**Risk Factors Comparison 2024-02-29 to 2023-03-23 Form: 10-K**

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

Ownership of our securities involves a high degree of risk. You should carefully review and consider the risks, uncertainties and other factors described below before you decide whether to own our securities. Any of these factors could materially and adversely affect our business, financial condition, operating results and prospects and could negatively impact the market price of our common stock, and you may lose some or all of your investment. The risks and uncertainties described below are not the only ones facing our Company. Additional risks and uncertainties that we are unaware of, or that we currently deem immaterial, may also impair our business operations. You should also refer to the other information contained in this Form 10- K, including our financial statements and the related notes. Summary of Risk Factors Our business is subject to numerous risks and uncertainties, discussed in more detail in the following section. These risks include, among others, the following key risks: Risks Related to Our Business and Capital Requirements ● We have a history of operating losses, and we expect losses to continue for the foreseeable future. ● We have received a going concern opinion from our auditors. ● Our business will require continued funding. If we do not receive adequate funding, we may not be able to continue our operations. ● Significant disruptions of information technology systems or breaches of information security systems could adversely affect our business ~~. ● Our business could be adversely affected by widespread public health epidemics or other catastrophic events beyond our control~~ . Risks Related to Development and Commercialization of Product Candidates and Dependence on Third Parties ● Our products are still being developed and are unproven. These products may not be successful. ● We depend upon key personnel who may terminate their employment with us at any time. If we were to lose the services of any of these individuals, our business and operations may be adversely affected. ● Regulatory and legal uncertainties could result in significant costs or otherwise harm our business. ● We face intense competition and rapid technological change that could result in products that are superior to, or earlier to the market than, the products we will be commercializing or developing. ● Our product candidates are based on new medical technology and, consequently, are inherently risky. Concerns about the safety and efficacy of our products could limit our future success. ● We may experience delays in our clinical trials that could adversely affect our financial results and our commercial prospects. ● Failure to obtain timely regulatory approvals required to exploit the commercial potential of our products could increase our future development costs or impair our future sales. ● State pharmaceutical marketing compliance and reporting requirements may expose us to regulatory and legal action by state governments or other government authorities. ● Changes in healthcare law and implementing regulations, as well as changes in healthcare policy, may impact our business in ways that we cannot currently predict, and may have a significant adverse effect on our business and results of operations. ● We may not be successful in establishing collaborations for product candidates we seek to commercialize, which could adversely affect our ability to discover, develop, and commercialize products. ● We do not have manufacturing, sales or marketing experience. ● Our products under development may not gain market acceptance. ● We may be required to defend lawsuits or pay damages for product liability claims. ● Reimbursement decisions by third- party payors may have an adverse effect on pricing and market acceptance. If there is not sufficient reimbursement for our products, it is less likely that they will be widely used. Risks Related to Our Intellectual Property ● Our success depends on our ability to obtain, maintain, protect and enforce our intellectual property and our proprietary technologies. ● We could lose our license rights to our important intellectual property if we do not fulfill our contractual obligations to our licensors. ● Other parties may claim that we infringe their intellectual property or proprietary rights, which could cause us to incur significant expenses or prevent us from selling products. ● Any inability to protect our or our licensors' intellectual property rights in the United States and foreign countries could limit our ability to prevent others from manufacturing or selling our products. ● Changes in United States patent law could diminish the value of patents in general, thereby impairing our ability to protect our product candidates. ● The patent protection and patent prosecution for our product candidates is dependent in part on third parties. Risks Related to Our Common Stock ● The market price of our common stock is highly volatile. ● The sale or issuance of additional shares of our common stock or other equity securities could result in additional dilution to our stockholders. ● Certain provisions of our certificate of incorporation which authorize the issuance of shares of preferred stock may make it more difficult for a third party to effect a change in control. ● We have never paid dividends and have no plans to do so. ● Public company compliance may make it more difficult for us to attract and retain officers and directors. ● Our Certificate of Incorporation and Bylaws may be amended by the affirmative vote of a majority of our stockholders. ● Broker- dealers may be discouraged from effecting transactions in shares of our common stock if we are considered to be a penny stock and thus subject to the penny stock rules. **As** ~~● We may be delisted from the Nasdaq Stock MarketAs~~ a research and development- focused company, we have had no product revenue to date and revenues from our government grants and other collaborations have not generated sufficient cash flows to cover operating expenses. Since our inception, we have incurred operating losses each year due to costs incurred in connection with research and development activities and general and administrative expenses associated with our operations. We incurred a net loss of approximately $ ~~14~~ **26** million for the year ended December 31, ~~2022~~ **2023** . We expect to incur additional operating losses and expect cumulative losses to increase as our research and development, preclinical, clinical, and manufacturing efforts expand. Our ability to generate revenue and achieve profitability depends on our ability to successfully complete the development of our product candidates, conduct preclinical tests and clinical trials, obtain the necessary regulatory approvals, and manufacture and market or otherwise commercialize our products. Unless we are able to successfully meet these challenges, we will not be profitable and may not remain in business. We have received a" going concern" opinion from our independent registered public accounting firm, reflecting substantial doubt about our ability to continue as a going concern. Our

consolidated financial statements contemplate that we will continue as a going concern and do not contain any adjustments that might result if we were unable to continue as a going concern. Our ability to continue as a going concern is dependent upon our ability to raise additional capital and implement our business plan. If we are unable to achieve or sustain profitability or to secure additional financing on acceptable terms, we may not be able to meet our obligations as they come due, raising substantial doubts as to our ability to continue as a going concern. Any such inability to continue as a going concern may result in our stockholders losing their entire investment. There is no guarantee that we will become profitable or secure additional financing on acceptable terms. To date, we have financed our operations principally through the sale of our equity securities and through government grants and clinical trial support. We will require substantial additional financing at various intervals for our operations, including clinical trials, operating expenses, intellectual property protection and enforcement, for pursuit of regulatory approvals, and for establishing or contracting out manufacturing, marketing and sales functions. There is no assurance that such additional funding will be available on terms acceptable to us or at all. If we are not able to secure the significant funding that is required to maintain and continue our operations at current levels, or at levels that may be required in the future, we may be required to delay clinical studies or clinical trials, curtail operations, or obtain funds through collaborative arrangements that may require us to relinquish rights to some of our products or potential markets. We may pursue additional support from the federal government for our vaccine and immunotherapy development programs; however, as we progress to the later stages of our development activities, government financial support may be more difficult to obtain, or may not be available at all. Therefore, it will be necessary for us to look to other sources of funding to finance our development activities. We expect that our current working capital will be sufficient to support our planned level of operations into the ~~fourth~~ **second** quarter of ~~2023~~ **2024** . We will need to raise additional funds to significantly advance our vaccine development programs and to continue our operations. In order to meet our operating cash flow needs we plan to seek sources of non- dilutive capital through government grant programs and clinical trial support. We may also plan additional offerings of our equity securities, debt, or convertible debt instruments. Should the financing we require to sustain our working capital needs be unavailable or prohibitively expensive when we require it, the consequences could have a material adverse effect on our business, operating results, financial condition and prospects. Significant disruptions of information technology systems or breaches of information security systems could adversely affect our business. We rely upon a combination of information technology systems and traditional recordkeeping to operate our business. In the ordinary course of business, we collect, store, and transmit confidential information (including, but not limited to, personal information and intellectual property). We have also outsourced elements of our operations to third parties, including elements of our information technology systems and, as a result, we manage a number of independent vendor relationships with third parties who may or could have access to our confidential information. Our information technology and information security systems and records are potentially vulnerable to security breaches, service interruptions, or data loss from inadvertent or intentional actions by our employees or vendors. Our information technology and information security systems and records are also potentially vulnerable to malicious attacks by third parties. Such attacks are of ever- increasing levels of sophistication and are made by groups and individuals with a wide range of expertise and motives (including, but not limited to, financial crime, industrial espionage, and market manipulation). While we have invested, and continue to invest, a portion of our limited funds in our information technology and information security systems, there can be no assurance that our efforts will prevent security breaches, service interruptions, or data losses. Any security breaches, service interruptions, or data losses could adversely affect our business operations and / or result in the loss of critical or sensitive confidential information or intellectual property, and could result in financial, legal, business, and reputational harm to us or allow third parties to gain material, inside information that they may use to trade in our securities ~~. In addition to our reliance on our own employees and facilities, we depend on our collaborators, laboratories and other facilities for the continued operation of our business. Despite any precautions we take, public health epidemics, such as COVID- 19, or other catastrophic events, such as natural disasters, terrorist attacks, hurricanes, fire, floods and ice and snowstorms, may result in interruptions in our business~~ . To become profitable, we must generate revenue through sales of our products. However, our products are in varying stages of development and testing. Our products have not been proven in human clinical trials and have not been approved by any government agency for sale. If we cannot successfully develop and prove our products and processes, or if we do not develop other sources of revenue, we will not become profitable and at some point, we would discontinue operations. The success of our business strategy will depend to a significant degree upon the continued services of key management, technical and scientific personnel and our ability to attract and retain additional qualified personnel and managers. Competition for qualified personnel is intense among companies, academic institutions and other organizations. The ability to attract and retain personnel is adversely affected by our financial challenges. If we are unable to attract and retain key personnel and advisors, it may negatively affect our ability to successfully develop, test, commercialize and market our products and product candidates. To manufacture and sell our products, we must comply with extensive domestic and international regulation. In order to sell our products in the United States, approval from the U. S. Food and Drug Administration (the " FDA ") is required. Satisfaction of regulatory requirements, including FDA requirements, typically takes many years, and if approval is obtained at all, it is dependent upon the type, complexity and novelty of the product, and requires the expenditure of substantial resources. We cannot predict whether our products will be approved by the FDA. Even if they are approved, we cannot predict the time frame for approval. Foreign regulatory requirements differ from jurisdiction to jurisdiction and may, in some cases, be more stringent or difficult to meet than FDA requirements. As with the FDA, we cannot predict if or when we may obtain these regulatory approvals. If we cannot demonstrate that our products can be used safely and successfully in a broad segment of the patient population on a long- term basis, our products would likely be denied approval by the FDA and the regulatory agencies of foreign governments. The market for vaccines that protect against or treat human infectious diseases is intensely competitive and is subject to rapid and significant technological change. We have numerous competitors in the United States and abroad, including, among others, large companies with substantially greater resources than us. If any of our competitors develop

products with efficacy or safety profiles significantly better than our products, we may not be able to commercialize our products, and sales of any of our commercialized products could be harmed. Some of our competitors and potential competitors have substantially greater product development capabilities and financial, scientific, marketing and human resources than we do. Competitors may develop products earlier, obtain FDA approvals for products more rapidly, or develop products that are more effective than those under development by us. We will seek to expand our technological capabilities to remain competitive; however, research and development by others may render our technologies or products obsolete or noncompetitive or result in treatments or cures superior to ours. We are subject to the risks of failure inherent in the development of product candidates based on new medical technologies. These risks include the possibility that the products we create will not be effective, that our product candidates will be unsafe or otherwise fail to receive the necessary regulatory approvals, and that our product candidates will be difficult to manufacture on a large scale or will be uneconomical to market. Many pharmaceutical products cause multiple potential complications and side effects, not all of which can be predicted with accuracy and many of which may vary from patient to patient. Long term follow- up data may reveal previously unidentified complications associated with our products. The responses of potential physicians and others to information about complications could materially adversely affect the market acceptance of our products, which in turn would materially harm our business. We do not know whether planned pre- clinical and clinical trials will begin on time or whether we will complete any of our trials on schedule, if at all. Product development costs will increase if we have delays in testing or approvals, or if we need to perform more or larger clinical trials than planned. Significant delays may adversely affect our financial results and the commercial prospects for our products and delay our ability to become profitable. We rely heavily on independent clinical investigators, vaccine manufacturers, and other third- party service providers for successful execution of our clinical trials, but do not control many aspects of their activities. We are responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the trial. Moreover, the FDA requires us to comply with standards, commonly referred to as Good Clinical Practices, for conducting, recording, and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected. Our reliance on third parties that we do not control does not relieve us of these responsibilities and requirements. Third parties may not complete activities on schedule or may not conduct our clinical trials in accordance with regulatory requirements or our stated protocols. The failure of these third parties to carry out their obligations could delay or prevent the development, approval and commercialization of our product candidates. None of our vaccines are approved by the FDA for sale in the United States or by other regulatory authorities for sale in foreign countries. To exploit the commercial potential of our technologies, we are conducting and planning to conduct additional pre- clinical studies and clinical trials. This process is expensive and can require a significant amount of time. Failure can occur at any stage of testing, even if the results are favorable. Failure to adequately demonstrate safety and efficacy in clinical trials could delay or preclude regulatory approval and restrict our ability to commercialize our technology or products. Any such failure may severely harm our business. In addition, any approvals we obtain may not cover all of the clinical indications for which approval is sought or may contain significant limitations in the form of narrow indications, warnings, precautions or contraindications with respect to conditions of use, or in the form of onerous risk management plans, restrictions on distribution, or post- approval study requirements. Several states have enacted legislation requiring pharmaceutical companies to establish marketing compliance programs and file periodic reports on sales, marketing, pricing and other activities. Similar legislation is being considered in other states. Many of these requirements are new and uncertain, and available guidance is limited. Unless we are in full compliance with these laws, we could face enforcement action, fines, and other penalties and could receive adverse publicity, all of which could harm our business. Changes in healthcare law and implementing regulations, as well as changes in healthcare policy, may impact our business in ways that we cannot currently predict, and may have a significant adverse effect on our business and results of operations. In the United States and foreign jurisdictions, there have been, and continue to be, several legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of product candidates, restrict or regulate post- approval activities, and affect our ability to profitably sell any product candidates for which we obtain marketing approval. Among policy makers and payors in the United States and elsewhere, including in the European Union, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and / or expanding access. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives. There has also been heightened governmental scrutiny recently over the manner in which drug manufacturers set prices for their marketed products. There have been several Congressional inquiries and proposed bills, as well as state efforts, 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. In June 2017, the FDA issued a Drug Competition Action plan intended to lower prescription drug prices by encouraging competition from generic versions of existing products. In July 2018, the FDA issued a Biosimilar Action Plan, intended to similarly promote competition to prescription biologics from biosimilars. In August 2020, the Inflation Reduction Act included provisions to increase Medicare' s ability to negotiate prescription drug prices. Individual states in the United States have also become increasingly aggressive in passing legislation and implementing 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. For example, in September 2017, the California State Assembly approved SB17, which requires pharmaceutical companies to notify health insurers and government health plans at least 60 days before any scheduled increases in the prices of their products if they exceed 16 % over a two- year period, and further requiring pharmaceutical companies to explain the reasons for such increase and, effective in 2016, Vermont passed a law requiring certain manufacturers identified by the state to justify their price increases. We expect that these, and other healthcare reform measures that may be adopted in the future, may result in more

rigorous coverage criteria and lower reimbursement, and in downward pressure on the price that we receive for any approved product. Any reduction in reimbursement from Medicare or other government- funded programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our drugs, once marketing approval is obtained. We expect to seek collaborations for the development and commercialization of product candidates in the future. The timing and terms of any collaboration will depend on the evaluation by prospective collaborators of the clinical trial results and other aspects of a product' s safety and efficacy profile. If we are unable to reach agreements with suitable collaborators for any product candidate, we will be forced to fund the entire development and commercialization of such product candidates, ourselves, and we may not have the resources to do so. If resource constraints require us to enter into a collaboration agreement early in the development of a product candidate, we may be forced to accept a more limited share of any revenues the product may eventually generate. We face significant competition in seeking appropriate collaborators. Moreover, these collaboration arrangements are complex and time- consuming to negotiate and document. We may not be successful in our efforts to establish collaborations or other alternative arrangements for any product candidate. Even if we are successful in establishing collaborations, we may not be able to ensure fulfillment by collaborators of their obligations or our expectations. We do not have experience in manufacturing, selling, or marketing. To obtain the expertise necessary to successfully manufacture, market, and sell our products, we must develop our own commercial infrastructure and / or collaborative commercial arrangements and partnerships. Our ability to execute our current operating plan is dependent on numerous factors, including, the performance of third- party collaborators with whom we may contract. Our products may not gain market acceptance among physicians, patients, healthcare payers and the medical community. Significant factors in determining whether we will be able to compete successfully include: ● the efficacy and safety of our products; ● the time and scope of regulatory approval; ● reimbursement coverage from Medicare, Medicaid, insurance companies and others; ● the price and cost- effectiveness of our products, especially as compared to any competitive products; and ● the ability to maintain patent protection; and ● the market demand is not readily known. Product liability is a major risk in testing and marketing biotechnology and pharmaceutical products. We may face substantial product liability exposure in human clinical trials and for products that we sell after regulatory approval. We carry product liability insurance and we expect to continue such policies. However, product liability claims, regardless of their merits, could exceed policy limits, divert management' s attention, and adversely affect our reputation and demand for our products. Market acceptance of products we develop, if approved, will depend on reimbursement policies and may be affected by, among other things, future healthcare reform measures. Government authorities and third- party payors, such as private health insurers and health maintenance organizations, decide which drugs they will cover and establish payment levels. We cannot be certain that reimbursement will be available for any products that we may develop. Also, we cannot be certain that reimbursement policies will not reduce the demand for, or the price paid for our products. If reimbursement is not available or is available on a limited basis, we may not be able to successfully commercialize products that we develop. Our success depends on our ability to obtain, maintain, protect, and enforce our intellectual property and our proprietary technologies . In general, our commercial success will depend in part on our and our licensors' ability to obtain, maintain, protect, and enforce our intellectual property and proprietary technologies, including patent protection and trade secret protection for our product candidates, proprietary technologies and their uses as well as our ability to operate without infringing, misappropriating, or otherwise violating the intellectual property rights of others. If we or our licensors are unable to obtain, maintain, protect, or enforce our intellectual property rights or if our intellectual property rights are inadequate for our technology or our product candidates, our competitive position could be harmed, which could have a material adverse impact on our business, results of operations, financial conditions, and prospects. There can be no assurance that our patent applications will result in patents being issued or that issued patents will afford sufficient protection against competitors with similar technologies, nor can there be any assurance that the patents if issued will not be infringed, misappropriated, violated, designed around or invalidated by third parties. Even issued patents may later be found invalid or unenforceable or may be modified or revoked in proceedings instituted by third parties before various patent offices or in courts. The degree of future protection for our intellectual property is uncertain. Only limited protection may be available and may not adequately obtain, maintain, protect, and enforce our rights or permit us to gain or keep any competitive advantage. These uncertainties and / or limitations in our ability to properly obtain, maintain, protect, and enforce the intellectual property rights relating to our product candidates could have a material adverse effect on our financial condition and results of operations. We cannot be certain that the claims in our in- licensed pending patent applications will be considered patentable by the U. S. Patent and Trademark Office, or USPTO, courts in the United States or by the patent offices and courts in foreign countries, nor can we be certain that claims that may ultimately issue from our patent applications will not be found invalid or unenforceable if challenged. If we or our licensors are unable to obtain or maintain patent protection with respect to our product candidates, our business, financial condition, results of operations, and prospects could be materially harmed. Our rights to significant parts of the technology we use in our products are licensed from third parties and are subject to termination if we do not fulfill our contractual obligations to our licensors. Termination of intellectual property rights under any of our license agreements could adversely impact our ability to produce or protect our products. Our obligations under our license agreements include requirements that we make milestone payments to our licensors upon the achievement of clinical development and regulatory approval milestones, royalties as we sell commercial products, and reimbursement of patent filing and maintenance expenses. Should we become bankrupt or otherwise unable to fulfill our contractual obligations, our licensors could terminate our rights to critical technology that we rely upon. Our success will depend in part on our ability to operate without infringing the patents and proprietary rights of third parties. The manufacture, use and sale of biologic products have been subject to substantial patent litigation in the biopharmaceutical industry. Such lawsuits often relate to the validity or infringement of patents or other proprietary rights of third parties. Pharmaceutical companies, biotechnology companies, universities, research institutions or other third parties may have filed patent applications or may have been granted patents that

cover aspects of our products or our licensors' products, product candidates or other technologies. Future or existing patents issued to third parties may contain patent claims that cover our products or their use or manufacture. In particular, the patent landscape in the ~~COVID~~ **Covid** - 19 vaccine space is crowded, and a large number of patent applications have been filed by numerous entities since January 2020, including for the use of certain SARS- CoV- 2 antigens and antigenic combinations, including from Moderna, Janssen Pharmaceuticals, Inc., Sementis LTD., VaxBio, Inc., Oxford University, BioNTech, Ichan School of Medicine at Mount Sinai, Diosynvax LTD., The University of Alberta, **University of Texas,** and Tonix Pharmaceuticals. ~~We expect~~ **If a third party were** to **assert an** ~~be subject to~~ infringement ~~claims~~ **claim** ~~from time to time in the ordinary course of business, and third parties could assert infringement claims~~ against us in the future with respect to our current products or with respect to products that we may develop or license ~~.~~**, such** ~~Litigation~~ **litigation** or interference proceedings could force us to: ● stop or delay selling, manufacturing or using products that incorporate, or are made using the challenged intellectual property; ● pay damages; or ● enter into licensing or royalty agreements that may not be available on acceptable terms, if at all. Any litigation or interference proceedings, regardless of their outcome, **may** ~~would likely~~ delay the regulatory approval process, be costly and require significant time and attention of our key management and technical personnel. Any inability to protect our or our licensors' intellectual property rights in the United States and foreign countries could limit our ability to prevent others from manufacturing or selling our products. We will rely on trade secrets, unpatented proprietary know- how, continuing technological innovation and, in some cases, patent protection to preserve our competitive position. Our patents and licensed patent rights may be challenged, invalidated, infringed or circumvented, and the rights granted in those patents may not provide proprietary protection or competitive advantages to us. We and our licensors may not be able to develop patentable products with acceptable patent protection. Even if patent claims are allowed, the claims may not issue, or in the event of issuance, may not be sufficient to protect the technology owned by or licensed to us. If patents containing competitive or conflicting claims are issued to third parties, we may be prevented from commercializing the products covered by such patents or may be required to obtain or develop alternate technology. In addition, other parties may duplicate, design around or independently develop similar or alternative technologies. Some of our patent families and our in- licensed patent families are in an early stage of prosecution and cannot be enforced against third parties practicing the technology claimed in such applications unless, and until, patents are issued from such applications, and then only to the extent the issued claims cover the third- party technology. There can be no assurance that our patent applications will result in patents being issued or that issued patents will afford sufficient protection against competitors with similar technologies. There can be no assurance that the patents if issued will not be infringed, misappropriated, violated, designed around or invalidated by third parties. Even issued patents may later be found invalid or unenforceable or may be modified or revoked in proceedings instituted by third parties before various patent offices or in courts. The degree of future protection for our intellectual property is uncertain. Only limited protection may be available and may not adequately obtain, maintain, protect, and enforce our rights or permit us to gain or keep any competitive advantage. These uncertainties and / or limitations in our ability to properly obtain, maintain, protect, and enforce the intellectual property rights relating to our product candidates could have a material adverse effect on our financial condition and results of operations. We may not be able to prevent third parties from infringing or using our intellectual property, and the parties from whom we may license intellectual property may not be able to prevent third parties from infringing or using the licensed intellectual property. We generally attempt to control and limit access to, and the distribution of, our product documentation and other proprietary information. Despite efforts to protect this proprietary information, unauthorized parties may obtain and use information that we may regard as proprietary. Other parties may independently develop similar know- how or may even obtain access to these technologies. The laws of some foreign countries do not protect proprietary information to the same extent as the laws of the United States, and many companies have encountered significant problems and costs in protecting their proprietary information in these foreign countries. Furthermore, even if our or our licensors' patent applications are granted, the patent term may be inadequate to protect our competitive position on our product candidates for an adequate amount of time. Patents have a limited lifespan. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest United States 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 our product candidates have been or are obtained, once the patent life has expired, we may be open to competition from competitive products. Given the amount of time required for the development, testing, and regulatory review of product candidates, patents protecting our product candidates might expire before or shortly after such candidates are commercialized. As a result, our patent portfolio may not provide us with sufficient rights to exclude others from commercializing product candidates similar or identical to ours. As is the case with other biotechnology companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing biotechnology patents is costly, time- consuming, and inherently uncertain. Changes in either the patent laws or in the interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property and may increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. We cannot predict the breadth of claims that may be allowed or enforced in our patents or in third- party patents. In addition, Congress or other foreign legislative bodies may pass patent reform legislation that is unfavorable to us. For example, the Leahy- Smith America Invents Act, or the Leahy- Smith Act, signed into law on September 16, 2011, includes a number of significant changes to U. S. patent law. These include provisions that affect the way patent applications are prosecuted, redefine prior art and provide more efficient and cost- effective avenues for competitors to challenge the validity of patents. These include allowing third- party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by USPTO administered post- grant proceedings, including post- grant review, inter partes review, and derivation proceedings. Further, because of a lower evidentiary standard in these USPTO post- grant proceedings compared to the evidentiary standard in United States federal courts necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though

the same evidence would be insufficient to invalidate the claim if first presented in a district court action. Accordingly, a third party may attempt to use the USPTO procedures to invalidate our patent claims that would not have been invalidated if first challenged by the third party as a defendant in a district court action. Thus, the Leahy- Smith Act and its implementation can increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business, financial condition, results of operations and prospects. After March 2013, under the Leahy- Smith Act, the United States transitioned to a first inventor to file system in which, assuming that the other statutory requirements are met, the first inventor to file a patent application is entitled to the patent on an invention regardless of whether a third- party was the first to invent the claimed invention. A third party that files a patent application in the USPTO after March 2013, but before we file an application covering the same invention, could therefore be awarded a patent covering an invention of ours even if we had made the invention before it was made by such third party. This will require us to be cognizant going forward of the time from invention to filing of a patent application. ~~Since~~ **Because** patent applications in the United States and most other countries are confidential for a period of time after filing or until issuance, we cannot be certain that we or our licensors were the first to either (i) file any patent application related to our product candidates and other proprietary technologies we may develop or (ii) invent any of the inventions claimed in our or our licensor' s patents or patent applications. Even where we have a valid and enforceable patent, we may not be able to exclude others from practicing the claimed invention where the other party can show that they used the invention in commerce before our filing date or the other party benefits from a compulsory license. However, the Leahy- Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business, financial condition, results of operations and prospects. In addition, the patent positions of companies in the development and commercialization of biologics and pharmaceuticals are particularly uncertain. Recent United States Supreme Court and Federal Circuit rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. For example, recent Federal Circuit rulings such as Ariad Pharms., Inc. v. Eli Lilly & Co., 598 F. 3d 1336, 1340 (Fed. Cir. 2010) (en banc), Wyeth & Cordis Corp. v. Abbott Labs, 720 F. 3d 1380 (Fed. Cir. 2013), Enzo Life Scis., Inc. v. Roche Molecular Sys., 928 F. 3d 1340 (Fed. Cir. 2019), and Idenix Pharms. LLC v. Gilead Scis. Inc., 941 F. 3d 1149 (Fed. Cir. 2019), and Amgen Inc. v. Sanofi, ~~987 F~~ **598 U** . ~~3d 1080~~ **S. 594** ( ~~Fed. Cir. 2021~~ **2023** ) have significantly heightened the standard for securing broad claims to pharmaceutical and biological products **. In addition, recent Federal Circuit rulings such as In re Cellect, 81 F. 4th 1216 (Fed. Cir. 2023) have expanded the bases for invalidating a patent under the judicially created doctrine of obviousness- type double patenting** . In addition to heightened patentability requirements, recent Supreme Court and Federal Circuit cases relating to biosimilar product approval under the BPCIA, have held that the " patent dance " provisions of the statute, which are intended to resolve any patent infringement issues before the approval of a biosimilar, are discretionary, and a biosimilar applicant can opt out by refusing to provide a copy of its application and manufacturing information to the biologic sponsor (see Sandoz Inc. v. Amgen Inc., 137 S. Ct. 1664 (2017). It may be that we do not learn of a biosimilar application until after FDA publishes its approval (see Immunex v. Samsung Bioepsis, 2: 19- cv- 117555- CCC- MF (D. N. J. Apr. 30, 2019). In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by Congress, the United States federal courts, the USPTO, or similar authorities in foreign jurisdictions, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents we might obtain in the future. We or our licensors 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 strengthen our patent position. It is possible that defects of form in the preparation or filing of our patents or 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 or our licensors, fail to establish, maintain, or protect such patents and other intellectual property rights, such rights may be reduced or eliminated. If our licensors are not fully cooperative or disagree with us as to the prosecution, maintenance, or enforcement of any patent rights, such patent rights could be compromised. 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. Any of these outcomes could impair our ability to prevent competition from third parties, which may have an adverse impact on our business. We rely on third parties to file and prosecute patent applications and maintain patents and otherwise protect the licensed intellectual property under some of our license agreements. We have not had and do not have primary control over these activities for **some of** our **in- licensed** patents or patent applications and other intellectual property rights. We cannot be certain that such activities by third parties have been or will be conducted in compliance with applicable laws and regulations or will result in valid and enforceable patents or other intellectual property rights. Pursuant to the terms of the license agreements with some of our licensors, the licensors may have the right to control enforcement of our licensed patents or defense of any claims asserting the invalidity of these patents and even if we are permitted to pursue such enforcement or defense, we will require the cooperation of our licensors. We cannot be certain that our licensors will allocate sufficient resources or prioritize their or our enforcement of such patents or defense of such claims to protect our interests in the licensed patents. Even if we are not a party to these legal actions, an adverse outcome could harm our business because it might prevent us from continuing to license intellectual property that we may need to operate our business. If any of our licensors fail to appropriately prosecute and maintain patent protection for patents covering our product candidates, our ability to develop and commercialize those product candidates may be adversely affected and we may not be able to prevent competitors from making, using, and selling competing products. In addition, even where we have the right to control patent prosecution of patents and patent applications we have acquired or licensed from third parties, we may still be adversely affected or prejudiced by actions or inactions of our predecessors or

licensors and their counsel that took place prior to us assuming control over patent prosecution. Our technology acquired or licensed from various third parties may be subject to retained rights. Our predecessors or licensors often retain certain rights under their agreements with us, including the right to use the underlying technology for non- commercial academic and research use, to publish general scientific findings from research related to the technology, and to make customary scientific and scholarly disclosures of information relating to the technology. It is difficult to monitor whether our predecessors or licensors limit their use of the technology to these uses, and we could incur substantial expenses to enforce our rights to our licensed technology in the event of misuse. In addition, the research resulting in certain of our in- licensed patent rights and technology was funded in part by the United States government. As a result, the government may have certain rights, or march- in rights, to such patent rights and technology. When new technologies are developed with government funding, the government generally obtains certain rights in any resulting patents, including a nonexclusive license authorizing the government to use the invention for noncommercial purposes. These rights may permit the government to disclose our confidential information to third parties and to exercise march- in rights to use or allow third parties to use our licensed technology. The United States government also has the right to take title to these inventions if the applicable licensor fails to disclose the invention to the government or fails to file an application to register the intellectual property within specified time limits. The government can exercise its march- in rights if it determines that action is necessary because we fail to achieve practical application of the government- funded technology, because action is necessary to alleviate health or safety needs, to meet requirements of federal regulations, or to give preference to United States industry. In addition, our rights in such inventions may be subject to certain requirements to manufacture products embodying such inventions in the United States. Any exercise by the government of such rights could harm our competitive position, business, financial condition, results of operations, and prospects. The market price of our common stock has been, and is expected to continue to be, highly volatile. Certain factors, including announcements of new developments by us or other companies, regulatory matters, new or existing medicines or procedures, concerns about our financial position, operating results, litigation, government regulation, developments or disputes relating to agreements, patents or proprietary rights, may have a significant impact on the market price of our stock. In addition, potential dilutive effects of future sales of shares of common stock by us, and subsequent sales of common stock by the holders of our options and warrants could have an adverse effect on the market price of our shares. In addition, the securities markets from time- to- time experience significant price and volume fluctuations that are unrelated to the operating performance of particular companies. These market fluctuations may also materially and adversely affect the market price of our common stock. In order to meet our operating cash flow needs, we may plan additional offerings of our equity securities, debt, or convertible debt instruments. The sale of additional equity securities could result in significant additional dilution to our stockholders. The incurrence of indebtedness could result in debt service obligations and operating and financing covenants that would restrict our operations. We cannot assure investors that financing will be available in amounts or on terms acceptable to us, if at all. We are obligated to issue additional shares of our common stock in connection with our outstanding warrants if the warrant holders choose to exercise them. There are warrants exercisable for ~~approximately13~~ -- **approximately 2** . ~~4~~ **0** million shares ~~at~~ **, 374, 000 of which are prefunded ($- 0-** exercise ~~prices~~ - **price** ~~ranging from~~ **) with the remainder having a weighted- average exercise price of** $ ~~1~~ **14** . **58** ~~65 to $ 13. 00 per share~~ . The exercise of these warrants will cause us to issue additional shares of our common stock and will dilute the percentage ownership of our shareholders. Our certificate of incorporation authorizes our Board of Directors to issue up to 10, 000, 000 shares of preferred stock. The shares of preferred stock may be issued in one or more series, the terms of which may be determined at the time of issuance by our Board of Directors without further action by the stockholders. These terms may include voting rights, including the right to vote as a series on particular matters, preferences as to dividends and liquidation, conversion rights, redemption rights and sinking fund provisions. The issuance of any newly issued preferred stock could diminish the rights of holders of our common stock, and therefore could reduce the value of our common stock. In addition, specific rights granted to future holders of preferred stock could be used to restrict our ability to merge with, or sell assets to, a third party. The ability of our Board of Directors to issue preferred stock could make it more difficult, delay, discourage, prevent or make it costlier to acquire or effect a change- in- control, which in turn could prevent the stockholders from recognizing a gain in the event that a favorable offer is extended and could materially and negatively affect the market price of our common stock. Holders of shares of our common stock are entitled to receive such dividends as may be declared by our Board of Directors. To date, we have paid no cash dividends on our shares of common stock and we do not expect to pay cash dividends on our common stock in the foreseeable future. We intend to retain future earnings, if any, to provide funds for operations of our business. Therefore, any potential return investors may have in our common stock will be in the form of appreciation, if any, in the market value of their shares of common stock. The Sarbanes- Oxley Act, the Dodd- Frank Act, the JOBS Act, the FAST Act, and rules subsequently implemented by the SEC have required changes in corporate governance practices of public companies. As a public company, we expect these rules and regulations, and amendments to them, to contribute to our compliance costs and to make certain activities more time **-** consuming and costly. As a public company, we also expect that these rules and regulations may make it difficult and expensive for us to obtain director and officer liability insurance and we may be required to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. As a result, it may be difficult for us to attract and retain qualified persons to serve on our board of directors or as executive officers. Our Certificate of Incorporation and Bylaws may be amended by the affirmative vote of a majority of our stockholders. Under the Delaware General Corporation Law, a corporation' s certificate of incorporation may be amended by the affirmative vote of the holders of a majority of the outstanding shares entitled to vote, and a majority of the outstanding shares of each class entitled to vote as a class, unless the articles require the vote of a larger percentage of shares. Our Certificate of Incorporation, as amended, does not require the vote of a larger percentage of shares. As permitted under the Delaware General Corporation Law, our Bylaws give our board of directors the power to adopt, amend, or repeal our Bylaws. Our stockholders entitled to vote have concurrent power to adopt, amend, or repeal our Bylaws. The SEC has adopted a number

of rules to regulate " penny stocks " that restrict transactions involving stock which is deemed to be penny stock. Such rules include Rules 3a51- 1, 15g- 1, 15g- 2, 15g- 3, 15g- 4, 15g- 5, 15g- 6, 15g- 7, and 15g- 9 under the Exchange Act. These rules may have the effect of reducing the liquidity of penny stocks. " Penny stocks " generally are equity securities with a price of less than $ 5. 00 per share (other than securities registered on certain national securities exchanges or quoted on Nasdaq if current price and volume information with respect to transactions in such securities is provided by the exchange or system). Our securities have in the past constituted, and may again in the future, if we are delisted from Nasdaq, constitute, " penny stock " within the meaning of the rules. The additional sales practice and disclosure requirements imposed upon U. S. broker- dealers may discourage broker- dealers from effecting transactions in shares of our common stock, which could severely limit the market liquidity of such shares and impede their sale in the secondary market. A U. S. broker- dealer selling penny stock to anyone other than an established customer or " accredited investor " (generally, an individual with net worth in excess of $ 1, 000, 000 (exclusive of personal residence) or an annual income exceeding $ 200, 000, or $ 300, 000 together with his or her spouse) must make a special suitability determination for the purchaser and must receive the purchaser' s written consent to the transaction prior to sale, unless the broker- dealer or the transaction is otherwise exempt. In addition, the " penny stock " regulations require the U. S. broker- dealer to deliver, prior to any transaction involving a " penny stock ", a disclosure schedule prepared in accordance with SEC standards relating to the " penny stock " market, unless the broker- dealer or the transaction is otherwise exempt. A U. S. broker- dealer is also required to disclose commissions payable to the U. S. broker- dealer and the registered representative and current quotations for the securities. Finally, a U. S. broker- dealer is required to submit monthly statements disclosing recent price information with respect to the " penny stock " held in a customer' s account and information with respect to the limited market in " penny stocks ". Stockholders should be aware that, according to the SEC, the market for " penny stocks " has suffered in recent years from patterns of fraud and abuse. Such patterns include (i) control of the market for the security by one or a few broker- dealers that are often related to the promoter or issuer; (ii) manipulation of prices through prearranged matching of purchases and sales and false and misleading press releases; (iii) " boiler room " practices involving high- pressure sales tactics and unrealistic price projections by inexperienced sales persons; (iv) excessive and undisclosed bid-ask differentials and markups by selling broker- dealers; and (v) the wholesale dumping of the same securities by promoters and broker- dealers after prices have been manipulated to a desired level, resulting in investor losses. Our management is aware of the abuses that have occurred historically in the penny stock market. Although we do not expect to be in a position to dictate the behavior of the market or of broker- dealers who participate in the market, management will strive within the confines of practical limitations to prevent the described patterns from being established with respect to our securities. ~~We currently do not meet certain of Nasdaq Capital Market' s continued listing requirements and other Nasdaq rules. If we are unable to regain compliance, we are likely to be delisted. Delisting could negatively affect the price of our common stock, which could make it more difficult for us to sell securities in a future financing or for you to sell our common stock. We are required to meet the continued listing requirements of the Nasdaq Capital Market and other Nasdaq rules, including those regarding director independence and independent committee requirements, minimum stockholders' equity, minimum share price and certain other corporate governance requirements. For example, we are required to maintain a minimum bid price for our listed common stock of $ 1. 00 per share. If we do not meet these continued listing requirements, our common stock could be delisted. On December 9, 2022, we received a deficiency letter from the Listing Qualifications Department of the Nasdaq Stock Market (" Nasdaq ") notifying the Company that, for the preceding 30 consecutive business days, the closing bid price for the Company' s common stock was below the minimum $ 1. 00 per share requirement for continued inclusion on The Nasdaq Capital Market pursuant to Nasdaq Listing Rule 5550 (a) (2). In accordance with Nasdaq rules, the Company has been provided an initial period of 180 calendar days, or until June 7, 2023 (the " Compliance Date "), to regain compliance. If the Company does not regain compliance with the Bid Price Requirement by the Compliance Date and is not eligible for an additional compliance period at that time, the Nasdaq staff will provide written notification to the Company that its common stock will be subject to delisting. The Nasdaq Staff Deficiency Letter has no immediate effect on the listing or trading of our common stock. Delisting from the Nasdaq Capital Market would cause us to pursue eligibility for trading of these securities on other markets or exchanges, or on the " pink sheets. " In such case, our stockholders' ability to trade, or obtain quotations of the market value of our common stock would be severely limited because of lower trading volumes and transaction delays. These factors could contribute to lower prices and larger spreads in the bid and ask prices of these securities. There can be no assurance that our securities, if delisted from the Nasdaq Capital Market in the future, would be listed on a national securities exchange, a national quotation service, the over- the- counter markets or the pink sheets. Delisting from the Nasdaq Capital Market, or even the issuance of a notice of potential delisting, would also result in negative publicity, make it more difficult for us to raise additional capital, adversely affect the market liquidity of our securities, decrease securities analysts' coverage of us or diminish investor, supplier and employee confidence.~~ ITEM 1B. UNRESOLVED STAFF COMMENTS