

Risk Factors Comparison 2025-02-27 to 2024-02-28 Form: 10-K

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You should carefully consider the following risk factors in evaluating our business. A number of risks could cause our actual results to differ materially from those that are indicated by forward-looking statements. Some risks relate principally to our business and the industry in which we operate. Others relate principally to the securities market and ownership of our common stock. The risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties of which we are unaware, or that we currently deem immaterial, also may become important factors that affect us. Any of the following risks could result in material adverse impacts on our business, financial condition, or results of operations. You also should consider the other information included in this Annual Report on Form 10-K as well as our other filings with the SEC. Summary of Risk Factors Our business is subject to numerous risks. The following is a summary of the principal risk factors described in this section:

- We have a history of losses and our future profitability is uncertain.
- We will continue to require significant funding to maintain our current level of operations and fund the further development of our vaccine candidates.
- **Our existing collaboration, funding and supply agreements, including the Sanofi CLA and or our APAs, do not assure success of our vaccine candidates or vaccines or that we will be able to fully fund our vaccine candidates or vaccines or our operations, and if we are unable to satisfy the performance obligations under such agreements, we may not be eligible to receive milestone payments under such agreements, the agreements may be terminated, the purchase commitments may be reduced or we may be required to refund advance payments.**
- Because our vaccine product development **and commercialization** efforts depend on new and rapidly evolving technologies, **we cannot be certain that** our efforts ~~may not succeed~~ **will be successful.**
- **We are a biotechnology company and face significant risk in developing, manufacturing, and commercializing our products and product candidates.**
- **We must identify vaccines for development with our technologies and establish successful third-party relationships.**
- The regulatory and commercial success of our COVID-19 Vaccine remains uncertain. While we have received **CMA, EUA or full approval** ~~MA, provisional registration, CMA, or EUA~~ for our prototype COVID-19 Vaccine and our updated COVID-19 vaccine in a number of jurisdictions, we may be unable to obtain full regulatory approvals in the U. S. or other jurisdictions for our updated vaccine or new versions in the future, or produce a successful vaccine in a timely manner, if at all.
- ~~The emergence and transmissibility of variants of the SARS-CoV-2 virus, may affect market acceptance or sales of our COVID-19 Vaccine, and our strategy to develop new versions of our COVID-19 Vaccine to protect against certain variants may not be successful.~~
- ~~We are a biotechnology company and face significant risk in developing, manufacturing, and commercializing our products and product candidates.~~
- Because we depend on third parties to conduct some of our laboratory testing and clinical trials, and a significant amount of our vaccine manufacturing and distribution, we may encounter delays in or lose some control over our efforts to develop and supply products.
- ~~We are highly dependent on the commercial success of our COVID-19 Vaccine, and even though we have received provisional registration, CMA, EUA or full marketing authorization in certain jurisdictions for our COVID-19 Vaccine, and even if we have products~~ **product candidates** ~~licensed in additional markets, our vaccine products may not be initially or ever profitable.~~
- The risks associated with COVID-19 and related governmental public health policies continue to evolve, which may have unpredictable effects on the prospects for commercial success of our COVID-19 Vaccine.
- Many of our competitors have significantly greater resources and experience, which may negatively impact our commercial opportunities and those of our current and future licensees.
- There is significant competition in the development of a vaccine against COVID-19 and a combined vaccine against COVID-19 and influenza, and we may never see returns on the significant resources we are devoting to our vaccine candidates.
- We may not succeed in obtaining full U. S. FDA licensure or foreign regulatory approvals necessary to sell our vaccine candidates.
- Our product candidates might fail to meet their primary endpoints in clinical trials, meaning that we will not have the clinical data required to support full regulatory approvals.
- ~~The~~ **We may fail to obtain** regulatory pathway **approval** for our **prototype COVID-19 Vaccine vaccine and NVX-CoV2601 or for our other current or future product candidates on a timely basis or comply with our continuing regulatory obligations if approval is obtained** ~~continually evolving, and such evolution may result in unexpected or unforeseen challenges.~~
- We have conducted, are conducting, and plan to conduct in the future, a number of clinical trials for our COVID-19 Vaccine at sites outside the U. S. and the U. S. FDA may ~~not accept data from trials conducted in such locations.~~
- The later discovery of previously unknown problems with a product, manufacturer, or facility may result in restrictions, including withdrawal of a vaccine that had previously received regulatory approval in certain jurisdictions from the market.
- Our success depends on our ability to maintain the proprietary nature of our technology.
- Our business may be adversely affected if we do not successfully execute our business development initiatives.
- ~~Given our current cash position and cash flow forecast, and significant uncertainties related to 2024 revenue, substantial doubt exists regarding our ability to continue as a going concern through one year from the date that the financial statements included in this Annual Report were issued.~~
- Servicing our 5.00% convertible senior unsecured notes ~~due 2027~~ requires a significant amount of cash, and we may not have sufficient cash flow resources to pay our debt.
- Because our stock price has been and will likely continue to be highly volatile, the market price of our common stock may be lower or more volatile than expected.
- ~~Litigation or regulatory investigations~~ could have a material adverse impact on our results of operation and financial condition.
- We or the third parties upon whom we depend may be adversely affected by natural or man-made disasters or public health emergencies, such as the COVID-19 pandemic.

Risks Related to Our Financial Condition and Capital Requirements Our expenses have exceeded our revenue since our formation in 1987, and our accumulated deficit at December 31, ~~2023~~ **2024** was ~~\$ 4.5~~ **8.0** billion. Our revenue and expenses ~~have historically fluctuate~~ **fluctuated** significantly from period to period, **and we**

believe our revenue and expenses will continue to fluctuate in the future. For most of our history our expenses have exceeded our revenue, which may occur during most periods in the foreseeable future. Our net losses for the last three fiscal years were \$ **0-187.5 billion million in 2024, \$ 545.1 million** in 2023, **and \$ 0-657.79 billion million** in 2022, **and \$ 1.7 billion** in 2021. Historically, our losses have resulted predominantly from research and development expenses for our vaccine candidates, manufacturing-related expenses, expenses associated with efforts to obtain regulatory approvals, costs related to protection of our intellectual property, and other general and administrative operating expenses, a significant portion of which have been noncash. **Our We believe our research and development** expenses have exceeded our revenue since inception, **and we believe our expenses will fluctuate over time, and** may substantially increase in some years, as a result of continuing efforts to develop, test, manufacture, and make regulatory filings for our vaccine candidates, **and commercialize our COVID-19 Vaccine and any other product candidates that receive requisite regulatory approvals.** As of the end of fiscal year **2023-2024**, our investment in the development and manufacture of our COVID-19 Vaccine has been substantial, **and, As we evolve** expect such levels of investment to continue for the rest of 2024 and beyond, although the precise magnitude of our total investment will depend **operating model to focus on our partnership with Sanofi** the duration of the impact of COVID-19, the competitive landscape **development of our late-stage pipeline**, the timing **including our CIC and stand-alone influenza** results of our applications for regulatory approvals, the availability of funding, and whether and what booster shot protocols are recommended by governments, regulatory authorities, and healthcare providers. If we are unable to timely commercialize a vaccine **candidates** against COVID-19 in sufficient jurisdictions, **leveraging** we likely would never recoup our investments. We **Matrix-MTM technology to drive additional partnerships and deals, and our emerging, early-stage pipeline, we** expect to continue to incur significant operating expenses and anticipate significant losses over time as we seek to:

- conduct additional clinical trials and continue to seek regulatory approvals for our COVID-19 Vaccine, **CIC and stand-alone influenza vaccine candidates, RSV vaccine candidate** and other potential vaccine candidates;
- conduct preclinical studies for other potential vaccine candidates;
- **evaluate** expand our global manufacturing and distribution capacity, and further commercialize **commercial opportunities for the use of our COVID-19 Matrix -19 MTM adjuvant alongside Vaccine vaccine antigens produced by other manufacturers**;
- and • maintain, expand and protect our intellectual property portfolio.

As a result, we expect our cumulative operating losses to increase until such time, if ever, that product sales, licensing fees, royalties, milestones, contract research and other sources generate sufficient revenue to fully fund our operations. We may never achieve profitability and may not sustain profitability, if achieved. We do not currently generate sufficient revenue from product sales, licensing fees, royalties, milestones, contract research or other sources to fully fund our operations. We, therefore, will use our cash resources, and expect to require additional funds, to maintain our operations, continue our research and development programs, advance preclinical studies and clinical trials, seek regulatory approvals and manufacture and market our COVID-19 Vaccine and any other product candidates that are approved for commercialization. To date, we have financed our operations primarily through the sale of equity and debt securities, government funding and grant agreements, **non-refundable upfront payment under the Sanofi CLA, revenue from product sales,** and **upfront payments under APAs** supply agreements (also sometimes referred to as advance purchase agreements) for our COVID-19 Vaccine. Although we have entered into **APAs supply agreements** for our COVID-19 Vaccine that include prepayments from the purchasers, until we can generate sufficient product revenue from such agreements to fully fund our operations, which we may never do, we expect to finance our cash needs through a combination of **milestone payments, royalties, and payments for transition services and technology transfer under the Sanofi CLA, revenue from product sales,** additional public or private equity or debt financings, **as well as which may include at the market offerings,** existing cash **and cash equivalents, investments in marketable securities**, potential collaborations, strategic alliances **and,** marketing, distribution or licensing arrangements, funding from governmental and non-governmental funding entities, and potentially other sources. While we may continue to apply for contracts or grants from academic institutions, non-profit organizations and governmental entities, we may not be successful. Adequate additional funding may not be available to us on favorable terms, or at all. Furthermore, negative interpretations of clinical trial data or setbacks, or perceived setbacks, with respect to manufacturing ability and / or capacity or regulatory filing timelines for our **COVID-19 Vaccine or our other** vaccine candidates, as well as the competitive landscape posed by other **COVID-19** vaccines, may impair our ability to raise additional financing on favorable terms, or at all. **If we cannot raise the** Additionally **additional funds required for our anticipated operations**, **under** we may be required to delay significantly, reduce the scope of or eliminate one or more of our research or development programs, downsize our organization, or seek **alternative measures to avoid insolvency, including arrangements with collaborative partners or others that may require us to relinquish rights to** certain a material and adverse effect on the price of our common stock. Economic and political uncertainty may adversely affect our access to capital, cost of capital and ability to execute our business plan as scheduled. Generally, worldwide economic conditions remain uncertain, particularly due to the impact of increased interest rates, and inflation. In addition, our operations and performance may be affected by **changes in diplomatic and trade relationships, tariffs, trade protection measures, import or export licensing requirements, new or different customs duties, trade embargoes and sanctions and other trade barriers,** political or civil unrest or military action, including **the ongoing** conflicts between Russia and Ukraine and Israel and Hamas as well as hostilities elsewhere in the Middle East. Access to capital markets is critical to our ability to operate. Traditionally, biotechnology companies have funded their research and development expenditures by raising capital in the equity markets. Declines and uncertainties in these markets in the past have severely restricted raising new capital and have affected companies' ability to continue to expand or fund existing development, manufacturing, regulatory and commercialization efforts. We require significant capital for our current and expected operations. The general economic and capital market conditions, both in the U.S. and worldwide, have been volatile in the past and at times have adversely affected our access to capital and increased the cost of capital. The capital and credit markets may not be available to support future capital raising activity on favorable terms. If economic conditions decline, our future cost of equity or

debt capital and access to the capital markets could be adversely affected. In addition, if we are unable to access the capital markets on favorable terms, our ability to execute our business plan as contemplated would be compromised. Moreover, we rely and intend to rely on third parties, including clinical research organizations, contract manufacturing organizations and other important vendors and consultants. Global economic conditions may result in a disruption or delay in the performance of our third-party contractors and suppliers. If such third parties are unable to adequately satisfy their contractual commitments to us in a timely manner, our business could be adversely affected. Our existing funding and supply agreements or our advance purchase agreements do not assure success of our vaccine candidates or vaccines or that we will be able to fully fund our vaccine candidates or vaccines or our company operations, and if we are unable to satisfy the supply agreements, including the Sanofi CLA and our APAs, do not assure success of our vaccine candidates or vaccines or that we will be able to fully fund our vaccine candidates or vaccines or our operations, and if we are unable to satisfy the performance obligations under such agreements, we may not be eligible to receive milestone payments under such agreements, the agreements may be terminated, the purchase commitments may be reduced or we may be required to refund advance payments. We have entered into, and may in the future enter into, collaboration, funding, supply and other agreements for our vaccines or vaccine candidates to help fund the development, manufacture and / or commercialization of our vaccines or vaccine candidates. Certain of these agreements may contain development, technology transfer, launch, sales and other milestones related to our vaccines or vaccine candidates pursuant to which we may be eligible to receive milestone payments upon the achievement of the requisite milestone. For example, we are eligible to receive future milestone payments under the Sanofi CLA totaling up to \$ 650 million in the aggregate with respect to COVID- 19 Vaccine Products, including a payment of \$ 175 million upon the approval of the marketing authorization for a COVID- 19 Vaccine Product in a pre- filled syringe from the U. S. FDA, \$ 25 million upon the transfer of such approval to Sanofi, \$ 25 million upon the transfer of EMA approval of a COVID- 19 Vaccine Product in a pre- filled syringe to Sanofi, \$ 75 million upon the completion of the technology transfer of our manufacturing process for the COVID- 19 Vaccine Products to Sanofi, and up to \$ 350 million in CIC Product- related development and launch milestones. We may experience challenges in satisfying our obligations under these agreements, including as a result of delayed performance of our third- party contractors and suppliers, which may impact our ability to achieve such milestones, potentially expose us to damages or other liability pursuant to these agreements, including the Sanofi CLA, and have a material and adverse effect on our financial condition. Under certain APAs, if we do not timely achieve requisite regulatory milestones for our COVID- 19 Vaccine in the relevant jurisdictions, obtain supportive recommendations from governmental advisory committees, and / or achieve product volume or delivery timing obligations, purchasers may seek to terminate such agreements, reduce their purchase commitments, require us to refund all or some prepayments we have received, or renegotiate such agreements. If we cannot raise the additional funds required for our anticipated operations, each we may be required to delay significantly, reduce the scope of or eliminate one or more of our research or development programs, downsize our organization, or seek alternative measures to avoid insolvency, including arrangements with collaborative partners or others that may require us to relinquish rights to certain of our technologies or vaccine candidates. If we raise additional funds through future offerings of shares of our common stock or other securities, such offerings would cause dilution of current stockholders' percentage ownership in the Company, which could be substantial. Future offerings also could have a material and adverse effect on the price of our financial common stock. Economic and political uncertainty may adversely affect our access to capital, cost of capital and ability to execute our business plan as scheduled. Generally, worldwide economic conditions condition remain. For example, in the first quarter of 2025, the Company received written notice of a \$ 23 million claim related to uncertain -- certain, particularly due to the impact of..... if we are unable to satisfy the performance obligations under such an APA agreements- agreement the agreements may be terminated, the purchase commitments may be reduced or we may be required to refund advance payments. Our funding agreements with the U. S. government ("USG") and CEPI each reimburse a customer portion of the expenses associated with the development and commercialization of our COVID- 19 Vaccine. The Company believes To the extent funding commitments in such agreements are conditioned on our meeting certain milestones or conditions, we may not ultimately receive the full amount of committed funds and may require additional funding to support our COVID- 19 Vaccine development and commercialization activities, and we may be unable to timely obtain additional funding. For example, in July 2021, in connection with funding from the USG partnership formerly known as Operation Warp Speed, the USG instructed us to prioritize alignment with the FDA on our analytic methods before conducting additional U. S. manufacturing, and the USG indicated that it would not fund additional U. S. manufacturing until such alignment was reached, which did not occur until June 2022. In February 2023, in connection with the execution of Modification 17 to the USG Agreement, the U. S. government indicated to us that the award may not be extended past its current period of performance. The USG Agreement also includes provisions giving the USG termination rights based on a determination that the funded project will not produce beneficial results commensurate with the expenditure of resources and that termination would be in the USG's interest. Such a determination would result in the loss of funding under that agreement and could result in other actions by the USG. The CEPI funding agreement, meanwhile, provides CEPI certain " march- in " rights in the event of certain breaches of that agreement. Additionally, we have entered into, and plan to continue entering into, supply agreements (also sometimes referred to as has fulfilled advance purchase agreements) for our COVID- 19 Vaccine that include prepayments from the purchasers to help fund our development and manufacture of the vaccine. Under certain supply agreements, if we do not timely achieve requisite regulatory milestones for our COVID- 19 Vaccine in the relevant jurisdictions, obtain supportive recommendations from governmental advisory committees, and / or achieve product volume or delivery timing obligations, purchasers may seek to terminate such agreements, reduce their -- the requirements related purchase commitments, require us to this matter refund all or some prepayments we have received, or renegotiate such agreements, each of which could have a material and adverse effect on our financial condition is evaluating the merits of the claim. The timing to fulfill performance

obligations related to supply agreements will depend on timing of product manufacturing, receipt of marketing authorizations for additional indications, delivery of doses based on customer demand, and the ability of the customer to request variant vaccine in place of prototype COVID-19 vaccine under certain of our supply agreements. The supply agreements typically contain terms that include upfront payments intended to assist us in funding investments related to building out and operating our manufacturing and distribution network, among other expenses, in support of our global supply commitment, and are applied to billings upon delivery of COVID-19 Vaccine. Such upfront payments generally become non-refundable upon our achievement of certain development, regulatory and commercial milestones. We may not achieve such milestones, which could have a material and adverse effect on our financial condition. For example, in September 2022, following a delay in obtaining regulatory approval in the United Kingdom, we entered into the Amended and Restated UK Supply Agreement, which amended and restated in its entirety the Original UK Supply Agreement, which reduced the volume of vaccine doses that the Authority is committed to purchase as compared to the Original UK Supply Agreement. Under the terms of the Amended and Restated UK Supply Agreement, the Authority agreed to purchase a minimum of 1 million doses and up to an additional 15 million doses (the "Conditional Doses") of our prototype COVID-19 vaccine, with the number of Conditional Doses contingent on, and subject to reduction based on, our timely achievement of supportive recommendations from the JCVI that is approved by the UK Secretary of State for Health. If the Authority did not purchase the Conditional Doses or the number of such Conditional Doses was reduced below 15 million doses of our prototype COVID-19 vaccine, we would have to repay up to \$ 225.0 million related to the upfront payment previously received from the Authority under the Original UK Supply Agreement. Under the Amended and Restated UK Supply Agreement, the Authority also has had the option to purchase up to an additional 44 million doses, in one or more tranches, through 2024. As of November 30, 2022, the JCVI had not made a supportive recommendation with respect to our prototype vaccine, thereby triggering, under the terms of the Amended and Restated UK Supply Agreement, (i) a reduction of the number of Conditional Doses from 15 million doses to 7.5 million doses, which reduced number of Conditional Doses are were contingent on, and subject to further reduction based on, our timely achievement by November 30, 2023 of a supportive recommendation from JCVI that is approved by the UK Secretary of State for Health as described in the paragraph above, and (ii) an obligation for us to repay \$ 112.5 million related to the upfront payment previously received from the Authority under the Original UK Supply Agreement. In April 2023, we repaid the \$ 112.5 million related to the November 30, 2022 triggering event. As of November 30, 2023, the JCVI had not made a supportive recommendation with respect to the prototype vaccine, thereby triggering a reduction in the number of Conditional Doses from 7.5 million doses to zero. In November 2023, we entered into the Company is in discussions Settlement Agreement and the Settlement Agreement Amendment with the Authority, settling the disputes regarding the treatment Amended and Restated UK Supply Agreement and releasing both parties of all claims arising out of or connected with the remaining Amended and Restated UK Supply Agreement. Under the terms of the Settlement Agreement, the Authority and us agreed to terminate the Amended and Restated UK Supply Agreement and to fully settle the outstanding amount under dispute related to upfront amount payments of \$ 112.5 million previously received by us from the Authority under the Amended and Restated UK Supply Agreement. Pursuant to the Settlement Agreement, we agreed to pay the Settlement Payment to the Authority in equal quarterly installments of \$ 11.25 million over a three year period, ending which is reflected in June 2027. The Settlement Payment amount includes a \$ 11.3 million provision for interest over Other-- the current liabilities on our consolidated balance sheet period and may be avoided if we choose to accelerate payments. Under the terms of the Settlement Agreement Amendment, we made the first quarterly installment in November 2024. In July 2023, we entered into an amended amendment to the Australia APA. Pursuant to provide for replacement doses and to extend the amendment, we acknowledged the cancellation by Australia of the delivery schedule through 2025. As of February 2024, we had not yet received TGA authorization or delivered doses as contemplated in the July 2023 amendment and are in active discussions with the Australian government on both the TGA authorization and delivery of the doses previously scheduled for the fourth quarter of 2023. In February 2024, we received notice from the Australian government purporting to cancel its order for such prototype vaccine doses. We believe the cancellation was not proper under the amended Australia APA. However, if such a cancellation were determined to be allowable, \$ 6.0 million of the deferred revenue would become a credit towards future deliveries of doses and approximately \$ 48 million of the contract value related to future deliverables would no longer be available. In April 2023, we amended the Canada APA, pursuant to which the Canadian government forfeited certain doses originally of our COVID-19 Vaccine scheduled for delivery in-between the fourth quarter of 2022-2023 and the fourth quarter of 2025 and we agreed to credit approximately \$ 31 million of the advanced payment paid by Australia to us against outstanding invoices and invoices for a payment the future delivery of approximately 3 \$ 100.4 million doses, which we received in the second quarter of 2023 COVID-19 Vaccine without requiring additional cash payments. We also agreed to in June 2023, we entered into an additional updated delivery schedule providing for the potential delivery of COVID-19 Vaccine or future variant COVID-19 Vaccine through the end of 2029. The amendment (further provides for certain remedies for Australia, including return of unused credit, cancellation of doses, or termination of the "June 2023 Australia APA, in the event we miss or under deliver doses to Australia or fail to receive regulatory approval of a variant COVID-19 vaccine. The Amendment amendment") also provides Australia with the right to cancel doses if we fail to timely notify Australia of changes to our commercialization plans. Pursuant to the Canada APA - Pursuant to the June 2023 Amendment, (i) the Canadian government may terminate forfeited certain doses of COVID-19 Vaccine previously scheduled for delivery and agreed to pay a total amount of \$ 349.6 million to us in two equal installments, which total amount equaled the remaining balance owed by the Canadian government with respect to such forfeited vaccine doses, (ii) the amount of doses of COVID-19 Vaccine due for delivery was reduced, (iii) the delivery schedule for the remaining doses of COVID-19 Vaccine to be delivered was revised, and (iv) the parties agreed Novavax would use the Biologics Manufacturing Centre ("BMC") Inc. to produce bulk antigen for doses in 2024 and 2025.

The June 2023 Amendment maintained the total contract value of the original Canada APA. The first installment of \$ 174.8 million was payable upon execution of the June 2023 Amendment and received by Novavax in July 2023, and the second installment of \$ 174.8 million was contingent and payable upon the delivery of vaccine doses in the second half of 2023 and received by Novavax in January 2024. The Canadian government may terminate the Canada APA, as amended, if **as we fail failed** to receive regulatory approval for our COVID-19 Vaccine using bulk antigen produced at BMC on or before December 31, 2024. **Therefore** Our 2024 plans do not currently anticipate the submission for regulatory approval of our COVID-19 Vaccine using bulk antigen produced at BMC, and we plan to work **are in discussions** with the Canadian **Canada** government on an **regarding a potential** amendment **that to the Canada APA to** addresses **address** possible alternatives, which may not be achievable **on acceptable terms or at all**. As of December 31, 2023 **2024**, \$ 102 **555**. **8-7** million was classified as **current** short-term Deferred revenue and \$ 485.3 million was classified as long-term Deferred revenue with respect to the **Canadian** **Canada** APA **on in** our consolidated balance sheet. If the Canadian government terminates the Canada APA, \$ 28.0 million of the deferred revenue **advanced payments previously received** would become refundable, **which was classified as Other current liabilities in our consolidated balance sheet**, and approximately \$ 224 million of the contract value related to future deliverables would no longer be available. **In July 2024, Pharmac provided notice of its termination of the New Zealand APA. Pharmac has requested a refund of certain advanced payments, and we are in discussion with Pharmac regarding whether a refund of the advanced payments is appropriate under the New Zealand APA. As of December 31, 2024, \$ 31.3 million was classified as Other current liabilities with respect to the New Zealand APA in our consolidated balance sheet. Approximately \$ 125 million of the contract value related to future deliverables may no longer be available if the New Zealand APA is terminated. We responded to Pharmac in September 2024 indicating we do not believe Pharmac has the right to unilaterally terminate the contract or receive a refund of any part of the remaining upfront payment. We are in ongoing discussions with Pharmac to resolve this matter, which may not be achievable on acceptable terms or at all. We have identified a material weakness in our internal control over financial reporting, and we may identify additional material weaknesses in the future. If we fail to maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial results and current and potential stockholders may lose confidence in our financial and other public reporting, which would harm our business and have a negative effect on the trading price of our common stock. We are required by the Sarbanes Oxley Act of 2002 to establish and maintain adequate internal control over financial reporting that provides reasonable assurance regarding the reliability of our financial reporting and the preparation of financial statements in accordance with GAAP. We are likewise required, on an annual basis, to evaluate the effectiveness of our internal controls and to disclose on a quarterly basis any material changes in those internal controls. As described in Item 9A – Controls and Procedures elsewhere in this Annual Report on Form 10-K, in connection with the audit of our financial statements for the year ended December 31, 2024, we identified a material weakness in our internal control over financial reporting with regard to deficiencies specifically related to ineffective change management review and periodic access review controls, with respect to our human resources information system (see Note 3 “HRIS”), which was implemented in 2024. As a result of the deficiencies, certain change management and user access controls, as well as the related process-level IT dependent manual controls and automated application controls across various processes impacted by the HRIS were also determined to be ineffective. We performed additional substantive procedures and concluded that there were no instances of inappropriate access, unauthorized ~~our~~ or inappropriate changes to the system or material misstatements. While this material weakness did not result in a material misstatement of our financial statements, there is a reasonable possibility that business processes that depend on the HRIS or data from the HRIS could be adversely impacted and result in a material misstatement in our annual or interim consolidated financial statements that would not be detected. As Accordingly, we determined that the deficiencies when considered in aggregate constituted a material weakness. Our disclosure controls and procedures were also determined to not be effective because of the material weakness. We are in the process of implementing measures designed to remediate the control deficiencies that led to the material weakness as of December 31, 2024. However, our remediation efforts with respect to our identified material weakness may be inadequate. The elements of our remediation plan can only be accomplished over time and our remediation plan may not ultimately have its intended effects. We may have additional material weaknesses or significant deficiencies in our internal control over financial reporting in the future. Any failure to maintain such internal controls could adversely impact our ability to report our financial results on a timely and accurate basis and could restrict our future access to the capital markets. If our financial statements are not accurate, investors may not have a complete understanding of our operations or may lose confidence in our reported financial information. Likewise, if our financial statements are not filed on a timely basis as required by the SEC and Nasdaq, we could face severe consequences from those authorities. In either case, it could result in a material adverse effect on**, our existing funding and supply agreements or **our business our** or have a negative effect on **advance purchase agreements do not assure success of our vaccine candidates and may be insufficient to fully fund the trading price** development and commercialization of our vaccine candidates, our vaccines or **our common stock** our company operations and if we are unable to satisfy the performance obligations under such agreements the agreements may be terminated, the purchase commitments may be reduced or we may be required to refund advance payments. **Risks Related to Product Development and Commercialization** **Because our vaccine product development and commercialization efforts depend on new and rapidly evolving technologies, our efforts may not succeed.** Our vaccine development efforts depend on new, rapidly evolving technologies and on the marketability and profitability of our **current and future** products. **Our The** development and commercialization efforts and, if those are successful, commercialization of our COVID-19 Vaccine and **our royalty and other payments received from Sanofi for their commercialization of our COVID-19 Vaccine and the development and, if successful, commercialization efforts of our other vaccines vaccine candidates**

could fail for a variety of reasons, including if: • our recombinant nanoparticle vaccine technologies, any or all of the products based on such technologies or our proprietary manufacturing process prove ineffective or unsafe; • new strains of COVID- 19 evolve, with respect to which our COVID- 19 Vaccine **or future COVID- 19 variant strain containing formulations** ~~prove~~ **prove** less effective; • we or our third- party manufacturer facilities fail to reproducibly scale- up and maintain manufacturing with sufficiently high yields at reasonable cost and on projected timelines, or such manufacturing fails to generate product that consistently satisfies purity, potency, quality, stability, and shelf- life standards necessary for obtaining regulatory approvals or achieving commercial viability; • the products are uneconomical to market or manufacture; • some or all of the products that we or our third- party partners have manufactured may be determined to be unsalable based on criteria imposed by regulators as they complete regulatory approvals; • our in- house or third- party manufacturing facilities fail regulatory inspections; • proprietary rights of third- parties prevent us or our collaborators from exploiting technologies, and manufacturing or marketing products; or • third- party competitors achieve and maintain greater market share due to earlier approvals or superior marketing capabilities. The regulatory and commercial success of our COVID- 19 Vaccine remains uncertain. While we have received ~~provisional registration, conditional marketing authorization or~~ emergency use authorization **or full approval** for our COVID- 19 Vaccine in a number of jurisdictions, we may be unable to obtain full regulatory approvals in the U. S. or other jurisdictions for our updated **COVID- 19** vaccine or new versions in the future or produce a successful vaccine in a timely manner, if at all. In response to the outbreak of COVID- 19, we began pursuing, and continue to pursue, the development and manufacture of our COVID- 19 Vaccine. Even though we have reported positive data from Phase 1, 2 and 3 clinical trials, and we and our partners have received either ~~provisional registration, conditional marketing authorization, emergency use authorization, or full approval~~ from ~~the World Health Organization and in~~ several jurisdictions **or the WHO**, such results may not be sufficient to support regulatory submissions, authorizations and approvals, accelerated or otherwise, in any other relevant jurisdictions on our projected timelines, if at all. **Additionally, We will continue to commercialize our updated vaccine for the 2024- 2025 vaccination season and, beginning in 2025 and continuing during the term of the Sanofi CLA, we and Sanofi will commercialize our COVID- 19 Vaccine worldwide in accordance with a commercialization plan agreed by us and Sanofi.** ~~even~~ **Even** though our COVID- 19 Vaccine has received regulatory authorizations in certain jurisdictions and may receive further regulatory approval in others, successful commercialization depends on our ability to ~~effectively scale up and~~ maintain manufacturing capabilities at our own locations and those of our manufacturing partners and contractors. ~~In May 2020 to~~ **supply our existing APA partners**, we acquired Novavax CZ (formerly Praha Vaccines, a. s.) including its vaccine **Takeda and SII**, our ability to timely and successfully transfer know- how related to our manufacturing **process for our COVID- 19 Vaccine to Sanofi and our facility** ~~ability to operationalize the Sanofi CLA with Sanofi. We~~ in Bohumil, Czech Republic and approximately 150 of its employees but we have **entered** yet to receive regulatory approval at this site. We also ~~are actively entering~~ into agreements with third parties to manufacture the antigen component of **our** COVID- 19 Vaccine and our proprietary Matrix- M™ adjuvant, as well as to distribute our COVID- 19 Vaccine. Because of contractual restraints and the limited number of third- party manufacturers with the relevant expertise, required regulatory approvals and facilities to manufacture our COVID- 19 Vaccine and its components at commercial scale, replacement of a manufacturer may be expensive and time- consuming and may cause interruptions in production. Manufacturing of our COVID- 19 Vaccine and its components involves a complicated process that ~~will require~~ **requires** significant investments of time and financial resources to implement, and our efforts to establish and maintain manufacturing capabilities may not meet expectations as to timing, scale- up, reproducibility, yields, purity, cost, potency or quality. Shortages of raw materials and supplies also negatively impact our manufacturing efforts. We may not be able to timely and effectively produce or receive regulatory approvals for our COVID- 19 Vaccine in adequate quantities to address global demand. We have limited experience with the commercial launch of vaccine products. ~~In addition~~ **We have historically experienced challenges related** to scaling up our manufacturing capabilities, ~~we need to~~ **delivering our COVID- 19 vaccine on time and in certain product presentations for the beginning of a vaccination season, develop** ~~developing~~ **developing** global distribution channels and ~~form~~ **forming** partnerships with third parties worldwide, as well as ~~hire~~ **hiring**, ~~train~~ **training** and ~~integrate~~ **integrating** additional management, administrative and sales and marketing personnel. ~~Rapid and significant growth may strain our administrative and operational infrastructure, imposing significant additional responsibilities on our organization, and our efforts to establish and maintain these capabilities may not meet expectations as to timing, scale- up, reproducibility, yields, purity, cost, potency or quality. If we fail to successfully manage our growth and the increased complexity of our operations, our business, financial position, results of operations and prospects may be materially and adversely affected.~~ The emergence and transmissibility of variants of the SARS- CoV- 2 virus, ~~and the demand for bivalent vaccines,~~ may affect market acceptance or sales of our COVID- 19 Vaccine, and our strategy to develop new versions of our COVID- 19 Vaccine to protect against certain variants may not be successful. Our prototype vaccine was a monovalent vaccine developed based upon the genetic sequence of the SARS- CoV- 2 virus that was first discovered in December 2019. Our updated vaccine is a monovalent vaccine developed based upon the **XBB- JN. 1. 5** strain for the ~~fall 2023~~ **2024 COVID- 19 Vaccine 2025 vaccination** season. As the SARS- CoV- 2 virus continues to evolve, new strains of the virus, or those that are already in circulation, ~~may prove more transmissible or~~ **have in the past (in the** ~~cause~~ **cases** ~~more severe forms of COVID- 19 disease than the predominant strains to date. For example, Alpha, Beta, Delta and Omicron (including subvariants such as XBB. 1. 5 and JN. 1) variants have been observed to be~~) **and may in the future prove** more transmissible, ~~or contagious,~~ **cause more severe forms of COVID- 19 disease** than previous variants ~~the predominant strains to date~~. Our COVID- 19 Vaccine may not be as effective in protecting against these or other future variant strains. ~~Additionally, we expect the demand for bivalent vaccines to continue to increase, which may negatively impact the demand, particularly in the U. S., for our COVID- 19 Vaccine and would likely require significant expenditures by the Company to successfully market a bivalent formulation, particularly in the U. S.~~ Our COVID- 19 Vaccine may fail to achieve market acceptance or significant sales, despite gaining regulatory approval, ~~provisional registration, conditional marketing authorization or emergency use authorization in a number of~~

jurisdictions, including emergency use authorization the U. S., as demand for variant- specific ~~or bivalent~~ vaccines increases - ~~We have several variant-specific vaccine candidates in development, including for Omicron subvariants and may develop others in the future.~~ However, if these efforts are unsuccessful, these candidates do not receive regulatory approvals expeditiously, we are slower to develop variant- specific ~~or bivalent~~ vaccines than competitors, these vaccine candidates prove less effective than competitors' vaccines, or we are unable to successfully manufacture, distribute or market such vaccine candidates once approved, these shortcomings may lead to reputational harm, loss of market share, and adverse financial results. Our ~~2024-2025~~ revenue depends on our ~~and Sanofi's~~ ability to successfully develop, manufacture, distribute, ~~or and~~ market ~~in accordance with the Sanofi CLA,~~ an updated monovalent ~~or bivalent~~ formulation of a vaccine candidate for COVID- 19 ~~in a single dose vial or pre-filled syringe for the fall 2024-2025 COVID vaccine - 2026 vaccination~~ season, which is inherently uncertain and subject to a number of risks, including regulatory approval. We experienced delays in early 2023 in manufacturing our BA. 5 clinical trial materials, which delayed regulatory approval from the U. S. FDA for our vaccine candidate for the ~~fall 2023 COVID vaccine - 2024 vaccination~~ season. Further, counterparties to certain of our existing ~~APAs~~ supply agreements may request variant- specific vaccines in place of our COVID- 19 Vaccine and, depending on when we are able to offer such variant- specific vaccines, if at all, such counterparties may seek to delay, reduce or otherwise renegotiate their purchase commitments, which may adversely impact our ability to realize the full financial benefit of such ~~APAs~~ supply agreements. In addition, we may expend significant resources adapting our COVID- 19 Vaccine or conducting clinical trials to protect against variants of the SARS- CoV- 2 virus, but a market for this adapted vaccine may not develop and demand may not align with our projections or cost expenditures. We are a biotechnology company and face significant risk in developing, manufacturing and commercializing our products. We focus our research and development activities on vaccines, an area in which we believe we have particular strengths and a technology that appears promising. The outcome of any research and development program is highly uncertain. Only a small fraction of biopharmaceutical development programs ultimately result in commercial products or even product candidates and a number of events could delay our development efforts and negatively impact our ability to make regulatory submissions or obtain regulatory approval for, and to manufacture, market and sell, our COVID- 19 Vaccine or any other vaccine on our projected timelines, if at all. Vaccine candidates that initially appear promising often fail to yield successful products, and we may not ultimately be able to demonstrate the safety, potency, purity, stability and efficacy necessary to obtain or maintain regulatory authorization to market our product candidates. In many cases, preclinical studies or clinical trials will show that a product candidate is not efficacious or that it raises safety concerns or has other side effects that outweigh its intended benefit. Success in preclinical or early clinical trials may not translate into success in large- scale clinical trials. **For example, in October 2024, the U. S. FDA placed a clinical hold on the IND for our CIC and stand- alone influenza vaccine candidates from a spontaneous report of a serious adverse event in a participant who received the CIC vaccine candidate in a Phase 2 trial that completed in 2023. After providing the U. S. FDA with the requested additional information, this event was assessed as not related to vaccination. The information provided to the FDA supported our assessment that the serious adverse event was not related to our CIC vaccine candidate, and the U. S. FDA removed the clinical hold in November 2024.** Further, success in clinical trials often leads to increased investment, accelerating cumulative losses. Even if clinical trial results appear positive, regulatory approval may not be obtained if the U. S. FDA, or a foreign equivalent, does not agree with our interpretation of the results ~~, and we may face challenges when scaling up the production process to commercial levels.~~ Even after a product is approved and launched, general usage or post- marketing clinical trials may identify safety or other previously unknown problems with the product, or manufacturing issues may emerge, either of which may result in regulatory approvals being suspended, limited to narrow the scope of the approval, or revoked, which may otherwise prevent successful commercialization. Intense competition in the vaccine industry could also limit the successful commercialization of any products for which we receive commercial approval. We will require approval from the U. S. FDA of any name we intend to use for our products regardless of whether we have secured a trademark registration from the USPTO. The U. S. FDA typically conducts a review of proposed product names, including an evaluation of potential for confusion with other product names. The U. S. FDA may object to any product name we submit if it believes the name inappropriately implies medical claims. If the U. S. FDA objects to any of our proposed product names, we may be required to adopt an alternative name for our proposed products. If we adopt an alternative name, we would lose the benefit of any existing trademark applications for such developmental candidate and may be required to expend significant additional resources in an effort to identify a suitable product name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the U. S. FDA. We may be unable to build a successful brand identity for a new trademark in a timely manner or at all, which would limit our ability to commercialize our products, if approved. **Because we depend on third parties to conduct some of our laboratory testing and clinical trials, and a significant amount of our vaccine manufacturing and distribution, we may encounter delays in or lose some control over our efforts to develop and supply products.** We are highly dependent on third- party organizations to conduct some of our laboratory testing and clinical trials and a significant amount of our vaccine manufacturing activities and distribution. If we are unable to obtain any necessary services on acceptable terms, we may not complete our product development or commercialization efforts in a timely manner. We may lose control over these activities or become too dependent upon these parties. These third parties may not complete testing, manufacturing or distribution activities on schedule, or in satisfaction of regulatory or commercial requirements. In particular, we currently depend significantly on ~~SHPL~~ **SII** and ~~SLS~~ for co- formulation, filling, and finishing our COVID- 19 Vaccine ~~(except in Europe, where we rely on PCI Pharma Services ("PCI"))~~. If ~~SII~~ **SII** ~~SLS~~ or ~~PCI~~ is unable to provide sufficient co- formulation, ~~fill~~ **filling**, and ~~finish~~ **finishing** services to us, fails to meet regulatory requirements, or otherwise defaults on its obligations to us, we may not be able to obtain alternative co- formulation, ~~fill~~ **filling**, and ~~finish~~ **finishing** services from other providers on acceptable terms in a timely manner or at all, which could prevent or delay delivery of customer orders, or otherwise negatively affect our business. ~~Certain of our facilities are also contracted for defined time frames and through~~

association with USG and CEPI, and we may not be able to access those facilities for sufficient periods of time to provide adequate supply. We are responsible for confirming that each of our clinical trials is conducted in accordance with its general investigational plan and protocol. Moreover, the U. S. FDA and foreign regulatory agencies require us to comply with regulations and standards, commonly referred to as good clinical practices, for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, safety and welfare of clinical trial participants are adequately protected. The U. S. FDA and foreign regulatory agencies also require us to comply with good manufacturing practices. Our reliance on third parties does not relieve us of these responsibilities and requirements. These third parties may not successfully carry out their contractual duties or regulatory obligations. Furthermore, if a third- party manufacturer is producing materials or products for themselves or other companies, that manufacturer is exposed to regulatory risks for the production of such materials and products. As a result, failure to meet the regulatory requirements for the production of those materials and products may generally affect the regulatory status of the third- party manufacturer' s facility, which could impact its ability to produce our materials and products. Any of our third- party service providers may need to be replaced, the quality or accuracy of the data they obtain may be compromised, the services provided to us may be delayed, or the product they manufacture may be contaminated and unusable due to the failure to adhere to our clinical and manufacturing protocols, regulatory requirements or for other reasons. In any such event, our preclinical development activities or clinical trials may be extended, delayed, suspended or terminated, and we may not be able to obtain regulatory approval of, or successfully commercially manufacture on a timely basis, our vaccine candidates. We may have product liability exposure. The administration of drugs or vaccines to humans, whether in clinical trials or after marketing approval, can result in product liability claims. We maintain product liability insurance coverage for our current clinical programs, including our NVX- CoV2373 and, NVX- CoV2601, **CIC and stand- alone influenza and R21 / Matrix- MTM adjuvant malaria vaccine** trials, and for commercialization of our updated **COVID- 19** vaccine. However, we may not be able to obtain additional insurance coverage or maintain insurance coverage on commercially reasonable terms, at a reasonable cost or in sufficient amounts to protect us against losses due to liability. Furthermore, such insurance coverage and our resources may not be sufficient to satisfy all liabilities that result from product liability claims. A successful claim may prevent us from obtaining adequate product liability insurance in the future on commercially desirable terms, if at all. Even if a claim is not successful, defending such a claim would be time- consuming and expensive, may damage our reputation in the marketplace and would likely divert management' s attention. In addition, ~~because we are developing our COVID- 19 Vaccine in response to the outbreak of COVID- 19, a global pandemic,~~ we have received ~~either provisional registration,~~ conditional marketing authorization, emergency use authorization, or full approval from the World Health Organization and various jurisdictions, and we have a widely used vaccine as an investigational vaccine or a product authorized for temporary or emergency use prior to our receipt of marketing approval in **certain** other jurisdictions ~~as well~~. Unexpected safety issues in these circumstances could lead to product liability claims and our existing insurance may not be adequate for such claims. Regardless of merit or eventual outcome, liability claims may result in: • decreased demand for our products; • withdrawal of regulatory authorizations and approvals; • voluntary or mandatory recalls of our products; • necessity for additional nonclinical or clinical studies, changes in labeling, or changes to manufacturing processes, specifications and / or facilities; • impairment of our business reputation and negative media attention; • withdrawal of clinical trial participants; • costs of related litigation; • substantial monetary awards to participants or other claimants; • loss of revenue; and • inability to commercialize our vaccine candidates. In the U. S., the PREP Act, when applicable, provides immunity for manufacturers from all claims under state or federal law for “ loss ” arising out of the administration or use of a “ covered countermeasure. ” However, injured persons may still bring a suit for “ willful misconduct ” against the manufacturer under some circumstances. “ Covered countermeasures ” include security countermeasures and “ qualified pandemic or epidemic products ”, including products intended to diagnose or treat pandemic or epidemic disease, such as pandemic vaccines, as well as treatments intended to address conditions caused by such products. For these immunities to apply, the Secretary of DHHS must invoke the PREP Act by issuing a declaration that a public health emergency or “ credible risk ” of a future public health emergency exists. Such a PREP Act declaration is separate from other declarations such as a PHE or EUA declaration and, among other things, defines the scope and duration of the PREP Act immunities. On March 17, 2020, the Secretary of DHHS issued a declaration under the PREP Act and has issued subsequent amendments thereto to provide liability immunity for activities related to certain countermeasures against the evolving effects of COVID- 19. The current declaration will end on December 31, ~~2024~~ **2029**, unless it is renewed. While we believe our products are covered under the current PREP Act declaration, this cannot be assured. Also, the Secretary of the DHHS may not make other declarations in the future that cover any of our other product candidates, and the U. S. Congress may reduce coverage under the PREP Act or repeal it altogether. Product liability lawsuits may result in substantial liabilities and may require us to limit commercialization of our product candidates. If we are unable to effectively manufacture our COVID- 19 Vaccine in sufficient quantities, **or** at sufficient yields ~~or are unable to obtain regulatory approvals for a manufacturing facility for our COVID- 19 Vaccine~~, we may experience delays or an adverse impact on product development, clinical trials, regulatory approvals and commercial distribution. We are continuing to pursue the manufacture, distribution and clinical testing of our COVID- 19 Vaccine for commercialization. Completion of our clinical trials and commercialization of our COVID- 19 Vaccine and our other vaccine candidates requires access to, or development of, facilities to effectively manufacture our COVID- 19 Vaccine and our other vaccine candidates at sufficient yields and at commercial -scale. We have limited experience manufacturing any of our vaccine candidates in the volumes necessary to support commercial sales. While we have increased our global manufacturing capacity for our COVID- 19 Vaccine, our efforts to establish and maintain manufacturing capabilities may not meet expectations as to timing, scale- up, reproducibility, yields, purity, cost, potency or quality. We are highly dependent on third- party organizations to conduct a significant amount of our vaccine manufacturing activities. We do not have sufficient internal manufacturing infrastructure to support global commercialization of our COVID- 19 Vaccine and we have

entered into third- party agreements for the components, as well as for commercial fill- finish manufacturing, for our COVID- 19 Vaccine. The antigen component of our COVID- 19 Vaccine is currently being manufactured at SHPL-- SII in India, and the Matrix- MTM adjuvant component of our COVID- 19 Vaccine is currently being manufactured at Novavax AB as well as our partnered manufacturing site at AGC Biologics in Europe. Challenges in manufacturing either the antigen component or the adjuvant, or issues in later manufacturing stages, could compromise production of our COVID- 19 Vaccine. Additionally, we currently depend substantially on SHPL-- SII and SLS for co- formulation, filling, and finishing our COVID- 19 Vaccine (other than in Europe) and PCI for finishing in Europe, and any delays or disruptions in these suppliers' operations could prevent or delay the delivery of customer orders. Additionally, to ensure adequate inventory supply and manage our operations, we forecast anticipated manufacturing requirements and customer demand to predict inventory needs and place orders with our third- party manufacturers based on such predictions. Our ability to accurately forecast demand for our COVID- 19 Vaccine could be negatively affected by many factors, including challenges in managing our commercial strategy, **including our commercial strategy with Sanofi for the 2025- 2026 vaccination season and for the duration of the Sanofi CLA**, unanticipated changes in general market conditions or regulatory matters, and market demand for variant- specific COVID- 19 vaccines, among others. If we underestimate our third- party manufacturing requirements, we may not be able to timely meet obligations under our customer supply agreements. Conversely, if we overestimate our third- party manufacturing requirements, we may end up with inventory levels in excess of customer demand that result in a portion of our inventory becoming obsolete or expiring, as well as inventory write- downs or write- offs, or we may need to cancel previously forecasted batches of product from our third- party manufacturers, which may result in material cancellation fees. ~~In September 2022, for example, we entered into a Confidential Settlement Agreement and Release with FUJIFILM under which we are responsible for up to \$ 185 million to FUJIFILM in connection with the termination of manufacturing activity. In December 2022, we agreed to approximately \$ 95 million in fees owed to AGC Biologics in connection with the cancellation of batches in 2022.~~ If we are unable to accurately forecast demand for our COVID- 19 Vaccine and the required services from third- party manufacturers, our results of operations could be materially harmed. Manufacturing our COVID- 19 Vaccine and our other vaccine candidates involves a complicated process with which we have limited experience **compared to some of our competitors**. If we and our third- party manufacturers are unable to manufacture our COVID- 19 Vaccine and our other vaccine candidates in clinical quantities or, if and when necessary, in commercial quantities and at sufficient yields and at required specifications, then clinical trials and commercialization will be delayed, and we will need to identify and reach supply arrangements with additional third parties. Third- party manufacturers also must receive U. S. FDA or equivalent foreign regulatory body approval before they can produce clinical material or commercial product which could cause delays and alter our production schedule. Our COVID- 19 vaccines- ~~Vaccine are is~~ in competition with other products for access to these third- party facilities and may be subject to **manufacturing delays in manufacture** if third parties prioritize other products. We may not be able to enter into any necessary additional third- party manufacturing arrangements on acceptable terms, or on a timely basis. In addition, we **must have to** enter into technical transfer agreements and share our know- how with the third- party manufacturers, which can be time- consuming and may result in delays. Because of contractual restraints and the limited number of third- party manufacturers with the expertise, required regulatory approvals and facilities to manufacture bulk vaccines at commercial -scale, replacement of a manufacturer may be expensive and time- consuming and may cause interruptions in the production of our vaccine and negatively impact our ability to timely meet obligations under our customer supply agreements. We and our third- party manufacturers may also encounter production challenges related to: • costs, scale up, and yields; • shortages of raw materials and supplies; • shipment delays or other supply chain disruptions • quality control and assurance; • contamination, lot consistency, potency, and purity; • shortages of qualified personnel and other capacity constraints; • compliance with strictly enforced and evolving federal, state and foreign regulations that vary in each country where products might be sold including nationalization or other territory restrictions placed on our owned and third- party manufacturing sites; and • capital funding. Delays or interruptions could have a material adverse effect on our business, financial condition, results of operations and cash flows. ~~We must identify vaccines for development with our technologies and establish successful third- party relationships.~~ The near and long- term viability of our **COVID- 19 Vaccine, our CIC vaccine candidate and our other** vaccine candidates ~~depend~~ **depends** in part on our ability to successfully establish ~~new~~, **operationalize and maintain** strategic collaborations with pharmaceutical and biotechnology companies, ~~non- profit organizations~~ and government agencies. Establishing **, operationalizing and maintaining** strategic collaborations and obtaining government funding is difficult and time- consuming. Potential collaborators may reject collaborations based upon their assessment of our financial, regulatory or intellectual property position or based on their internal pipelines; government agencies may reject contract or grant applications based on their assessment of public need, the public interest, our products' ability to address these areas, or other reasons beyond our expectations or control. Collaborators also may seek to modify or terminate relationships. Past success in establishing strategic collaborations with pharmaceutical and biotechnology companies, non- profit organizations and government agencies ~~in the past~~ is no guarantee of future success in entering into new relationships or in performing under existing relationships. If we fail to establish a sufficient number of collaborations or government relationships on acceptable terms, or fail to perform under collaborations or relationships to the satisfaction of counter- parties, we may not be able to commercialize our vaccine candidates or generate sufficient revenue to fund further research and development efforts. The collaborations we have established or may establish may not result in the successful development or commercialization of any vaccine candidates for several reasons, including the fact that: • we may not have the ability to control the activities of our partners and cannot provide assurance that they will fulfill their obligations to us, including with respect to the license, development and commercialization of **our COVID- 19 Vaccine or our** vaccine candidates, in a timely manner or at all; • such partners may not devote sufficient resources to our **COVID- 19 Vaccine or** vaccine candidates or properly maintain or defend our intellectual property rights; • our partners could independently develop, or develop with third parties, products that compete directly or indirectly with our **COVID- 19 Vaccine or** vaccine candidates if such partners believe

that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours; • any failure on the part of our partners to perform or satisfy their obligations to us could lead to delays in the development or commercialization of our **COVID-19 Vaccine or** vaccine candidates and affect our ability to realize product revenue; and • disagreements, including disputes over the ownership of technology developed with such collaborators, could result in litigation, which would be time consuming and expensive, and may delay or terminate research and development efforts, regulatory approvals and commercialization activities. If we or our collaborators fail to maintain our existing agreements or in the event we fail to establish agreements as necessary, we could be required to undertake research, development, manufacturing and commercialization activities solely at our own expense. These activities would significantly increase our capital requirements and, given our **limited** lack of sales, marketing and distribution capabilities, significantly delay the commercialization of our vaccine candidates. ~~We are highly dependent on the commercial success of our COVID-19 Vaccine, and even though we have received provisional registration, conditional marketing authorization or emergency use authorization in certain jurisdictions for our COVID-19 Vaccine, and even if we have products licensed in additional markets, our vaccine products may not be initially or ever profitable. We are highly dependent on the commercial success of our COVID-19 Vaccine, which is currently our only commercial product and source of product revenues. Whether we make a profit from the sale of our vaccine products is dependent on a number of variables, including the costs we incur manufacturing, testing and releasing, packaging and shipping such vaccine product. Additionally, the CEPI funding agreement necessitates that we allocate a certain number of doses of our COVID-19 Vaccine to certain middle and lower income countries which may impact negatively our ability to generate profit. We cannot predict when, if at all, our approved vaccine products will be profitable to the Company, and, ultimately, we may never generate sufficient revenues from our products to reach or maintain profitability or sustain our anticipated levels of operations.~~ Even if we successfully commercialize any of our vaccine candidates, either alone or in collaboration, we face uncertainty with respect to pricing, third- party reimbursement and healthcare reform, all of which could be subject to change and could adversely affect any commercial success of our vaccine candidates. Our ability to collect revenue from the commercial sale of our vaccines may depend on our ability, and that of any current or potential future collaboration partners or customers, to obtain and if obtained, maintain adequate levels of approval, coverage and reimbursement for such products from third- party payers such as: • government health administration authorities such as the Advisory Committee for Immunization Practices of the Centers for Disease Control and Prevention (**“ ACIP ”**); • private health insurers; • managed care organizations; • pharmacy benefit management companies; and • other healthcare related organizations. Third- party payers are increasingly challenging the prices charged for medical products and may deny coverage or offer inadequate levels of reimbursement if they determine that a product has not received appropriate clearances from the U. S. FDA, or foreign equivalent, or other government regulators; is not used in accordance with cost- effective treatment methods as determined by the third- party payer; or is experimental, unnecessary or inappropriate. Prices could also be driven down by managed care organizations that control or significantly influence utilization of healthcare products. In both the U. S. and some foreign jurisdictions, there have been a number of legislative and regulatory proposals and initiatives to change the health care system in ways that could affect our ability to sell vaccines and could adversely affect the prices that we receive for our vaccine candidates, if approved. Some of these proposed and implemented reforms could result in reduced drug pricing or reimbursement rates for medical products, and while we have no current vaccines available for commercial sale other than subject to **provisional registration**, conditional marketing authorization or emergency use authorization in certain foreign jurisdictions, the impact of such reform could nevertheless adversely affect our business strategy, operations and financial results. Our exposure to price- related regulation could depend on whether our products are reimbursed by Medicare under Part B or Part D. Medicare Part B vaccine coverage includes vaccines to prevent influenza, pneumococcal disease, hepatitis B for beneficiaries who are at medium or high risk, and COVID- 19. Vaccines for such conditions do not have any cost- sharing requirements. Meanwhile, Medicare Part D vaccine coverage includes all other commercially available vaccines that are determined to be reasonable and necessary to prevent illness. Part D vaccine coverage historically included cost- sharing requirements, but, effective January 1, 2023, the IRA provides access to CDC and ACIP- recommended vaccines covered under Medicare Part D without cost- sharing. Since the beginning of the COVID- 19 pandemic, the U. S. federal government has been the predominant purchaser of COVID- 19 vaccines, making it possible for population- wide access to vaccinations. This population- wide access may change as the pandemic moves past the crisis phase and the market transitions to a third - party reimbursement model. This transition to a more traditional third - party reimbursement model is not tied to the ending of the PHE and in part reflects the fact that the U. S. federal government has not received additional funds from Congress to continue to purchase more vaccines. As federal funding declines for COVID- 19 vaccines, the USG will most likely transition to standard commercial purchasing through different health care system channels, including commercial insurers and pharmacy benefit managers, and consequently shift the cost of COVID- 19 vaccines to insurers and patients (in the form of premiums and out- of- network costs). With respect to the government health care programs and commercial insurance, there may no longer be blanket coverage of COVID- 19 vaccines without, in certain instances, accompanying conditions of reimbursement, such as the institution of prior authorization protocols. Medicare (including traditional Medicare and Medicare Advantage) will continue to pay for vaccinations in full; effective January 1, 2023, all Medicare Part D plans are required to cover all adult vaccines recommended by the ACIP, with no cost- sharing, even if the beneficiary is in the deductible phase of the benefit. Provisions in the ARPA and IRA require Medicaid (specifically, with respect to enrollees who receive coverage under traditional Medicaid and all Medicaid medically needy enrollees in specified states) and CHIP programs to cover all ACIP - recommended vaccines, including COVID - 19 vaccines / boosters with no cost sharing even when the emergency declarations expire and there is no longer any supply of federally purchased vaccines. Under the ACA, people enrolled in non - grandfathered plans (i. e., the vast majority of people with private insurance) will continue to pay nothing for ACIP - recommended COVID - 19 vaccines and associated appointments, so long as the enrollee receives this care from an in - network provider. Even if consumers are

guaranteed free access or protected against some costs, they could face access challenges to our product if sufficient amounts of our product are not available compared to that of our competitors or not procured by pharmacies or other providers. Additionally, the pharmaceutical industry has also been the subject of significant publicity in recent years regarding the pricing of pharmaceutical products, including publicity and pressure resulting from prices charged by pharmaceutical companies for new products as well as price increases by pharmaceutical companies on older products that some people have deemed excessive. As a result, pharmaceutical product prices have been the focus of increased scrutiny by the United States government, including certain state attorneys general, members of Congress, presidential candidates and the United States Department of Justice. If reforms in the health care industry make reimbursement for our potential products less likely, the market for our potential products will be reduced, and we could lose potential sources of revenue. The existence or threat of cost control measures could cause our corporate collaborators to be less willing or able to pursue research and development programs related to our vaccine candidates. Further, it is also possible that additional governmental action is taken in response to the COVID- 19 pandemic. We cannot predict the ultimate content, timing or effect of any healthcare reform legislation or the impact of potential legislation on us. We **also cannot predict changes resulting from the 2024 U. S. election and resulting changes in DHHS leadership, including potential changes that might impact funding for vaccine research and development, reimbursement for vaccines and their administration, vaccine mandates and recommendations, and public perception of vaccine importance. DHHS Secretary Robert F. Kennedy Jr. has indicated intentions to overhaul the membership of outside committees that advise the federal government on vaccine recommendations and other public health decisions. This effort may impact the ACIP, which is responsible for making recommendations on vaccine use in the United States and other panels advising the U. S. FDA. On February 20, 2025, the first meeting of the ACIP for the year was postponed. These changes and the posture of the current administration could delay ACIP decisions and other elements of the approval pathway, potentially impacting vaccine availability and recommendations.** We have limited marketing capabilities, and if we are unable to enter into collaborations with marketing partners or develop our own sales and marketing capability, we may not be successful in commercializing any approved products. Although we have initiated commercialization of our COVID- 19 Vaccine **for the last three vaccination seasons**, we **are transitioning the commercialization of our COVID- 19 Vaccine to Sanofi for the 2025- 2026 vaccination season and for the duration of the Sanofi CLA and we otherwise** currently have limited dedicated sales, marketing or distribution capabilities. As a result, we depend on collaborations with third parties that have established distribution systems and sales forces, including our ~~collaboration~~ **collaborations** with **Sanofi and SHPL-- SII**, among others. To the extent that we enter into co- promotion or other licensing arrangements, **such as the Sanofi CLA**, our revenue will depend upon the efforts of third parties, over which we may have little or no control. If we are unable to reach and maintain agreements with one or more pharmaceutical companies or collaborators, we may be required to market our products directly. Developing a marketing and sales force is expensive and time- consuming and could delay a product launch. We may not be able to attract and retain qualified sales personnel or otherwise develop this capability. Our vaccine candidates may never achieve market acceptance even if we obtain full regulatory approvals. Even if we receive full regulatory approvals for the commercial sale of our vaccine candidates, the commercial success of these vaccine candidates will depend on, among other things, their acceptance by physicians, patients and third- party payers, such as health insurance companies and other members of the medical community, as a vaccine and cost- effective alternative to competing products. If our vaccine candidates fail to gain market acceptance, we may be unable to earn sufficient revenue to continue our business. Market acceptance of, and demand for, any product that we may develop and commercialize will depend on many factors, including: • our ability to provide acceptable evidence of safety and efficacy (including **for our COVID- 19 Vaccine**, against emerging COVID- 19 variants); • the prevalence and severity of adverse side effects; • whether our vaccines are differentiated from other vaccines; • availability, relative cost and relative efficacy of alternative and competing treatments; • the effectiveness of our marketing and distribution strategy; • publicity concerning our products or competing products and treatments; and • our ability to obtain sufficient third party insurance coverage or reimbursement. If our vaccine candidates do not become widely accepted by physicians, patients, third- party payers and other members of the medical community as well as the relevant public health authorities responsible for scheduling immunizations, our business, financial condition and results of operations could be materially and adversely affected. We may not be able to secure sufficient supplies of a key component of our adjuvant technology. Because an important component of our adjuvant technology is extracted from a species of soap- bark tree (Quillaja saponaria) grown in Chile, we need long term access to quillaja extract with a consistent and sufficiently high quality. **We need in order to maintain a secure supply of raw material for the development and manufacture of our adjuvant products. If we are unable to secure long term access to quillaja extract with a consistent and sufficiently high quality**, as well as **to secure** back- up suppliers, ~~or~~ **the development and manufacture of** our adjuvant products may be delayed and we may not be able to meet our obligations under our various collaboration and supply agreements. Current or future regional relationships may hinder our ability to engage in larger transactions. We have entered into regional collaborations to develop, manufacture and distribute our vaccine candidates in certain parts of the world, and we anticipate entering into additional regional collaborations. Our relationships with ~~SHPL--~~ **SII**, Takeda, and SK bioscience are examples of these regional relationships. These relationships often involve the licensing of our technology to our partner or entering into a distribution agreement, frequently on an exclusive basis. Generally, exclusive agreements are restricted to certain territories. Because we have entered into exclusive license and distribution agreements, larger companies may not be interested, or able, to enter into collaborations with us on a worldwide- scale. Also, these regional relationships may make us an unattractive target for an acquisition. Our product candidates are sensitive to shipping and storage conditions, which could subject our vaccine candidates to risk of loss or damage. Our vaccine candidates are sensitive to storage and handling conditions. Loss in vaccine candidates could occur if the product or product intermediates are not stored or handled properly. It is possible that our vaccine candidates could be lost due to expiration prior to use. If we do not effectively

maintain our supply logistics, then we may experience an unusual number of returned or out of date products. Failure to effectively maintain our supply logistics, by us or third parties, could lead to additional manufacturing costs and delays in our ability to supply required quantities for clinical trials or otherwise. Our vaccine candidates could become subject to a product recall which could harm our reputation, business, and financial results. The U. S. FDA and similar foreign governmental authorities have the authority to require the recall of certain vaccine candidates. Manufacturers may, under their own initiative, recall a product if any material deficiency in a product is found. A government- mandated or voluntary recall by us or our strategic collaborators could occur as a result of manufacturing errors, design or labeling defects or other deficiencies and issues. For example, **in May 2023**, we ~~have~~ extended a credit of \$ 64. 7 million **to the Australian government** under the Australia APA for a single lot of NVX- CoV2373 doses sold to the Australian government **in 2022** that , upon pre- planned 6- month stability testing , was found to have fallen below the defined specifications, and the lot was therefore removed from the market. Recalls of **our COVID- 19 Vaccine or** any of our vaccine candidates would divert managerial and financial resources and have an adverse effect on our financial condition and results of operations. Additionally, a recall announcement could harm our reputation with customers and negatively affect our sales.

Risks Related to Our Industry and Competition

The biotechnology and pharmaceutical industries are subject to intense competition and rapid and significant technological change. We have many potential competitors, including major pharmaceutical companies, specialized biotechnology firms, academic institutions, government agencies and private and public research institutions. Many of our competitors have significantly greater financial and technical resources, experience and expertise in:

- research and development;
- preclinical testing;
- designing and implementing clinical trials;
- regulatory processes and approvals;
- production and manufacturing; and
- sales and marketing of approved products.

Principal competitive factors in our industry include:

- the quality and breadth of an organization’ s technology;
- management of the organization and the execution of the organization’ s strategy;
- the skill and experience of an organization’ s employees and its ability to recruit and retain skilled and experienced employees;
- an organization’ s intellectual property portfolio;
- the range of capabilities, from target identification and validation to drug discovery and development to manufacturing and marketing; and
- the availability of substantial capital resources to fund discovery, development and commercialization activities.

Large and established companies, such as Merck & Co., Inc., GlaxoSmithKline plc, CSL Ltd., Sanofi Pasteur, SA, Pfizer Inc., ~~Johnson & Johnson~~, AstraZeneca, and Moderna, among others, compete in the vaccine market. In particular, these companies have greater experience and expertise in securing government contracts and grants to support their research and development efforts, conducting testing and clinical trials, obtaining regulatory approvals to market products, manufacturing such products on a broad scale and marketing approved products. **Regardless of the disease, smaller** ~~Smaller~~ **or early- stage companies and research institutions also may prove to be significant competitors , regardless of the diseases their product candidates target** , particularly through collaborative arrangements with large and established pharmaceutical companies. As these companies develop their technologies, they may develop proprietary positions, which may prevent or limit our product development and commercialization efforts. We will also face competition from these parties in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and participant registration for clinical trials and in acquiring and in- licensing technologies and products complementary to our programs or potentially advantageous to our business. If any of our competitors succeed in obtaining approval from the U. S. FDA or other regulatory authorities for their products sooner than we do or for products that are more effective or less costly than ours, our commercial opportunity could be significantly reduced. In order to effectively compete, we will have to make substantial investments in development, testing, manufacturing and sales and marketing or partner with one or more established companies. We may not be successful in gaining significant market share for any vaccine. Our technologies and vaccines also may be rendered obsolete or non-competitive as a result of products introduced by our competitors to the marketplace more rapidly and at a lower cost. Our COVID- 19 Vaccine has moved rapidly through the regulatory review and authorization processes in the U. S. and other jurisdictions. The speed at which COVID- 19 vaccines and therapeutics are being created and tested is atypical, and evolving or changing plans or priorities within the U. S. FDA or other regulatory authorities, including changes based on new knowledge of COVID- 19 and how the disease, and new variants of the virus, affect the human body, may significantly affect our ability to establish a competitive market share for our COVID- 19 Vaccine. A large number of vaccine manufacturers, academic institutions and other organizations have developed COVID- 19 vaccines or are developing COVID- 19 vaccine candidates. In particular, Moderna, and Pfizer / BioNTech have received full regulatory approvals for their COVID- 19 vaccines and, along with Johnson & Johnson have received emergency use authorizations for their COVID- 19 vaccines in the U. S. and other countries. All of these companies have obtained the relevant Emergency Use Licenses (“ EULs ”) from the World Health Organization for their respective vaccines to be supplied to the countries or international coalition partners, including the relevant United Nations agencies, which rely upon the World Health Organization’ s EULs to support the local immunization programs. Despite funding provided to us to date, many of our competitors pursuing vaccine candidates have significantly greater product candidate development, manufacturing and marketing resources than we do. Larger pharmaceutical and biotechnology companies have extensive experience in clinical testing and obtaining regulatory approval for their products and may have the resources to heavily invest to accelerate discovery and development of their vaccine candidates. The success of our COVID- 19 Vaccine will depend, in part, on its relative safety, efficacy (including against emerging variant strains), side effect profile, convenience, and cost. COVID- 19 vaccines approved prior to our vaccine have developed broad market acceptance that we are challenged to overcome. The U. S. FDA has also approved Gilead’ s Veklury (remdesivir) for treatment of COVID- 19 in both adult and pediatric populations, as well as Eli Lilly’ s Olumiant (baricitinib) and Genentech’ s Actemra (tocilizumab) for treatment of COVID- 19 in certain hospitalized adults **and Pfizer’ s Paxlovid (nirmatrelvir tablets; ritonavir tablets) for certain un- hospitalized adults** . Furthermore, if any competitors are successful in producing a more efficacious vaccine or other treatment for COVID- 19 (including against emerging variant strains), or if any competitors are able to manufacture and distribute any such vaccines or treatments with greater efficiency there may be a diversion of potential governmental and other

funding away from us and toward such other parties. We are allocating significant financial and personnel resources to the development and commercialization of our COVID- 19 Vaccine, which may cause delays in or otherwise negatively impact our other development programs. Our business could be negatively impacted by our allocation of significant resources to combating a global health threat that is unpredictable or against which our vaccine may ultimately prove unsuccessful or unprofitable. Many seasonal influenza vaccines are currently approved and marketed. Competition in the sale of these seasonal influenza vaccines is intense. Therefore, newly developed and approved products must be differentiated from existing vaccines in order to have commercial success. In order to show differentiation in the seasonal influenza market, a product may need to be more efficacious, particularly in older adults, be less expensive or quicker to manufacture, or contain other differentiating characteristics, such as being combined with another vaccine. Many competitors are working on new products and new generations of current products, intended to be more efficacious than those currently marketed. Our CIC vaccine candidate may not prove to be more efficacious than current or future seasonal influenza products or future COVID- 19 influenza combination products under development by our competitors. Further, our in- house or third- party manufacturing arrangements may not provide enough savings of time or money to provide the required differentiation for commercial success.

Risks Related to Regulatory and Compliance Matters The development, manufacture and marketing of our pharmaceutical and biological products are subject to government regulation by the U. S. FDA and regulatory authorities in other jurisdictions, including the EMA, ~~the Czech Republic's State Institute for Drug Control (SUKL) with respect to our manufacturing facility in the Czech Republic~~ and the Swedish Medical Products Agency (Läkemedelsverket, LV) with respect to our adjuvant product being developed in Sweden, as well as other country authorities into which active pharmaceutical ingredients and excipients are imported and / or manufactured by us or our sub- contracted manufacturers. In the U. S. and most foreign countries, we must complete rigorous preclinical testing and extensive clinical trials that demonstrate the safety and efficacy of a product in order to apply for regulatory approval to market the product. ~~Additionally, we must demonstrate that our manufacturing facilities, processes and controls are adequate with respect to such product to assure safety, purity and potency and comply with applicable good manufacturing practice requirements.~~ None of our vaccine candidates has yet gained full regulatory approval in the U. S., although our COVID- 19 Vaccine has received ~~provisional registration,~~ conditional marketing authorization, emergency use authorization, or full approval in the various jurisdictions. We also have vaccine candidates in clinical trials and preclinical laboratory or animal studies. **There is no guarantee that the results obtained in preclinical studies or our clinical trials of our prototype vaccine and NVX- CoV2601, for which we have submitted a BLA that the U. S. FDA has accepted for review, or of our other current and future vaccine candidates will be sufficient to obtain regulatory approval or marketing authorization for such vaccine candidates. Additionally, even if regulatory authorities agree with the design and implementation of the clinical trials set forth in an IND or other applicable regulatory submission, such regulatory authorities may change their requirements or recommendations in the future. Any delays or failure to obtain regulatory approvals or clearances to initiate our clinical trials may prevent us from completing our clinical trials or commercializing our current and future product candidates on a timely basis, if at all.** Our products might fail to meet their primary endpoints in clinical trials, meaning that we will not have the clinical data required to support regulatory approvals. The steps generally required by the U. S. FDA before our proposed investigational products may be marketed in the U. S. include: • performance of preclinical (animal and laboratory) tests; • submission to the U. S. FDA of an IND, which must become effective before clinical trials may commence; • performance of adequate and well controlled clinical trials to establish the safety and efficacy of the investigational product in the intended target population; • performance of a consistent and reproducible manufacturing process at commercial scale capable of passing U. S. FDA inspection; • submission to the U. S. FDA of a BLA or a NDA; and • U. S. FDA approval of the BLA or NDA before any commercial sale or shipment of the product. Clinical trials that we undertake in other countries will be subject to similar or equivalent processes and requirements. In Europe, as well as an authorization for the trial itself, it is necessary to obtain the consent of a local ethics committee for each trial site and to provide for publication specific information about the trial and its outcome. If endpoints are not met, this information will be made publicly available and could be damaging to the reputation of the Company. These processes are expensive and can take many years to complete, and we may not be able to demonstrate the safety, purity, potency and efficacy of our vaccine candidates to the satisfaction of regulatory authorities. The start of clinical trials can be delayed or take longer than anticipated for many and varied reasons, many of which are out of our control. Safety concerns may emerge that could lengthen the ongoing clinical trials or require additional clinical trials to be conducted. Promising results in early clinical trials may not be replicated in subsequent clinical trials. For example, the first batch of top line results from our Phase 2 CIC clinical trial evaluating safety and immunogenicity of different formulations of CIC may not be consistent with top line results from subsequent batches in such trial. Regulatory authorities may also require additional testing, and we may be required to demonstrate that our proposed products represent an improved form of treatment over existing therapies, which we may be unable to do without conducting further clinical trials. Moreover, if a regulatory authority grants regulatory approval of a product, the approval may be limited to specific indications or limited with respect to its distribution. Expanded or additional indications for approved products may not be approved, which could limit our revenue. Foreign regulatory authorities may apply similar limitations or may refuse to grant any approval. Consequently, even if we believe that preclinical and clinical data are sufficient to support regulatory approval for our vaccine candidates, the U. S. FDA and foreign regulatory authorities ultimately may not grant approval for commercial sale in their applicable jurisdiction, or may impose regulatory requirements that make further pursuit of approval uneconomical in one or more jurisdictions. If our vaccine candidates are not approved, our ability to generate revenue will be limited, and our business will be adversely affected. We may fail to obtain regulatory approval for our **prototype vaccine and for NVX- CoV2601 or for our other current or future products- product candidates** on a timely basis or comply with our continuing regulatory obligations ~~after if~~ approval is obtained. **In the U. S., we submitted a BLA for our prototype vaccine and NVX- CoV2601, and the U. S. FDA notified us that our BLA was**

accepted for review with a PDUFA date of April 2025. There is no guarantee that we will obtain approval of our BLA for prototype vaccine and for NVX- CoV2601 within the currently anticipated April 2025 timeline. Although FDA has accepted our BLA for review, we may receive requests for additional information during the U. S. FDA' s review of the BLA, or the U. S. FDA may request advisory committee input, which may be unfavorable to approval. The U. S. FDA may also determine that additional preclinical studies or clinical trials are needed before our BLA can be approved. If we were to conduct additional preclinical studies or clinical trials, the U. S. FDA may not agree with our interpretation of the results, and we may never receive approval for prototype vaccine and NVX- CoV2601. The U. S. FDA may extend or be unable to meet its April 2025 PDUFA goal date for completing its review of our BLA. Fluctuations in U. S. FDA funding, staffing, resources, priorities, and practices under the current administration are possible and may lead to variations and challenges in the review process, timeline and outcomes . Delays in obtaining regulatory approval can be extremely costly in terms of lost sales opportunities, loss of any potential marketing advantage of being early to market and increased clinical trial costs. For example, we did not receive EUA from the U. S. FDA for our XBB vaccine for the 2023-2024 vaccination season until several weeks after our competitors, and we were unable to accomplish the timely validation of the single- dose vial or pre- filled syringe presentation we had intended to use with our XBB Vaccine in the U. S. for the 2023- 2024 vaccination season, which resulted in our use of a five dose vial presentation for 2023- 2024 vaccination season, which we believe harmed our financial condition and results of operations. In addition , certain of our APAs and supply agreements may be terminated by the counterparty if we do not timely achieve requisite regulatory approval for our COVID- 19 Vaccine in the relevant jurisdictions under such agreements , which may harm our financial condition and results of operations. Under the Canada APA, we failed to receive regulatory approval for our COVID- 19 Vaccine using bulk antigen produced at BMC and the Canadian government may therefore terminate the Canada APA. In addition, under the Amended and Restated UK Supply Agreement, we failed to receive supportive recommendations from the JCVI, triggering obligations for us to repay the Authority and ultimately leading to our entry into the Settlement Agreement with the Authority in November 2024 . The speed with which we begin and complete the preclinical studies necessary to begin clinical trials, the clinical trials themselves and our applications for marketing approval will depend on several factors, including the following: • our ability to scale- up and maintain manufacturing capability that reproducibly generates consistent yields of product with required purity, potency and quality; that such scale- up occurs on a timely basis; and that we have access to sufficient quantities of materials for use in necessary preclinical studies and clinical trials; • regulatory authority review and approval of proposed clinical trial protocols; • approval of clinical trials protocols and informed consent forms by institutional review boards responsible for overseeing the ethical conduct of the trial; • the rate of participant enrollment and retention, which is a function of many factors, including the size of the participant population, the proximity of participants to clinical sites, the eligibility criteria for the clinical trial and the nature of the protocol; • unfavorable test results or side effects experienced by clinical trial participants; • analysis of data obtained from preclinical and clinical activities, which are susceptible to varying interpretations and which interpretations could delay, limit, result in the suspension or termination of, or prevent further conduct of clinical studies or regulatory approval; • the availability of skilled and experienced staff to conduct and monitor clinical trials and to prepare the appropriate regulatory applications; and • changes in the policies of regulatory authorities for drug or vaccine development and approval during the period of product development , including, but not limited to, as a result of the change in presidential administration and leadership of DHHS in January 2025 . We have somewhat limited experience in conducting and managing the preclinical studies and clinical trials necessary to obtain regulatory marketing approvals. We may not be permitted to continue or commence additional clinical trials. We also face the risk that the results of our clinical trials may be inconsistent with the results obtained in preclinical studies or clinical trials of similar products or that the results obtained in later phases of clinical trials may be inconsistent with those obtained in earlier phases. A number of companies in the biotechnology and product development industry have suffered significant setbacks in advanced clinical trials, even after experiencing promising results in early animal and human testing. Regulatory agencies may require us or our collaborators to delay, restrict or discontinue clinical trials on various grounds, including a finding that the participants are being exposed to an unacceptable health risk. In addition, we or our collaborators may be unable to submit applications to regulatory agencies within the time frame we currently expect. Once submitted, applications must be approved by various regulatory agencies before we or our collaborators can commercialize the product described in the application. All statutes and regulations governing the conduct of clinical trials are subject to change in the future, which could affect the cost of such clinical trials. Any unanticipated costs or delays in our clinical trials or regulatory submissions could delay our ability to generate revenue and harm our financial condition and results of operations. If we are unable to effectively pursue the manufacture, clinical testing, regulatory authorization, and export of our COVID- 19 Vaccine, or COVID- 19 vaccines against future strain changes, we may encounter delays or challenges in commercially distributing these vaccines as well as gaining market acceptance for them. We expect that regulatory authorities will continue to monitor and assess SARS- CoV- 2 evolution and recommend that manufacturers make corresponding updates to the composition of their COVID- 19 vaccines at least annually. Inherent to this evolving approach to manufacturing new strains of COVID- 19 vaccines, including our development of our COVID- 19 Vaccine, we may encounter regulatory authorization, manufacturing, and distribution challenges, including export challenges. In doing so, we expect to seek alignment and acceptance by regulatory authorities that would allow us to use manufacturing and analytical testing methods employed in earlier COVID- 19 vaccine production and commercialization efforts, that support an accurate characterization profile (including purity, potency, stability and like standards) of the relevant COVID- 19 vaccine. Our inability to overcome product development challenges and gaining regulatory authority alignment may adversely affect our ability to obtain licensure of our COVID- 19 vaccine or future COVID- 19 vaccines at all, or in a timely manner. Regarding future COVID- 19 vaccine development, we may fail to receive authorization for updated variants of SARS- CoV- 2 by regulatory authorities if we are unable to generate sufficient batch analysis data to demonstrate batch- to-

batch consistency at commercial scale, if the data generated from our incremental research and development program do not support continued effectiveness of the vaccine to protect individuals against the then- relevant variant of SARS- CoV- 2 because the vaccine does not induce an adequate level of neutralization titers against such variant, or if the product otherwise exhibits an unacceptable safety profile, rendering the benefit / risk balance unfavorable. Moreover, the new vaccine lots may not be accepted for distribution if required batch- release testing undertaken by officially designated laboratories does not show that such vaccine is of acceptable quality. ~~We were unable to accomplish the timely validation of the single- dose vial or pre- filled syringe presentation we had intended to use with the our COVID- 19 Vaccine in the U. S. As a result, the five dose vial presentation for the fall 2023 vaccination season may have adversely impacted market acceptance, rate of product returns, or required higher price concessions in the U. S and may adversely impact us in the future if a single- dose or pre- filled syringe presentation is not authorized.~~ Failure to obtain regulatory approval in foreign jurisdictions would prevent us from marketing our products internationally. We intend to have our vaccine candidates marketed outside the U. S. In furtherance of this objective, we have entered into supply agreements with various foreign governments and international distribution agreements with commercial entities. In order to market our products in various countries globally, we must obtain separate regulatory approvals and comply with numerous and varying regulatory requirements. The approval procedure varies among countries and can involve additional testing and data review. The time required to obtain foreign regulatory approval may differ from that required to obtain U. S. FDA approval. The foreign regulatory approval process may include all of the risks associated with obtaining U. S. FDA approval. Additionally, regulatory authorities outside the U. S. might not accept data from trials conducted in other countries. Although our COVID- 19 Vaccine has received ~~provisional registration,~~ conditional marketing authorization or emergency use authorization in a number of jurisdictions, we may not obtain regulatory approvals in other relevant jurisdictions on a timely basis, if at all. Approval by one regulatory agency does not ensure approval by regulatory agencies in other jurisdictions. However, a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in other jurisdictions, including approval by the U. S. FDA. The failure to obtain regulatory approval in foreign jurisdictions could harm our business. The regulatory pathway for our COVID- 19 Vaccine is continually evolving and may result in unexpected or unforeseen challenges. The regulatory pathway for our COVID- 19 Vaccine is evolving and failure by us to comply with any laws, rules and standards, some of which may not exist yet or are subject to interpretation and may be subject to change, could result in a variety of adverse consequences, including penalties, fines and delays in vaccine licensure. Efforts to comply with evolving laws, regulations and standards have resulted in, and are likely to continue to result in, increased general and administrative expenses and a diversion of management time and attention to regulatory compliance activities. ~~For example, the rules, regulations and standards governing the USG Agreement are uncertain and may evolve as the program progresses.~~ Such rules or standards may adversely affect our plans to develop our COVID- 19 Vaccine and failure by us to comply with any laws, rules or standards, some of which may not exist yet or may change, could result in a range of adverse consequences, such as penalties, fines or failure to receive funding. The speed at which multiple stakeholders are moving to create, test and approve vaccines for COVID- 19 is highly unusual and may increase the risks associated with traditional vaccine development, which typically takes between eight and ten years. Given this accelerated timeline, we and regulators, such as the U. S. FDA, the EMA, and the ~~UK’s Medicines and Healthcare Products Regulatory Agency (“MHRA”)~~ may make decisions more rapidly than is typical. Evolving or changing plans or priorities at the U. S. FDA or other regulatory bodies to whom we wish to apply for authorization, including based on new knowledge of COVID- 19 and how the disease affects the human body, ~~and~~ **new variants of the virus , and regulatory policy changes (including those at U. S. agencies such as the DHHS, U. S. FDA, and CDC due to the change in U. S. presidential administration in January 2025) ,** may significantly affect the regulatory pathway for our COVID- 19 Vaccine . **For example, in May 2023, the COVID- 19 PHE expired in the U. S. and the WHO determined that the COVID- 19 pandemic no longer fit the definition of a Public Health Emergency of National Concern, which removed the justification for shortened regulatory timelines .** 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 U. S. FDA’ s or other regulatory authorities’ analysis of clinical data may differ from our interpretation, or regulators’ requirements and expectations for vaccine authorization or approval may change over time, with the result that the U. S. FDA or other regulators may require that we conduct additional clinical trials or non- clinical studies. The evolving regulatory pathway may impede the development, commercialization and / or licensure of our COVID- 19 Vaccine. In addition, because the path to licensure of any vaccine against COVID- 19 is unclear, we may have a widely used vaccine in circulation in certain countries as an investigational vaccine or a product authorized for temporary or emergency use prior to our receipt of full marketing approval. Unexpected safety issues in these circumstances could lead to significant reputational damage for **Novavax- us** and our technology platform going forward and other issues, including delays in our other programs, the need for re- design of our clinical trials and the need for significant additional financial resources. For example, although we currently operate under an emergency use authorization provided by the U. S. FDA for our updated COVID- 19 Vaccine, the U. S. FDA may revoke such authorization if it determines that the underlying health emergency no longer exists or warrants such authorization, and we cannot predict how long such authorization will remain in place. Such revocation could adversely impact our business in a variety of ways. We have conducted, continue to conduct and plan to conduct in the future, a number of clinical trials for our COVID- 19 Vaccine **and other vaccine candidates** at sites outside the U. S. and the U. S. FDA may not accept data from trials conducted in such locations. We have **conducted** and are currently conducting several clinical trials of our COVID- 19 Vaccine at sites outside the U. S., including a Phase 3 pediatric study (2019nCoV- 503) in the Dominican Republic, Guatemala, Honduras, the Philippines, and Mexico. Although the U. S. FDA may accept data from clinical trials conducted outside the U. S., acceptance of these data is subject to conditions imposed by the U. S. FDA. For example, the clinical trial must be well designed and conducted and be performed by qualified investigators in accordance with ethical principles. The trial population

must also adequately represent the U. S. population, and the data must be applicable to the U. S. population and U. S. medical practice in ways that the U. S. FDA deems clinically meaningful. Other regulatory authorities impose equivalent requirements for their countries. In addition, while these clinical trials are subject to the applicable local laws, where the data is to be used to support our BLA, U. S. FDA acceptance of the data will depend on its determination that the trials also complied with all applicable U. S. laws and regulations. If the U. S. FDA does not accept the data from any trial that we conduct outside the U. S., it could result in delay pending completion of our trials conducted in the U. S. or result in the need for additional trials, which would be costly and time-consuming and could delay or permanently halt our development and commercialization of our COVID-19 Vaccine. The later discovery of previously unknown problems with a product, manufacturer or facility may result in restrictions, including withdrawal of a vaccine that had previously received regulatory approval in certain jurisdictions from the market. Even after a product gains regulatory approval, the product and the manufacturer of the product will be subject to continuing regulatory review, including adverse event reporting requirements and prohibitions against promoting products for unapproved uses. Failure to comply with any post-approval requirements can, among other things, result in warning letters, product seizures, recalls, substantial fines, injunctions, suspensions or revocations of marketing authorizations or licenses, operating restrictions and criminal prosecutions. Any such enforcement actions, any unanticipated changes in existing regulatory requirements or the adoption of new requirements, or any safety issues that arise with any approved products, could adversely affect our ability to market products and generate revenue and thus adversely affect our ability to continue our business. We also may be restricted or prohibited from marketing or manufacturing a product, even after obtaining product approval, if previously unknown problems with the product or its manufacture are subsequently discovered. We cannot provide assurance that newly discovered or developed safety issues will not arise following regulatory approval. With the use of any vaccine by a wide patient population, serious adverse events may occur from time to time that did not arise in the clinical trials of the product or that initially appeared to be unrelated to the vaccine itself and only with the collection of subsequent information were found to be causally related to the product. Any such safety issues could cause us to suspend or cease marketing of our approved products, possibly subject us to substantial liabilities, and adversely affect our ability to generate revenue and our financial condition. ~~Our ability to produce a successful vaccine may be curtailed by one or more government actions or interventions, which may be more likely during a global health crisis such as COVID-19. Given the significant global impact of the COVID-19 pandemic, it is possible that one or more government entities may take actions, including under the USG under the Defense Production Act of 1950, as amended, that directly or indirectly have the effect of diminishing some of our rights or opportunities with respect to our COVID-19 Vaccine, and the economic value of a COVID-19 vaccine to us could be limited. In addition, during a global health crisis, such as the COVID-19 pandemic, where the spread of a disease needs to be controlled, closed or heavily regulated national borders create challenges and delays in our development, production and distribution activities and may necessitate that we pursue strategies to develop, produce and distribute our vaccine candidates within self-contained national or international borders or with additional safety measures or checks in place, at potentially much greater expense and with longer timeframes for public distribution.~~ Inadequate funding for the U. S. FDA, the SEC and other regulatory authorities could hinder their ability to hire and retain key leadership and other personnel, or otherwise perform their normal functions on which the operation of our business may rely, which could negatively impact our ability to develop or commercialize new products or services, access capital markets, or otherwise operate our business. The ability of the U. S. FDA and other regulatory authorities to review and approve new product applications is affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory and policy changes, **including those related to a change in presidential administration**. For example, average review times at the U. S. FDA have fluctuated in recent years as a result **of such factors**. 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 U. S. FDA and other agencies may also slow the time necessary for new drugs to be reviewed and approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, the **USG U. S. government** has shut down several times and certain regulatory agencies, such as the U. S. FDA and the SEC, have had to furlough employees and stop or slow the pace of critical activities. ~~Equally~~ **Also**, the move of the EMA's relocation to the Netherlands from London caused a significant loss of experienced staff and the UK's MHRA's loss of funding from the **EU E. U.** has caused a loss of funding and ~~consequently of~~ staff. If a prolonged government shutdown or slowdown of the relevant regulatory authority occurs, it could significantly impact the ability of ~~that such government or Authority~~ **authority** to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, in our operations as a public company, 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. Fast Track Designation by the U. S. FDA, the issue of conditional marketing authorizations by the EMA or MHRA, or other regulatory acceleration options may not actually lead to a faster development or regulatory review or approval process and does not assure approval. If a drug is intended for the treatment of a serious or life-threatening condition and the drug demonstrates the potential to address an unmet medical need for this condition, the drug sponsor may apply for U. S. FDA Fast Track Designation or similar fast track processes with other regulatory agencies. In the EU and the UK, rolling review procedure was relied upon for conditional marketing authorizations to be granted. However, Fast Track Designation or conditional authorizations do not ensure that the drug sponsor will receive marketing approval or that approval will be granted within any particular timeframe. The U. S. FDA granted Fast Track Designation for our ~~prototype vaccine in November 2020, and for our~~ recombinant quadrivalent seasonal influenza vaccine candidate ~~in January~~ **2020 and prototype vaccine in November 2020**. We may also seek Fast Track Designation for more of our other vaccine candidates. If we do seek Fast Track Designation for our other vaccine candidates, we may not receive it, and even if we receive Fast Track Designation, we may not experience a faster development process, review or approval compared to conventional U. S. FDA procedures. In addition, the

U. S. FDA may withdraw Fast Track designation if it believes that the designation is no longer supported by data from our clinical development program. Fast Track Designation alone does not guarantee qualification for the U. S. FDA's priority review procedures. Obtaining a Fast Track Designation does not change the standards for product approval, but may expedite the development or approval process. Even though the U. S. FDA has granted such designation for our prototype vaccine, it may not actually result in faster clinical development or regulatory review or approval. Furthermore, such a designation does not increase the likelihood that our COVID- 19 Vaccine will receive marketing approval in the U. S. **We intend to seek accelerated approval from the U. S. FDA for our CIC vaccine. Accelerated approval by the U. S. FDA, even if granted for any of our vaccine candidates, may not lead to a faster development or regulatory review or licensure process, and does not increase the likelihood that our vaccine candidates will receive licensure. We intend to seek accelerated approval for our CIC vaccine, and we may in the future seek accelerated approval for our other current or future product candidates. Under the accelerated approval program, the U. S. FDA may grant accelerated approval to a product candidate designed to treat a serious or life- threatening condition that provides meaningful therapeutic benefit over available therapies upon a determination that the product candidate has an effect on a surrogate endpoint or intermediate clinical endpoint that is reasonably likely to predict clinical benefit. As a condition of approval, the U. S. FDA requires that a sponsor of a product receiving accelerated approval perform a post- marketing confirmatory clinical trial or trials. In addition, the U. S. FDA requires as a condition for accelerated approval the pre- submission of promotional materials to U. S. FDA for review. We are actively developing a proposal to support a potential accelerated approval pathway for our CIC vaccine. There can be no assurance that after our evaluation of feedback from the U. S. FDA or other factors that we will decide to pursue accelerated approval for this vaccine candidate. Furthermore, if we decide to submit an application for accelerated approval for any vaccine candidate, there can be no assurance that such submission will be accepted or that the U. S. FDA will determine that the vaccine candidate is eligible for grant of accelerated approval. A failure to obtain any planned accelerated approval for our vaccine candidates could result in a longer time period to commercialization for our vaccine candidates, if approved, and could increase the cost of development of our vaccine candidates. If we receive accelerated approval for any of our vaccine candidates, the U. S. FDA may withdraw accelerated approval if, among other things, a confirmatory trial required to verify the predicted clinical benefit of the product fails to verify such benefit or if such trial is not conducted with due diligence. Withdrawal of any accelerated approval could substantially harm our business. Due to the recent change in presidential administration, we face uncertainty regarding potential regulatory developments that may adversely affect our business. We face uncertainty regarding the potential for changes in the regulatory environment following the change in presidential administration in January 2025. While many of the Trump administration's proposed policies appear to be focused on deregulation, the new administration and federal government could adopt legislation, regulation, or policy that adversely affects our business or creates a more challenging and costly environment to pursue the development and commercialization of vaccines or other products. For example, the federal government, including the U. S. Department of Health and Human Services, the U. S. FDA, and the Centers for Disease Control and Prevention, may implement legislative, regulatory, or policy changes regarding the standards for approving new or updated vaccines, vaccine safety requirements, recommended immunization schedules for COVID- 19 and other vaccinations and other information shared with the public regarding vaccines, vaccine coverage and reimbursement under federal healthcare programs, and manufacturer liability for vaccine- associated injuries. Additionally, because one objective of the current Trump administration appears to be to decrease spending in the federal government, the U. S. FDA could face staff reductions, which could impact the U. S. FDA's ability to engage in routine regulatory and oversight activities and result in delays or limitations on our ability to proceed with clinical development programs and obtain regulatory approvals. It is difficult to predict how executive actions that may be taken under the current Trump administration may affect the U. S. FDA's ability to exercise its regulatory authority. If such executive actions impose constraints on the U. S. FDA's ability to engage in routine oversight and product review activities in the normal course, our business may be negatively impacted.** Because we are subject to environmental, health and safety laws, we may be unable to conduct our business in the most advantageous manner. We are subject to various laws and regulations relating to safe working conditions, laboratory and manufacturing practices, the experimental use of animals, emissions and wastewater discharges, and the use and disposal of hazardous or potentially hazardous substances used in connection with our research, including infectious disease agents. We also cannot accurately predict the extent of regulations that might result from any future legislative or administrative action. Any of these laws or regulations could cause us to incur additional expense or restrict our operations. Our facilities in Maryland are subject to various local, state and federal laws and regulations relating to safe working conditions, laboratory practices, the experimental use of animals and the use and disposal of hazardous or potentially hazardous substances, including chemicals, microorganisms and various hazardous compounds used in connection with our research and development activities. In the U. S., these laws include the Occupational Safety and Health Act, the Toxic Test Substances Control Act and the Resource Conservation and Recovery Act. Similar national and local regulations govern our facilities in Sweden, the Czech Republic, and Switzerland. We cannot eliminate the risk of accidental contamination or discharge or injury from these materials. Federal, state and local laws and regulations govern the use, manufacture, storage, handling and disposal of these materials. We could be subject to civil damages in the event of an improper or unauthorized release of, or exposure of individuals to, these hazardous materials. In addition, claimants may sue us for injury or contamination that results from our use or the use by third parties of these materials, and our liability may exceed our total assets. Compliance with environmental laws and regulations may be expensive, and current or future environmental regulations may impair our research, development or production efforts. Although we have general liability insurance, these policies contain exclusions from insurance against claims arising from pollution from chemicals or pollution from conditions arising from our operations. Our collaborators are working with these

types of hazardous materials in connection with our collaborations. In the event of a lawsuit or investigation, we could be held responsible for any injury we or our collaborators cause to persons or property by exposure to, or release of, any hazardous materials. However, we believe that we are currently in compliance with all material applicable environmental and occupational health and safety regulations. For our product candidates, we will be subject to additional healthcare laws and our failure to comply with those laws could have a material adverse effect on our results of operations and financial conditions. Within the U. S. (and within foreign countries), if we obtain full approval for any of our product candidates and begin commercializing them, our operations may be directly, or indirectly through our arrangements with third- party payors and customers, subject to additional healthcare regulation and enforcement by the federal and state governments (or the regulatory bodies or governments of foreign countries), which may constrain the business or financial arrangements and relationships through which we sell, market and distribute our products. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, structuring and commission (s), certain customer incentive programs and other business arrangements generally. Activities subject to these laws also involve the improper use of information obtained in the course of patient recruitment for clinical trials. The applicable U. S. federal and state healthcare laws and regulations (which may be comparable to foreign laws existing in foreign countries) that may affect our ability to operate include:

- the Federal Food, Drug and Cosmetic Act, which among other things, strictly regulates drug product marketing and promotion and prohibits manufacturers from marketing such products for unapproved uses;
- the federal Anti- Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, receiving or providing remuneration, directly or indirectly, to induce the referral for an item or service or the purchasing or ordering of a good or service, for which payment may be made under federal healthcare programs such as Medicare and Medicaid;
- federal false claims laws, including the FCA, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, information or claims for payment from Medicare, Medicaid, or other third- party payers that are false or fraudulent;
- manufacturers can be held liable under the FCA even when they do not submit claims directly to government payors if they are deemed to “ cause ” the submission of false or fraudulent claims; the FCA also permits a private individual acting as whistleblower to bring actions on behalf of the federal government alleging violations of the FCA and to share in any monetary recovery;
- federal laws that require pharmaceutical manufacturers to report certain calculated product prices to the government or provide certain discounts or rebates to government authorities or private entities, often as a condition of reimbursement under government healthcare programs;
- the federal Physician Payment Sunshine Act and its implementing regulations, which require manufacturers of drugs, devices, biologicals, and medical supplies for which payment is available under Medicare, Medicaid or the Children’s Health Insurance Program (with certain exceptions) to report annually to the DHHS information related to payments or other transfers of value made to physicians (defined to include doctors, dentists, optometrists and chiropractors) and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members; effective January 1, 2022, these reporting obligations extend to include transfers of value made to certain non- physician providers such as physician assistants and nurse practitioners; similar reporting requirements have also been enacted on the state level in the U. S., and an increasing number of countries worldwide either have adopted or are considering similar laws requiring disclosure of interactions with health care professionals;
- the federal law known as HIPAA, which, in addition to privacy protections applicable to healthcare providers and other entities, prohibits executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;
- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers;
- state law equivalents of the above federal laws, such as anti- kickback and false claims laws which may apply to items or services reimbursed by any third- party payer, including commercial insurers, and state gift ban and transparency laws, many of which state laws differ from each other in significant ways and often are not preempted by federal laws, thus complicating compliance efforts; and
- state laws restricting interactions with healthcare providers and other members of the healthcare community or requiring pharmaceutical manufacturers to implement certain compliance standards. Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available, it is possible that some of our business activities could be subject to challenge under one or more of such laws. If our operations are found to be in violation of any of such laws or any other governmental regulations that apply to us, we may be subject to, on a corporate or individual basis, penalties, including civil and criminal penalties, damages, fines, the curtailment or restructuring of our operations, the exclusion from participation in federal and state healthcare programs and even imprisonment, any of which could materially adversely affect our ability to operate our business and our financial results. In addition, the cost of implementing sufficient systems, controls, and processes to ensure compliance with all of the aforementioned laws could be significant. Any action for violation of these laws, even if successfully defended, could cause us to incur significant legal expenses and divert management’s attention from the operation of the company’s business. If any of the physicians or other healthcare providers or entities with whom we expect to do business is found not to be in compliance with applicable laws, that person or entity may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs. Prohibitions or restrictions on sales or withdrawal of future marketed products could materially affect business in an adverse way. It is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent inappropriate conduct may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. Efforts to ensure that our business arrangements will comply with applicable healthcare laws may involve substantial costs. It is possible that governmental and enforcement authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law interpreting applicable fraud and abuse or other healthcare laws and regulations. If any such actions are instituted against us and we are not successful in defending ourselves or asserting our rights those actions, our business may be impaired. We are also subject to anti- bribery and anti- corruption laws, including the FCPA, the UK Bribery Act, and other similar worldwide anti- bribery laws, as well as various trade laws and

regulations (including economic sanctions, export laws, and customs laws), and our failure to comply with those laws could have a material adverse effect on our results of operations and financial conditions. The FCPA and similar worldwide anti-bribery and anti-corruption laws prohibit companies and their intermediaries from corruptly providing any payments or other benefits to foreign government officials for the purpose of obtaining or retaining business. The U. S. Departments of Justice, Securities & Exchange Commission, Commerce, State and Treasury and other federal agencies and authorities have a broad range of civil and criminal penalties they may seek to impose against corporations and individuals for violations of the FCPA, economic sanctions laws, export control laws, and other federal statutes and regulations, including those established by the Office of Foreign Assets Control, or OFAC. In addition, the UK Bribery Act of 2010, or the Bribery Act, prohibits both domestic and international bribery, as well as bribery across both private and public sectors. An organization that fails to prevent bribery by anyone associated with the organization can be charged under the Bribery Act unless the organization can establish the defense of having implemented adequate procedures to prevent bribery. Similarly, U. S. and similar worldwide trade laws, including economic sanctions, export laws, and customs laws, regulate our ability to conduct business with certain jurisdictions and counterparties, and regulate the ways in which we may export and import products around the world. In connection with these laws, various government agencies may require us to obtain export licenses, and may impose modifications to business practices, including requiring the cessation of business activities in or with countries, entities, and individuals targeted with sanctions. The breadth and dynamic nature of these laws and regulations may increase compliance costs, and may subject us to fines. ~~Novavax has~~ **We have** received a number of regulatory approvals in ex- U. S. jurisdictions and has commenced commercial operations in these international locations, including partnering with third- parties in certain higher- risk jurisdictions. Further, a portion of our business with respect to our manufacturing is conducted outside of the U. S. in higher-risk jurisdictions. We expect our international activities to increase in the future. Though we maintain policies, internal controls and other measures reasonably designed to promote compliance with applicable anti-corruption and trade laws and regulations, our employees or agents may nevertheless engage in improper conduct for which we might be held responsible. Any violations of these anti-corruption or trade laws, or even allegations of such violations, can lead to an investigation and / or enforcement action, which could disrupt our operations, involve significant management distraction, and lead to significant costs and expenses, including legal fees. If we, or our employees or agents acting on our behalf, are found to have engaged in practices that violate these laws and regulations, we could be subject to criminal and civil enforcement action, suffer severe fines and penalties, profit disgorgement, injunctions on future conduct, securities litigation, bans on transacting government business, delisting from securities exchanges and other consequences that may have a material adverse effect on our business, financial condition and results of operations. In addition, our reputation, our revenue or our stock price could be adversely affected if we become the subject of any negative publicity related to actual or potential violations of anti-corruption or trade laws and regulations. Risks Related to our Intellectual Property Our success in large part depends on our ability to maintain the proprietary nature of our technology and other trade secrets. To do so, we must prosecute and maintain existing patents, obtain new patents and pursue trade secret and other intellectual property protection. We also must operate without infringing the proprietary rights of third- parties or allowing third- parties to infringe our rights. We currently have or have rights to over ~~630~~ **680** U. S. and foreign patents and patent applications covering our technologies. However, patent issues relating to pharmaceuticals and biologics involve complex legal, scientific and factual questions. To date, no consistent policy has emerged regarding the breadth of biotechnology patent claims that are granted by the U. S. Patent and Trademark Office (“ USPTO ”) or enforced by the federal courts. Therefore, we do not know whether any particular patent applications will result in the issuance of patents, or that any patents issued to us will provide us with any competitive advantage. We also cannot be sure that we will develop additional proprietary products that are patentable. Furthermore, there is a risk that others will independently develop or duplicate similar technology or products or circumvent the patents issued to us. Although our patent filings include claims covering various features of our vaccine candidates, including composition, methods of manufacture and use, our patents do not provide us with complete protection against the development of competing products. Some of our know- how and technology is not patentable. To protect our proprietary rights in unpatentable intellectual property and trade secrets, we require employees, consultants, advisors and collaborators to enter into confidentiality agreements. These agreements may not provide meaningful protection for our trade secrets, know- how or other proprietary information, and such risk has been enhanced by the departure of employees in connection with our global restructuring and cost reduction plan. Failure to obtain trademark registrations for proposed product names / brands, in the U. S. or abroad, may adversely impact our business. Trademark registration to protect the trademarks for our proposed products will require approval from the USPTO in the U. S. and in trademark offices throughout the world in our key markets. The USPTO or a trademark office in a key international jurisdiction may refuse registration of any of our trademarks on a variety of potential grounds. If registration is not granted to one of our trademarks in the U. S. or in another key international jurisdiction, we may be required to adopt an alternative name for that proposed product. If we adopt an alternative name, we ~~would~~ **may** lose the benefit of any existing trademark applications for such developmental candidate and may be required to expend significant additional resources in an effort to identify a suitable product name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the U. S. FDA and other regulatory authorities. Third parties may claim we infringe their intellectual property rights. Our research, development and commercialization activities, including any vaccine candidates resulting from these activities, may be found to infringe patents or trademarks owned by third- parties and to which we do not hold licenses or other rights. There may be rights we are not aware of, including applications that have been filed, but not published that, when issued, could be asserted against us. These third- parties could bring claims against us, and that may cause us to incur substantial expenses and, if successful against us, could cause us to pay substantial damages. Further, if a patent or trademark infringement suit were brought against us, we could be forced to stop or delay research, development, manufacturing or sales of the product or biologic drug candidate that is the subject of the suit. As a result of patent or trademark infringement claims, or in order to avoid potential claims, we

may choose or be required to seek a license from the third party. These licenses may not be available on acceptable terms, or at all. Even if we are able to obtain a license, the license would likely obligate us to pay license fees or royalties or both, and the rights granted to us might be non-exclusive, which could result in our competitors gaining access to the same intellectual property. Ultimately, we could be prevented from commercializing a product, or be forced to cease some aspect of our business operations, if, as a result of actual or threatened patent or trademark infringement claims, we are unable to enter into licenses on acceptable terms. All of the issues described above could also impact our collaborators, which would also impact the success of the collaboration and therefore us. There has been substantial litigation and other proceedings regarding patent, trademark, and other intellectual property rights in the pharmaceutical and biotechnology industries. We may become involved in litigation to defend or enforce our intellectual property or the intellectual property of our collaborators or licensors, which could be expensive and time-consuming. Competitors may infringe our patents or the patents of our collaborators or licensors. As a result, we may be required to file patent infringement suits to prevent unauthorized uses. This can be expensive and time-consuming. In addition, in an infringement proceeding, a court may decide that a patent of ours is not valid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover its technology. An adverse determination of any litigation or defense proceeding could put one or more of our patents at risk of being invalidated or interpreted narrowly and could put our patent applications at the risk of not issuing. Competitors may infringe our trademarks or the trademarks of collaborators or licensors. As a result, we may be required to file suit to counter infringement for unauthorized use of an identical or confusingly similar trademark. This can be expensive and time-consuming. Even if we are successful, litigation may result in substantial costs and distraction to our management. Even with a broad portfolio, we may not be able, alone or with our collaborators and licensors, to prevent misappropriation of our proprietary rights, particularly in countries where the laws may not protect such rights as fully as in the U. S. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. In addition, during the course of litigation, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If investors perceive these results to be negative, the market price for our common stock could be significantly harmed. The scope, validity, and ownership of our patent claims may be challenged in various venues and, if we do not prevail, our ability to exclude competitors may be harmed, potentially reducing our ability to succeed commercially. We may be subject to a variety of challenges from third parties that relate to the scope of the claims or to their validity. Such challenges can be mounted in **certain US District Court proceedings**, post-grant review, ex parte re-examination, and inter partes review proceedings before the USPTO, or similar adversarial proceedings in other jurisdictions. If we are unsuccessful in any such challenge, the scope of our claims could be narrowed or could be invalidated. Any such outcome could impair our ability to exclude competitors from the market in those countries, potentially impacting our commercial success. Our patents may be subject to various challenges related to ownership and inventorship, including interference or derivation proceedings. Third parties may assert that they are inventors on our patents or that they are owners of the patents. While we perform inventorship analyses to insure that the correct inventors are listed on our patents, we cannot be certain that a court of competent jurisdiction would arrive at the same conclusions we do. If we are unsuccessful in defending against ownership or inventorship challenges, a court may require us to list additional inventors, may invalidate the patent, or may transfer ownership, **or vest joint ownership**, of the patent to a third party. Any of these outcomes may harm our ability to exclude competitors and potentially impact our commercial success. Further, if ownership is transferred to a third party we may be required to seek a license to those rights to preserve our exclusive ability to practice the invention. Such a license may not be available on commercially reasonable terms, or at all. If we are unable to obtain a license, we may be required to expend time, effort, and other resources to design around the patent. Any such license may be non-exclusive and if a competitor is able to obtain a license from the third party, our ability to exclude that competitor from the market may be negatively impacted. Even if we are ultimately successful, defending any such challenges may cause us to incur substantial expenses and may require us to divert substantial financial and management resources that we would otherwise be able to devote to our business. The scope, validity, and ownership of our trademark rights / registrations may be challenged in various venues in the U. S. and abroad and, if we do not prevail, our ability to exclude competitors from using and registering confusingly similar trademarks may be harmed, potentially reducing our ability to succeed commercially. We may be subject to a variety of challenges from third parties that relate to the validity of our trademark registrations in the U. S. and internationally. Such challenges can be mounted in trademark cancellation and opposition proceedings before the USPTO, or similar adversarial proceedings in other jurisdictions. If we are unsuccessful in any such challenge, our trademark registrations could be narrowed or could be refused or canceled. Any such outcome could impair our ability to exclude competitors from using a confusingly similar mark, potentially impacting our commercial success. Our trademark registrations may be subject to various challenges related to likelihood of confusion, use of a trademark in commerce, or other grounds in the U. S. and internationally. Third parties may assert that our trademarks infringe on their prior rights or that we are not using a trademark in a particular jurisdiction in connection with the goods / services identified in the trademark registration. While we perform trademark clearance searches and analysis to determine that we are not infringing upon the trademark rights of others, we cannot be certain that a court of competent jurisdiction would arrive at the same conclusions we do. If we are unsuccessful in defending against such challenges, a court may cancel our trademark registration and / or issue an injunction requiring that we cease use of the trademark. We may also not be able to rely on common law rights that we may have in any trademark. Any of these outcomes may potentially impact our commercial success. We may need to license intellectual property from third parties and, if our right to use the intellectual property we license is affected, our ability to develop and commercialize our vaccine candidates may be harmed. We have in the past, and we expect in the future to license intellectual property from third parties and that these licenses will be material to our business. We will not own the patents or patent applications that underlie these licenses, and we may not control either the prosecution or the enforcement of the patents.

Under such circumstances, we may be forced to rely upon our licensors to properly prosecute and file those patent applications and prevent infringement of those patents. While many of the licenses under which we have rights provide us with rights in specified fields, the scope of our rights under these and other licenses may be subject to dispute by our licensors or third parties. In addition, our rights to use these technologies and practice the inventions claimed in the licensed patents and patent applications are subject to our licensors abiding by the terms of those licenses and not terminating them. Any of our licenses may be terminated by the licensor if we are in breach of a term or condition of the license agreement, or in certain other circumstances. Further, any disputes regarding obligations in licenses may require us to take expensive and time-consuming legal action to resolve, and, even if we are successful, may delay our ability to commercialize products and generate revenue. Further, if we are unable to resolve license issues that arise we may lose rights to practice intellectual property that is required to make, use, or sell products. Any such loss could compromise our development and commercialization efforts for current or future product candidates and / or may require additional effort and expense to design around. Our vaccine candidates and potential vaccine candidates will require several components that may each be the subject of a license agreement. The cumulative license fees and royalties for these components may make the commercialization of these vaccine candidates uneconomical. If patent laws or the interpretation of patent laws change, our competitors may be able to develop and commercialize our discoveries. Important legal issues remain to be resolved as to the extent and scope of available patent protection for biopharmaceutical products and processes in the U. S. and other important markets outside the U. S., such as Europe and Japan. In addition, foreign markets may not provide the same level of patent protection as provided under the U. S. patent system. Litigation or administrative proceedings may be necessary to determine the validity and scope of certain of our and others' proprietary rights. Any such litigation or proceeding may result in a significant commitment of resources in the future and could force us to do one or more of the following: cease selling or using any of our products that incorporate the challenged intellectual property, which would adversely affect our revenue; obtain a license from the holder of the intellectual property right alleged to have been infringed, which license may not be available on reasonable terms, if at all; and redesign our products to avoid infringing the intellectual property rights of third parties, which may be time-consuming or impossible to do. In addition, changes in, or different interpretations of, patent laws in the U. S. and other countries may result in patent laws that allow others to use our discoveries or develop and commercialize our products. We cannot provide assurance that the patents we obtain or the unpatented technology we hold will afford us significant commercial protection. In Europe, a new unitary patent system, which took effect on June 1, 2023, may significantly impact European patents, including those granted before the introduction of the new system. Under the new system, applicants can, upon grant of a patent, opt for that patent to become a Unitary Patent which will be subject to the jurisdiction of a new Unitary Patent Court ("UPC"). Patents granted before the implementation of the new system can be opted out of UPC jurisdiction, remaining as national patents in the UPC countries. Patents that remain under the jurisdiction of the UPC may be challenged in a single UPC-based revocation proceeding that, if successful, could invalidate the patent in all countries who are signatories to the UPC. Further, because the UPC is a new court system and there is no precedent for the court's laws, there is increased uncertainty regarding the outcome of any patent litigation. We are unable to predict what impact the new patent regime may have on our ability to exclude competitors in the European market. In addition to changes in patents laws, geopolitical dynamics, including Russia's incursion into Ukraine, may also impact our ability to obtain and enforce patents in particular jurisdictions. If we are unable to obtain and enforce patents as needed in particular markets, our ability to exclude competitors in those markets may be reduced. If we do not obtain patent term extension and / or patent term adjustment in the U. S. under the Hatch-Waxman Act and similar extensions in foreign countries, our ability to exclude competitors may be harmed. In the U. S., the patent term is 20 years from the earliest U. S. non-provisional filing date. Extensions of patent term may be available under certain circumstances. Depending upon the timing, duration and conditions of U. S. FDA marketing approval of our product candidates, we may be able to extend the term of one patent that covers a marketed product under the Drug Price Competition and Patent Term Restoration Act of 1984, (the "Hatch-Waxman Amendments") and similar legislation in the European Union and the United Kingdom. The Hatch-Waxman Amendments permit 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 U. S. FDA regulatory review process. We may not receive any extension if we 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. 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 that product will be shortened and our competitors may obtain approval to market competing products sooner. Patent term covering our products may also be extended for time spent during the prosecution of the patent application in the USPTO. This extension is referred to as Patent Term Adjustment ("PTA"). The laws and regulations governing how the USPTO calculates the PTA is subject to change and changes in the law can reduce or increase any such PTA. Further, the PTA granted by the USPTO may be challenged by a third party. If we do not prevail under such a challenge, the PTA may be reduced or eliminated, shortening the patent term, which may negatively impact our ability to exclude competitors.

Risks Related to Employee Matters, Managing Growth and Information Technology We anticipate growing through both internal development projects, **such as well as our late-stage pipeline, Matrix- MTM technology and emerging, early-stage pipeline, and** external opportunities, **such as which include the acquisition, partnering and in-licensing of products, technologies and companies or** the entry into strategic alliances and collaborations. The availability of high quality opportunities is limited, and we may fail to identify candidates that we and our stockholders consider suitable or complete transactions on terms that prove advantageous. In order to pursue such opportunities, we may require significant additional financing, which may not be available to us on favorable terms, if at all. ~~Even if we are able to successfully identify and complete acquisitions, like our business combinations with Novavax CZ (formerly Praha Vaccines) and Novavax AB, strategic~~ **Strategic** transactions involve many risks, including, among others, those related to diversion of management's attention from other business concerns,

unanticipated expenses and liabilities, and increased complexity of our operations, which could prevent us from effectively exploiting acquired facilities, successfully integrating the acquired business and personnel, or fully realizing expected synergies. To effectively manage our current and future potential growth, we will need to continue to enhance our operational, financial and management processes and to effectively expand, train and manage our employee base. Supporting our growth initiatives will require significant expenditures and management resources, including investments in research and development, manufacturing in-house and through third-party manufacturers and other areas of our business. If we do not successfully manage our growth and do not successfully execute our growth initiatives, then our business and financial results may be adversely impacted, and we may incur asset impairment or restructuring charges. Given our current cash position and cash flow forecast, and significant uncertainties related to 2024 revenue substantial doubt exists regarding our ability to continue as a going concern through one year from the date that the financial statements included in this Annual Report were issued. Our management must evaluate whether there are conditions or events, considered in the aggregate, that raise substantial doubt about our ability to continue as a going concern within one year after the date the financial statements are issued. At December 31, 2023, we had \$ 0.6 billion in cash and cash equivalents and restricted cash. During 2023, we incurred a net loss of \$ 545.1 million and had net cash flows used in operating activities of \$ 714.0 million. While our current cash flow forecast for the one-year going concern look forward period estimates that we have sufficient capital available to fund operations, this forecast is subject to significant uncertainty, including as it relates to the following:

- **2024 Revenue:** Our 2024 revenue depends on our ability to successfully develop, manufacture, distribute, or market an updated monovalent or bivalent formulation of a vaccine candidate for COVID-19 in a single dose vial or pre-filled syringe product presentation for the fall 2024 COVID-19 vaccine season, which is inherently uncertain and subject to a number of risks, including regulatory authorizations and our ability to introduce a single-dose vial or pre-filled syringe product presentation for the U.S. commercial and certain other markets. Management believes that, given the significance of these uncertainties, substantial doubt exists regarding our ability to continue as a going concern through one year from the date that these financial statements are issued. Our ability to fund Company operations is dependent upon revenue related to vaccine sales for our products and product candidates, if such product candidates receive marketing approval and are successfully commercialized; the resolution of certain matters; and management's plans, which may include raising additional capital through a combination of equity and debt financing, collaborations, strategic alliances, and marketing, distribution, or licensing arrangements. New financings may not be available to us on commercially acceptable terms, or at all. Also, any collaborations, strategic alliances, and marketing, distribution, or licensing arrangements may require us to give up some or all of our rights to a product or technology, which in some cases may be at less than the full potential value of such rights. In addition, the regulatory and commercial success of our COVID-19 Vaccine and our other vaccine candidates, including CIC vaccine candidate, or future COVID-19 variant strain-containing monovalent or bivalent formulations, remains uncertain. If we are unable to obtain additional capital, we will assess our capital resources and may be required to delay, reduce the scope of, or eliminate some or all of our operations, or downsize our organization, any of which may have a material adverse effect on our business, financial condition, results of operations, and ability to operate as a going concern. Our announced global restructuring and cost reduction plans may not result in anticipated reductions in combined research and development and selling, general, and administrative expenses and may disrupt our business. In May 2023, we announced a global restructuring and cost reduction plan. This plan includes a more focused investment in our COVID-19 commercial program, reduction to our pipeline spending, the continued rationalization of our manufacturing network, a reduction to our global workforce, as well as the consolidation of facilities and infrastructure. The planned workforce reduction includes an approximately 25% reduction in our global workforce, comprised of an approximately 20% reduction in full-time Novavax employees and the remainder comprised of contractors and consultants. We ~~expect~~ **realized** the full annual impact of the cost savings ~~to be realized~~ in 2024. During 2023, we recorded a charge of \$ 4.5 million related to one-time employee severance and benefit costs and \$ 10.1 million **of** costs related to the consolidation of facilities and infrastructure, the majority of which were incurred in the second quarter of 2023. Additionally, in January 2024 we announced an additional 12% reduction of our global workforce, comprised of an additional 9% reduction in the Company's full-time employees and the remainder comprised of contractors and consultants. ~~We~~ **The Company expects** ~~expect~~ the full annual impact of the cost savings to be realized in 2025 and approximately 85% of the annual impact, excluding one-time charges, to be realized in 2024 due to timing of implementing the measures and the applicable laws, regulations and other factors in the jurisdictions in which it operates. ~~We~~ **The Company is expected to record** ~~recorded~~ an additional charge of approximately ~~\$ 12.84 million to \$ 7 million~~ **\$ 12.84 million** related to one-time employee severance and benefit costs, ~~the majority of which is expected~~ **and \$ 4.1 million costs related** to be incurred in the **Impairment** first quarter of **long-lived assets during the year ended December 31, 2024**. ~~Upon completion, the resulting Company workforce is expected to be approximately 30% lower as compared to the end of the first quarter of 2023.~~ We may not realize, in full or in part, the anticipated benefits, savings and improvements in our cost structure from these efforts due to unforeseen difficulties, delays or unexpected costs. If we are unable to realize the potential development progress and cost savings from the global restructuring and cost reduction plan, including the reduction to our global workforce, our business strategy, operating results and financial condition would be adversely affected. Our workforce reductions could yield unanticipated consequences, such as attrition beyond planned workforce reductions or disruptions in our day-to-day operations. Our global restructuring and cost reduction plan, including the reduction to our global workforce, could also harm our ability to attract and retain qualified management and development personnel who are critical to our business. If we are unable to realize the expected benefits from the restructuring and cost reduction plan, we may decide to undertake additional workforce reductions. Security breaches and other disruptions to our information technology systems or those of the vendors on whom we rely could compromise our information and expose us to liability, reputational damage, or other costs. In the ordinary course of our business, we and many of our current and future strategic partners, vendors, contractors, and consultants collect and store sensitive data, including intellectual property, our proprietary business information and data about

our clinical participants, suppliers and business partners, including **sensitive** personally identifiable information. The **security** ~~secure maintenance~~ of this information is critical to our operations and business strategy. Some of this information represents an attractive target of criminal attack by malicious third parties with a wide range of motives and expertise, including nation- states, organized criminal groups, “hacktivists,” patient groups, disgruntled current or former employees and others. Our ongoing operating activities also depend on functioning information technology systems. We are required to expend significant resources in an effort to protect against security incidents, and may be required or choose to spend additional resources or modify our business activities, particularly where required by applicable data privacy and security laws or regulations or industry standards. Cyber attacks are of ever- increasing levels of sophistication and frequency and, despite our security measures, our information technology systems and infrastructure and those of our vendors and partners are not immune to such attacks or breaches. Our ~~profile as a recipient of funding under the USG Agreement and our~~ development of our COVID- 19 Vaccine may result in greater risk of cyber attack. Any such attack could result in a material compromise of our networks, and the information stored there could be accessed, publicly disclosed, lost, or rendered permanently or temporarily inaccessible. Furthermore, we may not promptly discover a system intrusion. Like other companies in our industry, we have and third parties with connections to our systems or with data relevant to our business have experienced attacks on our data and systems, including malware and computer viruses. Additionally, we partner with sites that store our clinical trial data, and their systems are also subject to the risk of cyberattacks, disruptions, or other security incidents. Attacks could have a material impact on our business, operations or financial results. Any access, disclosure or other loss of information, whether stored by us or our partners, or other cyberattack causing disruption to our business, including ransomware, could result in reputational, business, and competitive harms, significant costs related to remediation and strengthening our cyber defenses, legal claims or proceedings, **government** **governmental** investigations, liability including under laws that protect the privacy of personal information, and increased insurance premiums, any of which could have a material adverse effect on our business, operations or financial results. **These costs may exceed our insurance**. We also may need to pay a ransom if a “ransomware” infection prevents access or use of our systems and we may face reputational and other harms in addition to the cost of the ransom if an attacker steals certain critical data in the course of such an attack. Compliance with global privacy and data security requirements could result in additional costs and liabilities or inhibit our ability to collect and process data globally, and our failure to comply with data protection laws and regulations could lead to government enforcement actions, fines, and other harms which would cause our business and reputation to suffer. Evolving state, federal and foreign laws, regulations and industry standards regarding privacy and security apply to our collection, use, retention, protection, disclosure, transfer and other processing of personal data. Privacy and data protection laws may be interpreted and applied differently from country to country and may create inconsistent or conflicting requirements, which increases the costs incurred by us in complying with such laws, which may be substantial. For example, the GDPR, which became effective in May 2018, imposes a broad array of requirements for processing personal data, including elevated disclosure requirements regarding collection and use of such data, requirements that companies allow individuals to exercise data protection rights such as their right to obtain copies or demand deletion of personal data held by those companies, limitations on retention of information, and public disclosure of significant data breaches, among other things. The GDPR provides for substantial penalties for non- compliance of up to the greater of € 20 million or 4 % of global annual revenue for the preceding financial year. From January 1, 2021 the GDPR has been retained in UK, as it forms part of the law of England and Wales, Scotland and Northern Ireland by virtue of section 3 of the European Union (Withdrawal) Act 2018, as amended by the Data Protection, Privacy and Electronic Communications (Amendments etc.) (EU Exit) Regulations 2019 (SI 2019 / 419) (“UK GDPR”), alongside the UK’s Data Protection Act 2018. The UK GDPR mirrors the fines under the GDPR, i. e., fines up to the greater of € 20 million (£ 17. 5 million) or 4 % of global turnover. **In May 2024, the EU approved a new regulation on AI (the “EU AI Act”), parts of which took effect in late 2024. The EU AI Act is a legal framework that governs the development and deployment of AI in the EU. The framework bans certain uses of AI outright and imposes material obligations on both the providers and deployers of certain other AI activities. Violations are subject to fines, and regulators have powers to remove non- compliant products from the EU market**. Our efforts to comply with GDPR, the UK GDPR and other privacy and data protection laws impose significant costs and challenges that are likely to increase over time, and we may be exposed to substantial penalties or litigation related to violations of existing or future data privacy laws and regulations. Furthermore, transferring personal information across international borders is complex and subject to legal and regulatory requirements as well as active litigation and enforcement in a number of jurisdictions around the world, each of which could have an adverse impact on our ability to process and transfer personal data as part of our business operations. For example, the GDPR and UK GDPR impose strict restrictions surrounding the transfer of personal data to countries outside the EEA and the UK. The mechanisms that we and many other companies rely upon for European data transfers (for example, Standard Contractual Clauses and the EU- US Data Privacy Framework) are the subject of legal challenge, regulatory interpretation and judicial decisions by the Court of Justice of the European Union. The suitability of Standard Contractual Clauses for data transfer in some scenarios has recently been the subject of legal challenge, and while the United States and the European Union reached agreement on the EU- US Data Privacy Framework, there are legal challenges to that data transfer mechanism as well. We continue to closely monitor for developments related to valid transfer mechanisms available for transferring personal data outside the European Economic Area (including the EU- US Data Privacy Framework) and other countries that have similar trans- border data flow requirements and adjust our practices accordingly. If we are unable to implement a valid compliance mechanism for cross- border personal information transfers, we may face increased exposure to regulatory actions, substantial fines and injunctions against processing or transferring personal information from Europe to the U. S. An inability to import personal information from Europe to the U. S. may significantly and negatively impact our business operations, including by limiting our ability to conduct clinical trials in Europe ; limiting our ability to collaborate with contract research organizations, service providers, contractors and other companies subject to the GDPR; or requiring us to increase our

data processing capabilities in Europe at significant expense. Several other countries have also established specific legal requirements for cross-border transfers of personal information and certain countries have also established specific legal requirements for data localization (such as where personal data must remain stored in the country). **The U. S. has also enacted the Protecting Americans' Data from Foreign Adversaries Act of 2024 which establishes new restrictions on transfers of certain personally identifiable sensitive data to foreign adversary countries and entities controlled by a foreign adversary. Similarly, regulations issued pursuant to Executive Order 14117, "Preventing Access to Americans' Bulk Sensitive Personal Data and United States Government-Related Data by Countries of Concern" may restrict data transfers involving countries of concern or covered persons, including the People's Republic of China (including Hong Kong and Macau), Russia, Iran, North Korea, Cuba, and Venezuela.** If other countries implement more restrictive regulations for cross-border data transfers or do not permit data to leave the country of origin, such developments could adversely impact our business and our enterprise customers' business, our financial condition and our results of operations in those jurisdictions. Privacy laws and regulations are also expanding in the U. S. For example, the CCPA requires disclosures to California consumers, imposes rules for collecting or using information about minors and affords consumers abilities, such as the right to know whether their data is sold or disclosed and to whom, the right to request that a company delete their personal information, the right to opt-out of the sale of personal information and the right to non-discrimination in terms of price or service when a consumer exercises a privacy right. Like the GDPR, the CCPA establishes potentially significant penalties for violation. The CCPA also provides a private right of action along with statutory damages for certain data breaches. The California Privacy Rights Act ("CPRA"), which became operational in 2023 and expands on the CCPA, creating new consumer rights and protections, including the right to correct personal information, the right to opt out of the use of personal information in automated decision making, the right to opt out of "sharing" consumer's personal information for cross-context behavioral advertising, and the right to restrict use and disclosure of sensitive personal information. **Virginia, Connecticut and Utah almost 20 other states have also now passed comprehensive privacy laws that became effective effect in 2023, or will come into effect at various times over the next few years. Several states have passed specific medical and similar health-data related laws have been passed, such as the Washington My Health My Data Act, The Colorado Artificial Intelligence Act, California's Assembly Bill 2181 on Generative Artificial Intelligence, and other U. S. statutes may also impact or our ability to use artificial intelligence, restrict innovations or result in liability for prohibited uses of artificial intelligence technologies. All of these evolving compliance and operational requirements impose significant costs that are being considered in several likely to increase over time, may require us to modify our data processing practices and policies, divert resources from other initiatives and projects and could restrict the way services involving data are offered, all of which may adversely affect our results of operations. Certain states state laws may be more stringent or broader in scope, as well as at the or offer greater individual rights, than federal or other state laws, and local levels such laws may differ from each other, which may complicate compliance efforts. State laws are changing rapidly and there is ongoing discussion in Congress of a new federal data protection and privacy law to which we may be subject.** We will need to evaluate and update our privacy program to seek to comply with applicable the CPRA, VCDPA, CPA and other federal and state privacy and data security laws, and we expect to incur additional expense in our effort to comply. Such legislation may add additional complexity, variation in requirements, restrictions and potential legal risk, and may require additional investment of resources in compliance programs, impact strategies, reduce the availability of previously useful data and result in increased compliance costs and / or changes in business practices and policies. Collaborations and contracts of our wholly owned subsidiaries subsidiary Novavax AB and Novavax CZ with partners such as Sanofi, with regional partners, such as SHPL-- SII, Takeda and SK bioscience, as well as with international providers, expose us to additional risks associated with doing business outside the U. S. Swedish-based Novavax AB is a and Czech Republic-based Novavax CZ are wholly owned subsidiaries subsidiary of Novavax, Inc. We also have entered into the Sanofi CLA, a supply and license agreement with SHPL-- SII, collaboration and license agreements with each of Takeda and SK bioscience and other agreements and arrangements with foreign governments and companies in other countries. We plan to continue to enter into collaborations or partnerships with companies, non-profit organizations and local governments in various parts of the world. Risks of conducting business outside the U. S. include negative consequences of: • the costs associated with seeking to comply with multiple regulatory requirements that govern our ability to develop, manufacture and sell products in local markets; • failure to comply with anti-bribery laws such as the U. S. Foreign Corrupt Practices Act and similar anti-bribery laws in other jurisdictions; • new or changes in interpretations of existing trade measures, including tariffs, embargoes, sanctions, import restrictions, and export licensing requirements; • difficulties in and costs of staffing, managing and operating our international operations; • changes in environmental, health and safety laws; • fluctuations in foreign currency exchange rates; • new or changes in interpretations of existing tax laws; • political instability and actual or anticipated military or potential conflicts (including, without limitation, the ongoing conflict between Russia and Ukraine, Israel and Hamas, and a wider European or global conflict); • economic instability, inflation, recession and interest rate fluctuations; • minimal or diminished protection of intellectual property in many jurisdictions; and • possible nationalization and expropriation. These risks, individually or in the aggregate, could have a material adverse effect on our business, financial conditions, results of operations and cash flows. If we are unable to attract or retain key management or other personnel, our business, operating results and financial condition could be materially adversely affected. We depend on our senior executive officers, as well as key scientific and other personnel. The loss of these individuals or our failure to implement an appropriate succession plan could harm our business and significantly delay or prevent the achievement of research, development or business objectives. Turnover in key executive positions resulting in lack of management continuity and long-term history with our Company could result in operational and administrative inefficiencies and added costs. These risks have increased since our global restructuring and cost reduction plan and related workforce reduction implemented in May 2023 and January 2024, which increased the risk that we will lose technical know-how or other

trade secrets as experienced personnel depart. We may not be able to attract qualified individuals for key positions on terms acceptable to us. Competition for qualified employees is intense among pharmaceutical and biotechnology companies, and the loss of qualified employees, or an inability to attract, retain and motivate additional highly skilled employees could hinder our ability to complete clinical trials successfully and otherwise develop marketable products. We also rely from time to time on outside advisors who assist us in formulating our research and development and clinical strategy. We may not be able to attract and retain these individuals on acceptable terms, which could delay our development efforts.

Risks Related to Our Convertible Senior Notes Servicing our 5.00% convertible senior unsecured notes due 2027 requires a significant amount of cash, and we may not have sufficient cash flow to pay our debt. In 2022, we issued \$175.3 million aggregate principal amount of Notes. Our ability to make scheduled payments of the principal of, to pay interest on, or to refinance our indebtedness, including the Notes, depends on our future performance, which is subject to economic, financial, competitive and other factors beyond our control. We do not expect our business to be able to generate cash flow from operations sufficient to service our debt and make necessary capital expenditures and may therefore be required to adopt one or more alternatives, such as selling assets, restructuring debt or obtaining additional equity capital on terms that may be onerous or highly dilutive. Our ability to refinance our indebtedness, which matures in 2027, unless earlier converted, redeemed, or repurchased, will depend on the capital markets and our financial condition at such time. We may not be able to engage in any of these activities or engage in these activities on desirable terms, which could result in a default on our debt obligations, and limit our flexibility in planning for and reacting to changes in our business. We may not have the ability to raise the funds necessary to repurchase the Notes as required upon a fundamental change, and our future debt may contain limitations on our ability to repurchase the Notes. Holders of the Notes will have the right to require us to repurchase their Notes for cash upon the occurrence of a fundamental change at a fundamental change repurchase price equal to 100% of the principal amount of the Notes to be repurchased, plus accrued and unpaid interest, if any. A fundamental change may also constitute an event of default or prepayment under, and result in the acceleration of the maturity of, our then-existing indebtedness. We cannot assure that we will have sufficient financial resources, or will be able to arrange financing, to pay the fundamental change repurchase price in cash with respect to any Notes surrendered by holders for repurchase upon a fundamental change. In addition, restrictions in our then-existing credit facilities or other indebtedness, if any, may not allow us to repurchase the Notes upon a fundamental change. Our failure to repurchase the Notes upon a fundamental change when required would result in an event of default pursuant to the indenture governing the Notes which could, in turn, constitute a default under the terms of our other indebtedness, if any. If the repayment of the related indebtedness were to be accelerated after any applicable notice or grace periods, we may not have sufficient funds to repay the indebtedness and repurchase the Notes.

Risks Related to Ownership of Our Common Stock Our stock price has been highly volatile. From January 1, 2023-2024 through December 31, 2023-2024, the closing sale price of our common stock has been as low as \$ 43.80-76 per share and as high as \$ 12-20. 48-97 per share. The stock market in general and the market for biotechnology companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. For example, the trading prices of biopharmaceutical companies in particular have been highly volatile as a result of the COVID-19 pandemic, inflation and increased interest rates. These broad market fluctuations may cause the market price of our common stock to be lower or more volatile than expected. Furthermore, given the global focus on the COVID-19 pandemic and our investment in developing a COVID-19 vaccine, information in the public arena on this topic, whether or not accurate, has had and will likely continue to have an outsized impact (positive or negative) on our stock price. Information related to our development, manufacturing, regulatory and commercialization efforts with respect to our COVID-19 Vaccine, or information regarding such efforts by competitors with respect to their COVID-19 vaccines and vaccine candidates, may meaningfully impact our stock price. 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 of our common stock may be influenced by many other factors, including:

- future announcements about us or our collaborators or competitors, including the results of testing, technological innovations or new commercial products;
- clinical trial results;
- delays in making regulatory submissions;
- depletion of our cash reserves;
- sale of equity securities or issuance of additional debt;
- announcement by us of significant strategic partnerships, collaborations, joint ventures, capital commitments or acquisitions;
- changes in government regulations;
- impact of competitor successes and in particular development success of vaccine candidates that compete with our own vaccine candidates;
- developments in our relationships with our collaboration and funding partners;
- announcements relating to health care reform and reimbursement levels for new vaccines and other matters affecting our business and results, regardless of accuracy;
- sales of substantial amounts of our stock by us or existing stockholders (including stock by insiders or 5% stockholders);
- development, spread or new announcements related to pandemic diseases;
- litigation;
- public concern as to the safety of our products;
- significant setbacks or concerns with the industry or the market as a whole;
- regulatory inquiries, reviews and potential action, including from the U.S. FDA or the SEC;
- demand for bivalent vaccines;
- recommendations by securities analysts or changes in earnings estimates; and
- the other factors described in this Risk Factors section.

In the past, following periods of volatility in the market price of a company's securities, securities class-action litigation often has been instituted against that company. Such litigation, if instituted against us, could cause us to incur substantial costs to defend such claims and divert management's attention and resources, which could seriously harm our business, financial condition, and results of operations, and prospects. Raising additional capital by issuing securities or through collaboration and licensing arrangements may cause dilution to existing stockholders or require us to relinquish rights to our technologies or vaccine candidates. If we are unable to partner with a third-party to advance the development of one or more of our vaccine candidates, we will need to raise money through additional debt or equity financings. To the extent that we raise additional capital by issuing equity securities, our stockholders will experience immediate dilution, which may be significant. There is also a risk that such equity issuances may cause an ownership change under the Internal Revenue Code of 1986, as amended, and similar state provisions, thus limiting our ability to use our net operating loss carryforwards and credits. To the extent that we raise additional capital through licensing arrangements or

arrangements with collaborative partners, we may be required to relinquish, on terms that may not be favorable to us, rights to some of our technologies or vaccine candidates that we would otherwise seek to develop or commercialize ourselves. In addition, economic conditions may also negatively affect the desire or ability of potential collaborators to enter into transactions with us. They may also have to delay or cancel research and development projects or reduce their overall budgets. Provisions of our Second Amended and Restated Certificate of Incorporation and Amended and Restated By- Laws and Delaware law could delay or prevent the acquisition of the Company, even if such acquisition would be beneficial to stockholders, and could impede changes in our Board. Provisions in our organizational documents could hamper a third party's attempt to acquire, or discourage a third- party from attempting to acquire control of, the Company. Stockholders who wish to participate in these transactions may not have the opportunity to do so. Our organizational documents also could limit the price investors are willing to pay in the future for our securities and make it more difficult to change the composition of our Board in any one year. For example, our organizational documents provide for a staggered board with three classes of directors serving staggered three- year terms and advance notice requirements for stockholders to nominate directors and make proposals. As a Delaware corporation, we are also afforded the protections of Section 203 of the Delaware General Corporation Law, which will prevent us from engaging in a business combination with a person who acquires at least 15 % of our common stock for a period of three years from the date such person acquired such common stock, unless advance board or stockholder approval was obtained. Any delay or prevention of a change of control transaction or changes in our Board or management could deter potential acquirers or prevent the completion of a transaction in which our stockholders could receive a substantial premium over the then current market price for their shares. We have never paid dividends on our capital stock, and we do not anticipate paying any such dividends in the foreseeable future. We have never paid cash dividends on our common stock. We currently anticipate that we will retain all of our earnings for use in the development of our business and do not anticipate paying any cash dividends in the foreseeable future. As a result, capital appreciation, if any, of our common stock would be the only source of gain for stockholders until dividends are paid, if at all. General Risk Factors **Litigation or regulatory investigations could have a material adverse impact on our results of operation and financial condition.** In addition to intellectual property litigation, from time to time, we may be subject to other litigation or regulatory investigations. Regardless of the merits of any claims that may be brought against us, litigation or regulatory investigations could result in a diversion of management's attention and resources and we may be required to incur significant expenses defending against these claims. If we are unable to prevail in litigation or regulatory investigations, we could incur substantial liabilities. Where we can make a reasonable estimate of the liability relating to pending litigation and determine that it is probable, we record a related liability. As additional information becomes available, we assess the potential liability and revise estimates as appropriate. However, because of uncertainties relating to litigation, the amount of our estimates could be wrong. Our operations, and those of our clinical research organizations, contract manufacturing organizations, vendors of materials needed in manufacturing, collaboration partners, distributors and other third parties upon whom we depend, could be subject to fires, extreme weather conditions, earthquakes, power shortages, telecommunications failures, water shortages, floods, hurricanes, typhoons, war, political unrest, sabotage or terrorism and other natural or man- made disasters, as well as public health emergencies, such as the COVID- 19 pandemic. The occurrence of any of these business disruptions could prevent us from using all or a significant portion of our facilities and it may be difficult or impossible for us to continue certain activities for a substantial period of time. The disaster recovery and business continuity plans we have in place may prove inadequate in the event of a serious disaster or similar event and we may incur substantial expenses and delays as a result. Our ability to manufacture our product candidates and obtain necessary clinical supplies for our product candidates could be disrupted if the operations of our contract manufacturing organizations or suppliers are affected by a natural or man- made disaster, or a public health emergency. We are a target for public scrutiny, and our business may be impacted by unfavorable publicity. Given that COVID- 19 represented an unprecedented urgent public health crisis and that we have received significant funding from the U. S. and foreign governments and other sources to support the development and commercialization of our COVID- 19 Vaccine, we have observed and are likely to continue to face significant public attention and scrutiny over the complex decisions we have made and will be making regarding the development, testing, manufacturing, allocation and pricing of our COVID- 19 Vaccine. If we are unable to successfully manage these risks, we could face significant reputational harm, which could negatively affect our stock price. The intense public interest, including speculation by the media, in the development of our COVID- 19 Vaccine has caused significant volatility in our stock price, which we expect to continue as data and other information from our ongoing clinical trials become publicly available. If concerns should arise about the actual or anticipated efficacy or safety of any of our product candidates, such concerns could adversely affect the market's perception of these candidates, which could lead to a decline in investors' expectations and a decline in the price of our common stock. The increasing use of social media platforms presents new risks and challenges to our business. Social media is increasingly being used to communicate about pharmaceutical companies' research, product candidates, and the diseases such product candidates are being developed to prevent. Social media practices in the pharmaceutical industry continue to evolve and regulations relating to such use are not always clear. This evolution creates uncertainty and risk of noncompliance with regulations applicable to our business, resulting in potential regulatory actions against us. For example, subjects may use social media channels to comment on their experience in an ongoing blinded clinical trial or to report an alleged adverse event. When such events occur, there is a risk that we fail to monitor and comply with applicable adverse event reporting obligations or we may not be able to defend our business or the public's legitimate interests in the face of the political and market pressures generated by social media due to restrictions on what we may say about our investigational product candidates. There is also a risk of inappropriate disclosure of sensitive information or negative or inaccurate posts or comments about us on any social media or networking website. If any of these events were to occur or we otherwise fail to comply with applicable regulations, we could incur liability, face regulatory actions, or incur reputational or other harm to our business. **63**