Risk Factors Comparison 2025-02-25 to 2024-02-27 Form: 10-K

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Our business involves significant risks, some of which are described below. You should carefully consider the risks described below, as well as the other information in this Annual Report on Form 10- K, including " Management' s Discussion and Analysis of Financial Condition and Results of Operations " and the consolidated financial statements and the related notes. The occurrence of any of the events or developments described below could harm our business, financial condition, results of operations and growth prospects. In such an event, the market price of our common stock could decline and you may lose all or part of your investment. Additional risks and uncertainties not presently known to us or that we currently deem immaterial also may impair our business operations. This Annual Report on Form 10- K also contains forward- looking statements that involve risks and uncertainties. Our actual results could differ materially from those anticipated in the forward- looking statements as a result of factors that are described below and elsewhere in this Annual Report on Form 10- K. Risks Related to Our Financial Position and Capital Needs We are in the clinical or preclinical stages of vaccine development and have a ~~very~~ limited operating history and no products approved for commercial sale, which may make it difficult for you to evaluate the success of our business to date and to assess our future viability. To date, we have devoted substantially all of our resources to performing research and development, undertaking preclinical studies, advancing our vaccine candidates through clinical trials, enabling manufacturing activities in support of our product development efforts, acquiring and developing our technology and vaccine candidates, organizing and staffing our company, performing business planning, establishing our intellectual property portfolio and raising capital to support and expand such activities. As an organization, we have not yet demonstrated an ability to successfully complete clinical development, obtain regulatory approvals, manufacture a commercial- scale product or conduct sales and marketing activities necessary for successful commercialization or arrange for a third party to conduct these activities on our behalf. Consequently, any predictions about our future success or viability may not be as accurate as they could be if we had a longer operating history. Our current vaccine candidate pipeline includes **two clinical and** three preclinical programs ~~and two clinical programs~~. We may encounter unforeseen expenses, difficulties, complications, delays **, changes in the regulatory environment,** and other known or unknown factors in achieving our business objectives, including with respect to our vaccine candidates. We will need to transition at some point from a company with a research and development focus to a company capable of supporting commercial activities. We may not be successful in such a transition. We have incurred significant net losses since inception and anticipate that we will continue to incur substantial net losses for the foreseeable future. We currently have no source of product revenue and may never achieve profitability. Our stock is a highly speculative investment. We are a clinical- stage biotechnology vaccine company. Investment in clinical- stage companies and vaccine development is highly speculative because it entails substantial upfront capital expenditures and significant risk that any potential vaccine candidate will not gain regulatory approval or become commercially viable. We do not have any products approved for sale and have not generated any revenue from product sales. As a result, we are not profitable and have incurred losses in each year since inception. Our net losses were $ **463. 9 million and $** 402. 3 ~~million and $ 223. 5~~ million for the years ended December 31, **2024 and** 2023 ~~and 2022~~, respectively. As of December 31, ~~2023~~ **2024**, we had an accumulated deficit of $ ~~924~~ **1**. 4 ~~million~~ **billion**. We expect to continue to spend significant resources to fund research and development of, and seek regulatory approvals for, our vaccine candidates. We expect to incur substantial and increasing operating losses over the next several years as our research, development, manufacturing, preclinical testing and clinical trial activities increase. As a result, our accumulated deficit will also increase significantly. We may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. The size of our future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenue. However, we do not expect to generate any revenue from commercial product sales unless and until we successfully complete development and obtain regulatory approval for one or more of our vaccine candidates, which we expect will take a number of years. Our prior losses and expected future losses have had and will continue to have an adverse effect on our stockholders' equity and working capital. Even if we eventually generate revenue, we may never be profitable and, if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. We will require substantial additional funding to finance our operations, which may not be available to us on acceptable terms, or at all. If we are unable to raise additional capital when needed, we could be forced to delay, reduce or terminate certain of our development programs or other operations. As of December 31, ~~2023~~ **2024**, we had cash, cash equivalents and investments of $ ~~1~~ **3**, ~~242~~ **134**. ~~9~~ **7** ~~million~~ **billion**. We believe our existing cash, cash equivalents and investments will fund our current operating plans through at least 12 months from the filing date of this Annual Report on Form 10- K. However, our operating plan may change as a result of many factors currently unknown to us, and we may need to seek additional funds sooner than planned. Furthermore, we will need to raise substantial additional capital to complete the development, manufacturing and commercialization of our drug candidates. We expect to finance our cash needs through public or private equity or debt financings, third- party (including government) funding and marketing and distribution arrangements, as well as other collaborations, strategic alliances and licensing arrangements or any combination of these approaches. ~~In July 2021, we entered into an Open Market Sales AgreementSM (the " Original ATM Sales Agreement ") with Jefferies LLC (" Jefferies "), which provided that, upon the terms and subject to the conditions and limitations set forth in the Original ATM Sales Agreement, we may elect to issue and sell, from time to time, shares of our common stock having an aggregate offering price of up to $ 150. 0 million through Jefferies acting as our sales agent or principal. As of February 27, 2023, we had sold 4, 995, 709 shares of our common stock under the Original ATM Sales Agreement at an average price of $ 27. 57 per share for~~

~~aggregate gross proceeds of $ 137. 8 million. On February 27, 2023, we and Jefferies entered into an amendment to the Original ATM Sales Agreement (as amended, the " Amended ATM Sales Agreement ") pursuant to which we may offer and sell shares of our common stock having an aggregate offering price of up to $ 400. 0 million, which is in addition to the $ 150. 0 million aggregate offering price under the Original ATM Sales Agreement. The material terms and conditions of the Original ATM Sales Agreement otherwise remain unchanged. As of December 31, 2023, we have sold 1, 588, 807 shares of our common stock under the Amended ATM Sales Agreement at an average price of $ 44. 06 per share for aggregate gross proceeds of $ 70. 0 million ($ 68. 6 million net of commissions and offering expenses).~~ Our ability to raise additional capital may be adversely impacted by potential worsening global economic conditions, including higher inflation rates and changes in interest rates and the recent disruptions to and volatility in the credit and financial markets in the United States and worldwide, including the trading price of common stock, resulting from civil and political unrest in certain countries and regions. Our future capital requirements will depend on many factors, including: • the timing, scope, progress, results and costs of research and development, testing, screening, manufacturing, preclinical development and clinical trials; • the costs of future commercialization activities, including product manufacturing, marketing, sales, royalties and distribution, for any of our vaccine candidates for which we receive marketing approval; • the outcome, timing and cost of seeking and obtaining regulatory approvals from the U. S. Food and Drug Administration (" FDA ") and comparable foreign regulatory authorities, **which may** ~~including the potential for such authorities to require that we perform field efficacy studies for our pneumococcal conjugate vaccine (" PCV ") candidates,~~ require more studies than those that we currently expect or change their requirements regarding the data required to support a marketing application; • the costs of establishing additional manufacturing capacity to meet potential incremental supply requirements following the initial commercial launch of VAX- ~~24~~ **31 if approved; •** ~~or~~ **our** ~~VAX~~ **ability to set an acceptable price for our product candidates and obtain coverage and adequate reimbursement from third** - ~~31~~ **party payors** ; • the costs of building a sales force in anticipation of any product commercialization; • our ability to maintain existing, and establish new, strategic collaborations, licensing or other arrangements and the financial terms of any such agreements, including the timing and amount of any future milestone, royalty or other payments due under any such agreement **; • market acceptance of our product candidates in the medical community and with third- party payors and consumers** ; • any product liability or other lawsuits related to our products; • the revenue, if any, received from commercial sales, or sales to foreign governments, of our vaccine candidates for which we may receive marketing approval; • the costs to establish, maintain, expand, enforce and defend the scope of our intellectual property portfolio, including the amount and timing of any payments we may be required to make, or that we may receive, in connection with licensing, preparing, filing, prosecuting, defending and enforcing our patents or other intellectual property rights; • expenses needed to attract, hire and retain skilled personnel; and • macroeconomic factors that may exacerbate the magnitude of the factors discussed above. Our ability to raise additional funds will depend on financial, economic and other factors, many of which are beyond our control. We cannot be certain that additional funding will be available on acceptable terms, or at all. We have no committed source of additional capital and 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 the development or commercialization of our vaccine candidates or other research and development initiatives. Our license agreements may also be terminated if we are unable to meet the payment obligations or milestones under the agreements. We could be required to seek collaborators for our vaccine candidates at an earlier stage than otherwise would be desirable or on terms that are less favorable than might otherwise be available, or relinquish or license on unfavorable terms our rights to our vaccine candidates in markets where we otherwise would seek to pursue development or commercialization ourselves. **In addition, in February 2025, the National Institutes of Health (" NIH ") announced that it would cap indirect costs for grants at 15 %. If we cannot find additional funds to cover the gap created by the new funding gap, we may need to change or terminate our vaccine development program for VAX- GI, which is currently funded in part by grants obtained from the NIH and administered by the University of Maryland, Baltimore.** Due to the significant resources required for the development of our vaccine candidates, and depending on our ability to access capital, we must prioritize development of certain vaccine candidates. Moreover, we may expend our limited resources on vaccine candidates that do not yield a successful vaccine and fail to capitalize on vaccine candidates that may be more profitable or for which there is a greater likelihood of success. Due to the significant resources required for the development of our vaccine candidates, we must decide which vaccine candidates to pursue and advance and the amount of resources to allocate to each. Our decisions concerning the allocation of research, development, management and financial resources toward particular vaccine candidates may not lead to the development of any viable commercial vaccines and may divert resources away from better opportunities **. For example, although we allocated resources for the development of VAX- 24 in the adult population through a Phase 1 / 2 program, we made the determination to suspend further development of VAX- 24 for the adult indication because we have chosen to advance exclusively VAX- 31 for an adult Phase 3 program following the positive results of the VAX- 31 adult Phase 1 / 2 study** . Similarly, our potential decisions to delay, terminate, license or collaborate with third parties in respect of certain vaccine candidates may subsequently also prove to be less than optimal and could cause us to miss valuable opportunities. If we make incorrect determinations regarding the viability or market potential of any of our vaccine candidates or misread trends in the biopharmaceutical industry, in particular for vaccines, our business could be seriously harmed. As a result, we may fail to capitalize on viable commercial products or profitable market opportunities, be required to forego or delay pursuit of opportunities with other vaccine candidates that may later prove to have greater commercial potential than those we choose to pursue or relinquish valuable rights to such vaccine candidates through collaboration, licensing or other royalty arrangements in cases in which it would have been advantageous for us to invest additional resources to retain sole development, manufacturing and commercialization rights. Risks Related to Our Business and Industry Our approach to the discovery and development of our vaccine candidates is based on novel technologies that are unproven, which may expose us to unforeseen risks, require us to modify processes, and make it difficult to predict the

time and cost of vaccine candidate development and the timing to apply for and obtain regulatory approvals. We are developing a pipeline of vaccine candidates utilizing our cell- free protein synthesis platform, which is comprised of the ~~XpressCF~~ **XpressCFTM** platform exclusively licensed from Sutro Biopharma, Inc. (" Sutro Biopharma ") and our proprietary know- how for vaccine applications against infectious disease **. Our** ~~, and our~~ future success depends on the successful application of this approach to vaccine development. We are in the clinical or preclinical stages of developing our vaccine candidates and there can be no assurance that any development problems we **may** experience in the future will not cause significant delays or unanticipated costs, or that such development problems can be overcome. For example, although we have achieved proof- of- concept for our carrier- sparing approach with VAX- **31 and VAX-** 24, our approach may not be validated for our other vaccine candidates or subsequent trials of **VAX- 31 or** VAX- 24. We may also experience delays in developing a sustainable, reproducible and scalable manufacturing process or transferring that process to manufacturing partners, which may prevent us from completing our clinical trials or commercializing our products on a timely or profitable basis, if at all. In addition, since we have not yet completed clinical development **on any of our product candidates** , we do not know the specific doses that may be effective in the clinic or, if approved, commercially. Finding a suitable dose may delay our anticipated clinical development timelines. **We may also encounter difficulty recruiting sufficient participants for our clinical studies, or the FDA may impose additional requirements on us regarding trial size or a long- term safety study that will significantly slow or forestall our development program.** Furthermore, our expectations with regard to our scalability and costs of manufacturing may vary significantly as we develop our vaccine candidates and ~~understand~~ **learn more about** these critical factors. Conjugate vaccine development is highly complex, and development of broad- valency **pneumococcal conjugate vaccines (" PCVs ")** is further complicated by the number of components, analytical assays and potential for adjustments, including **,** but not limited to **,** changes in raw materials, composition, formulation, manufacturing methods and dosing, which could result in drug substances and / or drug product that may vary between preclinical and clinical studies over time. Over the course of the development and manufacturing of VAX- 24, we ~~have~~ **previously** encountered process- related matters that ~~have~~ required us to make adjustments to our processes. ~~We~~ **For example, we** encountered such process- related matters during our drug substance manufacturing campaign for VAX- 24 at Lonza, Ltd. (" Lonza "). The cumulative impact of the time required to make adjustments to our processes led to a delay of our drug substance manufacturing campaign due to scheduling conflicts and capacity constraints at Lonza. There can be no assurance that we or Lonza will be able to successfully manufacture drug substances in a timely manner in the future, or at all. Such process changes and manufacturing delays have caused a change in our Investigational New Drug (" IND ") application timelines in the past and future changes or delays could impact future timelines for VAX- ~~24~~ **31** , VAX- ~~31~~ **24** or for our other product candidates **. In addition, if we encounter similar manufacturing issues after product approval, it will require inspection and approval of the new manufacturing site and submission of a Biologics License Application (" BLA ") supplement, which may further impede or delay commercialization** . In addition, the preclinical and clinical trial requirements of the FDA, European Medicines Agency (" EMA ") and other regulatory agencies and the criteria these regulators use to determine the safety and **immunogenicity or** efficacy of a vaccine candidate are determined according to the type, complexity, novelty and intended use and market of the potential products **, taking into consideration the benefits and risks for the intended population who will receive the vaccine, as well as the disease (s) to be prevented. Regulatory agencies also evaluate a sponsor' s data to determine whether the manufacturing and facility information assure product quality and consistency** . Approvals by the FDA and EMA for existing pneumococcal vaccines, such as Pfizer Inc.' s (" Pfizer ~~'s~~ ") Prevnar 13 **®** (" PCV13 ") ~~,~~ **and** Prevnar 20 **®** (" PCV20 ") **,** and Merck & Co., Inc.' s (" Merck ") VAXNEUVANCETM (" PCV15 ") **, CapvaxiveTM (" PCV21 ")** and Pneumovax **®** 23 (" PPSV23 "), may not be indicative of what these regulators may require for approval of our vaccine candidates. For example, the FDA may challenge our VAX- ~~24~~ **31** Phase 3 ~~chemistry~~ **Chemistry** , ~~manufacturing~~ **Manufacturing** and ~~controls~~ **Controls** (" CMC ") strategy, which could cause significant delays or unanticipated costs. Additionally, novel aspects of our vaccine candidates and manufacturing processes may create further challenges in obtaining regulatory approval. The regulatory approval process for our novel vaccine candidates can be more complex and consequently more expensive and take longer than for other, better known or extensively studied pharmaceutical or other vaccine candidates. More generally, approvals by any regulatory agency may not be indicative of what any other regulatory agency may require for approval or what such regulatory agencies may require for approval in connection with new vaccine candidates. Moreover, our vaccine candidates may not perform successfully in clinical trials. **In addition, leadership of the FDA' s Center for Biologic Evaluation and Research, which oversees vaccine development, is supportive of novel approaches to vaccine development. If that leadership changes, we may face additional hurdles to development or may have to change our approach to meet regulatory expectations.** Our vaccine candidates are in clinical or preclinical stages of development and may fail in development or suffer delays that materially and adversely affect their commercial viability. If we are unable to complete development of or commercialize our vaccine candidates or experience significant delays in doing so, our business would be materially harmed ~~. None of our vaccine candidates have been the subject of late- stage or pivotal clinical trials. On October 24, 2022, we announced positive topline results from our Phase 1 / 2 clinical proof- of- concept study of VAX- 24 in adults ages 18 to 64. On April 17, 2023, we announced positive results from the VAX- 24 Phase 2 study in adults aged 65 and older, as well as data from the full six- month safety assessment and prespecified pooled immunogenicity analyses from both the Phase 2 study in adults aged 65 and older and the prior Phase 1 / 2 study in adults aged 18- 64. Our VAX- 24 adult regulatory strategy includes several interactions with the FDA to finalize our Phase 3 clinical program and Biologics License Application (" BLA ") submission requirements. In October 2023, we completed a successful End- of- Phase 2 meeting with the FDA. The meeting focused on the VAX- 24 adult Phase 3 clinical program, including the design of the pivotal, non- inferiority study and other Phase 3 studies needed to support a BLA submission. Based on the End- of- Phase 2 meeting we believe there is agreement with the FDA on the clinical design of the potential adult Phase 3 program, including the approximate overall number of subjects, the primary and secondary endpoints for the pivotal, non- inferiority study as well as confirmation that the~~

~~planned immunogenicity analyses are sufficient to support licensure and an efficacy study is therefore not required. In January 2024, we announced that we received encouraging input from ongoing discussions with the FDA about the VAX- 24 adult program to further inform our CMC licensure requirements and that we expect to seek additional CMC- focused input from the FDA as we prepare for and potentially conduct our VAX- 24 adult Phase 3 program. Even with FDA guidance, we still may be unable to successfully complete development to the FDA' s satisfaction, and any delay or inability to obtain commercial approval would materially harm our business. In October 2023, we announced that the FDA cleared our adult IND application for VAX- 31, a 31- valent PCV candidate designed to prevent IPD. We initiated the VAX- 31 Phase 1 / 2 clinical study in adults in the November 2023 and in January 2024, we announced the completion of enrollment in the Phase 1 / 2 clinical study evaluating VAX- 31 in healthy adults aged 50 and older. We expect to announce topline safety, tolerability and immunogenicity results in the third quarter of 2024. In addition to our PCV franchise, our pipeline includes VAX- A1, a novel conjugate vaccine candidate designed to prevent disease caused by Group A Streptococcus, Group A Strep; VAX- PG, a novel protein vaccine candidate targeting the keystone pathogen responsible for periodontitis; VAX- GI, novel preclinical vaccine candidate being developed as a preventative treatment for dysentery and shigellosis, which is caused by Shigella bacteria; and other discovery- stage programs~~ . Our ability to achieve and sustain profitability depends on obtaining regulatory approvals for and successfully commercializing our vaccine candidates, either alone or with third parties, and we cannot guarantee that we will ever obtain regulatory approval for any of our vaccine candidates. We have limited experience in conducting and managing the clinical trials necessary to obtain regulatory approvals, including approval by the FDA. **None of our vaccine candidates have been the subject of late- stage or pivotal clinical trials, and we may never be able to obtain marketing approval for any of our product candidates.** Before obtaining regulatory approval for the commercial distribution of our vaccine candidates, we must conduct extensive preclinical studies and clinical trials to demonstrate the safety and **immunogenicity or** efficacy of our vaccine candidates. We may not have the financial resources to continue development of, or to enter into new collaborations for, a vaccine candidate if we experience any issues that delay or prevent regulatory approval of, or our ability to commercialize, vaccine candidates, including: • negative or inconclusive results from our preclinical or clinical trials, leading to a decision or requirement to conduct additional preclinical studies or clinical trials or abandon a program; • product- related adverse effects experienced by volunteers in our clinical trials; • difficulty achieving successful development of our manufacturing processes, including process development and scale- up activities to supply products for preclinical studies, clinical trials and commercial sale, if approved; • timely completion of our preclinical studies and clinical trials, including any field efficacy studies that may be required, which may be significantly slower or cost more than we currently anticipate and will depend substantially upon the performance of third- party contractors; • inability of us or any third- party contract manufacturer to scale up manufacturing of our vaccine candidates to supply the needs of preclinical studies, clinical trials and commercial sales, and to manufacture such products in conformity with regulatory requirements; • delays in submitting IND applications or ~~compatible~~ **comparable** foreign applications or delays or failures in obtaining necessary ~~approvals~~ **authorizations** from regulators to commence a clinical trial, or suspension or termination of a clinical trial once commenced; • conditions imposed by the FDA or similar foreign authorities regarding the scope or design of our clinical trials, including any requirements to perform field efficacy studies; • challenges by the FDA to our clinical or regulatory strategies **; • changes in FDA personnel that alter the FDA' s advice with respect to our development strategy** ; • delays in enrolling subjects in our clinical trials; • inadequate supply or quality of vaccine candidate components or materials or other supplies necessary for conducting clinical trials; • inability to obtain alternative sources of supply for which we have a single source for vaccine candidate components; • the availability of coverage and adequate reimbursement and pricing from third- party payors, including government authorities, pertaining to the vaccine candidate, once approved, and patients' willingness to pay out- of- pocket if third- party payor reimbursement is limited or not available; • greater than anticipated costs of our clinical trials, including CMC activities related to our clinical trials; • harmful side effects or inability of our vaccine candidates to meet **immunogenicity or** efficacy endpoints; • unfavorable FDA or other regulatory agency inspection and review of one or more of our clinical trial sites or our contract manufacturers' facilities; • failure of our third- party contractors or investigators to comply with regulatory requirements or otherwise meet their obligations in a timely manner, or at all; • delays and changes in regulatory requirements, policy and guidelines, including the imposition of additional regulatory oversight around clinical testing generally or with respect to our technology or vaccine candidates in particular; or • varying interpretations of our data by the FDA and comparable foreign regulatory authorities. In ~~particular, while we believe our PCVs could receive regulatory approval based on well- defined surrogate immune endpoints, consistent with how other PCVs have obtained regulatory approval in the past, rather than requiring clinical field efficacy studies, there can be no assurance that the FDA or comparable foreign regulatory authorities will provide approvals on such basis. In~~ addition, changes to the standard- of- care or the approval ~~of~~ **standards for** new vaccines could change the threshold for achievement of non- inferiority using the established surrogate immune endpoints that our PCVs will need to meet in our clinical trials. Our inability to complete development of or commercialize our vaccine candidates, or significant delays in doing so due to one or more of these factors, could have a material and adverse effect on our business, financial condition, results of operations and prospects. Moreover, principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and receive compensation in connection with such services. Under certain circumstances, we may be required to report some of these relationships to the FDA or comparable foreign regulatory authorities. The FDA or comparable foreign regulatory authorities may conclude that a financial relationship between us and a principal investigator has created a conflict of interest or otherwise affected interpretation of the study. The FDA or comparable foreign regulatory authorities may therefore question the integrity of the data generated at the applicable clinical trial site and the utility of the clinical trial itself may be jeopardized. This could result in a delay in approval, or rejection, of our marketing applications by the FDA or comparable foreign regulatory authorities, as the case may be, and may ultimately lead to the denial of marketing approval of one or more of our vaccine candidates. Our business is highly dependent on the success of our PCV candidates, VAX- ~~24~~ **31** and VAX- ~~31~~ **24** , both of

which are in clinical development. If we are unable to successfully develop, obtain approval for and effectively commercialize VAX- ~~24~~ **31** or VAX- ~~31~~ **24** , our business would be significantly harmed. Our business and future success depends on our ability to successfully develop, obtain regulatory approval of, and then commercialize our PCV candidates, which include ~~VAX- 24, our most advanced vaccine candidate, and~~ VAX- 31, our 31- valent clinical PCV candidate **in development for both the adult and pediatric populations, and VAX- 24, our 24- valent clinical PCV candidate in development for the pediatric population** . Although VAX- ~~24~~ **31** has produced positive topline results in **a Phase 1 / 2 clinical study in adults, it may not demonstrate the same results in future adult pivotal Phase 3 studies needed to obtain marketing approval from the FDA or comparable foreign regulatory authorities or in infant** clinical studies ~~, it may not demonstrate the same results in future pivotal studies~~ . **In addition, ~~Past~~ past ~~and future~~** VAX- 24 results **in adults** may not be indicative of future **results in infant clinical trials.** VAX- 31 **and ~~results.~~** VAX- 24 ~~and VAX- 31~~ will require additional ~~preclinical,~~ clinical and non- clinical development, regulatory review and approval in multiple jurisdictions, substantial investment, access to sufficient clinical and commercial manufacturing capacity and significant marketing efforts before we can generate any revenue from product sales. We cannot provide any assurance that we will be able to successfully advance VAX- **31 and VAX-** 24 ~~or~~ **through the development process. The clinical and commercial success of** VAX- 31 **,** ~~through the development process. The clinical and commercial success of~~ VAX- 24, ~~VAX- 31~~ and future vaccine candidates will depend on a number of factors, including the following: • our ability to raise any additional required capital on acceptable terms, or at all; • our ability to complete IND- enabling studies and successfully submit IND or comparable applications; • the ability of third parties with whom we contract to manufacture adequate clinical study and commercial supplies of our lead vaccine candidates or any future vaccine candidates, remain in good standing with regulatory agencies and develop, validate and maintain commercially viable manufacturing processes that are compliant with current good manufacturing practices (" cGMP ") and do so in a timely manner; • timely completion of our preclinical studies and clinical trials, which may be significantly slower or cost more than we currently anticipate and will depend substantially upon the performance of third- party contractors; • whether we are required by the FDA or similar foreign regulatory agencies to conduct additional clinical trials, including field efficacy studies, **long- term safety studies,** or other studies beyond those planned to support the approval and commercialization of our vaccine candidates or any future vaccine candidates; • acceptance of our proposed indications and primary surrogate endpoint assessments for our PCV candidates by the FDA and similar foreign regulatory authorities; • any changes to the required threshold for the achievement of non- inferiority using established surrogate immune endpoints that our PCVs will need to meet in our clinical trials; • our ability to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities the safety ~~,~~ **and immunogenicity or** efficacy and acceptable risk to benefit profile of **VAX- 31,** VAX- 24 **and ~~, VAX- 31 or~~** any future vaccine candidates; • the pace and prevalence of serotype replacement following the introduction of VAX- ~~24 or~~ **31,** VAX- ~~31~~ **24** or other vaccines targeting pneumococcal disease; • any vaccine- vaccine interference studies that may be required, particularly with the standard- of- care pediatric vaccine regimen; • the prevalence, duration and severity of potential side effects or other safety issues experienced with our vaccine candidates or future approved products, if any; • the timely receipt of necessary marketing approvals from the FDA or comparable foreign regulatory authorities; • achieving, maintaining and, where applicable, ensuring that our third- party contractors achieve and maintain compliance with our contractual obligations and with all regulatory requirements applicable to our lead vaccine candidates or any future vaccine candidates or approved products, if any; • obtaining and maintaining an Advisory Committee on Immunization Practices (" ACIP ") preferred recommendation or comparable foreign regulatory authority' s recommendation of our vaccine candidates and the willingness of physicians, operators of clinics and patients to utilize or adopt any of our future vaccine candidates to prevent or treat age- associated diseases; • our ability to successfully develop a commercial strategy and thereafter commercialize our vaccine candidates or any future vaccine candidates in the United States and internationally, if approved for marketing, reimbursement, sale and distribution in such countries and territories, whether alone or in collaboration with others; • the convenience of our treatment or dosing regimen; • acceptance by physicians, payors and patients of the benefits, safety and **immunogenicity or** efficacy of our vaccine candidates or any future vaccine candidates, if approved, including relative to alternative and competing treatments; • patient demand for our vaccine candidates, if approved; • our ability to establish and enforce intellectual property rights in and to our vaccine candidates or any future vaccine candidates; • our ability to avoid third- party patent interference, intellectual property challenges or intellectual property infringement claims **; • our ability to set an acceptable price for our product candidates and obtain coverage and adequate reimbursement from third- party payors** ; and These factors, many of which are beyond our control, could cause us to experience significant delays or an inability to obtain regulatory approvals or commercialize our vaccine candidates. Even if regulatory approvals are obtained, we may never be able to successfully commercialize any of our vaccine candidates. Accordingly, we cannot provide assurances that we will be able to generate sufficient revenue through the sale of our vaccine candidates or any future vaccine candidates to continue our business or achieve profitability. Our primary competitors have significantly greater resources and experience than we do, which may make it difficult for us to successfully develop and commercialize our vaccine candidates, or may result in others discovering, developing or commercializing products before or more successfully than us. The vaccine market is intensely competitive and is dominated by a small number of multinational, globally established pharmaceutical corporations with significant resources; in recent history, Pfizer, Merck, GSK plc (" GSK ") and Sanofi have been responsible for developing and introducing most new vaccines to the world. We may also face competition from many different sources, including pharmaceutical and biotechnology companies, academic institutions, governmental agencies and public and private research institutions. Vaccine candidates that we successfully develop and commercialize may compete with existing vaccines and new vaccines that may become available in the future. Many of our competitors have substantially greater financial, lobbying, technical, human and other resources than we do and may be better equipped to develop, manufacture and market technologically superior vaccines, including the potential that our competitors may develop chemical processes or utilize novel technologies for developing vaccines that may be superior to those we employ.

In addition, many of these competitors have significantly greater experience than we have in undertaking preclinical studies and clinical trials of new products and in obtaining regulatory approvals, including for many vaccine franchises. Accordingly, our competitors may succeed in obtaining FDA approval or a preferred recommendation from ACIP for their products. For example, PCV13 obtained FDA approval for the prevention of invasive pneumococcal disease (" IPD ") in infants based on non- inferior IgG antibody responses relative to Prevnar, using the surrogate immune endpoints established by the prior Prevnar field efficacy study. Pfizer implemented a similar approach to **the** development of its 20- valent PCV vaccine candidate, PCV20, which was approved by the FDA in June 2021 for use in adults and in April 2023 for use in infants and children. **Pfizer announced in July 2024 and October 2024 that it is developing a 25- valent PCV candidate that is currently in adult and pediatric Phase 2 clinical trials. Pfizer also announced in October 2024 that it is working on a 30- plus valent PCV candidate that is in preclinical development.** Merck received approval for PCV15, its 15- valent PCV, in July 2021 for use in adults and in June 2022 for use in infants and children. Merck announced in ~~April~~ **June** ~~2022~~ **2024** that ~~V116~~ **PCV21** , **its** ~~Merck' s investigational~~ 21- valent PCV **, received approval from the FDA** for **use in** adults ~~, received Breakthrough Therapy designation from the FDA. In July 2023, Merck announced positive topline results from two Phase 3 trials evaluating V116, in vaccine- naïve and previously vaccinated individuals. In November 2023, Merck presented positive results from a Phase 3 study evaluating V116 in pneumococcal vaccine- naïve adults. Merck reported that V116 elicited non- inferior immune responses compared to PCV20 for the common 10 serotypes and superior responses for 10 of the 11 unique serotypes and that safety and tolerability endpoints were met. In December 2023, Merck also announced that based on these Phase 3 results, the FDA accepted for priority review a new BLA for V116 and set a Prescription Drug User Fee Act (" PDUFA "), or target action date, of June 17, 2024~~ . In addition, Sanofi and SK Chemicals have partnered to develop a 21- valent PCV and, in June 2023, announced positive results from their Phase 2 clinical trials in infants. **In December 2024, Sanofi and SK Chemicals announced the initiation of a global pediatric Phase 3 clinical study of their 21- valent PCV candidate, as well as an expanded agreement to develop, license and commercialize" next- generation" PCVs for both pediatric and adult populations.** GSK, which previously acquired Affinivax, is developing a 24- valent affinity- bound pneumococcal vaccine **for infants, which is currently in a pediatric Phase 2 clinical trial with data anticipated in 2026 or later** . **In October 2024,** GSK ~~also has~~ **announced they have ceased the development of their 24- valent program in adults in favor of** a **preclinical** 30- plus valent ~~pneumococcal~~ candidate ~~vaccine in preclinical development~~ . Many of our competitors have established distribution channels for the commercialization of their vaccine products, whereas we have no such established channels or capabilities. In addition, many competitors have greater name recognition, more extensive collaborative relationships or the ability to leverage a broader vaccine portfolio. Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize vaccines that are safer, more effective, more convenient, less expensive or with a more favorable label than any vaccine candidates that we may develop. As a result of these factors, our competitors may obtain regulatory approval of their products before we are able to, which may limit our ability to develop or commercialize our vaccine candidates, or achieve a competitive position in the market. This would adversely affect our ability to generate revenue. Our competitors may also develop vaccines that are safer, more effective, more widely accepted or less expensive than ours, and may also be more successful than we are in manufacturing and marketing their products. These advantages could render our vaccine candidates obsolete or non- competitive before we can recover the costs of such vaccine candidates' development, manufacturing and commercialization. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller and early- stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with us in recruiting and retaining qualified scientific, management and commercial personnel, establishing clinical trial sites and subject enrollment for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. We and our contract manufacturers may face difficulty satisfying CMC requirements imposed by the FDA and comparable foreign regulatory authorities. To date, no product developed using a cell- free manufacturing platform has received approval from the FDA or been commercialized. While we are designing and developing a manufacturing process that we believe can scale to address clinical and commercial vaccine supply, we do not own or operate any manufacturing facilities. We rely on contract manufacturing organizations (" CMOs "), including our strategic partnership with our contract manufacturer, Lonza, to access resources to facilitate the development and, if approved, commercialization of VAX- ~~24~~ **31** or VAX- ~~31~~ **24** and our other vaccine candidates. Advancing our vaccine candidates may create significant challenges **for our CMOs** , including: • manufacturing our vaccine candidates to our specifications, including process development, analytical development and quality control testing, and in a timely manner to support our preclinical and clinical trials and, if approved, commercialization **; • maintaining a cGMP- compliant facility and passing a pre- approval inspection** ; • sourcing the raw materials used to manufacture our vaccine candidates for preclinical, clinical and, if approved, commercial supplies; and • establishing sales and marketing capabilities upon obtaining any regulatory approval to gain market acceptance of our vaccines. Before we can initiate a clinical trial or commercialize any of our vaccine candidates, we must demonstrate to the FDA that the CMC for our vaccine candidates meet applicable requirements, and prior to authorization in the European Union (" EU "), a manufacturing authorization must be obtained from the appropriate EU regulatory authorities. Because no product manufactured on a cell- free manufacturing platform has been approved in the United States, there is no manufacturing facility that has demonstrated the ability to comply with FDA requirements, and, therefore, the timeframe for demonstrating compliance to the FDA' s satisfaction is uncertain. ~~In January 2024, we announced that we received encouraging input from ongoing discussions with the FDA about the VAX- 24 adult program to further inform our CMC licensure requirements and that we expect to seek additional CMC- focused input from the FDA as we prepare for and potentially conduct our VAX- 24 adult Phase 3 program.~~ Delays in establishing ~~that~~ our manufacturing process and **ensuring** the facilities we utilize for manufacturing comply with cGMP or disruptions in our manufacturing processes, implementation of novel technologies or scale- up activities, may delay or disrupt our development efforts. Even if we obtain regulatory approval

of our vaccine candidates, the products may not gain market acceptance among regulators, advisory boards, physicians, patients, third- party payors and others in the medical community necessary for commercial success. Even if any of our vaccine candidates receive marketing approval, they may fail to receive recommendations for use by regulators or advisory boards that recommend vaccines, or gain market acceptance by physicians, patients, third- party payors and others in the medical community. If such vaccine candidates do not achieve an adequate level of acceptance, we may not generate significant product revenue and may not become profitable. The degree of market acceptance of any vaccine candidate, if approved for commercial sale, will depend on a number of factors, including **,** but not limited to: • receiving **the U. S.** Centers for Disease Control and Prevention (" CDC ") and ACIP recommendations for use, as well as recommendations of comparable foreign regulatory and advisory bodies; • prevalence and severity of the disease targets for which our vaccine candidates are approved; • physicians, hospitals, third- party payors and patients considering our vaccine candidates as safe and effective; • the potential and perceived advantages of our vaccine candidates over existing vaccines, including with respect to spectrum of coverage or immunogenicity; • the prevalence and severity of any side effects; • product labeling or product insert requirements of the FDA or comparable foreign regulatory and advisory bodies; • limitations or warnings contained in the labeling approved by the FDA or comparable foreign regulatory and advisory bodies; • the timing of market introduction of our vaccine candidates as well as competitive products; • the cost in relation to alternatives; • the availability of coverage and adequate reimbursement and pricing by third-party payors, including government authorities; • the willingness of patients to pay out- of- pocket in the absence of coverage and adequate reimbursement by third- party payors, including government authorities; • relative convenience and ease of administration, including as compared to competitive vaccines and alternative treatments; and • the effectiveness of our sales and marketing efforts. In the United States, the CDC and ACIP develop vaccine recommendations for both children and adults, as do similar agencies around the world. To develop its recommendations, **the** ACIP forms working groups that gather, analyze and prepare scientific information. The ACIP also considers many of the factors above, as well as myriad additional factors such as the value of vaccination for the target population regarding the outcomes, health economic data and implementation issues. **The** ACIP recommendations are also made within categories, such as in an age group or a specified risk group. For example, the ACIP may determine that a preferred recommendation in a smaller child population may be more economical than recommending vaccinations for a larger adult population, which could adversely impact our market opportunity. New pediatric vaccines that receive an ACIP preferred recommendation are almost universally adopted, and adult vaccines that receive a preferred recommendation are widely adopted. For example, in 2014, the ACIP voted to recommend PCV13 for routine use to help protect adults aged 65 years and older against pneumococcal disease, which caused PCV13 to become the standard- of-care along with continued use of PPSV23. **The** ACIP can also modify its preferred recommendation. For instance, in June 2019, the ACIP voted to revise the pneumococcal vaccination guidelines and recommend PCV13 for adults 65 and older based on the shared clinical decision making of the provider and patient, rather than a preferred use recommendation, which means the decision to vaccinate should be made at the individual level between health care providers and their patients. In October 2021, the ACIP voted to recommend the use of either PCV20, or PCV15 with PPSV23, for routine use in adults aged 65 years and older as well as for those between the ages of 19 and 64 years with certain underlying medical conditions or other risk factors **who had not previously received a PCV or whose previous vaccination history was unknown** . In June 2022, **the** ACIP voted to recommend that PCV15 may be used as an option to the ~~currently available~~ **then recommended** PCV13 for children aged under 19 years according to ~~currently~~ **then** recommended PCV13 dosing and schedules. In June 2023, **the** ACIP voted to recommend the use of ~~either~~ **PCV20 as an option to** PCV15 ~~or PCV20~~ for routine use in children under the age of two, and as a " catch up " vaccination for healthy children between the ages of 24 and 59 months with incomplete PCV vaccination status and children between the ages of 24 and 71 months with certain underlying conditions and an incomplete PCV vaccination **status** . Further, **the** ACIP voted to recommend that children between the ages of two and 18 years with any risk condition who have received all recommended **PCV** doses before the age of six do not need additional doses if they have received at least one dose of PCV20. If children between the ages of two and 18 years with any risk condition received PCV13 or PCV15, but not PCV20, **the** ACIP recommend that they should receive a dose of PCV20 or PPSV23. **The** ACIP also voted to recommend that children between the ages of six and 18 years with any risk condition who have not received any dose of PCV13, PCV15 or PCV20 should receive a single dose of PCV15 or PCV20. When PCV15 is used in this instance, **the** ACIP recommended that it should be followed by a dose of PPSV23 at least eight weeks later if not previously given. **In June 2023, the ACIP also recommended shared clinical decision- making regarding PCV20 use for adults aged 65 years and older who have completed the recommended vaccine series with both PCV13 and PPSV23. In June 2024, the ACIP voted to recommend PCV21 as an option to either PCV20, or PCV15 with PPSV23 for (i) adults aged 65 years and older who have not previously received a PCV or whose previous vaccination history is unknown, (ii) adults between the ages of 19 and 64 with certain underlying medical conditions or other risk factors who have not previously received a PCV or whose previous vaccination history is unknown and (iii) adults aged 19 years and older who have received PCV13 but not all recommended doses of PPSV23. Additionally, the ACIP recommended shared clinical decision- making regarding a supplemental dose of PCV21 for adults aged 65 and older who have completed their vaccine series with both PCV13 and PPSV23. In October 2024, the ACIP voted to recommend lowering the age- based pneumococcal vaccination guidelines for pneumococcal vaccination in adults from 65 years and older to 50 years and older. In line with this recommendation, the ACIP voted to recommend either a dose of PCV20 or PCV21, or PCV15 with PPSV23, for (i) adults aged 50 and older who have not previously received a PCV or whose previous vaccination history is unknown and (ii) adults between the ages of 19 and 49 with certain underlying medical conditions or other risk factors who have not previously received a PCV or whose previous vaccination history is unknown. The membership of the ACIP is influenced by the Department of Health and Human Services (" HHS "). Changes in the ACIP representation could impact the viability of new vaccines receiving a positive recommendation, particularly if there is a change in the federal government' s posture towards**

vaccines. If our vaccine candidates are approved but fail to receive CDC and ACIP recommendations, or recommendations of other comparable foreign regulatory and advisory bodies, or achieve market acceptance among physicians, healthcare providers, patients, third- party payors or others in the medical community, we will not be able to generate significant revenue. Even if our products achieve market acceptance, we may not be able to maintain that market acceptance over time if new products or technologies are introduced that are more favorably received than our products, are more cost effective or render our products obsolete. We may not be successful in our efforts to use our cell- free protein synthesis platform to expand our pipeline of vaccine candidates and develop marketable products. The success of our business depends in large part upon our ability to identify, develop and commercialize products based on our cell- free protein synthesis platform. We intend to pursue clinical development of additional vaccine candidates beyond VAX- ~~24~~ **31** and ~~,~~VAX- ~~31~~ **24** for IPD, including VAX- A1 for Group A **Streptococcus (" Group A** Strep **")** , VAX- PG for periodontitis and VAX- GI for dysentery and shigellosis. Our research programs may fail to identify potential vaccine candidates for clinical development for a number of reasons or we may focus our efforts and resources on potential programs or vaccine candidates that ultimately prove to be **successful in a smaller subset of patients than expected or completely** unsuccessful. In addition, we cannot provide any assurance that we will be able to successfully advance any of our existing or future vaccine candidates through the development process. Our potential vaccine candidates may be shown to have harmful side effects **, cause allergic reactions,** or may have other characteristics that may make the products unmarketable or unlikely to receive marketing approval. If any of these events occur, we may be forced to abandon our development efforts for a program or for multiple programs, which would materially harm our business and could potentially cause us to cease operations. Even if we receive FDA approval to market additional vaccine candidates, we cannot provide assurance that any such vaccine candidates will be successfully commercialized, widely accepted in the marketplace or more effective than other commercially available alternatives. In addition, **we believe** current PCVs do not ~~address the majority~~ **provide adequate coverage** of ~~circulating~~ **the** strains **currently** causing **pneumococcal disease or those that previously caused** pneumococcal disease. There has been a decrease in the incidence of disease attributable to the strains covered by existing vaccines but an increase in incidence attributable to non- covered strains that now cause most residual disease. Such change is driven by the void created when strains are taken out of circulation after widespread vaccination, which is a phenomenon known as serotype replacement. As a result of such change, broader spectrum PCVs are required to maintain protection against historically pathogenic strains while expanding coverage to current circulating and emerging strains. There can be no assurance that we will be able to develop higher- valent vaccines to address serotype replacement. In addition, because VAX- **31 and VAX-** 24 ~~is~~ **are** our most advanced vaccine ~~candidate~~ **candidates** , and because our other vaccine candidates are also based on our cell- free protein synthesis platform, if VAX- **31 or VAX-** 24 ~~encounters~~ **encounter** safety or ~~efficacy~~ **immunogenicity** problems, manufacturing problems, developmental delays, regulatory issues or other problems, our development plans and business would be significantly harmed. We currently rely on third- party manufacturing and supply partners, including Lonza and Sutro Biopharma, to supply raw materials and components for, and the manufacture of, our preclinical and clinical supplies as well as our vaccine candidates. Our inability to procure necessary raw materials or to have sufficient quantities of preclinical and clinical supplies or the inability to have our vaccine candidates manufactured, including delays or interruptions at our third- party manufacturers, or our failure to comply with applicable regulatory requirements or to supply sufficient quantities at acceptable quality levels or prices, or at all, would materially and adversely affect our business. Efficient and scalable manufacturing and supply is a vital component of our business strategy. We do not own or operate any manufacturing facilities. We are designing and developing a manufacturing process that we believe can scale to address clinical and commercial vaccine supply. However, our assumptions as to our ability and our CMOs' ability to produce vaccines at the scale needed for clinical development, manufacturing and commercial demand, in particular for our PCVs, may prove to be wrong. If we encounter substantial problems in our manufacturing processes or in our ability to scale to address commercial vaccine supply, our business would be materially adversely affected. Examples of potential issues related to our manufacturing processes or our ability to scale include difficulties with production costs, yields and quality control, including stability of the drug substance or drug product. We rely on third- party contract manufacturers to manufacture preclinical and clinical trial product materials and supplies for our needs. There can be no assurance that our preclinical and clinical development product supplies will not be limited or interrupted or be of satisfactory quality or continue to be available on acceptable terms. Over the course of the development and manufacturing of VAX- 24, we ~~have~~ **previously** encountered process- related matters that ~~have~~ required us to make adjustments to our processes. ~~We~~ **For example, we** encountered such process- related matters during our drug substance manufacturing campaign for VAX- 24 at Lonza. The cumulative impact of the time required to make adjustments to our processes led to a delay of our drug substance manufacturing campaign due to scheduling conflicts and capacity constraints at Lonza. There can be no assurance that we or Lonza will be able to successfully manufacture drug substances in a timely manner in the future, or at all. Such process changes and manufacturing delays have caused a change in our IND timelines in the past and future changes or delays could impact future timelines for VAX- ~~24~~ **31** , VAX- ~~31~~ **24,** or for our other product candidates. Since we utilize a third- party manufacturer, we are also subject to Lonza' s scheduling commitments for its other clients. Scheduling conflicts with Lonza' s other clients have contributed to manufacturing delays in the past, and there is no guarantee that future scheduling conflicts or related capacity constraints will not affect our manufacturing campaigns and related timelines. Certain aspects of our manufacturing process for our clinical trial product materials and supplies have also been adversely affected by macroeconomic factors **in** ~~, such as~~ the **past** ~~COVID- 19 pandemic,~~ and ~~could~~ **may in the future** be adversely affected by **these and numerous other factors, including** earthquakes and other natural or man- made disasters, equipment failures, labor shortages, health epidemics, power failures and **tariffs** ~~numerous other factors in the future~~ . The manufacturing process for a vaccine candidate is subject to FDA or comparable foreign regulatory authority review. Our suppliers and manufacturers must meet applicable manufacturing requirements and undergo rigorous facility and process validation tests **and inspections** required by regulatory authorities in order to comply with regulatory

standards, such as cGMPs. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or comparable foreign regulatory authorities **, or if they cannot pass a pre- approval inspection** , we may not be able to rely on their manufacturing facilities for the manufacture of elements of our vaccine candidates. Moreover, we do not control the manufacturing process at our contract manufacturers and are completely dependent on them for compliance with current regulatory requirements. In the event that any of our manufacturers fails to comply with such requirements or to perform its obligations in relation to quality, timing or otherwise, or if our supply of components or other materials becomes limited or interrupted for other reasons, we may be forced to manufacture the materials ourselves or enter into an agreement with another third party, which we may not be able to do on reasonable terms, if at all. In some cases, the technical skills, raw materials or technology required to manufacture our vaccine candidates may be unique or proprietary to the original manufacturer or supplier, and we may have difficulty applying such skills or technology or sourcing such raw materials ourselves, or in transferring such skills, technology or raw materials to another third party, or such transfer may be subject to certain consent obligations and payment terms to Lonza. These factors would increase our reliance on such manufacturer or require us to obtain a license from such manufacturer in order to enable us, or to have another third party, manufacture our vaccine candidates. If we are required to change manufacturers for any reason, we will be required to verify that the new manufacturer maintains facilities and procedures that comply with quality standards and with all applicable regulations and guidelines, and we may be required to repeat some of the development program **and submit a supplement to our application** . The delays associated with the verification of a new manufacturer could negatively affect our ability to develop vaccine candidates in a timely manner or within budget. We expect to continue to rely on third- party manufacturers and suppliers, including Lonza, if we receive regulatory approval for any PCV or any other vaccine candidates. For example, in October 2023, **we** ~~Vaxcyte Switzerland GmbH (" Vaxcyte GmbH "), a Swiss limited liability company and wholly owned subsidiary of ours,~~ entered into a pre- commercial services and commercial manufacturing supply agreement (the " Commercial Manufacturing and Supply Agreement ") with Lonza, pursuant to which Lonza will (i) construct and build out a dedicated suite (" Suite ") at Lonza' s facilities in Visp, Switzerland to manufacture certain key components (including drug substance) for our proprietary PCV franchise and any other products or intermediates **we** ~~Vaxcyte GmbH~~ may choose (collectively, the " Products "), and (ii) maintain and operate the Suite (utilizing Lonza' s employees) to manufacture the Products as a service provided to **us** ~~Vaxcyte GmbH~~ , including conducting related quality control and quality assurance operations. Pursuant to the Commercial Manufacturing and Supply Agreement, Lonza will be a preferred, non- exclusive, supplier of the Products to **us** ~~Vaxcyte GmbH~~ , and **we** ~~Vaxcyte GmbH retains~~ **retain** the right to procure the Products from one or more alternate and / or backup manufacturers of the Products (including at our own facilities). To the extent that we have existing, or enter into future, manufacturing arrangements with third parties, we will depend on these third parties to perform their obligations in a timely manner consistent with contractual and regulatory requirements, including those related to quality control and assurance. In December 2019, we exercised our right to require Sutro Biopharma to establish a second supplier for extract and custom reagents to support our anticipated clinical and commercial needs. In December 2022, we entered into an option **grant** agreement with Sutro Biopharma (the " Option Agreement "). Pursuant to the Option Agreement, we acquired from Sutro Biopharma (i) authorization to enter into an agreement with an independent alternate CMO to directly source Sutro Biopharma' s cell- free extract, allowing us to have direct oversight over financial and operational aspects of the relationship with the CMO; and (ii) a right, but not an obligation, to obtain certain exclusive rights to internally manufacture and / or source extract from certain CMOs and the right to independently develop and make improvements to extract (including the right to make improvements to the extract manufacturing process as well as cell lines) for use in connection with the exploitation of certain vaccine compositions (the " Option "). We and Sutro Biopharma agreed to negotiate the terms and conditions of a form definitive agreement to be entered into in the event we exercise the Option, which would include the terms and conditions set forth in an executed term sheet between us (the " Term Sheet ") and such terms that were necessary to give effect to each of the terms and conditions set forth in the Term Sheet (the " Form Definitive Agreement "). On September 28, 2023, we and Sutro Biopharma mutually agreed in writing upon the Form Definitive Agreement to become effective in the event that we exercise the Option. In November 2023, we exercised the Option and entered into a manufacturing rights agreement (the " Manufacturing Rights Agreement ") with Sutro Biopharma to obtain control over the development and manufacture of cell- free extract. Pursuant to the Manufacturing Rights Agreement, we obtained exclusive rights to independently, or through certain third parties, develop, improve and manufacture cell- free extract for use in connection with our vaccine candidates. If Sutro Biopharma, the independent alternate CMO or the designated third parties are unable to provide a sufficient supply of cell- free extract, our third- party manufacturers may be delayed in their production of intermediate components, which may lead to delays of our drug substance manufacturing campaigns. If we are unable to obtain additional or maintain third- party manufacturing for vaccine candidates, or to do so on commercially reasonable terms, we may not be able to develop and commercialize our vaccine candidates successfully. Our or a third party' s failure to execute on our manufacturing requirements and comply with cGMPs could adversely affect our business in a number of ways, including: • an inability to initiate or complete clinical trials of vaccine candidates under development; • delay in submitting regulatory applications, or receiving regulatory approvals, for our vaccine candidates; • subjecting third- party manufacturing facilities to additional inspections by regulatory authorities; • requirements to cease distribution or to recall batches of our vaccine candidates; and • in the event of approval to market and commercialize a vaccine candidate, an inability to meet commercial demands for our products. In addition, because VAX- ~~24~~ **31** , VAX- ~~31~~ **24** and our other vaccine candidates are also based on our cell- free protein synthesis platform, if our vaccine candidates encounter safety **and immunogenicity** or efficacy problems, manufacturing problems, developmental delays, regulatory issues or other problems, our development plans and business would be significantly harmed. Additionally, we and our contract manufacturers may experience manufacturing difficulties due to limited vaccine manufacturing experience, resource constraints or as a result of labor disputes or unstable political environments. If we or our contract manufacturers were to

encounter any of these difficulties, our ability to manufacture sufficient vaccine supply for our preclinical studies and clinical trials, or to provide product for patients once approved, would be jeopardized. Our vaccine candidates may cause undesirable side effects or have other properties, including interactions with existing vaccine regimens, that could halt their clinical development, prevent their regulatory approval, limit their commercial potential or result in significant negative consequences. Adverse effects or other undesirable or unacceptable side effects caused by our vaccine candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or other comparable foreign regulatory authorities. Results of our clinical trials could reveal a high and unacceptable severity and prevalence of side effects or unexpected characteristics. In such an event, our clinical trials could be suspended or terminated, and the FDA or comparable foreign regulatory authorities could order us to cease further development of or deny approval of our vaccine candidates. Such side effects could also affect trial recruitment or the ability of enrolled subjects to complete the clinical trial or result in potential product liability claims. ~~A~~ **An independent** data safety monitoring board **(" DSMB")** may also suspend or terminate a clinical trial at any time on various grounds, including a finding that the research volunteers are being exposed to an unacceptable health risk. Vaccine- related side effects could also affect recruitment or the ability of enrolled subjects to complete the trial or result in potential product liability claims. In addition, any vaccine to be approved in pediatric populations may need to undergo extensive vaccine- vaccine interference studies with the standard- of-care pediatric vaccine regimen. Further, to the extent field efficacy studies are required, prophylactic vaccines typically require clinical testing in thousands to tens of thousands of healthy volunteers to define an approvable benefit- risk profile. The need to show a high degree of safety and tolerability when dosing healthy individuals could result in rare and even spurious safety findings, negatively impacting a program prior to or after commercial launch. Any of these occurrences may harm our business, financial condition and prospects significantly. Negative developments and negative public opinion of **vaccines or** new technologies on which we rely may damage public perception of our vaccine candidates or adversely affect our ability to conduct our business or obtain regulatory approvals for our vaccine candidates. Negative developments and negative public opinion of **vaccines or** new or existing technologies on which we rely may damage public perception of our vaccine candidates or adversely affect our ability to conduct our business or obtain regulatory approvals for our vaccine candidates. Public perception may be influenced by claims that vaccines are unsafe, and products incorporating new vaccine technology may not gain the acceptance of the public or the medical community. Adverse public attitudes may negatively impact our ability to enroll subjects in clinical trials. Moreover, our success will depend upon physicians prescribing, and their patients being willing to receive, our vaccine candidates in lieu of, or in addition to, existing, more familiar vaccines for which greater clinical data may be available. ~~Any~~ **Changes at the HHS could alter regulators' postures, or the public' s views, toward vaccines. For example, the HHS could disband the ACIP or fill the committee with membership that has a skeptical view of vaccines, change legal protections for vaccine manufacturers, and work with state governments as well as the Centers for Medicare & Medicaid Services (" CMS ") to remove requirements or reimbursement for childhood vaccines.** ~~increase~~ **Increases** in negative perceptions of **vaccines or** the technologies that we rely on **by regulators** may result in **the FDA not approving our products or, if approved,** fewer physicians prescribing our products ~~or~~ **. It also** may reduce the willingness of patients to utilize our products or participate in clinical trials for our vaccine candidates. We may not be able to file IND applications to commence clinical trials on the timelines we expect, and even if we are able to, the FDA may not permit us to proceed. Our timing of submitting the IND applications for our product candidates is dependent on preclinical and manufacturing success, and if we experience additional delays, we may fail to meet our anticipated timelines. In addition, we cannot be sure that submission of an IND application or IND application amendment will result in the FDA allowing testing and clinical trials to begin, or that, once begun, issues will not arise that suspend or terminate such clinical trials. Additionally, even if ~~such~~ regulatory authorities agree with the design and implementation of the clinical trials set forth in an IND or clinical trial application, we cannot guarantee that such regulatory authorities will not change their requirements in the future. We may encounter substantial delays in our clinical trials or may not be able to conduct our trials on the timelines we expect. Clinical testing is expensive, time consuming and subject to uncertainty. We cannot guarantee that any clinical studies will be conducted as planned or completed on schedule, if at all. Even if these trials begin as planned, issues may arise that could suspend or terminate such clinical trials. A failure of one or more clinical studies can occur at any stage of testing, and our future clinical studies may not be successful. Events that may prevent successful or timely completion of clinical development include, but are not limited to: • inability to generate sufficient preclinical, toxicology or other in vivo or in vitro data to support the initiation of clinical trials; • delays in sufficiently developing, characterizing or controlling a manufacturing process suitable for advanced clinical trials; • delays in reaching a consensus with regulatory agencies on study design or clinical or regulatory strategies; • delays in reaching agreement on acceptable terms with prospective CROs and clinical study sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and clinical study sites; • delays in obtaining required institutional review board (" IRB ") approval at each clinical study site; • imposition of a temporary or permanent clinical hold by regulatory agencies for a number of reasons, including after review of an IND application or amendment, or equivalent application or amendment; as a result of a new safety finding that presents unreasonable risk to clinical trial participants; a negative finding from an inspection of our clinical study operations or study sites; developments on trials conducted by competitors for related technology that raise FDA concerns about risk to patients of the technology broadly; or if the FDA finds that the investigational protocol or plan is clearly deficient to meet its stated objectives; • delays in adding a sufficient number of trial sites and recruiting volunteers to participate in our clinical trials; • failure by our CROs, other third parties or us, to adhere to clinical study requirements; • failure to perform in accordance with the FDA' s good clinical practice (" GCP ") requirements or applicable regulatory guidelines in other jurisdictions; • transfer of manufacturing processes to any new CMO or our own manufacturing facilities or any other development or commercialization partner for the manufacture of vaccine candidates; • delays in having subjects complete participation in a study or return for post- injection follow- up; •

subjects dropping out of a study; • occurrence of side effects associated with our vaccine candidates that are viewed to outweigh their potential benefits; • changes in regulatory requirements and guidance that require amending or submitting new clinical protocols; • changes in the standard- of- care on which a clinical development plan was based, which may require new or additional trials; • the cost of clinical trials of our vaccine candidates being greater than we anticipate; • clinical studies of our vaccine candidates producing negative or inconclusive results, which may result in our deciding, or regulators requiring us, to conduct additional clinical studies or abandon product development programs; • delays or failure to secure supply agreements with suitable raw material suppliers, or any failures by suppliers to meet our quantity or quality requirements for necessary raw materials; and • delays in manufacturing, testing, releasing, validating or importing / exporting sufficient stable quantities of our vaccine candidates for use in clinical studies or the inability to do any of the foregoing. For example, based on the positive topline results from the VAX- 24 Phase 1 / 2 proof- of- concept study, which evaluated the safety, tolerability and immunogenicity of VAX- 24 in adults 18- 64 years of age, the FDA supported the initiation of a pediatric study in infants. This study could uncover risks in this study population that could have potentially been discovered during a child and / or toddler study, which could then delay **or stop the** completion of clinical development. Any inability to successfully complete preclinical and clinical development could result in additional costs to us or impair our ability to generate revenue. In addition, if we make manufacturing or formulation changes to our vaccine candidates, we may be required to or we may elect to conduct additional studies to bridge our modified vaccine candidates to earlier versions. Clinical trial delays could also shorten any periods during which our products have patent protection and may allow our competitors to bring products to market before we do, which could impair our ability to successfully commercialize our vaccine candidates and may harm our business and results of operations. If we encounter difficulties enrolling subjects in any clinical trials we may conduct, including any field efficacy trials that may be required, our clinical development activities could be delayed or otherwise adversely affected. We may experience difficulties in enrolling subjects in any clinical trials we may conduct for a variety of reasons. The timely completion of clinical trials in accordance with their protocols depends, among other things, on our ability to enroll a sufficient number of subjects who remain in the study until its conclusion. The enrollment of subjects depends on many factors, including but not limited to: • the eligibility and exclusion criteria defined in the protocol; • the size of the population required for analysis of the trial' s primary endpoints; • the proximity of volunteers to study sites; • the design of the trial; • our ability to recruit clinical trial investigators with the appropriate competencies and experience; • our ability to obtain and maintain subject consents; • the ability to monitor volunteers adequately during and after injection; • the risk that volunteers enrolled in clinical trials will drop out of the trials before the injection of our vaccine candidates or trial completion; and • the risks and disruptions related to patient and physician investigator recruitment and retention and study site initiation and clinical trial activities. ~~To~~ **Based on our VAX- 24 End- of- Phase 2 meeting with the FDA in October 2023, we believe there was agreement with the FDA on the clinical design of the** ~~the~~ **then** ~~extent~~ **planned VAX- 24 adult Phase 3 program, including the approximate overall number of subjects, the primary and secondary endpoints for the pivotal, non- inferiority study as well as confirmation that immunogenicity analyses would have been sufficient to support licensure and an efficacy study therefore would not have been required. Following the topline results of the VAX- 31 Phase 1 / 2 study in adults 50 and older, we selected VAX- 31 to exclusively advance to an adult Phase 3 program. We plan to hold an End- of- Phase 2 meeting for the VAX- 31 adult program in advance of commencing a Phase 3 program. However, we believe the FDA position related to the previously discussed VAX- 24 adult Phase 3 program will also apply to the VAX- 31 adult Phase 3 program. In the event that** we are required to conduct any field efficacy studies **for VAX- 31 or any of our other product candidates** , enrollment of a sufficient number of subjects may require additional time and resources given widespread vaccination rates in the United States, particularly in the pediatric population. As a result, we may be required to conduct any such trials outside the United States, which could cause additional complexity and delay. Delays in enrollment may result in increased costs or may affect the timing or outcome of any clinical trials we may conduct, which could prevent completion of these trials and adversely affect our ability to advance the development of our vaccine candidates. Interim topline and preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data. From time to time, we may publish interim topline or preliminary data from our preclinical or clinical trials. Interim topline data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as more patient data become available. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data when we publish such data. As a result, the topline results that we report may differ from future results of the same studies, or different conclusions or considerations may qualify such results once additional data have been received and fully evaluated. Preliminary or topline data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we may publish. As a result, interim and preliminary data should be viewed with caution until the final data are available. Adverse differences between preliminary or interim data and final data could significantly harm our business prospects. Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular vaccine candidate and our company in general. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, and you or others may not agree with what we determine is the material or otherwise appropriate information to include in our disclosure. Any information we determine not to disclose may ultimately be deemed significant by you or others with respect to future decisions, conclusions, views, activities or otherwise regarding a particular vaccine candidate or our business. If the topline data that we report differ from final results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, vaccine candidates may be harmed, which could significantly harm our

business prospects. We have in the past and may in the future seek ~~Breakthrough~~ **breakthrough** ~~Therapy~~ **therapy** designation **(" BTD")** or Fast Track designation by the FDA for one or more of our vaccine candidates, but we may not receive the designations we seek, and even if we do, such designation may not lead to a faster development or regulatory review or approval process and it does not increase the likelihood that our vaccine candidates will receive marketing approval. We have in the past and may in the future seek **BTD** ~~Breakthrough Therapy~~ or Fast Track designation for some of our vaccine candidates. For instance, in August 2022 we announced that the FDA granted Fast Track designation to VAX- 24 in adults ages 18 and older and, in January 2023, we announced that the FDA granted **a BTD** ~~Breakthrough Therapy designation~~ for VAX- 24 for the prevention of IPD in adults. A sponsor may seek FDA designation of its vaccine candidate as a ~~Breakthrough~~ **breakthrough** ~~Therapy~~ **therapy** if the vaccine candidate is intended to treat a serious or life- threatening disease or condition and preliminary clinical evidence indicates that the therapy may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. For vaccines that have been designated as Breakthrough Therapies, the FDA may take actions to expedite the development and review of the application, and interaction and communication between the FDA and the sponsor of the trial can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens. A vaccine designated as a ~~Breakthrough~~ **breakthrough** ~~Therapy~~ **therapy** by the FDA may also be eligible for expedited review and approval. If a vaccine candidate is intended for the treatment of a serious or life- threatening condition and clinical or preclinical data demonstrate the potential to address unmet medical needs for this condition, the sponsor may apply for Fast Track designation. The FDA has broad discretion whether or not to grant this designation, so even if we believe a particular vaccine candidate is eligible for this designation, we cannot assure you that the FDA would decide to grant it. Even when we obtain Fast Track designation for one or more of our vaccine candidates, we may not experience a faster development process, review or approval compared to non- expedited FDA review procedures. ~~For instance, although the FDA has granted Fast Track designation to VAX- 24 in adults, we may not experience a faster development, review or approval process compared to the conventional process.~~ In addition, the FDA may withdraw Fast Track designation from ~~VAX- 24, or from~~ any ~~other~~ of our vaccine candidates that may receive the designation in the future, if it believes that the designation is no longer supported. Fast Track designation alone does not guarantee qualification for the FDA' s Priority Review procedures. Whether to grant ~~Breakthrough Therapy~~ **a BTD** or Fast Track ~~designations~~ **designation** ~~are~~ **is** within the discretion of the FDA. Accordingly, even if we believe one of our vaccine candidates meets the criteria for these designations, the FDA may disagree and instead determine not to make such designation. In any event, the receipt of either of these designations for a vaccine candidate may not result in a faster development process, review or approval compared to vaccine candidates considered for approval under non- expedited FDA review procedures and does not assure ultimate approval by the FDA. In addition, even when one or more of our vaccine candidates qualify for either of these designations, the FDA may later decide that the vaccine candidate no longer meets the conditions for qualification and rescind the designations. We currently have no marketing and sales organization, and as an organization have no experience in marketing products. If we are unable to establish marketing and sales capabilities or enter into agreements with third parties to market and sell our vaccine candidates, we may not be able to generate product revenue. We currently have no sales, marketing or distribution capabilities and as an organization have no experience in marketing products. If we develop an in- house marketing organization and sales force, we will require significant capital expenditures, management resources and time, and we will have to compete with other pharmaceutical and biotechnology companies to recruit, hire, train and retain marketing and sales personnel. If we are unable or decide not to establish internal sales, marketing and distribution capabilities, we will pursue collaborative arrangements regarding the sales and marketing of our products; however, there can be no assurance that we will be able to establish or maintain such collaborative arrangements, or if we are able to do so, that they will have effective sales forces. Any revenue we receive will depend upon the efforts of such third parties, which may not be successful. We may have little or no control over the marketing and sales efforts of such third parties and our revenue from product sales may be lower than if we had commercialized our vaccine candidates ourselves. We also face competition in our search for third parties to assist us with the sales and marketing efforts of our vaccine candidates. There can be no assurance that we will be able to develop in- house sales and distribution capabilities or establish or maintain relationships with third- party collaborators to commercialize any product that receives regulatory approval in the United States or overseas. If we are unable to develop in- house sales and distribution capabilities or enter into relationships with third- party collaborators on acceptable terms or at all, we may not be able to successfully commercialize our products. If we are not successful in commercializing our products or any future products, either on our own or through arrangements with one or more third parties, we may not be able to generate any future product revenue and we would incur significant additional losses. A variety of risks associated with potentially conducting research and clinical trials abroad and marketing our vaccine candidates internationally could materially adversely affect our business. As we pursue approval and commercialization for our vaccine candidates overseas and conduct CMC and other operations overseas, we will be subject to additional risks related to operating in foreign countries, including but not limited to: • differing regulatory requirements in foreign countries; • ~~unexpected changes in~~ tariffs **(including tariffs that have been or may in the future be imposed by the U. S. and other countries)** , trade barriers **(including further legislation or actions taken by the U. S. or other countries that restrict trade), trade protection measures** , price and exchange controls and other regulatory requirements **, as well as protectionist or retaliatory measures taken by the U. S. and other countries** ; • increased difficulties in managing the logistics and transportation of storing and shipping vaccine candidates abroad; • import and export requirements and restrictions; • differing and changing data protection and privacy regimes and requirements; • economic weakness, including inflation and interest rates, or political instability in particular foreign economies and markets; • compliance with tax, employment, immigration and labor laws for employees living or traveling abroad; • foreign taxes, including withholding of payroll taxes; • foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country; •

difficulties staffing and managing foreign operations; • workforce uncertainty in countries where labor unrest is more common than in the United States; • differing payor reimbursement regimes, governmental payors or patient self- pay systems and price controls; • potential liability under the U. S. Foreign Corrupt Practices Act of 1977, as amended, or comparable foreign regulations; • challenges enforcing our contractual and intellectual property rights, especially in those foreign countries that do not respect and protect intellectual property rights to the same extent as the United States; • production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and • business interruptions resulting from geopolitical actions, including war and terrorism. These and other risks associated with our international operations and our collaborations with Lonza, based in Switzerland, may materially adversely affect our ability to attain or maintain profitable operations. We are highly dependent on our key personnel, and if we are not able to retain these members of our management team or recruit and retain highly qualified personnel, we may not be able to successfully implement our business strategy. Our ability to compete in the highly competitive biotechnology and pharmaceutical industries depends upon our ability to attract and retain highly qualified managerial, scientific and medical personnel. We are highly dependent on our management, scientific and medical personnel, including our Chief Executive Officer, our President and Chief Financial Officer, our Vice President of Research and our Executive Vice President and Chief Operating Officer. The loss of the services of any of our executive officers, other key employees and other scientific and medical advisors, and our inability to find suitable replacements, could result in delays in product development and harm our business. We conduct substantially all of our operations at our facilities in the San Francisco Bay Area. This region is headquarters to many other biopharmaceutical companies and many academic and research institutions. Competition for skilled personnel in our market is intense and may limit our ability to hire and retain highly qualified personnel on acceptable terms or at all. To induce valuable employees to remain at our company, in addition to salary and cash incentives, we have provided stock options and restricted stock units (“ RSUs ”) that vest over time. The value to employees of stock options and RSUs that vest over time may be significantly affected by movements in our stock price that are beyond our control and may at any time be insufficient to counteract more lucrative offers from other companies. Despite our efforts to retain valuable employees, members of our management and scientific and development teams may terminate their employment with us on short notice. Although we have employment agreements with our key employees, these employment agreements provide for at- will employment, which means that any of our employees could leave our employment at any time, with or without notice. We do not maintain “ key person ” insurance policies on the lives of these individuals or the lives of any of our other employees. 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. We have grown rapidly and will need to continue to grow the size of our organization, and we may experience difficulties in managing this growth. As our discovery, development, manufacturing and commercialization plans and strategies develop, we have rapidly expanded our employee base and expect to continue to add managerial, operational, sales, research and development, marketing, financial and other personnel. Current and future growth imposes significant added responsibilities on members of management, including but not limited to: • identifying, recruiting, integrating, maintaining and motivating additional employees; • managing our internal development efforts effectively, including the clinical and FDA review process for our vaccine candidates, while complying with our contractual obligations to contractors and other third parties; and • improving our operational, financial and management controls, reporting systems and procedures. Our future financial performance and our ability to commercialize our vaccine candidates will depend, in part, on our ability to effectively manage our growth. Our management may also have to divert a disproportionate amount of its attention away from day- to- day activities in order to devote a substantial amount of time to managing these growth activities. If we are not able to effectively expand our organization by hiring new employees and expanding our groups of consultants and contractors, we may not be able to successfully implement the tasks necessary to further develop and commercialize our vaccine candidates and, accordingly, may not achieve our research, development, manufacturing and commercialization goals. Obtaining and maintaining regulatory approval of our vaccine candidates in one jurisdiction does not mean that we will be successful in obtaining regulatory approval of our vaccine candidates in other jurisdictions. Obtaining and maintaining regulatory approval of our vaccine candidates in one jurisdiction does not guarantee that we will be able to obtain or maintain regulatory approval in any other jurisdiction, while a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in others. For example, even if the FDA grants marketing approval of a vaccine candidate, comparable regulatory authorities in foreign jurisdictions must also approve the manufacturing, marketing and promotion of the vaccine candidate in those countries. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from, and greater than, those in the United States, including additional preclinical studies or clinical trials as clinical studies conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. In many jurisdictions outside the United States, a vaccine candidate must be approved for reimbursement before it can be approved for sale in that jurisdiction. In some cases, the price that we intend to charge for our products is also subject to approval. We may also submit marketing applications in other countries. Regulatory authorities in jurisdictions outside of the United States have requirements for approval of vaccine candidates with which we must comply prior to marketing in those jurisdictions. Obtaining foreign regulatory approvals and compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our products in certain countries. If we fail to comply with the regulatory requirements in international markets and / or receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of our vaccine candidates will be harmed. We may form or seek strategic alliances or enter into additional licensing arrangements in the future, and we may not realize the benefits of such alliances or licensing arrangements. We may form or seek strategic alliances, create joint ventures or collaborations or enter into additional licensing arrangements with third parties that we believe will complement or augment our discovery, development, manufacturing and commercialization efforts with respect to our vaccine candidates and any future vaccine candidates that we may seek to develop.

Any of these relationships may require us to incur non- recurring and other charges, increase our near and long- term expenditures, issue securities that dilute our existing stockholders or disrupt our management and business. In addition, we face significant competition in seeking appropriate strategic partners, and the negotiation process is time- consuming and complex. Moreover, we may not be successful in our efforts to establish a strategic partnership or other alternative arrangements for our vaccine candidates because they may be deemed to be at too early of a stage of development for collaborative effort, and third parties may not view our vaccine candidates as having the requisite potential to demonstrate safety ~~and~~ **, immunogenicity or** efficacy. Any delays in entering into new strategic partnership agreements related to our vaccine candidates could delay the development, manufacturing and commercialization of our vaccine candidates in certain geographies for certain indications, which would harm our business prospects, financial condition and results of operations. If we license products or businesses, we may not be able to realize the benefit of such transactions if we are unable to successfully integrate them with our existing operations and company culture. We cannot be certain that, following a strategic transaction or license, we will achieve the results, revenue or specific net income that justifies such transaction. Revenue from any " catch up " opportunity may decline over time as more of the patient population is vaccinated. We intend to initially seek approval of ~~our VAX- 24 or~~ VAX- 31 ~~vaccine candidates~~ in adults. If approved, we believe it may have the potential to serve as a " catch up " or booster to those adults who have previously received PPSV23 or a lower- valent PCV. Previous vaccines with a " catch up " opportunity have seen a high initial capture rate, but sales may decline over time as the number of individuals who remain unvaccinated with the new vaccine, and eligible for " catch up " opportunities, declines. Such decline could adversely affect our revenue over time. If our information technology systems or those of the third parties upon which we rely, are or were compromised, we could experience adverse consequences resulting from such compromise, including but not limited to significant fines or other liability; regulatory investigations or actions; disruptions of our development programs or business operations; harms to our reputation, and other adverse consequences. In the ordinary course of our business, we and the third parties upon which we rely collect, receive, use, retain, safeguard, disclose, share, transfer, make accessible, dispose of, transmit or otherwise process proprietary, confidential and sensitive information, including personal data (including, key- coded data, health information, data we collect about trial participants in connection with clinical trials and other special categories of personal data), intellectual property, trade secrets, and proprietary business information owned or controlled by ourselves or other parties, and other sensitive third- party data (collectively, " Sensitive Information "). We may use third- party service providers and subprocessors, including our CROs, to help us operate our business and engage in processing on our behalf in a variety of contexts, including, without limitation, cloud- based infrastructure, data center facilities, encryption and authentication technology, employee email and other functions. We may also share Sensitive Information with our partners or other third parties in connection with our business. Our ability to monitor these third parties' cybersecurity practices is limited, and these third parties may not have adequate information security measures in place. If our third- party service providers experience a ~~security~~ **cybersecurity** incident or other interruption **, including a system outage** , we could experience adverse consequences. While we may be entitled to damages if our third- party service providers fail to satisfy their privacy or security- related obligations to us, any award may be insufficient to cover our damages, or we may be unable to recover such award. In addition, supply- chain attacks have increased in frequency and severity, and we cannot guarantee that third parties' infrastructure in our supply chain or our third- party partners' supply chains have not been compromised. Cyberattacks **and cybersecurity incidents, system outages** , malicious internet- based activity, online and offline fraud, and other similar activities threaten the confidentiality, integrity, and availability of our Sensitive Information and our information technology systems, and those of the third parties upon which we rely. Such threats are prevalent and continue to increase, are increasingly difficult to detect, and come from a variety of sources, including traditional computer " hackers "; threat actors; " hacktivists **"** ; ~~"~~ organized criminal threat actors; personnel (through theft or misuse); and sophisticated nation- state and nation- state supported actors. Some actors now engage and are expected to continue to engage in cyber- attacks, including without limitation nation- state actors for geopolitical reasons and in conjunction with military conflicts and defense activities. During times of war and other major conflicts, we and the third parties upon which we rely may be vulnerable to a heightened risk of these attacks, including retaliatory cyber- attacks, that could materially disrupt our systems and operations, supply chain, and ability to produce, sell and distribute our services. We and the third parties upon which we rely are subject to a variety of evolving threats, including but not limited to software bugs; malicious code (such as viruses and worms); social- engineering attacks (including through deep fakes, which may be increasingly more difficult to identify as a fake, and phishing attacks); employee error, theft or misuse; denial- of- service attacks (such as credential stuffing); malware (including as a result of advanced persistent threat intrusions); natural disasters; terrorism; war; telecommunication and electrical failures; supply- chain attacks; ransomware attacks; attacks enhanced or facilitated by **artificial intelligence ("** AI **")** ; and ~~,~~ other similar threats. In particular, severe ransomware attacks, including those perpetrated by organized criminal threat actors, nation- states, and nation- state- supported actors, are becoming increasingly prevalent and can lead to significant interruptions in our operations, loss of data and income, reputational harm and diversion of funds. Extortion payments may alleviate the negative impact of a ransomware attack, but we may be unwilling or unable to make such payments due to, for example, applicable laws or regulations prohibiting such payments. We may also be the subject of server malfunction, software or hardware failures, supply- chain cyberattacks, loss of data or other computer assets and other similar issues. Remote and hybrid work has become more common and has increased risks to our information technology systems and data, as more of our employees utilize network connections, computers and devices outside our premises or network, including working at home, while in transit and in public locations. Future or past business transactions (such as acquisitions or integrations) could expose us to additional cybersecurity risks and vulnerabilities, as our systems could be negatively affected by vulnerabilities present in acquired or integrated entities' systems and technologies. Furthermore, we may discover security issues that were not found during due diligence of such acquired or integrated entities, and it may be difficult to integrate companies into our information technology environment and security program. While we have implemented security measures designed to protect against

~~security~~ **cybersecurity** incidents, there can be no assurance that these measures will be effective. We take steps designed to detect, mitigate, and remediate vulnerabilities in our information systems (such as our hardware and / or software, including that of third parties upon which we rely). We may not, however, be able to detect and remediate all such vulnerabilities, including on a timely basis. Despite our efforts to identify and remediate vulnerabilities, if any, in our information technology systems, our efforts may not be successful. Further, we may experience delays in developing and deploying remedial measures designed to address any such identified vulnerabilities. Vulnerabilities could be exploited and result in a ~~security~~ **cybersecurity** incident. Any of the previously identified or similar threats could cause a ~~security~~ **cybersecurity** incident or other interruption. A ~~security~~ **cybersecurity** incident or other interruption could result in unauthorized, unlawful, or accidental acquisition, modification, destruction, loss, alteration, encryption, disclosure of, or access to data and could disrupt our ability (and that of third parties upon whom we rely) to provide our products or operate our business. We may be required to expend significant resources, fundamentally change our business activities and practices, or modify our operations, including our clinical trial activities, or information technology in an effort to protect against **cybersecurity incidents or other** security breaches and to mitigate, detect and remediate actual or potential vulnerabilities. Certain data privacy and security obligations may require us to implement and maintain specific security measures or industry- standard or reasonable security measures to protect our information technology systems and Sensitive Information. If we (or a third party upon which we rely) experience a ~~security~~ **cybersecurity** incident or are perceived to have experienced a ~~security~~ **cybersecurity** incident, we may experience adverse consequences, including interruptions in our operations, which could result in a disruption of our development programs and our business operations. For example, the loss of clinical trial data from clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further development, manufacturing and commercialization of our vaccine candidates could be delayed. Furthermore, consequences from an actual or perceived security breach may include: government enforcement actions (for example, investigations, fines, penalties, audits, and inspections); additional reporting requirements and / or oversight; restrictions on processing data (including personal data); litigation (including class claims); indemnification obligations; negative publicity; reputational harm; monetary fund diversions; interruptions in our operations (including availability of data); financial loss; and other similar harms. ~~Security~~ **Cybersecurity** incidents and attendant consequences may cause customers to stop using our platform / products / services, deter new customers from using our products, and negatively impact our ability to grow and operate our business. Additionally, applicable data privacy and security obligations, including, without limitation, laws, regulations, guidance as well as our internal and external policies and our contractual obligations, may require us to notify relevant stakeholders of **cybersecurity incidents or other** security breaches, including affected individuals, partners, collaborators, regulators, law enforcement agencies, credit reporting agencies and others. Such disclosures are costly, and the disclosure or the failure to comply with such requirements could lead to litigation or other liability, fines, harm to our reputation, significant costs, or other materially adverse effects. There can be no assurance that any limitations or exclusions of liability in our contracts would be enforceable or adequate or protect us from liability or damages. We cannot be sure that our insurance coverage, if any, will be adequate or otherwise protect us from or adequately mitigate liabilities or damages with respect to claims, costs, expenses, litigation, fines, penalties, business loss, data loss, regulatory actions or other materially adverse impacts arising out of our processing activities, privacy and security practices, or security breaches we may experience. The successful assertion of one or more large claims against use that exceeds our available insurance coverage, or results in changes to our insurance policies (including premium increases or the imposition of large excess or deductible or co- insurance requirements), could result in substantial cost increase or prevent us from obtaining insurance on acceptable terms. Additionally, our contracts may not contain limitations of liability, and even where they do, there can be no assurance that limitations of liability in our contracts are sufficient to protect us from liabilities, damages, or claims related to our data privacy and security obligations. In addition to experiencing a ~~security~~ **cybersecurity** incident, third parties may gather, collect, or infer sensitive data about us from public sources, data brokers, or other means that reveals competitively sensitive details about our organization and could be used to undermine our competitive advantage or market position. Additionally, Sensitive Information of **ours** ~~the Company~~ , ~~its~~ **our** vendors, or ~~its~~ **our** partners could be leaked, disclosed, or revealed as a result of or in connection with our employees', personnel' s, or vendors' use of generative AI technologies. **Use of artificial intelligence in our operations could result in reputational or competitive harm and legal or regulatory liability. We have incorporated, and may continue to incorporate, certain AI solutions into our operations, and the use of AI involves various risks and challenges that could adversely affect our** ~~Business~~ **business . The development and deployment of AI systems involve inherent technical complexities and uncertainties, and our AI systems may encounter unexpected technical difficulties, limitations or errors, including inaccuracies in data processing or flawed algorithms. In addition, our competitors or other third parties may incorporate AI into their operations and products more quickly or more successfully than us, which could impair our ability to compete effectively. The use of AI applications, including large language models, may in the future result in cybersecurity incidents that implicate the personal data of end users of such applications. Any such cybersecurity incidents related to our use of AI applications could adversely affect our business and reputation. AI also presents emerging ethical issues, and if our use of AI becomes controversial, we may experience brand or reputational harm, competitive harm, regulatory scrutiny or legal liability. In addition, use of personal data in generative AI technologies is subject to various privacy laws and other privacy obligations. Governments have passed and are likely to pass additional laws regulating generative AI. The introduction of AI technologies into our operations may result in new or enhanced governmental or regulatory scrutiny, litigation, confidentiality or security risks or other complications that could adversely affect our business. The regulatory landscape governing AI technologies is evolving rapidly, and changes in laws, regulations or enforcement practices may**

impose new compliance requirements, restrict certain AI applications or increase our regulatory obligations, which could negatively impact our business. Natural or man- made disasters or business disruptions could seriously harm our future revenue and financial condition and increase our costs and expenses. Our operations, and those of our CMOs, CROs and other contractors and consultants, could be subject to earthquakes, power shortages, telecommunications failures, water shortages, floods, hurricanes, typhoons, fires, extreme weather conditions, medical epidemics and other natural or man- made disasters or business interruptions, for which we are predominantly self- insured. The impact of climate change may increase these risks due to changes in weather patterns, such as increases in storm intensity, sea- level rise, melting of permafrost and temperature extremes on facilities or operations. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses. Our ability to manufacture our vaccine candidates could be disrupted if our operations or those of our suppliers are affected by a man- made or natural disaster or other business interruption. Our corporate headquarters are located in California near major earthquake faults and fire zones. The ultimate impact on us, our significant suppliers and our general infrastructure of being located near major earthquake faults and fire zones and being consolidated in certain geographical areas is unknown, but our operations and financial condition could suffer in the event of a major earthquake, fire or other natural disaster. If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of our vaccine candidates. We face an inherent risk of product liability as a result of the clinical testing of our vaccine candidates and will face an even greater risk if we commercialize any products. For example, we may be sued if our vaccine candidates cause or are perceived to cause injury or are found to be otherwise unsuitable during clinical testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability or a breach of warranties. Claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our vaccine candidates. Even successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in: • decreased demand for our vaccine candidates; • injury to our reputation; • withdrawal of clinical trial participants; • initiation of investigations by regulators; • costs to defend the related litigation; • a diversion of management' s time and our resources; • substantial monetary awards to trial participants or patients; • product recalls, withdrawals or labeling, marketing or promotional restrictions; • loss of revenue; • exhaustion of any available insurance and our capital resources; • the inability to commercialize any vaccine candidate; and • a decline in our share price. Our inability to obtain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of products we develop, alone or with corporate collaborators. Our insurance policies may also have various exclusions, and we may be subject to a product liability claim for which we have no coverage. Assuming we obtain clinical trial insurance for our clinical trials, we may have to pay amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts. Even if our agreements with any future corporate collaborators entitle us to indemnification against losses, such indemnification may not be available or adequate should any claim arise. Our employees, principal investigators, consultants and commercial partners may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements and insider trading. We are exposed to the risk of fraud or other misconduct by our employees, principal investigators, consultants and commercial partners. Misconduct by these parties could include intentional failures, reckless and / or negligent conduct or unauthorized activities that violate (i) the laws and regulations of the FDA and other regulatory authorities, including those laws requiring the reporting of true, complete and accurate information to such authorities, (ii) manufacturing standards, (iii) federal and state data privacy, security, fraud and abuse and other healthcare laws and regulations in the United States and abroad and (iv) laws that require the true, complete and accurate reporting of financial information or data. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Such misconduct also could involve the improper use of individually identifiable information, including, without limitation, information obtained in the course of clinical trials, creating fraudulent data in our preclinical studies or clinical trials or illegal misappropriation of drug product, which could result in regulatory sanctions and cause serious harm to our reputation. It is not always possible to identify and deter misconduct by employees and other third parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from government investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. Additionally, we are subject to the risk that a person or government could allege such fraud or other misconduct, even if none occurred. If any such actions are instituted against us and we are not successful in defending ourselves or asserting our rights, those actions could result in significant civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from participating in government- funded healthcare programs, such as Medicare and Medicaid, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of noncompliance with these laws, contractual damages, reputational harm and the curtailment or restructuring of our operations, any of which could have a negative impact on our business, financial condition, results of operations and prospects. Changes in tax laws or tax rulings could affect our financial position. In December 2017, the Tax Cuts and Jobs Act (" Tax Act ") was signed into law. The Tax Act, among other things, contains significant changes to corporate taxation, including (i) changes to the expensing of research and development expenses for tax years beginning after December 31, 2021, (ii) reduction of the corporate tax rate from a top marginal rate of 35 % to a flat rate of 21 %, (iii) limitation of the tax deduction for interest expense to 30 % of adjusted earnings (with certain exceptions, including for certain small businesses), (iv) limitation of the deduction for post- 2017

net operating losses (“ NOL ”) to 80 % of current- year taxable income and elimination of net operating loss carrybacks for post-2017 NOLs, (v) immediate deductions for certain new investments instead of deductions for depreciation expense over time and (vi) modifying or repealing many business deductions and credits (including reducing the business tax credit for certain clinical testing expenses incurred in the testing of certain drugs for rare diseases or conditions generally referred to as “ orphan drugs ”). Effective January 1, 2022, we are also subject to mandatory capitalization of Section 174 research and development expenditures. The capitalized expenses are subject to amortization over five and fifteen years for expenses incurred within the U. S. and outside of U. S., respectively. ~~In March 2020, the Coronavirus Aid, Relief, and Economic Security (“ CARES Act ”) was signed into law. The CARES Act changed certain provisions of the Tax Act. Under the CARES Act, NOLs arising in taxable years beginning after December 31, 2017 and before January 1, 2021 may be carried back to each of the five taxable years preceding the tax year of such loss, but NOLs arising in taxable years beginning after December 31, 2020 may not be carried back. In addition, the CARES Act eliminated the limitation on the deduction of NOLs to 80 % of current year taxable income for taxable years beginning before January 1, 2021, and increased the amount of interest expense that may be deducted to 50 % of adjusted taxable income for taxable years beginning in 2019 or 2020. Notwithstanding the reduction in the corporate income tax, these benefits do not impact our current tax provision. On December 21, 2020, the President of the United States signed into law the “ Consolidated Appropriations Act, 2021, ” which includes further COVID- 19 economic relief and extension of certain expiring tax provisions. The relief package includes a tax provision clarifying that businesses with forgiven Paycheck Protection Program (“ PPP ”) loans can deduct regular business expenses that are paid for with the loan proceeds. Additional pandemic relief tax measures include an expansion of the employee retention credit, enhanced charitable contribution deductions and a temporary full deduction for business expenses for food and beverages provided by a restaurant for tax years 2021 and 2022.~~ The Infrastructure Investment and Jobs Act was signed on November 15, 2021, and it contained several tax provisions **,** including changes to the Employee Retention Tax Credit and changes to excise taxes. These provisions do not have a material ~~impactful~~ --- **impact** to our current tax provision. In accordance with the 2017 Tax Act, research and experimental (“ R & E ”) expenses under Internal Revenue Code Section 174 are required to be capitalized beginning in 2022. R & E expenses are required to be amortized over a period of five years for domestic expenses and 15 years for foreign expenses. We have capitalized research and experimental expenditures in our current tax provision as a result. The IRA of 2022 specifically introduces the topic of corporate alternative minimum tax on adjusted financial statement income on applicable corporations for taxable years beginning after December 31, 2022. There is no impact to our current tax provision. The American Rescue Plan Act was signed on March 11, 2021. One of the provisions of the Act included expanding the definition of covered employees subject to IRC 162 (m) to include an additional top five highest compensated ~~officers~~ **employees** beyond the CEO, CFO ~~,~~and three highest paid ~~employees~~ **officers** currently covered under IRC 162 (m). This expanded provision is applicable for tax years beginning after December 31, 2026. We do not believe that this update to IRC 162 (m) would have a material impact on our income tax provision currently and will continue to monitor this **provision** . We are unable to predict what tax changes may be enacted in the future or what effect such changes would have on our business, but such changes could affect our effective tax rate and could have an adverse effect on our overall tax position in the future, along with increasing the complexity, burden, and cost of tax compliance. Our ability to utilize our NOL carryforwards and certain other tax attributes may be limited. We have incurred substantial losses since inception and do not expect to become profitable in the near future, if ever. As of December 31, ~~2023~~ **2024** , we had federal and state NOL carryforwards of $ ~~351~~ **430** . ~~9~~ **2** million and $ ~~693~~ **1, 188** . ~~6~~ **1** million, respectively. The federal and state loss carryforwards, except the federal loss carryforward arising in tax years beginning after December 31, 2017, begin to expire in 2034 unless previously utilized. Federal NOLs arising in tax years beginning after December 31, 2017 have an indefinite carryforward period and do not expire. As of December 31, ~~2023~~ **2024** , we also had federal and state research credit carryforwards of $ ~~12~~ **28** . **3 million and $** 8 ~~million and $ 4~~ . ~~6~~ **1** million, respectively. The federal research and development tax credit carryforwards expire beginning in 2039 unless previously utilized, and the state research and development tax credits can be carried forward indefinitely. In general, under Sections 382 and 383 of the U. S. Internal Revenue Code of 1986, as amended, a corporation that undergoes an “ ownership change ” (generally defined as a greater than 50 percentage point change (by value) in its equity ownership by certain stockholders over a rolling three- year period) is subject to limitations on its ability to utilize its pre- change NOLs to offset future taxable income. We have experienced ownership changes in the past. There were no ownership changes identified in ~~2023~~ **2024** , as such we have determined that no federal research credits will expire unutilized or are excluded from our research carryforwards as of December 31, ~~2023~~ **2024** . Subsequent ownership changes may affect the limitation in future years. As a result, if, and to the extent that we earn net taxable income, our ability to use our pre- change NOLs to offset such taxable income may be subject to limitations. Our insurance policies may be inadequate and potentially expose us to unrecoverable risks. Although we intend to maintain product liability insurance coverage, such insurance may not be adequate to cover all liabilities that we may incur. We anticipate that we will need to increase our insurance coverage each time we commence a clinical trial and if we successfully commercialize any vaccine candidate. Insurance availability, coverage terms and pricing continue to vary with market conditions. We endeavor to obtain appropriate insurance coverage for insurable risks that we identify; however, we may fail to correctly anticipate or quantify insurable risks, we may not be able to obtain appropriate insurance coverage and insurers may not respond as we intend to cover insurable events that may occur. Conditions in the insurance markets relating to nearly all areas of traditional corporate insurance change rapidly and may result in higher premium costs, higher policy deductibles and lower coverage limits. For some risks, we may not have or maintain insurance coverage because of cost or availability. Risks Related to Our Reliance on Third Parties We rely and will continue to rely on third parties to conduct our preclinical studies and clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval of or commercialize our vaccine candidates. We currently do not have the ability to independently conduct preclinical or clinical studies that comply with the regulatory requirements known as good laboratory practices and GCP. The FDA and

regulatory authorities in other jurisdictions require us to comply with GCP requirements for conducting, monitoring, recording and reporting the results of clinical trials, in order to ensure that the data and results are scientifically credible and accurate and that the trial subjects are adequately informed of the potential risks of participating in clinical trials. We rely on independent investigators and collaborators, such as universities, medical institutions, CROs and strategic partners, to conduct our preclinical and clinical trials under agreements with us. We will need to negotiate budgets and contracts with CROs and study sites, which may result in delays to our development timelines and increased costs. We will rely heavily on these third parties over the course of our clinical trials, and we control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our studies is conducted in accordance with applicable protocol and legal, regulatory and scientific standards, and our reliance on third parties does not relieve us of our regulatory responsibilities. We and these third parties are required to comply with GCPs, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for vaccine candidates in clinical development. Regulatory authorities enforce these GCPs through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of these third parties fail to comply with applicable GCP regulations, the clinical data generated in our clinical trials may be deemed unreliable, and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. There can be no assurance that, upon inspection, such regulatory authorities will determine that any of our clinical trials comply with the GCP regulations. In addition, our clinical trials must be conducted with biologic product produced under cGMPs and will require a large number of test subjects. Our failure or any failure by these third parties to comply with these regulations or to recruit a sufficient number of subjects may require us to repeat clinical trials, which would delay the regulatory approval process. Moreover, our business may be implicated if any of these third parties violates federal or state fraud and abuse or false claims laws and regulations or healthcare privacy and security laws. Any third parties conducting our preclinical studies and clinical trials will not be our employees and, except for remedies available to us under our agreements with such third parties, we cannot control whether or not they devote sufficient time and resources to our programs. These third parties may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials or other drug development activities, which could affect their performance on our behalf. If these third parties do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to complete development of, obtain regulatory approval of or successfully commercialize our vaccine candidates. As a result, our financial results and the commercial prospects for our vaccine candidates would be harmed, our costs could increase and our ability to generate revenue could be delayed. If any of our relationships with trial sites or any CRO that we may use in the future terminate, we may not be able to enter into arrangements with alternative trial sites or CROs or do so on commercially reasonable terms. Switching or adding third parties to conduct our clinical trials involves substantial cost and requires extensive management time and focus. In addition, there is a natural transition period when a new third party commences work. As a result, delays occur, which can materially impact our ability to meet our desired clinical development timelines. We rely on third parties, including Sutro Biopharma and Lonza, to supply raw materials and manufacture our preclinical and clinical product supplies of our vaccine candidates, and expect to rely on third parties to supply raw materials and produce and process our vaccine candidates, if approved. The loss of these suppliers or their failure to comply with applicable regulatory requirements or provide us with sufficient quantities at acceptable quality levels or prices, or at all, would materially and adversely affect our business. We do not have the infrastructure or capability internally to manufacture supplies for our vaccine candidates or the materials necessary to produce our vaccine candidates for use in the conduct of our preclinical studies or clinical trials, and we lack the internal resources and the capability to manufacture any of our vaccine candidates on a preclinical, clinical or commercial scale. We have entered into an agreement with Sutro Biopharma to supply us with extract and custom reagents for use in manufacturing non- clinical and certain clinical supply of vaccine compositions. Pursuant to the Manufacturing Rights Agreement, we obtained exclusive rights to independently, or through certain third parties, develop, improve and manufacture cell- free extract for use in connection with our vaccine candidates. We have engaged Lonza to perform manufacturing process development and clinical manufacture and supply of components for VAX- **31 and VAX-** 24, including the manufacture of polysaccharide antigens, our proprietary eCRM protein carrier and conjugated drug substances. ~~We also engaged Lonza to perform manufacturing process development and clinical manufacture and supply of VAX- 24 finished drug product.~~ In addition, Lonza is currently in the process of manufacturing **certain components of** our vaccine candidates on a clinical scale. In October 2023, **we** ~~Vaxcyte GmbH~~ and Lonza entered into the Commercial Manufacturing and Supply Agreement pursuant to which Lonza will (i) construct and build out a Suite at Lonza' s facilities in Visp, Switzerland to manufacture the Products, and (ii) maintain and operate the Suite (utilizing Lonza' s employees) to manufacture the Products as a service provided to **us** ~~Vaxcyte GmbH~~ . Pursuant to the Commercial Manufacturing and Supply Agreement, Lonza will be a preferred, non- exclusive, supplier of the Products to **us** ~~Vaxcyte GmbH~~ , and **we** ~~Vaxcyte GmbH retains~~ **retain** the right to procure the Products from one or more alternate and / or backup manufacturers of the Products (including at our own facilities). Our agreements with Lonza are denominated in Swiss Francs **(" CHF ")** . Fluctuations in the exchange rate for **CHF** ~~Swiss Francs~~ may increase our costs and affect our operating results. We have not yet caused our vaccine candidates to be manufactured on a commercial scale and may not be able to achieve commercial scale manufacturing and may be unable to create an inventory of mass- produced product to satisfy demands for any of our vaccine candidates. We do not yet have sufficient information to reliably estimate the cost of the commercial manufacturing and processing of our vaccine candidates, and the actual cost to manufacture and process our vaccine candidates could materially and adversely affect the commercial viability of our vaccine candidates. As a result, we may never be able to develop a commercially viable product. In addition, our anticipated reliance on a limited number of third- party suppliers and manufacturers exposes us to the following risks, among

others: • We may be unable to identify manufacturers on acceptable terms or at all because the number of potential manufacturers is limited and the FDA may have questions regarding any replacement contractor. This may require new testing and regulatory interactions. In addition, a new manufacturer would have to be educated in, or develop substantially equivalent processes for, production of our products after receipt of FDA questions, if any; • Our third- party suppliers and manufacturers might be unable to timely formulate and manufacture or supply raw materials for our vaccine candidates or produce the quantity and quality required to meet our clinical and commercial needs, if any. For example, if Sutro Biopharma, the independent alternate CMO or the designated third parties under the Manufacturing Rights Agreement are unable to provide a sufficient supply of cell- free extract, our third- party manufacturers may be delayed in their production of intermediate components, which may lead to delays of our drug substance manufacturing campaigns. Additionally, if Lonza is unable to identify a timely or manageable solution for handling cell- free extract during our clinical studies, such studies may be delayed, and we will incur additional costs; • Contract manufacturers may not be able to execute our manufacturing procedures appropriately; • Our future contract manufacturers may not perform as agreed or may not remain in the contract manufacturing business for the time required to supply our clinical trials or to successfully produce, store and distribute our products; • Manufacturers are subject to ongoing periodic unannounced inspection by the FDA, the Drug Enforcement Administration and corresponding state agencies to ensure strict compliance with cGMP and other government regulations and corresponding foreign standards. We do not have control over third- party manufacturers' compliance with these regulations and standards; • We may not own, or may have to share, the intellectual property rights to any improvements made by our third- party manufacturers in the manufacturing process for our products; and • Our third- party suppliers and manufacturers could breach or terminate their agreement with us. Each of these risks could delay our clinical trials, the approval, if any, of our vaccine candidates by the FDA or the commercialization of our vaccine candidates, or result in higher costs or deprive us of potential product revenue. In addition, we will rely on third parties to perform release tests on our vaccine candidates prior to delivery to patients. If these tests are not appropriately done and test data are not reliable, patients could be put at risk of serious harm. If we or our third- party suppliers use hazardous, non-hazardous, biological or other materials in a manner that causes injury or violates applicable law, we may be liable for damages. Our research and development activities involve the controlled use of potentially hazardous substances, including chemical and biological materials. We and our suppliers are subject to federal, state and local laws and regulations in the United States governing the use, manufacture, storage, handling and disposal of medical and hazardous materials. Although we believe that we and our suppliers' procedures for using, handling, storing and disposing of these materials comply with legally prescribed standards, we and our suppliers cannot completely eliminate the risk of contamination or injury resulting from medical or hazardous materials. As a result of any such contamination or injury, we may incur liability or local, city, state or federal authorities may curtail the use of these materials and interrupt our business operations. In the event of an accident, we could be held liable for damages or penalized with fines, and the liability could exceed our resources. We do not have any insurance for liabilities arising from medical or hazardous materials. Compliance with applicable environmental laws and regulations is expensive, and current or future environmental regulations may impair our research, development and production efforts, which could harm our business prospects, financial condition or results of operations. Risks Related to Government Regulation The FDA regulatory approval process is lengthy and time- consuming, and we may experience significant delays in the clinical development and regulatory approval of our vaccine candidates. The research, testing, manufacturing, labeling, approval, selling, import, export, marketing and distribution of drug products, including biologics such as conjugate vaccines, are subject to extensive regulation by the FDA and other regulatory authorities in the United States. We expect that our vaccine candidates will be regulated by the FDA as biologics. We are not permitted to market any biological drug product in the United States until we receive approval of a BLA from the FDA. We have not previously submitted a BLA to the FDA, or similar ~~approval filings~~ **requests for marketing authorization** to comparable foreign regulatory authorities. A BLA must include extensive preclinical and clinical data and supporting information to establish the vaccine candidate' s safety **, purity,** and ~~effectiveness~~ **potency** for each desired indication ~~. Further, because our vaccine candidates that are subject to regulation as biological drug products, we will need to demonstrate that they are safe, pure and potent for use in their target indications~~ . The BLA must also include significant information regarding the CMC for the product, including with respect to chain of identity and chain of custody of the product and various comparability assessments. The FDA' s review of our BLA may be significantly delayed if the FDA views that the CMC information included in our submission is not adequate or requests additional CMC information or data. Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process. The results of preclinical studies of our vaccine candidates may not be predictive of the results of early- stage or later- stage clinical trials, and results of early clinical trials of our vaccine candidates may not be predictive of the results of later- stage clinical trials. The results of clinical trials in one set of patients or indications may not be predictive of those obtained in another. In some instances, there can be significant variability in safety **and immunogenicity** or efficacy results between different clinical trials of the same vaccine candidate due to numerous factors, including changes in trial procedures set forth in protocols, differences in the size and type of the patient populations, changes in and adherence to the dosing regimen and other clinical trial protocols and the rate of dropout among clinical trial participants. Vaccine candidates in later stages of clinical trials may fail to show the desired safety and **immunogenicity or** efficacy profile despite having progressed through preclinical studies and initial clinical trials. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of **immunogenicity or** efficacy or unacceptable safety issues, notwithstanding promising results in earlier trials. Most vaccine candidates that begin clinical trials are never approved by regulatory authorities for commercialization. In addition, even if such clinical trials are successfully completed, we cannot guarantee that the FDA or foreign regulatory authorities will interpret the results as we do, and more trials could be required before we submit a BLA or other marketing application. We may also experience delays in completing planned clinical trials for a variety of reasons, including delays related to: • obtaining regulatory authorization to begin a trial, if applicable; • the

availability of financial resources to commence and complete the planned trials; • reaching agreement on acceptable terms with prospective CROs and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites; • obtaining approval at each clinical trial site by an independent IRB; • recruiting suitable volunteers to participate in and complete a trial; • clinical trial sites deviating from trial protocol or dropping out of a trial; • addressing any safety concerns that arise during the course of a trial; • adding new clinical trial sites; or • manufacturing sufficient quantities of qualified materials under cGMPs and applying them for use in clinical trials. We could also ~~encounter~~ **experience** delays if physicians encounter unresolved ethical issues associated with enrolling patients in clinical trials of our vaccine candidates in lieu of using existing vaccines that have established safety and **immunogenicity or** efficacy profiles. Further, a clinical trial may be suspended or terminated by us, the IRBs for the institutions in which such trials are being conducted or by the FDA or other regulatory authorities due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a vaccine candidate, changes in governmental regulations or administrative actions, lack of adequate funding to continue the clinical trial or based on a recommendation by the **DSMB** ~~data safety monitoring board~~ . If we experience termination of, or delays in the completion of, any clinical trial of our vaccine candidates, the commercial prospects for our vaccine candidates will be harmed, and our ability to generate product revenue will be delayed. In addition, any delays in completing our clinical trials will increase our costs, slow down our product development and approval process and jeopardize our ability to commence product sales and generate revenue **. The development of our product candidates also may be delayed by other events beyond our control. For example, U. S. government actions to limit federal agency budgets or personnel, may result in reductions to the FDA' s budget, employees, and operations, which may lead to slower response times and longer review periods, potentially affecting our ability to progress development of our product candidates or obtain regulatory approval for our product candidates** . Many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may ultimately lead to the denial of regulatory approval of our vaccine candidates. The FDA may disagree with our regulatory plan, and we may fail to obtain regulatory approval of our vaccine candidates. The general approach for FDA approval of a new biologic or drug is for the sponsor to provide dispositive data from two Phase 3 clinical trials of the relevant biologic or drug in the relevant patient population. Phase 3 clinical trials typically involve ~~hundreds~~ **thousands** of patients, have significant costs and are time consuming. While we are still in the process of having discussions with the FDA regarding our Phase 3 regulatory plans, including discussions regarding our CMC strategy, the FDA may ultimately disagree with our regulatory strategy or we may be unable to successfully complete development to the FDA' s satisfaction. We believe our previously reported topline results for VAX- ~~24~~ **31** support clinical non-inferiority to PCV20, but there can be no assurance that this approach in pivotal studies will be sufficient for regulatory approval ~~or that certain regulators will not require field efficacy trials~~ . We may seek Accelerated Approval from the FDA for our vaccine candidates and, if granted, the FDA may require us to perform post- marketing studies as a condition of approval to verify and describe the predicted effect on irreversible morbidity or mortality or other clinical endpoints. If the results from such post-marketing studies are not positive or otherwise fail to show the predicted effect, ~~the drug or~~ **our** ~~biologic~~ **vaccine candidate** may be subject to expedited withdrawal procedures by the FDA. In addition, the standard ~~–~~of ~~–~~care may change with the approval of new products in the same disease areas that we are studying. This may result in the FDA or other regulatory agencies requesting additional studies to show that our vaccine candidate is non- inferior or superior to the new products. Our clinical trial results may also not support approval. In addition, our vaccine candidates could fail to receive regulatory approval for many reasons, including the following: • the FDA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials; • we may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that our vaccine candidates are safe and effective; • the results of clinical trials may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval; • we may be unable to demonstrate that our vaccine candidates' clinical and other benefits outweigh their safety risks; • any vaccine to be approved in pediatric populations may need to undergo extensive vaccine- vaccine interference studies with the standard- of- care pediatric vaccine regimen; • the need to perform superiority or field efficacy trials, which can be larger, longer and more costly, if an existing vaccine is approved for a disease indication; • the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials; • the data collected from clinical trials of our vaccine candidates may not be sufficient to the satisfaction of the FDA or comparable foreign regulatory authorities to support the submission of a BLA or other comparable submission in foreign jurisdictions or to obtain regulatory approval in the United States or elsewhere; • the FDA or comparable foreign regulatory authorities will inspect the commercial manufacturing facilities we may utilize and may not approve such facilities; and • the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval. Even if we receive regulatory approval of our vaccine candidates, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense, and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our vaccine candidates. Any regulatory approvals that we receive for our vaccine candidates may also be subject to limitations on the approved indicated uses for which a product may be marketed or to the conditions of approval, or contain requirements for potentially costly post- marketing testing, including post- marketing clinical trials, and surveillance to monitor the safety and efficacy of the vaccine candidate. In addition, if the FDA or a comparable foreign regulatory authority approves our vaccine candidates, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, conduct of post- marketing studies, storage, sampling, advertising, promotion, import, export and recordkeeping for our vaccine candidates will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post- marketing information and reports, registration and continued

compliance with cGMPs and GCPs for any clinical trials that we conduct post- approval. As such, we and our contract manufacturers will be subject to continual review and inspections to assess compliance with cGMP and adherence to commitments made in any BLA, other marketing application and previous responses to inspectional observations. Accordingly, we and others with whom we work must continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production and quality control. In addition, the FDA could require us to conduct another study to obtain additional safety or biomarker information. Further, we will be required to comply with FDA promotion and advertising rules, which include, among others, standards for direct- to- consumer advertising, restrictions on promoting products for uses or in patient populations that are not described in the product' s approved uses (known as " off- label use "), limitations on industry- sponsored scientific and educational activities and requirements for promotional activities involving the internet and social media. Later discovery of previously unknown problems with our vaccine candidates, including side effects of unanticipated severity or frequency, or with our third- party suppliers or manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical trials to assess new safety risks; or imposition of distribution or other restrictions. Other potential consequences include, among other things: • restrictions on the marketing or manufacturing of our vaccine candidates, withdrawal of the product from the market or voluntary or mandatory product recalls; • fines, warning letters or holds on clinical trials; • refusal by the FDA to approve pending applications or supplements to approved applications filed by us or suspension or revocation of regulatory approvals; • **exclusion from participating in government- funded healthcare programs, such as Medicare and Medicaid; •** product seizure or detention, or refusal to permit the import or export of our vaccine candidates; and • injunctions or the imposition of civil or criminal penalties. The FDA' s and other regulatory authorities' policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our vaccine candidates **. For example, on June 28, 2024, the U. S. Supreme Court, in Loper Bright Enterprises v. Raimondo, overturned long- standing precedent regarding the deference courts owe to agencies' interpretation of ambiguous statutes in their rulemaking. While the impact of the Loper Bright decision on our business and regulatory strategy is unknown, the decision generally may, among other things, increase the frequency of challenges to decisions and rulemaking of health regulators, including FDA determinations of drug approval and market exclusivity and the CMS rules regarding reimbursement, and also impact the speed at which such health regulators make decisions and issue regulations** . We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained, and we may not achieve or sustain profitability. Any government investigation of alleged violations of law could require us to expend significant time and resources in response, and could generate negative publicity. Any failure to comply with ongoing regulatory requirements may significantly and adversely affect our ability to commercialize and generate revenue from our products. If regulatory sanctions are applied or if regulatory approval is withdrawn, the value of our company and our operating results will be adversely affected. We expect the vaccine candidates we develop will be regulated as biological products, or biologics, and therefore they may be subject to competition sooner than anticipated. The Biologics Price Competition and Innovation Act of 2009 (the " BPCIA ") established an abbreviated pathway for the approval of biosimilar and interchangeable biological products. The regulatory pathway establishes legal authority for the FDA to review and approve biosimilar biologics, including the possible designation of a biosimilar as " interchangeable " based on its similarity to an approved biologic. Under the BPCIA, an application for a biosimilar product cannot be approved by the FDA until ~~twelve~~ **12** years after the reference product was approved under a BLA **and the FDA will not accept an application for a biosimilar or interchangeable product based on the reference biological product until four years after the date of first licensure of the reference product, and will not approve a biosimilar until 12 years after the date of first licensure** . **These periods of exclusivity can be extended by six months by obtaining pediatric exclusivity. In addition, if the reference product is protected by patents, the biosimilar manufacturer and reference product manufacturer must engage in a complex process called the " patent dance. "** The ~~law~~ **FDA has not yet approved a biosimilar vaccine. In addition, there** is ~~complex and is still being interpreted and implemented by the FDA. As~~ a **risk that** ~~result, its ultimate impact, implementation and meaning are subject to uncertainty. While it is uncertain when such processes intended to implement the BPCIA may be fully adopted by the FDA,~~ any **exclusivity period we receive** ~~such processes could have a material adverse effect on the future commercial prospects~~ for ~~our biological products. We believe that~~ any of the vaccine candidates we develop that is approved in the United States as a biological product under a BLA ~~should qualify for the 12- year period of exclusivity. However, there is a risk that this exclusivity~~ could be shortened due to congressional action or otherwise, or that the FDA will not consider the subject vaccine candidates to be reference products for competing products, potentially creating the opportunity for ~~generic~~ **biosimilar** competition sooner than anticipated. ~~Moreover~~ **The FDA has been approving biosimilar products as interchangeable without requiring switching studies** , ~~the extent to~~ which ~~a~~ **has allowed** ~~biosimilar~~ **biosimilars to** ~~, once approved, will~~ be **automatically** substituted for ~~any one of~~ the reference ~~products~~ **product upon approval** ~~in a way that is similar to traditional generic substitution for non- biological products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing~~ . Our relationships with customers, physicians and third- party payors are subject, directly or indirectly, to federal and state healthcare fraud and abuse laws, health information privacy and security laws and other healthcare laws and regulations. If we or our employees, independent contractors, consultants, commercial partners and vendors violate these laws, we could face substantial penalties. Healthcare providers, including physicians and third- party payors, in the United States and elsewhere will play a primary role in the recommendation and prescription of any vaccine candidates for which we obtain marketing approval. Our current and future arrangements with healthcare professionals, principal investigators, consultants, customers and third- party payors subject us to various federal and

state fraud and abuse laws and other healthcare laws. These laws may constrain the business or financial arrangements and relationships through which we conduct our operations, including how we research, market, sell and distribute our vaccine candidates, if approved. Such laws include: • the U. S. federal Anti- Kickback Statute, which prohibits, among other things, persons or entities from knowingly and willfully soliciting, offering, receiving or providing any remuneration (including any kickback, bribe or certain rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, lease, order or recommendation of, any good, facility, item or service, for which payment may be made, in whole or in part, under any U. S. federal healthcare program, such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation; • the U. S. federal civil and criminal false claims laws, including the civil False Claims Act, which can be enforced through civil whistleblower or qui tam actions, and civil monetary penalties laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, to the U. S. federal government, claims for payment or approval that are false or fraudulent, knowingly making, using or causing to be made or used, a false record or statement material to a false or fraudulent claim, or from knowingly making a false statement to avoid, decrease or conceal an obligation to pay money to the U. S. federal government. Pharmaceutical manufacturers can cause false claims to be presented to the U. S. federal government by engaging in impermissible marketing practices, such as the off- label promotion of a product for an indication for which it has not received FDA approval. In addition, the government may assert that a claim **,** including items and services resulting from a violation of the U. S. federal Anti- Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act; • the Health Insurance Portability and Accountability Act of 1996 (" HIPAA ") which ~~prohibits~~ , among other things, **imposes criminal liability for** knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program **, regardless of the payor (e. g., public or private)** , or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement, in connection with the delivery of, or payment for, healthcare benefits, items or services. Similar to the U. S. federal Anti- Kickback Statute, a person or entity does not need to have actual knowledge of the healthcare fraud statute implemented under HIPAA or specific intent to violate it in order to have committed a violation; • HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act (the " HITECH ") and its implementing regulations, which also impose certain obligations, including mandatory contractual terms, with respect to safeguarding the privacy and security of individually identifiable health information of covered entities subject to the rule, including health plans, healthcare clearinghouses and certain healthcare providers **,** and their business associates ~~, independent contractors of a covered entity~~ that perform certain services involving the use or disclosure of individually identifiable health information for or on their behalf, as well as their covered subcontractors **. HITECH also created tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions** ; • the Federal Food Drug or Cosmetic Act, which prohibits, among other things, the adulteration or misbranding of drugs, biologics and medical devices; • the U. S. Physician Payments Sunshine Act and its implementing regulations, which require certain manufacturers of drugs, devices, biologics and medical supplies that are reimbursable under Medicare, Medicaid or the Children' s Health Insurance Program, with specific exceptions, to report annually to the ~~Centers for Medicare & Medicaid Services (" CMS ")~~ information related to certain payments and other transfers of value to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), other healthcare professionals (such as physician assistants and nurse practitioners), and teaching hospitals, as well as information regarding ownership and investment interests held by the physicians described above and their immediate family members; • analogous U. S. state laws and regulations, including: state anti- kickback and false claims laws, which may apply to our business practices, including but not limited to, research, distribution, sales and marketing arrangements and claims involving healthcare items or services reimbursed by any third- party payor, including private insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry' s voluntary compliance guidelines and the relevant compliance guidance promulgated by the U. S. federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws and regulations that require drug manufacturers to file reports relating to pricing and marketing information, which require tracking gifts and other remuneration and items of value provided to healthcare professionals and entities; state and local laws requiring the registration of pharmaceutical sales representatives; and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts; • similar healthcare laws and regulations in the EU and other jurisdictions, including reporting requirements detailing interactions with and payments to healthcare providers; and • laws governing the privacy and security of certain protected information, such as the EU GDPR, and the CCPA, which impose obligations and restrictions on the collection, use and disclosure of personal data (including health data) relating to individuals located in the European Economic Area (" EEA ") and California, respectively. We may also be subject to other laws, such as the U. S. Foreign Corrupt Practices Act of 1977, as amended, which prohibit, among other things, U. S. companies and their employees and agents from authorizing, promising, offering or providing, directly or indirectly, corrupt or improper payments or anything else of value to foreign government officials, employees of public international organizations and foreign government owned or affiliated entities, candidates for foreign political office and foreign political parties or officials thereof, as well as federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers. Ensuring that our internal operations and business arrangements with third parties comply with applicable healthcare laws and regulations will likely be costly. It is possible that governmental authorities will conclude that our business practices, including our relationships with physicians and other healthcare providers, some of whom are compensated in the form of stock options for consulting services provided, may not comply with current or future statutes,

regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, injunctions, damages, fines, disgorgement, imprisonment, exclusion from participating in government- funded healthcare programs, such as Medicare and Medicaid, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of noncompliance with these laws, contractual damages, reputational harm and the curtailment or restructuring of our operations. Even if resolved in our favor, litigation or other legal proceedings relating to healthcare laws and regulations may cause us to incur significant expenses and could distract our technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. 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, manufacturing, sales, marketing or distribution activities. Uncertainties resulting from the initiation and continuation of litigation or other proceedings relating to applicable healthcare laws and regulations could have an adverse effect on our ability to compete in the marketplace. In addition, if the physicians or other providers or entities with whom we expect to do business are found not to be in compliance with applicable laws, they may be subject to significant criminal, civil or administrative sanctions, including exclusions from government- funded healthcare programs. Coverage and reimbursement may be limited or unavailable in certain market segments for our vaccine candidates, which could make it difficult for us to sell our vaccine candidates, if approved, profitably. Successful sales of our vaccine candidates, if approved, depend on the availability of coverage and adequate reimbursement from third- party payors , including governmental healthcare programs, such as Medicare and Medicaid, managed care organizations and commercial payors, among others. Significant uncertainty exists as to the coverage and reimbursement status of any vaccine candidates for which we obtain regulatory approval. Patients who receive vaccines generally rely on third- party payors to reimburse all or part of the associated costs. Obtaining coverage and adequate reimbursement from third- party payors is critical to new product acceptance. Third- party payors decide which drugs and treatments they will cover and the amount of reimbursement. Reimbursement by a third- party payor may depend upon a number of factors, including, but not limited to, the third- party payor' s determination that use of a product is: • a covered benefit under its health plan; • safe, effective and medically necessary; • appropriate for the specific patient; • cost-effective; and • neither experimental nor investigational. Obtaining coverage and reimbursement of a product from a government or other third- party payor is a time- consuming and costly process that could require us to provide to the payor supporting scientific, clinical and cost- effectiveness data for the use of our products. Even if we obtain coverage for a given product, if the resulting reimbursement rates are insufficient, hospitals may not approve our product for use in their facility or third- party payors may require co- payments that patients find unacceptably high. Patients are unlikely to use our vaccine candidates unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of our vaccine candidates. Separate reimbursement for the product itself may or may not be available. Instead, the hospital or administering physician may be reimbursed only for administering the product. Further, from time to time, CMS revises the reimbursement systems used to reimburse health care providers, including the Medicare Physician Fee Schedule and Outpatient Prospective Payment System, which may result in reduced Medicare payments. In some cases, private third- party payors rely on all or portions of Medicare payment systems to determine payment rates. Changes to government healthcare programs that reduce payments under these programs may negatively impact payments from third- party payors and reduce the willingness of physicians to use our vaccine candidates ~~. Certain ACA marketplace and other private payor plans are required to include coverage for certain preventative services, including vaccinations recommended by the ACIP without cost share obligations (i. e., co- payments, deductibles or co- insurance) for plan members. Children through 18 years of age without other health insurance coverage may be eligible to receive such vaccinations free- of- charge through the CDC' s Vaccines for Children Program (" VFC "). For Medicare beneficiaries, vaccines may be covered under either the Part B program or Part D depending on several criteria, including the type of vaccine and the beneficiary' s coverage eligibility. If our vaccine candidates, once approved, are covered only under the Part D program, physicians may be less willing to use our products because of the claims adjudication costs and time related to the claims adjudication process and collection of co- payments associated with the Part D program~~ . In the United States, no uniform policy of coverage and reimbursement for products exists among third- party payors. Therefore, coverage and reimbursement for products can differ significantly from payor to payor. Further, one payor' s determination to provide coverage for a product does not assure that other payors will also provide coverage for the product. Adequate third- party reimbursement may not be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment in product development. Further, coverage policies and third- party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future. We intend to seek approval to market our vaccine candidates in both the United States and in selected foreign jurisdictions. If we obtain approval in one or more foreign jurisdictions for our vaccine candidates, we will be subject to rules and regulations in those jurisdictions. In some foreign countries, particularly those in Europe, the pricing of biologics is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after obtaining marketing approval of a vaccine candidate. Some of these countries may require the completion of clinical trials that compare the cost- effectiveness of a particular vaccine candidate to currently available vaccines. Other member states allow companies to fix their own prices for medicines but monitor and control company profits. The downward pressure on health care costs has become very intense. As a result, increasingly high barriers are being erected to the entry of new products. In addition, in some countries, cross- border imports from low- priced markets exert a commercial pressure on pricing within a country. The marketability of any vaccine candidates for which we receive regulatory approval for commercial sale may suffer if government and other third- party payors

fail to provide coverage and adequate reimbursement. We expect downward pressure on pharmaceutical pricing to continue. Further, coverage policies and third- party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future. Healthcare legislative reform measures may have a negative impact on our business, financial condition, results of operations and prospects. In the United States and some foreign jurisdictions, there have been, and we expect there will continue to be, several legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of vaccine candidates, restrict or regulate post- approval activities and affect our ability to profitably sell any vaccine candidates for which we obtain marketing approval. In particular, there have been and continue to be a number of initiatives at the U. S. federal and state levels that seek to reduce healthcare costs and improve the quality of healthcare. For example, in March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010 (collectively, the " ACA "), was passed, which substantially changed the way healthcare is financed by both **the** ~~governmental~~ -- **government** and private ~~payors~~ **in insurers and significantly impacts** the ~~United States~~ **U. S. pharmaceutical industry** . The ACA, among other things: (i) increased the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program and extended the rebate program to individuals enrolled in Medicaid managed care organizations; (ii) created a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for certain drugs and biologics that are inhaled, infused, instilled, implanted or injected; (iii) established an annual, nondeductible fee on any entity that manufactures or imports certain specified branded prescription drugs and biologic agents apportioned among these entities according to their market share in specific government healthcare programs; (iv) expanded the eligibility criteria for Medicaid programs; (v) created a new Patient- Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research; (vi) created a ~~new~~ Medicare Part D coverage gap discount program ~~, in which manufacturers must now agree to offer 70 % point- of- sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer' s outpatient drugs to be covered under Medicare Part D~~ ; (vii) and established a Center for Medicare & Medicaid Innovation ~~at the Centers for Medicare & Medicaid Services~~ (" ~~CMS~~ **CMMI** ") **at the CMS** to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drugs. There have been executive, judicial and Congressional ~~challenges~~ **efforts** to **repeal, substantially modify or invalidate some or all of the provisions of** the ACA **, some of which have been successful** . For example, the Tax Act included a provision that repealed, effective January 1, 2019, the tax- based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year, which is commonly referred to as the " individual mandate. " On June 17, 2021, the United States Supreme Court dismissed a challenge on procedural grounds that argued the ACA is unconstitutional in its entirety because the " individual mandate " was repealed by Congress. ~~Moreover~~ **More recently** , ~~prior~~ **a challenge** to **the ACA is advancing in federal courts. Other legislative changes also have been proposed and adopted in** the United States **since** ~~Supreme Court ruling, on January 28, 2021, President Biden issued an executive order that initiated a special enrollment period for purposes of obtaining health insurance coverage through~~ the ACA ~~marketplace~~ **was enacted** . ~~The~~ **These have** ~~executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare~~ , ~~including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA. On August 16, 2022, President Biden signed the IRA, into law, which~~ among other things, ~~extends enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025. The IRA also eliminates the " donut hole " under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out- of- pocket cost and creating a new manufacturer discount program. It is possible that the ACA will be subject to judicial or Congressional challenges in the future. It is unclear how additional healthcare reform measures of the Biden administration will impact the ACA. Other legislative changes have been proposed and adopted in the United States since the ACA was enacted. These changes include aggregate reductions to Medicare payments to providers of 2 % per fiscal year pursuant to the Budget Control Act of 2011, which began in 2013 and, due to subsequent legislative amendments to the statute, including the Bipartisan Budget Act of 2015 and the Consolidated Appropriations Act of 2023, will remain in effect until 2032 unless additional Congressional action is taken. The American Taxpayer Relief Act of 2012, among other things, further~~ reduced Medicare payments to several types of providers, including hospitals **, imaging centers** and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers ~~from three to five years~~ . **Another notable** ~~Additional changes that may affect our business include the expansion of new programs such as~~ Medicare **healthcare reform** ~~payment for performance initiatives~~ - **initiative,** ~~for physicians~~ under the Medicare Access and CHIP Reauthorization Act of 2015 (" MACRA "), ~~which ended the use of the statutory formula for clinician payment and~~ established a quality payment incentive program ~~, also referred to as the Quality Payment Program. This program provides clinicians with two ways to participate, including~~ through **which reimbursement is adjusted up or down** ~~the Advanced Alternative Payment Models (" APM ") and the Merit-~~ based **on various** ~~Incentive Payment System (" MIPS "). Under both APMs and MIPS,~~ performance data collected each performance year ~~will affect Medicare payments in later years, including potentially reducing payments. At this time, the full impact of the introduction of the Medicare quality payment program on overall physician reimbursement remains unclear~~ . Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. Further, in the United States **,** there has been heightened governmental scrutiny over the manner in which 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 drug and biological product pricing, reduce the cost of prescription drugs and biological products under government payor programs and review the

relationship between pricing and manufacturer patient programs. ~~At the federal level, the Trump administration used several means to propose or~~ **For example** ~~implement drug pricing reform, including through federal budget proposals, executive orders and policy initiatives. In July 2021, the Biden administration released an executive order, " Promoting Competition in the American Economy, " with multiple provisions aimed at prescription drugs. In response to Biden' s executive order, on September 9, 2021, the Department of Health and Human Services (" HHS ") released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug pricing reform and sets out a variety of potential legislative policies that Congress could pursue as well as potential administrative actions HHS can take to advance these principles. Further~~ , the IRA ~~will~~ , among other things, (i) ~~directs~~ **enables the** HHS to ~~negotiate~~ **assert control over** the ~~price~~ **prices** of certain ~~high- expenditure,~~ single- source drugs and biologics covered under Medicare, ~~and~~ **(ii)** ~~subject~~ **subjects** drug manufacturers to civil monetary penalties and a potential excise tax ~~by~~ **for** offering a price that is not equal to or less than the negotiated " maximum fair price " under the law, ~~and~~ (~~ii~~ **iii**) imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation **, and (iv) redesigns the funding and benefit structure of the Medicare Part D program, potentially increasing manufacturer liability while capping annual out- of- pocket drug expenses for Medicare beneficiaries. The IRA also eliminates patient cost sharing for FDA- approved adult vaccines that are recommended by the ACIP and covered under Medicare Part D, and mandates that all state Medicaid programs cover FDA- approved adult vaccines that are recommended by the ACIP and their administration without cost sharing. In addition, in January 2025, the HHS announced the list of 15 drugs that will be subject to the second round of price negotiations. The IRA is currently subject to legal challenges and it is unclear how the IRA will be effectuated or changed under the current U. S. administration** . However, the IRA does not change either the **CDC' s Vaccines for Children program ("** VFC **")** or the provisions added in 2010 under the ACA. **The** VFC was established to give first- dollar coverage to children up to 18 years of age whose families could not pay for vaccinations while the ACA guaranteed coverage of vaccines without cost sharing for Americans who are either privately insured or newly covered in states that expanded Medicaid. ~~The IRA did help with vaccine access by eliminating cost sharing for adult vaccines covered under Medicare Part D and mandating that all state Medicaid programs cover certain adult vaccines and their administration without cost sharing.~~ Further, many vaccines are excluded from Medicare Part B rebate requirements. **Additional action** ~~The IRA permits HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years. These provisions take effect progressively starting in fiscal year 2023. On August 29, 2023, HHS announced the list of the first ten drugs that will be subject to price negotiations, although the Medicare drug negotiation program is currently subject to legal challenges. HHS~~ has **been taken** ~~and will continue~~ to **limit or change healthcare policies pursued by** ~~issue and update guidance as these programs are implemented. It is currently unclear how the IRA will be effectuated but is likely to have a significant impact on the pharmaceutical industry. Further, in response to~~ the Biden administration ~~' s October 2022~~ **. For example, an** executive order **issued by former President Biden was recently rescinded** , **pursuant to which the CMMI created** ~~on February 14, 2023, HHS released a report outlining~~ three ~~new models for testing by the CMS Innovation Center which will be evaluated on their ability to lower the cost of drugs~~ - **drug pricing experiments** , ~~promote accessibility,~~ and **it** ~~improve quality of care. It~~ is unclear whether the **CMMI will continue to pursue some or any of these** models **. Likewise, it remains unclear whether the current U. S. administration** will **continue** ~~be utilized in any~~ - **an initiative announced by** ~~health reform measures in the future. Further, on December 7, 2023,~~ the Biden administration ~~announced an initiative~~ to control the price of prescription drugs through the use of march- in rights under the Bayh- Dole Act. ~~On December 8, 2023, the National Institute of Standards and Technology published for comment a Draft Interagency Guidance Framework for Considering the Exercise of March- In Rights which for the first time includes the price of a product as one factor an agency can use when deciding to exercise march- in rights. While march- in rights have not previously been exercised, it is uncertain if that will continue under the new framework.~~ At the state level, legislatures **and regulatory agencies** have increasingly passed legislation and implemented regulations designed to control **drug** ~~pharmaceutical and biological product~~ pricing, including ~~price or patient reimbursement constraints, discounts,~~ restrictions on ~~certain product access and~~ **pricing or reimbursement at the state government level, limitations on discounts to patients, advance notices of price increases,** marketing cost disclosure and transparency measures **,** and, in some cases, ~~designed~~ **policies** to encourage importation from other countries **(subject to federal approval)** and bulk purchasing ~~. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine which drugs, biological products and suppliers will be included in their healthcare programs. Furthermore, there has been increased interest by third- party payors and governmental authorities in reference pricing systems and publication of discounts and list prices~~ . We expect that additional U. S. federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that the U. S. federal government will pay for healthcare products and services, which could result in reduced demand **,** ~~for our current or any future vaccine candidates~~ or additional pricing pressures **on, any of our vaccine candidates approved in the future** . We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action in the United States or any other jurisdiction. If we or any third parties we may ~~engage~~ **rely on** are slow or unable to adapt to changes in existing or new requirements or policies, or if we or such third parties are not able to maintain regulatory compliance, ~~our~~ **any** current or ~~any~~ future vaccine candidates we ~~may~~ develop may lose any regulatory approval that may have been obtained and we may not achieve or sustain profitability. We expect that these and other healthcare reform measures that may be adopted in the future may result in more rigorous coverage criteria and in additional downward pressure on the price that we **may** receive for any **product** approved ~~product~~ **in the future** , which could have an adverse effect on demand for our vaccine candidates. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The ~~implementation~~ **adoption** of cost containment measures or other healthcare reforms **, and our associated compliance obligations,** may prevent us from being able to generate revenue, attain profitability or commercialize ~~our~~ **any** ~~products~~ - **product candidates, if approved** . Changes in funding for the FDA and other government

agencies could hinder ~~our~~ **their** ability to hire and retain key leadership and other personnel, or otherwise prevent new products and services from being developed or commercialized in a timely manner, which could negatively impact our business. The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels **for critical departments, payment of user fees and reauthorization of user fee programs** , ability to hire and retain key personnel ~~and accept~~ **involved in** the ~~payment~~ **review** of ~~user fees and~~ **sponsor applications, as well as** statutory, regulatory and policy changes. ~~Average review times at the FDA have fluctuated in recent years as a result.~~ In addition, ~~government~~ funding of other government agencies that ~~fund~~ **support** research and development activities **relevant to FDA review, such as research to understand new technologies or establish new standards,** is subject to the political process, which is inherently fluid and unpredictable. ~~Disruptions at~~ **If the federal government implements efforts to downsize critical departments involved in the review of sponsor applications; removes job elimination protections for federal workers necessary to these activities; limits certain communications; changes the user fee reauthorization process or fails to reauthorize user fee programs; or cuts teams critical to** the FDA ~~and~~ **' s ability to conduct regular inspections, reviews, or** other ~~agencies may also slow the time necessary for new drugs to be reviewed and / or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, including for 35 days beginning on December 22, 2018, the U. S. government has shut down several times and certain~~ regulatory ~~agencies~~ **activities** , ~~such as~~ the FDA **' s** ~~, have had to furlough critical FDA employees and stop critical activities. If a prolonged government shutdown occurs, it could significantly impact the~~ ability ~~of the FDA~~ to timely review ~~and process~~ our regulatory submissions ~~, which~~ could **be affected. This, in turn, could delay the development and regulatory approval of new products and related services and** have a material adverse effect on our business. ~~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 or other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business.~~ We are **increasingly** subject to ~~increasingly~~ stringent and rapidly changing U. S. and foreign laws, regulations, and rules, contractual obligations, industry standards, policies and other obligations related to privacy and data security. The **obligations and** restrictions ~~and costs~~ imposed by these requirements **can lead to substantial related implementation costs. In addition** , ~~or~~ our actual or perceived failure to comply with ~~them,~~ **applicable laws and other obligations related to privacy and data security** could lead to regulatory investigations or actions; litigation (including class claims) and mass arbitration demands; reputational harm; fines and penalties; loss or revenue or profits; and other adverse business consequences. In the ordinary course of business, we process personal data and other Sensitive Information. We are subject to or affected by numerous evolving federal, state and foreign laws and regulations, as well as policies, contracts and other obligations governing the collection, use, disclosure, retention, and security of personal data. The global data **privacy and** protection landscape is rapidly evolving, and implementation standards and enforcement practices are likely to remain uncertain for the foreseeable future. For example, HIPAA, as amended by HITECH, imposes requirements relating to the privacy and security of individually identifiable health information ~~on~~ **used, stored, or transmitted by** health plans, healthcare clearinghouses and certain healthcare providers, ~~and~~ **as well as** their respective contractors and their covered subcontractors that perform services for them involving individually identifiable health information. Additionally, certain states have adopted healthcare privacy and security laws and regulations **that impose restrictions and obligations** comparable to **those listed under** HIPAA, some of which ~~may~~ **can** be more stringent than HIPAA. In the event we fail to properly maintain the privacy and security of individually identifiable health information governed by HIPAA or comparable state laws, or we are responsible for an unauthorized disclosure or security breach of such information, we could be subject to enforcement action under HIPAA or comparable state laws, and significant civil and criminal penalties, and fines. In the United States, federal, state, and local governments have enacted numerous data privacy and data security laws beyond HIPAA and other healthcare privacy laws, including data breach notification laws, personal data privacy laws, consumer protection laws (e. g., Section 5 of the Federal Trade Commission Act), and other similar laws (e. g., wiretapping laws). For example, the CCPA imposes obligations on **covered** businesses ~~to which it applies~~ , including but not limited to, providing specific disclosures in privacy notices and affording California residents certain rights related to their personal data. In addition, the CPRA expanded the CCPA' s requirements, including by adding ~~a~~ new ~~right~~ **rights** ~~of~~ **allowing** individuals to **opt out of the sharing (as defined under the CCPA) of and** correct their personal data and **limit the use and disclosure of their sensitive personal data, as well as by** establishing a new California Privacy Protection Agency to implement and enforce **, alongside the California Attorney General,** the CCPA **. Other U. S. states have also recently enacted comprehensive data privacy laws — including Virginia, Connecticut, Utah, Colorado, Delaware, Indiana, Iowa, Kentucky, Montana, New Hampshire, New Jersey, Oregon, Tennessee, and Texas — and other local, state, and federal laws are currently under consideration** . Certain states also impose stricter requirements ~~for processing certain personal data, including sensitive information~~ , such as conducting data privacy impact assessments **, for processing certain personal data, including sensitive information** . These state laws allow for statutory fines for noncompliance. For example, the CCPA allows for fines of up to $ 7, 500 per intentional violation and allows for private litigants affected by certain data breaches to recover significant statutory damages. ~~Other U. S. states have recently enacted comprehensive data privacy laws — including Virginia, Connecticut, Utah, and Colorado — and other local, state, and federal laws are currently under consideration.~~ While these states, like the CCPA, also exempt some data processed in the context of clinical trials, these developments further complicate compliance efforts, and increase legal risk and compliance costs for us and the third parties upon which we rely. If we become subject to new data privacy laws, at the state level, the risk of enforcement action against us could increase because we may become subject to additional obligations, and the number of individuals or entities that can initiate actions against us may increase (including individuals, via a private right of action, and state actors). **We** ~~In addition, our employees and personnel may use generative artificial intelligence (" AI ") technologies to perform their work, and the disclosure and use of personal data in generative AI technologies is subject to various privacy laws~~

~~and other privacy obligations. Governments have passed and~~ are ~~likely to pass additional laws regulating generative AI. Our use of this technology could result in additional compliance costs, regulatory investigations~~ and ~~actions, and lawsuits. If we are unable to use generative AI, it could make our business less efficient and result in competitive disadvantages. We~~ may also **additionally** become subject to a growing body of privacy, data security and data protection laws outside of the United States as we expand our business and clinical trial activities. For example, the EU GDPR and the UK GDPR impose strict requirements for processing the personal data of individuals located, respectively within the EEA and the United Kingdom (the " UK "). Under either law, companies may face temporary or definitive bans on data processing and other corrective actions, fines of up to 20 million Euros under the EU GDPR, 17. 5 million pounds sterling under the UK GDPR or, in each case, 4 % of annual global revenue, whichever is greater; or private litigation related to processing of personal data brought by classes of data subjects or consumer protection organizations authorized at law to represent their interests. In addition, many jurisdictions have enacted data localization laws and cross- border personal data transfer laws. These laws may make it more difficult for ~~us~~ **companies** to transfer personal data across jurisdictions, which could impede our business. In particular, the EEA and the UK have significantly restricted the transfer of personal data to the United States and other countries whose privacy laws it generally believes are inadequate. Other jurisdictions may adopt similarly stringent interpretations of their data localization and cross- border data transfer laws **.** Although there are currently various mechanisms that may be used to transfer personal data from the EEA and UK to the United States in compliance with law, such as the EEA standard contractual clauses, the UK' s International Data Transfer Agreement / Addendum, and the EU- U. S. Data Privacy Framework and the UK extension thereto (which allows for transfers to relevant U. S.- based organizations who self- certify compliance and participate in the Framework), these mechanisms are subject to legal challenges, and there is no assurance that we can satisfy or rely on these measures to lawfully transfer personal data to the United States. If we need but cannot implement a valid compliance mechanism for cross- border privacy and security transfers, or if the requirements for a legally ~~-~~-compliant transfer are too onerous, we may face increased exposure to regulatory actions, substantial fines, and injunctions against processing or transferring personal data from Europe or elsewhere. The inability to import personal data to the United States could significantly and negatively impact our business operations, including by limiting our ability to conduct clinical trial activities in Europe and elsewhere; limiting our ability to collaborate with parties that are subject to European and other data privacy and security laws; or requiring us to increase our personal data processing capabilities in Europe and / or elsewhere at significant expense. Additionally, companies that transfer personal data out of the EEA and UK to other jurisdictions, particularly to the United States, are subject to increased scrutiny from regulators, individual litigants, and activist groups. In addition to data privacy and security laws, we are contractually subject to industry standards adopted by industry groups and may become subject to such obligations in the future. We are also bound by other contractual obligations related to data privacy and security, and our efforts to comply with such obligations may not be successful. Obligations related to data privacy and security (and consumers' data privacy expectations) are quickly changing in an increasingly stringent fashion, creating some uncertainty as to the effective future legal framework. Additionally, these obligations may be subject to differing applications and interpretations, which may be inconsistent or in conflict among jurisdictions. Preparing for and complying with these obligations requires us to devote significant resources (including, without limitation, financial and time- related resources), which may necessitate changes to our information technologies, systems, and practices and to those of any third parties upon which we rely. In addition, these obligations may require us to change our business model. Although we endeavor to comply with all applicable data privacy and security obligations, we may at times fail (or be perceived to have failed) to do so. Moreover, despite our efforts, our personnel or third parties upon which we rely may fail (or be perceived to have failed) to comply with such obligations, which could negatively impact our business operations and compliance posture. If we or the third parties on which we rely fail, or are perceived to have failed, to address or comply with data privacy and security obligations, we could face significant consequences. These consequences may include, but are not limited to, government enforcement actions (e. g., investigations, fines, penalties, audits, inspections, and similar); litigation (including class- related claims) and mass arbitration demands; **consent decrees that impose** additional reporting requirements and / or oversight; bans on processing personal data; orders to destroy or not use personal data; and imprisonment of company officials. In particular, plaintiffs have become increasingly more active in bringing privacy- related claims against companies, including class claims and mass arbitration demands. Some of these claims allow for the recovery of statutory damages on a per violation basis, and, if viable, carry the potential for monumental statutory damages, depending on the volume of data and the number of violations. Any of these events could have a material adverse effect on our reputation, business, or financial condition, including but not limited to: loss of customers; interruptions or stoppages in our business operations (including clinical trials); inability to process personal data or to operate in certain jurisdictions; limited ability to develop or commercialize our products; expenditure of time and resources to defend any claim or inquiry; adverse publicity; or revision or restructuring of our operations. Risks Related to Our Intellectual Property If we are unable to obtain and maintain patent protection for our technology and products, or if the scope of the patent protection obtained is not sufficiently broad, we may not be able to compete effectively in our markets. We rely upon a combination of patents, trademarks, trade secret protection and confidentiality agreements to protect the intellectual property related to our vaccine development programs and vaccine candidates. Our success depends in large part on our ability to obtain and maintain patent protection in the United States and other countries with respect to VAX- ~~24~~ **31** , VAX- ~~31~~ **24** and any future vaccine candidates, as well as methods of making our vaccine candidates and components thereof. We seek to protect our proprietary position by filing patent applications in the United States and abroad related to our development programs and vaccine candidates. The patent prosecution process is expensive and time- consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. The patents and patent applications that we own or in- license may fail to result in issued patents with claims that protect VAX- **31, VAX-** 24 or any future vaccine candidate in the United States or in other foreign countries. There is no assurance that all of the potentially relevant prior art relating to our patents and patent applications has

been found, which can prevent a patent from issuing from a pending patent application, or be used to invalidate a patent. Even if patents do successfully issue and even if such patents cover VAX- **31, VAX-** 24 or any future vaccine candidate, third parties may challenge their validity, enforceability or scope, which may result in such patents being narrowed, invalidated or held unenforceable. Any successful opposition to these patents or any other patents owned by or licensed to us could deprive us of rights necessary for the successful commercialization of any vaccine candidates or companion diagnostic that we may develop. Further, if we encounter delays in regulatory approvals, the period ~~of time~~ during which we could market a vaccine candidate under patent protection could be reduced. If the patent applications we hold or have in- licensed with respect to our development programs and vaccine candidates fail to issue, if their breadth or strength of protection is threatened, or if they fail to provide meaningful exclusivity for **VAX- 31,** VAX- 24 or any future vaccine candidate, it could dissuade companies from collaborating with us to develop vaccine candidates and threaten our ability to commercialize future vaccines. Any such outcome could have a materially adverse effect on our business. The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has been and will continue to be the subject of litigation and new legislation. In addition, the laws of foreign countries may not protect our rights to the same extent as the laws of the United States. For example, many countries restrict the patentability of methods of treatment of the human body. Publications of discoveries in scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot know with certainty whether we were the first to make the inventions claimed in our owned or licensed patents or pending patent applications, or that we were the first to file for patent protection of such inventions. As a result of these and other factors, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Our pending and future patent applications may not result in patents being issued which protect our technology or products, in whole or in part, or which effectively prevent others from commercializing competitive technologies and products. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection. Moreover, we may be subject to a third- party pre- issuance submission of prior art to the U. S. Patent and Trademark Office (“ USPTO ”) or become involved in opposition, derivation, reexamination, inter partes review, post- grant review or interference proceedings challenging our patent rights or the patent rights of others. The costs of defending our patents or enforcing our proprietary rights in post- issuance administrative proceedings and litigation can be substantial and the outcome can be uncertain. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology or products and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third- party patent rights. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future vaccine candidates. The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our owned and licensed patents may be challenged in the courts or patent offices in the United States and abroad. Such challenges may result in loss of exclusivity or freedom to operate or in 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. Generally, issued patents are granted a term of 20 years from the earliest claimed non- provisional filing date. In certain instances, **a** patent term can be adjusted to recapture a portion of delay by the USPTO in examining the patent application (patent term adjustment **(“ PTA ”)**) or extended to account for **the** term effectively lost as a result of the FDA regulatory review period (patent term extension), or both. The scope of patent protection may also be limited. Without patent protection for our current or future vaccine candidates, we may be open to competition from generic versions of such products. Given the amount of time required for the development, testing and regulatory review of new vaccine candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours. If we fail to comply with our obligations under any license, collaboration or other agreements, we may be required to pay damages and could lose intellectual property rights that are necessary for developing and protecting our vaccine candidates. We have licensed certain intellectual property rights related to the ~~XpressCF~~ **XpressCFTM** platform, components of our PCV candidates, and methods of making components of **VAX- 31 or** VAX- 24 from Sutro Biopharma and University of Georgia Research Foundation, Inc. We also license certain intellectual property rights related to a non- cross- reactive Group A Strep carbohydrate antigen and related methods of production from the Regents of the University of California. If, for any reason, these agreements are terminated or we otherwise lose those rights, it could adversely affect our business. These agreements impose, and any future collaboration agreements or license agreements we enter into are likely to impose, various development, commercialization, funding, milestone, royalty, diligence, sublicensing, insurance, patent prosecution and enforcement or other obligations on us. If we breach any material obligations, or use the intellectual property licensed to us in an unauthorized manner, we may be required to pay damages and the licensor (s) may have the right to terminate the license, which could result in us being unable to develop, manufacture and sell products that are covered by the licensed technology or enable a competitor to gain access to the licensed technology. Obtaining and maintaining our 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 noncompliance with these requirements. Periodic maintenance fees on any issued patent are due to be paid to the USPTO and other foreign patent agencies in several stages over the lifetime of the patent. The USPTO and various foreign national or international patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance 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. Noncompliance events that could result in abandonment or lapse of patent rights include, but are not limited to, failure to timely file national and regional stage patent applications based on our international patent application, failure to respond to official actions within prescribed time limits, non- payment of fees and failure to properly legalize and submit formal documents. If we or our licensors fail to maintain the patents and patent applications covering VAX- **31, VAX-** 24 or any future vaccine candidate, or the ~~XpressCF~~ **XpressCFTM** platform, our competitors might be able to enter the market, which would have an adverse effect on our business. Third- party claims or litigation alleging infringement of patents or other proprietary rights, or seeking to invalidate our patents or other proprietary rights, may delay or prevent the development, manufacturing and commercialization of **VAX- 31 or** VAX- 24 and any future vaccine candidate. Our commercial success depends in part on our avoiding infringement and other violations of the patents and proprietary rights of third parties. There is a substantial amount of litigation, both within and outside the United States, involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries, including patent infringement lawsuits, interferences, derivation and administrative law proceedings, inter partes review and post- grant review before the USPTO, as well as oppositions and similar processes in foreign jurisdictions. Numerous U. S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we and our collaborators are developing vaccine candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, and as we gain greater visibility and market exposure as a public company, the risk increases that our vaccine candidates or other business activities may be subject to claims of infringement of the patent and other proprietary rights of third parties. Third parties may assert that we are infringing their patents or employing their proprietary technology without authorization. Also, there may be third- party patents or patent applications with claims to materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our vaccine candidates. Because patent applications can take many years to issue, there may be currently pending patent applications which may later result in issued patents that our vaccine candidates may infringe. In addition, third parties may obtain patent rights in the future and claim that use of our technologies infringes upon these rights. If any third- party patents were held by a court of competent jurisdiction to cover the manufacturing process of any of our vaccine candidates, any molecules formed during the manufacturing process or any final product itself, the holders of any such patents may be able to block our ability to commercialize such vaccine candidate unless we obtained a license under the applicable patents, or until such patents expire. Similarly, if any third- party patent were held by a court of competent jurisdiction to cover aspects of our formulations, processes for manufacture or methods of use, including combination therapy, the holders of any such patent may be able to block our ability to develop and commercialize the applicable vaccine candidate unless we obtained a license or until such patent expires. In either case, such a license may not be available on commercially reasonable terms or at all. In addition, we may be subject to claims that we are infringing other intellectual property rights, such as trademarks or copyrights, or misappropriating the trade secrets of others, and to the extent that our employees, consultants or contractors use intellectual property or proprietary information owned by others in their work for us, disputes may arise as to the rights in related or resulting know- how and inventions. Parties making claims against us may obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize one or more of our vaccine candidates. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. In the event of a successful infringement or other intellectual property claim against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, obtain one or more licenses from third parties, pay royalties or redesign our affected products, which may be impossible or require substantial time and monetary expenditure. We cannot predict whether any such license would be available at all or whether it would be available on commercially reasonable terms. Furthermore, as the vaccine patent landscape is crowded and highly competitive, even in the absence of litigation we may need to obtain licenses from third parties to advance our research or allow commercialization of our vaccine candidates, and we have done so from time to time. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. In that event, we would be unable to further develop and commercialize one or more of our vaccine candidates, which could harm our business significantly. We cannot provide any assurances that third-party patents do not exist which might be enforced against vaccine candidates resulting in either an injunction prohibiting our sales, or, with respect to our sales, an obligation on our part to pay royalties or other forms of compensation to third parties. We may become involved in lawsuits to protect or enforce our patents, the patents of our licensors or our other intellectual property rights, which could be expensive, time consuming and unsuccessful. Competitors may infringe or otherwise violate our patents, the patents of our licensors or our other intellectual property rights. To counter infringement or unauthorized use, we may be required to file legal claims, which can be expensive and time- consuming. In addition, in an infringement proceeding, a court may decide that a patent of ours or our licensors is not valid or is 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. An adverse result in any litigation or defense proceedings could put one or more of our patents at risk of being invalidated or interpreted narrowly and could put our patent applications at risk of not issuing. The initiation of a claim against a third party may also cause the third party to bring counter claims against us such as claims asserting that our patents are 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, non-enablement, written description, or lack of patentable subject matter. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant material information from the USPTO, or made a materially misleading statement, during prosecution. Third parties may also raise similar validity claims before the USPTO in post- grant proceedings such as ex parte reexaminations, inter partes review or post- grant review, or oppositions or similar proceedings outside the United States, in parallel with litigation or even outside the context of litigation. The outcome

following legal assertions of invalidity and unenforceability is unpredictable. We cannot be certain that there is no invalidating prior art, of which we and the patent examiner were unaware during prosecution. For the patents and patent applications that we have licensed, we may have limited or no right to participate in the defense of any licensed patents against challenge by a third party. If a defendant were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of any future patent protection on our current or future vaccine candidates. Such a loss of patent protection could harm our business. We may not be able to prevent, alone or with our licensors, misappropriation of our intellectual property rights, particularly in countries where the laws may not protect those rights as fully as in the United States. Our business could be harmed if in litigation the prevailing party does not offer us a license on commercially reasonable terms. Any litigation or other proceedings to enforce our intellectual property rights may fail, and even if successful, may result in substantial costs and distract our management and other employees. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have an adverse effect on the price of our common shares. Changes in U. S. patent law or the patent law of other countries or jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our products. The United States has enacted and implemented wide- ranging patent reform legislation. The U. S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on actions by the U. S. Congress, the federal courts and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce patents that we have licensed or that we might obtain in the future. For example, recent decisions raise questions regarding the award of ~~patent term adjustment (~~ PTA ~~)~~ for patents in families where related patents have issued without PTA. Thus, it cannot be said with certainty how PTA will / will not be viewed in future and whether patent expiration dates may be impacted. Similarly, changes in patent law and regulations in other countries or jurisdictions or changes in the governmental bodies that enforce them or changes in how the relevant governmental authority enforces patent laws or regulations may weaken our ability to obtain new patents or to enforce patents that we have licensed or that we may obtain in the future. For example, the complexity and uncertainty of European patent laws have also increased in recent years. In Europe, a new unitary patent system took effect June 1, 2023, which will significantly impact European patents, including those granted before the introduction of such a system. Under the unitary patent system, European applications **may** ~~have the option~~ , upon grant of a patent, **become** ~~of becoming~~ a Unitary Patent which will be subject to the jurisdiction of the Unitary Patent Court (" UPC "). As the UPC is a new court system, there is no precedent for the court, increasing the uncertainty of any litigation. Patents granted before the implementation of the UPC **may be opted** ~~have the option of opting~~ out of the jurisdiction of the UPC and remaining as national patents in the UPC countries. Patents that remain under the jurisdiction of the UPC will be potentially vulnerable to a single UPC- based revocation challenge that, if successful, could invalidate the patent in all countries who are signatories to the UPC. We cannot predict with certainty the long- term effects of any potential changes. Any trademarks we may obtain may be infringed or successfully challenged, resulting in harm to our business. We expect to rely on trademarks as one means to distinguish any of our vaccine candidates that are approved for marketing from the products of our competitors. We have not yet selected trademarks for our vaccine candidates and have not yet begun the process of applying to register trademarks for our current or any future vaccine candidates. Once we select trademarks and apply to register them, our trademark applications may not be approved. Third parties may oppose our trademark applications or otherwise challenge our use of the trademarks. In the event that our trademarks are successfully challenged, we could be forced to rebrand our products, which could result in loss of brand recognition and could require us to devote resources to advertising and marketing new brands. Our competitors may infringe our trademarks, and we may not have adequate resources to enforce our trademarks. In addition, any proprietary name we propose to use with our current or any other vaccine candidate in the United States must be approved by the FDA, regardless of whether we have registered it, or applied to register it, as a trademark. The FDA typically conducts a review of proposed product names, including an evaluation of the potential for confusion with other product names. If the FDA 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 proprietary product name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the FDA. We may not be able to protect our intellectual property rights throughout the world, which could impair our business. Filing, prosecuting and defending patents covering our current vaccine candidates and any future vaccine candidate throughout the world would be prohibitively expensive. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we may obtain patent protection, but where patent enforcement is not as strong as that in the United States. These products may compete with our products in jurisdictions where we do not have any issued or licensed patents and any future patent claims or other intellectual property rights may not be effective or sufficient to prevent them from so competing. The ongoing conflict in Ukraine and related sanctions could significantly devalue our Eurasian patents validated in Russia, and Eurasian patent applications. Russian decrees may also significantly limit our ability to enforce Russian patents. We cannot predict when or how this situation will change. Our reliance on third parties requires us to share our trade secrets, which increases the possibility that a competitor will discover them or that our trade secrets will be misappropriated or disclosed. Because we rely on third parties to manufacture VAX- ~~24~~ **31** , VAX- ~~31~~ **24** and potentially future vaccine candidates, and we collaborate with third parties on the development of VAX- ~~24~~ **31** , VAX- ~~31~~ **24** and potentially future vaccine candidates, we must, at times, share trade secrets with them. We also conduct joint research and development that may require us to share trade secrets under the terms of our research and

development partnerships or similar agreements. We seek to protect our proprietary technology in part by entering into confidentiality agreements and, if applicable, material transfer agreements, consulting agreements or other similar agreements with our advisors, employees, third- party contractors and consultants prior to beginning research or disclosing proprietary information. These agreements typically limit the rights of the third parties to use or disclose our confidential information, including our trade secrets. Despite the contractual provisions employed when working with third parties, the need to share trade secrets and other confidential information increases the risk that such trade secrets become known by our competitors, are inadvertently incorporated into the technology of others or are disclosed or used in violation of these agreements. Given that our proprietary position is based, in part, on our know- how and trade secrets, a competitor' s discovery of our trade secrets or other unauthorized use or disclosure would impair our competitive position and may have an adverse effect on our business and results of operations. Further, disputes may arise under these agreements regarding inventorship or ownership of proprietary information generated during research and development. In addition, these agreements typically restrict the ability of our advisors, employees, third- party contractors and consultants to publish data potentially relating to our trade secrets, although our agreements may contain certain limited publication rights. Despite our efforts to protect our trade secrets, our competitors may discover our trade secrets, either through breach of our agreements with third parties, independent development or publication of information by any of our third- party collaborators. A competitor' s discovery of our trade secrets would impair our competitive position and have an adverse impact on our business. We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of their former employers or other third parties. We employ individuals who were previously employed at other biotechnology or pharmaceutical companies. Although we seek to protect our ownership of intellectual property rights by ensuring that our agreements with our employees, collaborators and other third parties with whom we do business include provisions requiring such parties to assign rights in inventions to us, we may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed confidential information of our employees' former employers or other third parties. We may also be subject to claims that former employers or other third parties have an ownership interest in our patents. Litigation may be necessary to defend against these claims. There is no guarantee of success in defending these claims, and if we 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, valuable intellectual property. Even if we are successful, litigation could result in substantial cost and be a distraction to our management and other employees. Risks Related to Ownership of Our Common Stock The price of our stock may be volatile, and the value of our common stock may decline. The market price of our common stock may be highly volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control, including limited trading volume. In addition to the factors discussed in this " Risk Factors " section and elsewhere in this Annual Report on Form 10- K, these factors include, but are not limited to: • the commencement, enrollment or results of our planned or future preclinical studies or clinical trials of our vaccine candidates and those of our competitors; • regulatory or legal developments in the United States and abroad **, including as a result of the change in the U. S. administration in 2025** ; • the success of competitive vaccines or technologies; • developments or disputes concerning patent applications, issued patents or other proprietary rights; • the level of expenses related to our vaccine candidates or preclinical and clinical development programs; • the results of our efforts to develop additional vaccine candidates; • actual or anticipated changes in estimates as to financial results, development timelines or recommendations or reports by securities analysts; • the level of expenses and capital investment related to manufacturing our vaccine candidates; • our inability to obtain or delays in obtaining adequate supply for any approved vaccine candidate; • significant lawsuits, including patent or stockholder litigation; • variations in our financial results or those of companies perceived to be similar to us; • changes in the structure of healthcare payment systems, including coverage and adequate reimbursement for any approved vaccine; • general economic, political and market conditions, including high inflation rates, bank failures, changes in interest rates, government tapering policies and the conflicts in Ukraine and the Middle East, **tariffs,** and overall fluctuations in the financial markets in the United States and abroad; and • investors' general perception of us and our business. In addition, the stock market in general, and the Nasdaq Global Select Market and biopharmaceutical companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance. In the past, securities class action litigation has often been instituted against companies following periods of volatility in the market price of a company' s securities. You may not realize any return on your investment in us and may lose some or all of your investment. In the past, securities class action litigation has often been instituted against companies following periods of volatility in the market price of a company' s securities. This type of litigation, if instituted, could result in substantial costs and a diversion of management' s attention and resources, which would harm our business, operating results or financial condition. We do not intend to pay dividends on our common stock so any returns will be limited to the value of our stock. We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. Any return to stockholders will therefore be limited to the appreciation of their stock. Expectations relating to environmental, social and governance programs may impose additional costs and expose us to new risks. There is an increasing focus from certain investors and other key stakeholders concerning corporate responsibility, specifically related to environmental, social and governance (" ESG ") factors **, and new ESG laws and regulations are expanding mandatory disclosure, reporting and diligence requirements** . As a result, there is an increased emphasis on corporate responsibility ratings and a number of third parties provide reports on companies in order to measure and assess corporate responsibility performance. In addition, the ESG factors by which companies' corporate responsibility practices are assessed may change, which could result in greater expectations of us and cause us to undertake costly initiatives to satisfy such new criteria. Alternatively, if we are unable to satisfy such new criteria, investors may conclude that our policies with

respect to corporate responsibility are inadequate. We risk damage to our brand and reputation if our corporate responsibility procedures or standards do not meet the standards set by various constituencies **or comply with new laws and regulations or changes to legal or regulatory requirements concerning ESG** . We may be required to make investments in matters related to ESG, which could be significant and adversely impact our results of operations. Furthermore, if our competitors' corporate responsibility performance is perceived to be greater than ours, potential or current investors may elect to invest with our competitors instead. In addition, if we communicate certain initiatives and goals regarding ESG matters, we could fail, or be perceived to fail, in our achievement of such initiatives or goals, or we could be criticized for the scope of such initiatives or goals. If we fail to satisfy the expectations of investors and other key stakeholders or our initiatives are not executed as planned **or do not meet evolving legal and regulatory standards** , our reputation and financial results could be materially and adversely affected. Future sales of a substantial number of shares of our common stock, or the perception that such sales could occur, could cause our stock price to fall. Sales of a substantial number of shares of our common stock in the public market could occur at any time. These sales, or the public' s perception that such sales could occur, could have an adverse effect on the market price of our common stock. Provisions in our corporate charter documents and under Delaware law could make an acquisition of us, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove our current management. Provisions in our amended and restated certificate of incorporation and amended and restated bylaws may discourage, delay or prevent a merger, acquisition or other change in control of us that stockholders may consider favorable, including transactions in which you might otherwise receive a premium for your shares. These provisions also could limit the price that investors might be willing to pay in the future for shares of our common stock, thereby depressing the market price of our common stock. In addition, because our board of directors ~~, or~~ **(“** Board ~~,~~ **”)** is responsible for appointing the members of our management team, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our Board. Among other things, these provisions: • establish a classified Board such that not all members of the Board are elected at one time; • allow the authorized number of our directors to be changed only by resolution of our Board; • limit the manner in which stockholders can remove directors from the Board; • establish advance notice requirements for stockholder proposals that can be acted on at stockholder meetings and nominations to our Board; • require that stockholder actions must be effected at a duly called stockholder meeting and prohibit actions by our stockholders by written consent; • prohibit our stockholders from calling a special meeting of our stockholders; • authorize our Board to issue preferred stock without stockholder approval, which could be used to institute a stockholder rights plan, or so- called “ poison pill, ” that would work to dilute the stock ownership of a potential hostile acquirer, effectively preventing acquisitions that have not been approved by our Board; and • require the approval of the holders of at least 66 2 ⁄ 3 % of the votes that all our stockholders would be entitled to cast to amend or repeal certain provisions of our charter or bylaws. Moreover, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law (“ DGCL ”), which prohibits a person who owns 15 % or more of our outstanding voting stock from merging or combining with us for a period of three years after the date of the transaction in which the person acquired 15 % or more of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner. These provisions could discourage potential acquisition proposals and could delay or prevent a change in control transaction. They could also have the effect of discouraging others from making tender offers for our common stock, including transactions that may be in your best interests. These provisions may also prevent changes in our management or limit the price that investors are willing to pay for our stock. Claims for indemnification by our directors and officers may reduce our available funds to satisfy successful third- party claims against us and may reduce the amount of money available to us. Our amended and restated certificate of incorporation and amended and restated bylaws provide that we will indemnify our directors and officers, in each case, to the fullest extent permitted by Delaware law. Delaware law provides that directors of a corporation will not be personally liable for monetary damages for any breach of fiduciary duties as directors, except liability for: • any breach of the director' s duty of loyalty to the corporation or its stockholders; • any act or omission not in good faith or that involves intentional misconduct or a knowing violation of law; • unlawful payments of dividends or unlawful stock repurchases or redemptions; or • any transaction from which the director derived an improper personal benefit. Such limitation of liability does not apply to liabilities arising under federal securities laws and does not affect the availability of equitable remedies such as injunctive relief or rescission. Our amended and restated bylaws provide that we are required to indemnify our directors and officers to the fullest extent permitted by Delaware law and may indemnify our other employees and agents. Our amended and restated bylaws also provide that, on satisfaction of certain conditions, we will advance expenses incurred by a director or officer in advance of the final disposition of any action or proceeding, and permit us to secure insurance on behalf of any officer, director, employee or other agent for any liability arising out of his or her actions in that capacity regardless of whether we would otherwise be permitted to indemnify him or her under the provisions of Delaware law. We have entered and expect to continue to enter into agreements to indemnify our directors and executive officers. With certain exceptions, these agreements provide for indemnification for related expenses, including attorneys' fees, judgments, fines and settlement amounts incurred by any of these individuals in connection with any action, proceeding or investigation. We believe that these amended and restated certificate of incorporation and amended and restated bylaws provisions and indemnification agreements are necessary to attract and retain qualified persons as directors and officers. While we maintain directors' and officers' liability insurance, such insurance may not be adequate to cover all liabilities that we may incur, which may reduce our available funds to satisfy third- party claims and may adversely impact our cash position. Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware will, to the fullest extent permitted by applicable law, be the exclusive forum for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees. Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware (or, in the event that the Court of

Chancery does not have jurisdiction, the federal district court for the District of Delaware or other state courts of the State of Delaware), to the fullest extent permitted by applicable law, is the exclusive forum for the following types of actions or proceedings under Delaware statutory or common law: • any derivative action or proceeding brought on our behalf; • any action or proceeding asserting a claim of breach of a fiduciary duty owed by any of our current or former directors, officers or other employees to us or our stockholders; • any action or proceeding asserting a claim against us or any of our current or former directors, officers or other employees, arising out of or pursuant to any provision of the DGCL, our certificate of incorporation or our bylaws; • any action or proceeding to interpret, apply, enforce or determine the validity of our certificate of incorporation or our bylaws; and • any action or proceeding asserting a claim against us by any of our directors, officers or other employees governed by the internal affairs doctrine. This provision would not apply to suits brought to enforce a duty or liability created by the Exchange Act. Furthermore, Section 22 of the Securities Act of 1933 (as amended, the " Securities Act ") creates concurrent jurisdiction for federal and state courts over all such Securities Act actions. Accordingly, both state and federal courts have jurisdiction to entertain such claims. To prevent having to litigate claims in multiple jurisdictions and the threat of inconsistent or contrary rulings by different courts, among other considerations, our amended and restated certificate of incorporation provides that the federal district courts of the United States will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act. While the Delaware courts have determined that such choice of forum provisions are facially valid, a stockholder may nevertheless seek to bring a claim in a venue other than those designated in the exclusive forum provisions. In such instance, we would expect to vigorously assert the validity and enforceability of the exclusive forum provisions of our amended and restated certificate of incorporation. This may require significant additional costs associated with resolving such action in other jurisdictions and there can be no assurance that the provisions will be enforced by a court in those other jurisdictions. These exclusive- forum provisions may limit a stockholder' s ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage these types of lawsuits. If a court were to find the exclusive- forum provision contained in our amended and restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could harm our business. General Risk Factors Raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish rights to our technologies or vaccine candidates. We may seek additional capital through a combination of public and private equity offerings, debt financings, strategic partnerships and alliances and licensing arrangements, including through the use of our " at- the- market " facility. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms may include liquidation or other preferences that adversely affect your rights as a stockholder. The incurrence of indebtedness would result in increased fixed payment obligations and could involve certain restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. If we raise additional funds through strategic partnerships and alliances and licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies or vaccine candidates, or grant licenses on terms unfavorable to us. Unstable market and economic conditions may have serious adverse consequences on our business, financial condition and stock price. The global credit and financial markets have experienced extreme volatility and disruptions in the past several years, including as a result worsening global economic conditions, including higher inflation rates and changes in interest rates, and civil and political unrest in certain countries and regions. Such volatility and disruptions have caused and may continue to cause severely diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, increases in unemployment rates and uncertainty about economic stability. There can be no assurance that further deterioration in credit and financial markets and confidence in economic conditions will not occur. Our general business strategy may be adversely affected by any such economic downturn, including higher inflation rates and changes in interest rates, volatile business environment or continued unpredictable and unstable market conditions. If the current equity and credit markets deteriorate, it may make any necessary debt or equity financing more difficult, more costly and more dilutive. Failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our growth strategy, financial performance and stock price and could require us to delay or abandon clinical development plans. In addition, there is a risk that one or more of our current service providers, manufacturers and other partners may not survive an economic downturn, which could directly affect our ability to attain our operating goals on schedule and on budget. The cash and cash equivalents that we use to meet our working capital and operating expense needs and investments we hold are held and managed with financial institutions. If any of the financial institutions in which we hold such funds fails or is subject to significant adverse conditions in the financial or credit markets, we could be subject to a risk of loss of all or a portion of such uninsured funds or be subject to a delay in accessing all or a portion of such uninsured funds. Any such loss or lack of access to these funds could adversely impact our short- term liquidity and ability to meet our operating expense obligations. For example, on March 10, 2023, the California Department of Financial Protection and Innovation took control of Silicon Valley Bank (" SVB ") and appointed the Federal Deposit Insurance Corporation (" FDIC ") as receiver. While SVB was our primary bank at the time, we **have not experienced any losses on our deposits or investments with SVB as a result of this market event. We continue to** ~~maintained --~~ **maintain a** banking ~~relationships -~~ **relationship** with ~~other major banks. The substantial majority~~ **SVB, which is almost entirely comprised** of **our** funds ~~we held at SVB, which included cash, cash equivalents and investments were~~ held in custodial accounts of a third- party institution for which SVB Asset Management was the advisor (" SVB Custodial Accounts ") ~~. On March 12, 2023, the FDIC confirmed that depositors of SVB would have access to all of their money and, as a result, we regained access to all of our funds deposited with SVB. The FDIC subsequently transferred SVB' s deposits and loans to a newly created bridge bank, named Silicon Valley Bridge Bank, N. A. (" Silicon Valley Bridge Bank "). On March 26, 2023, the FDIC announced that First Citizens Bank & Trust Company (" First Citizens Bank ") had agreed to purchase and assume all~~

~~deposits and loans of Silicon Valley Bridge Bank. We have not experienced any losses on these deposits or investments as a result of this market event. We continue to maintain a banking relationship with SVB, which is almost entirely comprised of our funds held in SVB Custodial Accounts~~ . While we were able to recover all deposited amounts from SVB, and continue to have access to all investments held in the SVB Custodial Accounts, there can be no assurance that our current or future banks will not face similar risks as SVB or that we will be able to recover in full our deposits in the event of similar closures. If one or any of the financial institutions in which we hold our funds for working capital and operating expense needs were to fail, we cannot provide any assurances that such governmental agencies would take action to protect our uninsured deposits in a similar manner. Our financial condition and results of operations may fluctuate from quarter to quarter and year to year, which makes them difficult to predict. We expect our financial condition and results of operations to fluctuate from quarter to quarter and year to year due to a variety of factors, many of which are beyond our control. Accordingly, you should not rely upon the results of any quarterly or annual periods as indications of future operating performance. If we fail to maintain proper and effective internal control over financial reporting, our ability to produce accurate and timely **consolidated** financial statements could be impaired, investors may lose confidence in our financial reporting and the trading price of our common stock may decline. Pursuant to Section 404 of the Sarbanes- Oxley Act, we are required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm with our annual reports on Form 10- K. The rules governing the standards that must be met for management to assess our internal control over financial reporting are complex and require significant documentation, testing and possible remediation. To comply with the Sarbanes- Oxley Act, the requirements of being a reporting company under the Exchange Act and any complex accounting rules in the future, we may need to upgrade our information technology systems, implement additional financial and management controls, reporting systems and procedures, and hire additional accounting and finance staff. We are currently in the process of hiring additional accounting and finance staff as we grow our business. If we are unable to hire the additional accounting and finance staff necessary to comply with these requirements, we may need to retain additional outside consultants. If we or, if required, our auditors, are unable to conclude that our internal control over financial reporting is effective, investors may lose confidence in our financial reporting and the trading price of our common stock may decline. There can be no assurance that there will not be material weaknesses in our internal control over financial reporting in the future. Any failure to maintain internal control over financial reporting could severely inhibit our ability to accurately report our financial condition, results of operations or cash flows. If we are unable to conclude that our internal control over financial reporting is effective, or if our independent registered public accounting firm determines that we have a material weakness in our internal control over financial reporting, investors may lose confidence in the accuracy and completeness of our financial reports, the market price of our common stock could decline and we could be subject to sanctions or investigations by Nasdaq, the SEC or other regulatory authorities. Failure to remedy any material weakness in our internal control over financial reporting, or to implement or maintain other effective control systems required of public companies, could also restrict our future access to the capital markets. Our reported financial results may be adversely affected by changes in accounting principles generally accepted in the United States. Generally accepted accounting principles in the United States are subject to interpretation by the Financial Accounting Standards Board, the SEC and various bodies formed to promulgate and interpret appropriate accounting principles. A change in these principles or interpretations could have a significant effect on our reported financial results, may retroactively affect previously reported results, could cause unexpected financial reporting fluctuations and may require us to make costly changes to our operational processes and accounting systems. Our disclosure controls and procedures may not prevent or detect all errors or acts of fraud. We designed our disclosure controls and procedures to reasonably assure that information we must disclose in reports we file or submit under the Exchange Act is accumulated and communicated to management, and recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC. We believe that any disclosure controls and procedures or internal controls and procedures, no matter how well- conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. These inherent limitations include the realities that judgments in decision- making can be faulty, and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements due to error or fraud may occur and not be detected. If securities or industry analysts do not publish research or publish inaccurate or unfavorable research about our business, our stock price and trading volume could decline. The trading market for our common stock depends in part on the research and reports that securities or industry analysts publish about us or our business. We do not have control over these analysts. If securities or industry analysts do not publish research or reports about our business, the trading price for our stock would likely be negatively impacted. If one or more of the analysts who cover us downgrades our stock or publishes inaccurate or unfavorable research about our business, our stock price may decline. If one or more of these analysts ceases coverage of our company or fails to publish reports on us regularly, demand for our stock could decrease, which might cause our stock price and trading volume to decline. ~~108~~