Risk Factors Comparison 2024-03-14 to 2023-03-15 Form: 10-K

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You should carefully consider the following risk factors, as well as the other information in this Annual Report, including our **consolidated** financial statements and the related notes and " Management' s Discussion and Analysis of Financial Condition and Results of Operations ", as well as our other public filings. The occurrence of any of the following risks could harm our business, financial condition, results of operations and / or growth prospects or cause our actual results to differ materially from those contained in forward- looking statements we have made in this Annual Report and those we may make from time to time. You should consider all of the risk factors described when evaluating our business. We operate in a rapidly changing environment that involves a number of risks, some of which are beyond our control. This discussion highlights some of the risks that may affect future operating results. These are the risks and uncertainties we believe are most important to consider. We cannot be certain that we will successfully address these risks. If we are unable to address these risks, our business may not grow, our stock price may suffer and we may be unable to stay in business. Additional risks and uncertainties not presently known to us, which we currently deem immaterial or which are similar to those faced by other companies in our industry or business in general, may also impair our business operations. Summary of Risk Factors Our business is subject to numerous risks and uncertainties, discussed in more detail in the following section. These risks include, among others, the following key risks: Risks Related to Our Business, Financial Position and Capital Requirements ● Throughout our operating history, we have generated limited product revenue. ● We have incurred significant losses since our inception and expect to continue to incur significant losses for the foreseeable future and may never achieve or maintain profitability. ● We are largely dependent on the success of our tablet vaccine candidates for the prevention of norovirus and coronavirus infection. ● We have not yet produced a commercially viable vaccine and we may be never able to. ● We will require additional capital to fund our operations. ● We will need to expand our organization and may experience difficulties in managing growth. ● Our business may be adversely affected by a pandemic, epidemic, or outbreak of an infectious disease, such as the ongoing coronavirus pandemic and the emergence of additional variants. Risks Related to Clinical Development, Regulatory Approval and Commercialization ● The regulatory pathway for coronavirus vaccines is evolving, as is the random appearance of novel variants, which may result in unexpected or unforeseen challenges. ● Clinical trials are very expensive, time- consuming, difficult to design and implement and involve an uncertain outcome. ● We face significant competition from other biotechnology and pharmaceutical companies. ● Our tablet vaccine candidates may cause adverse effects resulting in failure to obtain approval from the U. S. Food and Drug Administration (the " FDA ") and / or product liability lawsuits against us. ● We may be unable to manufacture sufficient bulk vaccine for our ongoing needs. ● We are dependent on third parties for manufacturing and clinical trials. ● We face numerous risks associated with our intellectual property. Risks Related to Dependence on Third Parties ● Our dependence on third parties could delay or prevent the development, approval, manufacturing, or any eventual commercialization of our product candidates. ● We rely on third- party contract manufacturers for certain portions of our manufacturing process. If third- party contract manufacturers do not perform, fail to manufacture according to our specifications, or fail to comply with strict government regulations, our preclinical studies or clinical trials could be adversely affected and the development of our product candidates could be delayed or terminated, or we could incur significant additional expenses. **Risks Related to Intellectual Property ● If we are unable to obtain and maintain patent protection for our oral vaccine platform technology and product candidates 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 may be 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. ● If a third party claims we are infringing on its intellectual property rights, we could incur significant expenses, or be prevented from further developing or commercializing our product candidates, which could materially harm our business. ● Obtaining and maintaining our patent protection depends on compliance with various procedures, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non- compliance with these requirements. ● We may not be able to protect our intellectual property rights throughout the world, which could impair our business. ● 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.** Even though we generate royalty revenue from Inavir, our commercialized influenza product, we are at an early stage in our clinical development process and have not yet successfully completed a large- scale, pivotal clinical trial, obtained marketing approval, manufactured our tablet vaccine candidates at commercial scale, or conducted sales and marketing activities that will be necessary to successfully commercialize our product candidates. Consequently, predictions about our future success or viability may not be as accurate as they could be if we had a history of successfully developing and commercializing product candidates. Our ability to generate significant revenue and achieve and maintain profitability will depend upon our ability to successfully complete the development of our tablet vaccine candidates for the prevention of norovirus, **coronavirus and** ~~SARS- CoV- 2,~~ influenza ~~, and respiratory syncytial virus (" RSV ")~~ infection and the treatment of cervical cancer and dysplasia caused by human papillomavirus (" HPV ") and other infectious diseases, and to obtain the necessary regulatory approvals. As disclosed elsewhere in this document, the Company is evaluating the best way to progress certain programs. Even if we receive regulatory approval for the sale of any of our product candidates, we do not know when we will begin to generate significant revenue, if at all. Our ability to generate significant revenue depends on a number of factors, including our ability to: ● set an acceptable price for our product candidates and obtain coverage and adequate reimbursement

from third- party payors; ● receive royalties on our products and product candidates including in connection with sales of Inavir; ● establish sales, marketing, manufacturing and distribution systems; ● add or continue to scale our operational, financial and management information systems and personnel, including personnel to support our clinical, manufacturing and planned future clinical development and commercialization efforts; ● develop, in collaboration with others, manufacturing capabilities for bulk materials and manufacture commercial quantities of our product candidates at acceptable cost levels; ● achieve broad market acceptance of our product candidates in the medical community and with third- party payors and consumers; ● attract and retain an experienced management and advisory team; ● launch commercial sales of our product candidates, whether alone or in collaboration with others; ● develop, in- license or acquire product candidates or commercial- stage products that we believe can be successfully developed and commercialized; and ● maintain, expand and protect our intellectual property portfolio. Because of the numerous risks and uncertainties associated with vaccine development and manufacturing, we are unable to predict the timing or amount of increased development expenses, or when we will be able to achieve or maintain profitability, if at all. Our expenses could increase beyond expectations if we are required by the FDA, or comparable non- U. S. regulatory authorities, to perform studies or clinical trials in addition to those we currently anticipate. Even if our product candidates are approved for commercial sale, we anticipate incurring significant costs associated with the commercial launch of and the related commercial- scale manufacturing requirements for our product candidates. If we cannot successfully execute on any of the factors listed above, our business may not succeed. We have generated only limited product revenues and we expect to continue to incur substantial and increasing losses as we continue to pursue our business strategy. Our product candidates have not been approved for marketing in the United States and may never receive such approval. As a result, we are uncertain when or if we will achieve profitability and, if so, whether we will be able to sustain it. Our ability to generate significant revenue and achieve profitability is dependent on our ability to complete development, obtain necessary regulatory approvals, and have our product candidates manufactured and successfully marketed. We cannot be sure that we will be profitable even if we successfully commercialize one of our product candidates. If we do successfully obtain regulatory approval to market our tablet vaccine candidates, our revenues will be dependent, in part, upon the size of the markets in the territories for which regulatory approval is received, the number of competitors in such markets, the price at which we can offer our product candidates and whether we own the commercial rights for that territory. If the indication approved by regulatory authorities is narrower than we expect, or the treatment population is narrowed by competition, physician choice or treatment guidelines, we may not generate significant revenue from sales of our product candidates, even if approved. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. If we fail to become and remain profitable, the market price of our common stock and our ability to raise capital and continue operations will be adversely affected. We expect overall research and development expenses to increase significantly for any of our tablet vaccines, including those for the prevention of norovirus, **coronavirus and** ~~SARS- CoV- 2,~~ influenza ~~and RSV infection~~ , as well as those for the treatment of HPV- related dysplasia and cancer, although we intend to fund a significant portion of these costs through partnering and collaboration agreements. In addition, even if we obtain regulatory approval, significant sales and marketing expenses will be required to commercialize the tablet vaccine candidates. As a result, we expect to continue to incur significant and increasing operating losses and negative cash flows for the foreseeable future. These losses have had and will continue to have an adverse effect on our financial position and working capital. As of December 31, ~~2022~~ **2023** , we had an accumulated deficit of $ ~~327~~ **409** . ~~1~~ **6** million **. Our recurring losses from operations and negative cash flows have raised substantial doubt regarding our ability to continue as a going concern. We will require substantial additional funding to finance our operations, and if we are unable to raise capital, we could be forced to delay, reduce the scope of or eliminate certain of our development programs, or explore other strategic options. Our recurring losses from operations and negative cash flows raise substantial doubt about our ability to continue as a going concern. As of December 31, 2023, we had $ 39. 7 million of cash, cash equivalents and investments. Since December 31, 2023, we raised $ 10. 0 million before estimated offering expenses through a registered direct offering in January 2024 and, through March 12, 2024, we raised $ 5. 7 million in gross proceeds net of commissions from the issuance of shares under the Controlled Equity Offering Sales Agreement. We believe these funds are sufficient to fund our operations into the fourth quarter of 2024. Our ability to continue as a going concern is dependent upon our ability to raise additional capital through outside sources. We plan to raise additional capital through the sale of convertible stock, additional equity, debt financings, government programs, or strategic alliances with third parties. Such financing and funding may not be available at all, or on terms that are favorable to us. Failure to raise additional capital could have a material adverse effect on our business, results of operations, financial condition and / or our ability to fund our scheduled obligations on a timely basis or at all. If we are unable to continue as a going concern, we may be forced to liquidate our assets and the values we receive for our assets in liquidation or dissolution could be significantly lower than the values reflected in our consolidated financial statements** . We are largely dependent on the success of our tablet vaccines for the prevention of norovirus and coronavirus infection, which are still in early- stage clinical development, and if one or both of these tablet vaccines do not receive regulatory approval or are not successfully commercialized, our business may be harmed. None of our product candidates are in late- stage clinical development or approved for commercial sale and we may never be able to develop marketable tablet vaccine candidates. We expect that a substantial portion of our efforts and expenditures over the next few years will be devoted to our tablet vaccine candidates for norovirus and coronavirus. We are committing financial resources to the development of a norovirus vaccine and a coronavirus vaccine, which may cause delays in or otherwise negatively impact our other development programs. In addition, our management and scientific teams have dedicated substantial efforts to our norovirus vaccine and coronavirus vaccine development. Accordingly, our business currently depends heavily on the successful development, regulatory approval and commercialization of our norovirus and coronavirus tablet vaccine. These tablet vaccines may not receive regulatory approval or be successfully commercialized even if regulatory approval is received. The research, testing, manufacturing, labeling, approval,

sale, marketing and distribution of tablet vaccine candidates are and will remain subject to extensive regulation by the FDA and other regulatory authorities in the United States and other countries that each have differing regulations. We are not permitted to market our tablet vaccines in the United States until we receive approval of a Biologics License Application (" BLA ") from the FDA, or in any foreign countries until we receive the requisite approval from such countries. To date, we have only completed early- stage clinical trials for our norovirus vaccine candidate and our COVID- 19 vaccine candidate. As a result, we have not submitted a BLA to the FDA or comparable applications to other regulatory authorities and do not expect to be in a position to do so for the foreseeable future. Obtaining approval of a BLA is an extensive, lengthy, expensive and inherently uncertain process, and the FDA may delay, limit or deny approval of our tablet vaccines for many reasons, including: ● We may not be able to demonstrate that our tablet vaccine is safe and effective to the satisfaction of the FDA; ● the FDA may not agree that the completed Phase 1 **and Phase 2** clinical trials of the norovirus vaccine and the Phase 1 and Phase 2 clinical trials of the COVID- 19 vaccine satisfy the FDA' s requirements and may require us to conduct additional testing; ● the results of our clinical trials may not meet the level of statistical or clinical significance required by the FDA for marketing approval; ● the FDA may disagree with the number, design, size, conduct or implementation of one or more of our clinical trials; ● the contract research organizations, or CROs, that we retain to conduct clinical trials may take actions outside of our control that materially and adversely impact our clinical trials; ● the FDA may not find the data from our preclinical studies and clinical trials sufficient to demonstrate that the clinical and other benefits of our tablet vaccines outweigh the safety risks; ● the FDA may disagree with our interpretation of data from our preclinical studies and clinical trials; ● the FDA may not accept data generated at our clinical trial sites; ● if our NDA or BLA is reviewed by an advisory committee, the FDA may have difficulties scheduling an advisory committee meeting in a timely manner or the advisory committee may recommend against approval of our application or may recommend that the FDA require, as a condition of approval, additional preclinical studies or clinical trials, limitations on approved labeling or distribution and use restrictions; ● the FDA may require development of a risk evaluation and mitigation strategy as a condition of approval; ● the FDA may identify deficiencies in our manufacturing processes or facilities; and ● the FDA may change its approval policies or adopt new regulations. Our development of a norovirus **vaccine candidate and a coronavirus** vaccine candidate is at an early stage. We may be unable to produce an effective vaccine that successfully immunizes humans against norovirus **or an effective vaccine that successfully immunizes humans against coronavirus** in a timely manner, if at all. We are in the business of developing oral vaccines that are administered by tablet rather than by injection. Our development of the norovirus vaccine **and a coronavirus vaccine** is at an early stage, and we may be unable to produce an effective vaccine that successfully immunizes humans against norovirus **or an effective vaccine that successfully immunizes humans against coronavirus** in a timely manner, if at all. If we are unsuccessful in maintaining our relationships with critical third parties such as CROs and CMOs, our ability to develop our oral norovirus **vaccine candidate or our oral coronavirus** vaccine candidate and consequently compete in the marketplace could be impaired, and our results of operations may suffer. Even if we are successful, we cannot assure you that these relationships will result in successful development and commercialization of our oral norovirus vaccine candidate. Our failure, or the failure of such partners or potential partners, to comply with applicable regulations could result in sanctions being imposed on us, including clinical holds, delays, suspension or withdrawal of approval to conduct clinical investigations, license revocation, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our potential norovirus vaccine. Manufacturing any drug product with recombinant technology such as our adenovirus type 5 based vaccines presents technical challenges. Our manufacturing partners may not be able to successfully manufacture any vaccine with our VAAST platform, or to comply with cGMP, regulations or similar regulatory requirements. The number of doses of our potential vaccine that we are able to produce is dependent on our ability to successfully and rapidly scale- up manufacturing capacity. The number of doses that we will be able to produce is also dependent in large part on the dose of the vaccine required to be administered to patients which will be determined in our clinical trials. To properly scale- up and develop a commercial process, we may need to expend significant resources, expertise, and capital. Scale up can present problems such as difficulties with production costs and yields, quality control, including stability of the product candidate and quality assurance testing, shortages of qualified personnel or key raw materials, and compliance with strictly enforced federal, state, and foreign regulations. Our contract manufacturers may not perform as agreed. If any manufacturer encounters these or other difficulties, our ability to provide product candidates to patients in our clinical trials could be jeopardized. We will require additional capital to fund our operations, and if we fail to obtain necessary financing, we may not be able to complete the development and commercialization of our tablet vaccine candidates. We expect to spend substantial amounts to complete the development of, seek regulatory approvals for and commercialize our tablet vaccine candidates. We will require substantial additional capital to complete the development and potential commercialization of our tablet vaccine candidates for norovirus, **coronavirus** ~~SARS- CoV- 2~~, influenza ~~, RSV~~ and HPV and the development of other product candidates. If we are unable to raise capital or find appropriate partnering or licensing collaborations, when needed or on acceptable terms, we could be forced to delay, reduce or eliminate one or more of our development programs or any future commercialization efforts. In addition, attempting to secure additional financing may divert the time and attention of our management from day- to- day activities and harm our development efforts. As of December 31, ~~2022~~ **2023**, we had $ ~~95~~ **39**. 7 million of cash, cash equivalents ~~, restricted cash~~ and ~~marketable securities~~ **investments. Since December 31, 2023, we raised $ 10. 0 million before estimated offering expenses through a registered direct offering in January 2024 and, through March 12, 2024, we raised $ 5. 7 million in gross proceeds net of commissions from the issuance of shares under the Controlled Equity Offering Sales Agreement**. We maintain our cash, cash equivalents ~~, restricted cash~~ and **investments** ~~marketable securities~~ with high quality, accredited financial institutions. However, some of these accounts exceed federally insured limits, and, while we believe the Company is not exposed to significant credit risk due to the financial strength of these depository institutions or investments, the failure or collapse of one or more of these depository institutions or default on these investments could materially adversely affect our ability to recover these assets and /

or materially harm our financial condition. Although we believe such cash, cash equivalents ~~, restricted cash~~ and **investments** ~~marketable securities~~ are **not** sufficient to fund our operations under our current operating plan for at least one year from the date of issuance of this Annual Report, our estimate as to what we will be able to accomplish is based on assumptions that may prove to be inaccurate, and we could exhaust our available capital resources sooner than is currently expected. Because the length of time and activities associated with successful development of our product candidates is highly uncertain, we are unable to estimate the actual funds we will require for development and any approved marketing and commercialization activities. Our future funding requirements, both near and long- term, will depend on many factors, including, but not limited to: ● our ability to enter into partnering and collaboration agreements; ● the initiation, progress, timing, costs and results of our planned clinical trials; ● the outcome, timing and cost of meeting regulatory requirements established by the FDA, the European Medicines Agency, or EMA, and other comparable foreign regulatory authorities; ● the cost of filing, prosecuting, defending and enforcing our patent claims and other intellectual property rights; ● the cost of defending potential intellectual property disputes, including any patent infringement actions brought by third parties against us now or in the future; ● the effect of competing technological and market developments; ● the cost of establishing sales, marketing and distribution capabilities in regions where we choose to commercialize our product candidates on our own; and ● the initiation, progress, timing and results of the commercialization of our product candidates, if approved, for commercial sale. Additional funding may not be available on acceptable terms, or at all. If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may have to significantly delay, scale back or discontinue the development or commercialization of our product candidates or potentially discontinue operations. Raising additional funds by issuing securities may cause dilution to existing stockholders, and raising funds through lending and licensing arrangements may restrict our operations or require us to relinquish proprietary rights. We expect that significant additional capital will be needed in the future to continue our planned operations. Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of equity offerings, royalties, debt financings **, government programs** , strategic alliances and license and development agreements in connection with any collaborations. We do not currently have any committed external source of funds. To the extent that we raise additional capital by issuing equity securities, our existing stockholders' ownership may experience substantial dilution, and the terms of these securities may include liquidation or other preferences that adversely affect our common stockholders' rights. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures, declaring dividends, creating liens, redeeming our stock or making investments. If we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, or through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties on acceptable terms, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise develop and market ourselves. The price of our common stock has been volatile and fluctuates substantially, which could result in substantial losses for stockholders. Our stock price has been, and in the future may be, subject to substantial volatility. As a result of this volatility, our stockholders could incur substantial losses. The stock market in general, and the market for biopharmaceutical companies in particular, has experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, you may not be able to sell your common stock at or above your initial purchase price. The market price for our common stock may be influenced by many factors, including the results of clinical trials of our products or those of our competitors, regulatory or legal developments, developments, disputes, or other matters concerning patent applications, issued patents, or other proprietary rights, our ability to recruit and retain key personnel, public announcements by us or our strategic collaborators regarding the progress of our development candidates similar public announcements by our competitors, and other factors set forth in this quarterly report and our other reports filed with the SEC. If our quarterly or annual results fall below the expectations of investors or securities analysts, the price of our common stock could decline substantially. Furthermore, any quarterly or annual fluctuations in our results may, in turn, cause the price of our stock to fluctuate substantially. We believe that period- to- period comparisons of our results are not necessarily meaningful and should not be relied upon as an indication of our future performance. In addition, public statements by us, government agencies, the media or others relating to the SARS- CoV- 2 outbreak (including regarding efforts to develop a COVID- 19 vaccine) have in the past resulted, and may in the future result, in significant fluctuations in our stock price. Given the global focus on the coronavirus outbreak, any information in the public arena on this topic, whether or not accurate, could have an outsized impact (either positive or negative) on our stock price. Information related to our development, manufacturing and distribution efforts with respect to our vaccine candidates, or information regarding such efforts by competitors with respect to their potential vaccines, may also impact our stock price. Our stock price is likely to continue to be volatile and subject to significant price and volume fluctuations in response to market and other factors, including the other factors discussed in our filings incorporated by reference herein or in future periodic reports; variations in our quarterly operating results from our expectations or those of securities analysts or investors; downward revisions in securities analysts' estimates; and announcement by us or our competitors of significant acquisitions, strategic partnerships, joint ventures or capital commitments. Market prices for securities of early- stage pharmaceutical, biotechnology and other life sciences companies have historically been particularly volatile. Some of the factors that cause the market price of our common stock to fluctuate include: ● our ability to develop product candidates and conduct clinical trials that demonstrate our product candidates are safe and effective; ● our ability to negotiate and receive royalty payments on the sales of our product candidates including Inavir; ● our ability to obtain regulatory approvals for our product candidates, and delays or failures to obtain such approvals; ● failure of any of our product candidates to demonstrate safety and

efficacy, receive regulatory approval and achieve commercial success; ● failure to maintain our existing third- party license, manufacturing and supply agreements; ● our failure, or that of our licensors, to prosecute, maintain, or enforce our intellectual property rights; ● changes in laws or regulations applicable to our product candidates; ● any inability to obtain adequate supply of product candidates or the inability to do so at acceptable prices; ● adverse regulatory authority decisions; ● introduction of new or competing products by our competitors; ● failure to meet or exceed financial and development projections that we may provide to the public; ● the perception of the pharmaceutical industry by the public, legislatures, regulators and the investment community; ● announcements of significant acquisitions, strategic partnerships, joint ventures, or capital commitments by us or our competitors; ● disputes or other developments relating to proprietary rights, including patents, litigation matters, and our ability to obtain intellectual property protection for our technologies; ● additions or departures of key personnel; ● significant lawsuits, including intellectual property or stockholder litigation; ● if securities or industry analysts do not publish research or reports about us, or if they issue adverse or misleading opinions regarding our business and stock; ● changes in the market valuations of similar companies; ● general market or macroeconomic conditions; ● sales of our common stock by our existing stockholders in the future; ● trading volume of our common stock; ● adverse publicity relating to our markets generally, including with respect to other products and potential products in such markets; ● changes in the structure of health care payment systems; and ● period- to- period fluctuations in our financial results. Moreover, the stock markets in general have experienced substantial volatility that has often been unrelated to the operating performance of individual companies. These broad market fluctuations may also adversely affect the trading price of our common stock. If we cannot continue to satisfy the listing requirements of The Nasdaq Capital Market, our securities may be delisted, which could negatively impact the price of our securities and stockholders' ability to sell them. Although our common stock is listed on The Nasdaq Capital Market, we may be unable to continue to satisfy the continued listing requirements and rules, including the minimum bid price per share requirement and certain financial metrics relating to our stockholders' equity, market value of listed securities, or net income from continuing operations. If we are unable to satisfy The Nasdaq Capital Market criteria for maintaining our listing, our securities could be subject to delisting. If The Nasdaq Capital Market delists our securities, we could face significant consequences, including: ● a limited availability for market quotations for our securities; ● reduced liquidity with respect to our securities; ● a determination that our common stock is a " penny stock, " which will require brokers trading in our common stock to adhere to more stringent rules and possibly result in reduced trading; ● activity in the secondary trading market for our common stock; ● limited amount of news and analyst coverage; and ● a decreased ability to issue additional securities or obtain additional financing in the future. In addition, we would no longer be subject to The Nasdaq Capital Market rules, including rules requiring us to have a certain number of independent directors and to meet other corporate governance standards. **Unless our common stock continues to be listed on a national securities exchange it will become subject to the so- called " penny stock " rules that impose restrictive sales practice requirements. If we are unable to maintain the listing of our common stock on Nasdaq or another national securities exchange, our common stock could become subject to the so- called " penny stock " rules if the shares have a market value of less than $ 5. 00 per share. The SEC has adopted regulations that define a penny stock to include any stock that has a market price of less than $ 5. 00 per share, subject to certain exceptions, including an exception for stock traded on a national securities exchange. The SEC regulations impose restrictive sales practice requirements on broker- dealers who sell penny stocks to persons other than established customers and " accredited investors " as defined by relevant SEC rules. These additional requirements may discourage broker- dealers from effecting transactions in securities that are classified as penny stocks, which could severely limit the market price and liquidity of such securities and the ability of purchasers to sell such securities in the secondary market. This means that if we are unable to maintain the listing of our common stock on a national securities exchange, the ability of stockholders to sell their common stock in the secondary market could be adversely affected. If a transaction involving a penny stock is not exempt from the SEC' s rule, a broker- dealer must deliver a disclosure schedule relating to the penny stock market to each investor prior to a transaction. The broker- dealer also must disclose the commissions payable to both the broker- dealer and its registered representative, current quotations for the penny stock, and, if the broker- dealer is the sole market- maker, the broker- dealer must disclose this fact and the broker- dealer' s presumed control over the market. Finally, monthly statements must be sent disclosing recent price information for the penny stock held in the customer' s account and information on the limited market in penny stocks.** Our business could be adversely affected by health epidemics in regions where we have concentrations of clinical trial sites or other business activities and could cause significant disruption in the operations of third- party contract manufacturers and contract research organizations upon whom we rely, as well as our ability to recruit patients for our clinical trials. For example, the ongoing coronavirus (COVID- 19) pandemic continues to have unpredictable impacts on global societies, economies, financial markets, and business practices around the world. The extent to which the ongoing coronavirus pandemic may impact our business, results of operations, and future growth prospects will depend on a variety of factors and future developments, which are highly uncertain and cannot be predicted with confidence, including the duration, scope, and severity of the pandemic, particularly as virus variants continue to spread. The outbreak and any preventative or protective actions that governments or we may take in respect of any epidemic may result in a period of business disruption and reduced operations. Any resulting financial impact cannot be reasonably estimated at this time but may materially affect our business, financial condition and results of operations. The extent to which an epidemic impacts our results will depend on future developments, which are highly uncertain and cannot be predicted, including new information which may emerge concerning the severity of an epidemic and the actions to contain the epidemic or treat its impact, among others. There may be interruptions to our supply chain due to the inability of manufacturers to continue normal business operations and to ship products. In addition, a significant outbreak of an infectious disease could result in a widespread health crisis that could adversely affect the economies and financial markets worldwide, resulting in an economic downturn that could impact our business, financial condition and results of operations. We are

currently working to enhance our business continuity plans to include measures to protect our employees in the event of infection in our corporate offices, or in response to potential mandatory quarantines. ~~The ongoing~~ **Ongoing** military ~~conflict~~ **conflicts** ~~between Russia and Ukraine~~ could cause geopolitical instability, economic uncertainty, financial markets volatility and capital markets disruption ~~, which~~ may adversely affect our revenue, financial condition, or results of operations. ~~The current~~ **Current** military ~~conflict~~ **conflicts** ~~between Russia and Ukraine~~ may disrupt or otherwise adversely impact our operations and those of third parties upon which we rely. Related sanctions, export controls or other actions that have already been initiated or may in the future be initiated by nations including the U. S., the European Union or Russia (e. g., potential cyberattacks, disruption of energy flows, etc.) can adversely affect our business, our contract research organizations, contract manufacturing organizations and other third parties with which we conduct business. Resulting volatility, disruption, or deterioration in the credit and financial markets may further make any necessary debt or equity financing more difficult and more costly. 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 be adversely impacted by deteriorating economic conditions, which could directly affect our ability to attain our operating goals and to accurately forecast and plan our future business activities. If we fail to obtain or maintain adequate reimbursement and insurance coverage for our product candidates, our ability to generate significant revenue could be limited. The availability and extent of reimbursement by governmental and private payors is essential for most patients to be able to afford expensive treatments. Sales of any of our product candidates that receive marketing approval will depend substantially, both in the United States and internationally, on the extent to which the costs of our product candidates will be paid by health maintenance, managed care, pharmacy benefit and similar healthcare management organizations, or reimbursed by government health administration authorities, private health coverage insurers and other third- party payors. If reimbursement is not available, or is available only on a limited basis, we may not be able to successfully commercialize our product candidates. Even if coverage is provided, the approved reimbursement amount may not be high enough to allow us to establish or maintain adequate pricing that will allow us to realize a sufficient return on our investment. Outside the United States, international operations are generally subject to extensive governmental price controls and other market regulations, and we believe the increasing emphasis on cost- containment initiatives in Europe, Canada and other countries may cause us to price our product candidates on less favorable terms that we currently anticipate. In many countries, particularly the countries of the European Union, the prices of medical products are subject to varying price control mechanisms as part of national health systems. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost- effectiveness of our product candidates to other available therapies. In general, the prices of products under such systems are substantially lower than in the United States. Other countries allow companies to fix their own prices for products, but monitor and control company profits. Additional foreign price controls or other changes in pricing regulation could restrict the amount that we are able to charge for our product candidates. Accordingly, in markets outside the United States, the level of reimbursement for our products is likely to be reduced compared with the United States and may be insufficient to generate commercially reasonable revenues and profits. Moreover, increasing efforts by governmental and third- party payors, in the United States and internationally, to cap or reduce healthcare costs may cause such organizations to limit both coverage and level of reimbursement for newly approved products and, as a result, they may not cover or provide adequate payment for our product candidates. We expect to experience pricing pressures in connection with the sale of any of our product candidates due to the trend toward managed healthcare, the increasing influence of health maintenance organizations and additional legislative changes. The downward pressure on healthcare costs in general, particularly prescription drugs and surgical procedures and other treatments, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products into the healthcare market. Our future success depends on our ability to retain executive officers and attract, retain and motivate qualified personnel. We rely on our executive officers and the other principal members of the executive and scientific teams. The employment of our executive officers is at- will and our executive officers may terminate their employment at any time. The loss of the services of any of our senior executive officers could impede the achievement of our research, development and commercialization objectives. We do not maintain " key person " insurance for any executive officer or employee. Recruiting and retaining qualified scientific, clinical and sales and marketing personnel is also critical to our success. We may not be able to attract and retain these personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. Our industry has experienced an increasing rate of turnover of management and scientific personnel in recent years. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in devising our research and development and commercialization strategy. Our consultants and advisors may be employed by third parties and have commitments under consulting or advisory contracts with other entities that may limit their availability to advance our strategic objectives. If any of these advisors or consultants can no longer dedicate a sufficient amount of time to us, our business may be harmed. We will need to expand our organization, and may experience difficulties in managing this growth, which could disrupt operations. Our future financial performance and our ability to commercialize our product candidates, continue to earn royalties and compete effectively will depend, in part, on our ability to effectively manage any future growth. As of December 31, ~~2022~~ **2023**, we had **109** ~~164 full- time~~ employees, which we believe would be insufficient to commercialize our vaccine product candidates. We may have operational difficulties in connection with identifying, hiring and integrating new personnel. Future growth would impose significant additional responsibilities on our management, including the need to identify, recruit, maintain, motivate and integrate additional employees, consultants and contractors. Also, our management may need to divert a disproportionate amount of its attention away from our day- to- day

activities and devote a substantial amount of time to managing these growth activities. We may not be able to effectively manage the expansion of our operations, which may result in weaknesses in our infrastructure, give rise to operational mistakes, loss of business opportunities, loss of employees and reduced productivity among remaining employees. Our expected growth could require significant capital expenditures and may divert financial resources from other projects, such as the development of our product candidates. If we are unable to effectively manage our growth, our expenses may increase more than expected, our ability to generate and / or grow revenues could be reduced, and we may not be able to implement our business strategy. Many of the other pharmaceutical companies that we compete against for qualified personnel and consultants have greater financial and other resources, different risk profiles and a longer history in the industry than us. They may also provide more diverse opportunities and better chances for career advancement. Some of these characteristics may be more appealing to high- quality candidates and consultants than what we are able to offer. If we are unable to continue to attract and retain high- quality personnel and consultants, the rate and success at which we can select and develop our product candidates and our business will be limited. We are subject to certain legal proceedings, and may be subject to additional legal proceedings, which may result in substantial costs, divert management' s attention and have a material adverse effect on our business, financial condition and results of operations. We are currently subject to certain pending legal proceedings, as described in this report. We may become involved in additional legal proceedings relating to the aforementioned matters or, from time to time, we may become involved in legal proceedings involving unrelated matters. Due to the inherent uncertainties in legal proceedings, we cannot accurately predict their ultimate outcome. Our stock price has been extremely volatile, and we may become involved in additional securities class action lawsuits in the future. Any such legal proceedings, regardless of their merit, could result in substantial costs and a diversion of management' s attention and resources that are needed to successfully run our business, could impair the Company' s ability to recruit and retain directors, officers, and other key personnel, could impact its ability to secure financing, insurance, and other transactions (or the terms of any such financings, insurance, or other transactions), and for these and other reasons could have a material adverse impact on our business, financial condition, results of operations, and prospects. If securities or industry analysts do not publish research, or publish inaccurate or unfavorable reports about our business, our stock price and trading volume could decline. The trading market for our common stock is influenced by independent research and reports that securities or industry analysts publish about us or our business from time to time. If one or more of the analysts who cover us should downgrade our shares or change their opinion of our business prospects, our share price would likely decline. In light of the COVID- 19 pandemic, it is possible that one or more government entities may take actions that directly or indirectly have the effect of abrogating some of our rights or opportunities. If we were to develop a COVID- 19 vaccine, the economic value of such a vaccine to us could be limited. Various government entities, including the U. S. government, are offering incentives, grants and contracts to encourage additional investment by commercial organizations into preventative and therapeutic agents against coronavirus, which may have the effect of increasing the number of competitors and / or providing advantages to known competitors. Accordingly, there can be no assurance that we will be able to successfully establish a competitive market share for our COVID- 19 vaccine, if any. We are a smaller reporting company and the reduced disclosure requirements applicable to smaller reporting companies may make our common stock less attractive to investors. We are currently a " smaller reporting company " as defined in the Exchange Act. Smaller reporting companies are able to provide simplified executive compensation disclosures in their filings and have certain other decreased disclosure obligations in their SEC filings. We cannot predict whether investors will find our common stock less attractive because of our reliance on the smaller reporting company exemption. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile. There are currently no approved vaccines for the prevention of norovirus- related illness. Therefore, the regulatory pathway for any approval of a norovirus vaccine is not entirely clear and may result in unexpected or unforeseen challenges. As there are currently no vaccines for the prevention of norovirus that are approved by the FDA or another regulatory agency, the regulatory pathway for any approval of a norovirus vaccine is not entirely clear and may result in unexpected or unforeseen challenges. Successful discovery and development of a norovirus vaccine is highly uncertain and dependent on numerous factors, many of which are beyond our control. Our development of the vaccine is in early stages, and we may be unable to produce a vaccine that successfully treats the virus in a timely manner, if at all. Results from clinical testing may raise new questions and require us to redesign proposed clinical trials, including revising proposed endpoints or adding new clinical trial sites or cohorts of subjects. In addition, the FDA' s analysis of clinical data may differ from our interpretation and the FDA may require that we conduct additional analyses. The regulatory pathway for COVID- 19 vaccines is evolving and may result in unexpected or unforeseen challenges. The speed at which all parties are acting to create and test therapeutics and vaccines for COVID- 19 is unusual, and evolving or changing plans or priorities within the FDA, including changes based on new knowledge of COVID- 19 and how the disease affects the human body, may significantly affect the regulatory timeline for **COVID vaccine candidates** ~~VXA- CoV2- 1 or VXA- CoV2- 1. 1- S~~ . Results from clinical testing may raise new questions and require us to redesign proposed clinical trials, including revising proposed endpoints or adding new clinical trial sites or cohorts of subjects. Results from our vaccine (and other COVID- 19) trials may require us to perform additional preclinical studies in order to advance our vaccine candidates. Discussions with FDA regarding the design of the anticipated Phase 2 and 3 studies for ~~VXA-~~ **COVID** - **19 vaccine candidates** ~~CoV2- 1 or VXA- CoV2- 1. 1- S~~ are ongoing and important aspects of the trial design have yet to be determined, including the number of patients to be enrolled, the specific endpoints of the trial and the methods for obtaining and testing samples in the trial. The incidence of COVID- 19 in the communities where our studies might be conducted will vary across different locations. If the overall incidence of COVID- 19 in those locations is low, it may be difficult for us to recruit subjects or for any study we might perform to demonstrate differences in infection rates between participants in the study who receive placebo and participants in the study who receive ~~VXA-~~ **COVID** - **19 vaccine candidates** ~~CoV2- 1 or VXA- CoV2- 1. 1- S~~ . The availability of other authorized vaccines may decrease the population of clinical trial subjects willing to participate in our future trials. The FDA has

the authority to grant an Emergency Use Authorization to allow unapproved medical products to be used in an emergency to diagnose, treat, or prevent serious or life- threatening diseases or conditions when there are no adequate, approved, and available alternatives. If we are granted an Emergency Use Authorization for ~~VXA-~~**COVID** - **19 vaccine candidates** ~~CoV2- 1 or VXA- CoV2- 1. 1- S-~~, we would be able to commercialize the vaccine candidate prior to FDA approval. Furthermore, the FDA may revoke an Emergency Use Authorization where it is determined that the underlying health emergency no longer exists or warrants such authorization, and we cannot predict how long, if ever, an Emergency Use Authorization would remain in place. Such revocation could adversely impact our business in a variety of ways, including if the vaccine candidate is not yet approved by the FDA and if we and our manufacturing partners have invested in the supply chain to provide the vaccine candidate under an Emergency Use Authorization. In addition, any success in preclinical testing we might observe for our COVID- 19 vaccine candidates may not be predictive of the results of later- stage human clinical trials. Factors such as efficacy, immunogenicity, and adverse events can emerge at any time in clinical testing and have the potential to have adverse consequences for our ability to proceed with clinical trials. Other factors such as manufacturing challenges, availability of raw materials, and **slowdowns** ~~slow- downs~~ in the global supply chain may delay or prevent us from receiving regulatory approval of our vaccine candidate or, if we do receive regulatory approval, prevent a successful product launch. We may not be successful in developing a vaccine, or another party may be successful in producing a more efficacious vaccine or other treatment for COVID- 19 **. Evolving dynamics in the market for COVID- 19 vaccines are likely to impact our financial results. With the global transition of COVID- 19 from pandemic to endemic, the commercial market for COVID- 19 vaccines is facing several challenges, including a more fragmented customer base, less predictability in orders, greater seasonality of demand, increased distribution costs, and higher costs of goods sold due to single- dose or lower- dose presentations. Such factors could impact the potential market for our COVID- 19 vaccine, if approved. Further, our continued development efforts for our COVID- 19 vaccine could face increased research and development costs, including for clinical trials, when updating COVID- 19 vaccines for new variants of concern** . If we fail to continue to develop and refine the formulations of our tablet vaccine candidates, we may not obtain regulatory approvals, and even if approved, the commercial acceptance of our tablet vaccine candidates would likely be limited. In our H1N1 influenza Phase 2 trial we used vaccine tablets that contained approximately 1. 5 x 1010 IU of vaccine. Accordingly, subjects in this trial were required to take seven tablets in a single setting to reach the aggregate dose of 1 x 1011 IU, the target dose for this trial. We believe that in order to fully capture the commercial success of our seasonal influenza vaccine candidate, we will need to continue to refine our formulation and develop influenza vaccine tablets that contain the desired dose for each vaccine strain in a single tablet, resulting in a vaccination regime of no more than ~~four~~ **three** tablets. Increasing the potency of the vaccine tablets may affect the stability profile of the vaccine and we may not be able to reduce the vaccination regime for an influenza strain to a single tablet or combine the ~~four~~ **three** influenza strains into one vaccine tablet. In addition, increasing the potency of the vaccine tablets or combining the influenza strains necessary to create a ~~quadrivalent~~ **trivalent** vaccine may adversely affect manufacturing yields and render such tablets too costly to manufacture at commercial scale. Our efforts to develop tablet vaccine candidates for norovirus ~~and RSV~~ face similar formulation challenges. If we are unable to further develop and refine the formulations of our tablet vaccine candidates, we may be unable to obtain regulatory approval from the FDA or other regulatory authorities, and even if approved, the commercial acceptance of our tablet vaccine candidates would likely be limited. Clinical trials are very expensive, time- consuming, difficult to design and implement and involve an uncertain outcome, and if they fail to demonstrate safety and efficacy to the satisfaction of the FDA, or similar regulatory authorities, we will be unable to commercialize our tablet vaccine candidates. Our tablet vaccine candidates for norovirus **, coronavirus** and ~~seasonal~~ influenza are still in early- stage clinical development. ~~Both~~ **Our vaccine candidates** will require extensive additional clinical testing before we are prepared to submit a BLA for regulatory approval for either indication or for any other treatment regime. Such testing is expensive and time- consuming and requires specialized knowledge and expertise. We cannot predict with any certainty if or when we might submit a BLA for regulatory approval for any of our tablet vaccine candidates, which are currently in clinical development, or whether any such BLAs will be approved by the FDA. Human clinical trials are very expensive and difficult to design and implement, in part because they are subject to rigorous regulatory requirements. For instance, the FDA may not agree with our proposed endpoints for any clinical trial we propose, which may delay the commencement of our clinical trials. The clinical trial process is also time-consuming. We estimate that the clinical trials we need to conduct to be in a position to submit BLAs for our tablet vaccine candidates for norovirus, ~~seasonal~~ **coronavirus and** influenza ~~, and RSV~~ will take several years to complete. Furthermore, failure can occur at any stage of the trials, and we could encounter problems that cause us to abandon or repeat clinical trials. Our vaccine candidates in the later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through preclinical studies and initial clinical trials. Also, the results of early clinical trials of the tablet vaccine candidates for norovirus, ~~seasonal~~ **coronavirus and** influenza ~~, and RSV~~ may not be predictive of the results of subsequent clinical trials. Furthermore, the FDA may impose additional requirements to conduct preclinical studies to advance the HPV therapeutic vaccine candidates which could delay initiation of Phase 1 studies. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier trials. Moreover, preclinical and clinical data are often susceptible to multiple interpretations and analyses. Many companies that have believed their vaccine candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval of their products. Additionally, success in preclinical testing and early clinical trials does not ensure success in later clinical trials, which involve many more subjects and, for influenza, all four strains rather than the one strain we have studied in Phase 1 clinical trials to date. Accordingly, the results of later clinical trials may not replicate the results of prior clinical trials and preclinical testing or may be interpreted in a way that may not be sufficient for marketing approval. We may experience numerous unforeseen events during, or as a result of, clinical trials that could delay or prevent our ability to receive marketing approval or commercialize our tablet vaccine

candidates, including that: ● regulators or institutional review boards (" IRBs ") may delay or not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site; ● we may experience delays in reaching or fail to reach agreement on acceptable clinical trial contracts or clinical trial protocols with prospective trial sites or CROs; ● clinical trials of our tablet vaccine candidates may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon product development programs; ● the number of subjects required for clinical trials of our tablet vaccine candidates may be larger than we anticipate; enrollment in these clinical trials may be slower than we anticipate, or participants may drop out of these clinical trials at a higher rate than we anticipate; ● our third- party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all; ● regulators or IRBs may require that we or our investigators suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements or a finding that the participants are being exposed to unacceptable health risks; ● the cost of clinical trials of our tablet vaccine candidates may be greater than we anticipate; and ● the supply or quality of our tablet vaccine candidates or other materials necessary to conduct clinical trials may be insufficient or inadequate. If we are required to conduct additional clinical trials or other testing of our tablet vaccine candidates beyond those that we currently contemplate, if we are unable to successfully complete clinical trials of our tablet vaccine candidates or other testing, if the results of these trials or tests are not positive or are only modestly positive or if there are safety concerns, we may: ● be delayed in obtaining marketing approval for our tablet vaccine candidates; ● not obtain marketing approval at all; ● obtain approval for indications or patient populations that are not as broad as intended or desired; ● obtain approval with labeling that includes significant use or distribution restrictions or safety warnings, including boxed warnings; ● be subject to additional post-marketing testing requirements; or ● have the product removed from the market after obtaining marketing approval. Product development costs will also increase if we experience delays in testing or in receiving marketing approvals. We do not know whether any clinical trials will begin as planned, will need to be restructured or will be completed on schedule, or at all. Significant clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize our tablet vaccine candidates, could allow our competitors to bring products to market before we do, and could impair our ability to successfully commercialize our tablet vaccine candidates, any of which may harm our business and results of operations. **A resurgence of the** COVID- 19 **pandemic or the emergence of another public health emergency / pandemic** could adversely impact our preclinical studies and clinical trials. **We have active and planned preclinical studies and clinical trial sites** ~~Since the initial report of a novel strain of coronavirus, SARS- CoV- 2,~~ in ~~China in December 2019,~~ **the United States. While both** COVID- 19 **and countermeasures** ~~has spread to multiple countries, including the United States. We~~ have **abated to some degree,** ~~active and planned preclinical studies and clinical trial sites in the~~ **there** ~~United States. As~~ **can be no assurance that the** COVID- 19 ~~continues~~ **pandemic will not cause disruptions** to ~~spread~~ **our business development activities, including our clinical trials. In the event of a resurgence of the COVID- 19 pandemic or emergence of another public health emergency** , we may experience disruptions that could severely impact our planned and ongoing preclinical studies and clinical trials, including preclinical and clinical studies and manufacturing of ~~VXA- CoV2- 1 and VXA- CoV2- 1. 1- S and clinical trials of~~ our vaccine ~~candidate~~ **candidates** ~~for the GI. 1 and GII. 4 norovirus strains~~ . Effects on our preclinical studies and clinical trial programs include, but are not limited to: ● delays in procuring subjects in our preclinical studies; ● delays or difficulties in enrolling patients in our clinical trials; ● delays or difficulties in preclinical and clinical site initiation, including difficulties in establishing appropriate and safe social distancing and other safeguards at preclinical and clinical sites; ● diversion of healthcare resources away from the conduct of preclinical and clinical trials, including the diversion of hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our clinical trials; ● interruption of key preclinical study and clinical trial activities, such as preclinical and clinical trial site monitoring, subject recruitment and subject testing due to the course of the pandemic, limitations on freight and / or travel imposed or recommended by federal or state governments, employers and others; ● limitations in employee resources that would otherwise be focused on the conduct of our preclinical studies and clinical trials, including because of sickness of employees or their families, delays or difficulties in conducting site visits and other required travel, and the desire of employees to avoid contact with large groups of people; ● delays in receiving approval from local regulatory authorities to initiate or continue our planned preclinical studies and clinical trials; ● regulatory or legal developments in the United States or other countries; and ● the success of competitive vaccine products or COVID- 19 treatments and related technologies. If a patient participating in one of our clinical trials contracts COVID- 19, this could negatively impact the data readouts from these trials; for example, the patient may be unable to participate further (or may have to limit participation) in our clinical trial, the patient may show a different efficacy assessment than if the patient had not been infected, or such patient could experience an adverse event that could be attributed to our drug product. The ~~global outbreak of COVID- 19 continues to rapidly evolve. The~~ extent to which COVID- 19 may impact our preclinical studies and clinical trials will depend on future developments, which ~~are~~ **remains** highly uncertain and cannot be predicted with confidence ~~, such as the ultimate geographic spread of the disease, the duration of the outbreak, travel restrictions and social distancing in the United States and other countries, business closures or business disruptions and the effectiveness of actions taken in the United States and other countries to contain and treat the disease~~ . Our platform includes a novel vaccine adjuvant and all of our current tablet vaccine candidates include this novel adjuvant, which may make it difficult for us to predict the time and cost of tablet vaccine development as well as the requirements the FDA or other regulatory agencies may impose to demonstrate the safety of the tablet vaccine candidates. Novel vaccine adjuvants, included in some of our tablet vaccine candidates, may pose an increased safety risk to patients. Adjuvants are compounds that are added to vaccine antigens to enhance the activation and improve immune response and efficacy of vaccines. Development of vaccines with novel adjuvants requires evaluation in larger numbers of patients prior to approval than would be typical for therapeutic drugs. Guidelines for evaluation of vaccines with novel adjuvants have been established by the FDA and other regulatory bodies and expert committees. Our current tablet vaccine candidates, including for norovirus, include a novel adjuvant, and future vaccine candidates may also include one or more novel

vaccine adjuvants. Any vaccine, because of the presence of an adjuvant, may have side effects considered to pose too great a risk to patients to warrant approval of the vaccine. Traditionally, regulatory authorities have required extensive study of novel adjuvants because vaccines typically get administered to healthy populations, in particular infants, children and the elderly, rather than to people with disease. Such extensive study has often included long- term monitoring of safety in large general populations that has at times exceeded 10, 000 subjects. This contrasts with the few thousand subjects typically necessary for approval of novel therapeutics. To date, the FDA and other major regulatory agencies have only approved vaccines containing five adjuvants, which makes it difficult to determine how long it will take or how much it will cost to obtain regulatory approvals for our tablet vaccine candidates in the United States or elsewhere. Enrollment and retention of subjects in clinical trials is an expensive and time- consuming process and could be made more difficult or rendered impossible by multiple factors outside our control. We may encounter delays in enrolling, or be unable to enroll, a sufficient number of participants to complete any of our clinical trials. Once enrolled, we may be unable to retain a sufficient number of participants to complete any of our trials. Late- stage clinical trials of our tablet vaccine candidate for norovirus and **coronavirus** ~~SARS- CoV- 2~~, in particular, will require the enrollment and retention of large numbers of subjects. Subject enrollment and retention in clinical trials depends on many factors, including the size of the subject population, the nature of the trial protocol, the existing body of safety and efficacy data with respect to the study drug, the number and nature of competing treatments and ongoing clinical trials of competing drugs for the same indication, the proximity of subjects to clinical sites and the eligibility criteria for the study. Further, since there are no reliable animal models to norovirus infection, human challenge studies have been used to understand viral activity and possible immune correlates that prevent infection making trials costlier than animal- based studies. Furthermore, any negative results we may report in clinical trials of our tablet vaccine candidates may make it difficult or impossible to recruit and retain participants in other clinical trials of that same tablet vaccine candidate. Delays or failures in planned subject enrollment or retention may result in increased costs, program delays or both, which could have a harmful effect on our ability to develop our tablet vaccine candidates, or could render further development impossible. In addition, we expect to rely on CROs and clinical trial sites to ensure proper and timely conduct of our future clinical trials and, while we intend to enter into agreements governing their services, we will be limited in our ability to compel their actual performance in compliance with applicable regulations. Enforcement actions brought against these third parties may cause further delays and expenses related to our clinical development programs. We face significant competition from other biotechnology and pharmaceutical companies, and our operating results will suffer if we fail to compete effectively. Vaccine development is highly competitive and subject to rapid and significant technological advancements. We face competition from various sources, including larger and better funded pharmaceutical, specialty pharmaceutical and biotechnology companies, as well as academic institutions, governmental agencies and public and private research institutions. In particular, our influenza vaccine candidate would compete with products that are available and have gained market acceptance as the standard treatment protocol. Further, it is likely that additional drugs or other treatments will become available in the future for the treatment of the diseases we are targeting. For tablet vaccines, we face competition from approved vaccines, against which new tablet vaccines must demonstrate compelling advantages in efficacy, convenience, tolerability and safety, and from competitors working to patent, discover, develop or commercialize medicines before we can do the same with tablet vaccines. Many of our existing or potential competitors have substantially greater financial, technical and human resources than we do and significantly greater experience in the discovery and development of products for the treatment of diseases, as well as in obtaining regulatory approvals of those products in the United States and in foreign countries. Our current and potential future competitors also have significantly more experience commercializing drugs that have been approved for marketing. Mergers and acquisitions in the pharmaceutical and biotechnology industries could result in even more resources being concentrated among a small number of our competitors. Competition may increase further as a result of advances in the commercial applicability of technologies and greater availability of capital for investment in these industries. Our competitors may succeed in developing, acquiring or licensing, on an exclusive basis, drugs that are more effective or less costly than any tablet vaccine candidate that we may develop. We will face competition from other drugs currently approved or that will be approved in the future for the treatment of the other infectious diseases we are currently targeting. Therefore, our ability to compete successfully will depend largely on our ability to: ● develop and commercialize tablet vaccine candidates that are superior to other vaccines in the market; ● demonstrate through our clinical trials that our tablet vaccine candidates are differentiated from existing and future therapies; ● attract qualified scientific, vaccine development and commercial personnel; ● obtain patent or other proprietary protection for our tablet vaccine candidates; ● obtain required regulatory approvals; ● obtain coverage and adequate reimbursement from, and negotiate competitive pricing with, third- party payors; and ● successfully develop and commercialize, independently or with collaborators, new tablet vaccine candidates. The availability of our competitors' vaccines could limit the demand, and the price we are able to charge, for any tablet vaccine candidate we develop. The inability to compete with existing or subsequently introduced vaccines would have an adverse impact on our business, financial condition and prospects. Established pharmaceutical companies may invest heavily to accelerate discovery and development of novel compounds or to in- license novel compounds that could make any of our tablet vaccine candidates less competitive. In addition, any new vaccine that competes with an approved vaccine must demonstrate compelling advantages in efficacy, convenience, tolerability and safety in order to overcome price competition and to be commercially successful. Accordingly, our competitors may succeed in obtaining patent protection, discovering, developing, receiving the FDA' s approval for or commercializing medicines before we do, which would have an adverse impact on our business and results of operations. The biotechnology and pharmaceutical industries are characterized by intense competition to develop new technologies and proprietary products. While we believe that our proprietary tablet vaccine candidates provide competitive advantages, we face competition from many different sources, including biotechnology and pharmaceutical companies, academic institutions, government agencies, as well as public and private research institutions. Any products that we may commercialize will have to compete with existing products and therapies

as well as new products and therapies that may become available in the future. There are other organizations working to improve existing therapies, vaccines or delivery methods, or to develop new vaccines, therapies or delivery methods for their selected indications. Depending on how successful these efforts are, it is possible they may increase the barriers to adoption and success of our vaccine candidates, if approved. We anticipate that we will face intense and increasing competition as new vaccines enter the market and advanced technologies become available. We expect any tablet or other oral delivery vaccine candidates that we develop and commercialize to compete on the basis of, among other things, efficacy, safety, convenience of administration and delivery, price, availability of therapeutics, the level of generic competition and the availability of reimbursement from government and other third- party payors. Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than any products that we may develop. Our competitors also may obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for our vaccine candidates, which could result in our competitors establishing a strong market position before we are able to enter the market. In addition, our ability to compete may be affected in many cases by insurers or other third- party payors seeking to encourage the use of generic products. There is currently no approved norovirus vaccine for sale globally. We ~~believe~~ **are aware** that HilleVax, Inc. ~~is~~ **and Moderna, Inc. are** developing ~~a~~ norovirus ~~vaccine~~ **vaccines** ~~(originally developed by Takeda)~~ that would be delivered by injection. Another company developing a norovirus vaccine candidate is Anhui Zhifei Longcom Biopharmaceutical Co. Ltd. There may be other development programs that we are not aware of. There is significant competition in the COVID- 19 vaccine market. Pfizer- BioNTech' s COVID- 19 vaccine ~~and~~ **,** Moderna **' s COVID- 19 vaccine and Novavax** ' s COVID- 19 vaccine have been approved in the United States and many countries around the world. Johnson & Johnson' s COVID- 19 vaccine and AstraZeneca' s COVID- 19 vaccine have been approved in many countries around the globe and have supplied the majority of the" western doses" to the world ~~. Other vaccine companies that have received approval in countries around the world for their COVID- 19 vaccines include Sanofi S. A. and Novavax~~ . Our tablet vaccine candidates may cause adverse effects or have other properties that could delay or prevent their regulatory approval or limit the scope of any approved label or market acceptance. Adverse events caused by our tablet vaccine candidates could cause reviewing entities, clinical trial sites or regulatory authorities to interrupt, delay or halt clinical trials and could result in the denial of regulatory approval. If an unacceptable frequency or severity of adverse events are reported in clinical trials for our tablet vaccine candidates, our ability to obtain regulatory approval for such tablet vaccine candidates may be negatively impacted. Furthermore, if any of our tablet vaccines are approved and then cause serious or unexpected side effects, a number of potentially significant negative consequences could result, including: ● regulatory authorities may withdraw their approval of the tablet vaccine candidates or impose restrictions on their distribution or other risk management measures; ● regulatory authorities may require the addition of labeling statements, such as warnings or contraindications; ● we may be required to change the way our tablet vaccine candidates are administered or to conduct additional clinical trials; ● we could be sued and held liable for injuries sustained by patients; ● we could be subject to the Vaccine Injury Compensation Program; ● we could elect to discontinue the sale of our tablet vaccine candidates; and ● our reputation may suffer. Any of these events could prevent us from achieving or maintaining market acceptance of the affected tablet vaccine candidate and could substantially increase the costs of commercialization. If we are not able to obtain, or if there are delays in obtaining, required regulatory approvals, we will not be able to commercialize, or will be delayed in commercializing, our tablet vaccine candidates, and our ability to generate significant revenue will be impaired. Our tablet vaccine candidates and the activities associated with their development and commercialization, including their design, testing, manufacture, safety, efficacy, recordkeeping, labeling, storage, approval, advertising, promotion, sale and distribution, are subject to comprehensive regulation by the FDA and other regulatory agencies in the United States and by comparable authorities in other countries. Failure to obtain marketing approval for a tablet vaccine candidate will prevent us from commercializing the tablet vaccine candidate. We have not received approval to market any of our tablet vaccine candidates from regulatory authorities in any jurisdiction. We have only limited experience in filing and supporting the applications necessary to gain marketing approvals and expect to rely on CROs to assist us in this process. Securing regulatory approval requires the submission of extensive preclinical and clinical data and supporting information to the various regulatory authorities for each therapeutic indication to establish the tablet vaccine candidate' s safety and efficacy. Securing regulatory approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, the relevant regulatory authority. Our tablet vaccine candidates may not be effective, may be only moderately effective or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude us obtaining marketing approval or prevent or limit commercial use. The process of obtaining marketing approvals, both in the United States and elsewhere, is expensive, may take many years and can vary substantially based upon a variety of factors, including the type, complexity and novelty of the tablet vaccine candidates involved. We cannot be sure that we will ever obtain any marketing approvals in any jurisdiction. Changes in marketing approval policies during the development period, changes in or the enactment of additional statutes or regulations or changes in regulatory review for each submitted product application may cause delays in the approval or rejection of an application. The FDA and comparable authorities in other countries have substantial discretion in the approval process and may refuse to accept any application or may decide that our data is insufficient for approval and require additional preclinical or other studies, and clinical trials. In addition, varying interpretations of the data obtained from preclinical testing and clinical trials could delay, limit or prevent marketing approval of a tablet vaccine candidate. Additionally, any marketing approval we ultimately obtain may be limited or subject to restrictions or post- approval commitments that render the approved product not commercially viable. Even if we obtain FDA approval in the United States, we may never obtain approval for or commercialize our tablet vaccine candidates in any other jurisdiction, which would limit our ability to realize each product' s full market potential. In order to market any of our tablet vaccine candidates in a particular jurisdiction, we must establish and comply with numerous and varying regulatory requirements on a country- by- country basis

regarding safety and efficacy. Approval by the FDA in the United States does not ensure approval by regulatory authorities in other countries or jurisdictions. In addition, clinical trials conducted in one country may not be accepted by regulatory authorities in other countries, and regulatory approval in one country does not guarantee regulatory approval in any other country. Approval processes vary among countries and can involve additional tablet vaccine candidate testing and validation and additional administrative review periods. Seeking foreign regulatory approval could result in difficulties and costs for us and require additional preclinical studies or clinical trials which could be costly and time consuming. Regulatory requirements can vary widely from country to country and could delay or prevent the introduction of our tablet vaccine candidates in those countries. We do not have any tablet vaccine candidates approved for sale in any jurisdiction, including in international markets, and we do not have experience in obtaining regulatory approval in international markets. If we fail to comply with regulatory requirements in international markets or to obtain and maintain required approvals, or if regulatory approvals in international markets are delayed, our target market will be reduced and our ability to realize the full market potential of any tablet vaccine candidate we develop will be unrealized. Even if we obtain regulatory approval, we will still face extensive ongoing regulatory requirements and our tablet vaccine candidates may face future development and regulatory difficulties. Any tablet vaccine candidate for which we obtain marketing approval, along with the manufacturing processes, post- approval clinical data, labeling, packaging, distribution, adverse event reporting, storage, recordkeeping, export, import, advertising and promotional activities for such tablet vaccine candidate, among other things, will be subject to extensive and ongoing requirements of and review by the FDA and other regulatory authorities. These requirements include submissions of safety, efficacy and other post-marketing information and reports, establishment registration and drug listing requirements, continued compliance with current Good Manufacturing Practice, or cGMP, requirements relating to manufacturing, quality control, quality assurance and corresponding maintenance of records and documents, requirements regarding the distribution of samples to physicians and recordkeeping and current good clinical practice, or GCP, requirements for any clinical trials that we conduct post- approval. Even if marketing approval of a tablet vaccine candidate is granted, the approval may be subject to limitations on the indicated uses for which the tablet vaccine candidates may be marketed or to the conditions of approval. If a tablet vaccine candidate receives marketing approval, the accompanying label may limit the approved use of that tablet vaccine, which could limit sales. The FDA may also impose requirements for costly post- marketing studies or clinical trials and surveillance to monitor the safety and / or efficacy of our tablet vaccine candidates. The FDA closely regulates the post- approval marketing and promotion of drugs to ensure drugs are marketed only for the approved indications and in accordance with the provisions of the approved labeling. The FDA imposes stringent restrictions on manufacturers' communications regarding off- label use and if we do not market our tablet vaccine candidates for their approved indications, we may be subject to enforcement action for off- label marketing. Violations of the Federal Food, Drug, and Cosmetic Act relating to the promotion of prescription drugs may lead to FDA enforcement actions and investigations alleging violations of federal and state health care fraud and abuse laws, as well as state consumer protection laws. In addition, later discovery of previously unknown adverse events or other problems with our tablet vaccine candidates, manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may yield various results, including: ● restrictions on manufacturing such tablet vaccine candidate; ● restrictions on the labeling or marketing of a tablet vaccine candidate; ● restrictions on tablet vaccine distribution or use; ● requirements to conduct post-marketing studies or clinical trials; ● warning letters; ● withdrawal of the tablet vaccine candidate from the market; ● refusal to approve pending applications or supplements to approved applications that we submit; ● recall of such tablet vaccine candidate; ● fines, restitution or disgorgement of profits or revenues; ● suspension or withdrawal of marketing approvals; ● refusal to permit the import or export of such tablet vaccine candidate; ● tablet vaccine candidate seizure; or ● injunctions or the imposition of civil or criminal penalties. The FDA' s policies may change, and additional government regulations may be enacted, that could prevent, limit or delay regulatory approval of any of our tablet vaccine candidates. 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. Even if our tablet vaccine candidates receive marketing approval, they may fail to achieve market acceptance by physicians, patients, third- party payors or others in the medical community necessary for commercial success. If our tablet vaccine candidates, including our vaccine for coronavirus and norovirus, receive marketing approval, they may nonetheless fail to gain sufficient market acceptance by physicians, patients, third- party payors and others in the medical community. If they do not achieve an adequate level of acceptance, we may not generate significant revenues and become profitable. The degree of market acceptance, if approved for commercial sale, will depend on a number of factors, including but not limited to: ● the efficacy and potential advantages compared to alternative treatments; ● effectiveness of sales and marketing efforts; ● the cost of treatment in relation to alternative treatments; ● our ability to offer our tablet vaccine candidates for sale at competitive prices; ● the convenience and ease of administration compared to alternative treatments; ● the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies; ● the willingness of the medical community to offer customers our tablet vaccine candidate option in addition to, or in the place of, injectable vaccines; ● the strength of marketing and distribution support; ● the availability of third- party coverage and adequate reimbursement; ● the prevalence and severity of any side effects; and ● any restrictions on the use of our tablet vaccine together with other medications. Because we expect sales of our tablet vaccine candidate for coronavirus and / or norovirus, if approved, to generate substantially all of our revenues for the foreseeable future, the failure of these tablet vaccines to achieve market acceptance would harm our business and could require us to seek additional financing sooner than we would otherwise plan. If we fail to comply with state and federal healthcare regulatory laws, we could face substantial penalties, damages, fines, disgorgement, exclusion from participation in governmental healthcare programs, and the curtailment of our operations, any of which could harm our business. Although we do not provide healthcare services or submit claims for third- party reimbursement, we are subject to healthcare fraud and abuse regulation and enforcement by federal and state governments, which could significantly impact our business. The laws that may affect our ability to operate

include, but are not limited to: ● the federal Anti- Kickback Statute, which prohibits, among other things, persons and entities from knowingly and willfully soliciting, receiving, offering, or paying remuneration, directly or indirectly, in cash or in kind, in exchange for or to induce 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 federal healthcare programs such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of this statute or specific intent to violate it; ● the civil False Claims Act, or FCA, which prohibits, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid or other third- party payors that are false or fraudulent; knowingly making, using, or causing to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the government; or knowingly making, using, or causing to be made or used, a false record or statement to avoid, decrease or conceal an obligation to pay money to the federal government; ● the criminal FCA, which imposes criminal fines or imprisonment against individuals or entities who make or present a claim to the government knowing such claim to be false, fictitious or fraudulent; ● the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created federal criminal laws that prohibit executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters; ● the federal civil monetary penalties statute, which prohibits, among other things, the offering or giving of remuneration to a Medicare or Medicaid beneficiary that the person knows or should know is likely to influence the beneficiary' s selection of a particular supplier of items or services reimbursable by a federal or state governmental program; ● the federal physician sunshine requirements under the Affordable Care Act, which require certain manufacturers of drugs, devices, biologics, and medical supplies to report annually to the U. S. Department of Health and Human Services information related to payments and other transfers of value to physicians, other healthcare providers, and teaching hospitals, and ownership and investment interests held by physicians and other healthcare providers and their immediate family members; and ● state law equivalents of each of the above federal laws, such as anti- kickback and false claims laws that may apply to items or services reimbursed by any third- party payor, including commercial insurers; state laws that require pharmaceutical companies to comply with the device industry' s voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; and state laws that require device manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures. Further, the Affordable Care Act, among other things, amended the intent requirements of the federal Anti- Kickback Statute and certain criminal statutes governing healthcare fraud. A person or entity can now be found guilty of violating the statute without actual knowledge of the statute or specific intent to violate it. In addition, the Affordable Care Act provided that the government may assert that a claim including items or services resulting from a violation of the federal Anti- Kickback Statute constitutes a false or fraudulent claim for purposes of the FCA. Moreover, while we do not, and will not, submit claims and our customers will make the ultimate decision on how to submit claims, we may provide reimbursement guidance to our customers from time to time. If a government authority were to conclude that we provided improper advice to our customers or encouraged the submission of false claims for reimbursement, we could face action against us by government authorities. Any violations of these laws, or any action against us for violation of these laws, even if we successfully defend against it, could result in a material adverse effect on our reputation, business, results of operations and financial condition. We have entered into consulting and scientific advisory board arrangements with physicians and other healthcare providers. Compensation for some of these arrangements includes the provision of stock options. While we have worked to structure our arrangements to comply with applicable laws, because of the complex and far-reaching nature of these laws, regulatory agencies may view these transactions as prohibited arrangements that must be restructured, or discontinued, or for which we could be subject to other significant penalties. We could be adversely affected if regulatory agencies interpret our financial relationships with providers who influence the ordering of and use our products to be in violation of applicable laws. The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform, especially in light of the lack of applicable precedent and regulations. Federal and state enforcement bodies have recently increased their scrutiny of interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry. Responding to investigations can be time- and resource- consuming and can divert management' s attention from the business. Additionally, as a result of these investigations, healthcare providers and entities may have to agree to additional onerous compliance and reporting requirements as part of a consent decree or corporate integrity agreement. Any such investigation or settlement could increase our costs or otherwise have an adverse effect on our business. Product liability lawsuits against us could cause us to incur substantial liabilities and could limit the commercialization of any tablet vaccine candidates we may develop. We face an inherent risk of product liability exposure related to the testing of our tablet vaccine candidates in human clinical trials and will face an even greater risk if we commercially sell any products that we may develop after approval. For instance, since our norovirus tablet challenge study is being conducted in healthy human volunteers, any adverse reactions could result in claims from these injuries and we could incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in: ● decreased demand for any tablet vaccine candidates that it may develop; ● injury to our reputation and significant negative media attention; ● withdrawal of clinical trial participants; ● significant costs to defend any related litigation; ● substantial monetary awards to trial subjects or patients; ● loss of revenue; and ● the inability to commercialize any products we may develop. Although we maintain product liability insurance coverage in the amount of up to $ 10 million per claim and in the aggregate, it may not be adequate to cover all liabilities that we may incur. Additionally, seasonal influenza is a covered vaccine of the National Vaccine Injury Compensation Program, and our participation in that program may require time and resources that impede product uptake, if approved. We anticipate that we will need to increase our insurance coverage as we continue clinical trials and if we successfully commercialize any products. Insurance coverage is increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may

arise. If a product liability claim is successfully brought against us for uninsured liabilities, or such claim exceeds our insurance coverage, we could be forced to pay substantial damage awards that could materially harm our business. The use of any of our existing or future product candidates in clinical trials and the sale of any approved pharmaceutical products may expose us to significant product liability claims. We currently have product liability insurance coverage for our ongoing clinical trials in the amount of up to $ 5 million. Further, we also require clinical research and manufacturing organizations that assist us in the conduct of our trials or manufacture materials used in these trials to carry product liability insurance against such claims. This insurance coverage may not protect us against any or all of the product liability claims that may be brought against us in the future. We may not be able to acquire or maintain adequate product liability insurance coverage at a commercially reasonable cost or in sufficient amounts or scope to protect ourselves against potential losses. In the event a product liability claim is brought against us, we may be required to pay legal and other expenses to defend the claim, as well as uncovered damage awards resulting from a claim brought successfully against us. In the event any of our product candidates are approved for sale by the FDA or similar regulatory authorities in other countries and commercialized, we may need to substantially increase the amount of our product liability coverage. Defending any product liability claim or claims could require us to expend significant financial and managerial resources, which could have an adverse effect on our business. If we are unable to establish sales, marketing and distribution capabilities either on our own or in collaboration with third parties, we may not be successful in commercializing our tablet vaccine candidates, if approved. We do not have any infrastructure for the sales, marketing or distribution of our tablet vaccine candidates, and the cost of establishing and maintaining such an organization may exceed the cost- effectiveness of doing so. In order to market any tablet vaccine candidates that may be approved, it must build our sales, distribution, marketing, managerial and other non- technical capabilities or make arrangements with third parties to perform these services. To achieve commercial success for any tablet vaccine candidates for which we have obtained marketing approval, we will need a sales and marketing organization. While we expect to partner our tablet ~~vaccines~~ **vaccine** for seasonal influenza ~~and RSV~~, we expect to build a focused sales, distribution and marketing infrastructure to market our other tablet vaccine candidates in the United States, if approved. There are significant expenses and risks involved with establishing our own sales, marketing and distribution capabilities, including our ability to hire, retain and appropriately incentivize qualified individuals, generate sufficient sales leads, provide adequate training to sales and marketing personnel, and effectively manage a geographically dispersed sales and marketing team. Any failure or delay in the development of our internal sales, marketing and distribution capabilities could delay any tablet vaccine candidate launch, which would adversely impact commercialization. Factors that may inhibit our efforts to commercialize our tablet vaccine candidates on our own include: ● our inability to recruit, train and retain adequate numbers of effective sales and marketing personnel; ● the inability of sales personnel to obtain access to physicians or attain adequate numbers of physicians to administer our tablet vaccines; and ● unforeseen costs and expenses associated with creating an independent sales and marketing organization. We intend to pursue collaborative arrangements regarding the sale and marketing of our tablet vaccine candidates, if approved, for certain international markets; however, we may not be able to establish or maintain such collaborative arrangements and, if able to do so, our collaborators may not have effective sales. To the extent that we depend on third parties for marketing and distribution, any revenues we receive will depend upon the efforts of such third parties, and we cannot assure you that such efforts will be successful. If we are unable to build our own sales force in the United States or negotiate a collaborative relationship for the commercialization of our tablet vaccine candidates outside the United States **,** we may be forced to delay the potential commercialization or reduce the scope of our sales and marketing activities. We could have to enter into arrangements with third parties at an earlier stage than we would otherwise choose and we may be required to relinquish rights to our intellectual property or otherwise agree to terms unfavorable to us, any of which may have an adverse effect on our business, operating results and prospects. We may be competing with many companies that currently have extensive and well- funded marketing and sales operations. Without an internal team or the support of a third ~~-~~party to perform marketing and sales functions, we may be unable to compete successfully against these more established companies. If we obtain approval to commercialize any tablet vaccine candidates outside of the United States, a variety of risks associated with international operations could harm our business. If our tablet vaccine candidates are approved for commercialization, we intend to enter into agreements with third parties to market them in certain jurisdictions outside the United States. We expect that we will be subject to additional risks related to international operations or entering into international business relationships, including: ● different regulatory requirements for drug approvals and rules governing drug commercialization in foreign countries; ● reduced protection for intellectual property rights; ● unexpected changes in tariffs, trade barriers and regulatory requirements; ● economic weakness, including inflation, or political instability in particular foreign economies and markets; ● compliance with tax, employment, immigration and labor laws for employees living or traveling abroad; ● foreign reimbursement, pricing and insurance regimes; ● foreign taxes; ● foreign currency fluctuations, which could result in increased operating expenses and reduced revenues, and other obligations incident to doing business in another country; ● workforce uncertainty in countries where labor unrest is more common than in the United States; ● potential noncompliance with the U. S. Foreign Corrupt Practices Act, the U. K. Bribery Act 2010 and similar anti- bribery and anticorruption laws in other jurisdictions; ● tablet vaccination shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and ● business interruptions resulting from geopolitical actions, including war and terrorism, or natural disasters including earthquakes, typhoons, floods and fires. We have no prior experience in these areas. In addition, there are complex regulatory, tax, labor and other legal requirements imposed by both the European Union and many of the individual countries in Europe with which we will need to comply. Government involvement may limit the commercial success of our tablet vaccine candidates. Various government entities, including the U. S. government, are offering incentives, grants and contracts to encourage additional investment by commercial organizations into preventative and therapeutic agents against coronavirus and influenza, which may have the effect of increasing the number of competitors and / or providing advantages to known competitors. Accordingly, there can be no assurance that we will be able to successfully establish a competitive market

share for our coronavirus or influenza vaccines. In addition, current influenza vaccines are generally trivalent (containing three strains) or quadrivalent (containing four strains). If the FDA requires or recommends changes in influenza vaccines, for example, for a monovalent vaccine or for use of a strain that is not currently circulating in the human population, it is uncertain whether we will be able to produce or manufacture such a vaccine at commercially reasonable rates. The seasonal nature of our target indications, in particular influenza, and competition from new products may cause unpredictable royalty revenues from Inavir and significant fluctuations in our operating results. Influenza is seasonal in nature with sales of current vaccines occurring primarily in the first and fourth quarters of the calendar year. In addition, outbreaks of norovirus ~~and RSV~~ typically occur in the winter season. This seasonal concentration of product sales could cause quarter- to- quarter operating results to vary widely and can exaggerate the consequences of revenues of any manufacturing or supply delays, any sudden loss of inventory, any inability to satisfy product demand, the inability to estimate the effect of returns and rebates, normal or unusual fluctuations in customer buying patterns, or of any unsuccessful sales or marketing strategies during the sales seasons. We earn royalty revenue from the net sales of Inavir, which is marketed by our licensee. Although the royalty rates paid to us by our licensees are fixed at a proportion of the licensee' s net sales of these products, our periodic and annual revenues from these royalties have historically been variable and subject to fluctuation based on the seasonal incidence and severity of influenza. It is the seasonality of influenza, which occurs mainly in the winter months, that causes our revenue to be low in the second and third fiscal quarters, since our agreement with HealthCare Royalty Partners III, L. P. (see Note 7 to our **Consolidated** Financial Statements on Part II, Item 8) has no impact on total revenue recognized, it only impacts our net cash flow in the quarter following revenue recognition. We cannot predict with any certainty what our royalty revenues are likely to be in any given year. In addition, our licensee may encounter competition from new products entering the market, including generic copies of Inavir, which could adversely affect our royalty income. The last patent related to Inavir is set to expire in December 2029 in Japan, at which time royalty revenue will cease. However, the patent covering the laninamivir octanoate compound expires in 2024, at which time generic competition may enter the market, potentially decreasing or eliminating the royalties received. On February 23, 2018, Osaka- based drug maker Shionogi & Co., Ltd. gained marketing approval for Xofluza, a new drug to treat influenza in Japan. The drug was approved for use against type A and B influenza viruses and requires only a single dose regardless of age. Xofluza has gained significant market share from Inavir in Japan, substantially reducing the sales of Inavir. This will significantly decrease the royalty payments we receive from Daiichi Sankyo Company, Limited. Our success depends largely upon our ability to advance our product candidates through the various stages of drug development. If we are unable to successfully advance or develop our product candidates, our business will be materially harmed. Even though we generate royalty revenue from **a** ~~our two~~ commercialized influenza ~~products~~ **product**, all of our remaining product candidates are in early stages of development and their commercial viability remains subject to the successful outcome of future preclinical studies, clinical trials, manufacturing processes, regulatory approvals and the risks generally inherent in the development of pharmaceutical product candidates. Failure to advance the development of one or more of our product candidates may have a material adverse effect on our business. For example, the Phase 2 trial of teslexivir, a product acquired through the merger with Aviragen, was costly and diverted resources from our other product candidates and did not achieve the primary efficacy endpoint, resulting in abandonment of development activities. The long- term success of our business ultimately depends upon our ability to advance the development of our product candidates through preclinical studies and clinical trials, appropriately formulate and consistently manufacture them in accordance with strict specifications and regulations, obtain approval of our product candidates for sale by the FDA or similar regulatory authorities in other countries, and ultimately have our product candidates successfully commercialized, either by us or by a strategic partner or licensee. We cannot be sure that the results of our ongoing or future research, preclinical studies or clinical trials will support or justify the continued development of our product candidates, or that we will ultimately receive approval from the FDA, or similar regulatory authorities in other countries, to advance the development of our product candidates. Our product candidates must satisfy rigorous regulatory standards of safety, efficacy and manufacturing before we can advance or complete their development and before they can be approved for sale by the FDA or similar regulatory authorities in other countries. To satisfy these standards, we must engage in expensive and lengthy studies and clinical trials, develop acceptable and cost- effective manufacturing processes, and obtain regulatory approval of our product candidates. Despite these efforts, our product candidates may not: ● demonstrate clinically meaningful therapeutic or other medical benefits as compared to a patient receiving no treatment or over existing drugs or other product candidates in development to treat the same patient population; ● be shown to be safe and effective in future preclinical studies or clinical trials; ● have the desired therapeutic or medical effects; ● be tolerable or free from undesirable or unexpected side effects; ● meet applicable regulatory standards; ● be capable of being appropriately formulated and manufactured in commercially suitable quantities or scale and at an acceptable cost; or ● be successfully commercialized, either by us or by our licensees or collaborators. Even if we demonstrate favorable results in preclinical studies and early- stage clinical trials, we cannot be sure that the results of late- stage clinical trials will be sufficient to support the continued development of our product candidates. Many, if not most, companies in the pharmaceutical and biopharmaceutical industries have experienced significant delays, setbacks and failures in all stages of development, including late- stage clinical trials, even after achieving promising results in preclinical testing or early- stage clinical trials. Accordingly, results from completed preclinical studies and early- stage clinical trials of our product candidates may not be predictive of the results we may obtain in future late- stage trials. Furthermore, even if the data collected from preclinical studies and clinical trials involving any of our product candidates demonstrate a satisfactory safety, tolerability and efficacy profile, such results may not be sufficient to obtain regulatory approval from the FDA in the United States, or other similar regulatory agencies in other jurisdictions, which is required to market and sell the product. If the actual or perceived therapeutic benefits, or the safety or tolerability profile of any of our product candidates are not equal to or superior to other competing treatments approved for sale or in clinical development, we may terminate the development of any of our product candidates at any time, and our business prospects and potential profitability could be harmed. We are aware of a

number of companies marketing or developing various classes of anti- infective product candidates or products for the treatment of patients infected with HPV ~~and RSV~~ that are either approved for sale or further advanced in clinical development than ours, such that their time to approval and commercialization may be shorter than that for our product candidates ~~. Effective treatments of RSV infections in pediatrics, the elderly, and the immunocompromised are very limited. Currently, only Virazole (ribavirin) is indicated for the treatment of hospitalized infants and young children with severe lower respiratory tract infections due to RSV. Approved drug for the prevention of RSV infections in infants include MedImmune' s palivizumab (Synagis), a monoclonal antibody, and Sanofi and AstraZeneca' s nirsevimab (Beyfortus). There are several vaccines designed to prevent RSV infections in clinical development. Among the clinical stage product candidates in late- stage development are Pfizer' s RSVpreF vaccine, Moderna' s mRNA- 1345, Novavax' s RSV F vaccine, and GSK' s GSK3844766A vaccine~~ . If at any time we believe that any of our product candidates may not provide meaningful or differentiated therapeutic benefits, perceived or real, equal to or better than our competitors' products or product candidates, or we believe that our product candidates may not have as favorable a safety or tolerability profile as potentially competitive compounds, we may delay or terminate the future development of any of our product candidates. We cannot provide any assurance that the future development of any of our product candidates will demonstrate any meaningful therapeutic benefits over potentially competitive compounds currently approved for sale or in development, or an acceptable safety or tolerability profile sufficient to justify their continued development. Our product candidates may exhibit undesirable side effects when used alone or in combination with other approved pharmaceutical products, which may delay or preclude their development or regulatory approval or limit their use if ever approved. Throughout the drug development process, we must continually demonstrate the activity, safety and tolerability of our product candidates in order to obtain regulatory approval to further advance their clinical development, or to eventually market them. Even if our product candidates demonstrate adequate biologic activity and clear clinical benefit, any unacceptable side effects or adverse events, when administered alone or in the presence of other pharmaceutical products, may outweigh these potential benefits. We may observe adverse or serious adverse events or drug- drug interactions in preclinical studies or clinical trials of our product candidates, which could result in the delay or termination of their development, prevent regulatory approval, or limit their market acceptance if they are ultimately approved. If the results from preclinical studies or clinical trials of our product candidates, including those that are subject to existing or future license or collaboration agreements, are unfavorable, we could be delayed or precluded from the further development or commercialization of our product candidates, which could materially harm our business. In order to further advance the development of, and ultimately receive marketing approval to sell our product candidates, we must conduct extensive preclinical studies and clinical trials to demonstrate their safety and efficacy to the satisfaction of the FDA or similar regulatory authorities in other countries, as the case may be. Preclinical studies and clinical trials are expensive, complex, can take many years to complete, and have highly uncertain outcomes. Delays, setbacks, or failures can and do occur at any time, and in any phase of preclinical or clinical testing, and can result from concerns about safety, tolerability, toxicity, a lack of demonstrated biologic activity or improved efficacy over similar products that have been approved for sale or are in more advanced stages of development, poor study or trial design, and issues related to the formulation or manufacturing process of the materials used to conduct the trials. The results of prior preclinical studies or early- stage clinical trials are not predictive of the results we may observe in late- stage clinical trials. In many cases, product candidates in clinical development may fail to show the desired tolerability, safety and efficacy characteristics, despite having favorably demonstrated such characteristics in preclinical studies or early- stage clinical trials. In addition, we may experience numerous unforeseen events during, or as a result of, preclinical studies and the clinical trial process, which could delay or impede our ability to advance the development of, receive marketing approval for, or commercialize our product candidates, including, but not limited to: ● communications with the FDA, or similar regulatory authorities in different countries, regarding the scope or design of a trial or trials, or placing the development of a product candidate on clinical hold or delaying the next phase of development until questions or issues are satisfactorily resolved, including performing additional studies to answer their queries; ● regulatory authorities or IRBs not authorizing us to commence or conduct a clinical trial at a prospective trial site; ● enrollment in our clinical trials being delayed, or proceeding at a slower pace than we expected, because we have difficulty recruiting participants or participants drop out of our clinical trials at a higher rate than we anticipated; ● our third- party contractors, upon whom we rely to conduct preclinical studies, clinical trials and the manufacturing of our clinical trial materials, failing to comply with regulatory requirements or meet their contractual obligations to us in a timely manner; ● having to suspend or ultimately terminate a clinical trial if participants are being exposed to unacceptable health or safety risks; ● regulatory authorities or IRBs requiring that we hold, suspend or terminate our preclinical studies and clinical trials for various reasons, including non- compliance with regulatory requirements; and ● the supply or quality of material necessary to conduct our preclinical studies or clinical trials being insufficient, inadequate or unavailable. Even if the data collected from preclinical studies or clinical trials involving our product candidates demonstrate a satisfactory tolerability, safety and efficacy profile, such results may not be sufficient to support the submission of a BLA or NDA to obtain regulatory approval from the FDA in the United States, or other similar regulatory authorities in other foreign jurisdictions, which is required for us to market and sell our product candidates. We have a limited capacity for managing clinical trials, which could delay or impair our ability to initiate or complete clinical trials of our product candidates on a timely basis and materially harm our business. We have a limited capacity to recruit and manage all of the clinical trials necessary to obtain approval for our product candidates by the FDA or similar regulatory authorities in other countries. By contrast, larger pharmaceutical and biopharmaceutical companies often have substantial staff or departments with extensive experience in conducting clinical trials with multiple product candidates across multiple indications and obtaining regulatory approval in various countries. In addition, these companies may have greater financial resources to compete for the same clinical investigators, sites and patients that we are attempting to recruit for our clinical trials. As a result, we may be at a competitive disadvantage that could delay the initiation, recruitment, timing and completion of our clinical trials and obtaining of marketing approvals, if achieved at all, for

our product candidates. Our industry is highly competitive and subject to rapid technological changes. As a result, we may be unable to compete successfully or develop innovative or differentiated products, which could harm our business. Our industry is highly competitive and characterized by rapid technological change. Key competitive factors in our industry include, among others, the ability to successfully advance the development of a product candidate through preclinical and clinical trials; the efficacy, toxicology, tolerability, safety, resistance or cross- resistance, interaction or dosing profile of a product or product candidate; the timing and scope of marketing approvals, if ever achieved; reimbursement rates for and the average selling price of competing products and pharmaceutical products in general; the availability of raw materials and qualified contract manufacturing and manufacturing capacity to produce our product candidates; relative manufacturing costs; establishing, maintaining and protecting our intellectual property and patent rights; and sales and marketing capabilities. Developing pharmaceutical product candidates is a highly competitive, expensive and risky activity with a long business cycle. Many organizations, including the large pharmaceutical and biopharmaceutical companies that have existing products on the market or in clinical development that may compete with our product candidates, have substantially more resources than us, as well as much greater capabilities and experience than we have in research and discovery, designing and conducting preclinical studies and clinical trials, operating in a highly regulated environment, formulating and manufacturing drug substances, products and devices, and marketing and sales. Our competitors may be more successful than us in obtaining regulatory approvals for their product candidates and achieving broad market acceptance once they are approved. Our competitors' products or product candidates may be more effective, have fewer adverse effects, be more convenient to administer, have a more favorable resistance profile, or be more effectively marketed and sold than any product that we, or our potential future licensees or collaborators, may develop or commercialize. New drugs or classes of drugs from competitors may render our product candidates obsolete or non- competitive before we are able to successfully develop them or, if approved, before we can recover the expenses of developing and commercializing them. We anticipate that we, or our potential future licensees or collaborators, will face intense and increasing competition as new drugs and drug classes enter the market and advanced technologies or new drug targets become available. If our product candidates do not demonstrate any meaningful competitive advantages over existing products, or new products or product candidates, we may terminate the development or commercialization of our product candidates at any time. Our competitors, either alone or with their collaborators, may succeed in developing product candidates or products that are more effective, safer, less expensive or easier to administer than ours. Accordingly, our competitors may succeed in obtaining regulatory approval for their product candidates more rapidly than we can. Companies that can complete clinical trials, obtain required marketing approvals and commercialize their products before their competitors do so may achieve a significant competitive advantage, including certain patent and marketing exclusivity rights that could delay the ability of competitors to market certain products. We also face, and expect that we will continue to face, intense competition from other companies in a number of other areas, including (i) attracting larger pharmaceutical and biopharmaceutical companies to enter into collaborative arrangements with us to acquire, license or co- develop our product candidates, (ii) identifying and obtaining additional clinical- stage development programs to bolster our pipeline, (iii) attracting investigators and clinical sites capable of conducting our clinical trials, and (iv) recruiting patients to participate in our clinical trials. There can be no assurance that product candidates resulting from our research and development efforts, or from joint efforts with our potential future licensees or collaborators, will be able to compete successfully with our competitors' existing products or product candidates in development. We may be unable to successfully develop a product candidate that is the subject of an existing or future license agreement or collaboration if our licensee or collaborator does not perform or fulfill its contractual obligations, delays the development of our product candidate, or terminates the agreement. We expect to continue to enter into and rely on license and collaboration agreements in the future, or other similar business arrangements with third parties, to further develop and / or commercialize some or all of our existing and future product candidates. Such licensees or collaborators may not perform as agreed upon or anticipated, may fail to comply with strict regulations, or may elect to delay or terminate their efforts in developing or commercializing our product candidates even though we have met our obligations under the arrangement. A majority of the potential revenue from existing and any future licenses and collaborations we may enter into will likely consist of contingent milestone payments, such as payments received for achieving development or regulatory milestones, and royalties payable on the sales of approved products. Milestone and royalty revenues that we may receive under these licenses and collaborations will depend primarily upon our licensees' or collaborators' ability to successfully develop and commercialize our product candidates. In addition, our licensees or collaborators may decide to enter into arrangements with third parties to commercialize products developed under our existing or future collaborations using our technologies, which could reduce the milestone and royalty revenue that we may receive, if any. In many cases, we will not be directly or closely involved in the development or commercialization of our product candidates that are subject to licenses or collaborations and, accordingly, we will depend largely on our licensees or collaborators to develop or commercialize our product candidates. Our licensees may encounter competition from new products entering the market, which could adversely affect our royalty income. Our licensees or collaborators may fail to develop or effectively commercialize our product candidates because they: ● do not allocate the necessary resources due to internal constraints, such as limited personnel with the requisite scientific expertise, limited capital resources, or the belief that other product candidates or internal programs may have a higher likelihood of obtaining regulatory approval, or may potentially generate a greater return on investment; ● do not have sufficient resources necessary to fully support the product candidate through clinical development, regulatory approval and commercialization; ● are unable to obtain the necessary regulatory approvals; or ● prioritize other programs or otherwise diminish their support for developing and / or marketing our product candidate or product due to a change in management, business operations or strategy. Should any of these events occur, we may not realize the full potential or intended benefit of our license or collaboration arrangements, and our results of operations may be adversely affected. In addition, a licensee or collaborator may decide to pursue the development of a competitive product candidate developed outside of our agreement with them. Conflicts may also

arise if there is a dispute about the progress of, or other activities related to, the clinical development or commercialization of a product candidate, the achievement and payment of a milestone amount, the ownership of intellectual property that is developed during the course of the arrangement, or other license agreement terms. If a licensee or collaborator fails to develop or effectively commercialize our product candidates for any of these reasons, we may not be able to replace them with another third party willing to develop and commercialize our product candidates under similar terms, if at all. Similarly, we may disagree with a licensee or collaborator as to which party owns newly or jointly- developed intellectual property. Should an agreement be revised or terminated as a result of a dispute and before we have realized the anticipated benefits of the arrangement, we may not be able to obtain certain development support or revenues that we anticipated receiving. We may also be unable to obtain, on terms acceptable to us, a license from such collaboration partner to any of its intellectual property that may be necessary or useful for us to continue to develop and commercialize the product candidate. There can be no assurance that any product candidates will emerge from any existing or future license or collaboration agreements we may enter into for any of our product candidates. If government and third- party payers fail to provide adequate reimbursement or coverage for our products or those that are developed through licenses or collaborations, our revenues and potential for profitability may be harmed. In the United States and most foreign markets, product revenues or related royalty revenue, and therefore the inherent value of our products, will depend largely upon the reimbursement rates established by third- party payers for such products. Third- party payers include government health administration authorities, managed- care organizations, private health insurers and other similar organizations. Third- party payers are increasingly examining the cost effectiveness of medical products, services and pharmaceutical drugs and challenging the price of these products and services. In addition, significant uncertainty exists as to the reimbursement status, if any, of newly approved pharmaceutical products. Further, the comparative effectiveness of new products over existing therapies and the assessment of other non- clinical outcomes are increasingly being considered in the decision by payers to establish reimbursement rates. We, or our licensees or collaborators if applicable, may also be required to conduct post- marketing clinical trials in order to demonstrate the cost- effectiveness of our products. Such studies may require us to commit a significant amount of management time and financial resources. There can be no assurance that any products that we or our licensees or collaborators may successfully develop will be reimbursed in part, or at all, by any third- party payers in any country. Many governments continue to propose legislation designed to expand the coverage, yet reduce the cost, of healthcare, including pharmaceutical products. In many foreign markets, governmental agencies control the pricing of prescription drugs. In the United States, significant changes in federal health care policy were approved over the past several years and continue to evolve and will likely result in reduced reimbursement rates for many pharmaceutical products in the future. We expect that there will continue to be federal and state proposals to implement increased government control over reimbursement rates of pharmaceutical products. In addition, we expect that increasing emphasis on managed care and government intervention in the U. S. healthcare system will continue to put downward pressure on the pricing of pharmaceutical products there. Recent events have resulted in increased public and governmental scrutiny of the cost of drugs, especially in connection with price increases following companies' acquisitions of the rights to certain drug products. In particular, U. S. federal prosecutors recently issued subpoenas to a pharmaceutical company seeking information about its drug pricing practices, among other issues, and members of the U. S. Congress have sought information from certain pharmaceutical companies relating to post- acquisition drug- price increases. Our revenue and future profitability could be negatively affected if these inquiries were to result in legislative or regulatory proposals that limit our ability to increase the prices of our products that may be approved for sale in the future. Legislation and regulations affecting the pricing of pharmaceutical products may change before our product candidates are approved for sale, which could further limit or eliminate their reimbursement rates. Further, social and patient activist groups, whose goal it is to reduce the cost of healthcare, and in particular the price of pharmaceutical products, may also place downward pressure on the price of these products, which could result in decreases in the price of our products. If any product candidates that we develop independently, or through licensees or collaborators if applicable, are approved but do not gain meaningful acceptance in their intended markets, we are not likely to generate significant revenues. Even if our product candidates are successfully developed and we or a licensee or collaborator obtains the requisite regulatory approvals to market them in the future, they may not gain market acceptance or broad utilization among physicians, patients or third- party payers. The degree of market acceptance that any of our products may achieve will depend on a number of factors, including: ● the efficacy or perceived clinical benefit of the product, if any, relative to existing therapies; ● the timing of market approval and the existing market for competitive drugs, including the presence of generic drugs; ● the level of reimbursement provided by third- party payers to cover the cost of the product to patients; ● the net cost of the product to the user or third- party payer; ● the convenience and ease of administration of the product; ● the product' s potential advantages over existing or alternative therapies; ● the actual or perceived safety of similar classes of products; ● the actual or perceived existence, incidence and severity of adverse effects; ● the effectiveness of sales, marketing and distribution capabilities; and ● the scope of the product label approved by the FDA or similar regulatory agencies in other jurisdictions. There can be no assurance that physicians will choose to prescribe or administer our products, if approved, to the intended patient population. If our products do not achieve meaningful market acceptance, or if the market for our products proves to be smaller than anticipated, we may never generate significant revenues. Changes in funding for the FDA, the SEC and other government agencies could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal functions on which the operation of our business may rely, which could negatively impact our business. The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept payment of user fees, and statutory, regulatory, and policy changes. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of the SEC and other government agencies on which our operations may rely, including those that fund research and development activities is subject to the political process,

which is inherently fluid and unpredictable. Disruptions at the FDA and other 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~~ **past decade** ~~several years, including most recently on December 22, 2018~~, the U. S. government has shut down, at least partially, several times and certain regulatory agencies, such as the FDA and the SEC, have had to furlough critical FDA, SEC and other government 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 have a material adverse effect on our business. Further, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations. We depend on third- party collaborators, service providers, and others in the research, development, manufacturing, and any eventual commercialization of our product candidates. We rely heavily on these parties for multiple aspects of our drug development and manufacturing activities ~~,~~and anticipate that we will rely on third ~~-~~parties for commercialization activities including testing of our product candidates. We have very limited control over many aspects of those activities. Failure by one or more of the third- party collaborators, service providers, or others to complete activities on schedule or in accordance with our expectations or to meet their contractual or other obligations to us; failure of one or more of these parties to comply with applicable laws or regulations; or any disruption in the relationships between us and these parties, could delay or prevent the development, approval, manufacturing, or any eventual commercialization of our product candidates, expose us to suboptimal quality of service delivery or deliverables, result in repercussions such as missed deadlines or other timeliness issues, erroneous data and supply disruptions, and could also result in non- compliance with legal or regulatory requirements or industry standards or subject us to reputational harm, all with potential negative implications for our product pipeline and business. We rely on third- party contract manufacturers for certain portions of our manufacturing process. If third- party contract manufacturers fail to manufacture according to our specifications, or fail to comply with strict government regulations, our preclinical studies or clinical trials could be adversely affected and the development of our product candidates could be delayed or terminated, or we could incur significant additional expenses. To the extent that we rely on third- party contract manufacturers, which in some cases may be sole sourced, we are exposed to a number of risks, any of which could delay or prevent the completion of our preclinical studies or clinical trials, or the regulatory approval or commercialization of our product candidates, result in higher costs, or deprive us of potential product revenues in the future. Some of these risks include, but are not limited to: ● our potential contract manufacturers failing to develop an acceptable formulation to support late- stage clinical trials for, or the commercialization of, our product candidates; ● our potential contract manufacturers failing to manufacture our product candidates according to their own standards, our specifications, cGMP, or regulatory guidelines, or otherwise manufacturing material that we or regulatory authorities deem to be unsuitable for our clinical trials or commercial use; ● our potential contract manufacturers being unable to increase the scale of or the capacity for, or reformulate the form of, our product candidates, which may cause us to experience a shortage in supply or cause the cost to manufacture our product candidates to increase. There can be no assurance that our potential contract manufacturers will be able to manufacture our product candidates at a suitable commercial scale, or that we will be able to find alternative manufacturers acceptable to us that can do so; ● our potential contract manufacturers placing a priority on the manufacture of other customers' or their own products, rather than our products; ● our potential contract manufacturers failing to perform as agreed or exiting from the contract manufacturing business; and ● our potential contract manufacturers' plants being closed as a result of regulatory sanctions or a natural disaster. Manufacturers of pharmaceutical drug products are subject to ongoing periodic inspections by the FDA, the U. S. Drug Enforcement Administration, or DEA, and corresponding state and other foreign agencies to ensure strict compliance with FDA- mandated cGMP, other government regulations and corresponding foreign standards. We do not have control over our third- party contract manufacturers' compliance with these regulations and standards and accordingly, failure by our third- party manufacturers, or us, to comply with applicable regulations could result in sanctions being imposed on us or our manufacturers, which could significantly and adversely affect our business. In the event that we need to change a third- party contract manufacturer, our preclinical studies or our clinical trials, and the commercialization of our product candidates could be delayed, adversely affected or terminated, or such a change may result in the need for us to incur significantly higher costs, which could materially harm our business. Due to various regulatory restrictions in the United States and many other countries, as well as potential capacity constraints on manufacturing that occur from time- to- time in our industry, various steps in the manufacture of our product candidates are sole- sourced to certain contract manufacturers. In accordance with cGMPs, changing manufacturers may require the re-validation of manufacturing processes and procedures, and may require further preclinical studies or clinical trials to show comparability between the materials produced by different manufacturers. Changing a contract manufacturer may be difficult and could be extremely costly and time- consuming, which could result in our inability to manufacture our product candidates for an extended period of time and a delay, as well as an increase in costs, in the development of our product candidates. We may not be able to manufacture our product candidates in sufficient quantities to commercialize them. In order to receive FDA approval of our product candidates, we will need to manufacture such product candidates in larger quantities. We may not be able to successfully increase the manufacturing capacity for our product candidates in a timely or economic manner, or at all. In the event FDA approval is received, we will need to increase production of our product candidates. Significant scale- up of manufacturing may require additional validation studies, which the FDA must review and approve. If we are unable to successfully increase the manufacturing capacity for our product candidates, the clinical trials, the regulatory approval and the commercial launch of our product candidates may be delayed, or there may be a shortage in supply. Our product candidates require precise, high- quality manufacturing. Failure to achieve and maintain high- quality manufacturing, including the incidence of manufacturing errors, could result in patient injury or death, delays or failures in testing or delivery, cost overruns or other problems that could harm our business, financial condition and results of operations. The manufacture of pharmaceutical products in compliance with cGMP regulations requires significant expertise and capital investment, including

the development of advanced manufacturing techniques and process controls. Manufacturers of pharmaceutical products often encounter difficulties in production, including difficulties with production costs and yields, quality control, including stability of the product candidates and quality assurance testing, or shortages of qualified personnel. If we were to encounter any of these difficulties or otherwise fail to comply with our obligations under applicable regulations, our ability to provide study materials in our clinical trials would be jeopardized. Any delay or interruption in the supply of clinical trial materials could delay the completion of our clinical trials, increase the costs associated with maintaining our clinical trial programs and, depending upon the period of delay, require us to commence new trials at significant additional expense or to terminate the studies and trials completely. We must comply with cGMP requirements enforced by the FDA through its facilities inspection program. These requirements include, among other things, quality control, quality assurance and the maintenance of records and documentation. Manufacturers of our component materials may be unable to comply with these cGMP requirements and with other FDA, state and foreign regulatory requirements. The FDA or similar foreign regulatory agencies at any time may also implement new standards, or change their interpretation and enforcement of existing standards, for manufacture, packaging or testing of products. We have little control over our manufacturers' compliance with these regulations and standards. A failure to comply with these requirements may result in fines and civil penalties, suspension of production, suspension or delay in product approval, product seizure or recall, or withdrawal of product approval. If the safety of any product supplied is compromised due to our failure, or that our third- party manufacturers, to adhere to applicable laws or for other reasons, we may not be able to obtain regulatory approval for or successfully commercialize our products, and we may be held liable for any injuries sustained as a result. Any of these factors could cause a delay of clinical trials, regulatory submissions, approvals or commercialization of any product candidates we may develop or acquire in the future, or entail higher costs, or impair our reputation. We currently rely on single source vendors for key tablet vaccine components and certain strains needed in our tablet vaccine candidates, which could impair our ability to manufacture and supply our tablet vaccine candidates. We currently depend on single source vendors for certain raw materials used in the manufacture of our tablet vaccine candidates. Any production shortfall that impairs the supply of the relevant raw materials could have a material adverse effect on our business, financial condition and results of operations. An inability to continue to source product from these suppliers, which could be due to regulatory actions or requirements affecting the supplier, adverse financial or other strategic developments experienced by a supplier, labor disputes or shortages, unexpected demands or quality issues, could materially adversely affect our operating results or our ability to conduct clinical trials, either of which could significantly harm our business. We rely on third parties to conduct, supervise and monitor our clinical trials, and if those third parties perform in an unsatisfactory manner, it may harm our business. We rely on CROs and clinical trial sites to ensure the proper and timely conduct of our clinical trials, and we expect to have limited influence over their actual performance. We also rely on CROs to monitor and manage data for our clinical programs, as well as the execution of future nonclinical studies. We expect to control only certain aspects of our CROs' activities. Nevertheless, we will be responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards and our reliance on the CROs does not relieve us of these regulatory responsibilities. We and our CROs are required to comply with the Good Laboratory Practice and GCP, which are regulations and guidelines enforced by the FDA and are also required by the Competent Authorities of the Member States of the European Economic Area and comparable foreign regulatory authorities in the form of International Conference on Harmonization guidelines for any of our product candidates that are in preclinical and clinical development. The Regulatory authorities enforce GCP through periodic inspections of trial sponsors, principal investigators and clinical trial sites. If we or our CROs fail to comply with GCPs, 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. Accordingly, if our CROs fail to comply with these regulations or fail to recruit enough subjects, we may be required to repeat clinical trials, which would delay the regulatory approval process. Our CROs are not our employees, and we cannot control whether they devote sufficient time and resources to our clinical and nonclinical programs. These CROs 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 harm our competitive position. We face the risk of potential unauthorized disclosure or misappropriation of our intellectual property by CROs, which may reduce our trade secret protection and allow our potential competitors to access and exploit our proprietary technology. If our CROs do not successfully carry out their contractual duties or obligations, fail to meet expected deadlines, 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 any other reasons, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain regulatory approval for, or successfully commercialize, any product candidate that we develop. As a result, our financial results and the commercial prospects for any product candidate that we develop would be harmed, our costs could increase, and our ability to generate significant revenues could be delayed. If our relationships with these CROs terminate, we may not be able to enter into arrangements with alternative CROs or do so on commercially reasonable terms. Switching or adding additional CROs involves substantial cost and requires management time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays occur, which can materially impact our ability to meet our desired clinical development timelines. While we endeavor to carefully manage our relationships with our CROs, there can be no assurance that we will not encounter challenges or delays in the future or that these delays or challenges will not have an adverse impact on our business, financial condition and prospects. We may seek to selectively establish collaborations and, if we are unable to establish them on commercially reasonable terms, we may have to alter our development and commercialization plans. Our product development programs and the potential commercialization of our product candidates will require substantial additional cash to fund expenses. For some of our product candidates, including our seasonable influenza ~~and RSV tablets~~ **tablet**, we may decide to collaborate with governmental entities or additional pharmaceutical and biotechnology companies for the development and potential commercialization of those product candidates.

We face significant competition in seeking appropriate collaborators. Whether we reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator' s resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator' s evaluation of a number of factors. Those factors may include the design or results of clinical trials, the likelihood of approval by the FDA or similar regulatory authorities outside the United States, the potential market for the subject product candidate, the costs and complexities of manufacturing and delivering such product candidate to patients, the potential of competing products, the existence of uncertainty with respect to our ownership of technology, which can exist if there is a challenge to such ownership without regard to the merits of the challenge and industry and market conditions generally. The collaborator may also consider alternative product candidates for similar indications that may be available to collaborate on and whether such a collaboration could be more attractive than the one with us for our product candidate. Our relationships with customers and third- party payors will be subject to applicable anti- kickback, fraud and abuse and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings. Healthcare providers, physicians and third- party payors play a primary role in the recommendation and prescription of any product candidates for which we obtain marketing approval. Our future arrangements with third- party payors and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell and distribute our medicines for which we obtain marketing approval. Restrictions under applicable federal and state healthcare laws and regulations include the following: ● the federal Anti- Kickback Statute prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under federal and state healthcare programs such as Medicare and Medicaid; ● the federal FCA imposes criminal and civil penalties, including civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government; ● the federal HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program and imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information; ● the federal false statements statute prohibits 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; ● the federal transparency requirements under the Affordable Care Act requires manufacturers of drugs, devices, biologics and medical supplies to report to the Department of Health and Human Services information related to physician payments and other transfers of value and physician ownership and investment interests; and ● analogous state laws and regulations, such as state anti- kickback and false claims laws, may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non- governmental third- party payors, including private insurers, and some state laws require pharmaceutical companies to comply with the pharmaceutical industry' s voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government in addition to requiring vaccine manufacturers to report information related to payments to physicians and other health care providers or marketing expenditures. We may not be successful in establishing and maintaining additional strategic partnerships, which could adversely affect our ability to develop and commercialize products, negatively impacting our operating results. We continue to strategically evaluate our partnerships and, as appropriate, we expect to enter into additional strategic partnerships in the future, including potentially with major biotechnology or biopharmaceutical companies. We face significant competition in seeking appropriate partners for our product candidates, and the negotiation process is time- consuming and complex. In order for us to successfully partner our product candidates, potential partners must view these product candidates as economically valuable in markets they determine to be attractive in light of the terms that we are seeking and other available products for licensing by other companies. Even if we are successful in our efforts to establish strategic partnerships, the terms that we agree upon may not be favorable to us, and we may not be able to maintain such strategic partnerships if, for example, development or approval of a product candidate is delayed or sales of an approved product are disappointing. Any delay in entering into strategic partnership agreements related to our product candidates could delay the development and commercialization of such candidates and reduce their competitiveness even if they reach the market. If we are not able to generate revenue under our strategic partnerships when and in accordance with our expectations or the expectations of industry analysts, this failure could harm our business and have an immediate adverse effect on the trading price of our common stock. If we fail to establish and maintain additional strategic partnerships related to our unpartnered product candidates, we will bear all the risks and costs related to the development of any such product candidate, and we may need to seek additional financing, hire additional employees and otherwise develop expertise, such as regulatory expertise, for which we have not budgeted. If we were not successful in seeking additional financing, hiring additional employees or developing additional expertise, our cash burn rate would increase or we would need to take steps to reduce our rate of product candidate development. This could negatively affect the development of any unpartnered product candidate. Strategic partnerships or acquisitions we have made or may make could turn out to be unsuccessful. As part of our strategy, we monitor and analyze strategic partnership or acquisition opportunities that we believe will create value for our ~~shareholders~~ **stockholders** . We may acquire companies, businesses, products and technologies that complement or augment our existing business ~~,~~**;** however, such acquisitions could involve numerous risks that may prevent us from fully realizing the benefits that we anticipated as a result of such transactions. We may not be able to integrate any acquired business successfully or operate any acquired business profitably. In addition, integrating any newly acquired business could be expensive and time- consuming, place a significant strain on managerial, operational and financial resources and could prove to be more difficult or expensive than we predict. The diversion of our management' s attention and any delay or

difficulties encountered in connection with any future acquisitions we may consummate could result in the disruption of our ongoing business or inconsistencies in standards and controls that could negatively affect our ability to maintain third- party relationships. We may fail to derive any commercial value from the acquired technology, products and intellectual property, including as a result of the failure to obtain regulatory approval or to monetize products once approved, as well as risks from lengthy product development and high upfront development costs without guarantee of successful results. Patents and other intellectual property rights covering acquired technology and / or intellectual property may not be obtained, and if obtained, may not be sufficient to fully protect the technology or intellectual property. We may also be subject to liabilities, including unanticipated litigation costs, that are not covered by indemnification protection we may obtain. As we pursue strategic transactions, we may value the acquired company or partner incorrectly, fail to successfully manage our operations as our asset diversity increases, expend unforeseen costs during the acquisition or integration process, or encounter other unanticipated risks or challenges. We may fail to value a partnership or acquisition accurately, properly account for it in our consolidated financial statements, or successfully divest it or otherwise realize the value which we originally anticipated or have subsequently reflected in our consolidated financial statements. Moreover, we may need to raise additional funds through public or private debt or equity financing, or issue additional shares, to acquire any businesses or products, which may result in dilution for stockholders or the incurrence of indebtedness. Any failure by us to effectively limit such risks as we implement our strategic partnership or acquisitions could have a material adverse effect on our business, financial condition or results of operations and may negatively impact our net income and cause the price of our securities to fall. In the event that a third- party contract manufacturer cannot timely supply sufficient bulk vaccine to allow us to manufacture our vaccine tablets, our preclinical studies or our clinical trials and the commercialization of our product candidates could be delayed, adversely affected or terminated, or may result in the need for us to incur significantly higher costs, which could materially harm our business. Due to various regulatory restrictions in the United States and many other countries, as well as potential capacity constraints on manufacturing that occur from time- to- time in our industry, various steps in the manufacture of our product candidates are sole- sourced to certain contract manufacturers. In accordance with cGMP, changing manufacturers may require the re- validation of manufacturing processes and procedures, and may require further preclinical studies or clinical trials to show comparability between the materials produced by different manufacturers. Changing a contract manufacturer may be difficult and could be extremely costly and time consuming, which could result in our inability to manufacture our product candidates for an extended period and a delay in the development of our product candidates. Further, in order to maintain our development timelines in the event of a change in a third- party contract manufacturer, we may incur significantly higher costs to manufacture our product candidates. If third- party vendors, upon whom we rely to conduct our preclinical studies or clinical trials, do not perform or fail to comply with strict regulations, these studies or trials may be delayed, terminated, or fail, or we could incur significant additional expenses, which could materially harm our business. We have limited resources dedicated to designing, conducting and managing our preclinical studies and clinical trials. We have historically relied on, and intend to continue to rely on, third parties, including clinical research organizations, consultants and principal investigators, to assist us in designing, managing, conducting, monitoring and analyzing the data from our preclinical studies and clinical trials. We rely on these vendors and individuals to perform many facets of the clinical development process on our behalf, including conducting preclinical studies, the recruitment of sites and patients for participation in our clinical trials, maintenance of good relations with the clinical sites, and ensuring that these sites are conducting our trials in compliance with the trial protocol and applicable regulations. If these third parties fail to perform satisfactorily, or do not adequately fulfill their obligations under the terms of our agreements with them, we may not be able to enter into alternative arrangements without undue delay or additional expenditures, and therefore the preclinical studies and clinical trials of our product candidates may be delayed or prove unsuccessful. Further, the FDA, or similar regulatory authorities in other countries, may inspect some of the clinical sites participating in our clinical trials or our third- party vendors' sites to determine if our clinical trials are being conducted according to GCP or similar regulations. If we, or a regulatory authority, determine that our third- party vendors are not in compliance with, or have not conducted our clinical trials according to, applicable regulations, we may be forced to exclude certain data from the results of the trial, or delay, repeat or terminate such clinical trials. ~~Risks Related to Intellectual Property If we are unable to obtain and maintain patent protection for our oral vaccine platform technology and product candidates or if the scope of the patent protection obtained is not sufficiently broad, we may not be able to compete effectively in our markets.~~ Our success depends in large part on our ability to obtain and maintain patent protection in the United States and other countries. We seek to protect our proprietary position by filing patent applications in the United States and abroad related to our development programs and product 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, or maintain and enforce any patents that may issue from such patent applications, at a reasonable cost or in a timely manner. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. The patent applications that we own may fail to result in issued patents with claims that cover any of our product candidates in the United States or in other countries. There is no assurance that the entire potentially relevant prior art relating to our patents and patent applications has been found, which can invalidate a patent or prevent a patent from issuing from a pending patent application. Even if patents do successfully issue, third parties may challenge their validity, enforceability or scope, which may result in such patents being narrowed, invalidated, or held unenforceable. Any successful challenge 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 product 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 product candidate and companion diagnostic under patent protection could be reduced. If the patent applications we hold with respect to our platform technology and product candidates fail to issue, if their breadth or strength of protection is threatened, or if they fail to provide meaningful exclusivity for our product candidates, it could dissuade companies from collaborating with us to develop product candidates and threaten

our ability to commercialize future drugs. Any such outcome could harm our business. The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation. 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, European patent law restricts the patentability of methods of treatment of the human body more than U. S. law does. 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, 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 product candidates, in whole or in part, or which effectively prevent others from commercializing competitive technologies and vaccines. Even if our patent applications issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors from competing with us or otherwise provide us with any competitive advantage. Our competitors may be able to circumvent our patents by developing similar or alternative product candidates in a non- infringing manner. 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. Recent patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. On September 16, 2011, the Leahy- Smith America Invents Act, or the Leahy- Smith Act, was signed into law. The Leahy- Smith Act includes several significant changes to United States patent law. These include provisions that affect the way patent applications are prosecuted and may also affect patent litigation. The U. S. Patent Office recently developed new regulations and procedures to govern administration of the Leahy- Smith Act, and many of the substantive changes to patent law associated with the Leahy- Smith Act, notably, the first to file provisions, only became effective on March 16, 2013. Accordingly, it is not clear what, if any, impact the Leahy- Smith Act will have on the operation of our business. However, the Leahy- Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have an adverse effect on our business and financial condition. Moreover, we may be subject to a third- party pre- issuance submission of prior art to the U. S. Patent and Trademark Office, or USPTO, or become involved in derivation, reexamination, inter partes review, post- grant review or interference proceedings challenging our patent rights or the patent rights of others. In other countries, we may be subject to or become involved in opposition proceedings challenging our patent rights or the patent rights of others. An adverse determination in any such submission or proceeding could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology or product candidates and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize product candidates 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 product 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 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 tablet vaccines, or limit the duration of the patent protection of our technology and product candidates. Moreover, patents have a limited lifespan. In the United States and other countries, the natural expiration of a patent is generally 20 years after it is filed. Various extensions may be available, however, the life of a patent, and the protection it affords, is limited. Without patent protection for our current or future tablet vaccine candidates, we may be open to competition from generic versions of such product candidates. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing product candidates similar or identical to ours ~~. We may be 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 such 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 or lack of statutory 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 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 product 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 stock. ~~If a third party claims we are infringing on its intellectual property rights, we could incur significant expenses, or be prevented from further developing or commercializing our product candidates, which could materially harm our business.~~ Our success will largely depend on our ability to operate without infringing the patents and other proprietary intellectual property rights of third parties. This is generally referred to as having the " freedom to operate. " However, our research, development and commercialization activities may be subject to claims that we infringe or otherwise violate patents or other intellectual property rights owned or controlled by third parties. Numerous U. S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are pursuing development candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our current or future product candidates may be subject to claims of infringement of the patent rights of third parties. The biotechnology and pharmaceutical industries are characterized by extensive litigation regarding patents and other intellectual property rights. The defense and prosecution of intellectual property claims, interference proceedings and related legal and administrative proceedings, both in the United States and internationally, involve complex legal and factual questions. As a result, such proceedings are lengthy, costly and time-consuming, and their outcome is highly uncertain. We may become involved in protracted and expensive litigation in order to determine the enforceability, scope and validity of the proprietary rights of others, or to determine whether we have the freedom to operate with respect to the intellectual property rights of others. Patent applications in the United States are, in most cases, maintained in secrecy until approximately 18 months after the patent application is filed. The publication of discoveries in scientific or patent literature frequently occurs substantially later than the date on which the underlying discoveries were made. Therefore, patent applications relating to product candidates similar to ours may have already been filed by others without our knowledge. In the event that a third party has also filed a patent application covering our product candidate or other claims, we may have to participate in an adversarial proceeding, known as an interference proceeding, in the USPTO, or similar proceedings in other countries, to determine the priority of invention. In the event an infringement claim is brought against us, we may be required to pay substantial legal fees and other expenses to defend such a claim and, should we be unsuccessful in defending the claim, we may be prevented from pursuing the development and commercialization of a product candidate and may be subject to injunctions and / or damage awards. In the future, the USPTO or a foreign patent office may grant patent rights to our product candidates or other claims to third parties. Subject to the issuance of these future patents, the claims of which will be unknown until issued, we may need to obtain a license or sublicense to these rights in order to have the appropriate freedom to further develop or commercialize them. Any required licenses may not be available to us on acceptable terms, if at all. If we need to obtain such licenses or sublicenses, but are unable to do so, we could encounter delays in the development of our product candidates, or be prevented from developing, manufacturing and commercializing our product candidates at all. If it is determined that we have infringed an issued patent and do not have the freedom to operate, we could be subject to injunctions, and / or compelled to pay significant damages, including punitive damages. In cases where we have in-licensed intellectual property, our failure to comply with the terms and conditions of such agreements could harm our business. It is becoming common for third parties to challenge patent claims on any successfully developed product candidate or approved drug. If we or our licensees or collaborators become involved in any patent litigation, interference or other legal proceedings, we could incur substantial expense, and the efforts and attention of our technical and management personnel could be significantly diverted. A negative outcome of such litigation or proceedings may expose us to the loss of our proprietary position or to significant liabilities or require us to seek licenses that may not be available from third parties on commercially acceptable terms, if at all. We may be restricted or prevented from developing, manufacturing and selling our product candidates in the event of an adverse determination in a judicial or administrative proceeding, or if we fail to obtain necessary licenses. ~~Obtaining and maintaining our patent protection depends on compliance with various procedures, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.~~ Periodic maintenance fees on any issued patent are due to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of the patent. The USPTO and various foreign governmental patent agencies require compliance with several procedures, documentary fee payments and other 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. Non- compliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, 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 and our licensors fail to maintain the patents and patent applications covering our product candidates, our competitive position would be adversely affected. Changes in U. S. patent law could diminish the value of patents in general, thereby impairing our ability to protect our product candidates. The United States has recently enacted and implemented wide-

ranging patent reform legislation. The United States 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. ~~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 product candidates 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 vaccines and, further, may export otherwise infringing vaccines to territories where we may obtain patent protection, but where patent enforcement is not as strong as that in the United States. These vaccines may compete with our product candidates 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. We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of third parties or that our employees have wrongfully used or disclosed alleged trade secrets of their former employers. Many of our employees, including our senior management, were previously employed at universities or other biotechnology or pharmaceutical companies. These employees typically executed proprietary rights, non- disclosure and non- competition agreements in connection with their previous employment. Although we try to ensure that our employees do not use the proprietary information or know- how of others in their work for us, we may be subject to claims that it or these employees have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such employee' s former employer. We are not aware of any threatened or pending claims related to these matters, but in the future , litigation may be necessary to defend against such claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management ~~. 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~~ . We seek to protect our proprietary technology in part by entering into confidentiality agreements with third parties 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. 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. Patent terms may be inadequate to protect our competitive position on our product candidates for an adequate amount of time. Patents have a limited lifespan. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U. S. non- provisional filing date. Various extensions may be available, but the life of a patent, and the protection it affords, is limited. Even if patents covering our product candidates are obtained, once the patent life has expired for a product candidate, we may be open to competition from competitive vaccines and medications, including generic medications. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such product candidates might expire before or shortly after such product candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing product candidates similar or identical to ours. Depending upon the timing, duration and conditions of any FDA marketing approval of our product candidates, one or more of our U. S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch- Waxman Amendments, and similar legislation in the European Union. The Hatch- Waxman Amendments permit a patent term extension of up to five years for a patent covering an approved product as compensation for effective patent term lost during product development and the FDA regulatory review process. However, we may not receive an extension if we fail to exercise due diligence during the testing phase or regulatory review process, fail to apply within applicable deadlines, fail to apply prior to expiration of relevant patents or otherwise fail to satisfy applicable requirements. Moreover, the length of the extension could be less than we request. Only one patent per approved product can be extended, the extension cannot extend the total patent term beyond 14 years from approval and only those claims covering the approved drug, a method for using it or a method for manufacturing it may be extended. If we are unable to obtain patent term extension or the term of any such extension is less than we request, the period during which we can enforce our patent rights for the applicable product candidate will be shortened and our competitors may obtain approval to market competing products sooner. As a result, our revenue from applicable products could be reduced. Further, if this occurs, our competitors may take advantage of our investment in development and trials by referencing our clinical and preclinical data and launch their product earlier than might otherwise be the case, and our competitive position, business, financial condition, results of operations and prospects could be materially harmed. We are currently engaged in an

ongoing opposition proceeding, now at the appeal stage, of a Vaxart European patent in the European Patent Office. If we are not successful in these proceedings, we may not be able to prevent others in Europe from copying some of our product candidates for as long as we otherwise would if the European patent is upheld. We are currently engaged in an ongoing opposition proceeding of one of our European patents in the European Patent Office (EPO). European Patent No. 3307239, which has claims directed to vaccine compositions for norovirus ~~and RSV~~, was opposed in the EPO. The opposition challenged the validity of European Patent No. 3307239 and the EPO maintained the patent with the original independent claim and with cancelation of some subject matter from dependent claims. The opponent has appealed this decision and thus the ultimate outcome of the opposition remains uncertain. If Vaxart is not ultimately successful in the appeal, it may not be able to prevent others from copying its norovirus ~~and RSV products~~ **product** in some or all European countries where the patent is pending for as long as it otherwise might be able to if the patent' s validity is upheld in the opposition appeal. If the opposed European patent is partially or fully revoked by the EPO, competitors may be able to sell competing vaccines for norovirus ~~or RSV~~ earlier without Vaxart being able to assert patents against them. Vaxart has another patent in Europe that covers its norovirus ~~and RSV~~ products, but lack of success in the opposition appeal would prevent us from extending that patent protection out to 2036. We may be subject to claims challenging the inventorship of our patents and other intellectual property. We or our licensors may be subject to claims that former employees, collaborators or other third parties have an interest in our patents, trade secrets, or other intellectual property as an inventor or co- inventor. For example, we or our licensors may have inventorship disputes arise from conflicting obligations of employees, consultants or others who are involved in developing our product candidates. Litigation may be necessary to defend against these and other claims challenging inventorship or our or our licensors' ownership of our patents, trade secrets or other intellectual property. If we or our licensors fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, intellectual property that is important to our product candidates. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects. General Risk Factors **We expect that significant additional capital will be needed in the future to continue our planned operations. Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of equity offerings, royalties, debt financings, strategic alliances and license and development agreements in connection with any collaborations. We do not currently have any committed external source of funds. To the extent that we raise additional capital by issuing equity securities, our existing stockholders' ownership may experience substantial dilution, and the terms of these securities may include liquidation or other preferences that adversely affect our common stockholders' rights. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures, declaring dividends, creating liens, redeeming our stock or making investments.** Future sales of shares by existing stockholders could cause our stock price to decline. If our existing stockholders sell, or indicate an intention to sell, substantial amounts of our common stock in the public market, the trading price of our common stock could decline. Sales of a substantial number of shares of our common stock in the public market, or the perception that the sales might occur, could depress the market price of our common stock and could impair our ability to raise capital through the sale of additional equity securities. We are unable to predict the effect that sales may have on the prevailing market price of our common stock. Changes in tax laws and regulations or in our operations may impact our effective tax rate and may adversely affect our business, financial condition and operating results. Changes in tax laws in any jurisdiction in which we operate, or adverse outcomes from any tax audits that we may be subject to in any such jurisdictions, could result in an unfavorable change in our effective tax rate in the future, which could adversely affect our business, financial condition, and operating results. Anti- takeover provisions under Delaware law could make an acquisition more difficult and may prevent attempts by our stockholders to replace or remove our management. Because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the DGCL, which prohibits stockholders owning in excess of 15 % of the outstanding company voting stock from merging or combining with the company. Although we believe these provisions collectively provide for an opportunity to receive higher bids by requiring potential acquirers to negotiate with our board of directors, they would apply even if the offer was considered beneficial by some stockholders. In addition, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove management by making it more difficult for stockholders to replace members of our board of directors, which is responsible for appointing the members of management. Our business and operations would suffer in the event of system failures. Our business and operations, including our CROs, as well as the operations and systems of entities whose services are necessary to our operations, rely greatly on information technology systems and are vulnerable to damage in the event of failure, natural disasters, security breaches and attacks, interruptions or other cybersecurity incidents. These events may compromise the stability, integrity, or confidentiality of these systems, and the accuracy and integrity of information stored or processed through these systems, and may significantly interrupt our ability to run the business successfully. Ransomware attacks, which are becoming increasingly common across all industry sectors and have focused in part on businesses operating in health care markets, can disrupt and even halt ongoing business operations completely. Increasing global tensions, including the ongoing military conflict between Russia and Ukraine, among others, are likely to increase the frequency of cybersecurity incidents. Our systems, including onsite datacenters and cloud services, continue to increase in size and complexity making them potentially vulnerable to breakdown and other disruptions. Disruptions include issues with routine maintenance, upgrades, and patching. These systems continue to become more critical and integrated within our business, especially as we continue to work remotely, and our dependence on them will continue to increase. We rely on the high- availability and redundancies built into our cloud services, but these systems are managed and maintained by the providers and are out of our direct control. Any potential problems and interruptions associated with the implementation, support, security, availability, or maintenance of new or existing

systems could disrupt or reduce the efficiency of our operations, and materially impact the delivery of development programs. Cybersecurity incidents, including phishing and spear phishing attacks, distributed denial of service attacks, man- in- the- middle attacks, as well as ransomware and other malware insertions, are becoming more sophisticated and frequent. If these attempts to misappropriate or compromise confidential or proprietary information or infiltrate or sabotage enterprise IT systems were successful, they could result in a loss of or damage to data or applications and even the interruption of basic business operations and financial loss, as well as the risk of legal and regulatory liability. As a result, further development of our product candidates could be substantially delayed. A data breach could risk the exposure of mission critical data or other intellectual property, or expose PII (Personally Identifiable Information) and PHI (Protected Health Information) of company employees or people participating in clinical trials. A successful phishing attempt could lead to further hacking attempts, unauthorized email access or messaging, or other vertical / horizontal cyberattacks. Any of these events could cause substantial reputational injury impacting our business. **Artificial intelligence (" AI ") presents risks and challenges that can impact our business including by posing security risks to our confidential information, proprietary information and personal data. We incorporate AI solutions into our platform, and these applications may become important in our operations over time. AI presents risks such as inaccuracy, bias, toxicity, intellectual property infringement or misappropriation, data privacy and cybersecurity and data provenance. In addition, AI may have errors or inadequacies that are not easily detectable and may also be subject to data herding and interconnectedness (i. e., multiple market participants utilizing the same data), which may adversely impact our business. These issues, combined with an uncertain regulatory environment, may further result in reputational harm, liability, or other adverse consequences to our business operations. Our vendors may incorporate generative AI tools into their offerings without disclosing this use to us, and the providers of these generative AI tools may not meet existing or rapidly evolving regulatory or industry standards with respect to privacy and data protection and may inhibit our or our vendors' ability to maintain an adequate level of service and experience. If our vendors, or our third- party partners experience an actual or perceived breach or privacy or security incident because of the use of generative AI, we may lose valuable intellectual property and confidential information and our reputation and the public perception of the effectiveness of our security measures could be harmed. Further, bad actors around the world use increasingly sophisticated methods, including the use of AI, to engage in illegal activities involving the theft and misuse of personal information, confidential information, and intellectual property. Any of these outcomes could damage our reputation, result in the loss of valuable property and information, and adversely impact our business.** If we fail to maintain an effective system of internal controls, we may not be able to accurately report our financial results or detect fraud. Consequently, investors could lose confidence in our financial reporting and this may negatively impact the trading price of our common stock. We are required, pursuant to Section 404 of the Sarbanes- Oxley Act, to furnish a quarterly report by management on, among other things, the effectiveness of our internal control over financial reporting. This assessment needs to include disclosure of any material weaknesses identified by our management in our internal control over financial reporting. We are required to disclose changes made in our internal control over financial reporting on a quarterly basis. In addition, because our public float ~~is~~ **was** less than $ 700 million on June 30, 2022, we re- qualified as a smaller reporting company as of December 31, 2022 and, therefore, we are no longer subject to the requirements for auditor attestation for internal control over financial reporting. We must maintain effective disclosure and internal controls to provide reliable financial reports. We have been assessing our controls to identify areas that need improvement. Based on our evaluation as of December 31, ~~2022~~ **2023** , we concluded that our internal controls and procedures were effective as of December 31, ~~2022~~ **2023** , however we have identified material weaknesses in the past and may do so again in the future. A " material weakness " is a deficiency, or a combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of our annual or interim **consolidated** financial statements will not be prevented or detected on a timely basis. Failure to maintain the improvements in our controls as necessary to maintain an effective system of such controls could harm our ability to accurately report our operating results and cause investors to lose confidence in our reported financial information. Any such loss of confidence would have a negative effect on the trading price of our common stock. Most of our facilities are located near known earthquake fault zones. The occurrence of an earthquake, fire or any other catastrophic event could disrupt our operations or the operations of third parties who provide vital support functions to us, which could have a material adverse effect on our business and financial condition. We are vulnerable to damage from catastrophic events, such as power loss, natural disasters, terrorism and similar unforeseen events beyond our control. The majority of our operations are located in the San Francisco Bay Area, which in the past has experienced severe earthquakes and fires. We do not have a disaster recovery and business continuity plan in place. Earthquakes, floods, hurricanes or other natural disasters could severely disrupt our operations and have a material adverse effect on our business, results of operations, financial condition and prospects. If a natural disaster, power outage or other event occurred that prevented us from using all or a significant portion of our headquarters, damaged critical infrastructure, such as our financial systems or manufacturing facility, or that otherwise disrupted our operations, it may be difficult or, in certain cases, impossible for us to continue business operations for a substantial period of time. **Our business and operations are subject to risks related to climate change. The long- term effects of global climate change could present both physical risks and transition risks (such as regulatory or technology changes), which are expected to be widespread and unpredictable. Transitional risks include, for example, a disorderly global transition away from fossil fuels that may result in increased energy prices; customer preference for low or no- carbon products; stakeholder pressure to decarbonize assets; or new legal or regulatory requirements that result in new or expanded carbon pricing, taxes, restrictions on greenhouse gas emissions, and increased greenhouse gas disclosure and transparency. These risks could increase operating costs, including the cost of our electricity and energy use, or other compliance costs. Physical risks to our operations include water stress and drought; flooding and storm surge; wildfires; extreme temperatures and storms, which could impact trials, increase costs, or disrupt supply chains. Our supply chain is likely subject to these**

same transitional and physical risks and would likely pass along any increased costs to us. We do not anticipate that these risks will have a material financial impact to the Company in the near term. Increased scrutiny of our environmental, social or governance responsibilities have and will likely continue to result in additional costs and risks and may adversely impact our reputation, employee retention and willingness of customers and suppliers to do business with us. There is an increasing focus from certain customers, consumers, employees and other stakeholders concerning environmental, social and governance (“ ESG ”) matters, including corporate citizenship and sustainability. Additionally, public interest and legislative pressure related to public companies’ ESG practices continues to grow. If our ESG practices fail to meet regulatory requirements or stakeholders’ evolving expectations and standards for responsible corporate citizenship in areas including environmental stewardship, support for local communities, Board of Director and employee diversity, human capital management, employee health and safety practices, corporate governance and transparency and employing ESG strategies in our operations, our brand, reputation and employee retention may be negatively impacted, and customers and suppliers may be unwilling to do business with us. In addition, as we work to align our ESG practices with industry standards, we have expanded and, in the future, will likely continue to expand our disclosures in these areas. From time- to- time, we communicate certain initiatives, including goals, regarding environmental matters, responsible sourcing and social investments. We also expect to incur additional costs and require additional resources to monitor, report and comply with our various ESG practices. The standards for tracking and reporting on ESG matters are relatively new, have not been harmonized and continue to evolve. The disclosure frameworks we choose to align with, if any, may change from time- to- time and may result in a lack of consistent or meaningful comparative data from period to period. Ensuring there are systems and processes in place to comply with various ESG tracking and reporting obligations will require management time and expense. In addition, our processes and controls may not always comply with evolving standards for identifying, measuring and reporting ESG metrics, our interpretation of reporting standards may differ from those of others and such standards may change over time, any of which could result in significant revisions to our goals or reported progress in achieving such goals. If we fail to adopt ESG standards or practices as quickly as stakeholders desire, fail, or be perceived to fail, in our achievement of such initiatives or goals, or fail in fully and accurately reporting our progress on such initiatives and goals, our reputation, business, financial performance and growth may be adversely impacted. In addition, we could be criticized for the scope of such initiatives or goals or perceived as not acting responsibly in connection with these matters. Our business could be negatively impacted by such matters. Any such matters, or related corporate citizenship and sustainability matters, could have a material adverse effect on our business.