and could delay our ability to focus on other priorities. If the commercial launch of VYJUVEK in the United States is not successful for any reason, this would be costly, and our investment would be lost if we cannot retain or reposition our sales, marketing, market access **,** and medical affairs personnel or terminate on favorable terms any agreements entered into with third parties to support our commercialization efforts. Factors that may inhibit our efforts to commercialize VYJUVEK or any other product candidates, if approved, on our own in the United States or elsewhere include: • our inability to train and retain adequate numbers of effective sales, marketing, training, and support personnel; • the inability of sales personnel to obtain access to physicians, including key opinion leaders, or to educate an adequate number of physicians of the benefits of VYJUVEK or any approved product candidate; • the lack of complementary products to be offered by our sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive or integrated product offerings; and • unforeseen costs and expenses associated with establishing and maintaining an independent sales, marketing, training, and support organization. If our ~~salesforce~~ **sales force** , marketing, market access, and medical affairs teams and distribution capabilities fail, or are otherwise unsuccessful, it would materially adversely impact the commercial launch of VYJUVEK, impact our ability to generate revenue **,** and harm our business. If we are unable to expand our medical affairs, marketing, market access, sales, and distribution capabilities or collaborate with third parties to market and sell our product candidates for which we obtain marketing approval, we may be unable to generate sufficient product revenue. To successfully commercialize any products for which we obtain marketing approvals, we will need to expand our ~~salesforce~~ **sales force** , marketing, market access, and medical affairs teams and distribution capabilities, either on our own or in collaboration with others. The development of a ~~salesforce~~ **sales force** , marketing, market access, and medical affairs teams and distribution capabilities effort is expensive and time- consuming, and our expenses associated with maintaining our sales force may be disproportional compared to the revenue we may be able to generate on sales of VYJUVEK and future products. We cannot be certain that we will be able to internally develop this capability successfully. We may enter into collaborations regarding VYJUVEK or any future approved product candidates with other entities to utilize their established marketing and distribution capabilities. However, we may be unable to enter into such agreements on favorable terms, if at all. We compete with many companies that currently have extensive, experienced, and well- funded medical affairs, marketing, market access, distribution, and sales operations to recruit, hire, train and retain personnel, and we may not be able to hire or retain such talent on commercially reasonable terms, if at all. We also face competition in our search for third parties to assist us with the sales and marketing efforts. If any future collaborators do not commit sufficient resources to commercialize our product candidates, if approved, or we are unable to develop the necessary capabilities on our own, we will be unable to generate sufficient product revenue to sustain our business. Our efforts to educate the medical community and third- party payors on the benefits of VYJUVEK or our product candidates, if approved, may require significant resources and may never be successful. Such efforts may require more resources than are typically required due to the complexity and uniqueness of our products. If VYJUVEK or any of our product candidates that are approved fails to achieve market acceptance among physicians, patients, or third- party payors, we will not

be able to generate significant revenue from such product, which could have a material adverse effect on our business, financial condition, results of operations **,** and prospects. If the market opportunities for VYJUVEK or our product candidates are smaller than we believe they are, our product revenue may be adversely impacted, and our business may suffer. We focus our research and product development **primarily** on genetic medicines ~~for patients~~ **to treat diseases** with ~~debilitating diseases~~ **high unmet medical needs** . We base our market opportunity estimates on a variety of factors, including our estimates of the number of people who have these diseases, the potential scope of our approved product labels, the subset of people with these diseases who have the potential to benefit from treatment with VYJUVEK or our product candidates, various pricing scenarios, and our understanding of reimbursement policies in particular countries. These estimates are based on many assumptions and may prove incorrect, and new studies may reduce the estimated incidence or prevalence of these diseases. Estimating market opportunities can be particularly challenging for rare indications ~~, such as the ones we currently address~~ , as epidemiological data is often more limited than for more prevalent indications and can require additional assumptions to assess potential patient populations. For example, as we commercialize VYJUVEK in the United States and learn more about market dynamics and engage with regulators on additional potential marketing approvals, our view of VYJUVEK' s initial potential market opportunity will become more refined. The addressable patient population in the United States and internationally may turn out to be lower than expected, patients may not be otherwise amenable to treatment with VYJUVEK or our product candidates, if approved, or may become increasingly difficult to identify and access, all of which would adversely affect our business, financial condition, results of operations **,** and prospects. If we are unable to successfully commercialize VYJUVEK or any future product candidates with attractive market opportunities, our future product revenue may be smaller than anticipated, and our business may suffer. Further, there are several factors that could contribute to making the actual number of patients who receive VYJUVEK less than the potentially addressable market. These include the lack of widespread availability of, and limited reimbursement for, new therapies in many underdeveloped markets. Further, the severity of the progression of a disease up to the time of treatment **may** ~~will likely~~ diminish the therapeutic benefit conferred by a gene therapy due to irreversible cell damage. Lastly, certain patients' immune systems might prohibit the successful delivery of certain gene therapy products to the target tissue, thereby limiting the treatment outcomes. **In addition to determining market opportunities for our products, we need to accurately forecast demand and the timing of the demand, which is difficult. Incorrect demand estimates could adversely impact our business, financial condition, results of operations, and prospects. For example, if product demand is higher than we initially estimate, we may need to spend time and money increasing our manufacturing capabilities and / or changing our manufacturing processes. This could require greater capital expenditures than initially forecasted and potentially delay commercial availability of an approved product, which could adversely affect our business, financial condition, and results of operations.** The commercial success of VYJUVEK and our product candidates will depend upon their degree of market acceptance by physicians, patients, third- party payors, and others in the medical community. Even with the requisite approvals from the FDA in the United States, potential approvals of VYJUVEK from the EMA in the European Union **, PMDA in Japan,** and other regulatory authorities internationally (and potential approvals of any of our product candidates by regulatory authorities), the commercial success of VYJUVEK and our product candidates will depend, in part, on the acceptance of physicians, patients **,** and health care payors of gene therapy products in general, and VYJUVEK and our product candidates, in particular, as medically necessary, cost- effective, and safe. VYJUVEK and any product candidate that we commercialize may not gain acceptance by physicians, patients, health care payors **,** and others in the medical community. If these products do not achieve an adequate level of acceptance, we may not generate significant product revenue and may not become **consistently** profitable. The degree of market acceptance of gene therapy products and VYJUVEK and our product candidates, if approved for commercial sale, will depend on several factors, including: • the efficacy and safety of VYJUVEK and our product candidates as demonstrated in clinical trials; • the potential and perceived advantages of VYJUVEK and our product candidates over alternative treatments, if available; • the cost of VYJUVEK and our product candidates relative to alternative treatments if any are available; • the clinical indications for which VYJUVEK and our product candidates are approved by the FDA and other regulatory authorities; • the willingness of physicians to prescribe new therapies; • the willingness of the target patient population to try new therapies; • the prevalence and severity of any side effects; • product labeling or product insert requirements of the FDA, the EMA **, the PMDA** , or other regulatory authorities, including any limitations or warnings contained in a product' s approved labeling; • relative convenience and ease of administration; • the strength of marketing and distribution support; • the timing of market introduction of competitive products; • the availability of products and their ability to meet market demand; • publicity concerning VYJUVEK and our product candidates or competing products and treatments; • any restrictions on the use of VYJUVEK and our products together with other medications; and • favorable third- party payor coverage and adequate reimbursement. Even if a product candidate displays a favorable efficacy and safety profile in preclinical studies and clinical trials, market acceptance of the product will not be fully known until after it is launched. Government price controls or other changes in pricing regulation could restrict the amount that we are able to charge for VYJUVEK and our product candidates, if approved, which would adversely affect our revenue and results of operations. We expect that coverage and reimbursement of pharmaceuticals may be increasingly restricted both in the United States and internationally. The escalating cost of health care has led to increased pressure on the health care industry to reduce costs. Drug pricing by pharmaceutical companies recently has come under increased scrutiny and continues to be subject to intense political and public debate in the United States and abroad. Government and private third- party payors have proposed health care reforms and cost reductions. A number of federal and state proposals to control the cost of health care, including the cost of drug treatments, have been made in the United States. Specifically, there have been several recent U. S. Congressional inquiries and proposed bills designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs **,** and reform government program reimbursement methodologies for drugs. In some international markets, the government controls the pricing, which can affect the profitability of drugs. Current government regulations and

possible future legislation regarding health care may affect coverage and reimbursement for medical treatment by third- party payors, which may render VYJUVEK or our product candidates, if approved, not commercially viable or may adversely affect our anticipated future revenue and gross margins. We cannot predict the extent to which our business may be affected by ~~these~~ **proposed health care reforms and cost reductions** or ~~other~~ potential future legislative or regulatory developments. However, future price controls or other changes in pricing regulation or negative publicity related to the pricing of drugs or biologics generally could restrict the amount that we are able to charge for VYJUVEK or our product candidates, if approved, which would adversely affect our anticipated revenue and results of operations. The insurance coverage and reimbursement status of newly approved products is uncertain. Failure to obtain or maintain adequate coverage and reimbursement for VYJUVEK or our product candidates, if approved, could limit our ability to market those products and decrease our ability to generate product revenue. We expect that coverage and reimbursement by government and private payors will be essential for most patients to be able to afford our approved **genetic medicine** products. Accordingly, sales of VYJUVEK and our product candidates, if approved, will depend substantially, both domestically and abroad, on the extent to which the costs of our product or product candidates will be paid by health maintenance, managed care, pharmacy benefit **,** and similar healthcare management organizations, or will be reimbursed by government authorities, private health coverage insurers and other third- party payors. Coverage and reimbursement by a third- party payor may depend upon several factors, including the third- party payor' s determination that use of a product is: • a covered benefit under its health plan; • safe, effective, and medically necessary; • appropriate for the specific patient; • cost- effective; and • neither experimental nor investigational. Obtaining coverage and reimbursement for a product from third- party payors is a time- consuming and costly process that could require us to provide to the payor supporting scientific, clinical **,** and cost- effectiveness data. We may not be able to provide data sufficient to gain acceptance with respect to coverage and reimbursement. If coverage and reimbursement are not available, or are available only at limited levels, we may not be able to successfully commercialize our product candidates, if approved. Even if coverage is provided, the coverage may be more limited than the purposes for which the product is approved by the FDA or comparable foreign regulatory authorities. Moreover, eligibility for coverage and reimbursement does not imply that a product will be paid for in all cases or at a rate that covers our costs, including research, development, intellectual property **protection** , manufacture, sale, and distribution expenses, and therefore, the approved reimbursement amount may not be adequate to realize a sufficient return on our investment. There is significant uncertainty related to third- party coverage and reimbursement of newly approved drug products. In the United States, third- party payors, including government payors such as the Medicare and Medicaid programs, play an important role in determining the extent to which new drugs and biologics will be covered and reimbursed. The Medicare and Medicaid programs increasingly are used as models for how private payors and government payors develop their coverage and reimbursement policies. It is difficult to predict what CMS will decide with respect to coverage and reimbursement for fundamentally novel products such as ~~ours~~ **our** ~~, as there is no body of established practices and precedents for these types of products~~ **product candidates** . Moreover, reimbursement agencies in the European Union may be more conservative than CMS. For example, several cancer drugs have been approved for reimbursement in the United States and have not been approved for reimbursement in certain European Union Member States. It is difficult to predict what third- party payors will decide with respect to the coverage and reimbursement for our product candidates. Outside the United States, international operations generally are subject to extensive government price controls and other market regulations and increasing emphasis on cost- containment initiatives in the European Union and other countries may put pricing pressure on us. In many countries, the prices of medical products are subject to varying price control mechanisms as part of national health systems. It also can take a significant amount of time after approval of a product to secure pricing and reimbursement for such product in many counties outside the United States. In general, the prices of medicines under such systems are substantially lower than in the United States. Other countries allow companies to fix their own prices for medical products but monitor and control company profits. Additional foreign price controls or other changes in pricing regulation could restrict the amount that we are able to charge for our product candidates. Accordingly, in markets outside the United States, the reimbursement for our approved products may be reduced compared with the United States and may be insufficient to generate commercially reasonable product revenue. Moreover, increasing efforts by government and third- party payors in the United States and abroad to cap or reduce healthcare costs may cause such organizations to limit both coverage and the level of reimbursement for new products approved and, as a result, they may not cover or provide adequate payment for our product candidates. Payors increasingly are considering new metrics as the basis for reimbursement rates, such as Average Sales Price, Average Manufacturer Price, and Actual Acquisition Cost. The existing data for reimbursement based on some of these metrics is relatively limited, although certain states have begun to survey acquisition cost data for the purpose of setting Medicaid reimbursement rates, and CMS has begun making pharmacy National Average Drug Acquisition Cost and National Average Retail Price data publicly available on at least a monthly basis. Therefore, it may be difficult to project the impact of these evolving reimbursement metrics on the willingness of payors to cover product candidates that we are able to commercialize. We expect to experience pricing pressures in connection with the sale of any of our product candidates due to the trend toward managed healthcare, the increasing influence of health maintenance organizations, additional legislative changes, statements by elected officials, and administrative changes. The downward pressure on healthcare costs in general, particularly prescription drugs ~~and surgical procedures and other treatments~~ , has become intense. As a result, increasingly high barriers are being erected to the entry of new products such as ours. Ethical, legal, and social issues related to genetic testing may reduce demand for our product candidates, if approved. Prior to receiving VYJUVEK, patients are required to undergo genetic testing, and we anticipate that prior to receiving certain of our other product candidates, if approved, patients may be required to undergo genetic testing. Genetic testing has raised concerns regarding the appropriate utilization and the confidentiality of information provided by genetic testing. Genetic tests for assessing a person' s likelihood of developing a chronic disease have focused public attention on the need to protect the privacy of genetic information. For example, concerns have been expressed that insurance

carriers and employers may use these tests to discriminate based on genetic information, resulting in barriers to the acceptance of genetic tests by consumers. Concerns have also been raised about the accuracy of genetic testing. This could lead to governmental authorities restricting genetic testing or calling for additional regulation of genetic testing, particularly for diseases for which there is no known cure. **For example, on May 6, 2024, FDA released a final rule clarifying that in vitro diagnostic tests (IVDs) manufactured by laboratories are medical devices. If the rule withstands recent court challenges, such tests will be required to undergo premarket review and will be subject to other medical device regulations.** Any of these scenarios could decrease demand for VYJUVEK and our product candidates, if approved. Increasing demand for compassionate use or expanded access of our unapproved therapies could negatively affect our reputation and harm our business. We are developing our product candidates **principally** for illnesses for which there are currently limited to no available therapeutic options. At least one other company has been the target of disruptive social media campaigns related to a request for access to unapproved drugs for patients with significant unmet medical need. If we experience a similar social media campaign regarding our decision to provide or not provide our product candidates under an expanded access corporate policy, our reputation may be negatively affected, and our business may be harmed. ~~Recent media attention~~ **In 2018, the Right** to ~~individual~~ **Try Law was enacted, allowing eligible** patients ~~' expanded~~ **to request** access ~~requests has resulted in the introduction of legislation at the local and national level referred~~ to **certain investigation drugs** ~~as " Right to Try " laws~~, **including biologics** ~~such as the Right to Try Act~~, **that have not been FDA** ~~which are intended to give patients access to unapproved~~ -- **approved** ~~therapies~~. New and emerging legislation regarding expanded access to unapproved drugs for life-threatening illnesses could negatively impact our business in the future. A possible consequence of both activism and legislation in this area is the need for us to initiate an unanticipated expanded access program or to make our product candidates more widely available sooner than anticipated. We are a small company with limited resources and unanticipated trials or access programs could result in diversion of resources from our primary goals. In addition, some patients who receive access to unapproved drugs through compassionate use or expanded access programs have life- threatening illnesses and have exhausted all other available therapies. The risk for serious adverse events in this patient population is high which could have a negative impact on the safety profile of our product candidates if we were to provide them to these patients in accordance with our expanded access corporate policy, which could cause significant delays or an inability to successfully commercialize our product candidates, which could materially harm our business. If we were to provide patients with our product candidates under our expanded access corporate policy, we may in the future need to restructure or pause ongoing compassionate use and / or expanded access programs in order to perform the controlled clinical trials required for regulatory approval and successful commercialization of our product candidates, which could prompt adverse publicity or other disruptions related to current or potential participants in such programs. Risks Related to Our Intellectual Property If we are unable to obtain and maintain adequate United States and foreign patent protection for VYJUVEK, our current product candidates, and any future product candidates we may develop, and / or our vector platform, or if the scope of the patent protection obtained is not sufficiently broad, our competitors could develop and commercialize products and technologies similar or identical to ours, and our ability to successfully commercialize VYJUVEK, our current product candidates, any future product candidates we may develop, and our platform technologies may be adversely affected. Our success depends, in large part, on our ability to obtain and maintain patent protection in the United States and other countries with respect to our approved product, current product candidates, additional product candidates in our pipeline **,** and current and future innovations related to our vector platform. The patent prosecution process is expensive, time- consuming, and complex; we may not be able to file, prosecute, maintain, and / or enforce all necessary or desirable patent applications and issued patents at a reasonable cost or in a timely manner. Even if we are granted the patents we are currently pursuing, they may not issue in a form that will provide us with the full scope of protection we desire, they may not prevent competitors or other third parties from competing with us, and / or they may not otherwise provide us with a competitive advantage. Our competitors, or other third parties, may be able to circumvent our patents by developing similar or alternative technologies or products in a non- infringing manner. Moreover, our patent estate does not preclude third parties from having intellectual property rights that could interfere with our freedom to use our platform, including for our intended indications. Even assuming patents issue from our pending and future patent applications, changes in either the patent laws or interpretation of the patent laws in the United States and foreign jurisdictions may diminish the value of our patents or narrow their scope of protection. We also may not be aware of all third- party intellectual property rights potentially relating to technologies similar to our own. Publications of discoveries in the scientific literature often lag their actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after earliest priority date or, in some cases, not at all until patents are issued. Therefore, it is impossible to be certain that we were the first to develop the specific technologies as claimed in any owned patents or pending patent applications, or that we were the first to file for patent protection of such inventions. We may not be able to protect our intellectual property rights throughout the world. Filing, prosecuting, and defending patents on VYJUVEK, ~~each and every one of~~ our product candidates, and current and future innovations related to our vector platform, in all countries throughout the world would be prohibitively expensive, and intellectual property rights in some countries outside the United States may differ in scope from those eventually granted in the United States. Thus, in some cases, we may not have the opportunity to obtain patent protection for certain technologies in some jurisdictions outside the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, even in jurisdictions where we do pursue patent protection. Competitors may use our technologies in jurisdictions where we have not pursued and obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States. These products may compete with VYJUVEK and our product candidates that are approved, and our patents or other intellectual property rights may not be effective or sufficient to prevent

them from competing. Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets, and other intellectual property protection, particularly those relating to biotechnology products. Such challenges in enforcing rights in these countries could make it difficult for us to stop the infringement of our patents, if pursued and obtained, or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our current and future patent rights in foreign jurisdictions could result in substantial costs and may divert our efforts and attention from other aspects of our business; could put our patents at risk of being invalidated or interpreted narrowly; could put any future patent applications, including continuation and divisional applications, at risk of not issuing; and could provoke third parties to assert claims against us. We may not prevail in any lawsuits, and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce any intellectual property rights around the world stemming from intellectual property that we develop may be inadequate to obtain a significant commercial advantage in these foreign jurisdictions. Third parties may initiate legal proceedings alleging that we are infringing their intellectual property rights, the outcome of which would be uncertain and could have a material adverse effect on the success of our business. Our commercial success depends upon our ability (and the ability of any potential future collaborators) to market and sell VYJUVEK and to develop, manufacture, market , and sell our product candidates, and to freely use our proprietary technologies without infringing the rights and intellectual property of others. Many companies and institutions have filed, and continue to file, patent applications related to various aspects of gene therapy. Because patent applications can take many years to issue, may be confidential for 18 months or more after filing, and can be revised before issuance, there may be applications now pending which may later result in issued patents that a third- party asserts are infringed by the manufacture, use, sale, or importation of VYJUVEK or any of our product candidates, if approved. The biotechnology and pharmaceutical industries are characterized by extensive and complex litigation regarding patents and other intellectual property rights. We may become party to, or be threatened with, adversarial proceedings or litigation regarding intellectual property rights with respect to VYJUVEK ~~or~~ , our product candidates , or related technologies, including, for example, interference proceedings, post grant review challenges, and inter partes review before The United States Patent and Trademark Office. Our competitors or other third parties may assert infringement claims against us, alleging that our products, manufacturing methods, formulations or administration methods are covered by their patents. Moreover, we may face patent infringement claims from non- practicing entities that have no relevant product revenue, and against whom our patent portfolio may therefore have no deterrent effect. There is a risk that third parties may choose to engage in litigation with us to enforce or to otherwise assert their patents or other intellectual property rights against us. Even if we believe such claims are without merit, a court of competent jurisdiction could hold that these third- party patents are valid, enforceable, and infringed, which could materially and adversely affect our ability to commercialize VYJUVEK or any of our product candidates, if approved. In order to successfully challenge the validity of any such U. S. patent in federal court, we would need to overcome a presumption of validity. As this burden is a high one requiring us to present clear and convincing evidence as to the invalidity of any such U. S. patent claim, there is no assurance that a court of competent jurisdiction would invalidate the claims of any such U. S. patent. In such a hypothetical situation, there is no assurance that a court of competent jurisdiction would find that our product, product candidates , or technologies do not infringe a third- party patent. Patent and other types of intellectual property litigation can involve complex factual and legal questions, and their outcomes are uncertain. If we are found, or believe there is a risk that we may be found, to infringe a third- party' s valid and enforceable intellectual property rights, we could be required (or may choose) to obtain a license from such a third- party to continue developing, manufacturing and marketing our approved product, product candidates , and technologies. However, we may not be able to obtain any required license on commercially reasonable terms, if at all. Even if we were able to obtain a license, it could be non- exclusive, thereby giving our competitors and other third parties access to the same technologies licensed to us, and further, it could require us to make substantial licensing and royalty payments. We could be forced, including by court order, to cease developing, manufacturing, and commercializing the infringing product or technologies. We also could be found liable for monetary damages, including treble damages and attorneys' fees, if we are found to have willfully infringed a patent or other intellectual property right. A finding of infringement could prevent us from manufacturing and commercializing our products and technologies or force us to cease some or all our business operations. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on our business, financial condition, results of operations , and prospects. Intellectual property litigation could cause us to spend substantial resources and distract our personnel from their normal responsibilities. Litigation or other legal proceedings relating to intellectual property claims, with or without merit, is unpredictable and generally expensive and time consuming. Competitors may infringe our current or future patents, should such patents issue, or we may be required to defend against claims of infringement or other unauthorized use of intellectual property. 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 scientific and management personnel from their normal responsibilities. 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. 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 and adversely impact our financial results 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 adequately conduct such litigation or proceedings. 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. Accordingly, despite our efforts, we may not be able to prevent third parties from infringing, misappropriating, or successfully challenging our intellectual property rights. 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. We have been subject to claims asserting that we, our employees , or our advisors have wrongfully used or disclosed alleged trade secrets of other parties, and we may face such claims in the future or claims asserting ownership of what we regard as our own intellectual property. Certain of our employees or advisors are currently, or were previously, employed at universities or other biotechnology or pharmaceutical companies, including potential competitors, and we have and may in the future enter into agreements providing us with rights to intellectual property of third parties for limited purposes. Although we endeavor to observe the terms of agreements under which we obtain access to third- party intellectual property and to ensure that our employees 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 these individuals, or we, have used or disclosed intellectual property, including trade secrets or other proprietary information, of third parties or the current or former employers of employees or advisors. For instance, as described in Note 7 of the Notes to ~~the~~ Consolidated Financial Statements included in Part II, Item 8 of this Annual Report on Form 10- K, in April of 2022, we entered into a settlement agreement with PeriphaGen, Inc., which had alleged breach of contract and misappropriation of trade secrets. If we fail to successfully defend any such claims, in addition to paying monetary damages, we may be subject to an injunction and may lose valuable intellectual property rights or personnel. Moreover, any such litigation, or the threat thereof, may adversely affect our ability to hire new employees or contract with independent contractors. A loss of key personnel or their work product could hamper or prevent our ability to commercialize VYJUVEK or our product candidates, which could have an adverse effect on our business, results of operations, and financial condition. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management. While it is our policy to require our employees and contractors who may be involved in the conception of intellectual property to execute agreements assigning such intellectual property rights to us, unforeseen complications may arise when fully and adequately executing such an agreement with each party who, in fact, conceives of intellectual property that we regard as our own. Examples of such complications may include, for example, when we obtain agreements assigning intellectual property to us, the assignment of intellectual property rights may not be self- executing, or the assignment agreements may be breached. Such complications may lead to us being forced to bring claims against third parties or current and former employees, or defend claims that they may bring against us, to determine the ownership of what we regard as our intellectual property. Moreover, individuals executing agreements with us may have preexisting or competing obligations to a third- party, such as an academic institution, and thus an agreement with us may be insufficient in fully perfecting ownership of inventions developed by that individual. Disputes about the ownership of intellectual property may have a material adverse effect on our business. Changes in U. S. patent law could diminish the value of patents in general, thereby impairing our ability to protect VYJUVEK or our product candidates. Patent reform legislation could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. For example, in September 2011, the Leahy- Smith America Invents Act, or the Leahy- Smith Act, was signed into law. The Leahy- Smith Act included several significant changes to U. S. patent law, including provisions that affected the way patent applications are prosecuted, and altered strategies regarding patent litigation. These provisions also switched the United States from a " first- to- invent " system to a " first- to- file " system, allowed third- party submissions of prior art to the United States Patent and Trademark Office (" USPTO ") during patent prosecution, and set forth additional procedures to attack the validity of a patent through various post grant proceedings administered by the USPTO. As patent reform legislation can inject serious uncertainty into the patent prosecution and litigation processes, it is not clear what impact future patent reform legislation will have on the operation of our business. However, such future legislation, and its implementation, could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of any issued patents, all of which could have a material adverse effect on our business, financial condition, results of operations , and prospects. Moreover, the patent positions of companies engaged in the development and commercialization of biologics and pharmaceuticals are particularly uncertain given the ever evolving and constantly shifting nature of precedential patent cases decided by both the U. S. Court of Appeals for the Federal Circuit and the U. S. Supreme Court. We cannot assure you that our efforts to seek patent protection for our technology and product candidates will not be negatively impacted by future court decisions or changes in guidance or procedures issued by the USPTO. These decisions, and any guidance issued by the USPTO (or changes thereto), could have a material adverse effect on our existing patent portfolio and our ability to protect and enforce our intellectual property rights in the future. 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. Although we have registered certain of our trademarks and trade names, they may be challenged, infringed, circumvented, or declared generic or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names, which are important for building name recognition among potential partners or customers in our markets of interest. At times, competitors may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. There also could be potential trade name or trademark infringement claims brought by owners of other registered trademarks or trade names that incorporate variations of our registered or unregistered trademarks or trade names. 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 patents, trademarks, trade secrets, domain names, copyrights or other intellectual property may be ineffective and could result in substantial costs and diversion of resources and could adversely impact our financial condition or results of operations. Intellectual property rights and regulatory exclusivity rights do not necessarily address all potential threats. The degree of current and 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 gene therapy products that are similar to our approved product or any of our product candidates but that are not covered by the claims of our current

patents, or of patents that we may own or license in the future; • we, or any future license partners or collaborators, might not have been the first to file patent applications covering certain aspects of the concerned technologies; • others may independently develop similar or alternative technologies, or duplicate any of our technologies, potentially without falling within the scope of our current or future issued claims, thus not infringing our intellectual property rights; • it is possible that our filed or future patent applications will not lead to issued patents; • issued patents to which we currently hold rights or to which we may hold rights in the future may be held invalid or unenforceable, including as a result of legal challenges by third parties or our competitors; • others may have access to any future intellectual property rights licensed to us on a non- exclusive basis; • our competitors might conduct research and development activities in countries where we do not have or pursue patent rights, and then use the information learned from such activities to develop competitive products for sale in our major commercial markets; • we may not develop additional proprietary technologies that are patentable; • the patents or other intellectual property rights of others may have an adverse effect on our business; and • we may choose not to file a patent application covering certain of our trade secrets or know- how, and a third- party may subsequently file a patent covering such intellectual property. Should any of these events occur, they could significantly harm our business, financial condition, results of operations **,** and prospects. Risks Related to Our Financial Position and Need for Additional Capital We have incurred net losses in the past and may not sustain profitability. Although we generated net income ~~for~~ **starting with** the year ended December 31, 2023, we **previously** ~~have otherwise~~ incurred recurring losses and negative cash flows from operations since **our** inception. Our transition to **consistent** operating profitability depends on our ability to (i) successfully commercialize VYJUVEK in the **United States** ~~U. S.~~ and obtain the necessary regulatory approvals to commercialize VYJUVEK outside of the **United States** ~~U. S.~~ and then successfully commercialize VYJUVEK outside the **United States** ~~U. S.~~, and (ii) complete the development of, and obtain the regulatory approvals necessary to successfully commercialize our product candidates with significant market potential. We have devoted substantially all our efforts to date to (i) research and development of our gene therapy platform, product candidates and our manufacturing infrastructure, and, more recently, (ii) commercializing VYJUVEK in the **United States** ~~U. S~~. We expect to continue to incur significant expenses for the foreseeable future and our operating results may fluctuate significantly from quarter to quarter. We anticipate that our expenses will increase substantially if, and as, we: • manufacture, market **,** and sell our lead product, VYJUVEK, in the **United States** ~~U. S.~~ and prepare for regulatory approvals outside of the **United States** ~~U. S.~~ and if such approvals are received, commercialize VYJUVEK in those geographies; • continue our research, preclinical studies, and the clinical development of our current product candidates, including our current clinical trials and planned clinical trials; • initiate preclinical studies and clinical trials for any additional product candidates that we may pursue in the future; • prepare for regulatory approvals for our product candidates in the United States, EU and in other key geographies; • continue to operate our in- house commercial- scale ~~current good manufacturing practice, or~~ CGMP ~~,~~ manufacturing facilities, ANCORIS and ASTRA **, and as we seek to obtain FDA approval for commercial manufacture of VYJUVEK at ASTRA, which approval may not be granted** ; • manufacture material for commercial sales of VYJUVEK and clinical trials or potential commercial sales of our product candidates; • further develop our gene therapy platform; • further establish our sales, marketing **,** and distribution infrastructure to commercialize VYJUVEK and product candidates for which we may obtain marketing approval; • develop, maintain, expand **,** and protect our intellectual property portfolio; and • acquire or in- license other product candidates and technologies. To remain profitable, we must be successful in a range of challenging activities, including designing, initiating, and completing clinical trials for our product candidates, developing, validating, and maintaining commercial scale manufacturing processes, obtaining marketing approvals, manufacturing, marketing, and selling VYJUVEK and any product candidates for which we may obtain marketing approval, and satisfying any post- marketing requirements. If we were required to discontinue development of any of our product candidates, if VYJUVEK does not receive regulatory approvals outside the **United States** ~~U. S.~~, or any of our product candidates do not receive regulatory approvals, or if VYJUVEK or any of our product candidates, if approved, fails to achieve sufficient market acceptance for any indication, our ability to remain profitable ~~,~~ **and** our business prospects and financial condition could be materially adversely affected. Moreover, if we decide to leverage any success with VYJUVEK or any of our current product candidates to develop other product opportunities, we may not be successful in such efforts. In any such event, our business may be materially adversely affected. We currently have one product, VYJUVEK, approved by the FDA and several product candidates in the clinical trials stages. However, we may never develop, acquire or in- license additional product candidates. We may never generate revenue from any of our product candidates. We may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to remain profitable would decrease the value of our company and could impair our ability to raise capital, maintain our research and development efforts, expand our business, or continue our operations. A decline in the value of our company also could cause stockholders to lose all or part of their investment. Because of the numerous risks and uncertainties associated with pharmaceutical product and biological development, we are unable to accurately predict the timing or amount of increased expenses. If we are required by the FDA, the EMA, **the PMDA,** or other regulatory authorities to perform studies in addition to those currently expected, or if there are any delays in completing our clinical trials or the development of our product candidates, our expenses could increase and potential revenue from product candidates in development could be delayed. We may need to raise additional funding to maintain and expand our commercialization capabilities ~~for VYJUVEK~~ and to complete the development of, and obtain the regulatory approvals necessary to, commercialize our product candidates. Such funding may not be available on acceptable terms, or at all. Failure to obtain this necessary capital when needed may force us to delay, limit **,** or terminate certain of our product development efforts or other operations. To complete the process of obtaining regulatory approval for our product candidates and to continue building the manufacturing, sales, marketing, and distribution infrastructure that we believe is or will be necessary to successfully commercialize VYJUVEK and ~~commercialize~~ our product candidates, if approved, we may require substantial additional funding. We expect to continue to incur significant expenses related to sales, medical affairs, marketing, manufacturing, and distribution of VYJUVEK **in the United States and abroad** . In addition, if we obtain marketing approval

for our product candidates, we expect to incur significant additional expenses related to product sales, medical affairs, marketing, manufacturing , and distribution. We may need additional funding to complete the development of our product candidates and to commercialize any such approved products. Our future capital requirements will depend on many factors, including: • the ability of VYJUVEK to generate sufficient revenue; • the costs of product sales, medical affairs, marketing, manufacturing, and distribution for VYJUVEK; • the outcome, timing and costs of seeking regulatory approvals for VYJUVEK outside the **United States** ~~U. S.; • the progress, timing, results, and costs of any clinical trials required for VYJUVEK outside the U. S.~~; • the progress, timing, results, and costs of our current and planned clinical trials ~~of B- VEC (in Japan), KB105, KB301, KB407, KB707, and KB408~~ ; • the continued development and the filing of IND applications for **our** ~~KB104 and other~~ product candidates; • the initiation, scope, progress, timing, costs and results of drug discovery, laboratory testing, manufacturing, preclinical studies, and clinical trials for any product candidates that we may pursue in the future; • the costs of maintaining our own commercial- scale CGMP manufacturing facilities; • the outcome, timing, and costs of seeking regulatory approvals for any of our product candidates; • the costs associated with the manufacturing process development and evaluation of third- party suppliers or manufacturers, if necessary; • the costs of future activities, including product sales, medical affairs, marketing, manufacturing, and distribution, in the event we receive marketing approval for any of our current and future product candidates; • the extent to which the costs of our product candidates, if approved, will be paid by health maintenance, managed care, pharmacy benefit , and similar healthcare management organizations, or will be reimbursed by government authorities, private health coverage insurers , and other third- party payors; • subject to receipt of marketing approval, if any, revenue received from commercial sale of our current and future product candidates; • the terms and timing of any current or future collaborations, distribution, licensing, consulting, or other arrangements; • the amount and timing of any payments we may be required to make, or that we may receive, in connection with the licensing, filing, prosecution, maintenance, defense , and enforcement of any patents or other intellectual property rights, including milestone and royalty payments and patent prosecution fees that we are obligated to pay pursuant to our license agreements, if any; • the terms of our license agreements, if any, and our achievement of milestones under those agreements; • our ability to establish and maintain collaborations and licenses on favorable terms, if at all; and • the extent to which we acquire or in- license other product candidates and technologies. Identifying product candidates and conducting preclinical testing 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 marketing approval and achieve product sales for our product candidates in development or future product candidates. Revenue will be derived from VYJUVEK until we have another product candidate receive marketing approval. Accordingly, we may need to continue to rely on additional financing to achieve our business objectives. Any additional fundraising efforts may divert our management from their day- to- day activities, which may adversely affect our ability to develop and commercialize our product candidates. Moreover, the terms of any financing may adversely affect the holdings or the rights of our stockholders and the issuance of additional securities, whether equity or debt, by us, or the possibility of such issuance, may cause the market price of our ~~shares~~ **common stock** to decline. The sale of additional equity or convertible securities would dilute all **of** our **existing** stockholders. Existing stockholders may not agree with our financing plans or the terms of such financings. Adequate additional financing may not be available to us on acceptable terms, or at all. The terms of additional financing may be impacted by, among other things, general market conditions, the market' s perception of our approved product, VYJUVEK, and product candidates, our growth potential, and the market price per share of our common stock. See " Raising additional capital could cause the price of our common stock to decline and cause dilution to our stockholders, restrict our operations or require us to relinquish rights. " **Failure to obtain necessary capital when needed could force us to delay, limit, or terminate certain of our product development efforts or other operations, which could significantly harm our business, financial condition, results of operations, and prospects.** Changes in tax law may adversely affect our business and financial condition We are subject to evolving and complex tax laws in the **United States** ~~U. S.~~ and the foreign jurisdictions in which we operate. New income, sales, use or other tax laws, statutes, rules, regulations, or ordinances could be enacted at any time, or interpreted, changed, modified, or applied adversely to us, any of which could adversely affect our business operations and financial performance. Changes to tax laws (which could apply retroactively) could adversely affect us and our stockholders. In recent years, such changes have been made and changes are likely to occur in the future, which could have a material adverse effect on our business, cash flow, financial condition, and results of operations. Our ability to use our net operating loss carryforwards and certain tax credit carryforwards may be subject to limitation. We have U. S. federal and state net operating loss carryforwards, which are available to reduce future taxable income. Federal net operating loss carryforwards generated in tax years beginning after December 31, 2017 may be carried forward indefinitely but are limited to offset 80 % of taxable income in any tax year. ~~Our other~~ **All of our remaining** federal net operating loss carryforwards ~~and our~~ **may be carried forward indefinitely. Our** state net operating loss carryforwards expire beginning in 2037. We also have federal research and development tax credits which may be used to offset future tax liabilities and expire beginning in 2039. We also have federal orphan drug tax credits which may be used to offset future tax liabilities, which expire beginning in 2039. Under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, changes in our ownership may limit the amount of our net operating loss carryforwards and tax credit carryforwards that could be utilized annually to offset our future taxable income. This limitation would generally apply in the event of a cumulative change in ownership of our company of more than 50 % within a three- year period. Any such limitation may significantly reduce our ability to utilize our net operating loss carryforwards and tax credit carryforwards before they expire ~~. Private placements and other transactions that have occurred since our inception, as well as our initial public offering, may trigger such an~~ **and** ~~ownership change pursuant to Sections 382 and 383. Any such limitation, whether as the result of the initial public offering, prior private placements, sales of our common stock by our existing stockholders or additional sales of our common stock by us,~~ could have a material adverse effect on our results of operations in future years ~~. Our limited operating history may make it difficult for you to evaluate the success of our business to date and to assess our~~

~~future viability. We commenced operations in 2016. Our efforts to date have been primarily related to organizing and staffing our company, business planning, raising capital, developing our vector platform and related technologies, identifying potential gene therapy product candidates, undertaking preclinical studies and clinical trials, scaling our manufacturing capabilities, obtaining FDA approval for VYJUVEK, and commercializing VYJUVEK. Consequently, any predictions you make about our future success, performance or viability may not be as accurate as they could be if we had more experience developing and commercializing gene therapy products. We expect our financial condition and operating results to continue to fluctuate from quarter to quarter and year to year due to a variety of factors, many of which are beyond our control. We are transitioning from a company with a research and development focus to a company undertaking commercial activities. We may encounter unforeseen expenses, difficulties, complications and delays and may not be successful in such a transition. Accordingly, you should not rely upon the results of any particular quarterly or annual period as indications of future operating performance~~ . Risks Related to Ownership of Our Common Stock Our Chief Executive Officer and Chairman of the Board of Directors and our Founder, President, Research & Development and Director will have the ability to substantially influence all matters submitted to stockholders for approval. ~~As of December 31, 2023,~~ Krish S. Krishnan and Suma M. Krishnan, our Chief Executive Officer and Chairman of the Board and our Founder, President, Research & Development and Director, respectively, in the aggregate, beneficially ~~owned~~ -- **own over 10** ~~shares representing approximately 14~~ % of our outstanding common stock. As a result, they will be able to substantially influence all matters submitted to our stockholders for approval, as well as our management and affairs. For example, these persons would substantially influence the election of directors and approval of any merger, consolidation, or sale of all or substantially all our assets. This concentration of voting power could delay or prevent an acquisition of our company on terms that other stockholders may desire or result in management of our company that our public stockholders disagree with. If securities analysts publish negative evaluations of our stock, the price of our stock could decline. The trading market for our common stock relies in part on the research and reports that industry or financial analysts publish about us or our business. If securities analysts covering our business downgrade their evaluations of our stock, the price of our stock could decline. If one or more of these analysts cease to cover our stock, we could lose visibility in the market for our stock, which in turn could cause our stock price to decline. **Raising additional capital could cause the price of our common stock to decline and cause dilution to our stockholders, restrict our operations, or require us to relinquish rights.** Until such time ~~, if ever,~~ as we can generate substantial and consistent product revenue, we ~~expect~~ **may need** to finance our cash needs through a combination of private and public equity offerings, debt financings, collaborations, strategic alliances, and licensing arrangements. We may issue additional common stock or restricted securities as part of such financing activities and any such issuances may have a dilutive effect on our then- existing stockholders. Sales of substantial amounts of our common stock in the open market, or the availability of such shares for sale, could adversely affect the price of our common stock. The incurrence of indebtedness would result in fixed payment obligations and a portion of our operating cash flows, if any, being dedicated to the payment of principal and interest on such indebtedness, and we may be required to agree to certain restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire, sell **,** or license intellectual property rights **,** and other operating restrictions that could adversely impact our ability to conduct our business. If we are unable to raise additional funds through equity or debt financings when needed, and instead raise additional capital through marketing and distribution agreements or other collaborations, strategic alliances, or licensing arrangements with third parties, we may have to relinquish certain valuable rights to our current and future product candidates, technologies, future revenue streams **,** or discovery programs or grant licenses on terms that may not be favorable to us. The price of our common stock may be volatile and fluctuate substantially, which could result in substantial losses for holders of our common stock. The price of our common stock has been and is likely to continue to be volatile. The stock market in general and the market for biopharmaceutical or pharmaceutical companies specifically has experienced extreme volatility that has often been unrelated to the operating performance of such companies. As a result of this volatility, a stockholder may not be able to sell their common stock at or above the price that they paid for it. The market price of our common stock may be influenced by many factors, including: • our ability to successfully commercialize VYJUVEK; • our ability to successfully proceed to and conduct clinical trials; • results of clinical trials of our product candidates or those of our competitors; • our ability to obtain regulatory approval for our product candidates and our ability to successfully commercialize any of our approved product candidates; • the success of competitive products or technologies; • commencement or termination of collaborations; • regulatory or legal developments in the United States and other countries; • the recruitment or departure of key personnel; • the level of expenses related to VYJUVEK or any of our product candidates or clinical development programs; • the results of our efforts to discover, develop, acquire **,** or in- license additional product candidates; • actual or anticipated changes in estimates as to financial results, development timelines **,** or recommendations by securities analysts; • our inability to manufacture adequate product supply for VYJUVEK and any other approved product or inability to do so at acceptable prices; • disputes or other developments relating to proprietary rights, including patent applications, and issued patents; • our ability to obtain patent protection for our product candidates and technologies; • significant lawsuits, including patent or stockholder litigation; • variations in our financial results or those of companies that are perceived to be similar to us; • changes in the structure of healthcare payment systems; • market conditions in the pharmaceutical and biotechnology sectors; • general economic, industry **,** and market conditions; and • the other factors described in this " Risk Factors " section. If we fail to maintain effective internal control over financial reporting, we may not be able to accurately report our financial results, which may adversely affect investor confidence in our company and, as a result, the value of our common stock. Our management is responsible for establishing and maintaining adequate internal control over financial reporting and is required to have an independent auditor assess the effectiveness of our internal control over financial reporting, pursuant to Section 404 of the Sarbanes- Oxley Act of 2002, as amended (the " Sarbanes- Oxley Act "). We cannot give any assurances that material weaknesses will not be identified in the future in connection with our compliance with the provisions of Section 404 of the Sarbanes- Oxley Act. The existence of any material weakness would preclude a conclusion by

management and our independent auditors that we maintained effective internal control over financial reporting. Our management may be required to devote significant time and expense to remediate any material weaknesses that may be discovered and may not be able to remediate any material weakness in a timely manner. The existence of any material weakness in our internal control over financial reporting could also result in errors in our financial statements that could require us to restate our financial statements, cause us to fail to meet our reporting obligations **,** and cause investors to lose confidence in our reported financial information, all of which could lead to a decline in the market price of our common stock. Provisions in our corporate charter documents and under Delaware law could make an acquisition of us, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove our current management. Provisions in our corporate charter and our bylaws may discourage, delay, or prevent a merger, acquisition, or other change in control of us that stockholders may consider favorable, including transactions in which stockholders might otherwise receive a premium for their shares. These provisions also could limit the price that investors might be willing to pay in the future for shares of our common stock, thereby depressing the market price of our common stock. In addition, because our board of directors is responsible for appointing the members of our management team, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors. Among other things, these provisions: • establish a classified board of directors such that not all members of the board are elected at one time; • allow the authorized number of our directors to be changed only by resolution of our board of directors; • limit the manner in which stockholders can remove directors from the board; • establish advance notice requirements for stockholder proposals that can be acted on at stockholder meetings and nominations to our board of directors; • require that stockholder actions must be effected at a duly called stockholder meeting and prohibit actions by our stockholders by written consent; • limit who may call stockholder meetings; • authorize our board of directors to issue preferred stock without stockholder approval, which could be used to institute a stockholder rights plan, or so- called " poison pill, " that would work to dilute the stock ownership of a potential hostile acquirer, effectively preventing acquisitions that have not been approved by our board of directors; and • require the approval of the holders of at least 80 % of the votes that all our stockholders would be entitled to cast to amend or repeal certain provisions of our bylaws. Moreover, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which prohibits a person who owns in excess of 15 % of our outstanding voting stock from merging or combining with us for a period of three years after the date of the transaction in which the person acquired in excess of 15 % of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner. We have broad discretion in the use of our cash, cash equivalents **,** and marketable securities and may not use them effectively. Our management has broad discretion in the application of our cash, cash equivalents **,** and marketable securities and could spend these funds in ways that do not improve our results of operations or enhance the value of our common stock. The failure by our management to apply these funds effectively could result in financial losses that could have a material adverse effect on our business, cause the price of our common stock to decline **,** and delay the development of our product candidates. Pending their use, we may invest our cash and cash equivalents in a manner that does not produce income or that loses value. Because we do not anticipate paying any cash dividends on our common stock in the foreseeable future, capital appreciation, if any, will be stockholders' sole source of gain. We have never declared or paid cash dividends on our common stock ~~. We currently intend to retain all our future earnings to finance the growth and development of our business~~ . In addition, the terms of any future debt agreements may preclude us from paying dividends. As a result, capital appreciation, if any, of our common stock will be stockholders' sole source of gain for the foreseeable future. Issuing additional shares of our common stock could cause the price of our common stock to decline and cause dilution to our stockholders. To the extent we raise additional capital by issuing additional shares of our common stock, or securities convertible into or exchangeable or exercisable for common stock, our existing stockholders may experience substantial dilution. Additionally, if we issue additional shares of our common stock or instruments convertible into our common stock, the trading price of our common stock could decline. We cannot predict whether we will raise additional capital by issuing shares of our common stock, or securities convertible into or exchangeable or exercisable for common stock, the size of any future issuances, or the effect, if any, that they may have on the market price for our common stock. We also have stock options, restricted common stock, restricted stock units, and performance **- based restricted** stock units outstanding, and we expect to issue additional equity awards to directors and employees. The issuance of restricted common stock, common stock upon exercise of outstanding options, common stock upon vesting of restricted stock units, or common stock upon vesting of performance **- based restricted** stock units would be dilutive and may cause the market price for our common stock to decline. If we issue preferred stock in the future, the holders of that preferred stock could gain rights superior to our existing stockholders, such as liquidation and other preferences, or the market price of our common stock could be adversely affected.