Risk Factors Comparison 2024-03-14 to 2023-03-20 Form: 10-K

Legend: **New Text** ~~Removed Text~~ Unchanged Text Moved Text Section

Risks Related to our Business and Industry **We will require substantial additional capital to fund our operations and execute our business strategy, and we may not be able to raise adequate capital on a timely basis, on favorable terms, or at all. Based on our current financial condition and forecasts of available cash, we will not have sufficient capital to fund our operations for the 12 months following the issuance date of the accompanying consolidated financial statements. We can provide no assurance that we will be able to obtain additional capital when needed, on favorable terms, or at all. If we cannot raise capital when needed, on favorable terms or at all, we will need to reevaluate our planned operations and may need to reduce expenses, file for bankruptcy, reorganize, merge with another entity, or cease operations. If we become unable to continue as a going concern, we may have to liquidate our assets, and might realize significantly less than the values at which they are carried on our financial statements, and stockholders may lose all or part of their investment in our common stock. Our future funding requirements, both near- and long- term, will depend on many factors, including, but not limited to: ● our ability to enter into strategic partnerships to deploy our mRNA technology platform, and the terms of such strategic partnerships, including the economic terms and the proceeds we receive, if any, thereunder; ● the pace and success of our potential strategic partners in developing and commercializing their product candidates and / or products that deploy our mRNA technology platform and the proceeds to us, if any, as a result; ● the cost of filing, prosecuting, defending and enforcing our patent claims and other intellectual property rights; ● the cost of defending potential intellectual property disputes, including patent infringement actions brought by third parties against us or any of our potential strategic partners or collaborators; and ● the effect of competing market developments. We may seek to raise additional capital through a variety of means, including through equity, equity- linked or debt securities offerings, collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties. Our past success in raising capital through equity and convertible note offerings should not be viewed as an indication we will be successful in raising capital through those or any other means in the future. We expect that our ability to raise additional capital and the amount of capital available to us will depend not only on progress we make toward entering into strategic partnerships to deploy our mRNA technology platform and the terms thereof, but also on factors outside of our control, such as the pace and success of our potential strategic partners in developing and commercializing their product candidates and / or products that deploy our mRNA technology platform and the proceeds to us, if any, as a result, macroeconomic and financial market conditions. To the extent that we raise additional capital by issuing equity or equity- linked securities, existing stockholder ownership may experience substantial dilution, and the securities may include preferred shares with liquidation or other preferences that could harm the rights of a common stockholder. Servicing the interest and principal repayment obligations under our outstanding convertible notes and under any other debt we incur will divert funds that might otherwise be available to support our operations. In addition, debt financing involves covenants that restrict our ability to operate our business. To the extent we raise additional capital through arrangements with third parties, such arrangements would likely require us to relinquish valuable rights to our technologies or grant licenses on terms that may not be favorable to us. Unstable and unfavorable market and economic conditions may harm our ability to raise additional capital. An economic downturn, recession or recessionary concerns, increased inflation, rising interest rates, adverse developments affecting financial institutions or the financial services industry, or the occurrence or continued occurrence of events similar to those in recent years, such as the COVID- 19 pandemic or other public health emergencies, geopolitical conflict, natural / environmental disasters, terrorist attacks, strained relations between the U. S. and a number of other countries, social and political discord and unrest in the U. S. and other countries, and government shutdowns, among others, increase market volatility and have long- term adverse effects on the U. S. and global economies and financial markets. Volatility and deterioration in the financial markets and liquidity constraints or other adverse developments affecting financial institutions may make equity or debt financings more difficult, more costly or more dilutive and may increase competition for, or limit the availability of, funding from other third- party sources, such as from strategic collaborations. We cannot be certain that additional capital will be available on acceptable terms, or at all. If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may have to significantly delay, scale back or discontinue our business activities, or potentially discontinue operations altogether. In addition, attempting to secure additional capital may divert the time and attention of our management from day- to- day activities and harm its ability to execute on our business strategy. We have a limited operating history, have incurred significant losses since our inception and expect to continue to incur losses for the foreseeable future, which, together with our limited financial resources and substantial capital requirements, make it difficult to assess our prospects. We have a limited operating history upon which to evaluate our business and prospects. We were formed in September 2018, for the purpose of consummating a business combination with IRX Therapeutics, Inc., which business combination was consummated in November 2018. Since inception, we have incurred significant net losses. As of December 31, 2023, we had an accumulated deficit of approximately $ 187. 0 million. Since inception, we have primarily financed our operations by raising capital through the sale of shares of our common stock, warrants to purchase shares of our common stock and convertible notes. We have not been profitable since we commenced operations and may never achieve profitability. We devoted significant resources to the development of our former product candidate, IRX- 2, and in 2022 we determined to cease the development of IRX- 2.**

Our near- term focus is now on entering into strategic partnerships to deploy our mRNA technology platform. As discussed above, we must raise additional capital to finance our operations and remain a going concern and adequate additional capital may not be available to us on a timely basis, or at all. We depend substantially, and expect in the future to continue to depend, on in- licensed intellectual property. Such licenses impose obligations on our business, and if we fail to comply with those obligations, we could lose license rights, which would substantially harm our business. We **rely** ~~are dependent~~ on patents, know- how and proprietary technology licensed from Factor Limited under the ~~Exclusive~~ **A & R** Factor License Agreement. We may in the future become party to additional license agreements pursuant to which we in- license key intellectual property ~~for the development of therapeutics products both through strategic partnerships and internally. We are party to the Exclusive Factor License Agreement with Factor Limited, pursuant to which we acquired our mRNA technology platform~~. The ~~Exclusive~~ **A & R** Factor License Agreement imposes various sublicense fees and other obligations on us. For example, we are obligated to pay the expenses incurred by Factor Limited in preparing, filing, prosecuting and maintaining the Factor Patents and **have** agreed to bear all costs and expenses associated with enforcing and defending the Factor Patents in any action or proceeding arising from pursuit of sublicensing opportunities under the license granted under the ~~Exclusive~~ **A & R** Factor License Agreement. Factor Limited has customary termination rights under the ~~Exclusive~~ **A & R** Factor License Agreement, including in connection with certain uncured material breaches of the ~~Exclusive~~ **A & R** Factor License Agreement and specified bankruptcy events. Any termination of our existing or future licenses could result in the loss of significant rights and would harm our business significantly. Disputes may also arise between us and our licensors regarding intellectual property subject to a license agreement, including: • the scope of rights granted under the license agreement and other interpretation- related issues; • whether and the extent to which our technology and processes infringe intellectual property of the licensor that is not subject to the licensing agreement; • our right to sublicense patents and other intellectual property to third parties under the license agreement; **• our diligence obligations under the agreement and what activities satisfy those diligence obligations; • the priority of invention of patented technology;** and • the ownership of inventions and know- how resulting from any joint creation or use of intellectual property by our licensors and us or our partners. If disputes over intellectual property that we have licensed, or license in the future, prevent or impair our ability to maintain our current licensing arrangements on acceptable terms, we may be unable to successfully enter into strategic partnerships ~~or develop therapeutic products~~. In addition, the resolution of any such disputes could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology, or increase what we believe to be our financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, financial condition, results of operations, and prospects. Additionally, we may have limited control over the maintenance, prosecution or enforcement of rights we in- license, and we may also have limited control over activities previously or separately conducted by our licensors. For example, we cannot be certain that activities conducted by Factor Limited or any other present or future licensors have been or will be conducted in compliance with applicable laws and regulations or will result in valid and enforceable patents and other intellectual property rights. We may also have limited control over other intellectual property that is not licensed to us but that may be related to our in- licensed intellectual property. We may have limited control over the manner in which our licensors initiate an infringement proceeding against a third- party infringer or the intellectual property or defend certain of the intellectual property that is licensed to us. It is possible that the licensors' infringement proceedings or defense activities may be less vigorous than had we conducted them ourselves. **If we are unable to successfully obtain rights to required third- party intellectual property rights or maintain the existing intellectual property rights we have, we may have to abandon development of the relevant program or drug candidate and our business, financial condition, results of operations and prospects could suffer.** We are generally also subject to all of the same risks with respect to protection of intellectual property that we own, as we are for intellectual property that we license. If we or our licensors fail to adequately protect the intellectual property underlying our mRNA technology platform and any other in- licensed intellectual property, our ability to enter into strategic partnerships ~~or develop and commercialize therapeutic products~~ could materially suffer. ~~We~~ **Our intellectual property rights** may not ~~realize the benefits~~ **adequately protect our business. The degree** of ~~strategic~~ **future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations and may not adequately protect our business. For example: • we, or our license** ~~partnerships~~ **partners or current or future collaborators, might not have been the first to make the inventions covered by the issued patent or pending patent application** that we **license or** may ~~form~~ **own** in the future **; • we, or** ~~or~~ **our** ~~of potential~~ **license partners or current or** future ~~product acquisitions of licenses. We intend to form strategic partnerships leveraging our mRNA technology platform, and we may desire to create joint ventures of collaborations~~ **collaborators** , **might not have been** ~~enter into licensing agreements with third parties or acquire products or businesses, in each case that we believe will complement or augment this business strategy. These relationships or transactions, or those like them~~ **the first** ~~, may require us~~ to ~~incur nonrecurring and~~ **file patent applications covering certain of our or their inventions; •** ~~other~~ **others** ~~charges, increase~~ **may independently develop similar** ~~our~~ **or alternative technologies** ~~near- and long- term expenditures, issue securities that dilute our~~ **or duplicate** ~~existing stockholders, reduce the potential profitability of~~ any ~~products that are the subject~~ of ~~the relationship or~~ **our** ~~disrupt~~ **technologies without infringing, misappropriating** ~~our~~ **or otherwise violating** ~~management and business. In addition, we face significant competition in seeking appropriate strategic partnerships and transactions and the negotiation process is time- consuming and complex and there can be no assurance that we can enter into~~ any of **our owned** ~~these transactions even if we desire to do so. Moreover, we may not be able to realize the anticipated benefit of these transactions if our~~ **or** ~~strategic partners' development of therapeutic products using our in-~~ licensed intellectual property ~~does~~ **rights; • it is possible that our pending licensed patent applications or those that we may own in the future will** not ~~meet~~ **lead to issued patents; • issued patents that we hold rights to may be held invalid** ~~our~~ **or** ~~expectations. We cannot be~~ **unenforceable, including as a result of legal challenges by our competitors or other third parties; • our competitors or other third parties might conduct research and development activities in countries where**

we do not have patent rights and then use the information learned from such activities to develop competitive products for sale; • we may not develop additional proprietary technologies that are patentable; • the patents of others may harm our business; • we may choose not to file a patent in order to maintain certain ~~that~~ **trade secrets or proprietary know- how** , ~~following license~~ **and a third party may subsequently file a patent covering such intellectual property; and • our trade secrets or proprietary know- how may be unlawfully disclosed** , ~~we will achieve~~ **thereby losing their trade secret or proprietary status. Should any of these events occur,** ~~the~~ **they could have a material adverse effect on our business,** financial ~~or strategic~~ **condition,** results **of operations and prospects** ~~that would justify the transaction~~ . We are substantially dependent on intellectual property we **have** in- licensed from Factor Limited, and if we lose the license to such intellectual property or the ~~Exclusive~~ **A & R** Factor License Agreement is terminated for any reason, our ability to enter into strategic partnerships ~~or develop therapeutics products~~ would be harmed, and our business, financial condition and results of operations would be materially and adversely affected. Our business is **substantially** dependent upon the mRNA technology platform licensed from Factor Limited. Pursuant to the ~~Exclusive~~ **A & R** Factor License Agreement, Factor Limited has customary termination rights, including in connection with certain uncured material breaches of the ~~Exclusive~~ **A & R** Factor License Agreement, failure to make payments and specified bankruptcy events. Our ability to enter into strategic partnerships or develop therapeutics products using the Factor Patents depends entirely on the effectiveness and continuation of the ~~Exclusive~~ **A & R** Factor License Agreement. If we lose the right to license any of the mRNA technology platform, our ability to enter into strategic ~~partnerships or develop therapeutic products in the foreseeable future~~ would be harmed. Further, if the ~~Exclusive~~ **A & R** Factor License Agreement is terminated, there is no guarantee that we will be able to enter into a new license agreement that aligns with our business strategy on the same or similar terms, if at all, and our competitors could in- license the technology, which would result in a significant market disadvantage to us. We or our licensors may be subject to claims challenging the inventorship or ownership of the patents and other intellectual property that we own or license now or in the future. We or our licensors may be subject to claims that former employees, collaborators or other third parties have an ownership interest in the patents and intellectual property that we in- license or that we may own or in- license in the future. While it is our policy to require our employees or contractors who may be involved in the development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who in fact develops intellectual property that we regard as our own or such assignment may not be self- executing, for example, as part of employment or consulting agreements, or may be breached. Our licensors may face similar obstacles. Litigation may be necessary to defend against any claims challenging inventorship or ownership, including in derivation proceedings in the USPTO. If we or our licensors fail in defending any such claims, we may have to pay monetary damages and may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, intellectual property, which could adversely impact our business, results of operations and financial condition. ~~The failure of our licensees to fulfill their financial obligations with respect to royalty payments under their license agreements or to otherwise perform under their license agreement could have a material adverse effect on our business, financial condition and results of operations. Our revenues may be dependent on royalty payments made to us pursuant to strategic partnership arrangements or license agreements we may enter into with respect to the mRNA technology platform. We anticipate that such arrangements will often require that licensees advance payment to us for royalties or other milestone payments. The failure of our licensees to satisfy their financial obligations under these arrangements, or their inability to operate successfully or at all, could result in a breach of an agreement, early termination of an agreement or non- renewal of an agreement, each of which could eliminate some or all of that revenue stream. A decrease or elimination of revenue could have a material adverse effect on our financial condition, results of operations and cash flows. During the term of a license agreement, our revenues will substantially depend on our licensees' ability to develop a successful product candidate with the mRNA technology platform and their failure to do so could harm our future growth and prospects. If our strategic partnerships do not meet expectations and licensees are not successful, our business, financial condition and results of operation could be materially adversely affected. If conflicts arise between us and our future strategic partners or collaborators, these parties may act in a manner adverse to us and could limit our ability to implement our strategies. If conflicts arise between our future strategic partners or corporate or academic collaborators and us, the other party may act in a manner adverse to us and could limit our ability to implement our strategies. Future strategic partners or collaborators may develop, either alone or with others, products in related fields that are competitive with the products or potential products that are the subject of our collaborations with such partners or collaborators. Competing products, either developed by the collaborators or strategic partners or to which the collaborators or strategic partners have rights, may result in the withdrawal of partner support for any future product candidates based on our mRNA technology platform or other intellectual property. Our current or future strategic partners or collaborators may preclude us from entering into arrangements with their competitors, terminate their agreements with us prematurely, or fail to devote sufficient resources to the development and commercialization of products. Any of these developments could harm any future product development efforts, which could materially and adversely affect our business and operating results.~~ We have identified **a** material ~~weaknesses~~ -- **weakness** in our internal control over financial reporting. If we are unable to develop and maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial results in a timely manner, which may adversely affect investor confidence in us, and materially and adversely affect our business and operating results . In prior periods, we identified..... Annual Report on Form 10- K . A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected and corrected on a timely basis. Effective internal controls are necessary for us to provide reliable financial reports and prevent fraud. **In prior periods,we identified a material weakness as discussed below.** We were unable to timely file our ~~Q1~~ **Quarterly Report on Form 10- Q for the three months ended March 31,** 2022 ~~10Q~~ with the SEC due to identifying errors in our financial statements reported in the Annual Report on Form 10- K for the years ended December 31,2021 and 2020 during

our preparation of the financial statements for the quarter ended March 31,2022. **On June 30** ~~Management concluded that the errors were the result of accounting personnel' s lack of technical proficiency in complex matters.This material weakness remained unremediated as of December 31~~ ,2022 ~~. We~~ **,we** filed an amendment to our Annual Report on Form 10- K ~~/ A~~ for the years ended December 31,2021 and 2020 ~~on June 30,2022~~ to correct the errors in our financial statements for the years ended December 31,2021 and 2020 and for the quarters ended June 30,2020,September 30,2020,March 31,2021,June 30 **,2021 and September 30,2021.** Management ~~and~~ **concluded that the errors were the result of accounting personnel' s lack of technical proficiency in the accounting** for **complex matters.This material weakness remained unremediated as of December** ~~the quarters ended June 30,2020,September 30,2020,March~~ 31, ~~2021~~ **2023** ~~,June 30,2021 and September 30,2021~~ .As disclosed in Part II,Item 9A to this Annual Report on Form 10- K,our Chief Executive Officer and ~~Chief~~ **Senior Vice President of** ~~Financial~~ **Finance** ~~Officer~~ concluded that,as of December 31, ~~2022~~ **2023** ,our disclosure controls and procedures were not effective and did not provide reasonable assurance of achieving the desired control objectives.For a discussion of management' s consideration of its material weaknesses and ~~plans for remediation,see Part II~~ plans ~~to~~ **for remediation, see Part II, Item 9A: Controls and Procedures included in this Annual Report on Form 10- K. Management has** ~~implement~~ **implemented** measures designed to ensure that the deficiencies contributing to the ineffectiveness of our internal control over financial reporting are ~~promptly~~ remediated, such that the internal controls are designed, implemented and operating effectively. The remediation actions ~~planned~~ **implemented to date** include: enhancing the business process controls related to reviews over technical, complex, and non- recurring transactions; ~~and~~ providing additional training to accounting personnel and **using** ~~consulting with~~ an **external** accounting advisor ~~for~~ **to review management' s conclusions on certain** technical, complex and non- recurring matters ~~, with whom we have engaged and begun consulting~~ . We will continue to ~~evaluate steps~~ **season and further enhance the controls** to ~~remediate~~ **ensure that** ~~the~~ **they will continue** ~~material weaknesses in addition~~ to ~~those currently planned by~~ **operate effectively for a sufficient period of time before** management **can make conclusions on the operating effectiveness** . These remediation measures may be costly and there is no assurance that these initiatives will ultimately have the intended effects. If we identify any additional material weaknesses in the future, any such newly identified material weakness could limit our ability to prevent or detect a misstatement of our accounts or disclosures and could result in a material misstatement of our annual or interim financial statements. In such case, we may be unable to maintain compliance with securities law requirements regarding timely filing of periodic reports, investors may lose confidence in our financial reporting and our stock price may decline as a result. We cannot assure you that the measures we have taken to date, or any measures we may take in the future, will be sufficient to avoid potential future material weaknesses. We may face litigation and other risks as a result of the material weaknesses in our internal control over financial reporting. We identified ~~two~~ **a** material ~~weaknesses~~ -- **weakness** in our internal controls over financial reporting ~~, one of which was remediated as of December 31, 2022~~ . As a result of the material ~~weaknesses~~ -- **weakness** , restating our previously issued financial statements, and other matters that may in the future be raised by the SEC, we may face the potential for litigation or other disputes which may include, among others, claims invoking the federal and state securities laws, contractual claims or other claims arising from the material weakness in our internal control over financial reporting and the preparation of our financial statements. As of the date of this Annual Report on Form 10- K, we have no knowledge of any such litigation or dispute. However, we can provide no assurance that such litigation or dispute will not arise in the future. Any such litigation or dispute, whether successful or not, could have a material adverse effect on our business, results of operations and financial condition or our ability to complete a business combination. Our business and operations would suffer in the event of system failures, cyber- attacks or a deficiency in our cyber- security. Our computer systems, as well as those of various third parties on which ~~it relies~~ **we rely** , may sustain damage from computer viruses, unauthorized access, data breaches, phishing attacks, cybercriminals, natural disasters (including hurricanes and earthquakes), terrorism, war and telecommunication and electrical failures. We rely on our third- party providers to implement effective security measures and identify and correct for any such failures, deficiencies or breaches. The risk of a security breach or disruption, particularly through cyber- attacks or cyber intrusion, including by computer hackers, foreign governments and cyber terrorists, has generally increased as the number, intensity and sophistication of attempted attacks and intrusions from around the world have increased. If such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our drug development and other programs. 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 personal, confidential or proprietary information, we could incur liability and **it** ~~the further development of any product candidate~~ could ~~be delayed. We face~~ **have a material adverse effect on our** business ~~disruption~~ **, results of operations** and ~~related~~ **financial condition. See Part I, Item 1C. Cybersecurity for more information on information regarding our cybersecurity** ~~risks~~ - **risk** ~~resulting from a resurgence of the novel coronavirus (COVID- 19) pandemic~~ **management, strategy, and governance. If we are not successful in attracting and retaining highly qualified personnel, we may not be able to successfully implement** ~~or~~ **our** ~~a similar pandemic health event~~ **business strategy. Our ability to compete** in the ~~future~~ **highly competitive life science industry depends in large part upon the ability to attract highly qualified personnel** . In **order** ~~December 2019, Chinese officials reported a novel coronavirus (" COVID- 19 ") outbreak. COVID- 19 has since spread throughout the world, leading the World Health Organization~~ to ~~declare on March 11~~ **induce valuable employees to remain with us** , ~~2020,~~ **we intend to provide employees with stock options and / or restricted stock units** that **vest** ~~COVID- 19 reached the magnitude of a global pandemic. The rapid spread of COVID- 19 throughout the U. S. led federal, state and local governments to take significant steps in an attempt to reduce exposure to COVID- 19 and variants of the virus and control their negative effects on public health and the U. S. economy, which steps changed~~ over time ~~and varied~~ **. The value to employees of stock options that vest over time will be significantly affected** by **movements** ~~locality. The COVID- 19 pandemic has subsided with the normalization of living with COVID- 19 following the increase~~ in ~~accessibility to COVID- 19 vaccines and antiviral treatments. The development of our product candidates was disrupted by the COVID- 19 pandemic, and a resurgence of COVID- 19 could disrupt production~~

~~and cause delays in the supply and delivery of products used in our operations, may affect our operations, including the conduct of clinical studies or other~~ -- **the price** ~~collaborative activities by our strategic partners, may further divert the attention and efforts~~ of the ~~medical community to coping with the COVID- 19 and disrupt the marketplace in which we operate and may have a material adverse effects on our operations. COVID- 19 may also affect our employees and employees and operations at suppliers that may result in delays or disruptions in supply. In addition, a recession or market correction resulting from the spread of COVID- 19 could materially affect our business and the value of our~~ common stock ~~. A future pandemic unrelated~~ **that it will not be able** to ~~COVID~~ **control and may at** any time be insufficient to counteract more lucrative offers from other companies.Competition for skilled personnel in our industry is intense and competition for experienced scientists may limit our ability to hire and retain highly qualified personnel on acceptable terms.Despite our efforts to retain valuable employees, ~~members of~~ our **employees** ~~management,scientific and medical teams~~ may terminate their employment with us on short notice ~~.Our success also depends on our ability to continue to attract,retain and motivate highly skilled junior,mid- level,and senior managers as well as junior,mid- level,and senior scientific and medical personnel~~ .Other companies with which we compete for qualified personnel have greater financial **and other resources,different risk profiles,and a longer history in the industry than we do,and such companies also may provide more diverse opportunities and better chances for career advancement.Some of these characteristics may be more appealing to high** - ~~19 may lead~~ **quality candidates than what we have** to ~~similar disruptions~~ **offer. If we are unable** to **continue to attract and retain high- quality personnel,** our **business, results of** operations and **financial condition may be** materially **adversely** ~~affect~~ **affected** ~~our business and the value of our common stock~~ . Risks Related to New, Cutting Edge Technologies Because gene- editing and cell therapy product candidates that may be developed using our mRNA technology platform are based on novel technologies, we cannot assure that such products will be successful. Cellular immunotherapies, stem cell therapies, gene- edited, and iPSC- derived product candidates represent relatively new therapeutic areas, and the FDA has cautioned consumers about potential safety risks associated with them. To date, there are relatively few approved cell therapies. As a result, the regulatory approval process for a gene- editing or cellular therapy product candidates ~~are~~ **is** uncertain and may be more expensive and take longer than the approval process for product candidates based on other, better known or more extensively studied technologies and therapeutic approaches ~~. For example, there are no new FDA approved products with a label designation that supports the use of a product to treat and reduce the severity of ARDS in patients with COVID- 19, which makes it difficult to determine the clinical endpoints and data required to support an application or regulatory approval, and the time and cost required to obtain regulatory approval in the United States for the product candidates we or our strategic partners may develop~~ . Cell reprogramming technology and related cell therapy products using iPSC lines represent novel therapeutic approaches, and to our knowledge no iPSC- derived cell products are currently approved for commercial sale anywhere in the world. As such, it is difficult to accurately predict the type and scope of challenges that **potential strategic partners may confront in** ~~we will incur effecting our plan to develop~~ **developing** and ~~advance~~ **advancing** a pipeline of **iPSC- derived** therapeutic products ~~both internally and through strategic partnerships~~ . We and our strategic partners thus face uncertainties associated with the preclinical and clinical development, manufacture, and regulatory compliance for the initiation and conduct of clinical trials, regulatory approval, and reimbursement required for successful commercialization of **future** product candidates. ~~Regulatory~~ **Further, the** processes **and requirements imposed by the FDA or other applicable regulatory authorities may cause delays and additional costs in obtaining approvals for marketing authorization for any future product candidates. Because our platform is novel, and cell- and gene- based therapies are relatively new, regulatory agencies may lack experience in evaluating product candidates using our mRNA technology platform. This novelty may lengthen the regulatory review process, including the time it takes for the FDA to review IND applications if and when such applications are submitted, increase development costs, and delay or prevent commercialization of future products, if such products are approved for marketing. Due to the rapid advancements in cellular and genetic technologies, regulatory processes and requirements** in the United States **and in other jurisdictions** governing ~~cell~~ **cellular and gene** therapy products **are evolving** ~~have changed frequently~~ and the FDA or other regulatory bodies may change the requirements, or identify different regulatory pathways, for **the clinical testing and** approval of these product candidates. For example, ~~within~~ **in recent years** the FDA **has issued several** ~~, the Center for Biologics Evaluation and Research, CBER, restructured and created a~~ new **guidance documents related** ~~Office of Tissues and Advanced Therapies, OTAT,~~ to **developing** ~~better align its oversight activities with FDA Centers for Drugs~~ and **manufacturing cellular** ~~Medical Devices. It is possible that over time new or different divisions may be established or be granted the authority for regulating cell~~ and ~~/ or~~ gene therapy products **. In addition** , ~~including iPSC~~ **adverse developments in clinical trials of cellular gene therapy products conducted by others, or in treated patients after such products are commercialized, may cause the FDA or other oversight bodies to change the requirements for approval of any of our strategic partners' product candidates. For example, in November 2023, the FDA announced that it was investigating reports of T** - ~~derived~~ cell **malignancy in patients following their treatment with BCMA- directed or CD19- directed autologous chimeric antigen receptor (CAR) T- cell immunotherapies, although more recent public statements by agency leadership indicate that the benefits of such treatments are expected to still outweigh those risks. Future adverse events or safety issues could lead to more significant regulatory action applicable to either a specific product or a broader product class, based on case- by- case science- based benefit- risk assessments. Similarly, the EMA oversees the development of cellular and gene therapies in the EU and may issue new guidelines concerning the development and marketing authorization for cellular or gene therapy** products **and require that** ~~. As a result,~~ we **comply with these new guidelines. These regulatory agencies and committees and any new regulations, requirements or guidelines they promulgate may lengthen the regulatory review process, which may reduce the anticipated benefits of** ~~or~~ **our strategic partnerships or adversely affect the commercialization of any future therapeutic products they may develop. Accordingly,** our strategic partners may be required to change regulatory strategies or to modify applications for **clinical investigations or** regulatory approval, which could delay and impair ~~our~~ **their**

ability to complete the ~~pre- clinical~~ **preclinical** and clinical development and manufacture of, and obtain regulatory approval for, ~~our~~ **their** product candidates. Changes in regulatory authorities and advisory groups, or any new **regulations,** requirements or guidelines they promulgate, may lengthen the regulatory review process, require ~~us to perform~~ additional studies, increase development and manufacturing costs, lead to changes in regulatory pathways, positions and interpretations, delay or prevent approval and commercialization of product candidates developed through our strategic partners or lead to significant post-approval limitations or restrictions that may reduce the anticipated benefits of our strategic partnerships. Likewise, gene editing technology is relatively new, ~~and no products~~ **with the first cell-** based ~~on~~ **gene therapy product incorporating** such technology ~~have~~ **having** been approved ~~in~~ **by** the ~~U~~ **FDA in December 2023** . **In addition** ~~S. or the E. U. to date~~ , ~~and~~ only a limited number of clinical trials of product candidates based on gene- editing technologies have been commenced. **It** ~~As such, it~~ is **therefore** difficult to accurately predict the developmental challenges we may incur pursuing our business strategy. There may be long- term effects from treatment with any ~~such~~ product candidates that ~~we or~~ our strategic partners may develop that we cannot predict at this time. Any such product candidates may interact with genetic material (RNA / DNA) and because animal genetic materials differ from human genetic material, past testing of any such product candidates in animal models may not be predictive of results in human clinical trials ~~for~~ **designed to demonstrate** safety or efficacy. As a result of these factors, it is more difficult to predict the time and cost of such product candidate development, and we cannot predict whether the application of gene editing technology, or other similar or competitive gene editing technologies, will result in the identification, development ~~and~~ **or** regulatory approval of any products. The clinical trial requirements of the FDA, the 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 the product candidate. ~~No products based on~~ **Due to the novelty and complexity of** gene- **edited cellular products** ~~editing technologies have been approved by regulators to date. As a result~~ , the regulatory approval process for **such** product candidates ~~using such technology~~ is uncertain and may be more expensive and take longer than the approval process for product candidates based on other, better known or more extensively studied technologies. It is difficult to determine how long it will take or how much it will cost to obtain regulatory approvals for product candidates using this technology in either the United States or the E. U. or how long it will take to commercialize any product candidates. Delay or failure to obtain, or unexpected costs in obtaining, the regulatory approval necessary to bring a potential product candidate to market could decrease our ability to generate sufficient product revenue, and our business, financial condition, results of operations and prospects may be harmed. ~~Regulatory requirements~~ **We face intense competition and rapid technological change and the possibility that our competitors may develop therapies that are more advanced, safer, or more effective than any therapy we develop in the future, which may adversely affect our financial condition. We are engaged in the development of gene therapies, which is a competitive and rapidly changing field. We have competitors both** in the United States and ~~in~~ **internationally, including major multinational pharmaceutical companies, biotechnology companies, universities, and** other ~~jurisdictions governing~~ **research institutions. Many of our competitors have substantially greater financial, technical, research and human resources than we do, and may also have strategic partnerships and collaborative arrangements with leading companies and research institutions. Our competitors may succeed in developing, acquiring, or licensing on an exclusive basis, products that are more effective, safer, or less costly than any products that we may develop in the future, or achieve patent protection, marketing approval, product commercialization, and market penetration earlier than us. Additionally, technologies developed by our competitors may render any product candidates we are seeking to develop uneconomical or obsolete. For additional information regarding our competition, see " Part I, Item 1. Business — Competition ". Negative public opinion and increased regulatory scrutiny of gene therapy and genetic research may damage public perception of our future product candidates or adversely affect our ability to conduct our business or obtain and maintain marketing approvals for our future product candidates. Public perception may be influenced by claims that gene therapy, including gene editing technologies, is unsafe or unethical, and research activities and adverse events in the field, even if not ultimately attributable to us or our future product candidates, could result in increased governmental regulation, unfavorable public perception, challenges in recruiting patients to participate in future clinical studies involving product candidates using our mRNA technology platform, potential regulatory delays in the testing or approval of product candidates using our mRNA technology platform, labeling restrictions for any future approved products, and a decrease in demand for any such product. More restrictive government regulations or negative public opinion would have a negative effect on our business or financial condition and may delay or impair the development and commercialization of future product candidates using our mRNA technology platform or demand for any approved products. The manufacture of biotechnology products is complex, and manufacturers often encounter difficulties in production. The manufacture of biotechnology products, including cellular and** gene therapy products ~~have changed frequently and may continue to change in the future. In January 2020~~ , ~~the FDA issued several new guidance documents on gene therapy products. The FDA established the Office of Tissues and Advanced Therapies within its~~ **is** ~~Center~~ **generally complex and requires significant expertise and capital investment. Manufacturers** for ~~Biologics Evaluation and Research to consolidate the review of gene therapy and related products, and established the Cellular, Tissue and Gene Therapies Advisory Committee to advise this review. Adverse developments in clinical trials of gene therapy products conducted by others may cause the FDA or other oversight bodies to change the requirements for approval of~~ any ~~of our or our strategic partners'~~ product candidates **developed using our mRNA technology platform will be required to comply with cGMP regulations and guidelines for clinical trial product manufacture and subsequently for commercial product manufacture** . ~~Similarly~~ **Manufacturers of biotechnology products often encounter difficulties in production , particularly in scaling up, addressing product quality, product comparability, validating production processes and mitigating potential sources of contamination. These problems include difficulties with raw material procurement, production costs and yields, quality control, product quality,**

including stability of the ~~EMA governs~~ **product, quality assurance testing, operator error, shortages of qualified personnel, as well as compliance with strictly enforced federal, state and foreign regulations. Any delay or interruption in** the **supply of preclinical study supplies (or clinical trial supplies in the future) could delay the completion of such studies, increase the costs associated with the affected** development **programs and, depending upon the period** of ~~gene therapies~~ **delay, require new studies to be commenced at additional expense or terminated completely. Risks Related to Ownership of our Common Stock Six stockholders collectively own a significant percentage of our outstanding common stock, and as a result of such ownership, such stockholders may influence the election of directors and other matters submitted to stockholders. According to their most recent Schedule 13G filings and / or our corporate records, six stockholders — Charles Cherington, Nicholas Singer, John D. Halpern, George P. Denny III, Freebird Partners LP and IAF, LLC — collectively own approximately 43 % of our outstanding shares of common stock. Although, to our knowledge, such stockholders are not a " group " or " acting** in **concert, "** ~~the~~ **they** ~~EU~~ **have and are expected to continue to have, individually and / or collectively, the ability to influence the election of our board of directors and the outcome of other matters submitted to our stockholders. In addition, each of those stockholders own note warrants and convertible notes, which if exercised and / or converted would increase their ownership percentage of our outstanding common stock. Pursuant to the terms of the note warrants and convertible notes, the number of shares of common stock that may be acquired by a particular holder upon exercise of the note warrants and / or conversion of the convertible notes is limited, to the extent necessary, to ensure that following such exercise and / or conversion, the number of shares of common stock then beneficially owned by the holder and any other persons or entities whose beneficial ownership of common stock would be attributed to the holder for purposes of Section 13 (d) of the Exchange Act does not exceed 9. 99 % (for Messrs. Singer and Halpern and IAF, LLC) or 19. 99 % (for Messrs. Cherington and Denny and Freebird Partners LLP) of the total number of shares of our common stock then outstanding. The interests of these stockholders may not always coincide with our interests or the interests of other stockholders, and such stockholders, individually or collectively, may act in a manner that advances their best interests and not necessarily those of other stockholders. One consequence to this substantial influence is that it may be difficult for investors to remove our management and it could also deter unsolicited takeovers, including transactions in which stockholders might otherwise receive a premium for their shares over then current market prices. The sale of our common stock to Lincoln Park Capital Fund LLC (" Lincoln Park ") may cause dilution to our other stockholders and the subsequent sale of the shares of common stock acquired by Lincoln Park, or the perception that such sales may occur, could cause the price of our common stock to fall. Lincoln Park committed to purchase up to $ 10. 0 million of our common stock under a standby equity purchase agreement (" SEPA "). Through December 31, 2023, we have issued and sold approximately 214, 000 shares of our common stock to Lincoln Park for approximately $ 0. 3 million in gross proceeds under the SEPA, leaving** ~~and~~ **an approximately $ 9. 7 million balance of the $ 10. 0 million total commitment. The purchase price for the shares that we** may **sell to Lincoln Park under the SEPA is subject to a pricing formula in the SEPA and will vary based on the price of our common stock at the time we initiate the sale. Depending on market liquidity at the time, sales of such shares may cause the trading price of our common stock to fall. We generally have the right to control the timing and amount of any future sales of our shares to Lincoln Park under the SEPA. Sales of shares of our common stock to Lincoln Park under the SEPA, if any, will depend upon market conditions and other factors to be determined by us. We may ultimately decide to sell to Lincoln Park all, some or none of the shares of our common stock that may be available for us to sell pursuant to the SEPA. If and when we do sell shares to Lincoln Park, after Lincoln Park has acquired the shares, Lincoln Park may resell all, some or none of those shares at any time or from time to time in its discretion. Therefore, sales to Lincoln Park by us could result in substantial dilution to the interests of other holders of our common stock. Additionally, the sale of a substantial number of shares of our common stock to Lincoln Park, or the anticipation of such sales, could make it more difficult for us to sell equity or equity- related securities in the future at a time and at a price that we might otherwise wish to effect sales. There may be future sales or other dilution of our equity, which may adversely affect the market price of our common stock. We are generally not restricted from issuing additional common stock, including any securities that are convertible into or exchangeable for, or that represent the right to receive, common stock. To raise additional capital, we may in the future sell additional shares of our common stock or other securities convertible into or exchangeable for our common stock at prices that are lower than the prices paid by existing stockholders, and investors purchasing shares or other securities in the future could have rights superior to existing stockholders, which could result in substantial dilution to the interests of existing stockholders. The market price of our common stock could decline as a result of sales of common stock or securities that are convertible into or exchangeable for, or that represent the right to receive, common stock or the perception that such sales could occur. In addition, under the terms of the asset purchase agreement pursuant to which we acquired assets from Exacis Biotherapeutics Inc. (" Exacis "), we agreed to** issue ~~new guidelines concerning the development and~~ **to Exacis shares of our common stock as contingent consideration. If our** ~~marketing --- market authorization~~ **capitalization equals or exceeds $ 100. 0 million during the three- year period commencing on April 26, 2023 and ending on the three- year anniversary thereof, the number of shares of common stock we would issue is determined by a formula specified in the asset purchase agreement. In addition, if our market capitalization equals or exceeds $ 200. 0 million during the same three- year period, we agreed to issue to Exacis additional shares of our common stock determined by a formula specified in the asset purchase agreement. See Note 4 to the accompanying consolidated financial statements** for ~~gene therapy products and require~~ **additional information. In addition to the shares** that ~~we~~ **may be sold to Lincoln Park under the SEPA, a large number of shares may be issued and subsequently sold upon the exercise of outstanding options and warrants and upon the conversion of our outstanding convertible notes. As of March 12, 2024, there were approximately 5. 4 million shares of our common stock outstanding.**

In addition, there were approximately 2. 2 million shares of common stock issuable under outstanding options with a weighted average exercise price of $ 9. 29 per share, 20. 4 million shares of common stock issuable upon exercise of outstanding warrants with a weighted average exercise price of $ 2. 05 per share, 3. 1 million shares of common stock issuable upon conversion of our outstanding July 2023 convertible notes (assuming all principal and accrued interest is converted at a conversion rate of $ 2. 86 per share) and 4. 8 million shares of common stock issuable upon conversion of our outstanding December 2023 convertible notes (assuming all principal and accrued interest is converted at a conversion rate of $ 1. 9194 per share). To the extent that holders of such securities sell the shares of common stock issued upon the exercise or conversion of such securities, the market price of our common stock may decrease due to the additional selling pressure in the market. In addition to the risk of dilution from the sale of shares of our common stock to Lincoln Park described above, the risk of dilution from issuances of shares of common stock underlying outstanding securities and / or to Exacis described above may cause stockholders to sell their common stock, which could further decline in the market price. The terms of our convertible notes could limit our growth and our ability to finance our operations, fund our capital needs, respond to changing conditions and engage in other business activities that may be in our best interests. Our convertible notes contain a number of restrictive covenants that, among other things, generally limit our ability to create liens, pay dividends, acquire shares of capital stock and make payments on subordinated debt, incur indebtedness, or enter into transactions with affiliates. Our ability to comply with these ~~new guidelines.~~ **covenants may be adversely affected by events beyond our control, and we cannot assure you that we can comply with** ~~These~~ **these** ~~regulatory review agencies and committees and the new~~ **covenants. The financial covenants could limit our ability to make needed expenditures or otherwise conduct necessary or desirable business activities. The** ~~requirements~~ **requirement that we redeem** ~~or~~ **our convertible notes in cash could** ~~guidelines they promulgate may lengthen the regulatory review process, which may reduce the anticipated benefits of our strategic partnerships or~~ adversely affect **our business plan, liquidity, financial condition, and results of operations. If not converted, we are required to redeem some or all of the principal of our convertible notes for cash under certain circumstances. These obligations could have important consequences on our business. In particular,** ~~the~~ **they** ~~commercialization~~ **could: • limit our flexibility in planning for, or reacting to, changes in our businesses and the industries in which we operate; • increase our vulnerability to general adverse economic and industry conditions; and • place us at a competitive disadvantage compared to our competitors. No assurances can be given that we will be successful in making the required payments to the holders** of **our convertible notes or that we will be able to comply with the financial or other covenants in our convertible notes. If we are unable to make the required cash payments or otherwise comply with the covenants in our convertible notes: • the holders of our convertible notes may require us to repurchase some or all of their convertible notes at a price equal to 100 % of the principal amount being repurchased, plus accrued and unpaid interest; • the holders of our convertible notes could foreclose against our assets; and / or • we could be forced into bankruptcy or liquidation. Our failure to meet the continued listing requirements of Nasdaq could result in a delisting of our common stock. Our common stock is listed on The Nasdaq Capital Market. The Nasdaq Capital Market requires that listed companies satisfy continued listing requirements, one of which that listed companies have: (x) stockholders' equity of at least $ 2. 5 million; (y) a market value of listed securities of at least $ 35 million; or (z) net income from continuing operations of $ 500, 000 in the company' s most recently completed fiscal year or in two of the three most recently completed fiscal years. Our stockholders' equity at December 31, 2023 was approximately $ 2. 2 million and we do not currently meet either of the two alternative compliance standards described in clause (y) and (z). Accordingly, we expect to receive a notice from Nasdaq informing us that we do not meet the foregoing continued listing requirements. If we receive such a notice, we expect to be afforded 45 days to submit a plan to regain compliance with the stockholders' equity requirement for Nasdaq' s consideration, and if the plan is accepted, to be granted an extension period of up to 180 calendar days from the date of the deficiency notice to regain compliance. If the plan is not accepted or if we are unable to regain compliance within** any **extension period granted by Nasdaq, Nasdaq would be required to issue a delisting determination, which we expect we would be entitled to request a hearing before a Nasdaq Hearings Panel to present a plan to regain compliance and to request a further extension period to regain compliance. If we fail to satisfy any of the Nasdaq continued listing requirements, Nasdaq may take steps to delist our common stock. In the event of a delisting, we can provide no assurance that any action taken by us to restore compliance with Nasdaq continued listing requirements would be successful. If our common stock is ultimately delisted by Nasdaq, and we are not able to list our securities on another national securities exchange, we expect our securities could be quoted on an over- the- counter market. If this were to occur, then we could face significant material adverse consequences, including: a material reduction in the liquidity of our common stock and a corresponding material reduction in the trading price of our common stock; a more limited market quotations for our securities; a determination that our common stock is a " penny stock " that requires brokers to adhere to more stringent rules and possibly resulting in a reduced level of trading activity in the secondary trading market for our securities; more limited research coverage by stock analysts; loss of reputation; more difficult and more expensive equity financings in the** future ~~therapeutic products that we may~~ **; the potential loss of confidence by investors; and fewer business** ~~develop~~ **development opportunities** . ~~Risks Related to Ownership~~ **The National Securities Markets Improvement Act** of **1996, which is a federal statute, prevents** ~~our~~ **or preempts the states from regulating the sale of certain securities, which are referred to as " covered securities. " If our** ~~Common~~ **common** ~~Stock~~ **stock remains listed on Nasdaq, our common stock will be covered securities. Although the states are preempted from regulating the sale of our securities, the federal statute does allow the states to investigate companies if there is a suspicion of fraud, and, if there is a finding of fraudulent activity, then the states can regulate or bar the sale of covered securities in a particular case. If our securities were no longer listed on Nasdaq and therefore not " covered securities, " we would be subject to regulation in each state**

in which we offer our securities. Anti- takeover provisions of Delaware law and provisions in our charter and bylaws could make a third- party acquisition of us difficult. Because we are a Delaware corporation, the anti- takeover provisions of Delaware law could make it more difficult for a third party to acquire control of us, even if the change in control would be beneficial to stockholders. We **are subject to** ~~have a limited operating history and have never generated any product revenue. We were formed in September 2018, for~~ the ~~purpose~~ **provisions** of ~~consummating a~~ **Section 203 of the General Corporation Law of Delaware, which prohibits us from engaging in certain business combinations, unless the** business combination ~~with IRX Therapeutics,~~ **is approved in a prescribed manner.** ~~Inc~~ **In** ~~,~~ **addition** , **our restated certificate** ~~which business combination was consummated in November 2018. Since inception, we have incurred significant net losses. As~~ of **incorporation** ~~December 31, 2022, we had an~~ **and restated bylaws also contain** ~~accumulated deficit of approximately $ 165. 3 million. Since inception, we have financed our operations with capital contributions from the former beneficial holders of Eterna LLC' s Class A membership interests, as well as through the sale of our securities under the Purchase Agreements with the Investment Group and in connection with~~ certain **provisions** ~~private placement transactions. We have never been profitable, have no products approved for commercial sale, and have not generated any product revenue. While we plan to develop and advance a pipeline of therapeutic products both internally and through strategic partnerships, it is possible~~ that ~~none~~ **may make a third- party acquisition** of **us difficult, including** ~~such products will obtain necessary regulatory approvals or be commercialized. Our expenses could increase beyond expectations. Even if our strategic partners successfully develop and advance therapeutic products using our mRNA technology platform or our other~~ -- **the ability** ~~intellectual property and such products are commercialized, we may incur significant costs associated with the related strategic partnership. If we cannot successfully execute any one~~ of ~~the foregoing, our business may not succeed, and your~~ - **our** ~~investment will be negatively impacted. Furthermore, we sometimes estimate~~ **board of directors to issue preferred stock and the inability of our stockholders to call a special meeting** ~~for~~ - **or act** ~~planning purposes the timing of the accomplishment of various scientific, clinical, regulatory and other product development objectives~~ by **written consent** our strategic partners or collaborators, as..... pursue our business strategy would be limited . Risks Related to our Financial Position and Capital Requirements We may acquire businesses, assets or products, or form strategic alliances, in the future, and we may not realize the benefits of such acquisitions. We may acquire additional businesses, assets or products, form strategic alliances or create joint ventures with third parties that we believe will complement or augment our existing business. If we acquire businesses with promising intellectual property, markets or technologies, we may not be able to realize the benefit of acquiring such businesses if we are unable to successfully integrate them with our existing operations and company culture. We may encounter numerous difficulties in developing, manufacturing and marketing any new acquisition. Difficulties may prevent us from realizing its expected benefits or enhancing our business. We cannot assure you that, following any such acquisition, we will achieve the expected synergies to justify the transaction. **Our ability** ~~We will require substantial additional capital~~ to ~~fund~~ **utilize** our **net** ~~operations~~ - **operating** ~~,~~ **loss carryforwards** and **tax credit carryforwards** ~~if we fail to obtain the necessary financing, we~~ may ~~not~~ be ~~able~~ **subject** to **limitations** ~~pursue our business strategy~~ . **Our ability** ~~We will require additional capital~~ to ~~develop and advance our pipeline of therapeutic products both internally and through strategic partnerships. Because the length of time and activities associated with successful development of such products by us~~ **use** ~~or~~ **our federal and** ~~our strategic partners are highly uncertain, we are unable to estimate~~ --- **state net operating losses (" NOLs ") to offset potential future taxable income and related income taxes that would otherwise be due is dependent upon our generation of future taxable income, and we cannot predict** with certainty ~~the actual funds~~ **when, or whether,** we will ~~require for development~~ **generate sufficient taxable income to use all of our NOLs. Under Section 382 and Section 383 of the Code and corresponding provisions of state law, if a corporation undergoes** ~~and~~ - **an " ownership change** ~~commercialization activities. Our future funding requirements~~ , ~~both near~~ **" its ability to use its pre** - **change NOL carryforwards** and ~~long~~ **other pre** - ~~term, will depend on change tax attributes (such as research tax credits) to offset its post- change income~~ ~~many~~ - **may** ~~factors~~ **be limited. A Section 382 " ownership change " is generally defined as a greater than 50 percentage point change (by value) in its equity ownership by certain stockholders over a three- year period. Even if we achieve profitability** , **we may** ~~including, but~~ not ~~limited~~ **be able** to ~~: ● the cost~~ **utilize a material portion** of **our NOL carryforwards** ~~filing, prosecuting, defending and enforcing its patent claims~~ and other **tax attributes** ~~intellectual property rights; ● the cost of defending potential intellectual property disputes, including patent infringement actions brought by third parties against us or any of our strategic partners or collaborators; and ● the effect of competing market developments. Based on currently available information and our ongoing operations, we believe that our existing cash will not be sufficient for us to fund our operating expenses and capital expenditure requirements through the twelve- month period subsequent to the issuance date of this report. We intend to raise additional sources of capital~~ , which could ~~be in the form~~ **have a material adverse effect on cash flow and results** of ~~debt, grants~~ **operations. Similar provisions of state tax law may also apply to limit** ~~or~~ **our** ~~equity~~ **use of accumulated state tax attributes** . ~~We cannot be certain~~ **There is also a risk** that ~~additional capital will be available~~ **due to regulatory changes, such as suspensions** on **the** ~~acceptable terms, or at all. If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us~~ **use of NOLs** , ~~we may have to significantly delay, scale back or discontinue our~~ - **or** ~~business activities~~ **other unforeseen reasons** , ~~or~~ **our** ~~potentially discontinue operations altogether. In addition, attempting to secure additional capital may divert the time and attention of our management from day- to- day activities and harm its ability to execute on our overall strategy. We are unable to estimate the amounts of increased capital outlays, operating expenditures and capital requirements associated with our current commercialization strategy. Raising additional funds by issuing equity securities may cause dilution to~~ existing **NOLs could expire** ~~holders, raising additional funds through debt financings may involve restrictive covenants, and raising funds through lending and licensing arrangements may restrict our~~ - **or otherwise** ~~operations or require us to relinquish proprietary rights. We expect that significant additional capital will~~ be ~~needed in the~~ **unavailable to offset** future **income tax liabilities** ~~to continue our planned operations. Until such time, if ever, that we can generate substantial product revenue, directly~~

~~or through our strategic partnerships, we expect to finance our cash needs through a combination of equity offerings, debt financings, strategic alliances and license and development agreements or other collaborations. To the extent that we raise additional capital by issuing equity securities, existing stockholder ownership may experience substantial dilution, and the securities may include preferred shares with liquidation or other preferences that could harm the rights of a common stockholder. We plan to raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, and as a result we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates, or grant licenses on terms that may not be favorable to us~~ . Risks Related to Regulatory Requirements We are subject to extensive and costly government regulation. Product candidates employing medical technology are subject to extensive and rigorous domestic government regulation including regulation by the FDA, ~~the Centers for Medicare and Medicaid Services, or CMS,~~ other divisions of the United States Department of Health and Human Services, the United States Department of Justice, state and local governments, and their respective foreign equivalents. If products employing our technologies are marketed abroad, they will also be subject to extensive regulation by foreign governments, whether or not they have obtained FDA approval for **one or more** ~~a given product and its~~ uses. Such foreign regulation may be equally or more demanding than corresponding United States regulation. Government regulation substantially increases the cost and risk of researching, developing, manufacturing, and selling medical products. Even if we or our strategic partners are able to obtain regulatory approval for a particular product **candidate** , the approval may limit the indicated medical uses for the product, may otherwise limit ~~our~~ **the** ability to promote, sell, and distribute the product, may require costly post- marketing surveillance, and / or may require ongoing post- marketing studies. Material changes to an approved product, such as, for example, manufacturing changes or revised labeling, may require further regulatory review and approval. Once obtained, any approvals may be withdrawn, including, for example, if there is a later discovery of previously unknown problems with the product, such as a previously unknown safety issue. In addition, regulatory agencies may not approve the labeling claims that are necessary or desirable for the successful commercialization of a product candidate. For example, regulatory agencies may approve a product candidate for fewer or more limited indications than requested or may grant approval subject to the performance of post- marketing studies. Regulators may approve a product candidate for a smaller patient population, a different drug formulation or a different manufacturing process, than we or our strategic partners are seeking. **The regulatory approval processes of the FDA and comparable foreign regulatory authorities are lengthy, time- consuming and inherently unpredictable. If our potential strategic partners are ultimately unable to obtain regulatory approval for their product candidates, we may be unable to product revenue and our business will be substantially harmed. We cannot commercialize a product until the appropriate regulatory authorities have reviewed and approved the product candidate. The time required to obtain approval by the FDA and comparable foreign regulatory authorities is unpredictable, typically takes many years following the commencement of clinical studies and depends upon numerous factors, including the type, complexity, and novelty of the product candidates involved. Regulatory authorities have substantial discretion in the approval process and may refuse to accept an application for review, or may decide that our data are insufficient for approval and require additional non- clinical, clinical or other studies. We may never be able to obtain regulatory approval for any product candidates that we develop in the future. If our future product candidates are ultimately not approved for any reason, our business, prospects, results of operations and financial condition would be adversely affected. In addition, even once clinical development of a future product candidate is initiated, such clinical studies may not start or be completed on schedule, if at all. The completion or commencement of clinical studies can be delayed or prevented for a number of reasons, including, among others: • the FDA or comparable foreign regulatory authorities may not authorize us or our future clinical investigators to commence planned clinical studies, or require that we suspend ongoing clinical studies through imposition of clinical holds; • negative results from our ongoing studies or other industry studies involving engineered or gene- edited cell therapy product candidates; • delays in reaching or failing to reach agreement on acceptable terms with prospective clinical research organizations (" CROs ") and clinical study sites, the terms of which can be subject to considerable negotiation and may vary significantly among different CROs and study sites; • inadequate quantity or quality of a product candidate or other materials necessary to conduct clinical studies, for example delays in the manufacturing of sufficient supply of finished drug product; • difficulties obtaining ethics committee or IRB, approval to conduct a clinical study at a prospective site or sites; • challenges in recruiting and enrolling subjects to participate in clinical studies, the proximity of subjects to study sites, eligibility criteria for the clinical study, the nature of the clinical study protocol, the availability of approved effective treatments for the relevant disease and competition from other clinical study programs for similar indications; • severe or unexpected drug- related side effects experienced by subjects in a clinical study, such as severe neurotoxicity and cytokine release syndrome; • the FDA or comparable foreign regulatory authorities may disagree with a proposed clinical study design, implementation of clinical trials or our interpretation of data from clinical studies, or may change the requirements for approval even after it has reviewed and commented on the design for our clinical studies; • reports from non- clinical or clinical testing of other competing candidates that raise safety or efficacy concerns; and • difficulties retaining subjects who have enrolled in a clinical study but may be prone to withdraw due to rigors of the clinical studies, lack of efficacy, side effects, personal issues, or loss of interest. Changes in regulatory requirements, agency guidance or unanticipated events during our non- clinical studies and future clinical studies of our future product candidates may occur, which may result in changes to non- clinical or clinical study protocols or additional non- clinical or clinical study requirements, which could result in increased costs to us and could delay our projected development timeline. Changes in regulatory requirements or FDA or EMA guidance, or unanticipated events during our non- clinical studies and future clinical studies, may force us to amend non- clinical studies and future clinical study protocols. The FDA, EMA or comparable foreign regulatory authorities may also impose additional non- clinical studies and**

clinical study requirements. Amendments to protocols for or other aspects of our non- clinical studies may increase the cost or delay the timing or successful completion of those studies. If we experience delays completing, or if we terminate, any of our non- clinical or future clinical studies, or if we are required to conduct additional non- clinical or clinical studies, the commercial prospects for our future product candidates may be harmed and our ability to recognize product revenue will be delayed. The results of non- clinical studies and early- stage clinical trials of our future therapeutic candidates may not be predictive of the results of later stage clinical trials. Success in non- clinical studies and early clinical trials does not ensure that later and pivotal clinical trials will generate the same results, or otherwise provide adequate data to demonstrate the safety and efficacy of a therapeutic candidate. Frequently, therapeutic candidates that have shown promising results in non- clinical studies or early clinical trials have subsequently suffered significant setbacks in later clinical trials. There can be no assurance that any of our non- clinical and preclinical programs will ultimately be successful or support initiating clinical development of any of our future therapeutic candidates. A number of companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in clinical development even after achieving promising results in earlier non- clinical studies or clinical trials, and any such setbacks in our development pipeline could have a material adverse effect on our business and operating results. Disruptions at the FDA and other government agencies caused by funding shortages or other events or conditions outside of their control could negatively impact our business. The ability of the FDA to review and approve INDs, proposed clinical trial protocols, or new product candidates can be affected by a variety of factors, including, but not limited to, government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, statutory, regulatory, and policy changes, and other events that may otherwise affect the FDA' s ability to perform routine functions. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of the SEC and other government agencies on which our operations may rely, including those that fund research and development activities, is subject to the political process, which is inherently fluid and unpredictable. Disruptions at the FDA and other regulatory agencies may also slow the time necessary for new product candidates to be reviewed or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, the U. S. government has shut down several times and certain regulatory agencies, such as the FDA and the SEC, have had to furlough critical employees and stop critical activities. In addition, during the COVID- 19 pandemic, the FDA' s inspectional activities were interrupted and restarted on a risk- based basis, which had the effect of delaying review and potential approval of product candidate marketing applications. If a prolonged government shutdown occurs, or if global health concerns prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA to timely review and process our future regulatory submissions, 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 order to properly capitalize and continue our operations. If we do not comply with laws regulating the protection of the environment and health and human safety, our business could be adversely affected. We maintain quantities of various flammable and toxic chemicals in our facilities in Massachusetts that are used for our research and development activities. We are subject to federal, state and local laws and regulations governing the use, manufacture, storage, handling and disposal of these hazardous materials. We believe our procedures for storing, handling and disposing these hazardous materials in our laboratory facilities comply with the relevant guidelines of the relevant local, state, and the Occupational Safety and Health Administration of the U. S. Department of Labor. Although we believe that our safety procedures for handling and disposing of these materials comply with the standards mandated by applicable regulations, the risk of accidental contamination or injury from these materials cannot be eliminated. If an accident occurs, we could be held liable for resulting damages, which could be substantial. We are also subject to numerous environmental, health and workplace safety laws and regulations, including those governing laboratory procedures, exposure to blood- borne pathogens and the handling of animals and biohazardous materials. Any insurance coverage we have may not be sufficient to cover these liabilities. Additional federal, state and local laws and regulations affecting our operations may be adopted in the future. We may incur substantial costs to comply with, and substantial fines or penalties if we violate, any of these laws or regulations which would adversely affect our business. Healthcare legislative reform measures ~~and constraints on national budget social security systems~~ may have a material **and** adverse effect on our business ~~and~~ **, financial condition,** results of operations **, and prospects** . **Third- party** ~~Payors~~ **payors** , whether domestic or foreign, or governmental or ~~private~~ **commercial** , are developing increasingly sophisticated ~~or complex~~ methods of controlling healthcare costs ~~and those methods are not always specifically adapted for new technologies such as those we are developing~~ . In both the United States and certain foreign jurisdictions, there have been ~~a number of~~ **, and likely will continue to be,** legislative and regulatory ~~changes to~~ **proposals at** the **foreign, federal, and state levels directed at containing or lowering the cost of** ~~health~~ **healthcare . We cannot predict the initiatives that may be adopted in the future. The continuing efforts of the government, insurance companies, managed** care ~~system~~ **organizations, and other payors of healthcare services to contain or reduce costs of healthcare and / or impose price controls may adversely affect: • the demand for our therapeutic candidates, if we obtain marketing approval; • our ability to receive or set a price** that ~~could impact~~ **we believe is fair for our future products; •** our ability to ~~sell~~ **generate revenue and achieve** ~~our~~ **or** ~~products~~ **maintain** ~~profitably~~ **profitability ; •** ~~. In particular, in~~ the ~~United States,~~ **level of taxes that we are required to pay; and •** the **availability of capital. The** Affordable Care Act ~~, among~~ **of 2010 (" ACA ") includes measures that have significantly changed** ~~other~~ ~~-~~ **the** ~~things, subjects~~ **way healthcare is financed by both governmental and private insurers in the United States. It also included the provisions that created an abbreviated approval pathway for** ~~biologic~~ **biological** products ~~to potential competition by lower- cost biosimilars; addresses a new methodology by which rebates owed by manufacturers under~~

~~the Medicaid Drug Rebate Program are calculated for drugs~~ that are **biosimilar** ~~inhaled, infused, instilled, implanted or injected; increases the minimum Medicaid rebates owed by most manufacturers under the Medicaid Drug Rebate Program; extends the Medicaid Drug Rebate program~~ to ~~utilization of prescriptions of individuals enrolled in Medicaid managed care organizations; subjects manufacturers to new annual fees and taxes for~~ - **or interchangeable with** ~~certain branded prescription drugs; and~~ - **an** ~~provides incentives~~ **FDA- licensed reference biological product. The ACA continues** to **significantly impact** ~~programs that increase~~ the ~~federal government~~ **United States** ' s **pharmaceutical industry** ~~comparative effectiveness research~~ . ~~In addition, other legislative changes have been proposed and adopted in the United States since the Affordable Care Act was enacted. 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. 5 trillion for the years 2013 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 2 % per fiscal year, which went into effect in April 2013, and due to subsequent legislative amendments, including the BBA, will remain in effect through 2027 unless additional Congressional action is taken. The CARES Act, the Consolidated Appropriations Act of 2021, and the Act to Prevent Across- the- Board Direct Spending Cuts suspended the 2 % sequestration mandated by the Budget Control Act of 2011 and the American Relief Act of 2011 through December 31, 2021. In December 2021, Congress extended the suspension of the automatic 2 % reduction through March 2022 and reduced the sequestration adjustment to 1 % beginning on April 1, 2022 through June 30, 2022, with the full 2 % reduction for sequestration resuming thereafter. In January 2013, the American Taxpayer Relief Act of 2012, was signed into law, which, among other things, further reduced Medicare payments to several providers, including hospitals and cancer treatment centers, and increased the statute of limitations period for the government to recover~~ - **Moreover** ~~overpayments to providers from three to five years. We cannot anticipate whether Congress will further extend the sequestration and when the sequestration reimbursement will return. Also~~ , there has been heightened governmental scrutiny ~~recently~~ over the manner in which **prescription** drug **and biological product** manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products. ~~For example~~ **In August 2022** , ~~in November 2018~~ **President Biden signed into the law the Inflation Reduction Act of 2022 (" IRA ")** , **which includes (** ~~CMS issued a proposed rule for comment that would,~~ among other things ~~, provide~~ **) multiple provisions that may impact the prices of drug products that are both sold into the** Medicare **program and throughout the United States. A manufacturer of drug products covered by Medicare Parts B or D must pay a rebate to the federal government if their drug product' s price increases faster than the rate of inflation. The IRA is in the process of being implemented by CMS and its impact on the pharmaceutical industry in the United States remains uncertain at this time, in part because multiple large pharmaceutical companies and other stakeholders (e. g., the U. S. Chamber of Commerce) have initiated federal lawsuits against CMS arguing a separate price negotiation program is unconstitutional for a variety of reasons, among other complaints. Those lawsuits are currently ongoing. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. For example, in recent years, several states have formed** prescription drug **affordability boards (" PDABs "). These PDABs have attempted to implement upper payment limits on drugs sold in their respective states in both public and commercial health** plans **. For example, in August 2023, Colorado' s PDAB announced a list of five prescription drugs that would** ~~under~~ **undergo** ~~Part D~~ **an affordability review. The effects of these efforts similarly remain uncertain pending the outcomes of several federal lawsuits challenging state authority to regulate prescription drug payment limits. We expect that the ACA, the IRA, as well as other healthcare reform measures that may be adopted in the future, may result in additional reductions in Medicare and other healthcare funding,** more **rigorous coverage criteria** ~~transparency in pricing and greater flexibility to negotiate discounts for~~ , **lower reimbursement** ~~and in certain circumstances exclude~~ , ~~drugs in the six " protected " formulary classes~~ and ~~allow Medicare Advantage plans to use certain drug management tools such as step therapy for physician- administered drugs. The IRA, among other things, requires drug manufacturers to offer rebates if the prices rise faster than inflation. Although a number of these, and other proposed measures will require authorization through additional legislation to become effective, Congress and the Biden administration has each indicated that it will continue to seek~~ new **payment methodologies** ~~legislative and / or administrative measures to control drug costs~~ . **This could** ~~There have been, and likely will continue to be, legislative and regulatory proposals at the foreign, federal and state levels directed at broadening the availability of healthcare and containing or lowering~~ --- **lower** ~~the cost of healthcare. We cannot predict the initiatives that may be adopted in the future. The continuing efforts of these governments and other payors to contain or reduce costs of healthcare and / or impose price controls may adversely affect: ● the demand for our or our strategic partners' product candidates, if we or they~~ - **the** ~~obtain regulatory approval; ● the ability to set a~~ price that we **receive** ~~believe is fair~~ for ~~such~~ **any future approved therapeutic** ~~products~~ - **product** ~~; ● our ability to generate revenue and achieve or maintain profitability; ● the level of taxes that we are required to pay; and ● the availability of capital~~ . Any denial in coverage or reduction in reimbursement from Medicare or ~~any~~ other government **- funded** programs may result in a similar denial or reduction in payments from private payors, which may **prevent us from being able to generate sufficient revenue, attain profitability, or commercialize our future therapeutic candidates, if approved. In the European Union, similar political, economic and regulatory developments may affect our ability to profitably commercialize our current or any future products. In addition to continuing pressure on prices and cost containment measures, legislative developments at the European Union or member state level may result in significant additional requirements or obstacles that may increase**

our operating costs. In international markets, reimbursement and healthcare payment systems vary significantly by country, and many countries have instituted price ceilings on specific products and therapies. Our future products, if any, might not be considered medically reasonable and necessary for a specific indication or cost- effective by third-party payors, an adequate level of reimbursement might not be available for such products and third- party payors' reimbursement policies might adversely affect our **ability to sell any** future **products profitably. Legislative and regulatory proposals have also been made to expand post- approval requirements and restrict sales and promotional activities for biologic therapeutics, and FDA' s statutory authorities are periodically amended by Congress. For example, as part of the Consolidated Appropriations Act for 2023, Congress provided FDA additional authorities related to the accelerated approval pathway for human drugs and biologics. Under these recent amendments to the FDCA, the agency may require a sponsor of a product granted accelerated approval to have a confirmatory trial underway prior to approval. The amendments also give FDA the option of using expedited procedures to withdraw product approval if the sponsor' s confirmatory trial fails to verify the claimed clinical benefits of the product. We cannot be sure whether additional legislative changes will be enacted, or whether the FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of our therapeutic candidates, if any, may be. Increased scrutiny by the U. S. Congress of the FDA' s approval process may significantly delay or prevent marketing approval, as well as subject us to more stringent product labeling and post- approval testing and other requirements. In addition, in April 2023 the European Commission issued a proposal that will revise and replace the existing general pharmaceutical legislation governing drug and biological products intended for the EU market. If adopted and implemented as currently proposed, these revisions will significantly change several aspects of drug development and approval in the EU. 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, our therapeutic candidates may lose any marketing approval that may have been obtained and we may not achieve or sustain** profitability **, which would adversely affect our business** . Risks Relating to Eterna' s Intellectual Property If we are unable to obtain and maintain patent and other intellectual property protection, or if the scope of the patent and other intellectual property protection obtained is not sufficiently broad, our competitors could develop and commercialize products similar or identical to those derived from our intellectual property, and our ability to achieve profitability may be adversely affected. Our ability to compete effectively will depend, in part, on our ability to maintain the proprietary nature of our technology and manufacturing processes. We rely on research, manufacturing and other know- how, patents, trade secrets, license agreements and contractual provisions to establish our intellectual property rights. These legal means, however, afford only limited protection and may not adequately protect our rights. In certain situations, and as considered appropriate, we have sought, and we intend to continue to seek to protect our proprietary position by filing patent applications in the United States and, in at least some cases, one or more countries outside the United States relating to future products and product candidates that we or our strategic partners or collaborators may develop that are important to our business. However, we cannot predict whether the patent applications currently being pursued will issue as patents, or whether the claims of any resulting patents will provide us with a competitive advantage or whether we will be able to successfully pursue patent applications in the future relating to such products and product candidates. Moreover, the patent application and approval processes are expensive and time- consuming. We may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. Furthermore, we, or any future partners, collaborators, or licensees, may fail to identify patentable aspects of inventions made in the course of development and commercialization activities before it is too late to obtain patent protection on them. Therefore, we may miss potential opportunities to seek additional patent protection. It is possible that defects of form in the preparation or filing of patent applications may exist, or may arise in the future, for example with respect to proper priority claims, inventorship, claim scope, or requests for patent term adjustments. If we fail to establish, maintain or protect such patents and other intellectual property rights, such rights may be reduced or eliminated. If there are material defects in the form, preparation, prosecution or enforcement of our patents or patent applications, such patents may be invalid and / or unenforceable, and such applications may never result in valid, enforceable patents. Even if they are unchallenged, our patents and patent applications, if issued, may not provide us with any meaningful protection or prevent competitors from designing around our patent claims by developing similar or alternative technologies or therapeutics in a non- infringing manner. For example, a third party may develop a competitive therapy that provides benefits similar to one or more of the future products and product candidates that we or our strategic partners or collaborators may develop but that falls outside the scope of our patent protection. If the patent protection provided by the patents and patent applications we hold or pursue with respect to such product candidates is not sufficiently broad to impede such competition, the successful commercialization of such product candidates could be negatively affected. Other parties, many of whom have substantially greater resources and have made significant investments in competing technologies, have developed or may develop technologies that may be related or competitive with our approach, and may have filed or may file patent applications and may have been issued or may be issued patents with claims that overlap or conflict with our patent applications, either by claiming the same compositions, formulations or methods or by claiming subject matter that could dominate our patent position. In addition, the laws of foreign countries may not protect our rights to the same extent as the laws of the United States. As a result, any patents we may obtain in the future may not provide us with adequate and continuing patent protection sufficient to exclude others from commercializing products similar to future products and product candidates that we or our strategic partners or collaborators may develop. The patent position of biotechnology and pharmaceutical companies generally is highly uncertain. No consistent policy regarding the breadth of claims allowed in biotechnology and pharmaceutical patents has emerged to date in the United States or in many foreign jurisdictions. **The standards applied by the USPTO and foreign patent offices in granting patents are not always applied uniformly or predictably.** In addition, the

determination of patent rights with respect to pharmaceutical compounds commonly involves complex legal and factual questions, which has in recent years been the subject of much litigation. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Our competitors may also seek approval to market their own products similar to or otherwise competitive with our products. Alternatively, our competitors may seek to market generic versions of any approved products by submitting ANDAs or ABLAs to the FDA in which they claim that our patents are invalid, unenforceable or not infringed. In these circumstances, we may need to defend or assert our patents, or both, including by filing lawsuits alleging patent infringement. In any of these types of proceedings, a court or other agency with jurisdiction may find our patents invalid or unenforceable, or that our competitors are competing in a non- infringing manner. Thus, ~~even~~ **we cannot offer any assurances about which,** if **any,** ~~we have valid and enforceable~~ patents **will issue** , ~~these~~ -- **the breadth of any such** patents ~~still may not provide protection against~~ **, whether any issued patents will be found invalid and unenforceable or will be threatened by third parties or whether any issued patents will effectively prevent others from commercializing** competing **technologies and drug candidates** ~~products or processes sufficient to achieve our business objectives~~ . In addition to patent protection, we expect to rely heavily on trade secrets, know- how and other unpatented technology, which are difficult to protect. Although we seek such protection in part by entering into confidentiality agreements with our vendors, employees, consultants and others who may have access to proprietary information, we cannot be certain that these agreements will not be breached, adequate remedies for any breach would be available, or our trade secrets, know- how and other unpatented proprietary technology will not otherwise become known to or be independently developed by our competitors. If we are unsuccessful in protecting our intellectual property rights, sales of our products may suffer and our ability to generate revenue could be severely impacted. **We cannot ensure that patent rights relating to inventions described and claimed in our pending patent applications will issue, or that our issued patents or patents that issue in the future will not be challenged and rendered invalid and / or unenforceable. The patent application process is subject to numerous risks and uncertainties, and there can be no assurance that we or any of our potential future collaborators will be successful in protecting our drug candidates by obtaining and defending patents. We have pending and issued U. S. and foreign patents and patent applications in our portfolio; however, we cannot predict: • if and when patents may issue based on our patent applications; • the scope of protection of any patent issuing based on our patent applications; • whether the claims of any issued patent will provide protection against competitors; • whether or not third parties will find ways to invalidate or circumvent our patent rights; • whether or not others will obtain patents claiming aspects similar to those covered by our patents and patent applications; • whether we will need to initiate litigation or administrative proceedings to enforce and / or defend our patent rights which will be costly whether we win or lose; and / or • whether the patent applications will result in issued patents with claims that cover each of our drug candidates or uses thereof in the United States or in other foreign countries. We may be subject to a third- party pre- issuance submission of prior art to the USPTO or become involved in post- grant review procedures, oppositions, derivations, revocation, reexaminations, inter partes review or interference proceedings, in the United States or elsewhere, challenging our patent rights or the patent rights of others. An adverse determination in any such challenge may result in loss of exclusivity or in our patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical technology and products or limit the duration of the patent protection of our technology and products. Such challenges also may result in substantial cost and require significant time from our scientists and management, even if the eventual outcome is favorable to us. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations, and prospects. Furthermore, if the breadth or strength of protection provided by our patents and patent applications is threatened, regardless of the outcome, it could dissuade companies from collaborating with us to license, develop or commercialize current or future drug candidates. We may rely on more than one patent to provide multiple layers of patent protection for our drug candidates. If the latest- expiring patent is invalidated or held unenforceable, in whole or in part, the overall protection for the drug candidate may be adversely affected. For example, if the latest- expiring patent is invalidated, the overall patent term for our drug candidate could be adversely affected.** Issued patents covering future products and product candidates that we or our strategic partners or collaborators may develop could be found invalid or unenforceable if challenged in court or in administrative proceedings. We may not be able to protect our trade secrets in court. If we initiate legal proceedings against a third- party to enforce a patent covering future products and product candidates that we or our strategic partners or collaborators may develop, the defendant could counterclaim that the patent covering such products or product candidates is invalid or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, written description or non- enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld information material to patentability from the USPTO, or made a misleading statement, during prosecution. Third parties also may raise similar claims before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include re- examination, post grant review, inter partes review and equivalent proceedings in foreign jurisdictions. An adverse determination in any of the foregoing proceedings could result in the revocation or cancellation of, or amendment to, our patents in such a way that they no longer cover future products and product candidates that we or our strategic partners or collaborators may develop. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which the patent examiner and we were unaware during prosecution. If a defendant or third party were to prevail on a legal assertion of invalidity or unenforceability, we could lose at least part, and perhaps all, of the patent protection on one or more of the future products and product candidates that we or our strategic partners or collaborators may develop. Such a loss of patent protection could have a

material adverse impact on our business. In addition, our trade secrets may otherwise become known or be independently discovered by competitors. Competitors and other third parties could purchase future products and product candidates that we or our strategic partners or collaborators may develop and attempt to replicate some or all of the competitive advantages we derive from our development efforts, willfully infringe, misappropriate or otherwise violate our intellectual property rights, design around our protected technology or develop their own competitive technologies that fall outside of our intellectual property rights. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor or other third party, we would have no right to prevent them, or those to whom they communicate it, from using that technology or information to compete with us. If our trade secrets are not adequately protected or sufficient to provide an advantage over our competitors, our competitive position could be adversely affected, as could our business. Additionally, if the steps taken to maintain our trade secrets are deemed inadequate, we may have insufficient recourse against third parties for misappropriating our trade secrets. Obtaining and maintaining patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non- compliance with these requirements. Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and applications are required to be paid to the USPTO and various governmental patent agencies outside of the United States in several stages over the lifetime of the patents and applications. The USPTO and various non- U. S. governmental patent agencies require compliance with a number of procedurals, documentary, fee payment and other similar provisions during the patent application process and after a patent has issued. There are situations in which non- compliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. The terms of one or more licenses that we enter into the future may not provide us with the ability to maintain or prosecute patents in the portfolio and must therefore rely on third parties to do so. If we fail to obtain and maintain the patents and patent applications covering our products or procedures, we may not be able to stop a competitor from marketing products that are the same as our product candidates, which could have a material adverse effect on our business. If we do not obtain patent term extension ~~and data exclusivity~~ for future products ~~and product candidates~~ that we or our strategic partners or collaborators may **successfully** develop, our business may be materially harmed. Patents have a limited lifespan. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U. S. non-provisional filing date. Various extensions may be available, but the life of a patent, and the protection it affords, is limited. Even if patents covering future products and product candidates that we or our strategic partners or collaborators may develop are obtained, once the patent life has expired for a **particular** product ~~candidate~~, we or our strategic partners or collaborators may be open to competition from competitive products. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are **approved and** commercialized. As a result, our patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours. In the future, if we obtain an issued patent covering one of **the** ~~future products and~~ product candidates that we or our strategic partners or collaborators may develop, depending upon the timing, duration and specifics of any FDA marketing approval of such product candidates, such patent may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, or Hatch-Waxman Amendments. The Hatch- Waxman Amendments permit a patent extension term of up to five years as compensation for patent term lost during the FDA regulatory review process **for drugs and biologics** . A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, only one patent may be extended and only those claims covering the approved drug, a method for using it or a method for manufacturing it may be extended. A patent may only be extended once and only based on a single approved product. However, we may not be granted an extension because of, for example, failure to obtain a granted patent before approval of a product candidate, failure to exercise due diligence during the testing phase or regulatory review process, failure to apply within applicable deadlines, failure to apply prior to expiration of relevant patents or otherwise our failure to satisfy applicable requirements. A patent licensed to us by a third party may not be available for patent term extension. Moreover, the applicable time period or the scope of patent protection afforded could be less than we request. If we are unable to obtain patent term extension or the term of any such extension is less than we request, our competitors may obtain approval of competing products following our patent expiration, and our revenue could be reduced, possibly materially. Changes in patent law in the United States and other jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect future products and product candidates that we or our strategic partners or collaborators may develop. Changes in either the patent laws or the interpretation of the patent laws in the United States or other jurisdictions could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. On September 16, 2011, the Leahy- Smith America Invents Act, or the Leahy-Smith Act, was signed into law. When implemented, the Leahy- Smith Act included several significant changes to U. S. patent law that impacted how patent rights could be prosecuted, enforced and defended. In particular, the Leahy- Smith Act also included provisions that switched the United States from a " first- to- invent " system to a " first- to- file " system, allowed third-party submission of prior art to the USPTO during patent prosecution and set forth additional procedures to attack the validity of a patent by the USPTO administered post grant proceedings. Under a first- to- file system, assuming the other requirements for patentability are met, the first inventor to file a patent application generally will be entitled to the patent on an invention regardless of whether another inventor had made the invention earlier. The USPTO developed new regulations and procedures governing the administration of the Leahy- Smith Act, and many of the substantive changes to patent law associated with the Leahy- Smith Act, and in particular, the first to file provisions, only became effective on March 16, 2013. Some of the Company' s patents and patent applications have effective dates later than March 16, 2013 and thus will be subject to the provisions of the Leahy- Smith Act. In addition, the patent positions of companies in the development and commercialization of biologics and pharmaceuticals are particularly uncertain. Recent rulings from the U. S. Court of Appeals for the Federal Circuit

and the U. S. Supreme Court have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. This combination of events has created uncertainty with respect to the validity and enforceability of patents, once obtained. Depending on future actions by the U. S. Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that could have a material adverse effect on our existing patent portfolio and our ability to protect and enforce our intellectual property in the future. We may not be able to protect our intellectual property rights throughout the world. Filing, prosecuting, maintaining, defending and enforcing patents on products and product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States could be less extensive than those in the United States. The requirements for patentability may differ in certain countries, particularly in developing countries; thus, even in countries where we do pursue patent protection, there can be no assurance that any patents will issue with claims that cover our products. There can be no assurance that we will obtain or maintain patent rights in or outside the United States under any future license agreements. 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 utilizing our inventions in all countries outside the United States, even in jurisdictions where we pursue patent protection, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not 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 future products and product candidates that we or our strategic partners or collaborators may develop and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing **with us. Moreover, our ability to protect and enforce our intellectual property rights may be adversely affected by unforeseen changes in foreign intellectual property laws. Additionally, laws of some countries outside of the United States and Europe do not afford intellectual property protection to the same extent as the laws of the United States and Europe** . 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 **including India and China** , do not favor the enforcement of patents, trade secrets and other intellectual property protection, particularly those relating to biotechnology and pharmaceutical products, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. For example, many foreign countries have compulsory licensing laws under which a patent owner must grant licenses to third parties. **Consequently, we may not be able to prevent third parties from practicing our inventions in certain countries outside the United States and Europe. In addition, many countries limit the enforceability of patents against government authorities or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. If we are forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired, and our business, financial condition, results of operations, and prospects may be adversely affected.** Proceedings to enforce our patent rights, even if obtained, in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. While we intend to protect our intellectual property rights in major markets for our products, we cannot ensure that we will be able to initiate or maintain similar efforts in all jurisdictions in which we may wish to market our products. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop **. We may not identify relevant third-party patents or may incorrectly interpret the relevance, scope or expiration of a third- party patent, which might adversely affect our ability to develop and market our products. We cannot guarantee that any of our patent searches or analyses, including the identification of relevant patents, the scope of patent claims or the expiration of relevant patents, are complete or thorough, nor can we be certain that we have identified each and every third- party patent and pending application in the United States and abroad that is relevant to or necessary for the commercialization of our drug candidates in any jurisdiction. The scope of a patent claim is determined by an interpretation of the law, the written disclosure in a patent and the patent' s prosecution history. Our interpretation of the relevance or the scope of a patent or a pending application may be incorrect. For example, we may incorrectly determine that our products are not covered by a third- party patent or may incorrectly predict whether a third- party' s pending application will issue with claims of relevant scope. Our determination of the expiration date of any patent in the United States or abroad that we consider relevant may be incorrect. Our failure to identify and correctly interpret relevant patents may negatively impact our ability to develop and market our products** . We may be subject to claims by third parties asserting that our employees or we have misappropriated their intellectual property or claiming ownership of what we regard as our own intellectual property. Many of our current and former employees, including our senior management, were previously employed at universities or at other biotechnology or pharmaceutical companies, including some which may be competitors or potential competitors. Some of these employees may be subject to proprietary rights, non- disclosure and non- competition agreements, or similar agreements, in connection with such previous employment. Although we try to ensure that our employees do not use the proprietary information or know- how of others in their work for us, we may be subject to claims that we or these employees have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such third party. Litigation may be necessary to defend against such claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel or sustain damages. Such intellectual property rights could be awarded to a third party, and we could be required to obtain a license from such third party to commercialize our technology or

products. Such a license may not be available on commercially reasonable terms or at all. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management. In addition, while we typically require our employees, consultants and contractors who may be involved in the development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who in fact develops intellectual property that we regard as our own, which may result in claims by or against us related to the ownership of such intellectual property. If we fail in prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights. Even if we are successful in prosecuting or defending against such claims, litigation could result in substantial costs and be a distraction to our senior management and scientific personnel. We may **be subject to claims challenging the inventorship or ownership of our patents and other intellectual property. We or our licensors may be subject to claims that former employees, collaborators or other third parties have an interest in our patents, trade secrets, or other intellectual property as an inventor or co- inventor. For example, we or our collaborators may have inventorship disputes arise from conflicting obligations of employees, consultants or others who are involved in developing our drug candidates. Litigation may be necessary to defend against these and other claims challenging inventorship or ownership of our patents, trade secrets or other intellectual property. If we or our licensors fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, intellectual property that is important to our drug candidates. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects. We may** become involved in lawsuits to protect or enforce our patents and other intellectual property rights, which could be expensive, time- consuming and unsuccessful. Competitors may infringe our patents, trademarks, copyrights or other intellectual property. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time consuming and divert the time and attention of our management and scientific personnel. In addition, our patents may become, involved in inventorship, priority, or validity disputes. To counter or defend against such claims can be expensive and time- consuming, and our adversaries may have the ability to dedicate substantially greater resources to prosecuting these legal actions than we can. Any claims we assert against perceived infringers could provoke these parties to assert counterclaims against us alleging that we infringe their patents, in addition to counterclaims asserting that our patents are invalid or unenforceable, or both. In an infringement proceeding, a court may decide that a patent is invalid or unenforceable or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. Accordingly, despite our efforts, we may not be able to prevent third parties from infringing upon or misappropriating intellectual property rights we own or control. An adverse result in any litigation proceeding could put one or more of our owned or in- licensed patents at risk of being invalidated or interpreted narrowly. Further, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. Even if resolved in our favor, the court may decide not to grant an injunction against further infringing activity and instead award only monetary damages, which may or may not be an adequate remedy. Litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses and could distract our personnel from their normal responsibilities. **Alternatively, we may be required to obtain a license from such third party in order to use the infringing technology and continue developing, manufacturing or marketing the infringing drug candidate. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors access to the same technologies licensed to us.** In addition **, we could be found liable for monetary damages, including treble damages and attorneys' fees if we are found to have willfully infringed a patent. Furthermore** , there could be public announcements of the results of hearings, motions, or other interim proceedings or developments, and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing, or distribution activities. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources and more mature and developed intellectual property portfolios. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace. If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our marks of interest and our business may be adversely affected. Our **current or future** trademarks or trade names may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. We rely on both registration and common law protection for our trademarks. We may not be able to protect our rights to these trademarks and trade names or may be forced to stop using these names, which we need for name recognition by potential partners or customers in our markets of interest. During trademark registration proceedings, we may receive rejections. Although we would be given an opportunity to respond to those rejections, we may be unable to overcome such rejections. In addition, with the USPTO and with comparable agencies in many foreign jurisdictions, third parties are given an opportunity to oppose pending trademark applications and to seek to cancel registered trademarks. Opposition or cancellation proceedings may be filed against our trademarks, and our trademarks may not survive such proceedings. If we are unable to establish name recognition based on our trademarks and trade names, we may not be able to compete effectively and our business may be adversely affected. **We may license our trademarks and trade names to third parties, such as distributors. Although these license agreements may provide guidelines for how our trademarks and trade names may be used, a breach of these agreements or misuse of our trademarks and tradenames by our licensees may jeopardize our rights in or diminish the goodwill associated with our**

trademarks and trade names. Moreover, any proprietary name we have proposed to use with our drug candidates in the United States must be approved by the FDA, regardless of whether we have registered it, or applied to register it, as a trademark. Similar requirements exist in Europe. The FDA typically conducts a review of proposed proprietary product names, including an evaluation of potential for confusion with other product names. If the FDA (or an equivalent administrative body in a foreign jurisdiction) objects to any of our proposed proprietary product names, we may be required to expend significant additional resources in an effort to identify a suitable substitute name that would qualify under applicable trademark laws, not infringe the existing rights of third parties, and be acceptable to the FDA. Furthermore, in many countries, owning and maintaining a trademark registration may not provide an adequate defense against a subsequent infringement claim asserted by the owner of a senior trademark. At times, competitors or other third parties may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement claims brought by owners of other registered trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names. If we assert trademark infringement claims, a court may determine that the marks we have asserted are invalid or unenforceable, or that the party against whom we have asserted trademark infringement has superior rights to the marks in question. In this case, we could ultimately be forced to cease use of such trademarks. ITEM 1B. Unresolved Staff Comments