

2024

2024

# ANNUAL REPORT



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**140** Leadership & Corporate Information



APRIL 21, 2025

# A Message from Our CEO



To Our Shareholders,

2024 was a transformational year marked by significant accomplishments. We unveiled an ambitious corporate growth strategy aimed at maximizing the impact of our technology through R&D innovation, the expansion of our organic portfolio and building strategic partnerships, including the out-licensing of our technology platform and vaccine assets. This strategy also shaped our renewed mission and vision to reflect our long-term goals.

**Our Mission:** By leveraging our science, our technology and our people, we will innovate and collaborate to tackle the world's most significant health challenges.

**Our Vision:** We envision a world where our technology is amplified to touch the lives of billions, sparking transformation in global health.

To execute this strategy, we advanced key regulatory and clinical programs, strengthened our financial position creating a leaner and more focused operating model, and streamlined operations—laying the foundation for sustained growth. In 2025, we intend to continue advancing global health and driving shareholder value by focusing on **three strategic priorities**.

**01 Sanofi Partnership.** Our first priority is to be a partner of choice, expanding global access to our COVID-19 vaccine, Matrix-M® adjuvant and our emerging pipeline assets to drive revenue growth and strengthen Novavax's long-term financial stability through royalties and milestone payments.

Sanofi's role in commercializing our COVID-19 vaccine and their broad, non-exclusive access to our Matrix-M adjuvant significantly enhances the potential for multiple revenue streams. Sanofi's strong global presence and proven experience in vaccine commercialization, combined with Novavax's R&D expertise, helps give confidence that this partnership will deliver value to our shareholders and the people who would have broadened access to our vaccine technology—providing greater protection to communities globally.

**02 Leveraging Our Technology Platform and Pipeline to Forge Additional Partnerships.** Our goal is to develop an exciting portfolio of new vaccines, with the intent of creating additional partnership and collaboration opportunities for our advanced technology platform and pipeline. As our new pipeline begins to mature, we will also consider bringing forward assets on our own without a partner, if the market opportunity and revenue potential warrant it.

Our Matrix-M adjuvant offers the potential to enhance vaccine durability, immune response and cost efficiency. Our ongoing collaboration with Sanofi, and additional agreements with other leading pharmaceutical companies demonstrate a strong interest in Matrix-M, and we remain committed to exploring further partnership opportunities.

In our late-stage pipeline, we are advancing a stand-alone flu candidate and a COVID-19-Influenza Combination (CIC) vaccine candidate for adults aged 65 and older, addressing significant consumer demand for an all-in-one solution. We anticipate data by mid-year 2025 from the initial cohort of our Phase 3 clinical trial, and we are working to secure a partner to fund further clinical development.

**03 Advancing Our Technology Platform and Early-Stage Pipeline.** We are advancing our technology platform and early-stage pipeline focused on high-value market opportunities where we believe our technology can address significant unmet medical needs, supported by strong scientific rationale and a rigorous analysis of commercial potential. We began expanding our early-stage pipeline in 2024 with four new programs while maintaining a lean, capital-efficient and disciplined investment approach. In general, we aim to partner early-stage assets at proof of concept, staging further investment until a partner is secured to fund full clinical development and commercialization. For the right asset, where data and commercial opportunity indicate a unique high-value opportunity, we retain the potential of bringing that asset forward ourselves and will make that determination on a case-by-case basis as we learn more about these assets over time.

## Looking Ahead

2025 will be the first full year operating under our new growth strategy—a significant transition for Novavax. Our plan is to continue to optimize operations and lower expenses to create a leaner and more agile organization while shifting to a revenue model driven by milestone payments and future royalty streams. This evolution reflects our broader strategy—expanding our technology's reach through strategic partnerships and organic pipeline development, adapting our business for sustainable growth.

We are returning to our roots, focusing on what we do best and what drives our people—innovating to tackle the world's biggest health challenges.

Thank you to our dedicated employees whose passion, expertise and commitment drive Novavax forward, and to our shareholders for their trust and ongoing support.

John C. Jacobs  
President and Chief Executive Officer

# 2024 in Review

In 2024, Novavax experienced a significant year of transition, where we embarked upon a new corporate strategy, announced our wide-ranging partnership with Sanofi, made important progress on our portfolio and significantly improved our financial strength. With our new corporate growth strategy, we prioritized existing and potential new partnerships with other companies, leveraged our proven technology platform and expanded our pipeline to unlock future opportunities.



## Strategic Milestones

- **Sanofi Partnership:** Announced May partnership with Sanofi, transitioning our COVID-19 vaccine commercialization to a global industry leader, with the potential for milestone payments, long-term royalties and future collaborations using our proprietary Matrix-M® adjuvant. This includes Sanofi's two Fast Track designated influenza-COVID-19 combination vaccines utilizing our COVID-19 vaccine, as well as Sanofi's right to use our Matrix-M adjuvant in advancing multiple new vaccines within their pipeline. Sanofi's expertise in vaccine commercialization, combined with Novavax's R&D capabilities, ensures continued global access to our COVID-19 vaccine and Matrix-M adjuvant.
- **Regulatory Milestone:** Received U.S. FDA acceptance for our filing of a Biologics License Application (BLA) for our COVID-19 vaccine.
- **Updated COVID-19 Vaccine:** Launched our updated COVID-19 vaccine for the 2024-2025 vaccination season.



## Pipeline and R&D Expansion

- **Late-stage Pipeline:** Initiated the initial cohort for our Phase 3 trial of our COVID-19-Influenza-Combination and stand-alone flu vaccine candidates.
- **Early-stage Pipeline:** Identified areas to broaden our impact in infectious disease prevention in four new early-stage vaccine candidates targeting: C. difficile, varicella-zoster (shingles), pandemic flu and RSV combinations.
- **Matrix-M Innovation:** Initiated exploratory work on next-generation formulations and explored potential expansion beyond infectious diseases.

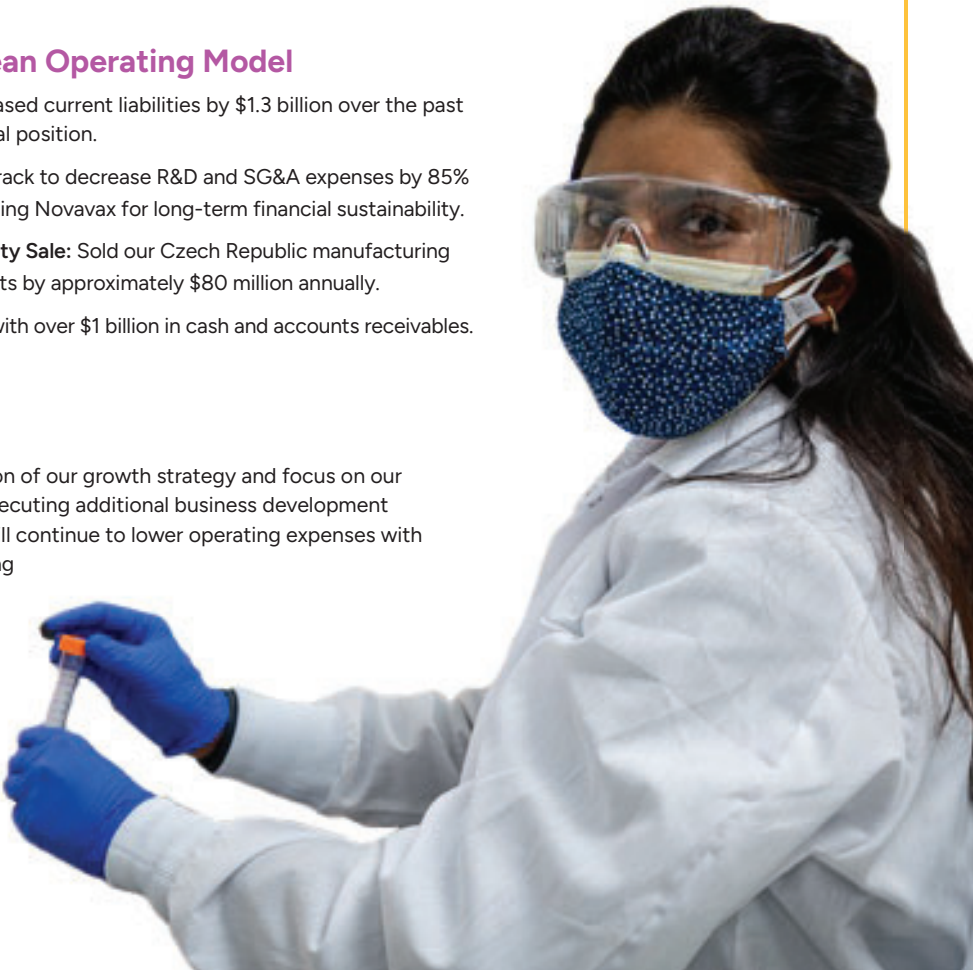


## Financial Strength and Lean Operating Model

- **Balance Sheet Improvement:** Decreased current liabilities by \$1.3 billion over the past two years, strengthening our financial position.
- **Continued Expense Reduction:** On track to decrease R&D and SG&A expenses by 85% by 2027, compared to 2022, positioning Novavax for long-term financial sustainability.
- **Czech Republic Manufacturing Facility Sale:** Sold our Czech Republic manufacturing facility for \$200 million, reducing costs by approximately \$80 million annually.
- **Cash Position:** Ended full year 2024 with over \$1 billion in cash and accounts receivables.

## Looking Ahead

As we transition our focus to 2025, we will drive execution of our growth strategy and focus on our three key priorities: optimizing the Sanofi partnership, executing additional business development deals and advancing our early-stage pipeline. Novavax will continue to lower operating expenses with the goal of making our organization leaner while executing against our growth strategy. We will shift to a revenue model centered on milestone payments and future royalty streams. Focused on expanding the reach of our technology through strategic partnerships and adapting our business for sustainable growth, we remain committed to innovation and delivering impactful solutions in global health.



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**UNITED STATES SECURITIES AND EXCHANGE COMMISSION**  
Washington, D.C. 20549

**Form 10-K**

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

**For the fiscal year ended December 31, 2024**

**OR**

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

**For the transition period from      to      .**

**Commission File No. 000-26770**

**NOVAVAX, INC.**

(Exact name of Registrant as specified in its charter)

**Delaware**

(State of incorporation)

**22-2816046**

(I.R.S. Employer Identification No.)

**700 Quince Orchard Road,**

**Gaithersburg, Maryland**

(Address of principal executive offices)

**20878**

(Zip Code)

**Registrant's telephone number, including area code: (240) 268-2000**

**Securities registered pursuant to Section 12(b) of the Act:**

<b>Title of each class</b>	<b>Trading Symbol</b>	<b>Name of each exchange on which registered</b>
Common Stock, Par Value \$0.01 per share	NVAX	The Nasdaq Global Select Market

**Securities registered pursuant to Section 12(g) of the Act: Not Applicable**

Indicate by check mark if the Registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☒ No ☐

Indicate by check mark if the Registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. Yes ☐ No ☒

Indicate by check mark whether the Registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the Registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer	<input checked="" type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input type="checkbox"/>	Smaller reporting company	<input type="checkbox"/>
Emerging growth company	<input type="checkbox"/>		

If an emerging growth company, indicate by check mark if the registrant had elected not to use the extended transition period for complying with any new or revised financial accounting standards provide pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☒

If securities are registered pursuant to Section 12(b) of the Exchange Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to § 240.10D-1(b). ☐

Indicate by check mark whether the Registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the Registrant (based on the last reported sale price of Registrant's common stock on June 30, 2024 on the Nasdaq Global Select Market) was approximately \$2,020,000,000.

As of February 18, 2025, there were 160,844,197 shares of the Registrant's common stock outstanding.

Documents incorporated by reference: Portions of the Registrant's Definitive Proxy Statement to be filed no later than 120 days after the fiscal year ended December 31, 2024 in connection with the Registrant's 2025 Annual Meeting of Stockholders are incorporated by reference into Part III of this Annual Report on Form 10-K to the extent indicated herein.

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**NOVAVAX, INC.**

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## CERTAIN DEFINITIONS

All references in this Annual Report on Form 10-K to "Novavax," the "Company," "we," "us," and "our" refer to Novavax, Inc. including its wholly-owned subsidiaries (unless the context otherwise indicates). All references in this Annual Report on Form 10-K to "NVX-CoV2373" or "prototype COVID-19 vaccine" refer to our Nuvaxovid™ prototype COVID-19 vaccine; all references to "NVX-CoV2601" or "XBB COVID-19 vaccine" refer to our Nuvaxovid™ COVID-19 vaccine for the 2023-2024 vaccination season; and all references to "NVX-CoV2705", "JN.1 COVID-19 vaccine" or "updated COVID-19 vaccine" refer to our Nuvaxovid™ COVID-19 vaccine for the 2024-2025 vaccination season. We refer to our prototype COVID-19 vaccine and updated COVID-19 vaccines, collectively, as our "COVID-19 vaccine". Local regulatory authorities have also specified nomenclature for our COVID-19 vaccine for labeling within their territories (e.g., "Novavax COVID-19 Vaccine, Adjuvanted", "Novavax COVID-19, Adjuvanted (2023-2024 or 2024-2025 Formula)", respectively, for the U.S., and "Nuvaxovid™" for ex-U.S. territories). The Company's partner, Serum Institute of India Pvt. Ltd., markets Novavax's COVID-19 vaccine as "Covovax™".

## NOTE REGARDING TRADEMARKS

Novavax™, Nuvaxovid™, Matrix-M™, Matrix-A™, Matrix-C™, Matrix-V™, Prepare™, Resolve™, and ResVax™ are trademarks of Novavax. Any other trademarks referred to in this Annual Report on Form 10-K are the property of their owners. All rights reserved. We do not intend our use or display of other companies' trade names or trademarks to imply an endorsement or sponsorship of us by such companies, or any relationship with any of these companies.

## FORWARD-LOOKING INFORMATION

This Annual Report on Form 10-K contains forward-looking statements that involve risks and uncertainties. As a result of many factors, such as those set forth under "Risk Factors" and elsewhere in this Annual Report on Form 10-K, our actual results may differ materially from those anticipated in these forward-looking statements. Please also see the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations."

## SUMMARY OF RISKS ASSOCIATED WITH OUR BUSINESS

Our business is subject to numerous risks which are discussed more fully under the heading "Risk Factors" in this Annual Report on Form 10-K. These risks include, but are not limited to, the following:

- 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 our collaboration and license agreement entered into with Sanofi Pasteur Inc. ("Sanofi") in May 2024 (the "Sanofi CLA") and or our advance purchase agreements ("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 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 conditional marketing authorization ("CMA"), or emergency use authorization ("EUA") or full approval 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 United States ("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.
- We are highly dependent on the commercial success of our COVID-19 Vaccine, and even though we have received CMA, EUA or full approval 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.
- 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 and product candidates.



- 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. Food and Drug Administration ("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.
- We may fail to obtain regulatory approval for our prototype COVID-19 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.
- 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.
- Servicing our 5.00% convertible senior unsecured notes due 2027 (the "Notes") 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 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.

## PART I

### Item 1. BUSINESS

#### Overview

Novavax, Inc., together with our wholly owned subsidiaries, is tackling global health challenges through scientific innovation that seeks to maximize our deep scientific expertise in vaccines and our cutting-edge technology platform. The differentiated platform features our recombinant protein-based nanoparticle technology and unique Matrix-M™ adjuvant.

Our corporate growth strategy is focused on delivering value through in-house early-stage research and development (“R&D”) to build a pipeline of high-value assets using our proven technology along with seeking to enter into partnerships to drive value creation for our R&D assets early in the development process and for our Matrix-M™ adjuvant alone. Our three strategic priorities are: focusing on our partnership with Sanofi announced in May 2024, leveraging our technology platform and pipeline to forge additional partnerships, and advancing our proven technology platform and early-stage pipeline. Our corporate growth strategy is supported by a lean and focused operating model.

Our technology platform, combined with our deep vaccine expertise, is the fuel for innovation and partnerships, and we believe it has the potential to create significant value. Our proprietary Matrix-M™ adjuvant when added to vaccines, has been shown to help induce a stronger and longer-lasting immune response. Our recombinant protein-based nanoparticle technology has been shown to be highly immunogenetic. Together, we believe that our technology platform can induce potent, durable and broad immune responses, with the potential to be antigen-sparing. Our Matrix-M™ adjuvant can increase both antibody and cell-mediated immune responses to the vaccine and it has demonstrated a favorable tolerability profile in clinical trials. Our technology platform is used in our authorized COVID-19 vaccine and the R21/Matrix-M™ adjuvant malaria vaccine (as defined below).

We have developed and manufactured our updated COVID-19 vaccine for the 2024-2025 vaccination season for use in individuals aged 12 and older. Our updated COVID-19 vaccine received Emergency Use Authorization (“EUA”) from the U.S. Food and Drug Administration (“FDA”) in August 2024, along with several additional global regulatory authorizations for use in the 2024-2025 vaccination season. In the U.S., our Biologics License Application (“BLA”) for our prototype COVID-19 vaccine and for our XBB COVID-19 vaccine is currently under U.S. FDA review with a Prescription Drug User Fee Act (“PDUFA”) date of April 2025.

In May 2024, we entered into a Collaboration and License Agreement with Sanofi (the “Sanofi CLA”), to co-commercialize our COVID-19 vaccine, including future updated versions that address seasonal COVID-19 variants. Under the terms of the agreement, we will continue to commercialize our updated COVID-19 vaccine through the end of the 2024-2025 vaccination season, and beginning in 2025 and continuing during the term of the Sanofi CLA, we and Sanofi will commercialize the COVID-19 vaccine worldwide in accordance with a commercialization plan agreed by us and Sanofi, under which we will continue to supply certain of our existing advance purchase agreement (“APA”) customers and strategic partners, including Takeda Pharmaceutical Company Limited (“Takeda”) and Serum Institute of India Pvt. Ltd. (“SII”). Upon completion of the existing APAs, we and Sanofi will jointly agree on commercialization activities of each party in each jurisdiction. Additionally, Sanofi has the right to develop novel influenza-COVID-19 combination vaccines utilizing our COVID-19 vaccine and Sanofi’s seasonal influenza vaccine, combination products containing our COVID-19 vaccine and one or more non-influenza vaccines, and multiple new vaccines utilizing our Matrix-M™ adjuvant.

In December 2024, Sanofi announced that the U.S. Food and Drug Administration (“U.S.FDA”) granted Fast Track designation to two Sanofi combination vaccine candidates: the first combination consists of Fluzone High-Dose combined with our COVID-19 vaccine, and the second combination consists of Flublok with our COVID-19 vaccine. Sanofi is evaluating the safety and immunogenicity of both combination vaccine candidates in two separate Phase 1/2 trials.

We are eligible to receive royalties and milestones associated with the ongoing sales of our COVID-19 vaccine and Sanofi’s influenza-COVID-19 combination vaccines and any other combination vaccines Sanofi may develop, as well as ongoing product royalties for vaccines developed with our Matrix-M™ adjuvant. We discuss this agreement in further detail in Note 4 to our accompanying consolidated financial statements.

Additionally, we are advancing our pipeline of both late- and early-stage programs with a focus on potentially high-value assets in areas with unmet medical need, compelling scientific rationale and strong commercial opportunity.

Our late-stage programs include a COVID-19-Influenza ("CIC") vaccine candidate, as well as a stand-alone influenza vaccine candidate. In December 2024, we initiated the initial cohort of a Phase 3 trial comparing our CIC vaccine and stand-alone influenza vaccine to our updated COVID-19 vaccine and a licensed seasonal influenza vaccine comparator in adults aged 65 and older. We intend to partner these vaccine candidates in order to advance to BLA filing and commercialization.

Furthermore, we provide our Matrix-M™ adjuvant for use in collaborations. These include the R21/Matrix-M™ adjuvant malaria vaccine, a malaria vaccine developed by our partner, the Jenner Institute, University of Oxford ("R21/Matrix-M™ adjuvant malaria vaccine") and manufactured by SII. R21/Matrix-M™ adjuvant malaria vaccine is authorized in several countries. Additionally, we provide Matrix-M™ adjuvant for use in various programs in preclinical and clinical stage, as well as preclinical investigations. Examples include an agreement with the Gates Foundation, and in a related master transfer agreement with a leading pharmaceutical company for exploration of Matrix-M™ adjuvant used as a potential advancement in their pipeline.

We continue to advance our strategic assessment of our emerging, early-stage pipeline. We intend to develop our early-stage pipeline using a disciplined and capital-efficient approach. Our R&D investment strategy seeks to place smart, lower-cost investments on the programs with the highest potential value, both within infectious disease and beyond, with the intent of partnering these assets at proof of concept and shifting late-stage development costs to our partners to finalize clinical development. We are pursuing early-stage research in diseases such as, respiratory syncytial virus ("RSV") combinations, varicella-zoster virus (shingles) and *Clostridioides difficile* (C. Diff.) colitis. We are actively working to evaluate several RSV combination candidates to progress forward toward an Investigational New Drug ("IND"). We are actively developing an H5N1 avian pandemic influenza vaccine candidate and the toxicology study is underway. We are actively monitoring the emerging public health situation and are pursuing funding opportunities to join preparedness efforts. Additionally, we are evaluating potential expansion beyond infectious diseases including therapeutic areas such as oncology, where we believe our technology could augment and improve upon current therapies.

We were incorporated in 1987 under the laws of the State of Delaware. Our principal executive offices are located at 700 Quince Orchard Road, Gaithersburg, Maryland, 20878, and our telephone number is (240) 268-2000. Our common stock is listed on the Nasdaq Global Select Market under the symbol "NVAX."

## **Technology Overview**

We believe our recombinant nanoparticle vaccine technology and our proprietary Matrix-M™ adjuvant are well suited for the development and commercialization of vaccine candidates targeting areas both within and beyond the infectious disease space.

### **Recombinant Nanoparticle Vaccine Technology**

Once a target of interest has been identified, the genetic sequence encoding an antigen is selected for developing the vaccine construct. The genetic sequence may be optimized to enhance protein stability or confer resistance to degradation. This genetic construct is inserted into the baculovirus *Spodoptera frugiperda* ("Sf-/BV") insect cell-expression system, which enables efficient, large-scale expression of the optimized protein. The Sf-/BV system produces protein-based antigens that are properly folded and modified, which can be critical for functional, protective immunity. Our testing shows this results in a highly immunogenic nanoparticle that is ready to be formulated with Matrix-M™ adjuvant.

### **Matrix-M™ Adjuvant**

Our proprietary Matrix-M™ adjuvant is a key differentiator within our platform. This adjuvant has enabled potent, well tolerated, and durable efficacy by stimulating the entry of antigen presenting cells ("APCs") into the injection site and enhancing antigen presentation in local lymph nodes. This in turn activates APCs, T-cell and B-cell populations, and plasma cells, which promote the production of high affinity antibodies, an immune boosting response. This potent mechanism of action enables a lower dose of antigen to achieve the desired immune response, thereby contributing to increased vaccine supply and manufacturing capacity. These immune-boosting and dose-sparing capabilities contribute to the adjuvant's highly unique profile.

We continue to evaluate commercial opportunities for the use of our Matrix-M™ adjuvant alongside vaccine antigens produced by other manufacturers. Matrix-M™ adjuvant is being evaluated in combination with several partner-led malaria vaccine candidates, including for R21/Matrix-M™ adjuvant malaria vaccine. The R21/Matrix-M™ adjuvant malaria vaccine has been licensed to SII for commercialization. In May 2024, pursuant to the Sanofi CLA, Sanofi received a non-exclusive license to develop and commercialize other vaccine products that include our Matrix-M™ adjuvant. In September 2024, we signed a Matrix-M™ adjuvant related

agreement with a leading pharmaceutical company to enable exploration of our technology for the potential advancement of their pipeline candidates.

### **COVID-19 Vaccine Regulatory and Licensure**

For our updated COVID-19 vaccine for the 2024-2025 vaccination season, in August 2024, we received EUA from the U.S. FDA for active immunization to prevent COVID-19 in individuals aged 12 and older. Our updated COVID-19 vaccine is included in the recommendations issued by the U.S. Centers for Disease Control and Prevention in June 2024. This follows the recommendation in April 2024, from the World Health Organization ("WHO") for the recommended use of a monovalent JN.1 lineage COVID-19 vaccine.

In the U.S., our updated COVID-19 vaccine for the 2024-2025 vaccination season is available in pre-filled syringe product presentation and available in independent pharmacies and major retailers.

In October 2024, the European Commission issued a decision approving our updated COVID-19 vaccine for use in individuals aged 12 and older for the prevention of COVID-19 in the EU. This decision followed the positive opinion from the Committee for Medicinal Products for Human Use of the European Medicines Agency ("EMA").

Additionally, in October 2024, we received BLA approval by the Taiwan Food and Drug Administration for our COVID-19 vaccine for use in individuals aged 12 and older.

In November 2024, we received approval from the UK Medicines and Healthcare Products Regulatory Agency ("MHRA") for our updated COVID-19 vaccine for use in individuals aged 12 and older.

In December 2024, we received approval from Singapore Health Sciences Authority for our updated COVID-19 vaccine for use in individuals aged 12 and older.

We are working to continue to expand our label for primary and re-vaccination in younger children, and to achieve supportive policy recommendations enabling broad market access and to support Sanofi's commercial efforts, pursuant to our agreement, that have begun in 2025. We continue to work closely with governments, regulatory authorities, and non-governmental organizations in our commitment to facilitate access to our COVID-19 vaccine.

### **APAs**

We have entered into APAs (also referred to as "supply agreements" throughout this Annual Report on Form 10-K) with various countries globally. The APAs 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. Such upfront payments generally become non-refundable upon our achievement of certain development milestones. We currently have \$1.0 billion in committed APAs anticipated for future delivery under existing agreements, comprised of \$225 million under our APA with the Vaccine Alliance ("Gavi"), \$556 million under our APA with His Majesty the King in Right of Canada as represented by the Minister of Public Works and Government Services, as successor in interest to Her Majesty the Queen in Right of Canada, as represented by the Minister of Public Works and Government Services (the "Canadian government"), and \$258 million under all other APAs.

We have an APA with the Commonwealth of Australia ("Australia") for the purchase of doses of COVID-19 Vaccine (the "Australia APA"). In December 2024, we entered into an amendment to the Australia APA with Australia. Pursuant to the amendment, we acknowledged the cancellation by Australia of the delivery of certain doses of our COVID-19 Vaccine scheduled for delivery between the fourth quarter of 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 the future delivery of approximately 3 million doses of COVID-19 Vaccine without requiring additional cash payments. We also agreed to an 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 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 also provides Australia with the right to cancel doses if we fail to timely notify Australia of changes to our commercialization plans. As of December 31, 2024, \$15.6 million was classified as current Deferred revenue and \$118.2 million was classified as non-current Deferred revenue with respect to the Australia APA in our consolidated balance sheet, which will be recognized in product revenue as doses are delivered to Australia.

We have an APA with the Pharmaceutical Management Agency ("Pharmac"), a New Zealand Crown entity, for the purchase of doses of COVID-19 Vaccine (the "New Zealand APA"). 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 an APA with the Canadian government, for the purchase of doses of COVID-19 Vaccine (the "Canada APA"). The Canadian government may terminate the Canada APA, as amended, as we failed to receive regulatory approval for our COVID-19 Vaccine using bulk antigen produced at Biologics Manufacturing Centre Inc. ("BMC") on or before December 31, 2024. Therefore, we are in discussions with Canada regarding a potential amendment to the Canada APA to address possible alternatives, which may not be achievable on acceptable terms or at all. As of December 31, 2024, \$555.7 million was classified as current Deferred revenue with respect to the Canada APA in our consolidated balance sheet. If the Canadian government terminates the Canada APA, \$28.0 million of 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 November 2024, we and The Secretary of State for Business, Energy and Industrial Strategy (as assigned to the UK Health Security Agency), acting on behalf of the government of the United Kingdom of Great Britain and Northern Ireland (the "Authority") entered into a Termination and Settlement Agreement (the "Settlement Agreement") and a Letter of Amendment to the Settlement Agreement (the "Settlement Agreement Amendment"), relating to the Amended and Restated SARS-CoV-2 Vaccine Supply Agreement (the "Amended and Restated UK Supply Agreement") and the SARS-CoV-2 Vaccine Supply Agreement, dated October 22, 2020 (the "Original UK Supply Agreement") by and between us and the Authority. The Settlement Agreement resolved the disputes regarding the Amended and Restated Supply Agreement and released both parties of all claims arising out of or connected with the Amended and Restated Supply Agreement.

Under the terms of the Settlement Agreement and Settlement Agreement Amendment, we and the Authority agreed to terminate the Amended and Restated Supply Agreement and to fully settle the outstanding amount under dispute related to upfront payments of \$112.5 million previously received by us from the Authority under the Amended and Restated Supply Agreement. Pursuant to the Settlement Agreement, we agreed to pay a refund of \$123.8 million (the "Settlement Payment") to the Authority in equal quarterly installments of \$10.3 million over a three year period, ending in June 2027. The Settlement Payment amount includes an \$11.3 million provision for interest over the period and may be avoided if we choose to accelerate payments. As of December 31, 2024, the remaining upfront payment previously received from the authority is classified as \$36.4 million of other current liabilities and \$58.8 million of Other non-current liabilities on our consolidated balance sheet.

We entered into an APA with Gavi in May 2021 (the "Gavi APA"), pursuant to which we received upfront payments of \$700 million from Gavi (the "Advance Payment Amount") to be applied against purchases of our prototype COVID-19 vaccine by certain countries participating in the COVAX Facility. As of December 31, 2023, the remaining Gavi Advance Payment Amount was \$696.4 million. In February 2024, we and Gavi entered into a Termination and Settlement Agreement (the "Gavi Settlement Agreement") terminating the Gavi APA, settling the arbitration proceedings, and releasing both parties of all claims arising from, under, or otherwise in connection with the Gavi APA. Pursuant to the Gavi Settlement Agreement, we are responsible for payment to Gavi of (i) an initial settlement payment of \$75 million, which we paid in February 2024, and (ii) deferred payments, in equal annual amounts of \$80 million payable each calendar year through a deferred payment term ending December 31, 2028. The deferred payments are due in variable quarterly installments beginning in the second quarter of 2024 and total \$400 million during the deferred payment term. Such deferred payments may be reduced through Gavi's use of an annual vaccine credit equivalent to the unpaid balance of such deferred payments each year, which may be applied to qualifying sales of any of our vaccines funded by Gavi for supply to certain low-income and lower-middle income countries. We have the right to price the vaccines offered to such low-income and lower-middle income countries in our discretion, and, when utilized by Gavi, we will credit the actual price per vaccine paid against the applicable credit. We intend to price vaccines offered via the tender process, consistent with our shared goal with Gavi to provide equitable access to those countries. Also, pursuant to the Gavi Settlement Agreement, we granted Gavi an additional credit of up to \$225 million that may be applied against qualifying sales of any of our vaccines for supply to such low-income and lower-middle income countries that exceed the \$80 million deferred payment amount in any calendar year during the deferred payment term. In total, the Gavi settlement agreement is comprised of \$700 million of potential consideration,

consisting of the \$75 million initial settlement payment, deferred payments of up to \$400 million that may be reduced through annual vaccine credits, and the additional credit of up to \$225 million that may be applied for certain qualifying sales.

We recorded the \$3.6 million difference between the refund liability recorded as of December 31, 2023 of \$696.4 million and the \$700 million of total consideration under the arrangement as a revenue adjustment during the year ended December 31, 2024. As of December 31, 2024, the remaining amounts included on our consolidated balance sheet are classified as \$225.0 million in non-current Deferred revenue for the additional credit that may be applied against future qualifying sales, \$85.0 million in Other current liabilities, and \$275.0 million in Other non-current liabilities. In addition, we and Gavi entered into a security agreement pursuant to which we granted Gavi a security interest in accounts receivable from SII under the SII R21 Agreement (see Note 3 to our accompanying consolidated financial statements), which will continue for the deferred payment term of the Gavi Settlement Agreement. On February 22, 2024, the claims and counterclaims were dismissed with prejudice.



## Product Pipeline

We are advancing our pipeline of late- and early-stage programs with a focus on potentially high-value assets in areas with unmet medical need, compelling scientific rationale and strong commercial opportunity. Development and advancement of our in-house pipeline leverages our core expertise and our experience in respiratory and infectious diseases and vaccines, and we intend to explore new opportunities with the potential to expand beyond infectious diseases. Our partnered pipeline includes our COVID-19 vaccine and our Matrix-M™ adjuvant used in collaboration for development of new and existing vaccines.

## In-House R&D Pipeline Diversification

Therapeutic Area	Candidate	Preclinical	Phase 1	Phase 2	Phase 3	Authorized Use	Partner
<b>Novavax</b>							
Respiratory diseases <b>COVID-19</b>	<b>Novavax COVID-19 Vaccine<sup>1</sup></b>	Matrix-M					<b>sanofi</b>
Respiratory diseases <b>COVID-19 + seasonal influenza</b>	<b>COVID-influenza combination (CIC) vaccine</b>	Matrix-M					
Respiratory diseases <b>Seasonal influenza</b>	<b>Influenza vaccine (older adults)</b>	Matrix-M					
Respiratory diseases <b>Respiratory syncytial virus (RSV)</b>	<b>RSV combinations (RSV, hMPV, other respiratory)</b>	Matrix-M					
Respiratory diseases <b>H5N1 avian pandemic influenza</b>	<b>Highly pathogenic H5N1 avian pandemic influenza vaccine</b>	Matrix-M					
Viral infection <b>Varicella-zoster virus (shingles)</b>	<b>Shingles vaccine</b>	Matrix-M					
Bacterial disease <b>Clostridioides difficile (C. diff) colitis</b>	<b>C. diff vaccine</b>	Matrix-M					

1. Authorized in select geographies under trade names Novavax COVID-19 Vaccine, Adjuvanted; Covovax™; and Nuvaxovid™.

## Additional Value Generation through Partnerships

Therapeutic Area	Candidate	Preclinical	Phase 1	Phase 2	Phase 3	Authorized Use	Partner
<b>Developed by partners leveraging Novavax technology</b>							
Parasitic diseases <b>Malaria</b>	<b>R21/Matrix-M™ adjuvant<sup>1</sup></b>	Matrix-M					<b>SII</b>
Respiratory diseases <b>COVID-19 + seasonal influenza</b>	<b>RIV3 (FLUBLOK) - NCT06695130<sup>2</sup></b>	Matrix-M	Phase 1/2				<b>sanofi</b>
Respiratory diseases <b>COVID-19 + seasonal influenza</b>	<b>TIV-HD (FLUZONE High-Dose) NCT06695117<sup>2</sup></b>	Matrix-M	Phase 1/2				<b>sanofi</b>
Respiratory diseases <b>Vaccines using our Matrix-M™ adjuvant</b>	<b>Licensed rights to develop vaccines using our Matrix-M™ adjuvant</b>						<b>sanofi</b>
<b>Additional Vaccines</b>	<b>Licensed rights to develop additional combination vaccines using our COVID-19 vaccine</b>						<b>sanofi</b>

1. Commercialized by Serum Institute of India; Granted prequalification by the WHO and distributed by UNICEF to endemic countries in Africa.  
2. Granted Fast Track designation in the US.



## Pipeline Overview

Our pipeline encompasses vaccine candidates for infectious diseases. Our COVID-19 vaccine, partnered with Sanofi, is our most advanced product. We will continue to commercialize our updated COVID-19 vaccine through the end of 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. Our COVID-19 vaccine has received authorizations from the U.S. FDA, the European Commission ("EC"), the WHO and several other countries for both adult and adolescent populations. We advanced our COVID-19 vaccine to a post-authorization Phase 3 safety and immunogenicity trial. Beyond our COVID-19 vaccine, our late-stage pipeline includes a CIC vaccine candidate, and our stand-alone influenza vaccine candidate.

Additionally, we intend to develop our early-stage pipeline using a disciplined and capital-efficient approach. Our R&D investment strategy seeks to place smart, lower-cost investments on the programs with the highest potential value, both within infectious disease and beyond, with the intent of partnering these assets at proof of concept and shifting late-stage development costs to our partners to finalize clinical development. We are actively developing an H5N1 avian pandemic influenza vaccine candidate. We are conducting early-stage research in diseases such as, RSV combinations, varicella-zoster virus (shingles) and *Clostridium difficile* (C. Diff.) colitis. Lastly, we are evaluating potential expansion beyond infectious diseases, including therapeutic areas such as oncology, where we believe our technology has the potential to augment and improve upon current therapies.

In addition to our own pipeline, we have several partnership opportunities. For example, our Matrix-M™ adjuvant is being used for collaboration in R21/Matrix-M™ adjuvant malaria vaccine. We believe our partner-led R21/Matrix™ adjuvant malaria vaccine presents significant potential. Based on preliminary results from an ongoing Phase 3 trial in infants and toddlers in Africa, showing 72-79% efficacy, the R21/Matrix™ adjuvant malaria vaccine has been authorized in Ghana, Nigeria, and Burkina Faso, and in December 2023, was granted prequalification by the WHO.

Under our agreement, we have also provided a sole license to Sanofi for the independent development of a COVID-19 and influenza combination product using our COVID-19 vaccine in combination with two of Sanofi's separately marketed influenza vaccines, Fluzone High-Dose and Flublok to evaluate immunogenicity and safety in Phase 1/2 combination vaccine trials. These two combination vaccine candidates were granted Fast Track designation by the U.S. FDA in December 2024 to prevent influenza and COVID-19 infections in individuals aged 50 and older. Sanofi also has a non-exclusive license to develop and commercialize combination products containing both our COVID-19 vaccine and one or more non-influenza vaccines, and a non-exclusive license to develop and commercialize other vaccine products selected by Sanofi that include our Matrix-M™ adjuvant.

## Coronavirus Vaccine Clinical Development

We continue efforts to expand our COVID-19 vaccine label within the adolescent and pediatric indications. Additionally, we continue to evaluate vaccine safety, immunogenicity, and effectiveness through ongoing clinical trials and collaborative evidence-generating real-world studies.

### Phase 3 Strain-Change and Re-vaccination Studies

In October 2024, we initiated and fully enrolled Study 315 to evaluate safety and immunogenicity of a single dose of the JN.1 subvariant vaccine NVX-CoV2705 in previously vaccinated adults. Topline data is expected in the first quarter of 2025 and is expected to support regulatory submissions in the U.S. and other jurisdictions for this and future variant strain formulations.

In July 2024, we locked the database for 338 participants aged 18 and older in Part 2 of the Study 313, which will evaluate the immunogenicity of a single dose of the XBB.1.5 subvariant vaccine NVX-CoV2601 in previously unvaccinated individuals. Data from Study 313 are intended to support BLA supplements and similar regulatory submissions in other territories for future variant strain formulations.

### Phase 2b/3 Pediatric Hummingbird™ Study

In December 2024, we achieved the \$50 million milestone under our agreement with Sanofi, associated with the database lock for one of the three cohorts in this study.

In August 2023, we announced topline results from our Phase 2b/3 Hummingbird™ trial that met its primary endpoints in children aged 6 through 11 years demonstrating both tolerability and immunologic responses. This ongoing trial is evaluating the

safety, effectiveness (immunogenicity), and efficacy of two doses of our prototype COVID-19 vaccine (NVX-CoV2373), followed by a booster 6 months after the primary vaccination series. The trial completed enrollment in September 2023 and includes three age de-escalation cohorts of 1,200 children each. In previous consultations with the U.S. FDA, the filing strategy included filing a supplemental BLA for children in these age cohorts once the initial BLA is approved. We are in discussion with the U.S. FDA regarding additional immunogenicity studies that will be needed to support a supplemental BLA to expand the pediatric indication in light of the progressive increase in the number of children with baseline COVID-19 natural immunity during the Phase 2b/3 Hummingbird™ trial enrollment period, which began in August 2022.

## **COVID-Influenza Combination and Stand-alone Influenza Program**

### **Phase 3 Clinical Trial of CIC and Stand-alone Influenza Vaccine Candidates**

In December 2024, we initiated a Phase 3 trial for our CIC and stand-alone influenza vaccine candidates to evaluate the immunogenicity and safety compared to our updated COVID-19 vaccine and a licensed seasonal influenza vaccine comparator in adults aged 65 and older. Our Phase 3 trial has been initiated with an initial cohort of approximately 2,000 participants. We are working with the U.S. FDA to assess the potential feasibility of the accelerated approval pathway for our CIC vaccine candidate. We are not seeking an accelerated approval for our stand-alone influenza vaccine candidate. We do not intend to launch these vaccine candidates without a partner and we therefore will not be making any additional investments in this program until a partner is in place. In October 2024, the U.S. FDA placed a clinical hold on the IND 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 on this event, the event term was updated from motor neuropathy to amyotrophic lateral sclerosis, a condition that is not known to be immune-mediated or associated with vaccination, which in 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 lifted the clinical hold on the IND in November 2024.

The Phase 3 trial builds on Phase 2 data that was previously shared in May 2023, where the vaccine candidates showed preliminary robust immune responses, reassuring safety profiles, and reactogenicity that was comparable to the licensed influenza vaccine comparator arms. The Phase 2 dose-confirming randomized, observer-blinded trial evaluated the safety and effectiveness (immunogenicity) of different formulations of the CIC and influenza vaccine candidates, and higher doses of Novavax's COVID-19 vaccine in 1,575 adults aged 50 through 80 years. The CIC vaccine candidate achieved both anti-SARS-CoV-2 immunoglobulin G (IgG) and neutralizing levels comparable to our prototype COVID-19 vaccine. In addition, several of the combination formulations achieved responses to both SARS-CoV-2 and to the four homologous influenza strains that were comparable to the reference comparators, supporting their prioritization for advanced development.

We continue to invest in development of our pipeline that uses our recombinant nanoparticle technology platform and Matrix-M™ adjuvant. We continue to believe these assets are key value drivers and intend to partner these assets towards a BLA filing.

## **Malaria**

Malaria is a life-threatening disease caused by a parasite that infects mosquitos and is subsequently transmitted to humans. According to the 2024 WHO World Malaria Report, in 2023, there were an estimated 263 million malaria cases and 597,000 malaria-related deaths worldwide. We believe malaria has the potential to be preventable through our partner-led R21/Matrix-M™ adjuvant malaria vaccine, which in 2024 the first doses were distributed and administered across the African region after in 2023 having received authorization in several countries and prequalification by the WHO.

### **R21/Matrix-M™ Adjuvant Malaria Vaccine**

R21/Matrix-M™ adjuvant malaria vaccine, formulated with our Matrix-M™ adjuvant is developed by our partner, the Jenner Institute, University of Oxford, and manufactured by SII. We have an agreement with SII related to its manufacture of R21/Matrix-M™ adjuvant malaria vaccine under which SII purchases our Matrix-M™ adjuvant for use in development activities at cost and for commercial purposes at a tiered commercial supply price, and pays a royalty in the single- to low-double digit range based on vaccine sales for a period of 15 years after the first commercial sale of the vaccine in each country.

In July 2024, first commercial doses of R21/Matrix-M™ adjuvant malaria vaccine have been administered to children in Cote d'Ivoire and South Sudan. As part of the WHO malaria program, at their discretion, the vaccine is expected to be included in countries such as Central African Republic, Chad, Democratic Republic of Congo, Mozambique, Nigeria and Uganda.

### **Phase 3 Clinical Trial of R21/Matrix-M™ Adjuvant Malaria Vaccine**

R21/Matrix-M™ adjuvant malaria vaccine is being evaluated in an ongoing Phase 3 trial conducted by our partner, the Jenner Institute, University of Oxford. In February 2024, peer-reviewed results from the Phase 3 efficacy trial were published in *The Lancet* reporting R21/Matrix-M™ adjuvant malaria vaccine has a well-tolerated safety profile and offers high-level efficacy against clinical malaria in African children at sites of both seasonal and perennial transmission. This Phase 3 trial enrolled 4,800 children aged 5 to 36 months across five sites in four African countries with differing malaria transmission intensities and seasonality. The trial demonstrated efficacy of 75% when administered prior to the high transmission season during the 12 months following a three-dose series and efficacy of 68% when administered in an age-based schedule in regions where malaria is present perennially during the 12 months following the first three doses. This R21/Matrix-M™ adjuvant malaria vaccine is a low-cost vaccine and has the potential to make a substantial contribution to reducing the burden of malaria disease and deaths in sub-Saharan Africa.

### **R21/Matrix-M™ Adjuvant Malaria Vaccine Regulatory and Licensure**

In December 2023, the WHO announced it prequalified the R21/Matrix-M™ adjuvant malaria vaccine to prevent malaria disease in children caused by the *P. falciparum* parasite in endemic areas. Prequalification status enables United Nations agencies to procure the vaccine for eligible countries and enabled rollout of the vaccine in mid-2024. The WHO recommended that the R21/Matrix-M™ adjuvant malaria vaccine be administered in a four-dose schedule beginning at five months of age.

### **License and Collaboration**

A summary of our license and collaboration agreements follows:

#### **Serum**

We previously granted SII exclusive and non-exclusive licenses for the development, co-formulation, filling and finishing, registration, and commercialization of our COVID-19 vaccine and our CIC vaccine candidate. SII agreed to purchase our Matrix-M™ adjuvant and we granted SII a non-exclusive license to manufacture the antigen drug substance component of our COVID-19 Vaccine in SII's licensed territory solely for use in the manufacture of COVID-19 Vaccine. We and SII equally split the revenue from SII's sale of COVID-19 Vaccine in its licensed territory, net of agreed costs. In May 2024, we and Serum Life Sciences Limited, a subsidiary of SII ("SLS"), entered into a supply agreement (the "SLS Supply Agreement") under which SLS agreed to supply us with antigen drug substance and finished COVID-19 Vaccine doses. The SLS Supply Agreement includes the general terms and conditions of supply orders between us and SLS. We and SLS execute firm purchase orders, which include specific quantities to be delivered under the SLS Supply Agreement. We agreed to supply SLS with all Matrix-M™ adjuvant needed to manufacture finished COVID-19 Vaccine doses. In March 2020, we entered into an agreement with SLS that granted SII a non-exclusive license for the use of Matrix-M™ adjuvant supplied by us to develop, manufacture, and commercialize R21/Matrix-M™ adjuvant malaria vaccine (the "SII R21 Agreement"). In December 2023, R21/Matrix-M™ adjuvant malaria vaccine received prequalification by the WHO. Under the SII R21 Agreement, SII purchases our Matrix-M™ adjuvant for use in development activities at cost and for commercial purposes at a tiered commercial supply price, and pays a royalty in the single-to low- double-digit range based on vaccine sales for a period of 15 years after the first commercial sale of the vaccine in each country.

#### **Takeda**

We have a collaboration and license agreement with Takeda Pharmaceutical Company Limited ("Takeda") under which we granted Takeda an exclusive license to develop, manufacture, and commercialize our COVID-19 Vaccine in Japan. Under the agreement, Takeda purchases Matrix-M™ adjuvant from us to manufacture doses of COVID-19 Vaccine, and we are entitled to receive milestone and sales-based royalty payments from Takeda based on the achievement of certain development and commercial milestones, as well as a portion of net profits from the sale of COVID-19 Vaccine.

#### **Sanofi**

In May 2024, we entered into the Sanofi CLA under which we granted and Sanofi received the following:

- i. A co-exclusive license to commercialize our current stand-alone COVID-19 Vaccine, including our prototype COVID-19 vaccine and updated COVID-19 vaccines, that address seasonal variants throughout the world (the "COVID-19 Vaccine Products");
- ii. A sole license to develop and commercialize combination products containing a potential combination of our COVID-19 Vaccine and Sanofi's seasonal influenza vaccine ("COVID-19 and influenza Combination Products" or "CIC Products");

- iii. A non-exclusive license to develop and commercialize combination products containing both our COVID-19 Vaccine and one or more non-influenza vaccines ("Other Combination Products" and together with the COVID-19 Vaccine Products, CIC Products, and Other Combination Products, "Licensed COVID-19 Products"); and
- iv. A non-exclusive license to develop and commercialize other vaccine products selected by Sanofi that include our Matrix-M™ adjuvant (as described below, the "Adjuvant Products").

We are also responsible for performing services related to the technology transfer of our manufacturing process for the COVID-19 Vaccine Products and Matrix-M™ components to Sanofi. Until the successful completion of such transfer, we will supply Sanofi with both COVID-19 Vaccine Products and Matrix-M™ intermediary components for Sanofi's use and we are eligible for reimbursement of such costs from Sanofi. In addition, we are responsible for certain research and development and medical affairs services related to the COVID-19 Vaccine.

Under the Sanofi CLA, we will continue to commercialize our updated COVID-19 vaccine through the end of the 2024-2025 vaccination season. Beginning in 2025 and continuing during the term of the Sanofi CLA, Sanofi and we will commercialize the COVID-19 Vaccine Products worldwide in accordance with a commercialization plan agreed by us and Sanofi, under which we will continue to supply our existing APA customers and strategic partners, including Takeda and SII. Upon completion of the existing APAs, we and Sanofi will jointly agree on commercialization activities of each party in each jurisdiction.

Pursuant to the Sanofi CLA, we received a non-refundable upfront payment of \$500 million in the second quarter of 2024. In addition, we are eligible to receive development, technology transfer, launch, and sales milestone payments totaling up to \$700 million in the aggregate with respect to the COVID-19 Vaccine Products and royalty payments on Sanofi's sales of such licensed products. Milestone payments are comprised of 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, \$50 million upon database lock of an existing Phase 2/3 clinical trial (identifier 2019nCoV-503), \$75 million upon the completion of the technology transfer of our manufacturing process for the COVID-19 Vaccine Products to Sanofi, \$125 million upon achievement of certain CIC Product-related development milestones, and \$225 million in CIC Product-related launch milestones. We achieved the \$50 million milestone for database lock of an existing Phase 2/3 clinical trial in 2024 and the amount is included in accounts receivable on our consolidated balance sheet.

We are also eligible to receive development, launch, and sales milestone payments of up to \$200 million for each of the first four Adjuvant Products and \$210 million for each Adjuvant Product thereafter, and royalty payments on Sanofi's sales of all such licensed products. In addition, a portion of the technology transfer costs and research and development costs incurred by us will be reimbursed by Sanofi in accordance with agreed upon plans and budgets.

## **Manufacturing and Supply**

We are committed to discovering, developing, and commercializing innovative vaccines to prevent serious infectious diseases directly and by leveraging our strategic global partnerships. In 2024, we modified and continued to assess our manufacturing needs and our global manufacturing footprint consistent with our contractual obligations to supply, and anticipated demand for COVID-19 Vaccine and Matrix-M™ adjuvant, and expected supply needs of Sanofi for both COVID-19 Vaccine Products and Matrix-M™ intermediary components for use under the Sanofi CLA.

A summary of our key manufacturing and supply arrangements follows:

### **Matrix-M™ Adjuvant**

We manufacture our proprietary saponin-based Matrix-M™ adjuvant at our Novavax AB facility in Uppsala, Sweden. We also have contract manufacturing arrangements with AGC Biologics and the Polypeptide Group to provide contract development and manufacturing services, supplying us with large-scale production of Matrix-M™ adjuvant.

### **Antigen Component of COVID-19 Vaccine**

We have a supply agreement with SII and SLS for the manufacture of the antigen component of COVID-19 Vaccine and the co-formulation, fill, and finishing of the finished vaccine product. In May 2024, we entered into the SLS Supply Agreement under which SLS agreed to supply us with antigen drug substance and finished COVID-19 Vaccine doses. The SLS Supply Agreement includes the general terms and conditions of supply orders between us and SLS. We and SLS execute firm purchase orders, which

include specific quantities to be delivered under the SLS Supply Agreement. We agreed to supply SLS with all Matrix-M™ adjuvant needed to manufacture finished COVID-19 Vaccine doses. Currently, we depend primarily on this supply agreement for co-formulation, filling and finishing of COVID-19 Vaccine doses.

## Competition

The vaccine market is intensely competitive, characterized by rapid technological progress. Our technology is based upon utilizing the baculovirus expression system in insect cells to make recombinant vaccines. Our Matrix-M™ adjuvant has demonstrated a potent and well-tolerated effect by stimulating the entry of antigen presenting cells into the injection site and enhancing antigen presentation in local lymph nodes, boosting immune response. We believe this baculovirus expression system with our nanoparticle configuration formulated with our Matrix-M™ adjuvant offers many advantages compared to other technologies, such as enabling dose-sparing effects and refrigerator temperature storage. We believe our technology platform is well suited for developing COVID-19 and combination vaccines, as well as vaccines against a number of other infectious diseases and potentially beyond the infectious disease area into other therapeutic areas where we believe our technology has the capability to augment and improve on current approaches. We face competition in the development of our COVID-19 Vaccine, seasonal influenza vaccine candidate, CIC vaccine candidate and the other vaccine candidates in our pipeline, including our early-stage vaccine candidates.

A number of vaccine manufacturers, research institutions, and other organizations have developed a vaccine for SARS-CoV-2, the virus that causes COVID-19. A variety of different vaccine technologies are being studied, including nucleic acid (RNA/DNA), viral vectors, live attenuated or inactivated, and protein-based vaccines. Novavax is the first protein-based COVID-19 vaccine that received EUA by the U.S. FDA and a CMA by the European Commission based on EMA in the European Union. As of February 2025, Novavax is one of three manufacturers that have a COVID-19 vaccine that has received authorization by the U.S. FDA for the 2024-2025 vaccination season, with the other manufacturers being Pfizer and Moderna. As of February 2025, the U.S. FDA has granted Pfizer and Moderna BLA approval for their updated vaccines in individuals 12 years and older and EUA for their updated vaccines in individuals 6 months to 11 years, while Novavax received EUA by the U.S. FDA for our updated COVID-19 vaccine in individuals 12 years and older. Based on our COVID-19 vaccine and its high efficacy against both the original and variant strains and its well-tolerated profile demonstrated in clinical trials, including two pivotal Phase 3 trials in the UK and U.S., we believe our COVID-19 vaccine will continue to play an important role in addressing this global public health need.

Furthermore, a number of companies are selling vaccines for seasonal influenza employing a number of vaccine technologies including inactivated, recombinant and live attenuated technologies. Starting in the 2024-2025 season, all flu vaccines in the U.S. were trivalent vaccines designed to protect against three different influenza viruses, including two influenza A viruses and an influenza B / Victoria virus. Many seasonal influenza vaccines are currently approved and marketed, and most of these are marketed by major pharmaceutical companies such as Sanofi, GSK, and Seqirus. Competition in the sale of seasonal influenza vaccines is intense. For the older adult segment in the U.S., the CDC preferentially recommends Fluzone-HD®, an egg-based high-dose flu vaccine, Flublok®, a recombinant flu vaccine manufactured by Sanofi and Fluad®, an egg-based adjuvanted flu vaccine manufactured by Seqirus. 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 or be less expensive and quicker to manufacture, all while still showing a comparable or improved tolerability profile. Many of our competitors are working on new products and new generations of current products, some by adding an adjuvant that is used to increase the immunogenicity of that product, each of which is intended to be more efficacious than currently marketed products. Several competitors are working on developing seasonal influenza vaccines using different technologies than those in existing marketed vaccines, the most notable being mRNA from companies including Sanofi, Moderna, and Pfizer. Despite the significant competition and advancing technologies, based on our completed Phase 2 trial results, we believe that our stand-alone influenza vaccine, our adjuvanted nanoparticle seasonal influenza product, has the potential to be at least as efficacious as current products or products being developed by our competitors. In December 2024, we initiated our Phase 3 trial for our stand-alone influenza vaccine candidate to evaluate the immunogenicity and safety in adults aged 65 and older with an initial cohort of 2,000 participants.

Additionally, we believe that our platform is well suited for combination vaccines, for example influenza and COVID-19. In December 2024, we initiated our Phase 3 trial for our CIC vaccine candidate to evaluate the immunogenicity and safety in adults aged 65 and older with an initial cohort of 2,000 participants. We are working with the U.S. FDA to determine the potential of our current CIC trial to support accelerated approval. Additionally, under the Sanofi CLA, our COVID-19 vaccine is being used in combination with two Sanofi vaccines that are separately marketed influenza vaccines, Fluzone High-Dose and Flublok, to evaluate immunogenicity and safety in Phase 1/2 combination trials. These two combination vaccine candidates were granted Fast Track designation by the U.S. FDA to prevent influenza and COVID-19 infections in individuals aged 50 and older. Other manufacturers



who are actively developing a COVID-19-influenza combination vaccine candidate in Phase 3 trials and are working with the U.S. FDA for regulatory approval and commercialization, include Moderna and Pfizer.

In general, competition among pharmaceutical products is based in part on product efficacy, safety, reliability, availability, price, and patent position. An important factor is the relative timing of the market introduction of our products and our competitors' products. Accordingly, the speed with which we can develop products, complete the clinical trials and approval processes, and supply commercial quantities of the products to the market is an important competitive factor. Our competitive position also may depend upon our ability to show differentiation with a product that is more efficacious and/or less expensive and quicker to manufacture. Other factors affecting our competitive position include our ability to attract and retain qualified personnel, obtain patent protection or otherwise develop proprietary products or processes, and secure sufficient capital resources for the lengthy period between technological conception and commercial sale.

## **Patents and Proprietary Rights**

We generally seek patent protection in the US and in select international countries to protect inventions that we or our partners consider important for our business interests. Patent protection in biotechnology and pharmaceuticals is uncertain and involved complex legal and factual questions. Our success will depend, in part, on whether we can:

- obtain patents to protect our own technologies and product candidates;
- obtain licenses to use the technologies of third-parties, which may be protected by patents; and
- protect our trade secrets and know-how.

### **Patent Rights; Licenses**

We have intellectual property (patents, licenses, know-how) related to our vaccines, manufacturing processes, and other technologies. Currently, we have or have rights to over 680 U.S. and foreign patents and patent applications relating to vaccines and vaccine-related technologies, including:

- RSV: We have more than 150 combined patents and pending applications in the US and internationally relating to respiratory syncytial virus (RSV) glycoproteins, compositions, and methods of treatment. These patents will expire from 2029 to beyond 2041.
- Clostridium Difficile: We have more than 15 combined patents and pending applications in the US and internationally relating to methods and compositions for treating or preventing C. Difficile infection. These patents will expire from 2038 to beyond 2039.
- Influenza: We currently have 2 U.S. patents and pending US and international applications related to multivalent influenza compositions. These patents are anticipated to expire in 2039 and beyond
- COVID/Influenza: We have more than 40 combined patents and pending applications in the US and internationally related to compositions and methods for inducing immune responses against both influenza and coronaviruses that will expire beyond 2042 when issued.
- COVID-19: We currently have more than 50 combined patents and pending applications directed to our COVID vaccine technology that are anticipated to expire beyond 2040.

In addition to protecting our vaccine programs, we are pursuing protection for our Matrix-M® Adjuvant program, with expiration dates extending to 2044 and beyond.

We continue to prepare, file, and prosecute patent applications to provide broad and strong protection of our proprietary rights related to our vaccine products and our adjuvant program.

The Federal Technology Transfer Act of 1986 and related statutory guidance encourages the dissemination of science and technology innovation. While our expired contract with the U.S. Department of Health and Human Services ("DHHS"), Biomedical Advanced Research and Development Authority provided us with the right to retain ownership in our inventions that may have arisen during performance of that contract, with respect to certain other collaborative research efforts with the U.S. government, certain developments and results that may have commercial potential are to be freely published, not treated as confidential, and we may be required to negotiate a license to developments and results in order to commercialize products. There can be no assurance that we will be able to successfully obtain any such license at a reasonable cost, or that such development and results will not be made available to our competitors on an exclusive or non-exclusive basis.

## **Trade Secrets**

We also rely significantly on trade secret protection and confidentiality agreements to protect our interests. It is our policy to require employees, consultants, contractors, manufacturers, collaborators, and other advisors to execute confidentiality agreements upon the commencement of employment, consulting, or collaborative relationships with us. We also require confidentiality agreements from any entity that is to receive confidential information from us. With respect to employees, consultants, and contractors, the agreements generally provide that all inventions made by the individual while rendering services to us shall be assigned to us as our property.

## **Human Capital**

### **Employees**

As of February 18, 2025, we have 952 full-time employees, of whom approximately 8% hold MD or PhD degrees, and approximately 20% hold other advanced degrees. Of our total workforce, approximately 71% of employees are engaged primarily in research, development, and manufacturing activities, and approximately 29% of employees are mainly engaged in executive, business development, commercial, finance and accounting, legal, and administrative functions. Except for certain employees located in Europe, who are covered by collective agreements with trade unions pursuant to local law, none of our employees are represented by a labor union or works council, and none of our employees have entered into a collective bargaining agreement with us.

### **Compensation and Benefits; Health and Wellness**

Our total rewards package is designed to attract, engage, motivate, and retain top talent. We strive to provide compensation, benefits and services that help meet the varying needs of our employees. Our total rewards package for employees in the U.S. includes competitive market pay and comprehensive benefits, including insurance to protect and maintain health; income protection through our short- and long-term disability programs and life insurance; adoption assistance and paid parental leave programs; and services to assist in balancing work and personal life, such as backup child, adult and elder care, and financial well-being programs, including monthly financial wellness seminars, one-on-one financial planning sessions, and debt and credit management support.

Our wellness initiatives include a monthly newsletter, which highlights organizations and partners, tools, and resources intended to enrich and improve our employees' physical and mental well-being. We offer several digital apps that allow our employees to connect to an online licensed therapist or to access activities that are designed to reduce stress and anxiety and increase mindfulness and emotional well-being. We have a robust employee assistance program that allows employees to access support for a variety of life events.

In addition, we offer the majority of employees the benefit of equity ownership in the Company through equity grants or participation in our employee stock purchase plan. We believe that equity compensation has been, and will continue to be, a critical component of our compensation package because it develops a culture of ownership among our employees and aligns their interests with the interests of our stockholders.

### **Recruitment, Development, and Training**

The attraction, development, and retention of employees is a critical factor for our success. We utilize a variety of recruitment vehicles to source top talent, including strategic partnerships with search firms, leveraging social media channels, and a robust employee referral program. In 2023, we launched the Leading@Novavax competency model to define great leadership. At Novavax, everyone is a leader, and this model and associated tools, resources, and programs are designed to develop leadership skills at all levels of the organization.

To support the growth and advancement of our employees, we offer tuition and continuing education reimbursement and an array of training and professional development opportunities, including on-the-spot coaching with executive coaches and access to the LinkedIn Learning library of over 16,000 on-demand video tutorials that address skills, knowledge and behaviors related to business, leadership, technology, and innovation. In the last 12 months, our employees have viewed and completed videos over 40,000 times. In addition, approximately 35 employees have participated in spot coaching. Professional development learning series are available to all employees and focus on self-awareness, collaboration, hybrid working, leadership and business acumen.



We provide an Executive Development Program for employees identified as having high potential and for employees who have been identified as potential successors to leadership positions through our talent review and succession planning process. Our Executive Development Program includes executive coaching engagements and leadership development programs designed to strengthen our leadership bench and accelerate and prepare our top talent for future growth. The Executive Development Program includes a diverse and global group of 20 employees annually. Professional development learning series are available to all employees and focus on self-awareness, collaboration, hybrid working, leadership, and business acumen.

### **Internal Communications**

We employ a variety of channels to facilitate open and direct communication, including global forums with executives and employee surveys. In 2024, we began small group meetings for employees to engage directly with members of the executive leadership team. Our executive leadership team recognizes the importance of increased employee engagement to the success of each individual's career and to our success as a whole.

### **Inclusion**

Our culture of inclusivity helps us to create, develop and leverage the strengths of our workforce to meet our growth objectives. We acknowledge the merits of a diverse workforce and teach our leaders to access different perspectives when generating ideas and decision making. In 2024, we also made progress in increasing representation of women at the Executive level. We commenced and completed the reviews of three people processes: Talent Acquisition, Promotion, and Performance Management. We also have intentionally incorporated inclusivity principles into our Novavax Leadership Model.

### **Empowering our Employees**

In 2024, Novavax sought to motivate and empower employees by providing tuition and education reimbursement and access to professional coaching and Executive Development programming for high-potential employees.

### **Sustainability**

In addition to the human capital initiatives described above, a range of other initiatives related to sustainability are underway. These include efforts related to vaccine access and affordability, governing responsibly and sustainability. We believe that our multi-stakeholder approach through these focus areas is critical to our long-term success and enhances value for our shareholders. Examples of initiatives supportive of these focus areas include the following:

#### **Access and Affordability**

- Focused on seeking to foster an environment with no barriers to use of our vaccines due to either physical availability or pricing of the product.
- In 2024 in the U.S., participated in the Vaccines for Children (VFC) Program, which serves as a critical safety net for children under 19 who are Medicaid-eligible, uninsured, underinsured or American Indian/Alaskan Native.
- Also participated in the 317 Program, which serves uninsured and underinsured adults.
- Participated in the "Bridge Access Program For COVID Vaccines and Treatments" to provide access to COVID-19 vaccine option for adults without other sources of coverage.
- R21/Matrix-M™ adjuvant malaria vaccine, developed by the University of Oxford and its Jenner Institute and the Serum Institute of India, and formulated with our Matrix-M adjuvant is expected to be offered in 15+ countries across Africa by 2025.
- Efforts focused on clinical trial diversity (economic, race, age).

#### **Governing Responsibly**

- Policy remains in place to comply with all government and regulatory agency requirements and industry standards with good laboratory practices ("GLP"), current good manufacturing practices ("cGMP") and good distribution practices ("GDP").
- Practice responsible animal welfare practices including searching for non-animal alternatives whenever possible, abiding by the 3R-principle (Reduce, Refine, Replace), working with accredited animal facilities with regional independent animal experimentation ethical review boards approving all experiments.
- "The NovaCode," a robust handbook of written standards and business ethics policies remains in place.
- Maintain a global hotline for reporting compliance concerns with established internal investigating protocols.
- Maintain a Strategic Compliance Governance Committee to help our partners comply with U.S. regulations.

- Hold company-wide business ethics training, guidance, and raw materials review.
- Keep an anti-bribery and anti-corruption policy in place to ensure a transparent and ethical business model.
- Standard operating procedures guide decision-making.
- Abide by robust cybersecurity standards, meeting elevated government contracting requirements.
- Chief Safety Officer continues to build out a robust epidemiology benefit / risk group to better understand the safety profiles of different vaccines.
- Ongoing employee training on our updated Safety Policy.
- Sustainability
- Resource management and greenhouse gas reduction strategy, which includes tracking emissions.
- An approach to Procurement that incorporates sustainability metrics into vendor evaluation and selection rubrics.
- Conserving water and monitoring energy use across multi-use leased and owned facilities.
- Sustainable saponin sourcing from our partner Desert King, the key supplier of the Quillaja saponaria (Soapbark), a tree native to central Chile. Saponin is used to produce the Matrix-M™ adjuvant.

## Government Regulations

The development, production, and marketing of biological products, which include the vaccine candidates being developed by Novavax or our collaborators, are subject to regulation for safety, efficacy, and quality by numerous governmental authorities in the U.S. and other countries. We focus on the U.S. regulatory process and the standards imposed by the U.S. FDA, the International Council for Harmonisation ("ICH"), and other agencies because we believe meeting U.S. and ICH standards generally allows us to also satisfy regulatory agencies' standards in other countries where we intend to do business. However, we are mindful that expectations in some venues, notably in the European Union and the United Kingdom (in relation to Great Britain), differ to some degree and we take proactive steps to address such differences by maintaining regular filings and correspondence and attending regular meetings with many other non-U.S. regulatory agencies. In the U.S., the development, manufacturing, and marketing of human pharmaceuticals and vaccines are subject to extensive regulation under the Federal Food, Drug, and Cosmetic Act, and biological products are subject to regulation under provisions of that act and the Public Health Service Act. The U.S. FDA not only assesses the safety and efficacy of these products, but it also regulates, among other things, the testing, manufacture, labeling, storage, record-keeping, advertising, and promotion of such products. The process of obtaining U.S. FDA licensure for a new vaccine is costly and time-consuming.

Vaccine clinical development in most countries follows the same general regulatory pathway as drugs and other biologics. Before applying for U.S. FDA licensure to market any new vaccine candidate, we expect to first submit an IND that explains to the U.S. FDA, among other things, the results of preclinical toxicology testing conducted in laboratory animals, the method of manufacture, quality control tests for release, the stability of the investigational product, and our proposed plans for human testing. At this stage, the U.S. FDA decides whether it is reasonably safe to move forward with testing the vaccine candidate in humans. We must then conduct Phase 1 clinical trials and larger-scale Phase 2 and 3 clinical trials that demonstrate the safety, immunogenicity, and efficacy of our vaccine candidate to the satisfaction of the U.S. FDA. The U.S. FDA may, before a clinical trial is initiated or at any time while a clinical trial is ongoing, impose a partial or complete clinical hold based on concerns for patient safety or noncompliance with regulatory requirements. Following successful completion of all three phases of clinical development, a BLA can be submitted to the U.S. FDA requesting licensure of the vaccine for marketing based on the vaccine's safety and efficacy. Similar pathways exist in Europe and other geographies.

The U.S. FDA will only approve a BLA if the vaccine is demonstrated to be safe, pure, and potent. During the U.S. FDA's review of a BLA, the proposed manufacturing facility undergoes a pre-approval inspection during which the U.S. FDA examines in detail the production of the vaccine, the manufacturing facility, and the quality documentation related to the vaccine. Vaccine licensure also requires the provision of adequate product labeling to allow health care providers to understand the vaccine's proper use, including its potential benefits and risks, to communicate with patients and parents, and to safely deliver the vaccine to the public. Until a vaccine is given to the general population, all potential adverse events cannot be anticipated. Thus, the U.S. FDA typically requires Phase 4 post-marketing clinical trials for vaccines after licensure to continue gathering safety, and sometimes effectiveness/efficacy data in the indicated and additional populations.

The Commissioner of the U.S. FDA may, following the issuance of an appropriate declaration by the Secretary of the DHHS, issue an EUA that would permit the use of an unapproved medical product or unapproved use of an approved medical product to diagnose, treat, or prevent serious or life-threatening diseases or conditions when there are no adequate, approved, and available alternatives. When issuing an EUA, the U.S. FDA imposes conditions of authorization, with which the EUA holder must comply. Such conditions include, but may not be limited to, compliance with labeling, distribution of materials designed to ensure proper use, reporting obligations, and restrictions on advertising and promotion. The EUA is only effective for the duration of the declaration

issued by the Secretary of the DHHS that EUAs are appropriate. The U.S. FDA may also revise or revoke the EUA sooner if the criteria for issuance are no longer met or other circumstances make a revision or revocation appropriate to protect the public health or safety. For example, an EUA may be revoked when the U.S. FDA determines that the underlying public health threat no longer exists or warrants such authorization, or for reasons such as significant adverse inspectional findings, reports of adverse events linked to or suspected of being caused by the EUA product, or newly emerging data that may demonstrate the product may not be effective. An EUA is separate from and not dependent on the issuance of a public health emergency ("PHE") by the Secretary of the DHHS. Therefore, although the COVID-19 PHE expired on May 11, 2023, that expiration will not terminate EUAs issued by the U.S. FDA.

In order to ensure continuing safety, the U.S. FDA and most other non-U.S. based regulatory agencies continue to oversee the production of vaccines even after the vaccine and manufacturing processes are approved. For example, monitoring of the vaccine and of production activities, including periodic facility inspections, must continue as long as the manufacturer holds a license for the product. Manufacturers may also be required to submit the results of their own tests for potency, safety, and purity for each vaccine lot, if requested by the relevant regulatory agency. They may also be required to submit samples of each vaccine lot to the agency for testing.

In addition to obtaining U.S. FDA licensure for each product, each domestic manufacturing establishment must be registered with the U.S. FDA, is subject to U.S. FDA inspection, and must comply with current Good Manufacturing Practices ("GMP") regulations. To supply products for use either in the U.S. or outside the U.S., including clinical trials, U.S. and foreign manufacturing establishments, including third-party facilities, must comply with GMP regulations and are subject to periodic inspection by the U.S. FDA or by corresponding regulatory agencies in their home country.

The EU and the UK similarly provide a faster means to achieve approval by offering CMA to fulfil unmet medical needs. CMAs are granted with the proviso of obtaining additional comprehensive data to confirm the benefit/risk so that the MA will eventually become unconditional standard MA. For the purpose of granting a CMA, the benefit to public health of the immediate availability on the market of the medicinal product concerned should outweigh the risk inherent in the fact that additional data are still required.

The U.S. FDA has several programs designed to expedite the development and approval of drugs and biological products intended to treat serious or life-threatening diseases or conditions, including fast track designation, breakthrough therapy designation, priority review designation, and accelerated approval. First, the U.S. FDA may designate a product for Fast Track review if it is intended, whether alone or in combination with one or more other products, for the treatment of a serious or life-threatening disease or condition and demonstrates the potential to address unmet medical needs for such a disease or condition. For Fast Track products, sponsors may have more frequent interactions with the U.S. FDA and the U.S. FDA may initiate review of sections of a Fast Track product's application before the application is complete. The U.S. FDA granted Fast Track Designation for our prototype COVID-19 vaccine in November 2020 and for our recombinant quadrivalent seasonal influenza vaccine candidate, in January 2020.

Second, a product may be designated as a Breakthrough Therapy if it is intended, either alone or in combination with one or more other products, to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the product may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints. The U.S. FDA may hold meetings with the sponsor throughout the development process, provide timely advice to the product sponsor regarding development and approval, involve more senior staff in the review process, assign a cross-disciplinary project lead for the review team, and take other steps to design the clinical trials in an efficient manner.

Third, the U.S. FDA may designate a product for priority review if it is a product that treats a serious disease or life-threatening condition and, if approved, would provide a significant improvement in safety or effectiveness over available therapies. Significant improvement may be illustrated by evidence of increased effectiveness in the treatment of a condition, elimination or substantial reduction of a treatment-limiting product reaction, documented enhancement of patient compliance that may lead to improvement in serious outcomes, and evidence of safety and effectiveness in a new subpopulation. A priority designation is intended to direct overall attention and resources to the evaluation of such applications, and, for a drug product (including a vaccine), to shorten the U.S. FDA's goal for taking action on a marketing application from ten months to six months.

Fourth, a product may be eligible for accelerated approval, if it treats a serious or life-threatening condition and generally provides a meaningful advantage over available therapies. In addition, it must demonstrate an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality ("IMM") that is reasonably likely to predict an effect on IMM or other clinical benefit. As a condition of approval, the U.S. FDA may require that a sponsor of a drug or biologic receiving accelerated approval perform adequate and well-controlled post-

marketing clinical trials to confirm efficacy using a clinically meaningful endpoint, thereby confirming efficacy observed pre-approval using a surrogate endpoint.

In addition to regulatory approvals that must be obtained in the U.S., an investigational product is also subject to regulatory approval in other countries in which it is intended to be marketed. No such product can be marketed in a country until the regulatory authorities of that country have approved an appropriate marketing application. U.S.FDA licensure does not guarantee approval by other regulatory authorities. In addition, in many countries, the government is involved in the pricing of the product. In such cases, the pricing review period often begins after market approval is granted.

We are also subject to regulation under the Occupational Safety and Health Act, the Environmental Protection Act, the Toxic Substances Control Act, the Resource Conservation and Recovery Act, and other present and potential federal, state, or local regulations, including national and local regulations that govern our facilities in Sweden and Switzerland. These and other laws govern our use, handling, and disposal of various biological and chemical substances used in, and waste generated by, our operations. Our research and development involves the controlled use of hazardous materials, chemicals, and viruses. Although we believe that our safety procedures for handling and disposing of such materials comply with the standards prescribed by state and federal regulations, the risk of accidental contamination or injury from these materials cannot be completely eliminated. In the event of such an accident, we could be held liable for any damages that result and any such liability could exceed our resources. Additionally, for formulations containing controlled substances, we are subject to Drug Enforcement Act regulations.

In both domestic and foreign markets, sales of any products for which we receive regulatory approval for commercial sale will depend in part on the availability of reimbursement from third-party payers. Third-party payers include government authorities or programs, private health insurers (including managed care plans), and other organizations. These third-party payers are increasingly challenging the price and examining the cost-effectiveness of medical products and services. In addition, significant uncertainty exists as to the reimbursement status of newly approved healthcare products. We may need to conduct expensive pharmacoeconomic studies in order to demonstrate the cost-effectiveness of our products. There may be significant delays in obtaining coverage and reimbursement for newly approved drugs, and coverage may be more limited than the indications for which the product is approved by the U.S. FDA or similar regulatory authorities outside the United States. Our product candidates may not be considered cost-effective at certain prices. Adequate third-party reimbursement may not be available in certain markets to enable us to maintain price levels sufficient to realize an appropriate return on our investment in product development. Third-party payors may also control access to, or manage utilization of, our products with various utilization management techniques. Decreases in third-party reimbursement for our product candidates or a decision by a third-party payer to not cover our product candidates could reduce physician utilization of our products and have a material adverse effect on our sales, results of operations, and financial condition.

Within the U.S., if we obtain appropriate approval in the future to market any of our product candidates, those products could potentially be covered by various government health benefit programs, as well as purchased by government agencies. The participation in such programs or the sale of products to such agencies is subject to regulation. In exchange for coverage, we may be obligated to provide rebates or offer discounts under government health programs or to government and private purchasers.

The U.S. and state governments continue to propose and pass legislation designed to reform delivery of, or payment for, health care, including initiatives to reduce the cost of healthcare. In March 2010, the U.S. Congress enacted the Patient Protection and Affordable Care Act and the Health Care and Education Reconciliation Act ("ACA"), which includes changes to the coverage and reimbursement of drug products under government health care programs. Since its enactment, there have been several executive, judicial and Congressional challenges to certain aspects of the ACA, and additional challenges and amendments to the ACA may reduce the profitability of drug products. Adoption of price controls and cost-containment measures and adoption of more restrictive policies in jurisdictions with existing controls and measures could further limit our net revenue and results.

Other legislative changes have been proposed and adopted in the United States since the ACA was enacted that impact drug pricing. For example, through the process created by the Budget Control Act of 2011, there are automatic reductions of Medicare payments to providers of up to 2% per fiscal year, which went into effect in April 2013 and will remain in effect through 2030. Medicare establishes payment allowances annually for COVID-19 vaccines. The Medicare payment rate for COVID-19 vaccine products and their administration is 95% of the Average Wholesale Price in the physician office setting and at reasonable cost in hospital outpatient departments. Under the Inflation Reduction Act of 2022 ("IRA"), Medicaid and CHIP programs and the Children's Health Insurance Program ("CHIP") are required to cover, without cost-sharing, only U.S. FDA-approved COVID-19 vaccines recommended by the ACIP. At the state level, payment rates for covered vaccines and their administration are set by the states or their contracted managed care plans.

There has been considerable public and government scrutiny in the U.S. of pharmaceutical pricing and proposals to address the perceived high cost of pharmaceuticals. There have also been several recent state legislative efforts to address drug costs, which generally have focused on increasing transparency around drug costs or limiting drug prices or price increases. Adoption of new legislation at the federal or state level could affect demand for, or pricing of, our product candidates if approved for sale. It is also possible that additional governmental action will be taken in response to the COVID-19 pandemic. We cannot predict the ultimate content, timing, or effect of any federal and state reform efforts. There is no assurance that federal or state health care reform will not adversely affect our future business and financial results.

Similarly, in many countries outside the U.S., pharmaceutical pricing is subject to regulatory market access control, particularly in countries where healthcare is provided mainly through government funding or government backed insurers. In such countries governmental organizations will generally determine firstly if a medicinal product might be adopted for use in the national health systems and reimbursed and secondly the maximum price payable.

Within the U.S., we may be subject to various federal and state laws pertaining to health care “fraud and abuse,” including anti-kickback laws and false claims laws, for activities related to future sales of any of our product candidates that may in the future receive regulatory and marketing approval. Anti-kickback laws generally prohibit a pharmaceutical manufacturer from soliciting, offering, receiving, or paying any remuneration to generate business, including the purchase, prescription, or use of a particular drug. Although the specific provisions of these laws vary, their scope is generally broad and there may not be regulations, guidance, or court decisions that apply the laws to particular industry practices. There is therefore a possibility that our practices might be challenged under such anti-kickback laws. False claims laws, including the federal False Claims Act (“FCA”), prohibit anyone from knowingly and willingly presenting, or causing to be presented, any claims for payment for reimbursed drugs or services to third party payers (including Medicare and Medicaid) that are false or fraudulent. Our activities relating to the sale and marketing of our products may be subject to scrutiny under these laws. Violations of fraud and abuse laws may be punishable by criminal or civil sanctions, including fines and civil monetary penalties, and exclusion from federal health care programs (including Medicare and Medicaid). In the U.S., federal and state authorities are paying increased attention to enforcement of these laws within the pharmaceutical industry and private individuals have been active in alleging violations of the laws and bringing suits on behalf of the government under the FCA. If we were subject to allegations concerning, or were convicted of violating, these laws, our business could be harmed.

On November 20, 2020, the DHHS published a Final Rule entitled “Removal of Safe Harbor Protection for Rebates to Plans or PBMs Involving Prescription Pharmaceuticals and Creation of New Safe Harbor Protection,” commonly referred to as the “Rebate Rule,” which amends the federal Anti-Kickback Statute discount safe harbor by eliminating protection for price concessions, including rebates, that are offered by pharmaceutical manufacturers to plan sponsors, or pharmacy benefit managers under contract with them, under the Medicare Part D program and Medicare Advantage Plans, unless the price reduction is one required by law. The IRA will delay implementation of this Rebate Rule until 2032. This new rule could result in a change in incentives for health plans and pharmacy benefit managers in negotiating rebates and discounts with manufactures for preferred formulary placement. At this time, we cannot predict how these developments may impact our business and operations if our products are commercialized in the U.S.

Within the European Union and the United Kingdom, the provision of benefits or advantages to physicians or others to induce or encourage the prescription, recommendation, endorsement, purchase, supply, order, or use of medicinal products is prohibited. The improper provision of benefits or advantages to physicians or other individuals is also governed by the national anti-bribery laws of EU Member States and the United Kingdom, such as the UK Bribery Act 2010. Infringement of these laws could result in substantial fines and imprisonment.

We are also subject to the U.S. Foreign Corrupt Practices Act (“FCPA”), which prohibits any U.S. individual or business from paying, offering, authorizing payment of, or offering anything of value, directly or indirectly, to any foreign official, political party, or candidate for the purpose of influencing any act or decision of the foreign entity in order to assist the individual or business in obtaining or retaining business. The FCPA also obligates companies whose securities are listed in the U.S. to comply with certain accounting provisions requiring the company to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations. Compliance with the FCPA can be expensive and difficult, particularly in countries in which corruption is a recognized problem. In addition, the FCPA presents particular challenges in the pharmaceutical industry, because, in many countries, hospitals are operated by the government, and doctors and other hospital employees are considered foreign officials. Certain payments to hospitals in connection with clinical trials and other work have been deemed to be improper payments to government officials and have led to FCPA enforcement actions. Companies can also be held liable for the improper actions of third parties with whom they contract to conduct business on their behalf. Various laws, regulations, and executive orders also



restrict the use and dissemination outside the U.S. or the sharing with certain non-U.S. nationals of information classified for national security purposes, as well as certain products and technical data relating to those products. As we expand our presence outside the U.S., it will require us to dedicate additional resources to comply with these laws, and these laws may preclude us from developing, manufacturing, or selling certain products and product candidates outside the United States, which could limit our growth potential and increase our development costs. We cannot guarantee that we, our employees, our consultants, or our third-party contractors are or will be in compliance with all federal, state, and foreign regulations regarding bribery and corruption. Moreover, our strategic collaborators and third-party contractors located outside the U.S. may have inadequate compliance programs or may fail to respect the laws and guidance of the territories in which they operate. The failure to comply with laws governing international business practices may result in substantial civil and criminal penalties and suspension or debarment from government contracting. The Securities and Exchange Commission ("SEC") also may suspend or bar issuers from trading securities on U.S. exchanges for violations of the FCPA's accounting provisions. Even if we are not determined to have violated these laws, government investigations into these issues typically require the expenditure of significant resources and generate negative publicity, which could also have an adverse effect on our business, financial condition, and results of operations.

The Federal Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), created additional federal criminal statutes that prohibit, among other actions, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private third-party payors; knowingly and willfully embezzling or stealing from a healthcare benefit program; willfully obstructing a criminal investigation of a healthcare offense; and knowingly and willfully falsifying, concealing, or covering up a material fact or making any materially false, fictitious, or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items, or services. HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act ("HITECH"), and their implementing regulations, impose requirements regarding the privacy and security of individually identifiable health information, including mandatory contractual terms, for covered entities, or certain healthcare providers, health plans, and healthcare clearinghouses, and their business associates that provide services to the covered entity that involve individually identifiable health information and their subcontractors that use, disclose, or otherwise process individually identifiable health information. HITECH also increased the civil and criminal penalties that may be imposed against covered entities and business associates and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce HIPAA. While pharmaceutical and biotechnology companies are typically not directly regulated by HIPAA, our business may be indirectly impacted by HIPAA in our interactions with providers, payors, and others that have HIPAA compliance obligations. We are also subject to state and foreign laws governing the privacy and security of health or personal information such as the European Union General Data Protection Regulation ("GDPR") and the California Consumer Privacy Act of 2018 ("CCPA").

There also are U.S. federal transparency requirements under the Physician Payments Sunshine Act that require manufacturers of U.S. FDA-approved drugs, devices, biologics and medical supplies covered by Medicare or Medicaid to report, on an annual basis, to CMS information related to payments and other transfers of value to physicians, teaching hospitals, and certain advanced non-physician health care practitioners and physician ownership and investment interests. Some U.S. states have transparency laws requiring the reporting of information that differs from the scope of information reported under the federal law, which permits these additional state requirements.

Within the European Union and the United Kingdom, payments made to physicians are subject to public disclosure governed by either national statutory or non-statutory industry self-regulatory rules. Moreover, agreements with physicians must in some countries be the subject of prior notification and approval by the physician's employer, their competent professional organization, or the regulatory authorities of the individual country. These requirements are provided in the national laws, industry codes, or professional codes of conduct, applicable in the European Union Member States. Failure to comply with these requirements could result in reputational risk, public reprimands, administrative penalties, fines, or imprisonment.

Laws and regulations have been enacted by the federal government and various states to regulate the sales and marketing practices of pharmaceutical manufacturers with marketed products. The laws and regulations generally limit financial interactions between manufacturers and health care providers and/or require disclosure to the government and public of such interactions. Many of these laws and regulations contain ambiguous requirements or require administrative guidance for implementation. Given the lack of clarity in laws and their implementation, any future activities (if we obtain approval and/or reimbursement from federal healthcare programs for our product candidates) could be subject to challenge.

Given the significant global impact of the COVID-19 pandemic, it is possible that one or more government entities may take actions, including the U.S. government under the Defense Production Act of 1950, as amended, which could 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 will create challenges and potential delays in our development and production activities and may necessitate that we pursue strategies to develop and produce our vaccine

candidates within self-contained national or international borders, at potentially much greater expense and with longer timeframes for public distribution.

We face an inherent risk of product liability as a result of the clinical testing of our product candidates and commercialization of our products. For example, we may be sued if any product we develop allegedly causes injury or is found to be otherwise unsuitable during product testing, manufacturing, marketing, or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability, and a breach of warranties. Claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our product candidates. In the United States, the Public Readiness and Emergency Preparedness Act (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. On March 17, 2020, the Secretary of DHHS issued a declaration under the PREP Act and has issued subsequent amendments thereto since then to provide liability immunity for activities related to certain countermeasures against the ongoing COVID-19 pandemic. On December 11, 2024, the Secretary of DHHS signed the 12th amendment to the declaration under the PREP Act to extend the duration of the PREP Act declaration to December 31, 2029. While we believe our products would be covered under the current PREP Act declaration, this cannot be assured.

Also, there can be no assurance that the Secretary of the DHHS will make other declarations in the future that cover any of our other product candidates or that the U.S. Congress will not act in the future to reduce coverage under the PREP Act or to repeal it altogether. If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of our product candidates.

The impacts of the 2024 U.S. election are unpredictable. Changes in leadership, especially within DHHS, have the potential to significantly impact vaccine-related policies and public health initiatives. Changes could have impacts that may include reduced funding for vaccine research and development, reduced reimbursement for vaccines and their administration, increased skepticism about vaccines among the public, and changes in vaccine mandates and recommendations.

### **Availability of Information**

Our website address is [www.novavax.com](http://www.novavax.com). We make available, free of charge and through our website, our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, and our other filings with the SEC, and any amendments to any such reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended, as soon as reasonably practicable after filed with or furnished to the SEC. The SEC maintains an Internet site that contains reports, proxy, and information statements, and other information regarding issuers that file electronically with the SEC at [www.sec.gov](http://www.sec.gov).

We use our website ([www.novavax.com](http://www.novavax.com)) as a means of disclosing material non-public information and for complying with our disclosure obligations under Regulation Fair Disclosure promulgated by the SEC. These disclosures are included on our website ([www.novavax.com](http://www.novavax.com)) in the "Investors" or "News" sections. Accordingly, investors should monitor these portions of our website ([www.novavax.com](http://www.novavax.com)), in addition to following our press releases, SEC filings, and public conference calls and webcasts.

Also available on our website is information relating to corporate governance at Novavax and our Board of Directors, including our Code of Conduct. We intend to disclose on our website any future amendments to and waivers from this code that apply to our Chief Executive Officer, Principal Financial Officer, Principal Accounting Officer and Controller, and persons performing similar functions, as promptly as practicable, as may be required under applicable SEC and Nasdaq rules.

We webcast our earnings calls and certain events we participate in or host with members of the investment community on the investor relations section of our website. Additionally, we provide notifications of news or announcements regarding press and earnings releases as part of the investor relations section of our website. The contents of our website are not part of this Annual Report on Form 10-K, or any other report we file with, or furnish to, the SEC.

### **Item 1A. RISK FACTORS**



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 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 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.
- 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 and product candidates.
- 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.
- We may fail to obtain regulatory approval for our prototype COVID-19 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.
- 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.
- Servicing our 5.00% convertible senior unsecured notes 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 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**

***We have a history of losses and our future profitability is uncertain.***

Our expenses have exceeded our revenue since our formation in 1987, and our accumulated deficit at December 31, 2024 was \$5.0 billion. Our revenue and expenses have historically 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 \$187.5 million in 2024, \$545.1 million in 2023, and \$657.9 million in 2022.

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. We believe our research and development expenses 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 our COVID-19 Vaccine.

As of the end of fiscal year 2024, our investment in the development and manufacture of our COVID-19 Vaccine has been substantial. As we evolve our operating model to focus on our partnership with Sanofi, the development of our late-stage pipeline, including our CIC and stand-alone influenza vaccine candidates, leveraging our 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 commercial opportunities for the use of our Matrix-MTM adjuvant alongside 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 will continue to require significant funding to maintain our current level of operations and fund the further development of our vaccine candidates.***

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 for our COVID-19 Vaccine. Although we have entered into APAs 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, which may include at the market offerings, existing cash and cash equivalents, investments in marketable securities, potential collaborations, strategic alliances, 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 vaccine candidates, as well as the competitive landscape posed by other vaccines, may impair our ability to raise additional financing on favorable terms, or at all. If we cannot raise the additional funds required for our anticipated operations, 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 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 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 collaboration, funding and 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, each of which could have a material and adverse effect on our financial condition. For example, in the first quarter of 2025, the Company received written notice of a \$23 million claim related to certain performance obligations under an APA agreement with a customer. The Company believes it has fulfilled the requirements related to this matter and 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 committed to purchase. 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 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 (i) a reduction of the number of Conditional Doses from 15 million doses to 7.5 million doses, which reduced number of Conditional Doses 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 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 2024, we entered into the Settlement Agreement and the Settlement Agreement Amendment with the Authority, settling the disputes regarding the Amended and Restated UK Supply Agreement and releasing both parties of all claims arising out of or connected with the 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 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 \$10.3 million over a three year period, ending in June 2027. The Settlement Payment amount includes a \$11.3 million provision for interest over the 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 December 2024, we entered into an amendment to the Australia APA. Pursuant to the amendment, we acknowledged the cancellation by Australia of the delivery of certain doses of our COVID-19 Vaccine scheduled for delivery between the fourth quarter of 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 the future delivery of approximately 3 million doses of COVID-19 Vaccine without requiring additional cash payments. We also agreed to an 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 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 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, the Canadian government may terminate the Canada APA, as amended, as we failed to receive regulatory approval for our COVID-19 Vaccine using bulk antigen produced at BMC on or before December 31, 2024. Therefore, we are in discussions with Canada regarding a potential amendment to the Canada APA to address possible alternatives, which may not be achievable on acceptable terms or at all. As of December 31, 2024, \$555.7 million was classified as current Deferred revenue with respect to the Canada APA in our consolidated balance sheet. If the Canadian government terminates the Canada APA, \$28.0 million of 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 ("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 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. 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 business or have a negative effect on the trading price of our common stock.



## 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. The development and commercialization efforts of our COVID-19 Vaccine and 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 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 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 conditional marketing authorization, 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 conditional marketing authorization, emergency use authorization, or full approval from 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.

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 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 maintain manufacturing capabilities at our own locations and those of our manufacturing partners and contractors to supply our existing APA partners, including 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 ability to operationalize the Sanofi CLA with Sanofi. We have entered 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 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. We have historically experienced challenges related to scaling up our manufacturing capabilities, delivering our COVID-19 vaccine on time and in certain product presentations

for the beginning of a vaccination season, developing global distribution channels and forming partnerships with third parties worldwide, as well as hiring, training and integrating additional management, administrative and sales and marketing personnel.

***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.***

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 JN.1 strain for the 2024-2025 vaccination season. As the SARS-CoV-2 virus continues to evolve, new strains of the virus, or those that are already in circulation, have in the past (in the cases of the Alpha, Beta, Delta and Omicron (including subvariants such as XBB.1.5 and JN.1) variants) and may in the future prove more transmissible or cause more severe forms of COVID-19 disease than the predominant strains to date.

Our COVID-19 Vaccine may not be as effective in protecting against these or other future variant strains. Our COVID-19 Vaccine may fail to achieve market acceptance or significant sales, despite gaining regulatory approval, conditional marketing authorization or emergency use authorization in a number of jurisdictions, including emergency use authorization the U.S., as demand for variant-specific vaccines increases. However, if these efforts are unsuccessful, these candidates do not receive regulatory approvals expeditiously, we are slower to develop variant-specific 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 2025 revenue depends on our and Sanofi's ability to successfully develop, manufacture, distribute, and market in accordance with the Sanofi CLA, an updated monovalent formulation of a vaccine candidate for COVID-19 for the 2025-2026 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 2023-2024 vaccination season.

Further, counterparties to certain of our existing APAs 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. 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. 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 SII for co-formulation, filling, and finishing our COVID-19 Vaccine. If SII is unable to provide sufficient co-formulation, filling, and 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, filling, and 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.

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, 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, we have received 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. 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, 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, 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 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 SII for co-formulation, filling, and finishing our COVID-19 Vaccine, 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. 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 Vaccine is in competition with other products for access to these third-party facilities and may be subject to manufacturing delays 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 enter into technical transfer agreements and share our know-how with 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 depends in part on our ability to successfully establish, operationalize and maintain strategic collaborations with pharmaceutical and biotechnology companies 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 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 sales, marketing and distribution capabilities, significantly delay the commercialization of our vaccine candidates.

***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 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 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 collaborations with Sanofi and 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 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, 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 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 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**

***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.***

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., 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.

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.

***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.***

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**

***We may not succeed in obtaining full U.S. FDA licensure or foreign regulatory approvals necessary to sell our vaccine candidates.***

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 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. None of our vaccine candidates has yet gained full regulatory approval in the U.S., although our COVID-19 Vaccine has received 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 product candidates on a timely basis or comply with our continuing regulatory obligations 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.

***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 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. 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 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, 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 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.



***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 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. Also, the EMA's relocation to the Netherlands from London caused a significant loss of experienced staff and the MHRA's loss of funding from the EU has caused a loss of funding and staff. If a prolonged government shutdown or slowdown of the relevant regulatory authority occurs, it could significantly impact the ability of such government or 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 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 Substances Control Act and the Resource Conservation and Recovery Act. Similar national and local regulations govern our facilities in Sweden 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.

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 depends on our ability to maintain the proprietary nature of our technology.***

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 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 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.

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.

***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**

***Our business may be adversely affected if we do not successfully execute our business development initiatives.***

We anticipate growing through both internal development projects, such as our late-stage pipeline, Matrix-MTM technology and emerging, early-stage pipeline, and external opportunities, such as 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. 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 fully realizing expected synergies.

***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 realized the full annual impact of the cost savings 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 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 recorded an additional charge of \$12.8 million related to one-time employee severance and benefit costs and \$4.1 million costs related to the Impairment of long-lived assets during the year ended December 31, 2024.

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 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 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, 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, created 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. In addition, almost 20 other states have now passed comprehensive privacy laws that have taken effect or will come into effect at various times over the next few years. Several states have passed specific medical and health-data related laws, such as the Washington My Health My Data Act. The Colorado Artificial Intelligence Act, California’s Assembly Bill 2013 on Generative Artificial Intelligence, and other U.S. statutes may also impact 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 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 state laws may be more stringent or broader in scope, or offer greater individual rights, than federal or other state laws, and 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 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 subsidiary Novavax AB with partners such as Sanofi, with regional partners, such as 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 wholly owned subsidiary of Novavax, Inc. We also have entered into the Sanofi CLA, a supply and license agreement with 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**

***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.***

Our stock price has been highly volatile. From January 1, 2024 through December 31, 2024, the closing sale price of our common stock has been as low as \$3.76 per share and as high as \$20.97 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 set-backs 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.

***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.***

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.

## **Item 1B. UNRESOLVED STAFF COMMENTS**

None.

## **Item 1C. CYBERSECURITY**

### **Risk Management and Strategy**

The Company has adopted a cybersecurity risk management program that includes processes designed to identify, assess, manage, and monitor risks from cybersecurity threats. We have integrated cybersecurity risk management into our broader risk management framework to promote a company-wide culture of cybersecurity awareness and risk management. Those processes include conducting an assessment of internal and external threats to the security, confidentiality, integrity and availability of Company data and systems along with other material risks to Company operations, at least annually or whenever there are material changes to the Company's systems or operations and responding to risks identified. The Company's information security program is developed using industry standards as a guide, including the National Institute of Standards and Technology Cybersecurity Framework. As part of our risk management process, the Company also engages outside providers to conduct periodic internal and external penetration testing and security assessments. As part of our third-party risk management program, we conduct assessments of vendor cybersecurity risks, including risks associated with our cloud vendors and other third parties.

As of the date of this report, we have not experienced a cybersecurity incident that resulted in a material effect on our business strategy, results of operations, or financial condition. Despite our continuing efforts, we cannot guarantee that our cybersecurity safeguards will prevent breaches or breakdowns of our or our third-party service providers' information technology systems, particularly in the face of continually evolving cybersecurity threats and increasingly sophisticated threat actors. For example, in 2020, several domestic and foreign security agencies announced that government actors or government-affiliated actors were specifically targeting organizations, like us, engaging in COVID-19 vaccine development and research. For more information, see Item 1A Risk Factors, "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."

### **Governance**

The cybersecurity risk management program is led by the Company's Chief Information Officer ("CIO") who has over 20 years of experience in information systems, cybersecurity, and data protection. The CIO reports to the Company's Audit Committee at least annually, as well as to the Board of Directors, the Company's Chief Executive Officer, and other members of our senior management as appropriate. These reports may feature an overall assessment of the Company's compliance with the Company's cybersecurity policies and include topics such as risk assessment, risk management and control decisions, service provider arrangements, test results, security incidents and responses, and recommendations for changes and updates to policies and procedures. Our program is evaluated by internal and external experts with the results of those reviews reported to senior management and the Board.

## **Item 2. PROPERTIES**

As of December 31, 2024, we leased approximately 170,000 square feet of office space in Gaithersburg, Maryland that serves as our corporate headquarters ("700QO"), and intend to use for manufacturing and research and development. The term of the 700QO lease agreement is approximately 15 years, and we have the option to extend the Lease Agreement for two successive five-year terms.

As of December 31, 2024, we also lease and own approximately 192,000 square feet of office and other space in the U.S., apart from our corporate headquarters and approximately 60,000 in various foreign locations. We use this space for our services and

support, commercial, research and development, manufacturing, and administrative personnel. Although we believe that our facilities are suitable and adequate for our present needs, the Company's management continues to review and assess real property requirements that may be necessary to address our current business plan.

### **Item 3. LEGAL PROCEEDINGS**

#### **Stockholder Litigation**

On November 12, 2021, Sothinathan Sinnathurai filed a purported securities class action in the U.S. District Court for the District of Maryland (the "Maryland Court") against the Company and certain members of senior management, captioned Sothinathan Sinnathurai v. Novavax, Inc., et al., No. 8:21-cv-02910-TDC (the "Sinnathurai Action"). The parties ultimately negotiated a settlement, which the Maryland Court approved on May 23, 2024. The Maryland Court closed the Sinnathurai Action on May 24, 2024.

After the Sinnathurai Action was filed, eight derivative lawsuits were filed: (i) Robert E. Meyer v. Stanley C. Erck, et al., No. 8:21-cv-02996-TDC (the "Meyer Action"), (ii) Shui Shing Yung v. Stanley C. Erck, et al., No. 8:21-cv-03248-TDC (the "Yung Action"), (iii) William Kirst, et al. v. Stanley C. Erck, et al., No. C-15-CV-21-000618 (the "Kirst Action"), (iv) Amy Snyder v. Stanley C. Erck, et al., No. 8:22-cv-01415-TDC (the "Snyder Action"), (v) Charles R. Blackburn, et al. v. Stanley C. Erck, et al., No. 1:22-cv-01417-TDC (the "Blackburn Action"), (vi) Diego J. Mesa v. Stanley C. Erck, et al., No. 2022-0770-NAC (the "Mesa Action"), (vii) Sean Acosta v. Stanley C. Erck, et al., No. 2022-1133-NAC (the "Acosta Action"), and (viii) Jared Needelman v. Stanley C. Erck, et al., No. C-15-CV-23-001550 (the "Needelman Action"). The Meyer, Yung, Snyder, and Blackburn Actions were filed in the Maryland Court. The Kirst Action was filed in the Circuit Court for Montgomery County, Maryland, and shortly thereafter removed to the Maryland Court by the defendants. The Needelman Action was also filed in the Circuit Court for Montgomery County, Maryland. The Mesa and Acosta Actions were filed in the Delaware Court of Chancery (the "Delaware Court"). The derivative lawsuits name members of the Company's board of directors and certain members of senior management as defendants. The Company is deemed a nominal defendant. The plaintiffs assert derivative claims arising out of substantially the same alleged facts and circumstances as the Sinnathurai Action. Collectively, the derivative complaints assert claims for breach of fiduciary duty, insider selling, unjust enrichment, violation of federal securities law, abuse of control, waste, and mismanagement. Plaintiffs seek declaratory and injunctive relief, as well as an award of monetary damages and attorneys' fees.

On February 7, 2022, the Maryland Court entered an order consolidating the Meyer and Yung Actions (the "First Consolidated Derivative Action"). The plaintiffs in the First Consolidated Derivative Action filed their consolidated derivative complaint on April 25, 2022. On May 10, 2022, the Maryland Court entered an order granting the parties' request to stay all proceedings and deadlines pending the earlier of dismissal or the filing of an answer in the Sinnathurai Action. On June 10, 2022, the Snyder and Blackburn Actions were filed. On October 5, 2022, the Maryland Court entered an order granting a request by the plaintiffs in the First Consolidated Derivative Action and the Snyder and Blackburn Actions to consolidate all three actions and appoint co-lead plaintiffs and co-lead and liaison counsel (the "Second Consolidated Derivative Action"). The co-lead plaintiffs in the Second Consolidated Derivative Action filed a consolidated amended complaint on November 21, 2022. On February 10, 2023, defendants filed a motion to dismiss the Second Consolidated Derivative Action. The plaintiffs filed their opposition to the motion to dismiss on April 11, 2023. Defendants filed their reply brief in further support of their motion to dismiss on May 11, 2023. On August 21, 2023, the court entered an order granting in part and denying in part the motion to dismiss. On September 5, 2023, the Company filed an Answer to the consolidated amended complaint. On September 6, 2023, the court entered an order granting the individual defendants an extension of time to file their answer until November 6, 2023. On October 6, 2023, the Board of Directors of the Company formed a Special Litigation Committee ("SLC") with full and exclusive power and authority of the Board to, among other things, investigate, review, and analyze the facts and circumstances surrounding the claims asserted in the pending derivative actions, including the claims that remain following the court's order on the motion to dismiss in the Second Consolidated Derivative Action. On November 7, 2023, the court entered an order granting the parties' request to stay the Second Consolidated Derivative Action for up to six months from the date of entry of the order, and, on April 15, 2024, the court entered a further order extending the stay until June 6, 2024. On June 7, 2024, the court entered another order extending the stay until August 5, 2024. On August 19, 2024, the court entered another order extending the stay until November 4, 2024, to allow the SLC and the parties to continue then-ongoing mediation efforts. On November 1, 2024, the parties notified the court that a settlement in principle had been reached and requested the stay to be extended until the definitive settlement agreement was filed. On November 22, 2024, the SLC filed its Unopposed Motion for Preliminary Approval of Derivative Settlement, Approval of Form and Manner of Notice, and Setting Hearing Date on Final Approval of Settlement and supporting documents. Under the terms of the proposed settlement, individual defendants Erck and Herrmann agreed to pay or cause their insurers to pay \$6.8 million to Novavax in exchange for a release of claims. In addition, Novavax and its Board of Directors agreed to adopt and implement certain governance provisions identified in the settlement stipulation. On December 12, 2024, the court entered an order granting preliminary approval of the derivative settlement and setting a date for a hearing on the final approval of the settlement. The hearing for final consideration of the

proposed settlement is presently scheduled to be held on March 7, 2025, at 9:30 a.m. EST at the United States District Court for the District of Maryland, Southern Division, 650 Cherrywood Lane, Greenbelt, MD 20770.

***A copy of the settlement agreement, together with the Notice, can be found on the “Investor Hub” section of Novavax’s website. The date and time of the final fairness hearing may change. Any updates to the date or time of the final fairness hearing can also be found on the “Investor Hub” section of Novavax’s website or on the Maryland Court’s website. The contents of Novavax’s website are not incorporated by reference into this Annual Report on Form 10-K and you should not consider information provided on Novavax’s website to be part of this Annual Report on Form 10-K.***

The Kirst Action was filed on December 28, 2021, and the defendants immediately removed the case to the Maryland Court. On July 21, 2022, the Maryland Court issued a memorandum opinion and order remanding the Kirst Action to state court. The plaintiffs filed an amended complaint on December 30, 2022. On January 23, 2023, defendants filed a motion to stay the Kirst action. On February 22, 2023, the parties in the Kirst Action filed for the Court’s approval of a stipulation staying the Kirst Action pending the resolution of defendants’ motion to dismiss in the Second Consolidated Derivative Action. On March 22, 2023, the Court entered the parties’ stipulated stay of the Kirst Action pending resolution of the motion to dismiss in the Second Consolidated Derivative Action.

On August 30, 2022, the Mesa Action was filed. On October 3, 2022, the Delaware Court entered an order granting the parties’ request to stay all proceedings and deadlines in the Mesa Action pending the earlier of dismissal of the Sinnathurai Action or the filing of an answer to the operative complaint in the Sinnathurai Action. On January 9, 2023, following the ruling on the motion to dismiss the Sinnathurai Action, the Delaware Court entered an order granting the Mesa Action parties’ request to set a briefing schedule in connection with a motion to stay by defendants. On February 28, 2023, the court granted the defendants’ motion and stayed the Mesa Action pending the entry of a final, non-appealable judgment in the Second Consolidated Derivative Action. On August 31, 2023, the Mesa plaintiffs filed a motion to lift the stay in the Mesa Action. On October 6, 2023, the Company filed an opposition to plaintiff’s motion to lift the stay. Plaintiff filed his reply on October 17, 2023. On December 27, 2023, the parties filed a letter informing the Court that the Second Consolidated Derivative Action had been stayed for a period of six months and asked the Court to stay further proceedings in the Mesa Action until expiration of that stay.

On December 7, 2022, the Acosta Action was filed. On February 6, 2023, defendants accepted service of the complaint and summons in the Acosta Action. On March 9, 2023, the court entered an order granting the parties’ request to stay the Acosta Action pending the entry of a final, non-appealable judgment in the Second Consolidated Derivative Action. On October 13, 2023, the parties filed, and the Delaware Court entered, a stipulated order providing that (i) if the Delaware Court declines to lift the stay in the Mesa Action, the Acosta Action will also remain stayed, and (ii) if the Delaware Court lifts the stay in the Mesa Action, the stay in the Acosta Action will also be lifted.

On April 17, 2023, the Needelman Action was filed. On July 12, 2023, the parties filed a stipulation and proposed order to stay the Needelman Action pending the Maryland Court’s decision on the motion to dismiss in the Second Consolidated Derivative Action. The court entered that order on July 17, 2023.

On November 30, 2023, the court entered an order consolidating the Kirst and Needelman Actions. On December 14, 2023, the parties filed a stipulation (i) extending the plaintiffs’ deadline to file a consolidated complaint until January 29, 2024, and (ii) otherwise staying all other proceedings in the case (including the defendants’ deadline to respond to the consolidated complaint) until February 12, 2024. On May 3, 2024, the plaintiffs filed a consolidated complaint. On May 14, 2024, the parties filed a stipulation staying the action until June 6, 2024. On July 12, 2024, the court entered an order staying the action until August 5, 2024. On September 24, 2024, the court entered another order staying the action until November 4, 2024. On November 4, 2024, the parties filed a stipulation requesting a status conference with the court and further requesting that the action remain stayed until such status conference takes place. To date, the court has not scheduled a status conference.

We are also involved in various other legal proceedings arising in the normal course of business. Although the outcomes of these other legal proceedings are inherently difficult to predict, we do not expect the resolution of these other legal proceedings to have a material adverse effect on our financial position, results of operations, or cash flows.

## PART II

### Item 4. MINE SAFETY DISCLOSURES

Not applicable.

### Item 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS, AND ISSUER PURCHASES OF EQUITY SECURITIES

Our common stock trades on the Nasdaq Global Select Market under the symbol "NVAX." Our common stock was held by approximately 164 stockholders of record as of February 18, 2025, one of which is Cede & Co., a nominee for Depository Trust Company ("DTC"). All of the shares of common stock held by brokerage firms, banks, and other financial institutions as nominees for beneficial owners are deposited into participant accounts at DTC, and are therefore considered to be held of record by Cede & Co. as one stockholder. We do not anticipate declaring or paying any cash dividends in the foreseeable future.

#### Securities Authorized for Issuance under our Equity Compensation Plans

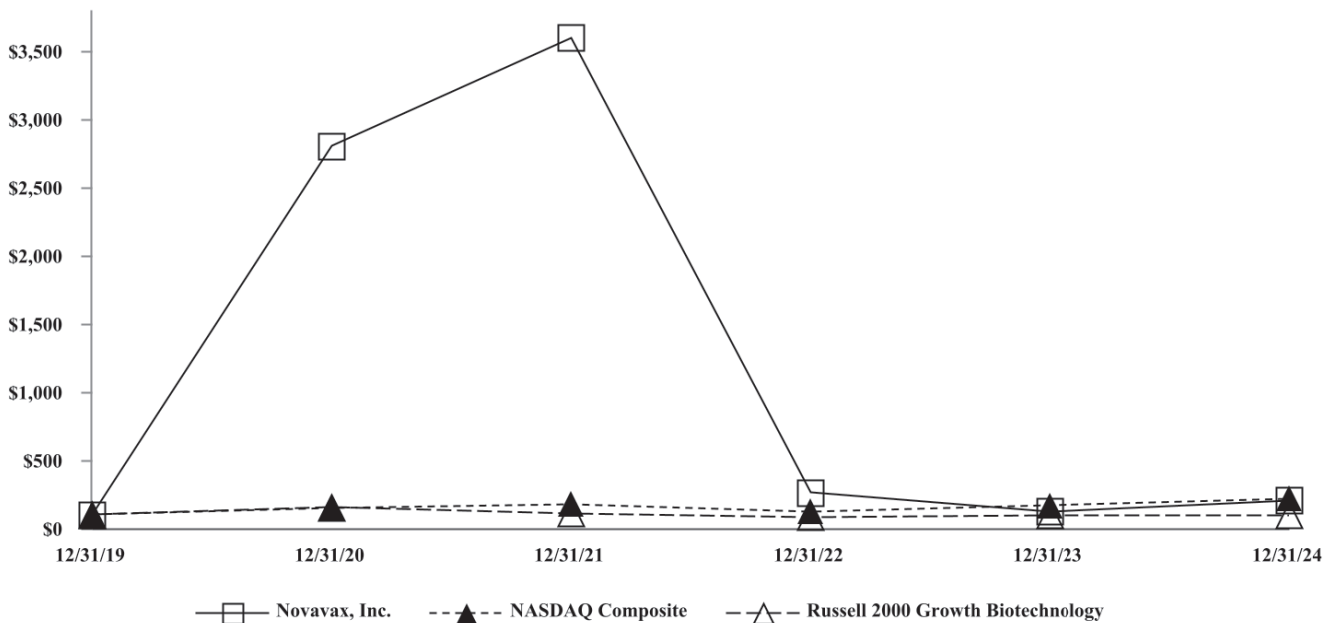
Information regarding our equity compensation plans, including both stockholder approved plans and non-stockholder approved plans, is included in Part III, Item 12 of this Annual Report on Form 10-K.

#### Performance Graph

The graph below matches Novavax, Inc.'s cumulative 5-Year total shareholder return on common stock with the cumulative total returns of the Nasdaq Composite Index and the Russell 2000 Growth Biotechnology Index. The graph tracks the performance of a \$100 investment in our common stock and in each index (with the reinvestment of all dividends) from December 31, 2019 to December 31, 2024.

#### COMPARISON OF 5 YEAR CUMULATIVE RETURN\*

Among Novavax Inc., the NASDAQ Composite index, and the Russell 2000 Growth Biotechnology Index



\*\$100 invested on 12/31/19 in stock or index, including reinvestment of dividends.  
Fiscal year ending December 31.



Value of \$100 invested on December 31, 2019 in stock or index, including reinvestment of dividends, for fiscal years ended:

	December 31,					
	2019	2020	2021	2022	2023	2024
Novavax, Inc.	\$ 100.00	\$2,801.76	\$3,594.72	\$ 258.29	\$ 120.60	\$ 202.01
NASDAQ Composite	\$ 100.00	\$ 143.64	\$ 174.36	\$ 116.65	\$ 167.30	\$ 215.22
Russell 2000 Growth Biotechnology	\$ 100.00	\$ 155.43	\$ 108.17	\$ 78.81	\$ 92.76	\$ 94.07

This graph is not "soliciting material," is not deemed "filed" with the SEC, and is not to be incorporated by reference in any filing of the Company under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date hereof and irrespective of any general incorporation language in any such filing.

## Item 6. RESERVED

## Item 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

Any statements in the discussion below and elsewhere in this Annual Report on Form 10-K about expectations, beliefs, plans, objectives, assumptions, or future events or performance of Novavax, Inc. ("Novavax," together with its wholly owned subsidiaries, the "Company," "we," or "us") are not historical facts and are forward-looking statements. Such forward-looking statements include, without limitation, statements about our capabilities, goals, expectations regarding future revenue and expense levels, and capital raising activities; our corporate growth strategy and key value drivers; our technology platform; our COVID-19 program (which currently includes our Nuvaxovid™ prototype COVID-19 vaccine ("NVX-CoV2373" or "prototype COVID-19 vaccine"), our Nuvaxovid™ COVID-19 vaccine for the 2023-2024 vaccination season ("XBB COVID-19 Vaccine") and our Nuvaxovid™ updated COVID-19 vaccine for the 2024-2025 vaccination season ("NVX-CoV2705" or "updated COVID-19 vaccine") collectively referred to as our ("COVID-19 Vaccine")); our operating plans and prospects, including our ability to continue as a going concern through one year from the date of Novavax' audited financial statements for the year ended December 31, 2024; our global restructuring and cost reduction plan ("Restructuring Plan"), which includes a more focused investment in our COVID-19 vaccine; our cash flow forecast and project revenue, including potential royalties and milestones pursuant to our collaboration and license agreement (the "Sanofi CLA") with Sanofi Pasteur Inc. ("Sanofi"); potential market sizes and demand for our products and product candidates; the efficacy, safety, and intended utilization of our products and product candidates; the development of our clinical-stage product candidates and our recombinant vaccine and adjuvant technologies; the development of our preclinical product candidates; our research and development investment strategy; the potential expansion of our pipeline beyond infectious diseases into other therapeutic areas; our expectations related to enrollment in our clinical trials; the conduct, timing, and potential results from clinical trials and other preclinical studies; plans for and potential timing of regulatory filings; our expectation of manufacturing capacity, timing, production, distribution, and delivery for our COVID-19 Vaccine by us and our partners; our expectations with respect to the anticipated ongoing development and commercialization or licensure of the COVID-19 Vaccine; our expectations with respect to the anticipated ongoing development of COVID-19 variant strain-containing formulations, including the Phase 2b/3 Hummingbird™ trial, our CIC vaccine candidate and our stand-alone influenza vaccine candidate; our partnership efforts for our COVID-19-Influenza ("CIC") vaccine candidate and stand-alone influenza vaccine candidate to advance towards a Biologics License Application ("BLA") filing and commercialization; efforts to expand our COVID-19 Vaccine label worldwide as a booster, and to various age groups and geographic locations; the expected timing, content, and outcomes of regulatory actions; funding under our advance purchase agreements ("APAs") and supply agreements and amendments to, termination of, discussion regarding, or legal disputes relating to any such agreement; our available cash resources and usage and the availability of financing generally; plans regarding partnering activities and business development initiatives; plans regarding APA amendments; and other matters referenced herein. Generally, forward-looking statements can be identified through the use of words or phrases such as "believe," "may," "could," "will," "would," "possible," "can," "estimate," "continue," "ongoing," "consider," "anticipate," "intend," "seek," "plan," "project," "expect," "should," "would," "aim," or "assume," the negative of these terms, or other comparable terminology, although not all forward-looking statements contain these words.

Forward-looking statements are neither historical facts nor assurances of future performance. Instead, they are based only on our current beliefs and expectations about the future of our business, future plans and strategies, projections, anticipated events and trends, the economy, and other future conditions. Forward-looking statements involve estimates, assumptions, risks, and uncertainties that could cause actual results or outcomes to differ materially from those expressed or implied in any forward-looking statements, and, therefore, you should not place considerable reliance on any such forward-looking statements. Such risks and uncertainties include, without limitation, our ability to successfully and timely manufacture, market, distribute, or deliver our updated COVID-19 vaccine and the impact of our not having received a BLA from the U.S. Food and Drug Administration (U.S.

FDA”) for the 2024-2025 vaccination season; challenges related to our partnership with Sanofi and in pursuing additional partnership opportunities; challenges satisfying, alone or together with partners, various safety, efficacy, and product characterization requirements, including those related to process qualification, assay validation, and stability testing, necessary to satisfy applicable regulatory authorities; challenges or delays in conducting clinical trials, or studies for our product candidates; challenges or delays in obtaining regulatory authorization for our product candidates, including for future COVID-19 variant strain changes, our CIC vaccine candidate, our stand-alone influenza vaccine candidate or other product candidates, including as a result of resource constraints at regulatory authorities including the U.S. FDA and the WHO; manufacturing, distribution or export delays or challenges; our substantial dependence on Serum Institute of India Pvt. Ltd. (“SII”) and Serum Life Sciences Limited (“SLS” and together with SII, “Serum”) for co-formulation and filling our COVID-19 vaccine and the impact of any delays or disruptions in their operations; difficulty obtaining scarce raw materials and supplies, including for our proprietary adjuvant; resource constraints, including human capital and manufacturing capacity, constraints on our ability to pursue planned regulatory pathways, alone or with partners; challenges in implementing the Restructuring Plan; our ability to timely deliver doses; challenges in obtaining commercial adoption and market acceptance of our COVID-19 vaccine, any COVID-19 variant strain-containing formulation, our CIC vaccine candidate, our stand-alone influenza vaccine candidate or our other product candidates; challenges meeting contractual requirements under agreements with multiple commercial, governmental, and other entities, including requirements to deliver doses that may require us to refund portions of upfront and other payments previously received or result in reduced future payments pursuant to such agreements; challenges related to the seasonality of vaccinations against COVID-19; challenges related to the demand for vaccinations against COVID-19 or influenza; challenges in identifying and successfully pursuing innovation expansion opportunities; our expectations as to expenses and cash needs may prove not to be correct for reasons such as changes in plans or actual events being different than our assumptions; and other risks and uncertainties identified in Part I, Item 1A “Risk Factors” of this Annual Report on Form 10-K, which may be detailed and modified or updated in other documents filed with the SEC from time to time, and are available at [www.sec.gov](http://www.sec.gov) and at [www.novavax.com](http://www.novavax.com). You are encouraged to read these filings as they are made.

We cannot guarantee future results, events, level of activity, performance, or achievement. Any or all of our forward-looking statements in this Annual Report on Form 10-K may turn out to be inaccurate or materially different from actual results. Further, any forward-looking statement speaks only as of the date when it is made, and we undertake no obligation to update or revise any forward-looking statements, whether as a result of new information, future events, or otherwise, unless required by law. New factors emerge from time to time, and it is not possible for us to predict which factors will arise. In addition, we cannot assess the impact of each factor on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements.

Information in this Annual Report on Form 10-K, includes a financial measure that was not prepared in accordance with U.S. generally accepted accounting principles (“GAAP”), which we refer to as adjusted cost of sales. We are presenting this non-GAAP financial measure to assist an understanding of our business and its performance. Adjusted cost of sales includes an estimate of standard manufacturing costs that were previously expensed to research and development prior to regulatory approvals for our COVID-19 Vaccine that would otherwise have been capitalized to inventory. Any non-GAAP financial measures presented are not, and should not be viewed as, substitutes for financial measures required by GAAP, have no standardized meaning prescribed by GAAP, and may not be comparable to the calculation of similar measures of other companies.

## **Overview**

We are a company tackling global health challenges through scientific innovation that seeks to maximize our deep scientific expertise in vaccines and our cutting-edge technology platform. The differentiated platform features our recombinant protein-based nanoparticle technology and unique Matrix-M™ adjuvant. Our three strategic priorities are: focusing on our partnership with Sanofi announced in May 2024, leveraging our technology platform and pipeline to forge additional partnerships, and advancing our proven technology platform and early-stage pipeline. Our corporate growth strategy is supported by a lean and focused operating model.

Our technology platform combined with our deep vaccine expertise, is the fuel for innovation and partnerships and we believe it has the potential to create significant value. Our proprietary Matrix-M™ adjuvant when added to vaccines, has been shown to help induce a stronger and longer-lasting immune response. Our recombinant protein-based nanoparticle technology has been shown to be highly immunogenetic. Together, we believe that our technology platform can induce potent, durable and broad immune responses, with the potential to be antigen-sparing. Our Matrix-M™ adjuvant can increase both antibody and cell-mediated immune responses to the vaccine and it has demonstrated a favorable tolerability profile in clinical trials. Our technology platform is used in our authorized COVID-19 vaccine and the R21/Matrix-M™ adjuvant malaria vaccine.

We have developed and manufactured our updated COVID-19 vaccine for the 2024-2025 vaccination season for use in individuals aged 12 and older. Our updated vaccine received Emergency Use Authorization ("EUA") from the U.S. FDA in August 2024, along with several additional global regulatory authorizations for use in the 2024-2025 vaccination season. In the U.S., our BLA for our prototype COVID-19 vaccine and for our XBB COVID-19 vaccine is currently under U.S. FDA review with a Prescription Drug User Fee Act ("PDUFA") date of April 2025.

In May 2024, we entered into a Collaboration and License Agreement with Sanofi, to co-commercialize our COVID-19 vaccine, including future updated versions that address seasonal COVID-19 variants. Under the terms of the agreement, we will continue to commercialize our updated COVID-19 vaccine through the end of the 2024-2025 vaccination season and beginning in 2025 and continuing during the term of the Sanofi CLA, we and Sanofi will commercialize the COVID-19 vaccine worldwide in accordance with a commercialization plan agreed by us and Sanofi, under which we will continue to supply certain of our existing APA customers and strategic partners, including Takeda Pharmaceutical Company Limited ("Takeda") and SII. Upon completion of the existing APAs, we and Sanofi will jointly agree on commercialization activities of each party in each jurisdiction. Additionally, Sanofi has the right to develop novel influenza-COVID-19 combination vaccines utilizing our COVID-19 vaccine and Sanofi's seasonal influenza vaccine, combination products containing our COVID-19 vaccine and one or more non-influenza vaccines, and multiple new vaccines utilizing our Matrix-M™ adjuvant.

In December 2024, Sanofi announced that the U.S. FDA granted Fast Track designation to two Sanofi combination vaccine candidates: the first combination consists of Fluzone High-Dose combined with our COVID-19 vaccine, and the second combination consists of Flublok with our COVID-19 vaccine. Sanofi is evaluating the safety and immunogenicity of both combination vaccine candidates in two separate Phase 1/2 trials.

We are eligible to receive royalties and milestones associated with the ongoing sales of our COVID-19 vaccine and Sanofi's influenza-COVID-19 combination vaccines and any other combination vaccines Sanofi may develop, as well as ongoing product royalties for vaccines developed with our Matrix-M™ adjuvant. We discuss this agreement in further detail in Note 4 to our accompanying consolidated financial statements.

Additionally, we are advancing our pipeline of both late- and early-stage programs with a focus on potentially high-value assets in areas with unmet medical need, compelling scientific rationale and strong commercial opportunity.

Our late-stage programs include a CIC vaccine candidate, as well as a stand-alone influenza vaccine candidate. In December 2024, we initiated the initial cohort of a Phase 3 trial comparing our CIC vaccine and stand-alone influenza vaccine to our updated COVID-19 vaccine and a licensed seasonal influenza vaccine comparator in adults aged 65 and older. We intend to partner these vaccine candidates in order to advance to BLA filing and commercialization.

Furthermore, we provide our Matrix-M™ adjuvant for use in collaborations. These include the R21/Matrix-M™ adjuvant malaria vaccine, a malaria vaccine developed by our partner, the Jenner Institute, University of Oxford ("R21/Matrix-M™ adjuvant malaria vaccine") and manufactured by SII. R21/Matrix-M™ adjuvant malaria vaccine is authorized in several countries. Additionally, we provide Matrix-M™ adjuvant for use in various programs in preclinical and clinical stage, as well as preclinical investigations. Examples include, an agreement with the Gates Foundation, and in a related master transfer agreement with a leading pharmaceutical company for exploration of Matrix-M™ adjuvant used as a potential advancement in their pipeline.

We continue to advance our strategic assessment of our emerging, early-stage pipeline. We intend to develop our early-stage pipeline using a disciplined and capital-efficient approach. Our R&D investment strategy seeks to place smart, lower-cost investments on the programs with the highest potential value, both within infectious disease and beyond, with the intent of partnering these assets at proof of concept and shifting late-stage development costs to our partners to finalize clinical development. We are pursuing early-stage research in diseases such as, respiratory syncytial virus ("RSV") combinations, varicella-zoster virus (shingles) and *Clostridioides difficile* (C. Diff.) colitis. We are actively working to evaluate several RSV combination candidates to progress forward toward an Investigational New Drug ("IND"). We are actively developing an H5N1 avian pandemic influenza vaccine candidate and the toxicology study is underway. We are actively monitoring the emerging public health situation and are pursuing funding opportunities to join preparedness options. Additionally, we are evaluating potential expansion beyond infectious diseases including therapeutic areas such as oncology, where we believe our technology could augment and improve upon current therapies.

## Business Highlights

### Fourth Quarter 2024 and Recent Highlights

#### ***Strategic Priority #1: Sanofi Partnership***

- Transitioned lead commercial responsibility of Nuvaxovid™ COVID-19 vaccine beginning with the 2025-2026 vaccination season for the U.S. and other select major markets.
- Achieved \$50 million milestone associated with the first pediatric database lock in the fourth quarter of 2024.
- Prescription Drug User Fee Act target action date of April 2025 for our COVID-19 vaccine BLA.
- Achievement of BLA approval triggers a \$175 million milestone payment from Sanofi.
- Marketing authorization transfers to Sanofi for U.S. and European Union markets are expected in late 2025.
- Achievement triggers an additional \$50 million in combined milestone payments from Sanofi.
- Sanofi announced it received U.S. FDA Fast Track designation for two combination vaccine candidates progressing to Phase 1/2 clinical trials, combining Novavax's proven COVID-19 vaccine with Sanofi's market-leading influenza vaccines.
- Potential for future \$350 million development and launch milestone payments associated with Sanofi influenza-COVID-19 combination products.

#### ***Strategic Priority #2: Leverage our technology platform and pipeline to forge additional partnerships***

- In December 2024, initiated an initial cohort of 2,000 participants for the Phase 3 trial for our CIC and stand-alone seasonal influenza vaccine candidates to evaluate immunogenicity and safety in adults aged 65 and older.
  - Initial cohort data expected by mid-2025.
  - Intend to partner both vaccine programs to advance all future clinical development, regulatory filing and commercialization activities.
- R21/Matrix-M™ adjuvant malaria vaccine launched in additional countries in Africa by SII.

#### ***Strategic Priority #3: Advance our technology platform and early-stage pipeline***

- Continued preclinical development of H5N1 avian pandemic influenza program evaluating multiple highly pathogenic avian influenza strains.
- Continued advancement of early-stage preclinical research for RSV combinations, varicella-zoster virus (shingles) and C. Diff. colitis vaccine candidates.
- Initiated exploratory preclinical work in areas outside of infectious disease, such as oncology.
- Advancing artificial intelligence capabilities to significantly accelerate predictive modeling, optimize discovery and enhance the precision of vaccine design.
- Initiated work on new potential Matrix formulations intended to enable different regimens and dosing schedules, improve vaccines and enable targeted approaches and advancements in therapeutic areas beyond infectious diseases.

## Financing Transactions

In August 2023, we entered into an At Market Issuance Sales Agreement (the "August 2023 Sales Agreement"), which allows us to issue and sell up to \$500 million in gross proceeds of shares of our common stock, and terminated our then-existing At Market Issuance Sales Agreement entered in June 2021 (the "June 2021 Sales Agreement"). During the year ended December 31, 2024, we sold 12.2 million shares of our common stock under our August 2023 Sales Agreement, resulting in net proceeds of approximately \$188 million. As of December 31, 2024, the remaining balance available under the August 2023 Sales Agreement was approximately \$51 million.

In May 2024, we also entered into a securities subscription agreement (the "Sanofi Subscription Agreement") with Sanofi, pursuant to which we sold and issued to Sanofi, in a private placement, 6.9 million shares of our common stock, at a price of \$10.00 per share, for aggregate gross proceeds to us of \$68.8 million.

During the year ended December 31, 2023, we sold 38.3 million shares of our common stock under our August 2023 Sales Agreement and 7.9 million shares of our common stock under our June 2021 Sales Agreement, resulting in net proceeds of approximately \$321 million, of which \$6.9 million was included in Prepaid expenses and other current assets as of December 31, 2023 and received in cash in January 2024.

In August 2023, we also entered into a Securities Subscription Agreement (the "SK Subscription Agreement") with SK bioscience Co., Ltd. ("SK"), pursuant to which we agreed to sell and issue to SK, in a private placement (the "Private Placement"), 6.5 million shares of our common stock at a price of \$13.00 per share (the "SK Shares") for aggregate gross proceeds to us of approximately \$84.5 million. The closing of the Private Placement occurred on August 10, 2023.

### **Critical Accounting Policies and Use of Estimates**

The discussion and analysis of our financial condition and results of operations are based upon our consolidated financial statements, which have been prepared in accordance with GAAP. The preparation of our consolidated financial statements requires us to make estimates, assumptions, and judgments that affect the reported amounts of assets, liabilities, and equity and disclosure of contingent assets and liabilities as of the date of the financial statements and the reported amounts of revenue and expenses during the reporting period. These estimates, particularly estimates relating to accounting for product sales revenue, licensing and transition services revenue, inventory realizability, and research and development expenses have a material impact on our consolidated financial statements and are discussed in detail throughout our analysis of the results of operations discussed below. We base our estimates on historical experience and various other assumptions that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets, liabilities, and equity that are not readily apparent from other sources. Actual results and outcomes could differ from these estimates and assumptions.

For an in-depth discussion of each of our significant accounting policies, including our critical accounting policies and further information regarding estimates and assumptions involved in their application, see Note 2 to the accompanying consolidated financial statements included in Part II, Item 8, "Financial Statements and Supplementary Data" of this Annual Report on Form 10-K.

#### ***Revenue Recognition, Product Sales - Advance Purchase Agreements ("APAs")***

Product sales include sales associated with COVID-19 Vaccine supply agreements, sometimes referred to as APAs, with various international governments. We recognize revenue from product sales related to these APA's based on the transaction price per dose calculated in accordance with Accounting Standards Codification ("ASC") Topic 606, Revenue from Contracts with Customers ("ASC 606"), at the point in time when control of the product transfers to the customer and customer acceptance has occurred, unless such acceptance provisions are deemed perfunctory. The APAs typically contain terms that include upfront payments, which are reflected in Deferred revenue. We constrain the transaction price for APA's until it is probable that a significant reversal in revenue recognized will not occur. Specifically, if an APA includes a provision whereby the customer may request a discount, return, or refund, or includes a term that may have the effect of decreasing the price per dose of previously delivered shipments, revenue is constrained based on an estimate of the impact of the transaction price until it is probable that a significant reversal in revenue recognized will not occur.

#### ***Revenue Recognition, Product Sales - U.S. Commercial***

Product sales in the U.S. are primarily made through large pharmaceutical wholesale distributors at the wholesale acquisition cost ("WAC"). We recognize revenue upon title transfer (which is typically at time of delivery), provided all other revenue recognition criteria have been met. The transaction price includes estimates of variable consideration for which reserves are established that primarily result from invoice discounts for prompt payment, wholesale distributor fees, chargebacks, and product returns (collectively, "gross-to-net deductions"). These estimates are based on the amounts earned or to be claimed for related sales and are classified as either reductions of gross accounts receivable or a current liability based on the nature of the estimate, the expected settlement method, and net position by individual customer. Where appropriate, these estimates are based on factors such as industry data and forecasted customer buying and payment patterns, our experience, current contractual and statutory requirements, specific known market events, and trends. Variable consideration is included in the transaction price only to the extent that it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur when the uncertainty associated with the variable consideration is subsequently resolved. If actual results vary from estimates, we will adjust the estimates, which would affect product sales in the period such variances become known.

Gross-to-net deductions include the following:



- Wholesale distributor fees, discounts, and chargebacks: We have arrangements under which our indirect customers such as retailers and healthcare providers receive discounts to the WAC. The chargeback represents the difference between the WAC and this negotiated discounted price. For distribution and related services, we pay service fees to our wholesale distributors. In addition, we typically offer wholesale distributor customers invoice discounts on product sales for prompt payments. We estimate chargebacks, discounts, and fees we will owe and deduct these amounts from gross product sales at the time the revenue is recognized based on the contractual terms and our expectations regarding future customer behaviors.
- Product returns: We offer wholesale distributors and indirect customers the right to return expired doses. Estimated returns for COVID-19 Vaccine are determined considering levels of inventory in the distribution channel, projected market demand, utilization data, returns claims received, and product shelf life. Our estimates of product returns are subject to significant uncertainty. Actual customer product returns could vary significantly from our estimates, resulting in changes to the estimates in subsequent periods. The estimated amount for product returns is deducted from gross product sales in the period the related product sales are recognized.
- Other: Fees payable to retailers, healthcare providers, and buying groups, including certain patient assistance programs, are deducted from gross product sales in the period the related product sales are recognized.

During the year ended December 31, 2024, we recognized gross-to-net deductions against U.S. commercial product sales of \$120.3 million for product returns and \$105.8 million for wholesale distributor fees, discounts and chargebacks. As of December 31, 2024, \$77.1 million and \$10.1 million related to product returns, wholesale distributor fees, discounts, and chargebacks were included in Accrued expenses and Accounts payable, respectively, and \$50.6 million was included in and reduced Accounts receivable on our consolidated balance sheet. During the year ended December 31, 2023, we recognized gross-to-net deductions against U.S. commercial product sales of \$84.7 million for product returns and \$47.0 million for wholesale distributor fees, discounts and chargebacks. As of December 31, 2023, \$82.5 million related to product returns and \$20.6 million related to wholesale distributor fees, discounts, and chargebacks were included in Accrued expenses and \$2.6 million was included in and reduced Accounts receivable on our consolidated balance sheet.

### ***Revenue Recognition, Licensing, Royalties, and Other - Licensing and Transition Services***

The terms of licensing agreements may contain multiple performance obligations, which may include licenses and transition services. We evaluate licensing agreements under ASC 606, to determine the distinct performance obligations. Prior to recognizing revenue, we estimate the transaction price, including variable consideration that is subject to a constraint. Variable consideration is included in the transaction price to the extent that it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur and when the uncertainty associated with the variable consideration is subsequently resolved. Total consideration may include nonrefundable upfront license fees, transition service fees, other payments based upon the achievement of specified milestones, and royalty payments based on product sales from licensed products.

For multiple performance obligation arrangements, we allocate the transaction price to each distinct performance obligation based on its relative stand-alone selling price. The stand-alone selling price is generally determined for each performance obligation based on the prices charged to customers, discounted cash flows, or using expected cost-plus margin. For stand-alone selling prices determined using discounted cash flows, we consider discounted, probability-weighted cash flows related to the performance obligation transferred. In developing such estimates, we apply judgment in determining the forecasted revenue, expected margins, and the discount rate. These estimates are subjective and require us to make assumptions about future cash flows. Revenue related to performance obligations satisfied at a point in time is recognized when the customer obtains control of the promised asset. For performance obligations recognized over time, we recognize revenue using an input method to measure progress by utilizing costs incurred to-date relative to total expected costs. Under this process, we consider the costs that have been incurred to-date, as well as projections to completion using various inputs and assumptions, including, but not limited to, progress towards completion, labor costs and level of effort, material and subcontractor costs, indirect administrative costs, and other identified risks. Estimating the total cost at completion of our performance obligation under a contract is subjective and requires us to make assumptions about future activity and cost drivers. Changes in these estimates can occur for a variety of reasons and may impact the timing of revenue recognition on our contracts. Changes in estimates related to the process are recognized in the period when such changes are made on a cumulative catch-up basis. We have not experienced any material adjustments as a result of changes in estimates arising from this process.

### ***Inventory Realizability***

We periodically analyze our inventories for excess amounts or obsolescence and write down obsolete or otherwise unmarketable inventory to its estimated net realizable value. We estimate excess or obsolete inventory and losses on firm purchase commitments of inventory quarterly based on multiple factors, including assumptions about expected future demand and market



conditions, current sales orders, and product expiry dates. Our assumptions about expected future demand are inherently uncertain and if we were to change any of these judgments or estimates, it could cause a material increase or decrease in the amount of inventory write down that we report in a particular period. For the year ended December 31, 2024, we recorded inventory write-downs of \$21.0 million and losses on firm purchase commitments of inventory of \$7.4 million. In addition, for the year ended December 31, 2024, we recorded recoveries on firm purchase commitments of \$0.7 million related primarily to negotiated reductions to previously recognized firm purchase commitments. For the year ended December 31, 2023, we recorded inventory write-downs of \$72.4 million and losses on firm purchase commitments of inventory of \$73.5 million. In addition, for the year ended December 31, 2023, we recorded recoveries on firm purchase commitments of \$40.2 million related primarily to negotiated reductions to previously recognized firm purchase commitments.

### ***Accounting for Research and Development Expenses***

We estimate our prepaid and accrued expenses related to our research and development activities using a process that involves reviewing contracts and purchase orders, communicating with our project managers and service providers to identify services that have been performed on our behalf, and estimating the level of service performed and the associated cost incurred for the service when we have not yet been invoiced or for which we have been invoiced in advance of the service. This estimation process includes a review of:

- expenses incurred under agreements with contract research organizations ("CROs") that conduct our clinical trials and third party consultants; and
- the cost of developing and manufacturing vaccine components under third-party contract manufacturing organizations ("CMOs") and contract development and manufacturing organizations ("CDMOs") agreements, including expenses incurred for the procurement of raw materials, laboratory supplies and equipment.

We base our expenses on our estimates of the services provided and efforts expended pursuant to contracts, statements of work and related change orders with the service provider, and discussion with internal personnel and external service providers as to the progress of the services and the agreed-upon fee to be paid for such services. The financial terms of these agreements are based on negotiated terms, vary from contract to contract, and may result in an uneven level of activity over time. There may be instances in which payments made to our vendors will exceed the level of services provided and result in a prepayment of the expense. Additionally, invoicing from third-party service providers may not coincide with actual work performed and can result in a prepaid or an accrual position at the end of the period. The estimation process requires us to make significant judgments and estimates in determining the services incurred as of the balance sheet date, which may result in either a prepaid or an accrual balance. As actual costs become known, we adjust our estimates. Although we do not expect our estimates to be materially different from amounts actually incurred, our understanding of the status and timing of services performed may vary from the related estimates and could result in us reporting amounts that are too high or too low in a particular period. Our prepaid and accrued expenses are dependent, in part, upon the receipt of timely and accurate reporting from CROs, CMOs, CDMOs, and third-party service providers. Due to the nature of the estimation process, there may be a difference between estimated costs and actual costs incurred. Historically, we have not experienced any material differences in prior periods.

### ***Recent Accounting Pronouncements***

See "Note 2—Summary of Significant Accounting Policies" included in our Notes to Consolidated Financial Statements (under the caption "*Recent Accounting Pronouncements*").

### **Results of Operations for Fiscal Years 2024 and 2023**

The following is a discussion of our historical consolidated financial condition and results of operations, and should be read in conjunction with the consolidated financial statements and notes thereto set forth in this Annual Report on Form 10-K. Additional information concerning factors that could cause actual results to differ materially from those in our forward-looking statements is described under Part I, Item 1A, "Risk Factors" of this Annual Report on Form 10-K.

For our discussion of the year ended December 31, 2023, compared to the year ended December 31, 2022, please read Item 7. *Management's Discussion and Analysis of Financial Condition and Results of Operations* located in Annual Report on Form 10-K for the year ended December 31, 2023.

## Revenue

	2024	2023	Change
<b>Revenue (in thousands):</b>			
Product sales	\$ 190,212	\$ 531,389	\$ (341,177)
Licensing, royalties, and other	491,950	24,993	466,957
Grants	—	427,323	(427,323)
<b>Total revenue</b>	<b>\$ 682,162</b>	<b>\$ 983,705</b>	<b>\$ (301,543)</b>

Revenue for the year ended December 31, 2024 was \$682.2 million as compared to \$983.7 million for the year ended December 31, 2023, a decrease of \$301.5 million. Revenue for the year ended December 31, 2024, was primarily comprised of revenue from licensing and product sales of COVID-19 Vaccine. Revenue for the year ended December 31, 2023, was primarily comprised of revenue from product sales of COVID-19 Vaccine and services performed under our USG Agreement. The decrease in revenue is due to a decrease in revenue under the USG Agreement and in the quantity of dose sales of COVID-19 Vaccine, partially offset by licensing, royalties, and other revenue from the Sanofi CLA.

### Product sales

Product sales for 2024 were \$190.2 million as compared to \$531.4 million for 2023, a decrease of \$341.2 million. The decrease in product sales is primarily due to a decreased quantity of dose sales of COVID-19 Vaccine under our APA agreements during the year ended December 31, 2024 as compared to 2023. The geographic distribution of product sales was as follows:

	2024	2023	Change
<b>Product Sales (in thousands)</b>			
North America	\$ 65,023	\$ 29,959	\$ 35,064
Europe	93,270	268,361	(175,091)
Rest of the world	31,919	233,069	(201,150)
<b>Total product sales revenue</b>	<b>\$ 190,212</b>	<b>\$ 531,389</b>	<b>\$ (341,177)</b>

### Licensing, royalties, and other

Licensing, royalties, and other revenues for 2024 were \$492.0 million as compared to \$25.0 million for 2023, an increase of \$467.0 million. The increase was primarily due to revenue from the Sanofi CLA.

	2024	2023	Change
<b>Licensing, royalties, and other (in thousands)</b>			
License fees	\$ 389,642	\$ 8,500	\$ 381,142
Sales-based royalties	8,579	—	8,579
Transition services and technology transfer	69,733	—	69,733
Matrix-M™ adjuvant	20,459	16,493	3,966
Other	3,537	—	3,537
<b>Total licensing, royalties, and other revenue</b>	<b>\$ 491,950</b>	<b>\$ 24,993</b>	<b>\$ 466,957</b>

### Grants

We did not have any Grants revenue during the year ended December 31, 2024, as compared to \$427.3 million during the year ended December 31, 2023, a decrease of \$427.3 million. Grant revenue for the year ended December 31, 2023 was comprised of

revenue for services performed under our USG Agreement. As of December 31, 2023, we had recognized the full contract funding under the USG Agreement in revenue.

#### Expenses:

	2024	2023	Change
<b>Expenses (in thousands):</b>			
Cost of sales	\$ 202,739	\$ 343,768	\$ (141,029)
Research and development	391,169	737,502	(346,333)
Selling, general, and administrative	337,185	468,946	(131,761)
Total expenses	<u>\$ 931,093</u>	<u>\$</u>	<u>\$ (619,123)</u>

#### *Cost of Sales*

Cost of sales decreased to \$202.7 million for 2024 as compared to \$343.8 million for 2023, a decrease of \$141.0 million. The decrease was primarily due to a decrease in the quantity of dose sales of COVID-19 Vaccine and a decrease in excess, obsolete, or expired inventory and losses on certain firm purchase commitments. Cost of sales for 2024 included expense of \$28.4 million related to excess, obsolete, or expired inventory and losses on certain firm purchase commitments, \$3.8 million ROU asset impairment charges for CMO manufacturing capacity of excess quantities, \$44.9 million related to unutilized manufacturing capacity, and a credit of \$0.7 million related to negotiated reductions to certain previously recognized firm purchase commitments. Cost of sales for 2023 included expense of \$145.9 million related to excess, obsolete, or expired inventory and losses on firm purchase commitments, \$6.1 million ROU asset impairment charges for CMO manufacturing capacity of excess quantities, \$64.0 million related to unutilized manufacturing capacity, and a credit of \$40.2 million related to negotiated reductions to certain previously recognized firm purchase commitments. The cost of sales as a percentage of product sales may fluctuate in the future as a result of changes to our customer mix, quantity of dose sales, or standard costs.

#### *Research and Development Expenses*

Research and development expenses decreased to \$391.2 million for 2024 as compared to \$737.5 million for 2023, a decrease of \$346.3 million. The decrease was primarily due to a reduction in overall expenditures relating to development activities on coronavirus vaccines, including our COVID-19 Vaccine and CIC, as summarized in the table below (in thousands):

	2024	2023
<b>Research and Development Expenses (in thousands):</b>		
Coronavirus vaccines	\$ 122,445	\$ 413,448
Other vaccine development programs	4,632	3,241
Total direct external research and development expense	127,077	416,689
Employee expenses	142,860	169,378
Stock-based compensation expense	20,868	41,211
Facility expenses	52,580	62,736
Other expenses	47,784	47,488
Total research and development expenses	<u>\$ 391,169</u>	<u>\$ 737,502</u>

Research and development expenses for coronavirus vaccines for the year ended December 31, 2024 and 2023 decreased to \$122.4 million from \$413.4 million primarily as a result of a reduction in coronavirus vaccines clinical and support costs. The decrease was also the result of a reduction in manufacturing and support costs due, in part, to a reduction in our global manufacturing footprint consistent with our contractual obligations to supply, and anticipated demand for, COVID-19 Vaccine, including embedded lease costs, under manufacturing supply agreements with CMOs and CDMOs.

We do not provide forward-looking estimates of costs and time to complete our research programs due to the many uncertainties associated with vaccine development. As we obtain data from preclinical studies and clinical trials, we may elect to discontinue or delay clinical trials in order to focus our resources on more promising vaccine candidates. Completion of clinical trials may take several years or more, but the length of time can vary substantially depending upon the phase, size of clinical trial,

primary and secondary endpoints, and the intended use of the vaccine candidate. The cost of clinical trials may vary significantly over the life of a project as a result of a variety of factors, including:

- the number of participants who participate in the clinical trials;
- the number of sites included in the clinical trials;
- if clinical trial locations are domestic, international, or both;
- the time to enroll participants;
- the duration of treatment and follow-up;
- the safety and efficacy profile of the vaccine candidate; and
- the cost and timing of, and the ability to secure, regulatory approvals.

As a result of these uncertainties, we are unable to determine the duration and completion costs of our research and development projects or when, and to what extent, we will generate future cash flows from our research projects.

For 2025, we expect research and development expenses to decrease as compared to 2024 as we continue to right-size our operating expenses as part of our cost reduction initiative.

### ***Selling, General, and Administrative Expenses***

Selling, general, and administrative expenses decreased to \$337.2 million for 2024 from \$468.9 million for 2023, a decrease of \$131.8 million. The decrease in selling, general, and administrative expenses is primarily due to cost containment measures to reduce our operating spend, including a decrease in advertising and promotion costs in support of our COVID-19 commercial program, employee expenses, and professional fees, partially offset by restructuring expenses.

### **Other Income (Expense), Net:**

	<b>2024</b>	<b>2023</b>	<b>Change</b>
<b>Other income (expense) (in thousands):</b>			
Interest expense	\$ (20,075)	\$ (14,416)	\$ (5,659)
Gain on disposition of Novavax CZ assets	51,949	—	51,949
Other income	40,442	37,896	2,546
<b>Total other income (expense), net</b>	<b>\$ 72,316</b>	<b>\$ 23,480</b>	<b>\$ 48,836</b>

We had total net other income of \$72.3 million for 2024 compared to total net other income of \$23.5 million for 2023, an increase of \$48.8 million. The increase in other income (expense), net is primarily due to the gain on the disposition of Novavax CZ assets, the favorable impact in 2024 as compared to 2023, of exchange rates on foreign currency denominated balances, including an intercompany loan with Novavax CZ, and additional interest income on Cash and cash equivalents and Marketable securities balances, partially offset by additional interest expense.

### **Income Tax Expense:**

During the years ended December 31, 2024 and 2023, we recognized \$10.9 million and \$2.0 million of income tax expense, respectively, related to federal, state, and foreign income taxes.

### **Net Loss:**

	<b>2024</b>	<b>2023</b>	<b>Change</b>
<b>Net Loss (in thousands, except per share information):</b>			
Net loss	\$ (187,499)	\$ (545,062)	\$ 357,563
Net loss per share, basic and diluted	\$ (1.23)	\$ (5.41)	\$ 4.18
Weighted average shares outstanding, basic and diluted	152,190	100,768	51,422

Net loss for 2024 was \$187.5 million, or \$1.23 per share, as compared to \$545.1 million, or \$5.41 per share, for 2023, a decrease of \$357.6 million, or \$4.18 per share. The decrease in net loss during the years ended December 31, 2024, was primarily due to a decrease in total expenses, partially offset by a decrease in total revenue.

The increase in weighted average shares outstanding for 2024 is primarily a result of sales of our common stock.

### **Liquidity Matters and Capital Resources**

Our future capital requirements depend on numerous factors including, but not limited to, revenue from our product sales, milestone payments, royalties and reimbursements under licensing arrangements with our strategic partners; our projected activities related to the development and commercial support of our COVID-19 Vaccine and our CIC and stand-alone influenza vaccine candidates, including significant commitments under various CRO, CMO, and CDMO agreements; the progress of preclinical studies and clinical trials; the time and costs involved in obtaining regulatory approvals; the costs of filing, prosecuting, defending, and enforcing patent claims and other intellectual property rights; and other manufacturing, sales, and distribution costs. We plan to continue developing other vaccines and product candidates, such as our potential combination vaccine and stand-alone influenza vaccine candidates, which are in various stages of development. Our ability to generate revenue from product sales is subject to uncertainty specifically as it relates to our ability to successfully develop, manufacture, distribute, and market our updated vaccine and to successfully execute on our APAs, as discussed below. Additionally, our plans include our ongoing restructuring and cost reduction measures (see Note 18 to our accompanying consolidated financial statements), and may also include raising additional capital through a combination of additional equity and debt financing, collaborations, strategic alliances, asset sales, and marketing, distribution, or licensing arrangements. New financings may not be available to us on commercially acceptable terms, or at all. 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 further downsize our organization, any of which may have a material adverse effect on our business, financial condition, results of operations.

In May 2024, we entered into the Sanofi CLA pursuant to which Sanofi received:

- i. A co-exclusive license to commercialize our current stand-alone COVID-19 Vaccine, including our prototype vaccine and updated vaccines, that address seasonal variants throughout the world (the "COVID-19 Vaccine Products");
- ii. A sole license to develop and commercialize combination products containing a potential combination of our COVID-19 Vaccine and Sanofi's seasonal influenza vaccine ("COVID-19 and influenza Combination Products" or "CIC Products");
- iii. A non-exclusive license to develop and commercialize combination products containing both our COVID-19 Vaccine and one or more non-influenza vaccines ("Other Combination Products" and together with the COVID-19 Vaccine Products, CIC Products, and Other Combination Products, "Licensed COVID-19 Products") and
- iv. A non-exclusive license to develop and commercialize other vaccine products selected by Sanofi that include our Matrix-M™ adjuvant.

Under the Sanofi CLA, we received a non-refundable upfront payment of \$500 million. We also achieved a \$50.0 million milestone, which is included in Accounts receivable on the Consolidated balance sheet as of December 31, 2024. We are eligible to receive development, technology transfer, launch, and sales milestone payments totaling up to an additional \$650.0 million in the aggregate with respect to the Licensed COVID-19 Products and royalty payments on Sanofi's sales of such licensed products. In addition, we are also eligible to receive development, launch, and sales milestone payments of up to \$200 million for each of the first four Adjuvant Products and \$210 million for each Adjuvant Product thereafter, and royalty payments on Sanofi's sales of all such licensed products.

Commencing shortly after the effective date of the Sanofi CLA, we commenced activities related to the technology transfer of our manufacturing process for the COVID-19 Vaccine Products and Matrix-M™ components to Sanofi. Until the successful completion of such transfer, we will supply Sanofi with both COVID-19 Vaccine Products and Matrix-M™ intermediary components for Sanofi's use and are eligible for reimbursement of such costs from Sanofi. Additionally, Sanofi will reimburse us for our research and development and medical affairs costs related to the COVID-19 Vaccine Products in accordance with agreed upon plans and budgets.

Under the Sanofi CLA, we will continue to commercialize the updated vaccine through the end of the 2024-2025 vaccination season. Beginning in 2025 and continuing during the term of the Sanofi CLA, we and Sanofi will commercialize the COVID-19 Vaccine Products worldwide in accordance with a commercialization plan agreed by us and Sanofi, under which we will continue to supply our existing APA customers and strategic partners, including Takeda and SII. Upon completion of the existing APAs, we and Sanofi will jointly agree on commercialization activities of each party in each jurisdiction.

In May 2024, we also entered into the Sanofi Subscription Agreement, pursuant to which we sold and issued to Sanofi, in a private placement, 6.9 million shares of our common stock at a price of \$10.00 per share for aggregate gross proceeds to us of \$68.8 million.

We have also entered into supply agreements, sometimes referred to as APAs, with various countries globally. As of December 31, 2024, the aggregate amount of the transaction price allocated to performance obligations that were unsatisfied (or partially unsatisfied), excluding amounts related to sales-based royalties under the licensing agreements, was approximately \$1.3 billion, of which \$1.1 billion is included in Deferred revenue on our consolidated balance sheet. Failure to timely meet regulatory milestones, obtain timely supportive recommendations from governmental advisory committees, or achieve product volume or delivery timing obligations under our APAs may require us to refund portions of upfront or other payments or result in reduced future payments, which could adversely impact our ability to realize revenue from our unsatisfied performance obligations or result in the reversal of previously recognized revenue. In the first quarter of 2025, we received written notice of a \$23 million claim related to certain performance obligations under an APA agreement with a customer. We believe we have fulfilled the requirements related to this matter and are evaluating the merits of the claim. The timing to fulfill performance obligations related to APAs 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 under certain of our APAs. The APAs 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. Additionally, for the remaining APA agreements, our intent is to deliver doses or when appropriate, amicably negotiate and exit agreements. The timing to fulfill performance obligations related to the Sanofi CLA will depend on the timing of costs incurred relative to total expected costs.

In August 2024, our updated COVID-19 vaccine received EUA from the U.S. FDA for active immunization to prevent COVID-19 in individuals aged 12 and older. Doses became available within the U.S. at many major pharmacy retailers, following the Center for Biologics Evaluation and Research release of vaccine batches. We have established reserves for gross-to-net deductions for amounts that we expect to return to our customers. As of December 31, 2024, gross-to-net deduction balances were \$116.7 million related to product returns and \$21.1 million related to wholesale distributor fees, discounts, and chargebacks. As of December 31, 2024, \$77.1 million of gross-to-net deductions were included in Accrued expenses, \$10.1 million were included Accounts payable, and \$50.6 million were included in and reduced Accounts receivable on the consolidated balance sheet.

Pursuant to the Settlement Agreement with Fujifilm (see Note 4 to our accompanying consolidated financial statements), in March 2024, we paid \$42.0 million to Fujifilm, the parties agreed to a mutual release of claims arising from, under or otherwise in connection with the prior confidential settlement agreement and release effective September 30, 2022, and Fujifilm agreed to dismiss its demand for arbitration with the Judicial Arbitration and Mediation Services ("JAMS"). This payment is less than amounts previously recognized as embedded lease expense and reflected in Research and development expenses from Fujifilm manufacturing activity and accordingly, during the year ended December 31, 2024, we recorded a benefit of \$26.6 million as Research and development expenses.

We have an APA with the Commonwealth of Australia ("Australia") for the purchase of doses of COVID-19 Vaccine (the "Australia APA"). In December 2024, we entered into an amendment to the Australia APA with Australia. Pursuant to the amendment, we acknowledged the cancellation by Australia of the delivery of certain doses of our COVID-19 Vaccine scheduled for delivery between the fourth quarter of 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 the future delivery of approximately 3 million doses of COVID-19 Vaccine without requiring additional cash payments. We also agreed to an 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 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 also provides Australia with the right to cancel doses if we fail to timely notify Australia of changes to our commercialization plans. As of December 31, 2024, \$15.6 million was classified as current Deferred revenue and \$118.2 million was classified as non-current Deferred revenue with respect to the Australia APA in our consolidated balance sheet, which will be recognized in product revenue as doses are delivered to Australia.

We have an APA with the Pharmaceutical Management Agency ("Pharmac"), a New Zealand Crown entity, for the purchase of doses of COVID-19 Vaccine (the "New Zealand APA"). 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 an APA with His Majesty the King in Right of Canada as represented by the Minister of Public Works and Government Services, as successor in interest to Her Majesty the Queen in Right of Canada, as represented by the Minister of Public Works and Government Services (the "Canadian government"), for the purchase of doses of COVID-19 Vaccine (the "Canada APA"). The Canadian government may terminate the Canada APA, as amended, as we failed to receive regulatory approval for our COVID-19 Vaccine using bulk antigen produced at Biologics Manufacturing Centre Inc. ("BMC") on or before December 31, 2024. Therefore, we are in discussions with Canada regarding a potential amendment to the Canada APA to address possible alternatives, which may not be achievable on acceptable terms or at all. As of December 31, 2024, \$555.7 million was classified as current Deferred revenue with respect to the Canada APA in our consolidated balance sheet. If the Canadian government terminates the Canada APA, \$28.0 million of 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 November 2024, we and The Secretary of State for Business, Energy and Industrial Strategy (as assigned to the UK Health Security Agency), acting on behalf of the government of the United Kingdom of Great Britain and Northern Ireland (the "Authority") entered into a Termination and Settlement Agreement (the "Settlement Agreement") and a Letter of Amendment to the Settlement Agreement (the "Settlement Agreement Amendment"), relating to the Amended and Restated SARS-CoV-2 Vaccine Supply Agreement (the "Amended and Restated UK Supply Agreement") and the SARS-CoV-2 Vaccine Supply Agreement, dated October 22, 2020 (the "Original UK Supply Agreement"). The Settlement Agreement resolved the disputes regarding the Amended and Restated Supply Agreement and released both parties of all claims arising out of or connected with the Amended and Restated Supply Agreement.

Under the terms of the Settlement Agreement and Settlement Agreement Amendment, we and the Authority agreed to terminate the Amended and Restated Supply Agreement and to fully settle the outstanding amount under dispute related to upfront payments of \$112.5 million previously received by us from the Authority under the Amended and Restated Supply Agreement. Pursuant to the Settlement Agreement, we agreed to pay a refund of \$123.8 million (the "Settlement Payment") to the Authority in equal quarterly installments of \$10.3 million over a three year period, ending in June 2027. The Settlement Payment amount includes an \$11.3 million provision for interest over the period and may be avoided if we choose to accelerate payments. As of December 31, 2024, the remaining upfront payment previously received from the authority is classified as \$36.4 million of other current liabilities and \$58.8 million of Other non-current liabilities on our consolidated balance sheet.

We entered into an APA with the Vaccine Alliance ("Gavi") in May 2021 (the "Gavi APA"), pursuant to which we received upfront payments of \$700 million from Gavi (the "Advance Payment Amount") to be applied against purchases of our prototype vaccine by certain countries participating in the COVAX Facility. As of December 31, 2023, the remaining Gavi Advance Payment Amount was \$696.4 million. In February 2024, we and Gavi entered into a Termination and Settlement Agreement (the "Gavi Settlement Agreement") terminating the Gavi APA, settling the arbitration proceedings, and releasing both parties of all claims arising from, under, or otherwise in connection with the Gavi APA. Pursuant to the Gavi Settlement Agreement, we are responsible for payment to Gavi of (i) an initial settlement payment of \$75 million, which we paid in February 2024, and (ii) deferred payments, in equal annual amounts of \$80 million payable each calendar year through a deferred payment term ending December 31, 2028. The deferred payments are due in variable quarterly installments beginning in the second quarter of 2024 and total \$400 million during the deferred payment term. Such deferred payments may be reduced through Gavi's use of an annual vaccine credit equivalent to the unpaid balance of such deferred payments each year, which may be applied to qualifying sales of any of our vaccines funded by Gavi for supply to certain low-income and lower-middle income countries. We have the right to price the vaccines offered to such low-income and lower-middle income countries in our discretion, and, when utilized by Gavi, we will credit the actual price per vaccine paid against the applicable credit. We intend to price vaccines offered via the tender process, consistent with our shared goal with Gavi to provide equitable access to those countries. Also, pursuant to the Gavi Settlement Agreement, we granted Gavi an additional credit of up to \$225 million that may be applied against qualifying sales of any of our vaccines for supply to such low-income and lower-middle income countries that exceed the \$80 million deferred payment amount in any calendar year during the deferred payment term. In total, the Gavi settlement agreement is comprised of \$700 million of potential consideration, consisting of the \$75 million initial settlement payment, deferred payments of up to \$400 million that may be reduced through annual vaccine credits, and the additional credit of up to \$225 million that may be applied for certain qualifying sales.

We recorded the \$3.6 million difference between the refund liability recorded as of December 31, 2023 of \$696.4 million and the \$700 million of total consideration under the arrangement as a revenue adjustment during the year ended December 31, 2024. As of December 31, 2024, the remaining amounts included on our consolidated balance sheet are classified as \$225.0 million in

non-current Deferred revenue for the additional credit that may be applied against future qualifying sales, \$85.0 million in Other current liabilities, and \$275.0 million in other non-current liabilities. In addition, we and Gavi entered into a security agreement pursuant to which we granted Gavi a security interest in accounts receivable from SII under the SII R21 Agreement (see Note 3 to our accompanying consolidated financial statements), which will continue for the deferred payment term of the Gavi Settlement Agreement. On February 22, 2024, the claims and counterclaims were dismissed with prejudice.

We continue to assess our manufacturing needs and modify our global manufacturing footprint consistent with our contractual obligations to supply, and anticipated demand for, COVID-19 Vaccine, and in doing so recognize that significant costs may be incurred. For the 2023-2024 vaccination season, we depended exclusively on Serum for co-formulation and filling and finishing. For the 2024-2025 vaccination season, we expanded our supply chain network and introduced new single-dose vial and pre-filled syringe product presentations in certain markets. In May 2024, we and SLS entered into a supply agreement (the "SLS Supply Agreement") under which SLS will supply us antigen drug substance and finished COVID-19 Vaccine doses. The SLS Supply Agreement includes the general terms and conditions of supply orders between us and SLS. We and SLS execute firm purchase orders to include specific quantities to be delivered under the SLS Supply Agreement. Pursuant to the SLS Supply Agreement, SLS or its authorized manufacturer is responsible for obtaining and maintaining all necessary permits or other regulatory approvals to manufacture drug substance and drug product. Unless otherwise earlier terminated, the SLS Supply Agreement will expire on the later of June 30, 2028 or two years after the expiration or termination of the last firm purchase order under the SLS Supply Agreement. Either party may terminate the SLS Supply Agreement if the other party commits a material breach of the SLS Supply Agreement that is not timely cured or is not curable. The SLS Supply Agreement contains certain customary representations and warranties of the parties along with certain customary covenants, including confidentiality and indemnity provisions. Any delays or disruptions in these suppliers' operations could prevent or delay the delivery of customer orders.

As of December 31, 2024, we had \$545.3 million in cash and cash equivalents and restricted cash and \$392.9 million in marketable securities as compared to \$583.8 million in cash and cash equivalents and restricted cash as of December 31, 2023.

We funded our operations in 2024 primarily with cash and cash equivalents, marketable securities, non-refundable upfront payment under the Sanofi CLA and Sanofi Subscription Agreement, proceeds from the sale of securities under our August 2023 Sales Agreement, upfront payments under APAs, and revenue from product sales. In May 2023, we announced our plan to restructure our global footprint to reduce our planned expenditures and in January 2024, we announced further reductions in our global workforce. We anticipate our future operations to be funded primarily by milestone payments, royalties, transition services and technology transfer under the Sanofi CLA, revenue and/or royalties from product sales, our cash and cash equivalents and investments in marketable securities, and other potential funding sources including equity financings, which may include at the market offerings, debt financings, collaborations, strategic alliances, asset sales, and marketing, distribution or licensing arrangements.

The following table summarizes cash flows for 2024 and 2023:

	2024	2023	Change
Net cash (used in) provided by:			
Operating activities	\$ (87,263)	\$ (713,967)	\$ 626,704
Investing activities	(204,038)	(58,806)	(145,232)
Financing activities	260,583	4,466	256,117
Effect on exchange rate on cash, cash equivalents, and restricted cash	(7,800)	3,272	(11,072)
Net decrease in cash, cash equivalents, and restricted cash	(38,518)	(765,035)	726,517
Cash, cash equivalents, and restricted cash at beginning of year	583,810	1,348,845	(765,035)
Cash, cash equivalents, and restricted cash at end of year	<u>\$ 545,292</u>	<u>\$ 583,810</u>	<u>\$ (38,518)</u>

Net cash used in operating activities was \$87.3 million for 2024, as compared to cash used in operating activities of \$714.0 million in 2023. The decrease in cash used in operating activities is primarily due to the non-refundable upfront payment under the Sanofi CLA and an overall decrease in operating expenses period-over-period, partially offset by the timing of payments to vendors.

Net cash used in investing activities was \$204.0 million for 2024, as compared to \$58.8 million in 2023. The increase in cash used in investing activities is primarily due to our investment in marketable securities, partially offset by proceeds on the disposition of Novavax CZ assets of 192.6 million and lower expenditures on equipment and leasehold improvements. Capital expenditures for the years ended December 31, 2024 and 2023 were \$13.1 million and \$53.8 million, respectively.

Net cash provided by financing activities was \$260.6 million for 2024, as compared to \$4.5 million in 2023. The increase in cash provided by financing activities is primarily as a result of the 2023 repayment of \$325.0 million of our 3.75% Convertible notes in 2023, partially offset by lower proceeds from the sale of shares under our August 2023 Sales Agreement and Sanofi Subscription Agreement, totaling \$263.3 million in 2024, as compared with proceeds from the sale of shares under our June 2021 Sales Agreement and August 2023 Sales Agreement and the sale of SK Shares, totaling \$360.2 million in 2023.

### **Going Concern**

The accompanying consolidated financial statements in Part II, Item 8, “Financial Statements and Supplementary Data,” of this Annual Report on Form 10-K have been prepared assuming that we will continue as a going concern within one year after the date that the financial statements are issued and contemplates the realization of assets and satisfaction of liabilities in the ordinary course of business. At December 31, 2024, we had \$530.2 million in cash and cash equivalents, \$392.9 million in marketable securities, and had negative working capital of \$25.5 million. During 2024, we incurred a net loss of \$187.5 million and had net cash flows used in operating activities of \$87.3 million.

In accordance with Accounting Standards Codification (“ASC”) Topic 205-40, *Presentation of Financial Statements - Going Concern*, we evaluated our ability to continue as a going concern within one year after the date that the accompanying consolidated financial statements are issued. Based on our current cash, cash equivalents and marketable securities balances and our current cash flow forecast for the one-year going concern look forward period, we concluded that we expect to have sufficient capital available to fund our operations for the one-year period from the date that these financial statements are issued. As of December 31, 2023, we had concluded that there was substantial doubt about our ability to continue as a going concern primarily due to significant uncertainty related to our ability to successfully develop, manufacture, distribute, and market our COVID-19 Vaccine and execute on certain cost-reduction initiatives. The Sanofi CLA, combined with proceeds from the disposition of assets held by Novavax CZ, cost reductions and the settlement of certain liabilities, alleviated the substantial doubt.

### **Contractual Obligations**

The following table summarizes our contractual obligations as of December 31, 2024 (in thousands):

Contractual Obligations:	Total	Less than One Year	1 – 3 Years	3 – 5 Years	More than 5 Years
Operating leases	\$ 37,603	10,855	14,231	11,113	1,404
Finance leases obligation	98,019	12,187	15,306	15,501	55,025
Convertible notes payable <sup>(1)</sup>	175,250	—	175,250	—	—
Contractual obligations recognized as of December 31, 2024	310,872	23,042	204,787	26,614	56,429
Purchase commitments <sup>(2)</sup>	36,701	33,893	2,699	72	37
Total contractual obligations	<u>\$ 347,573</u>	<u>\$ 56,935</u>	<u>\$ 207,486</u>	<u>\$ 26,686</u>	<u>\$ 56,466</u>

1) In 2022, we issued \$175.3 million of 5.00% convertible senior unsecured notes due in 2027.

2) Purchase commitments primarily represent our non-cancelable fixed payment obligations under certain CMO, CDMO, and laboratory supply agreements that we are not contractually able to terminate for convenience. Certain agreements provide for termination rights subject to termination fees. Under such agreements, we are contractually obligated to make payments to vendors, mainly to reimburse them for their estimated unrecoverable expenses incurred. As of December 31, 2024, these agreements are active ongoing arrangements and we expect to receive value from these arrangements in the future. The amount of such obligations is dependent on the timing of termination and the terms of the relevant agreement, and cannot be reasonably estimated. Our current obligations under non-cancelable purchase agreements are reflected on our consolidated balance sheets.

In addition to the above obligations, we enter into a variety of agreements and financial commitments in the normal course of business. The terms generally allow us the option to cancel, reschedule, or adjust our requirements based on our business needs, prior to the delivery of goods or performance of services. It is not possible to predict the maximum potential amount of future payments under these agreements due to the conditional nature of our obligations and the unique facts and circumstances involved in each particular agreement.

## **Item 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

We are subject to certain risks that may affect our results of operations, cash flows, and fair values of assets and liabilities, including volatility in foreign currency exchange rates and interest rate movements.

### ***Foreign Currency Exchange Risk***

Although we are headquartered in the U.S. our results of operations, including our foreign subsidiaries' operations, are subject to foreign currency exchange rate fluctuations, primarily the U.S. dollar against the Euro, Swedish Krona and Czech Koruna. This exchange exposure may have a material effect on our cash and cash equivalents, cash flows, and results of operations, particularly in cases of revenue generated under APAs that include provisions that impact our and our counterparty's currency exchange exposure. To date, we have not entered into any foreign currency hedging contracts, although we may do so in the future.

We also face foreign currency exchange exposure that arises from translating the results of our global operations to the U.S. dollar at exchange rates that have fluctuated from the beginning of the period. While the financial results of our global activities are reported in U.S. dollars, the functional currency for our foreign subsidiaries is generally their respective local currency. Fluctuations in the foreign currency exchange rates of the countries in which we do business will affect our operating results, often in ways that are difficult to predict. A 10% decline in the foreign exchange rates (primarily against the U.S. dollar) relating to our foreign subsidiaries would result in a increase in stockholders' deficit of approximately \$57 million as of December 31, 2024.

### ***Market and Interest Rate Risk***

The primary objective of our investment activities is preservation of capital, with the secondary objective of maximizing income.

Our exposure to interest rate risk is primarily confined to our investment portfolio. We do not believe that a change in the market rates of interest would have any significant impact on the realizable value of our investment portfolio. Changes in interest rates may affect the investment income we earn on our marketable securities when they mature and the proceeds are reinvested into new marketable securities and, therefore, could impact our cash flows and results of operations.

Interest and dividend income is recorded when earned and included in investment income. Premiums and discounts, if any, on marketable securities are amortized or accreted to maturity and included in investment income. The specific identification method is used in computing realized gains and losses on the sale of our securities.

Our convertible senior unsecured notes have a fixed interest rate and we have no additional material debt. As such, we do not believe that we are exposed to any material interest rate risk as a result of our borrowing activities.

## **Item 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA**

The information required by this item is set forth on pages F-1 to F-47.

## **Item 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE**

None.

## **Item 9A. CONTROLS AND PROCEDURES**

### ***Evaluation of Disclosure Controls and Procedures***

The term "disclosure controls and procedures" (defined in SEC Rule 13a-15(e)) refers to the controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files under the Securities Exchange Act of 1934 (the "Exchange Act") is recorded, processed, summarized, and reported, within time periods specified in the rules and forms of the Securities and Exchange Commission. "Disclosure controls and procedures" include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its principal executive and financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure.

The Company's management, with the participation of the chief executive officer and the chief financial officer, has evaluated the effectiveness of the Company's disclosure controls and procedures as of the end of the period covered by this Annual Report on Form 10-K (the "Evaluation Date"). Based on that evaluation, the Company's chief executive officer and chief financial officer have concluded that the Company's disclosure controls and procedures were not effective because of the material weakness identified in the operation of certain IT general controls described below.

### ***Management's Report on Internal Control over Financial Reporting***

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting is defined in Rules 13a-15(f) and 15d-15(f) promulgated under the Exchange Act, as a process designed by, or under the supervision of, the Company's principal executive officer and principal financial officer and effected by the Company's board of directors, management, and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with GAAP. Such internal control includes those policies and procedures that:

- pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of the assets of the Company;
- provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with GAAP, and that receipts and expenditures of the Company are being made only in accordance with authorizations of management and directors of the Company; and
- provide reasonable assurance regarding prevention or timely detection of an unauthorized acquisition, use, or disposition of the Company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Our management assessed the effectiveness of our internal control over financial reporting as of December 31, 2024. In making this assessment, management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in Internal Control- Integrated Framework (2013 Framework). Based on its assessment, our management has determined that, as of December 31, 2024, our internal controls over financial reporting were not effective because of the following identified material weakness:

- **IT general controls deficiencies.** These deficiencies specifically related to ineffective change management review and periodic access review controls, with respect to the Company's human resources information system ("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. Management performed additional substantive procedures and concluded that there were no instances of inappropriate access, unauthorized 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 the Company's annual or interim consolidated financial statements that would not be detected. Accordingly, we determined that the deficiencies when considered in aggregate constituted a material weakness.

Management is in the process of implementing measures designed to remediate the control deficiencies that led to material weaknesses as of December 31, 2024, and have begun to implement the following steps:

- Enhancing the assignment of control responsibilities and accountability to responsible operational and IT personnel;
- Improving oversight by senior management;
- Additional training for control performers of controls related to human resources and payroll processing; and
- Designing and implementing appropriate compensating controls.

The material weakness will not be remediated until ITGC controls operate for a sufficient period and management has concluded, through testing, that these controls are operating effectively.

Ernst & Young LLP has issued a report on our internal control over financial reporting. This report is included in the Reports of Independent Registered Public Accounting Firm in Item 15(a)(1).

***Changes in Internal Control over Financial Reporting***

Our management, including our chief executive officer and chief financial officer, has evaluated changes in our internal control over financial reporting that occurred during the year ended December 31, 2024 and, other than controls related to the HRIS discussed above, has concluded that there was no change that occurred during the year ended December 31, 2024 that materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

**Item 9B. OTHER INFORMATION**

During the three months ended December 31, 2024, no director or “officer” (as defined in Rule 16a-1(f) under the Securities Exchange Act of 1934, as amended) adopted or terminated a “Rule 10b5-1 trading arrangement” or “non-Rule 10b5-1 trading arrangement” as each term is defined in Item 408(a) of Regulation S-K.

**Item 9C. DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS**

Not applicable.



### PART III

#### Item 10. DIRECTORS, EXECUTIVE OFFICERS, AND CORPORATE GOVERNANCE

The information required by this item is incorporated by reference from our definitive Proxy Statement for our 2025 Annual Meeting of Stockholders scheduled to be held in June 2025 (the "2025 Proxy Statement"). We expect to file the 2025 Proxy Statement within 120 days after the close of the fiscal year ended December 31, 2024.

#### Item 11. EXECUTIVE COMPENSATION

We incorporate herein by reference the information required by this item concerning executive compensation to be contained in the 2025 Proxy Statement.

#### Item 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

We incorporate herein by reference the information required by this item concerning security ownership of certain beneficial owners and management and related stockholder matters to be contained in the 2025 Proxy Statement.

The following table provides our equity compensation plan information as of December 31, 2024. Under these plans, our common stock may be issued upon the exercise or vesting of equity awards and purchases under our Employee Stock Purchase Plan ("ESPP"). See also the information regarding our equity awards and ESPP in Note 13 to the consolidated financial statements included herewith.

##### Equity Compensation Plan Information

Plan Category	Number of Securities to be Issued Upon Exercise of Outstanding Options, Warrants and Rights (a)	Weighted-Average Exercise Price of Outstanding Options, Warrants and Rights (b)	Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (Excluding Securities Reflected in Column (a)) (c)
Equity compensation plans approved by security holders <sup>(1)</sup>	9,054,694	\$ 32.75	12,098,144
Equity compensation plans not approved by security holders (Inducement Plan) <sup>(2)</sup>	772,379	\$ 10.45	106,290
Total	9,827,073	\$ 30.02	12,204,434

1) Includes our 2015 Stock Incentive Plan and ESPP. The weighted-average exercise price in column (b) excludes restricted stock units, which are not subject to an exercise price.

2) Includes our 2023 Inducement Plan only.

#### Item 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

We incorporate herein by reference the information required by this item concerning certain relationships and related transactions and director independence to be contained in the 2025 Proxy Statement.

#### Item 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

We incorporate herein by reference the information required by this item concerning principal accountant fees and services to be contained in the 2025 Proxy Statement.

## PART IV

### Item 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

(a) The following documents are filed as part of the Annual Report on Form 10-K:

(1) Index to Financial Statements

<u>Reports of Independent Registered Public Accounting Firm (PCAOB ID:42)</u>	<u>F- 2</u>
<u>Consolidated Statements of Operations and Statements of Comprehensive Loss for the years ended December 31, 2024, 2023, and 2022</u>	<u>F- 7</u>
<u>Consolidated Balance Sheets as of December 31, 2024 and 2023</u>	<u>F- 8</u>
<u>Consolidated Statements of Stockholders' Deficit for the years ended December 31, 2024, 2023, and 2022</u>	<u>F- 9</u>
<u>Consolidated Statements of Cash Flows for the years ended December 31, 2024, 2023, and 2022</u>	<u>F- 10</u>
<u>Notes to Consolidated Financial Statements</u>	<u>F- 11</u>

(2) Financial Statement Schedules

Financial statement schedules are omitted because they are not applicable, not required under the instructions or all the information required is set forth in the financial statements or notes thereto.

(3) Exhibits

Exhibits marked with a single asterisk (\*) are filed herewith.

Exhibits marked with a double plus sign (++) refer to management contracts, compensatory plans, or arrangements.

Confidential information contained in exhibits marked with a caret (^) has been omitted pursuant to Item 601(b)(10)(iv) of Regulation S-K.

All other exhibits listed have previously been filed with the SEC and are incorporated herein by reference.

#### Exhibit list

Exhibit Number	Description
2.1 <sup>^*</sup>	Asset Purchase Agreement, by and between Novavax CZ a.s., Novo Nordisk Production Czech s.r.o. and Novo Nordisk A/S, dated as of December 3, 2024.
3.1	Second Amended and Restated Certificate of Incorporation of the Company (Incorporated by reference to Exhibit 3.1 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2015, filed on August 10, 2015 (File No. 000-26770))
3.2	Certificate of Amendment to the Second Amended and Restated Certificate of Incorporation of the Company (Incorporated by reference to Exhibit 3.2 to the Company's Current Report on Form 8-K filed on May 9, 2019 (File No. 000-26770))
3.3	Amended and Restated By-Laws of the Company (Incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed on April 4, 2023 (File No. 000-26770))
3.4	Certificate of Designation of Series A Convertible Preferred Stock of the Registrant (Incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed June 19, 2020 (File No. 000-26770))
4.1	Specimen stock certificate for shares of common stock of the Company, par value \$.01 per share (Incorporated by reference to Exhibit 4.1 to the Company's Registration Statement on Form S-3, filed on December 31, 2019 (File No. 333-235761))

4.2	Indenture (including form of Notes) with respect to the Company's 5.00% Convertible Senior Notes due 2027, dated as of December 20, 2022, between the Company and The Bank of New York Mellon Trust Company, N.A., as trustee (Incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K, filed on December 21, 2022 (File No. 000-26770))
4.3	Form of Series A Convertible Preferred Stock Certificate of the Company (Incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed June 19, 2020 (File No. 000-26770))
4.4*	Description of the Company's Securities
10.1++	The Company's Amended and Restated 2005 Stock Incentive Plan (Incorporated by reference to Exhibit 10.2 to the Company's Annual Report on Form 10-K for the year ended December 31, 2012, filed on March 12, 2013 (File No. 000-26770))
10.2++	Amendment to Amended and Restated 2005 Stock Incentive Plan (Incorporated by reference to Appendix 1 of the Company's Definitive Proxy Statement filed on April 30, 2014 in connection with the Annual Meeting held on June 12, 2014 (File No. 000-26770))
10.3++	Form of Non-Statutory Stock Option Award Agreement granted under the Company's Amended and Restated 2005 Stock Incentive Plan (Incorporated by reference to Exhibit 10.4 to the Company's Annual Report on Form 10-K for the year ended December 31, 2014, filed on February 27, 2015 (File No. 000-26770))
10.4++	Form of Incentive Stock Option Award Agreement granted under the Company's Amended and Restated 2005 Stock Incentive Plan (Incorporated by reference to Exhibit 10.5 to the Company's Annual Report on Form 10-K for the year ended December 31, 2014, filed on February 27, 2015 (File No. 000-26770))
10.5++	Amended and Restated Novavax, Inc. 2013 Employee Stock Purchase Plan (Incorporated by reference to Appendix D of the Company's Definitive Proxy Statement filed on May 2, 2022 in connection with the Annual Meeting held on June 16, 2022 (File No. 000-26770))
10.6++	Amended and Restated Novavax, Inc. 2015 Stock Incentive Plan (Incorporated by reference to Appendix B of the Company's Definitive Proxy Statement filed on April 28, 2023 in connection with the Annual Meeting held on July 11, 2023 (File No. 000-26770))
10.7++	Form of Non-Statutory Stock Option Award Agreement granted under the Amended and Restated Novavax, Inc. 2015 Stock Incentive Plan (Incorporated by reference to Exhibit 10.3 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2015, filed on August 10, 2015 (File
10.8++	Form of Non-Statutory Stock Option Award Agreement (Non-Employee Director) granted under the Company's Amended and Restated 2015 Stock Incentive Plan (Incorporated by reference to Exhibit 10.9 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2023, filed on August 8, 2023 (File No. 000-26770))
10.9++	Form of Global Non-Statutory Stock Option Award Agreement granted under the Company's Amended and Restated 2015 Stock Incentive Plan (Incorporated by reference to Exhibit 10.10 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2023, filed on August 8, 2023 (File No. 000-
10.10++	Form of Incentive Stock Option Award Agreement granted under the Amended and Restated Novavax, Inc. 2015 Stock Incentive Plan (Incorporated by reference to Exhibit 10.4 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2015, filed on August 10, 2015 (File No. 000-26770))
10.11++	Form of Incentive Stock Option Award Agreement granted under the Amended and Restated Novavax, Inc. 2015 Stock Incentive Plan (Incorporated by reference to Exhibit 10.9 to the Company's Annual Report on Form 10-K for the year ended December 31, 2016, filed on February 27, 2017 (File No. 000-26770))
10.12++	Form of Incentive Stock Option Agreement granted under the Amended and Restated Novavax, Inc. 2015 Stock Incentive Plan (Performance- and Time-Based Vesting) (Incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K, filed on November 16, 2016 (File No. 000-26770))
10.13++	Form of Restricted Stock Award Agreement granted under the Amended and Restated Novavax, Inc. 2015 Stock Incentive Plan (Incorporated by reference to Exhibit 10.5 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2015, filed on August 10, 2015 (File No. 000-26770))

10.14++	Form of Restricted Stock Unit Agreement granted under the Amended and Restated Novavax, Inc. 2015 Stock Incentive Plan (Incorporated by reference to Exhibit 10.12 to the Company's Annual Report on Form 10-K for the year ended December 31, 2019, filed on March 18, 2019 (File No. 000-26770))
10.15++	Form of Restricted Stock Unit Award Agreement (Non-Employee Director) granted under the Company's Amended and Restated 2015 Stock Incentive Plan (Incorporated by reference to Exhibit 10.11 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2023, filed on August 8, 2023 (File No. 000-26770))
10.16++	Form of Global Restricted Stock Unit Award Agreement granted under the Company's Amended and Restated 2015 Stock Incentive Plan (Incorporated by reference to Exhibit 10.12 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2023, filed on August 8, 2023 (File No. 000-26770))
10.17++	Form of Stock Appreciation Right Award Agreement granted under the Amended and Restated Novavax, Inc. 2015 Stock Incentive Plan (Incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2019, filed on November 7, 2019 (File No. 000-26770))
10.18++	Form of Director Deferred Fee Agreement (Incorporated by reference to Exhibit 10.10 to the Company's Annual Report on Form 10-K for the year ended December 31, 2015, filed on February 29, 2016 (File No. 000-26770))
10.19++	Novavax, Inc. 2023 Inducement Plan (Incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K, filed on January 9, 2023 (File No. 000-26770))
10.20++	Form of Non-Statutory Stock Option Agreement under the Novavax, Inc. 2023 Inducement Plan (Incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K, filed on January 9, 2023 (File No. 000-26770))
10.21++	Form of Restricted Stock Unit Award Agreement under the Novavax, Inc. 2023 Inducement Plan (Incorporated by reference to Exhibit 10.3 to the Company's Current Report on Form 8-K, filed on January 9, 2023 (File No. 000-26770))
10.22++	Employment Agreement between the Company and John C. Jacobs, dated as of January 5, 2023 (Incorporated by reference to Exhibit 10.18 to the Company's Annual Report on Form 10-K, filed on February 28, 2023 (File No. 000-26770))
10.23++	Employment Agreement between the Company and Stanley C. Erck, dated as of June 22, 2011 (Incorporated by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2011, filed on August 9, 2011 (File No. 000-26770))
10.24++	Consulting and Advisory Agreement between the Company and Stanley C. Erck, dated as of January 5, 2023 (Incorporated by reference to Exhibit 10.20 to the Company's Annual Report on Form 10-K, filed on February 28, 2023 (File No. 000-26770))
10.25++	Employment Agreement between the Company and Gregory M. Glenn dated July 1, 2010 (Incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K, filed on July 6, 2010 (File No. 000-26770))
10.26++	Consulting and Advisory Agreement between the Company and Dr. Gregory M. Glenn, dated as of March 20, 2023 (Incorporated by reference to Exhibit 10.4 to the Company's Quarterly Report on Form 10-Q filed on May 9, 2023 (File No. 000-26770))
10.27++	Employment Agreement between the Company and John A. Herrmann dated April 1, 2012 (Incorporated by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2016, filed on May 5, 2016 (File No. 000-26770))
10.28++*	Consulting and Advisory Agreement between the Company and John A. Herrmann, dated as of November 17, 2023
10.29++	Employment Agreement between the Company and John J. Trizzino dated March 3, 2014 (Incorporated by reference to Exhibit 10.3 to the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2016, filed on May 5, 2016 (File No. 000-26770))

10.30 <sup>++</sup>	Employment Agreement between the Company and James P. Kelly dated July 12, 2021 (Incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2021, filed on November 5, 2021 (File No. 000-26770))
10.31 <sup>++</sup>	Offer letter to James P. Kelly dated July 12, 2021 (Incorporated by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2021, filed on November 5, 2021 (File No. 000-26770))
10.32 <sup>++*</sup>	Offer letter to Mark Casey dated November 10, 2023
10.33 <sup>++*</sup>	Employment Agreement between the Company and Mark Casey dated November 10, 2023
10.34 <sup>++*</sup>	Offer Letter to Elaine O'Hara dated February 4, 2023
10.35 <sup>++*</sup>	Employment Agreement between the Company and Elaine O'Hara dated February 4, 2023
10.36 <sup>++</sup>	Form of Amendment to Employment Agreement, dated June 17, 2021, between the Company and each of Stanley C. Erck, Gregory M. Glenn, John J. Trizzino, Filip Dubovsky, and John A. Herrmann, III (Incorporated by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2021, filed on August 5, 2021 (File No. 000-26770))
10.37 <sup>+</sup>	Company Amended and Restated Change in Control Severance Benefit Plan (Incorporated by reference to Exhibit 10.4 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2021, filed on August 5, 2021 (File No. 000-26770))
10.38 <sup>++</sup>	Form of Indemnification Agreement entered into between the Company and its directors and officers (Incorporated by reference to Exhibit 10.19 to the Company's Annual Report on Form 10-K for the year ended December 31, 2009, filed on March 16, 2010 (File No. 000-26770))
10.39	Lease Agreement for space at 22 Firstfield Road between ARE-20/22/1300 Firstfield Quince Orchard, LLC and the Company, dated as of November 18, 2011 (Incorporated by reference to Exhibit 10.25 to the Company's Annual Report on Form 10-K for the year ended December 31, 2011, filed on March 14, 2012 (File No. 000-26770))
10.40	Deed of Lease for space at 21 Firstfield Road between Firstfield Holdco, LLC and the Company, dated as of February 4, 2015 (Incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K, filed on August 21, 2015 (File No. 000-26770))
10.41	First Amendment to Deed of Lease for space at 21 Firstfield Road between Firstfield Holdco, LLC and the Company, dated as of August 17, 2015 (Incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K, filed on August 21, 2015 (File No. 000-26770))
10.42	Second Amendment to Deed of Lease for space at 21 Firstfield Road between BMR-Firstfield LLC (formerly Firstfield Holdco, LLC) and the Company, dated as of March 31, 2017 (Incorporated by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2017, filed on May 8, 2017 (File No. 000-26770))
10.43	Deed of Lease for space at 700 Quince Orchard Road between ARE-MARYLAND NO. 51, LLC and the Company, dated October 22, 2020 (Incorporated by reference to Exhibit 10.27 to the Company's Annual Report on Form 10-K for the year ended December 31, 2020, filed on March 1, 2021 (File No. 000-26770))
10.44	Amendment to Deed of Lease for space at 700 Quince Orchard Road between ARE-MARYLAND NO. 51, LLC and the Company, dated June 22, 2021 (Incorporated by reference to Exhibit 10.33 to the Company's Annual Report on Form 10-K for the year ended December 31, 2021, filed on March 1, 2022 (File No. 000-26770))
10.45 <sup>^</sup>	Amended and Restated Supply and License Agreement, dated July 1, 2021, between the Company and Serum Institute of India Private Limited (Incorporated by reference to Exhibit 10.4 to the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2021, filed on November 5, 2021 (File No. 000-26770))

- 10.46^ Supply Agreement between the Company, Serum Institute of India Private Limited and Serum Life Sciences Limited, executed as of October 26, 2021 (Incorporated by reference to Exhibit 10.37 to the Company's Annual Report on Form 10-K for the year ended December 31, 2021, filed on March 1, 2022 (File No. 000-26770))
- 10.47^ Contract Development Manufacture Agreement, dated October 21, 2021, between the Company and Serum Life Sciences Limited (Incorporated by reference to Exhibit 10.3 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2022, filed on August 9, 2022 (File No. 000-26770))
- 10.48^ Amendment No. 1 to the Contract Development Manufacture Agreement, executed as of April 29, 2022, between the Company and Serum Life Sciences Limited (Incorporated by reference to Exhibit 10.4 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2022, filed on August 9, 2022 (File No. 000-26770))
- 10.49^ Statement of Work No. 1 to the Contract Development Manufacture Agreement, effective as of April 29, 2022, between the Company and Serum Life Sciences Limited (Incorporated by reference to Exhibit 10.5 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2022, filed on August 9, 2022 (File No. 000-26770))
- 10.50^ Collaboration and Exclusive License Agreement between the Company and SK bioscience Company Limited, dated as of February 12, 2021 (Incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2021, filed on May 10, 2021 (File No. 000-26770))
- 10.51^ First Amendment to Collaboration and Exclusive License Agreement between the Company and SK bioscience Company Limited, dated as of December 23, 2021 (Incorporated by reference to Exhibit 10.39 to the Company's Annual Report on Form 10-K for the year ended December 31, 2021, filed on March 1, 2022 (File No. 000-26770))
- 10.52^ Collaboration and Exclusive License Agreement between the Company and Takeda Pharmaceutical Company Limited, dated as of February 24, 2021 (Incorporated by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2021, filed on May 10, 2021 (File No. 000-26770))
- 10.53^ Amended and Restated SARS-CoV-2 Vaccine Supply Agreement, dated as of July 1, 2022, between the Company and The Secretary of State for Business, Energy and Industrial Strategy, acting on behalf of the government of the United Kingdom of Great Britain and Northern Ireland (Incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2022, filed on November 9, 2022 (File No. 000-26770))
- 10.54^ Letter of Amendment to the Amended and Restated SARS-CoV-2 Vaccine Supply Agreement, dated as of September 26, 2022, between the Company and The Secretary of State for Business, Energy and Industrial Strategy, acting on behalf of the government of the United Kingdom of Great Britain and Northern Ireland (Incorporated by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2022, filed on November 9, 2022 (File No. 000-26770))
- 10.55^ Advanced Purchase Agreement, effective as of December 31, 2020, between the Company and the Commonwealth of Australia as represented by the Department of Health (Incorporated by reference to Exhibit 10.36 to the Company's Annual Report on Form 10-K for the year ended December 31, 2020, filed on March 1, 2021 (File No. 000-26770))
- 10.56^ Amendment to Advanced Purchase Agreement between the Company, and the Commonwealth of Australia as represented by the Department of Health, dated as of December 23, 2021 (Incorporated by reference to Exhibit 10.47 to the Company's Annual Report on Form 10-K for the year ended December 31, 2021, filed on March 1, 2022 (File No. 000-26770))
- 10.57^ Amendment No. 2 to Advanced Purchase Agreement, dated as of April 6, 2022, between the Company and the Commonwealth of Australia as Represented by the Department of Health (Incorporated by reference to Exhibit 10.6 to the Company's Quarterly Report on Form 10-Q filed on August, 8 2023 (File No. 000-26770))



10.58^	Amendment No. 3 to Advanced Purchase Agreement, dated as of April 5, 2023, between the Company and the Commonwealth of Australia as Represented by the Department of Health (Incorporated by reference to Exhibit 10.7 to the Company's Quarterly Report on Form 10-Q filed on August, 8 2023 (File No. 000-26770))
10.59^	Amendment No. 4 to Advanced Purchase Agreement, dated as of July 5, 2023, between the Company and the Commonwealth of Australia as Represented by the Department of Health (Incorporated by reference to Exhibit 10.8 to the Company's Quarterly Report on Form 10-Q filed on August, 8 2023 (File No. 000-26770))
10.60^	Amendment No. 5 to Advanced Purchase Agreement, dated as of December 12, 2024, between the Company and the Commonwealth of Australia as Represented by the Department of Health
10.61^	Advanced Purchase Agreement, effective as of January 19, 2021, between the Company and Her Majesty the Queen in Right of Canada, as represented by the Minister of Public Works and Government Services (Incorporated by reference to Exhibit 10.37 to the Company's Annual Report on Form 10-K for the year ended December 31, 2020, filed on March 1, 2021 (File No. 000-26770))
10.62^	Amendment No. 1 to Advanced Purchase Agreement, effective as of January 26, 2022, between the Company and His Majesty the King in Right of Canada, as represented by the Minister of Public Works and Government Services, as successor in interest to Her Majesty the Queen in Right of Canada, as represented by the Minister of Public Works and Government Services (Incorporated by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q filed on August, 8 2023 (File No. 000-26770))
10.63^	Amendment No. 2 to Advanced Purchase Agreement, effective as of October 18, 2022, between the Company and His Majesty the King in Right of Canada, as represented by the Minister of Public Works and Government Services, as successor in interest to Her Majesty the Queen in Right of Canada, as represented by the Minister of Public Works and Government Services (Incorporated by reference to Exhibit 10.3 to the Company's Quarterly Report on Form 10-Q filed on August, 8 2023 (File No. 000-26770))
10.64^	Amendment No. 3 to Advanced Purchase Agreement, effective as of April 25, 2023, between the Company and His Majesty the King in Right of Canada, as represented by the Minister of Public Works and Government Services, as successor in interest to Her Majesty the Queen in Right of Canada, as represented by the Minister of Public Works and Government Services (Incorporated by reference to Exhibit 10.4 to the Company's Quarterly Report on Form 10-Q filed on August, 8 2023 (File No. 000-26770))
10.65^	Amendment No. 4 to Advanced Purchase Agreement, effective as of June 30, 2023, between the Company and His Majesty the King in Right of Canada, as represented by the Minister of Public Works and Government Services, as successor in interest to Her Majesty the Queen in Right of Canada, as represented by the Minister of Public Works and Government Services (Incorporated by reference to Exhibit 10.5 to the Company's Quarterly Report on Form 10-Q filed on August, 8 2023 (File No. 000-26770))
10.66^	Settlement Agreement and General Release, dated August 8, 2023, between the Company and SK bioscience Co., Ltd. (Incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2023, filed on November, 9 2023 (File No. 000-26770))
10.67^	Securities Subscription Agreement, dated as of August 8, 2023, between the Company and SK bioscience Co., Ltd. (Incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on August 8, 2023 (File No. 000-26770))
10.68^*	Termination and Settlement Agreement, dated as of February 16, 2024, between the Company and Gavi Alliance (Incorporated by reference to Exhibit 10.101 to the Company's Annual Report on Form 10-K for the year ended December 31, 2023, filed on February 28, 2024 (File No. 000-26770))
10.69^*	Termination and Settlement Agreement, dated November 1, 2024, by and between the Company and The Secretary of State for Health and Social Care, acting as part of the Crown, through the UK Health Security Agency
10.70^*	Letter Amendment to the Termination and Settlement Agreement, dated November 1, 2024, by and between the Company and The Secretary of State for Health and Social Care, acting as part of the Crown, through the UK Health Security Agency
14	Code of Conduct (Incorporated by reference to Exhibit 14 to the Company's Annual Report on Form 10-K for the year ended December 31, 2021, filed on March 1, 2022 (File No. 000-26770))
19	Insider Trading Policy

21*	Subsidiaries of the Company
23.1*	Consent of Ernst & Young LLP, Independent Registered Public Accounting Firm
31.1*	Certification of Chief Executive Officer pursuant to Rule 13a-14(a) or 15d-14(e) of the Securities Exchange Act
31.2*	Certification of Chief Financial Officer pursuant to Rule 13a-14(a) or 15d-14(e) of the Securities Exchange Act
32.1*	Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2*	Certification of Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
97*	Novavax, Inc. Amended and Restated Recoupment Policy
101	The following financial information from our Annual Report on Form 10-K for the year ended December 31, 2024, formatted in Extensible Business Reporting Language (XBRL): (i) the Consolidated Balance Sheets as of December 31, 2024 and 2023, (ii) the Consolidated Statements of Operations for the three years in the period ended December 31, 2024, (iii) the Consolidated Statements of Comprehensive Loss for the three years in the period ended December 31, 2024, (iv) the Consolidated Statements of Changes in Stockholders' Deficit for the three years in the period ended December 31, 2024, (v) the Consolidated Statements of Cash Flows for the three years in the period ended December 31, 2024, and (vi) the Notes to Consolidated
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101).

#### Item 16. FORM 10-K SUMMARY

Not applicable.

## SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

### NOVAVAX, INC.

By /s/ John C. Jacobs

John C. Jacobs

President and Chief Executive Officer

Date: February 27, 2025

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the Registrant and in the capacities and on the dates indicated:

Name	Title	Date
<u>/s/ John C. Jacobs</u> John C. Jacobs	President and Chief Executive Officer and Director (Principal Executive Officer)	February 27, 2025
<u>/s/ James P. Kelly</u> James P. Kelly	Executive Vice President, Chief Financial Officer, and Treasurer (Principal Financial and Accounting Officer)	February 27, 2025
<u>/s/ James F. Young</u> James F. Young	Chairman of the Board of Directors	February 27, 2025
<u>/s/ Gregg H. Alton</u> Gregg H. Alton	Director	February 27, 2025
<u>/s/ Richard H. Douglas</u> Richard H. Douglas	Director	February 27, 2025
<u>/s/ Rachel K. King</u> Rachel K. King	Director	February 27, 2025
<u>/s/ Margaret G. McGlynn</u> Margaret G. McGlynn	Director	February 27, 2025
<u>/s/ David M. Mott</u> David M. Mott	Director	February 27, 2025
<u>/s/ Richard J. Rodgers</u> Richard J. Rodgers	Director	February 27, 2025



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**Years ended December 31, 2024, 2023, and 2022**

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## ***Report of Independent Registered Public Accounting Firm***

To the Board of Directors and Stockholders of Novavax, Inc.

### **Opinion on the Financial Statements**

We have audited the accompanying consolidated balance sheets of Novavax, Inc. (the Company) as of December 31, 2024 and 2023, the related consolidated statements of operations, comprehensive loss, stockholders' deficit, and cash flows for each of the three years in the period ended December 31, 2024, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2024 and 2023, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2024, in conformity with U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the Company's internal control over financial reporting as of December 31, 2024, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) and our report dated February 27, 2025 expressed an adverse opinion thereon.

### **Basis for Opinion**

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

### **Critical Audit Matters**

The critical audit matters communicated below are matters arising from the current period audit of the financial statements that were communicated or required to be communicated to the audit committee and that: (1) relate to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matters below, providing a separate opinion on the critical audit matters or on the account or disclosures to which it relates.



### ***Revenue Recognition for Collaboration and Licensing Agreement with Sanofi***

#### ***Description of the Matter***

The Company recorded revenue from the collaboration and licensing agreement ("CLA") with Sanofi of \$459.3 million for the year ended December 31, 2024. As disclosed in Note 2 and Note 4, the terms of the Sanofi CLA include performance obligations related to the transfer of licenses for the Company's intellectual property and transition services. The transaction price includes nonrefundable upfront license fees, and may also include transition service fees, payments based upon the achievement of specified milestones, and royalty payments based on product sales from licensed products. The Company allocates the transaction price to each performance obligation based on its relative stand-alone selling price ("SSP"), which is estimated using discounted cash flows or expected cost-plus profit margin. Revenue related to the transition services performance obligations is recognized using an input method to measure progress utilizing actual costs incurred to-date relative to total expected costs.

Auditing the Company's accounting for revenue from the Sanofi CLA was complex and required significant judgment to identify which promises represented performance obligations to the customer. Also, due to the subjectivity of the assumptions driving the Company's SSP estimates, auditing these estimates required significant judgment. In addition, auditing the Company's progress towards the satisfaction of the transition services performance obligation also required significant judgment as it involves subjective management assumptions about future costs necessary to satisfy the performance obligations. The measurement and recognition of revenue for the Sanofi CLA is subject to these estimates and judgments developed by management.

#### ***How We Addressed the Matter in Our Audit***

Our audit procedures included, among others, reading the Sanofi CLA and evaluating the appropriateness of management's technical accounting analysis for the identification of performance obligations under the arrangement. To assess the reasonableness of the Company's estimate of SSP for the license performance obligation, we compared key assumptions, including forecasted revenue to available third-party sources, tested the accuracy and completeness of the underlying data used in making the estimates, and performed sensitivity analyses of key inputs. To assess the reasonableness of the Company's estimate for SSP for the transition services performance obligation, we inspected communications from the Company's research and development personnel who oversee the CLA and related clinical trials, compared the estimated future costs to third-party support, and performed sensitivity analyses of key inputs. With the assistance of our valuation specialists, we tested the methodology utilized for the calculation of SSP for each performance obligation, including the discount rates utilized, as well as the profit margin utilized for the transition services performance obligation. To test the measurement of efforts toward satisfying the transition services obligations recognized over time, we tested actual transition services costs incurred through December 31, 2024 and recalculated the revenue recognized for the period based on the ratio of costs incurred to date as compared to the total estimated costs through completion. We tested management's estimate of the remaining costs to complete the transition services as of December 31, 2024 by comparing the estimated future costs to third-party support, comparing actual costs incurred to date to prior estimates, inspecting updated communications from the Company's research and development personnel who oversee the CLA and related clinical trials, inspecting CLA steering committee minutes, and by performing sensitivity analysis of key inputs.

***Product Return Reserve Estimate - U.S. Commercial Sales***

*Description of  
the Matter*

As of December 31, 2024, the Company recorded a liability for estimated product returns related to US commercial sales of \$58.3 million. As disclosed in Note 2, the Company offers U.S. commercial customers the right to return its product. These return rights include the right of wholesale distributors and indirect customers to return expired doses. The Company estimates variable consideration resulting from these product returns based on quantitative and qualitative data from various internal and external sources.

Auditing management's estimate of product returns was complex and judgmental given the Company's limited history of U.S. commercial sales. In addition, there is significant estimation uncertainty involved in projecting market demand for the inventory in the distribution channel over the product shelf life.

*How We  
Addressed the  
Matter in Our  
Audit*

We obtained an understanding, evaluated the design, and tested the operating effectiveness of internal controls over the product return reserve estimation process for U.S. commercial sales, including management's review of the level of inventory in the distribution channel, as well as inputs and assumptions used to develop the estimate of the product returns reserve.

Our substantive audit procedures included, among others, testing the level of product in the channel held by the Company's wholesale distributors as of December 31, 2024 based upon shipments made to the wholesalers during the period and third-party chargeback data. For indirect customers, we obtained and reviewed the Company's analysis of estimated channel mix and compared relevant inputs to underlying third-party chargeback data. In addition, we assessed management's estimate of projected market demand for the product through the expiration dates, by analyzing available internal and third-party utilization and market size data for the product for the current vaccination season. We also evaluated the sensitivities of changes in projected demand on the product return reserve estimate recorded.

/s/ Ernst & Young LLP

We have served as the Company's auditor since 2014.

Tysons, Virginia  
February 27, 2025

## ***Report of Independent Registered Public Accounting Firm***

To the Board of Directors and Stockholders of  
Novavax, Inc.

### **Opinion on Internal Control over Financial Reporting**

We have audited Novavax, Inc.'s internal control over financial reporting as of December 31, 2024, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) (the COSO criteria). In our opinion, because of the effect of the material weakness described below on the achievement of the objectives of the control criteria, Novavax, Inc. (the Company) has not maintained effective internal control over financial reporting as of December 31, 2024, based on the COSO criteria.

A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the company's annual or interim financial statements will not be prevented or detected on a timely basis. The following material weakness has been identified and included in management's assessment. Management has identified a material weakness related to ineffective information technology (IT) general controls over change management and user access as well as the related process-level IT dependent manual controls and automated application controls across various processes impacted by a human resources information system ("HRIS") that was implemented in 2024.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the consolidated balance sheets of the Company as of December 31, 2024 and 2023, the related consolidated statements of operations, comprehensive loss, changes in stockholders' deficit, and cash flows for each of the three years in the period ended December 31, 2024, and the related notes. This material weakness was considered in determining the nature, timing and extent of audit tests applied in our audit of the 2024 consolidated financial statements, and this report does not affect our report dated February 27, 2025, which expressed an unqualified opinion thereon.

### **Basis for Opinion**

The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying *Management's Report on Internal Control over Financial Reporting* in Item 9A. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects.

Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

### **Definition and Limitations of Internal Control Over Financial Reporting**

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

/s/ Ernst & Young LLP

Tysons, Virginia  
February 27, 2025

**NOVAVAX, INC.**  
**CONSOLIDATED STATEMENTS OF OPERATIONS**  
(in thousands, except per share information)

	<b>Year Ended December 31,</b>		
	<b>2024</b>	<b>2023</b>	<b>2022</b>
Revenue:			
Product sales	\$ 190,212	\$ 531,389	\$
Licensing, royalties, and other	491,950	24,993	43,990
Grants	—	427,323	382,921
Total revenue	682,162	983,705	1,981,872
Expenses:			
Cost of sales	202,739	343,768	902,639
Research and development	391,169	737,502	1,235,278
Selling, general, and administrative	337,185	468,946	488,691
Total expenses	931,093	1,550,216	2,626,608
Loss from operations	(248,931)	(566,511)	(644,736)
Other income (expense):			
Interest expense	(20,075)	(14,416)	(19,880)
Gain on disposition of Novavax CZ assets	51,949	—	—
Other income	40,442	37,896	10,969
Loss before income tax expense	(176,615)	(543,031)	(653,647)
Income tax expense	(10,884)	(2,031)	(4,292)
Net loss	<u>\$ (187,499)</u>	<u>\$ (545,062)</u>	<u>\$ (657,939)</u>
Net loss per share:			
Basic and diluted	<u>\$ (1.23)</u>	<u>\$ (5.41)</u>	<u>\$ (8.42)</u>
Weighted average number of common shares outstanding:			
Basic and diluted	152,190	100,768	78,183

**CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS**  
(in thousands)

	<b>Year Ended December 31,</b>		
	<b>2024</b>	<b>2023</b>	<b>2022</b>
Net loss	\$ (187,499)	\$ (545,062)	\$ (657,939)
Other comprehensive income (loss):			
Net unrealized gains on marketable securities available-for-sale, net of reclassifications	40	—	—
Foreign currency translation adjustment	(25,321)	9,099	(5,024)
Other comprehensive income (loss)	(25,281)	9,099	(5,024)
Comprehensive loss	<u>\$ (212,780)</u>	<u>\$ (535,963)</u>	<u>\$ (662,963)</u>

The accompanying notes are an integral part of these financial statements.

**NOVAVAX, INC.**  
**CONSOLIDATED BALANCE SHEETS**  
(in thousands, except share and per share information)

	<b>December 31,</b>	
	<b>2024</b>	<b>2023</b>
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 530,230	\$ 568,505
Marketable securities	392,888	—
Restricted cash	10,626	10,424
Accounts receivable	108,285	297,240
Inventory	8,749	41,696
Prepaid expenses and other current assets	78,164	226,023
Total current assets	1,128,942	1,143,888
Property and equipment, net	138,413	305,771
Right of use asset, net	161,585	185,218
Goodwill	107,478	127,454
Other non-current assets	24,000	35,159
Total assets	<u>\$1,560,418</u>	<u>\$1,797,490</u>
<b>LIABILITIES AND STOCKHOLDERS' DEFICIT</b>		
Current liabilities:		
Accounts payable	\$ 41,579	\$ 132,610
Accrued expenses	211,165	394,668
Deferred revenue	675,067	241,310
Current portion of finance lease liabilities	7,009	5,142
Other current liabilities	219,596	861,408
Total current liabilities	1,154,416	1,635,138
Deferred revenue	446,819	622,210
Convertible notes payable	169,684	168,016
Non-current finance lease liabilities	53,726	55,923
Other non-current liabilities	359,614	33,130
Total liabilities	<u>2,184,259</u>	<u>2,514,417</u>
Commitments and contingencies (Note 17)		
Preferred stock, \$0.01 par value, 2,000,000 shares authorized at December 31, 2024 and 2023; no shares issued and outstanding at December 31, 2024 and 2023		
	—	—
Stockholders' deficit:		
Common stock, \$0.01 par value, 600,000,000 shares authorized at December 31, 2024 and 2023; and 161,942,677 shares issued and 160,421,136 shares outstanding at December 31, 2024 and 140,506,093 shares issued and 139,505,770 shares outstanding at December 31, 2023	1,619	1,405
Additional paid-in capital	4,501,403	4,192,164
Accumulated deficit	(5,008,450)	(4,820,951)
Treasury stock, 1,521,541 shares, cost basis at December 31, 2024 and 1,000,323 shares, cost basis at December 31, 2023	(95,854)	(92,267)
Accumulated other comprehensive income (loss)	(22,559)	2,722
Total stockholders' deficit	<u>(623,841)</u>	<u>(716,927)</u>
Total liabilities and stockholders' deficit	<u>\$1,560,418</u>	<u>\$1,797,490</u>

The accompanying notes are an integral part of these financial statements.



**NOVAVAX, INC.**  
**CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' DEFICIT**  
(in thousands, except share information)

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Treasury Stock	Accumulated Other Comprehensive Income (Loss)	Total Stockholders' Deficit
	Shares	Amount					
<b>Balance at December 31,</b>	<b>76,433,151</b>	<b>\$ 764</b>	<b>\$ 3,351,967</b>	<b>\$ (3,617,950)</b>	<b>\$ (85,101)</b>	<b>\$ (1,353)</b>	<b>\$ (351,673)</b>
Stock-based compensation	—	—	131,967	—	—	—	131,967
Stock issued under incentive programs	701,005	7	4,912	—	(5,558)	—	(639)
Issuance of common stock, net of issuance costs of \$7,216	9,672,398	97	249,133	—	—	—	249,230
Foreign currency translation adjustment	—	—	—	—	—	(5,024)	(5,024)
Net loss	—	—	—	(657,939)	—	—	(657,939)
<b>Balance at December 31,</b>	<b>86,806,554</b>	<b>868</b>	<b>3,737,979</b>	<b>(4,275,889)</b>	<b>(90,659)</b>	<b>(6,377)</b>	<b>(634,078)</b>
Stock-based compensation	—	—	85,850	—	—	—	85,850
Stock issued under incentive programs	902,742	9	1,758	—	(1,608)	—	159
Issuance of common stock, net of issuance costs of \$6,171	52,796,797	528	366,577	—	—	—	367,105
Foreign currency translation adjustment	—	—	—	—	—	9,099	9,099
Net loss	—	—	—	(545,062)	—	—	(545,062)
<b>Balance at December 31,</b>	<b>140,506,093</b>	<b>1,405</b>	<b>4,192,164</b>	<b>(4,820,951)</b>	<b>(92,267)</b>	<b>2,722</b>	<b>(716,927)</b>
Stock-based compensation	—	—	48,152	—	—	—	48,152
Stock issued under incentive programs	2,343,187	23	4,869	—	(3,587)	—	1,305
Issuance of common stock, net of issuance costs of \$3,830	19,093,397	191	256,218	—	—	—	256,409
Unrealized gain on available-for-sale marketable securities	—	—	—	—	—	40	40
Foreign currency translation adjustment	—	—	—	—	—	(25,321)	(25,321)
Net loss	—	—	—	(187,499)	—	—	(187,499)
<b>Balance at December 31,</b>	<b>161,942,677</b>	<b>\$ 1,619</b>	<b>\$ 4,501,403</b>	<b>\$ (5,008,450)</b>	<b>\$ (95,854)</b>	<b>\$ (22,559)</b>	<b>\$ (623,841)</b>

The accompanying notes are an integral part of these financial statements.

**NOVAVAX, INC.**  
**CONSOLIDATED STATEMENTS OF CASH FLOWS**  
(in thousands)

	Year Ended December 31,		
	2024	2023	2022
<b>Operating Activities:</b>			
Net loss	\$ (187,499)	\$ (545,062)	\$ (657,939)
Reconciliation of net loss to net cash used in operating activities:			
Depreciation and amortization	48,496	41,225	29,054
Gain on disposition of Novavax CZ assets	(51,949)	—	—
Right-of-use assets expensed, net of credits received	3,762	6,113	18,104
Non-cash stock-based compensation	48,152	85,357	130,300
Provision for excess and obsolete inventory	20,970	72,197	447,597
Impairment of long-lived assets	4,132	10,081	—
Other items, net	(21,809)	(7,042)	(21,903)
Changes in operating assets and liabilities:			
Inventory	12,914	(74,457)	(477,801)
Accounts receivable, prepaid expenses, and other assets	354,089	(274,442)	249,166
Accounts payable, accrued expenses, and other liabilities	(385,626)	(378,805)	913,399
Deferred revenue	67,105	350,868	(1,045,914)
Net cash used in operating activities	(87,263)	(713,967)	(415,937)
<b>Investing Activities:</b>			
Capital expenditures	(13,057)	(53,771)	(89,056)
Internal-use software	(1,582)	(5,035)	(3,929)
Proceeds from disposition of Novavax CZ assets	192,643	—	—
Purchases of marketable securities	(825,593)	—	—
Proceeds from maturities of marketable securities	443,551	—	—
Net cash used in investing activities	(204,038)	(58,806)	(92,985)
<b>Financing Activities:</b>			
Net proceeds from sales of common stock	263,272	360,243	249,230
Proceeds from issuance of 2027 Convertible notes	—	—	175,250
Payments of costs related to issuance of 2027 Convertible notes	—	(3,591)	(5,258)
Net proceeds from the exercise of stock-based awards	1,305	159	(639)
Repayment of 2023 Convertible notes	—	(325,000)	—
Finance lease payments	(3,994)	(27,345)	(93,595)
Net cash provided by financing activities	260,583	4,466	324,988
Effect of exchange rate on cash, cash equivalents, and restricted cash	(7,800)	3,272	4,520
Net decrease in cash, cash equivalents, and restricted cash	(38,518)	(765,035)	(179,414)
Cash, cash equivalents, and restricted cash at beginning of year	583,810	1,348,845	1,528,259
Cash, cash equivalents, and restricted cash at end of year	<u>\$ 545,292</u>	<u>\$ 583,810</u>	<u>\$ 1,348,845</u>
<b>Supplemental disclosure of non-cash activities:</b>			
Sale of common stock under the Sales Agreement not settled at year-end	\$ —	\$ 6,862	\$ —
Capital expenditures included in accounts payable and accrued expenses	\$ 1,063	\$ 7,899	\$ 17,665
Right-of-use assets from new lease agreements, net of tenant improvement allowance on facility leases	\$ (4,302)	\$ 103,299	\$ 91,855
<b>Supplemental disclosure of cash flow information:</b>			
Cash interest payments, net of amounts capitalized	\$ 17,572	\$ 17,349	\$ 18,035
Cash paid for income taxes, net of refunds received	\$ 949	\$ 190	\$ 17,980

The accompanying notes are an integral part of these financial statements.

**NOVAVAX, INC.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**Note 1 – Organization & Business**

Novavax, Inc. ("Novavax," and together with its wholly owned subsidiaries, the "Company") is tackling global health challenges through scientific innovation that seeks to maximize its deep scientific expertise in vaccines and cutting-edge technology platform. The differentiated platform features the Company's recombinant protein-based nanoparticle technology and its unique Matrix-M™ adjuvant.

The Company's corporate growth strategy is focused on delivering value through in-house early-stage research and development ("R&D") to build a pipeline of high-value assets using its proven technology along with seeking to enter into partnerships to drive value creation for its R&D assets early in the development process and for Matrix-M™ adjuvant alone. The Company's three strategic priorities are: focusing on its partnership with Sanofi Pasteur Inc. ("Sanofi") announced in May 2024, leveraging its technology platform and pipeline to forge additional partnerships, and advancing its proven technology platform and early-stage pipeline.

In May 2024, Novavax entered into a Collaboration and License Agreement with Sanofi (the "Sanofi CLA"), to co-commercialize the Company's COVID-19 vaccine, including future updated versions that address seasonal COVID-19 variants. Under the terms of the agreement, the Company will continue to commercialize its updated COVID-19 vaccine through the end of the 2024-2025 vaccination season. Beginning in 2025 and continuing during the term of the Sanofi CLA, the Company and Sanofi will commercialize the COVID-19 vaccine worldwide in accordance with a commercialization plan agreed by the parties, under which Novavax will continue to supply certain of its existing advance purchase agreement ("APA") customers and strategic partners, including Takeda Pharmaceutical Company Limited ("Takeda") and Serum Institute of India Pvt. Ltd. ("SII"). Upon completion of the existing APAs, the Company and Sanofi will jointly agree on commercialization activities of each party in each jurisdiction. Additionally, Sanofi has the right to develop novel influenza-COVID-19 combination vaccines utilizing Novavax's COVID-19 vaccine and Sanofi's seasonal influenza vaccine, combination products containing Novavax's COVID-19 vaccine and one or more non-influenza vaccines, and multiple new vaccines utilizing Novavax's Matrix-M™ adjuvant.

Novavax's prototype COVID-19 vaccine ("NVX-CoV2373," or "prototype vaccine"), the Company's XBB COVID-19 vaccine ("NVX-CoV2601"), and the Company's JN.1 COVID-19 ("NVX-CoV2705" or "updated vaccine") are collectively referred to as the Company's "COVID-19 vaccine". Local regulatory authorities have also specified nomenclature for the labeling of NVX-CoV2373, NVX-CoV2601 and NVX-CoV2705 within their territories (e.g., "Novavax COVID-19 Vaccine, Adjuvanted", "Novavax COVID-19, Adjuvanted (2023-2024 or 2024-2025 Formula)," respectively, for the U.S., and "Nuvaxovid™" for ex-U.S. territories). The Company's partner, SII, markets Novavax's COVID-19 vaccine as "Covovax™."

Currently, the Company significantly depends on its supply agreement with SII and its subsidiary, Serum Life Sciences Limited ("SLS" and together with SII, "Serum"), for co-formulation, filling, and finishing.

**Note 2 – Summary of Significant Accounting Policies**

***Basis of Presentation***

The consolidated financial statements include the accounts of Novavax, Inc. and its wholly owned subsidiaries. All intercompany accounts and transactions have been eliminated in consolidation.

***Liquidity and Going Concern***

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern within one year after the date that the financial statements are issued and contemplates the realization of assets and satisfaction of liabilities in the ordinary course of business. The accompanying consolidated financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might result from the outcome of the uncertainty described below.

As of December 31, 2024, the Company had \$530.2 million in cash and cash equivalents, \$392.9 million in marketable securities, and negative working capital of \$25.5 million. During the year ended December 31, 2024, the Company recognized net loss of \$187.5 million, and had net cash flows used in operating activities of \$87.3 million.

In accordance with Accounting Standards Codification ("ASC") Topic 205-40, *Presentation of Financial Statements - Going Concern*, the Company evaluated its ability to continue as a going concern within one year after the date that the accompanying consolidated financial statements are issued. Based on the Company's current cash, cash equivalents and marketable securities balances and the Company's current cash flow forecast for the one-year going concern look forward period, the Company has concluded that it expects to have sufficient capital available to fund its operations for the one-year period from the date that these financial statements are issued. As of December 31, 2023, the Company had concluded that there was substantial doubt about its ability to continue as a going concern primarily due to significant uncertainty related to its ability to successfully develop, manufacture, distribute, and market its COVID-19 Vaccine and execute on certain cost-reduction initiatives (see Note 18). The Sanofi CLA combined with proceeds from the disposition of assets held by Novavax CZ a.s. ("CZ") (see Note 19), cost reductions and the settlement of certain liabilities, alleviated the substantial doubt.

### ***Use of Estimates***

The preparation of the consolidated financial statements in conformity with generally accepted accounting principles in the United States ("U.S. GAAP") requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the consolidated financial statements and the reported amounts of revenue and expenses during the reporting period. Actual results could differ materially from those estimates.

### ***Revenue Recognition***

At contract inception, the Company analyzes its revenue arrangements to determine the appropriate accounting under U.S. GAAP. Currently, the Company's revenue arrangements represent customer contracts within the scope of ASC Topic 606, *Revenue from Contracts with Customers* ("ASC 606"). The Company recognizes revenue from arrangements within the scope of ASC 606 following the five-step model: (i) identify the contract(s) with a customer; (ii) identify the performance obligation(s) in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligation(s) in the contract; and (v) recognize revenue when (or as) it satisfies a performance obligation. The Company only recognizes revenue under the five-step model when it is probable that it will collect the consideration it is entitled to in exchange for the goods or services it transfers to its customer.

#### **Product Sales - APAs**

Product sales include sales associated with COVID-19 Vaccine supply agreements, sometimes referred to as APAs, with various international governments. The Company recognizes revenue from product sales related to these APAs based on the transaction price per dose calculated in accordance with ASC 606 at the point in time when control of the product transfers to the customer and customer acceptance has occurred, unless such acceptance provisions are deemed perfunctory. The APAs typically contain terms that include upfront payments, which are reflected in Deferred revenue. The Company constrains the transaction price for APA's until it is probable that a significant reversal in revenue recognized will not occur. Specifically, if an APA includes a provision whereby the customer may request a discount, return, or refund, or includes a term that may have the effect of decreasing the price per dose of previously delivered shipments, revenue is constrained based on an estimate of the impact of the transaction price until it is probable that a significant reversal in revenue recognized will not occur.

#### **Product Sales - U.S. Commercial**

In the fourth quarter of 2023, the Company commenced sales of COVID-19 Vaccine to the U.S. commercial market. Product sales in the U.S. are primarily made through large pharmaceutical wholesale distributors at the wholesale acquisition cost ("WAC"). The Company recognizes revenue upon title transfer (which is typically at time of delivery), provided all other revenue recognition criteria have been met. The transaction price includes estimates of variable consideration for which reserves are established that primarily result from invoice discounts for prompt payment, wholesale distributor fees, chargebacks, and product returns (collectively, "gross-to-net deductions"). These estimates are based on the amounts earned or to be claimed for related sales and are classified as either reductions of gross accounts receivable or a current liability based on the nature of the estimate, the expected settlement method, and net position by individual customer. Where appropriate, these estimates are based on factors such as industry data and forecasted customer buying and payment patterns, the Company's experience, current contractual and statutory requirements, specific known market events, and trends. Variable consideration is included in the transaction price only to the extent that it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur when the uncertainty associated with the variable consideration is subsequently resolved. If actual results vary from estimates, the Company will adjust the estimates, which would affect product sales in the period such variances become known.

Gross-to-net deductions include the following:

- Wholesale distributor fees, discounts, and chargebacks: The Company has arrangements under which indirect customers such as retailers, healthcare providers, and others receive discounts to the WAC. The chargeback represents the difference between the WAC and this negotiated discounted price. For distribution and related services, the Company incurs service fees to its wholesale distributors. In addition, the Company typically offers wholesale distributor customers invoice discounts on product sales for prompt payments. The Company estimates chargebacks, discounts, and fees it will owe and deducts these amounts from gross product sales at the time the revenue is recognized based on the contractual terms and the Company's expectations regarding future customer behaviors.
- Product returns: The Company offers wholesale distributors and indirect customers the right to return expired doses. Estimated returns for COVID-19 Vaccine are determined considering levels of inventory in the distribution channel, projected market demand, utilization data, returns claims received, and product shelf life. The estimated amount for product returns is deducted from gross product sales in the period the related product sales are recognized.
- Other: Fees payable to retailers, healthcare providers, and buying groups, including certain patient assistance programs, are deducted from gross product sales in the period the related product sales are recognized.

#### Licensing, royalties, and other

The Company also has various arrangements that include a right for a customer to use the Company's intellectual property as a functional license, where the Company's performance obligation is satisfied at the point in time at which the license is granted. These licensing arrangements include sales-based royalties, certain development and commercial milestone payments, and the sale of proprietary Matrix-M™ adjuvant. Because certain development milestone payments are contingent on the achievement of milestones, such as regulatory approvals, that are not within the Company or licensee's control, the payments are not considered probable of being achieved and are excluded from the transaction price until the milestone is achieved, at which point the Company recognizes revenue. For arrangements that include sales-based royalties related to a previously granted license, including milestone payments based upon the achievement of a certain level of product sales, the license is deemed to be the sole or predominant item to which the royalties relate and the Company recognizes revenue when the related sales occur.

The Company allocates the transaction price to each performance obligation based on a relative stand-alone selling price ("SSP") basis. The Company develops assumptions that require judgment to determine the stand-alone selling price for each performance obligation in consideration of applicable market conditions and relevant entity-specific factors, including factors that were contemplated in negotiating the agreement with the customer.

#### Revenue Recognition, Licensing and Transition Services

The terms of the Company's third-party licensing agreements may contain multiple performance obligations, including licenses and transition services. The Company evaluates licensing agreements under ASC 606 to determine the distinct performance obligations. Prior to recognizing revenue, the Company estimates the transaction price, including variable consideration that is subject to a constraint. Amounts of variable consideration are included in the transaction price to the extent that it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur and when the uncertainty associated with the variable consideration is subsequently resolved. Total consideration may include nonrefundable upfront license fees, transition service fees, other payments based upon the achievement of specified milestones, and royalty payments based on product sales from licensed products.

For multiple performance obligation arrangements, the Company allocates the transaction price to each distinct performance obligation based on its relative stand-alone selling price. The stand-alone selling price is generally determined for each performance obligation based on the prices charged to customers, discounted cash flows, or using expected cost-plus margin. For stand-alone selling prices determined using discounted cash flows, the Company considers discounted, probability-weighted cash flows related to the performance obligation transferred. In developing such estimates, the Company applies judgment in determining the forecasted revenue, expected margins, and the discount rate. These estimates are subjective and require the Company to make assumptions about future cash flows. Revenue related to performance obligations satisfied at a point in time is recognized when the customer obtains control of the promised asset. For performance obligations recognized over time, the Company recognizes revenue using an input method to measure progress by utilizing costs incurred to-date relative to total expected costs. Under this process, the Company considers the costs that have been incurred to-date, as well as projections to completion using various inputs and assumptions, including, but not limited to, progress towards completion, labor costs and level of effort, material and subcontractor costs, and indirect administrative costs. Estimating the total cost at completion of the Company's performance obligation under a contract is subjective and requires the Company to make assumptions about future

activity and cost drivers. Changes in these estimates can occur for a variety of reasons and may impact the timing of revenue recognition on the Company's contracts. Changes in estimates related to the process are recognized in the period when such changes are made on a cumulative catch-up basis.

#### Grants

Grant revenue includes revenue from government contracts. The Company performs research and development under government funding, grant, license, and clinical development agreements. The revenue primarily consists of funding under U.S. government contracts to advance the clinical development and manufacturing of COVID-19 Vaccine.

Under U.S. government contracts, the Company is entitled to receive funding on a cost-reimbursable or cost-reimbursable-plus-fixed-fee basis, to support certain activities related to the development, manufacture, and delivery of COVID-19 Vaccine to the U.S. government. The Company analyzed these contracts and determined that they are within the scope of ASC 606. The obligations under each of the contracts are not distinct in the context of the contract as they are highly interdependent or interrelated and, as such, they are accounted for as a single performance obligation. The transaction price under these arrangements is the consideration the Company is expecting to receive and consists of the funded contract amount and the unfunded variable amount to the extent that it is probable that a significant reversal of revenue will not occur. The Company recognizes revenue for these contracts over time as the Company transfers control over the goods and services and satisfies the performance obligation. The Company measures progress toward satisfaction of the performance obligation using an Estimate-at-Completion ("EAC") process, which is a cost-based input method that reviews and monitors the progress towards the completion of the Company's performance obligation. Under this process, management considers the costs that have been incurred to-date, as well as projections to completion using various inputs and assumptions, including, but not limited to, progress towards completion, labor costs and level of effort, material and subcontractor costs, indirect administrative costs, and other identified risks. Estimating the total allowable cost at completion of the performance obligation under a contract is subjective and requires the Company to make assumptions about future activity and cost drivers. Changes in these estimates can occur for a variety of reasons and, if significant, may impact the timing of revenue and fee recognition on the Company's contracts. Allowable contract costs include direct costs incurred on the contract and indirect costs that are applied in the form of rates to the direct costs. Progress billings under the contracts are initially based on provisional indirect billing rates, agreed upon between the Company and the U.S. government. These indirect rates are subject to review on an annual basis. The Company records the impact of changes in the indirect billing rates in the period when such changes are identified. These changes reflect the difference between actual indirect costs incurred compared to the estimated amounts used to determine the provisional indirect billing rates agreed upon with the U.S. government. The Company recognizes revenue on the U.S. government contracts based on reimbursable allowable contract costs incurred in the period up to the transaction price. For cost-reimbursable-plus-fixed-fee contracts, the Company recognizes the fixed-fee based on the proportion of reimbursable contract costs incurred to total estimated allowable contract costs expected to be incurred on completion of the underlying performance obligation as determined under the EAC process. The Company recognizes changes in estimates related to the EAC process in the period when such changes are made on a cumulative catch-up basis. The Company includes the transaction price comprising both funded and unfunded portions of customer contracts in this estimate.

#### ***Cost of Sales***

Cost of sales includes cost of raw materials, production, and manufacturing overhead costs associated with the Company's product sales during the period. Cost of sales also includes adjustments for excess, obsolete, or expired inventory; idle capacity; and losses on firm purchase commitments to the extent the cost cannot be recovered based on estimates about future demand. Cost of sales does not include certain expenses related to raw materials, production, and manufacturing overhead costs that were expensed prior to regulatory authorization as described under the caption "Inventory."

#### ***Research and Development Expenses***

Research and development expenses include salaries; stock-based compensation; laboratory supplies; consultants and subcontractors, including external contract research organizations ("CROs"), contract manufacturing organizations ("CMOs"), and contract development and manufacturing organizations ("CDMOs"); and other expenses associated with the Company's process development, manufacturing, clinical, regulatory, and quality assurance activities for its clinical development programs. In addition, related indirect costs such as fringe benefits and overhead expenses are also included in research and development expenses.

The Company estimates its research and development expense related to services performed under its contracts with external service providers based on an estimate of the level of service performed in the period. Research and development activities are expensed as incurred.



### ***Accrued Research and Development Expenses***

The Company accrues research and development expenses, including clinical trial-related expenses, as the services are performed, which may include estimates of those expenses incurred, but not invoiced. The Company uses information provided by third-party service providers and CRO, CMO, and CDMO invoices and internal estimates to determine the progress of work performed on the Company's behalf. Assumptions based on clinical trial protocols, contracts, and participant enrollment data are also used to estimate these accruals.

### ***Advertising Costs***

Advertising costs are expensed as incurred. The Company had advertising costs of \$33.7 million, \$91.5 million and \$84.0 million during the years ended December 31, 2024, 2023 and 2022, respectively.

### ***Stock-Based Compensation***

The Company accounts for stock-based compensation related to grants of stock options, stock appreciation rights ("SARs"), and restricted stock awards ("RSUs"), and purchases under the Company's Employee Stock Purchase Plan ("ESPP"), at fair value. The Company recognizes compensation expense related to such awards on a straight-line basis over the requisite service period (generally the vesting period) of the equity awards, based on the award's fair value at the grant date. The requisite service period is typically one to four years. Forfeitures for all awards are recognized as incurred. The Company settles stock-based awards with newly issued shares.

The fair value of stock options and SARs is measured on the date of grant using the Black-Scholes option pricing model. The expected term of stock options and SARs is based on the Company's historical option exercise experience and post-vesting forfeiture experience using the historical expected term from the vesting date, and the expected term for purchases under the ESPP is based on the purchase periods included in the offering. The expected volatility is determined using historical volatilities based on stock prices over a look-back period corresponding to the expected term. The risk-free interest rate is determined using the yield available for zero-coupon U.S. government issues with a remaining term equal to the expected term. The Company has never paid a dividend and the Company does not intend to pay dividends in the foreseeable future, and as such, the expected dividend yield is zero.

### ***Cash and Cash Equivalents***

Cash and cash equivalents consist of highly liquid investments with maturities of three months or less from the date of purchase. Cash equivalents are recorded at cost, which approximates fair value due to their short-term nature.

### ***Marketable Securities***

The Company invests its excess cash balances in marketable debt securities with readily determinable fair values that can be converted to cash to fund operations, as required. Investments with maturities greater than three months from the date of purchase are recognized in Current assets and are classified as "available-for-sale".

Available-for-sale securities are measured at fair value in the consolidated balance sheets. Marketable securities are evaluated for impairment considering multiple factors including whether a decline in value below the amortized cost basis is due to credit-related factors. Management reviews criteria, such as the magnitude and duration of the decline, as well as the Company's ability to hold the securities, including whether the Company will be required to sell a security prior to recovery of its amortized cost basis, the investment issuer's financial condition and business outlook. A credit-related impairment is recognized as an allowance against the value of the investment on the balance sheet with a corresponding adjustment to Other income (expense) in the consolidated statements of operations. Unrealized gains and noncredit-related losses on marketable securities are reported as a separate component of stockholders' equity (deficit) until realized.

Interest and dividend income is recorded when earned and included in other income in the consolidated statements of operations. Premiums and discounts, if any, on marketable securities are amortized or accreted to maturity and included in other income in the consolidated statements of operations. The specific identification method is used in computing realized gains and losses on the sale of the Company's marketable securities.

## Fair Value Measurements

The Company applies ASC Topic 820, *Fair Value Measurements and Disclosures* ("ASC 820"), for financial and non-financial assets and liabilities. ASC 820 discusses valuation techniques, such as the market approach (comparable market prices), the income approach (present value of future income or cash flow), and the cost approach (cost to replace the service capacity of an asset or replacement cost). The statement utilizes a fair value hierarchy that prioritizes the inputs to valuation techniques used to measure fair value into three broad levels. The following is a brief description of those three levels:

- Level 1: Observable inputs such as quoted prices (unadjusted) in active markets for identical assets or liabilities.
- Level 2: Inputs other than quoted prices that are observable for the asset or liability, either directly or indirectly. These include quoted prices for similar assets or liabilities in active markets and quoted prices for identical or similar assets or liabilities in markets that are not active.
- Level 3: Unobservable inputs that reflect the reporting entity's own assumptions.

## Restricted Cash

The Company's current and non-current restricted cash includes payments received under grant agreements and cash collateral accounts under letters of credit that serve as security deposits for certain facility leases. Payments received under grant agreements become unrestricted as the Company incurs expenses for services performed under these agreements.

## Accounts Receivable

The Company recognizes amounts due from customers as accounts receivable when its right to payment is unconditional. Gross-to-net deductions are classified as reductions of gross accounts receivable if settlement is expected to occur through a reduction in the amount paid to the Company by its customer. Account receivables are recorded net of any allowance for credit losses. The Company's estimate for the allowance for credit losses, which has not been significant to date, is determined based on the credit risk of its customers based on historical loss experience, economic conditions, the aging of receivables, and customer-specific risks.

## Concentration of Risk

Financial instruments expose the Company to concentration of credit risk and consist primarily of cash and cash equivalents and marketable securities. The Company's investment policy limits investments to certain types of instruments, including asset-backed securities, high-grade corporate debt securities, and money market funds; places restrictions on maturities and concentrations in certain industries; and requires the Company to maintain a certain level of liquidity. At times, the Company maintains cash balances in financial institutions that may exceed federally insured limits. The Company has not experienced any losses relating to such accounts and believes it is not exposed to a significant credit risk on its cash and cash equivalents and marketable securities.

The Company's accounts receivable arise from revenue arrangements with customers. The Company's revenue is primarily due to product sales, grants made by government-sponsored organizations, and royalties from its collaboration and license partners. The following customers accounted for more than 10% of total revenue or accounts receivable for the periods presented:

	Percentage of Revenue for Year Ended December 31,			Percentage of Accounts Receivable as of December 31,	
	2024	2023	2022	2024	2023
European Commission	13%	27%	40%	*	28%
Government of Australia	*	18%	21%	*	*
Government of Canada	*	*	10%	*	59%
Sanofi	68%	*	*	46%	*
Serum Institute of India	*	*	*	11%	*
McKesson Plasma and Biologics	*	*	*	14%	*
Cardinal Health	*	*	*	10%	*
U.S. Government <sup>1</sup>	*	43%	19%	*	*

\*Amounts represent less than 10%

(1) Including the USG Agreement (as defined in Note 3) and the U.S. Department of Defense.

The Company currently depends significantly on one supplier, SII and its subsidiary, SLS, for co-formulation, filling, and finishing of COVID-19 Vaccine. The loss of this supplier could prevent or delay the Company's delivery of customer orders.

### ***Inventory***

Inventory is recorded at the lower of cost or net realizable value under the First In, First Out methodology, taking into consideration the expiration of the inventory item. The Company determines the cost of raw materials using moving average costs and the cost of semi-finished and finished goods using a standard cost method adjusted on a periodic basis to reflect the deviation in the actual cost from the standard cost estimate. Standard costs consist primarily of the cost of manufacturing goods, including direct materials, direct labor, and the services and products of third-party suppliers. Manufacturing overhead costs are applied to semi-finished and finished goods based on expected production levels. The Company utilizes third-party CMOs, CDMOs, and other suppliers and service organizations to support the procurement and processing of raw materials, management of inventory, packaging, and the delivery process. Adjustments to reduce the cost of inventory to its net realizable value, if required, are made for estimated excess, obsolete, or expired inventory through cost of sales. At each reporting period, the Company assesses whether there are excess firm, non-cancelable, purchase commitment liabilities, resulting from supply agreements with third-party CMOs and CDMOs. The determination of net realizable value of inventory and firm purchase commitment liabilities requires judgment, including consideration of many factors, such as estimates of future product demand, current and future market conditions, potential product obsolescence, expiration and utilization of raw materials under firm purchase commitments, and contractual minimums.

Prior to initial regulatory authorization for its product candidates, the Company expenses costs relating to raw materials, production, and manufacturing overhead costs as research and development expenses in the consolidated statements of operations, in the period incurred. Subsequent to initial regulatory authorization for a product candidate, the Company capitalizes the costs of production for a particular supply chain as inventory when the Company determines that it has a present right to the economic benefit associated with the product.

### ***Property and Equipment***

Property and equipment are stated at cost, net of accumulated depreciation, and are depreciated using the straight-line method over the estimated useful lives of the assets. Repairs and maintenance costs are expensed as incurred. The estimated useful lives of property and equipment are described below:

	Useful Life
Buildings	25 years
Machinery and equipment	5 - 7 years
Computer hardware	3 years
Leasehold improvements	Shorter of useful life or remaining term of the lease

### ***Lease Accounting***

The Company enters into manufacturing supply agreements with CMOs and CDMOs to manufacture its vaccine candidates. Certain of these manufacturing supply agreements include the use of identified manufacturing facilities and equipment that are controlled by the Company and for which the Company obtains substantially all the output and may qualify as an embedded lease. The Company treats manufacturing supply agreements that contain an embedded lease as lease arrangements in their entirety. The evaluation of leases that are embedded in the Company's CMO and CDMO agreements is complex and requires judgment in determining whether the contract, either explicitly or implicitly, is for the use of an identified asset and the Company has the right to direct the use of, and obtain substantially all of the benefit from, the identified asset, which generally is the use of a portion of the manufacturing facility of the CMO or CDMO, the term of the lease, and the fixed lease payments under the contract. Depending on the contract, the lease commencement date, defined as the date on which the lessor makes the underlying asset available for use by the lessee and on which the Company is required to accrue lease expenses, may be different than the inception date of the contract. The Company determines the non-cancellable lease term of its embedded leases based on the impact of certain expected milestones on its option to terminate the lease where it is reasonably certain to not exercise that option. The Company evaluates changes to the terms and conditions of a lease contract to determine if they result in a new lease or a modification of an existing lease. For lease modifications, the Company remeasures and reallocates the remaining consideration in the contract and reassesses the lease classification at the effective date of the modification. Leases are classified as either operating or finance leases based on the economic substance of the agreement. The Company also enters into non-cancelable lease agreements for facilities and certain equipment.

For leases that have a lease term of more than 12 months at the lease commencement date, the Company recognizes lease liabilities, which represent the Company's obligation to make lease payments arising from the lease, and corresponding right-of-use ("ROU") assets, which represent the right to use an underlying asset for the lease term, based on the present value of the fixed future payments over the lease term. The Company calculates the present value of future payments using the discount rate implicit in the lease, if available, or the Company's incremental borrowing rate. For all leases that have a lease term of 12 months or less at the commencement date (referred to as "short-term" leases), the Company has elected to apply the practical expedient in ASC Topic 842, *Leases* ("ASC 842"), to not recognize a lease liability or ROU asset but, instead, recognize lease payments as an expense on a straight-line basis over the lease term and variable lease payments that do not depend on an index or rate as an expense in the period in which the variable lease costs are incurred based on performance or usage in accordance with contractual agreements. In determining the lease period, the Company evaluates facts and circumstances that could affect the period over which it is reasonably certain to use the underlying asset while taking into consideration the non-cancelable period over which it has the right to use the underlying asset and any option period to extend or terminate the lease if it is reasonably certain to exercise the option. The Company re-evaluates short-term leases that are modified and if they no longer meet the requirements to be treated as a short-term lease, recognizes and measures the lease liability and ROU asset as if the date of the modification is the lease commencement date. For short-term leases that are modified and continue to meet the requirements to be treated as a short-term lease, the Company remeasures the fixed lease payments under the modified lease and recognize lease payments as an expense on a straight-line basis over the modified lease term.

For operating leases, the Company recognizes lease expense related to fixed payments on a straight-line basis from the lease commencement date through the end of the lease term and lease expense related to variable payments as incurred based on performance or usage in accordance with the contractual agreements. For finance leases, the Company recognizes the amortization of the ROU asset over the shorter of the lease term or useful life of the underlying asset. The Company expenses ROU assets acquired for research and development activities under ASC Topic 730, *Research and Development*, if they do not have an alternative future use, in research and development projects or otherwise.

The Company uses assumptions and judgment in evaluating its lease contracts and other agreements under ASC 842, including the determination of whether an agreement is or contains a lease; whether a change in the terms and conditions of a lease contract represent a new or modified lease; whether a lease represents an operating or finance lease; the discount rate used to determine the present value of lease obligations; the term of a lease embedded in its manufacturing supply agreements; and the Company's incremental borrowing rate, which is determined using estimates such as the estimated value of the underlying leased asset and financial profile of comparable companies.

### ***Impairment of Long-Lived Assets***

Long-lived assets, including property and equipment, internal-use software, and ROU assets, are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset (or asset group) may not be recoverable based on the criteria for accounting for the impairment or disposal of long-lived assets under ASC Topic 360, *Property, Plant and Equipment*. If such events or changes in circumstances occur, the Company assesses the recoverability of the long-lived assets (or asset group) by comparing their projected future undiscounted net cash flows over their remaining lives against their respective carrying amounts. If the cash flows are not expected to be sufficient to recover the carrying amount of the assets (or asset group), they are written down to their estimated fair values.

### ***Restructuring***

The Company recognizes restructuring charges when such costs are incurred. The Company's restructuring charges consist of employee severance and other termination benefits related to the reduction of its workforce, the consolidation of facilities and infrastructure and other costs. Termination benefits are expensed on the date the Company notifies the employee, unless the employee must provide future service, in which case the benefits are expensed ratably over the future service period. Ongoing benefits are expensed when restructuring activities are probable and the benefit estimable.

See Note 18 for additional information on the severance and employee benefit costs for terminated employees and impairment of long-lived assets in connection with the Company's global restructuring and cost reduction plan ("Restructuring Plan") announced in May 2023.

## **Goodwill**

Goodwill is subject to impairment tests annually or more frequently should indicators of impairment arise. The Company has determined that, because its only business is in-house early-stage R&D to build a pipeline of high-value assets using its proven technology along with seeking to enter into partnerships to drive value creation for its assets, it operates as a single operating segment and has one reporting unit. The one-step impairment test, which requires a comparison of the fair value of a reporting unit to its carrying value, including goodwill, is required to be applied to all reporting units including reporting units with zero or negative carrying value. A reporting unit with a zero or negative carrying value likely will not have an impairment. If the carrying value of the reporting unit exceeds its fair value, step two of the impairment analysis is performed. In step two of the analysis, an impairment loss is recorded equal to the excess of the carrying value of the reporting unit's goodwill over its implied fair value, should such a circumstance arise.

As of December 31, 2024 and 2023, the Company had a negative carrying value and did not have any impairment of goodwill.

## **Income Taxes**

The Company accounts for income taxes in accordance with ASC Topic 740, *Income Taxes*. Under the liability method, deferred income taxes are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax basis and operating loss carryforwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the year in which those temporary differences are expected to be recovered or settled. The effect of changes in tax rates on deferred tax assets and liabilities is recognized in income in the period such changes are enacted. A valuation allowance is established when necessary to reduce net deferred tax assets to the amount expected to be realized.

The Global Intangible Low-Taxed Income ("GILTI") provisions under the Tax Cuts and Jobs Act of 2017 impose U.S. tax on certain foreign income in excess of a deemed return on tangible assets of foreign corporations. The Company has elected to treat any potential GILTI inclusions as period costs.

Tax benefits associated with uncertain tax positions are recognized in the period in which one of the following conditions is satisfied: (1) the more-likely-than-not recognition threshold is satisfied; (2) the position is ultimately settled through negotiation or litigation; or (3) the statute of limitations for the taxing authority to examine and challenge the position has expired. Tax benefits associated with an uncertain tax position are reversed in the period in which the more-likely-than-not recognition threshold is no longer satisfied.

The Company has historically generated significant federal, state, and foreign tax net operating losses, which may be subject to limitation in future periods. Management has fully reserved the related deferred tax assets with a valuation allowance in the current reporting period as it is more likely than not that the related benefit will not be realized. The Company is currently subject to examination in all open tax years.

## **Net Loss per Share**

Basic net loss per share is computed by dividing net loss by the weighted-average number of shares of common stock outstanding for the period and excludes the effects of any potentially dilutive securities. Diluted net loss per share is computed using the treasury stock method by dividing net loss by the weighted-average number of common shares outstanding after giving consideration to the dilutive effect of certain securities outstanding during the period. As of December 31, 2024, the Company's 2027 Notes (see Note 11) would have been convertible into approximately 14 million shares of the Company's common stock assuming the common stock price is equal to or greater than \$12.50. These shares, after giving effect to the add back of interest expense and unamortized discounts and debt issuance costs on the Notes are excluded from the computation, as their effect is antidilutive under the if-converted method. In addition, all stock options, SARs, and unvested RSUs are excluded from the computation as their effect is antidilutive.

## **Foreign Currency**

The accompanying consolidated financial statements are presented in U.S. dollars. The functional currency of the Company's international subsidiaries is generally the local currency. The financial statements of international subsidiaries are translated to U.S. dollars using the exchange rate in effect at the consolidated balance sheet date for assets and liabilities, historical rates for equity accounts, and average exchange rates for the consolidated statement of operations. Cash flows from operations

are translated at the average exchange rate in effect for the period, while cash flows from investing and financing activities are translated at the exchange rate in effect at the date of the underlying transaction. Translation gains and losses are recognized as a component of accumulated other comprehensive income (loss) in the accompanying consolidated balance sheets. The foreign currency translation adjustment balance included in accumulated other comprehensive income (loss) was \$22.6 million of losses and \$2.7 million of gains at December 31, 2024 and 2023, respectively. The aggregate foreign currency transaction gains and losses resulting from the conversion of the transaction currency to functional currency were \$4.4 million of losses, \$7.9 million of gains, and \$2.5 million of losses for the years ended December 31, 2024, 2023, and 2022, respectively, which are reflected in Other income (expense).

### ***Segment Information***

The Company manages its business as one operating segment, in-house early-stage R&D to build a pipeline of high-value assets using its proven technology along with seeking to enter into partnerships to drive value creation for its assets. Accordingly, it does not have separately reportable segments as defined by ASC Topic 280, *Segment Reporting* ("ASC 280"). The Company's Chief Executive Officer ("CEO") is its chief operating decision-maker ("CODM"). The accounting policies of this segment are described in Note 20.

### ***Recent Accounting Pronouncements***

#### **Not Yet Adopted**

In October 2023, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2023-06, *Disclosure Improvements: Codification Amendments in Response to the SEC's Disclosure Update and Simplification Initiative* ("ASU 2023-06"), to clarify or improve disclosure and presentation requirements of a variety of topics and align the requirements in the FASB ASC with the SEC's regulations. The effective date for each amendment in the Update is the effective date that the SEC removes the disclosure requirement from its regulations. The Company is currently evaluating ASU 2023-06, however, as the ASU codifies SEC regulations, the Company does not anticipate that its implementation will have a material effect on the Company's consolidated financial statements and disclosures.

In December 2023, the FASB issued ASU 2023-09, *Improvements to Income Tax Disclosures* ("ASU 2023-09"). The standard enhances transparency in income tax disclosures by requiring, on an annual basis, certain disaggregated information about a reporting entity's effective tax rate reconciliation and income taxes paid. The ASU also requires disaggregated disclosure related to pre-tax income (or loss) and income tax expense (or benefit) and eliminates certain disclosures related to the balance of an entity's unrecognized tax benefit and the cumulative amount of certain temporary differences. The ASU is effective for the Company beginning on January 1, 2025. The Company is completing its evaluation of the impact of ASU 2023-09 on its disclosures.

In November 2024, the FASB issued ASU 2024-03, *Income Statement-Reporting Comprehensive Income-Expense Disaggregation Disclosures (Subtopic 220-40)* ("ASU 2024-03"). The ASU includes enhanced disclosure requirements, which mandate transparency in financial statements by requiring detailed disclosures of specific expenses like inventory purchases, employee compensation, depreciation, and intangible asset amortization. ASU 2024-03 is effective for annual reporting periods beginning after December 15, 2026, and interim reporting periods within annual reporting periods beginning after December 15, 2027. Early



adoption is permitted. The Company is currently evaluating the impact of adopting this pronouncement on the Company's consolidated financial statements and disclosures.

### Adopted

In June 2016, the FASB issued ASU 2016-13, *Financial Instruments - Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments* ("ASU 2016-13"), with amendments in 2018, 2019, 2020, and 2022. The ASU sets forth a "current expected credit loss" model that requires companies to measure all expected credit losses for financial instruments held at the reporting date based on historical experience, current conditions, and reasonable supportable forecasts. ASU 2016-13 applies to financial instruments that are not measured at fair value, including receivables that result from revenue transactions. The Company adopted ASU 2020-06 on January 1, 2023, using a modified retrospective approach, and it did not have a material impact on the Company's consolidated financial statements.

In November 2023, the FASB issued ASU 2023-07, *Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures* ("ASU 2023-07"), which expands disclosures for reportable segments made by public entities and requires more detailed information about expenses within each reportable segment. Entities with a single reportable segment are required to provide on both an interim and annual basis, all segment disclosures required in ASC 280, including the new disclosures for reportable segments under the amendments in ASU 2023-07. The amendments do not change the existing guidance on how a public entity identifies and determines its reportable segments. The ASU is effective for the Company's annual period ended December 31, 2024 and interim periods thereafter and has been adopted by the Company (see Note 20).

### **Note 3 – Revenue**

The Company's accounts receivable, net, included \$102.9 million and \$286.4 million related to amounts that were billed to customers and \$5.4 million and \$10.8 million related to amounts which had not yet been billed to customers as of December 31, 2024 and 2023, respectively. During the years ended December 31, 2024 and 2023, changes in the Company's accounts receivables, allowance for credit losses, and deferred revenue balances were as follows (in thousands):

	Balance, Beginning of Period	Additions	Deductions	Balance, End of Period
<b>Accounts receivable:</b>				
Year ended December 31, 2024	\$ 304,916	\$ 1,083,036	\$ (1,271,992)	\$ 115,960
Year ended December 31, 2023	96,210	1,472,768	(1,264,062)	304,916
<b>Allowance for credit losses<sup>(1)</sup>:</b>				
Year ended December 31, 2024	(7,675)	—	—	(7,675)
Year ended December 31, 2023	(13,835)	—	6,160	(7,675)
<b>Deferred revenue:<sup>(2)</sup></b>				
Year ended December 31, 2024	863,521	411,659	(153,294) <sup>(2)</sup>	1,121,886
Year ended December 31, 2023	549,551	581,569	(267,599)	863,521

(1) There was no allowances for credit losses recorded in 2024. In 2023, there was a \$6.2 million reversal of a credit loss allowance due to the collection of a previously recognized allowance for credit losses. To estimate the allowance for credit losses, the Company evaluates the credit risk related to its customers based on historical loss experience, economic conditions, the aging of receivables, and customer-specific risks.

(2) Deductions from Deferred revenue generally relate to the recognition of revenue once performance obligations on a contract with a customer are met. In 2024, deductions from Deferred revenue included \$91.8 million that was realized in Revenue and \$61.5 million that was reclassified to Other current liabilities. In 2023, deductions from Deferred revenue included \$151.1 million that was realized in Revenue and \$112.5 million related to the Amended and Restated UK Supply Agreement, that was reclassified to Other current liabilities. In 2024, additions included a \$225 million reclassification of an upfront payment from Other current liabilities to Deferred revenue related to the settlement with Gavi as discussed below.

As of December 31, 2024, the aggregate amount of the transaction price allocated to performance obligations that were unsatisfied (or partially unsatisfied), excluding amounts related to sales-based royalties and constrained variable consideration, was \$1.3 billion, of which \$1.1 billion was included in Deferred revenue. Failure to meet regulatory milestones, obtain timely supportive recommendations from governmental advisory committees, or achieve product volume or delivery timing obligations under the Company's APAs may require the Company to refund portions of upfront and other payments or result in reduced future payments,

which could adversely impact the Company's ability to realize revenue from its unsatisfied performance obligations or result in the reversal of previously recognized revenue. In the first quarter of 2025, the Company received written notice of a \$23 million claim related to certain performance obligations under an APA agreement with a customer. The Company believes it has fulfilled the requirements related to this matter and is evaluating the merits of the claim. The timing to fulfill performance obligations related to APAs will depend on the 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 the Company's most recently updated vaccine under certain of the Company's APAs. The timing to fulfill performance obligations related to the Sanofi CLA will depend on the timing of delivery of Sanofi Transition Services and Sanofi Technology Transfer services and delivery of doses and other materials based on Sanofi demand.

Under an APA with Gavi, the Vaccine Alliance ("Gavi"), entered into in May 2021 (the "Gavi APA"), the Company received upfront payments of \$700 million from Gavi (the "Advance Payment Amount") to be applied against purchases of the Company's prototype vaccine by certain countries participating in the COVAX Facility. As of December 31, 2023, the remaining Gavi Advance Payment Amount was \$696.4 million. In February 2024, the Company entered into a Termination and Settlement Agreement with Gavi (the "Gavi Settlement Agreement") terminating the Gavi APA, settling the arbitration proceedings, and releasing both parties of all claims arising from, under, or otherwise in connection with the Gavi APA. In February 2024, the claims and counterclaims were dismissed with prejudice. Pursuant to the Gavi Settlement Agreement, the Company is responsible for payment to Gavi of (i) an initial settlement payment of \$75 million, which the Company paid in February 2024, and (ii) deferred payments, in equal annual amounts of \$80 million payable each calendar year through a deferred payment term ending December 31, 2028. The deferred payments are due in variable quarterly installments and total \$400 million during the deferred payment term. Such deferred payments may be reduced through Gavi's use of an annual vaccine credit equivalent to the unpaid balance of such deferred payments each year, which may be applied to qualifying sales of any of the Company's vaccines for supply to certain low-income and lower-middle income countries. The Company has the right to price the vaccines offered to such low-income and lower-middle income countries in its discretion, and, when utilized by Gavi, the Company will credit the actual price per vaccine paid against the applicable credit. The Company intends to price vaccines offered via the tender process, consistent with its shared goal with Gavi to provide equitable access to those countries. Also, pursuant to the Gavi Settlement Agreement, the Company granted Gavi an additional credit of up to \$225 million that may be applied against qualifying sales of any of the Company's vaccines for supply to such low-income and lower-middle income countries that exceed the \$80 million deferred payment amount in any calendar year during the deferred payment term. In total, the Gavi settlement agreement is comprised of \$700 million of potential consideration, consisting of the \$75 million initial settlement payment, deferred payments of up to \$400 million that may be reduced through annual vaccine credits, and the additional credit of up to \$225 million that may be applied for certain qualifying sales.

The Company recorded the \$3.6 million difference between the refund liability recorded as of December 31, 2023 of \$696.4 million and the \$700 million of total consideration under the arrangement as a reduction to revenue during the year ended December 31, 2024. As of December 31, 2024, the remaining amounts included on the Company's consolidated balance sheet were \$225.0 million in non-current Deferred revenue for the additional credit that may be applied against future qualifying sales, \$85.0 million in Other current liabilities, and \$275.0 million in Other non-current liabilities. In addition, the Company and Gavi entered into a security agreement pursuant to which Novavax granted Gavi a security interest in accounts receivable from SII under the SII R21 Agreement (see Note 4), which will continue for the deferred payment term of the Gavi Settlement Agreement

### **Product Revenue**

Product revenue by the Company's customer's geographic location was as follows (in thousands):

	Year Ended December 31,		
	2024	2023	2022
North America	\$ 65,023	\$ 29,959	\$ 194,480
Europe	93,270	268,361	823,542
Rest of the world	31,919	233,069	536,939
Total product revenue	<u>\$ 190,212</u>	<u>\$ 531,389</u>	<u>\$ 1,554,961</u>

Product sales in the U.S. are primarily made through large pharmaceutical wholesale distributors at the WAC. Product sales in the U.S. are recorded net of gross-to-net deductions, as described in Note 2.

During the years ended December 31, 2023 and 2024, changes in the Company's gross-to-net deductions balances were as follows (in thousands):

	Wholesale Distributor Fees, Discounts, and Chargebacks	Product Returns	Total
Balance as of December 31, 2022	\$ —	\$ —	\$ —
Amounts charged against product sales	47,028	84,688	131,716
Credits/deductions	(25,956)	(72)	(26,028)
Balance as of December 31, 2023	21,072	84,616	105,688
Amounts charged against product sales <sup>(1)</sup>	105,795	120,277	226,072
Credits/deductions	(105,731)	(88,196)	(193,927)
Balance as of December 31, 2024	\$ 21,136	\$ 116,697	\$ 137,833

(1) Amounts charged against product sales include changes in estimates of \$14.4 million of net adjustments made to prior period product sales, including adjustments of \$17.7 million due primarily to previously estimated product returns, which are no longer eligible for customer credits and therefore were recognized in product revenue during the year ended December 31, 2024, offset by increases to other gross-to-net deductions.

As of December 31, 2024, \$77.1 million of gross-to-net deductions were included in Accrued expenses, \$10.1 million were included Accounts payable, and \$50.6 million were included in and reduced Accounts receivable on the consolidated balance sheet. As of December 31, 2023, \$103.1 million of gross-to-net deductions were included in Accrued expenses and \$2.6 million were included in and reduced Accounts receivable on the consolidated balance sheet.

The Company has an APA with the Commonwealth of Australia ("Australia") for the purchase of doses of COVID-19 Vaccine (the "Australia APA"). In December 2024, the Company entered into an amendment to the Australia APA with Australia. Pursuant to the amendment, the Company acknowledged the cancellation by Australia of the delivery of certain doses of COVID-19 Vaccine scheduled for delivery between the fourth quarter of 2023 and the fourth quarter of 2025 and the parties agreed to credit approximately \$31 million of the advanced payment paid by Australia against outstanding invoices and invoices for the future delivery of approximately 3 million doses of COVID-19 Vaccine without requiring additional cash payments. The parties also agreed to an 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 APA, in the event the Company misses or under delivers doses to Australia or fails to receive regulatory approval of a variant COVID-19 vaccine. The amendment also provides Australia with the right to cancel doses if the Company fails to timely notify Australia of changes to its commercialization plans. As of December 31, 2024, \$15.6 million was classified as current Deferred revenue and \$118.2 million was classified as non-current Deferred revenue with respect to the Australia APA in the Company's consolidated balance sheet, which will be recognized in product revenue as doses are delivered to Australia.

The Company has an APA with His Majesty the King in Right of Canada as represented by the Minister of Public Works and Government Services, as successor in interest to Her Majesty the Queen in Right of Canada, as represented by the Minister of Public Works and Government Services (the "Canadian government"), for the purchase of doses of COVID-19 Vaccine (the "Canada APA"). The Canadian government may terminate the Canada APA, as amended, as the Company failed to receive regulatory approval for its COVID-19 Vaccine using bulk antigen produced at Biologics Manufacturing Centre ("BMC") Inc. on or before December 31, 2024. Therefore, the Company is in discussions with Canada regarding a potential amendment to the Canada APA to address possible alternatives, which may not be achievable on acceptable terms or at all. As of December 31, 2024, \$555.7 million was classified as current Deferred revenue with respect to the Canada APA in the Company's consolidated balance sheet. If the Canadian government terminates the Canada APA, \$28.0 million of advanced payments previously received would become refundable, which was classified as Other current liabilities in the Company's consolidated balance sheet, and approximately \$224 million of contract proceeds related to future deliverables would no longer be available.

In November 2024, the Company and Secretary of State for Business, Energy and Industrial Strategy (as assigned to the UK Health Security Agency), acting on behalf of the government of the United Kingdom of Great Britain and Northern Ireland (the "Authority") entered into a Termination and Settlement Agreement (the "Settlement Agreement") and a Letter of Amendment to the Settlement Agreement (the "Settlement Agreement Amendment"), relating to the Amended and Restated SARS-CoV-2 Vaccine Supply Agreement (the "Amended and Restated UK Supply Agreement") and the SARS-CoV-2 Vaccine Supply Agreement, dated October 22, 2020 (the "Original UK Supply Agreement"). The Settlement Agreement resolved the disputes regarding the Amended

and Restated Supply Agreement and released both parties of all claims arising out of or connected with the Amended and Restated Supply Agreement.

Under the terms of the Settlement Agreement and Settlement Agreement Amendment, the Company and the Authority agreed to terminate the Amended and Restated Supply Agreement and to fully settle the outstanding amount under dispute related to upfront payments of \$112.5 million previously received by the Company from the Authority under the Amended and Restated Supply Agreement. Pursuant to the Settlement Agreement, the Company agreed to pay a refund of \$123.8 million (the "Settlement Payment") to the Authority in equal quarterly installments of \$10.3 million over a three year period, ending in June 2027. The Settlement Payment amount includes an \$11.3 million provision for interest over the period and may be avoided if the Company chooses to accelerate payments. As of December 31, 2024, the remaining upfront payment previously received from the authority is classified as \$36.4 million of Other current liabilities and \$58.8 million of Other non-current liabilities on the Company's consolidated balance sheet.

The Company has an APA with the Pharmaceutical Management Agency ("Pharmac"), a New Zealand Crown, entity for the purchase of doses of COVID-19 Vaccine (the "New Zealand APA"). In July 2024, Pharmac provided notice of its termination of its APA. Pharmac has requested a refund of certain advanced payments, and the Company is 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 the Company's 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. The Company responded to Pharmac in September 2024 indicating it does not believe Pharmac has the right to unilaterally terminate the contract or receive a refund of any part of the remaining upfront payment. The Company is in ongoing discussions with Pharmac to resolve this matter, which may not be achievable on acceptable terms or at all.

### ***Licensing, Royalties, and Other***

Licensing, royalties, and other includes licensing payments, transition services revenue, and technology transfer revenue from the Sanofi CLA; royalty milestone payments; sales-based royalties; and Matrix-M™ adjuvant sales.

During year ended December 31, 2024, the Company recognized \$398.2 million in revenue related to license fees and sales-based royalties, \$20.5 million related to Matrix-M™ adjuvant sales, \$69.7 million of transition services revenue and technology transfer revenue, and \$3.5 million of other revenue.

During the year ended December 31, 2023, the Company recognized \$8.5 million in revenue related to license fees and \$16.5 million in revenue related to a Matrix-M™ adjuvant sales.

During the year ended December 31, 2022, the Company recognized \$9.0 million in revenue related to sales-based royalties, \$20.0 million related to milestone payments, and \$15.0 million in revenue related to a Matrix-M™ adjuvant sales.

### ***Grants***

The Company's U.S. government agreement consists of a Project Agreement (the "Project Agreement") and a Base Agreement with Advanced Technology International, the Consortium Management Firm acting on behalf of the Medical CBRN Defense Consortium in connection with the partnership formerly known as Operation Warp Speed (the Base Agreement together with the Project Agreement, the "USG Agreement").

The original USG Agreement required the Company to conduct certain clinical, regulatory, and other activities, including a pivotal Phase 3 clinical trial to determine the safety and efficacy of prototype vaccine, and to manufacture and deliver to the U.S. government 100 million doses of the vaccine candidate. Funding under the USG Agreement was payable to the Company for various development, clinical trial, manufacturing, regulatory, and other activities. The USG Agreement contains terms and conditions that are customary for U.S. government agreements of this nature, including provisions giving the U.S. government the right to terminate the Base Agreement or the Project Agreement based on a reasonable determination that the funded project will not produce beneficial results commensurate with the expenditure of resources and that termination would be in the U.S. government's interest. If the Project Agreement was terminated prior to completion, the Company is entitled to be paid for work performed and costs or obligations incurred prior to termination and consistent with the terms of the USG Agreement. As of December 31, 2023, the Company recognized the full \$1.8 billion funding in revenue.

## **Note 4 – Collaboration, License, and Supply Agreements**

### ***Serum***

The Company previously granted SII exclusive and non-exclusive licenses for the development, co-formulation, filling and finishing, registration, and commercialization of its COVID-19 vaccine, and its COVID-19-Influenza ("CIC") vaccine candidate. SII agreed to purchase the Company's Matrix-M™ adjuvant and the Company granted SII a non-exclusive license to manufacture the antigen drug substance component of the Company's COVID-19 Vaccine in SII's licensed territory solely for use in the manufacture of COVID-19 Vaccine. The Company and SII equally split the revenue from SII's sale of COVID-19 Vaccine in its licensed territory, net of agreed costs. In May 2024, the Company and SLS entered into a supply agreement (the "SLS Supply Agreement") under which SLS agreed to supply the Company with antigen drug substance and finished COVID-19 Vaccine doses. The SLS Supply Agreement includes the general terms and conditions of supply orders between the Company and SLS. The Company and SLS execute firm purchase orders, which include specific quantities to be delivered under the SLS Supply Agreement. The Company agreed to supply SLS with all Matrix-M™ adjuvant needed to manufacture finished COVID-19 Vaccine doses. In March 2020, the Company entered into an agreement with SII that granted SII a non-exclusive license for the use of Matrix-M™ adjuvant supplied by the Company to develop, manufacture, and commercialize R21/Matrix-M™ adjuvant ("SII R21 Agreement"), a malaria vaccine created by the Jenner Institute, University of Oxford ("R21/Matrix-M™"). In December 2023, R21/Matrix-M™ received prequalification by the World Health Organization ("WHO"). Under the SII R21 Agreement, SII purchases the Company's Matrix-M™ adjuvant for use in development activities at cost and for commercial purposes at a tiered commercial supply price, and pays a royalty in the single-to low- double-digit range based on vaccine sales for a period of 15 years after the first commercial sale of the vaccine in each country.

### ***Takeda Pharmaceutical Company Limited***

The Company has a collaboration and license agreement with Takeda Pharmaceutical Company Limited ("Takeda") under which the Company granted Takeda an exclusive license to develop, manufacture, and commercialize the Company's COVID-19 Vaccine in Japan. Under the agreement, Takeda purchases Matrix-M™ adjuvant from the Company to manufacture doses of COVID-19 Vaccine, and the Company is entitled to receive milestone and sales-based royalty payments from Takeda based on the achievement of certain development and commercial milestones, as well as a portion of net profits from the sale of COVID-19 Vaccine.

### ***Sanofi***

In May 2024, the Company entered into the Sanofi CLA under which the Company granted and Sanofi received the following:

- i) A co-exclusive license to commercialize the Company's current stand-alone COVID-19 Vaccine, including the Company's prototype vaccine and updated vaccines, that address seasonal variants throughout the world (the "COVID-19 Vaccine Products");
- ii) A sole license to develop and commercialize combination products containing a potential combination of the Company's COVID-19 Vaccine and Sanofi's seasonal influenza vaccine ("COVID-19 and influenza Combination Products" or "CIC Products");
- iii) A non-exclusive license to develop and commercialize combination products containing both the Company's COVID-19 Vaccine and one or more non-influenza vaccines ("Other Combination Products" and together with the COVID-19 Vaccine Products, CIC Products, and Other Combination Products, "Licensed COVID-19 Products"); and
- iv) A non-exclusive license to develop and commercialize other vaccine products selected by Sanofi that include the Company's Matrix-M™ adjuvant (as described below, the "Adjuvant Products").

The Company is also responsible for performing services related to the technology transfer of its manufacturing process for the COVID-19 Vaccine Products and Matrix-M™ components to Sanofi. Until the successful completion of such transfer, the Company will supply Sanofi with both COVID-19 Vaccine Products and Matrix-M™ intermediary components for Sanofi's use and is eligible for reimbursement of such costs from Sanofi. In addition, the Company is responsible for certain research and development and medical affairs services related to the COVID-19 Vaccine.



Under the Sanofi CLA, the Company will continue to commercialize its updated COVID-19 vaccine through the end of the 2024-2025 vaccination season. Beginning in 2025 and continuing during the term of the Sanofi CLA, Sanofi and the Company will commercialize the COVID-19 Vaccine Products worldwide in accordance with a commercialization plan agreed by the Company and Sanofi, under which the Company will continue to supply its existing APA customers and strategic partners, including Takeda and SII. Upon completion of the existing APAs, the Company and Sanofi will jointly agree on commercialization activities of each party in each jurisdiction.

Pursuant to the Sanofi CLA, the Company received a non-refundable upfront payment of \$500 million in the second quarter of 2024. In addition, the Company is eligible to receive development, technology transfer, launch, and sales milestone payments totaling up to \$700 million in the aggregate with respect to the COVID-19 Vaccine Products and royalty payments on Sanofi's sales of such licensed products. Milestone payments are comprised of a payment of \$175 million upon the approval of the marketing authorization for a currently selected strain of the COVID-19 Vaccine in a pre-filled syringe from the U.S. Food and Drug Administration ("U.S. FDA"), \$25 million upon the transfer of such approval to Sanofi, \$25 million upon the transfer of European Medicines Agency approval of a COVID-19 Vaccine Product in a pre-filled syringe to Sanofi, \$50 million upon database lock of an existing Phase 2/3 clinical trial (identifier 2019nCoV-503), \$75 million upon the completion of the technology transfer of the Company's manufacturing process for the COVID-19 Vaccine Products to Sanofi, \$125 million upon achievement of certain CIC Product-related development milestones, and \$225 million in CIC Product-related launch milestones. The Company achieved the \$50 million milestone for database lock of an existing Phase 2/3 clinical trial in 2024 and the amount is included in accounts receivable on the Company's consolidated balance sheet.

The Company is also eligible to receive development, launch, and sales milestone payments of up to \$200 million for each of the first four Adjuvant Products and \$210 million for each Adjuvant Product thereafter, and royalty payments on Sanofi's sales of all such licensed products. In addition, a portion of the technology transfer costs and research and development costs incurred by the Company will be reimbursed by Sanofi in accordance with agreed upon plans and budgets.

The Company assessed whether the Sanofi CLA fell within the scope of ASC 808, *Collaborative Arrangements* ("ASC 808") based on whether the arrangement involved joint operating activities and whether both parties have active participation in the arrangement and are exposed to significant risks and rewards. The Company determined that the Sanofi CLA did not fall within the scope of ASC 808, as the Company does not share in the significant financial risks of Sanofi's development or commercialization activities. The Company then analyzed the arrangement pursuant to the provisions of ASC 606 and determined that the arrangement represents a contract with a customer and is therefore within the scope of ASC 606.

The Company identified the following performance obligations in the Sanofi CLA and determined that they were within the scope of ASC 606: delivery of (i) the licenses described above (the COVID-19 Vaccine license, CIC Products license, Other Combination Product license, and Adjuvant Products license) (collectively the "Sanofi CLA Licenses"), (ii) research and development transition services that support further regulatory approval and development of the COVID-19 Vaccine, referred to as the "Sanofi Transition Services," and (iii) technology transfer of the existing manufacturing process for the COVID-19 Vaccine Products and Matrix-M™ adjuvant, referred to as the "Sanofi Technology Transfer."

The Company also evaluated whether certain options outlined in the Sanofi Agreement represented material rights that would give rise to a performance obligation and concluded that none of the options convey a material right to Sanofi and therefore are not considered separate performance obligations within the Sanofi CLA.

The Sanofi CLA Licenses performance obligations are considered functional intellectual property and distinct from other promises under the contract as Sanofi can benefit from the licenses on their own or together with other readily available resources. Also, the Sanofi Transition Services provide a distinct benefit to Sanofi within the context of the contract, separate from the licenses, as the services could be provided by Sanofi or another third party without the Company's assistance. The Sanofi Technology Transfer obligation is distinct as Sanofi can benefit from the Sanofi CLA Licenses transferred by the Company at the inception of the agreement with other readily available resources. Therefore, each represents a separate performance obligation within the contract with a customer under the scope of ASC 606 at contract inception.

The Company determined the initial transaction price at inception of the Sanofi CLA to be \$620.2 million, consisting of (i) fixed consideration (the \$500 million upfront nonrefundable fee), (ii) and \$120.2 million of variable consideration attributed to a \$50.0 million clinical milestone and \$70.2 million of estimated cost reimbursement related to Sanofi Transition Services and Sanofi Technology Transfer. Since the clinical milestone allocated to Sanofi Transition Services is entirely within the Company's control, and the cost reimbursement variable consideration allocated to Sanofi Transition Services and Sanofi Technology Transfer would be recognized as revenue only as the costs are incurred, the Company determined it is not probable that a significant reversal of



cumulative revenue would occur. The Company utilized the expected value method to determine the amount of these payments. The Company excluded certain regulatory and technology transfer milestones from the transaction price that were determined to be inherently uncertain of achievement and are highly susceptible to factors outside of the Company's control. Sales-based royalties and launch milestones are related to the license of the intellectual property rights and the Company will recognize revenue for these in the period when subsequent sales are made or sale-based milestones are achieved pursuant to the sales-based royalty exception under ASC 606. The Company will re-evaluate the transaction price in each reporting period as uncertain events are resolved or other changes in circumstances occur.

The Company allocated the fixed consideration (i.e., the \$500 million nonrefundable upfront fee) to the performance obligations in the Sanofi CLA based on each performance obligation's relative SSP, as follows:

- \$389.6 million for the upfront transfer of the licenses;
- \$106.9 million for Sanofi Transition Services; and
- \$3.5 million for Sanofi Technology Transfer.

The SSP for the licenses were determined using an approach that considered discounted, probability-weighted cash flows related to the license transferred. In developing such estimates, the Company applied judgment in determining the forecasted revenue and the discount rate. The SSP for the ongoing Sanofi Transition Services and Sanofi Technology Transfer were based on estimates of the associated effort and cost of these services, adjusted for a reasonable gross profit margin that would be expected to be realized under similar contracts and the discount rate.

The Company recognized revenue related to the licenses at a point in time upon transfer of the rights and control of the license to Sanofi during the second quarter of 2024. The Sanofi Transition Services and Sanofi Technology Transfer are recognized in revenue over time using an input method to measure progress by utilizing costs incurred to-date relative to total expected costs. Revenue recognized related to Sanofi Transition Services and Sanofi Technology Transfer for the year ended December 31, 2024 was \$69.7 million. The Company's consolidated balance sheet as of December 31, 2024 includes a deferred revenue balance of \$87.6 million (\$44.9 million included in Deferred revenue, current portion and \$42.6 million included in Deferred revenue, non-current portion) related to Sanofi Transition Services and Sanofi Technology Transfer.

The Company recognized an asset for \$35.0 million of direct costs incurred to obtain the Sanofi CLA. These costs are amortized to expense over the expected period of the benefit in a manner that is consistent with the transfer of the related goods and services in the Sanofi CLA. The Company recognized \$29.1 million of amortization expense related to the asset in Selling, general, and administrative expense for the year December 31, 2024, respectively.

In May 2024, the Company also entered into a securities subscription agreement (the "Sanofi Subscription Agreement") with Sanofi, pursuant to which the Company sold and issued to Sanofi, in a private placement, 6.9 million shares of the Company's common stock, at a price of \$10.00 per share for aggregate gross proceeds to the Company of \$68.8 million. The opening price of the Company's common stock on the date of the sale approximated \$10.00 per share and therefore all gross proceeds were allocated to stockholders' deficit.

#### ***Bill & Melinda Gates Medical Research Institute***

In May 2023, the Company entered into a 3-year agreement with the Bill & Melinda Gates Medical Research Institute to provide the Company's Matrix-M™ adjuvant for use in preclinical vaccine research.

### ***SK bioscience, Co., Ltd.***

In August 2023, the Company and SK bioscience, Co., Ltd. ("SK") entered into a Settlement Agreement and General Release (the "Settlement Agreement") regarding mutual release by the parties of all claims arising from or in relation to statements of work ("SOWs") canceled by the Company under a Development and Supply Agreement ("DSA") and the Collaboration and License Agreement ("CLA") (collectively the "Business Agreements"), and other SOWs under the Business Agreements (collectively, the "Subject SOWs"), in each case, in connection with the cessation of all drug substance and drug product manufacturing activity at SK for supply to the Company. Subject SOWs canceled by the Company under the Settlement Agreement included (i) Statement of Work No. 1 dated as of December 23, 2021 as amended to date under the CLA; (ii) Statement of Work No. 5 dated as of July 18, 2022 under the DSA; and (iii) Statement of Work No. 6 dated as of July 18, 2022, and as amended as of December 28, 2022 under the DSA.

Pursuant to the Settlement Agreement, the Company was responsible for payment of \$149.8 million to SK in connection with the cancellation of manufacturing activity for the SOWs under the Business Agreements, which was paid in 2023. Under the Settlement Agreement, the Company and SK agreed to a wind down plan with respect to the remaining products, materials and equipment under the SOWs.

In August 2023, the Company also entered into a Securities Subscription Agreement (the "SK Subscription Agreement") with SK, pursuant to which the Company agreed to sell and issue to SK, in a private placement (the "Private Placement"), 6.5 million shares of the Company's common stock, par value \$0.01 per share at a price of \$13.00 per share for aggregate gross proceeds to the Company of approximately \$84.5 million. The closing of the Private Placement occurred on August 10, 2023. The fair value of the Company's common stock on the date of closing, based on the quoted market price, was \$46.5 million, which results in a premium paid by SK of approximately \$38 million.

The Settlement Agreement and the SK Subscription Agreement were negotiated concurrently between the parties, and therefore were combined for accounting purposes and analyzed as a single arrangement. As a result, the Company recorded the \$46.5 million fair value of common stock issued to SK, based on the quoted market price on the date of close, as an equity transaction. The remaining elements of the arrangement were deemed to relate to the settlement of the Company's outstanding liabilities due to SK. These elements consist primarily of the cash payable to SK of \$149.8 million, offset by the premium paid on the common stock purchase by SK of \$38.0 million, which resulted in a net gain upon derecognition of the liabilities due to SK of \$79.2 million in connection with the settlement. As a result, during the year ended December 31, 2023, the Company recorded this net gain of \$79.2 million between research and development expense, for \$57.7 million, and cost of sales, for \$21.5 million, proportionally based on the where the underlying costs were originally recorded.

### ***Other Supply Agreements***

In March 2024, the Company, FUJIFILM Diosynth Biotechnologies UK Limited ("FDBK"), FUJIFILM Diosynth Biotechnologies Texas, LLC ("FDBT") and FUJIFILM Diosynth Biotechnologies USA, Inc. ("FDBU" and together with FDBK and FDBT, "Fujifilm") entered into a Confidential Settlement Agreement and Release (the "Settlement Agreement") to resolve disputes regarding amounts that Fujifilm claimed were due under a prior Confidential Settlement Agreement and Release effective September 30, 2022 (the "CSAR") by and between the Company and Fujifilm.

Under the CSAR, the Company agreed to pay up to \$185.0 million to Fujifilm in connection with the cancellation of manufacturing activity at FDBT. The final two quarterly installments due to Fujifilm in 2023 under the CSAR, totaling \$68.6 million, were subject to Fujifilm's obligation to use commercially reasonable efforts to mitigate losses associated with the vacant manufacturing capacity caused by the termination of manufacturing activities at FDBT. In October 2023, the Company sent Fujifilm a notice of breach and refused to pay the final two installments based on its contention that Fujifilm had not used commercially reasonable efforts to mitigate losses and should have offset some portion of the final two payments. In October 2023, Fujifilm filed a demand for arbitration with Judicial Arbitration and Mediation Services ("JAMS") seeking payment of the full amount (the "Fujifilm Arbitration").

Pursuant to the Settlement Agreement, in March 2024, the Company paid \$42.0 million to Fujifilm, the parties agreed to a mutual release of claims arising from, under or otherwise in connection with the CSAR, and Fujifilm agreed to dismiss the Fujifilm Arbitration. This payment is less than amounts previously accrued for and reflected in Research and development expense, and accordingly, the Company recorded a benefit of \$26.6 million as Research and development expense during the year ended December 31, 2024 upon the execution of the Settlement Agreement.

The Company continues to assess its manufacturing needs and intends to modify its global manufacturing footprint consistent with its contractual obligations to supply, and anticipated demand for, its COVID-19 Program, and in doing so, recognizes that significant costs may be incurred.

#### Note 5 – Cash, Cash Equivalents, and Restricted Cash

The following table provides a reconciliation of cash, cash equivalents, and restricted cash reported on the consolidated balance sheets that sum to the total of the same such amounts shown in the statement of cash flows (in thousands):

	December 31,		
	2024	2023	2022
Cash and cash equivalents	\$ 530,230	\$ 568,505	\$ 1,336,883
Restricted cash current	10,626	10,424	10,303
Restricted cash non-current <sup>(1)</sup>	4,436	4,881	1,659
Cash, cash equivalents, and restricted cash	<u>\$ 545,292</u>	<u>\$ 583,810</u>	<u>\$ 1,348,845</u>

(1) Classified as Other non-current assets as of December 31, 2024 and 2023.

#### Note 6 – Marketable Securities

Marketable securities classified as available-for-sale-comprised of (in thousands):

	December 31, 2024				December 31, 2023			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Treasury securities	\$ 184,438	\$ 116	\$ —	\$ 184,554	\$ —	\$ —	\$ —	\$ —
Corporate debt securities	208,410	—	(76)	208,334	—	—	—	—
Total marketable securities	<u>\$ 392,848</u>	<u>\$ 116</u>	<u>\$ (76)</u>	<u>\$ 392,888</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ —</u>

As of December 31, 2024, investments in marketable securities comprised of \$184.6 million of treasury securities, of which \$23.0 million mature in 2025 and \$161.5 million mature in 2026, and \$208.3 million of corporate debt securities, of which \$195.2 million mature in 2025 and \$13.1 million mature in 2026. Marketable securities are classified as Current assets in the Consolidated balance sheet of the Company as of December 31, 2024. Based on the Company's policy under the expected credit loss model, including an assessment of the investment portfolio as of December 31, 2024, the Company concluded that any unrealized losses for its marketable securities were not attributable to credit and therefore an allowance for credit losses has not been recorded as of December 31, 2024. As of December 31, 2024, the Company held no securities that were in an unrealized loss position for more than 12 months.

## Note 7 – Fair Value Measurements

The following table represents the estimated fair value of the Company's financial assets and liabilities (in thousands):

	Fair Value at December 31, 2024			Fair Value at December 31, 2023		
	Level 1	Level 2	Level 3	Level 1	Level 2	Level 3
<b>Assets</b>						
Money market funds <sup>(1)</sup>	\$ 287,393	\$ —	\$ —	\$ 171,824	\$ —	\$ —
Government-backed securities <sup>(1)</sup>	—	130,000	—	—	200,000	—
Treasury securities	—	184,554	—	—	—	—
Corporate debt securities <sup>(2)</sup>	—	243,158	—	—	45,622	—
Total	\$ 287,393	\$ 557,712	\$ —	\$ 171,824	\$ 245,622	\$ —
<b>Liabilities</b>						
5.00% Convertible notes due 2027	\$ —	\$ 174,386	\$ —	\$ —	\$ 100,909	\$ —
Total convertible notes payable	\$ —	\$ 174,386	\$ —	\$ —	\$ 100,909	\$ —

(1) Classified as cash and cash equivalents as of December 31, 2024 and 2023.

(2) Includes \$34.8 million and \$45.6 million classified as cash and cash equivalents as of December 31, 2024 and 2023, respectively, on the consolidated balance sheets.

Fixed-income investments categorized as Level 2 are valued at the custodian bank by a third-party pricing vendor's valuation models that use verifiable observable market data, such as interest rates and yield curves observable at commonly quoted intervals and credit spreads, bids provided by brokers or dealers, or quoted prices of securities with similar characteristics. Pricing of the Company's convertible notes has been estimated using observable inputs, including the price of the Company's common stock, implied volatility, interest rates, and credit spreads.

During the years ended December 31, 2024 and 2023, the Company did not have any transfers between Levels.

## Note 8 – Inventory

Inventory consisted of the following (in thousands):

	December 31,	
	2024	2023
Raw materials	\$ 2,087	\$ 6,614
Semi-finished goods	4,899	7,392
Finished goods	1,763	27,690
Total inventory	\$ 8,749	\$ 41,696

Inventory write-downs as a result of excess, obsolescence, expiry, or other reasons, and losses on firm purchase commitments, offset by recoveries of such commitments, are recorded as a component of cost of sales in the Company's consolidated statements of operations. For the year ended December 31, 2024, inventory write-downs were \$21.0 million and losses on firm purchase commitments were \$7.4 million. In addition, for the year ended December 31, 2024, the Company recorded recoveries on firm purchase commitments of \$0.7 million related primarily to negotiated reductions to previously recognized firm purchase commitments. For the year ended December 31, 2023, inventory write-downs were \$72.4 million, losses on firm purchase commitments were \$73.5 million, and recoveries on firm purchase commitments were \$40.2 million. For the year ended December 31, 2022, inventory write-downs were \$447.6 million and losses on firm purchase commitments were \$155.9 million. Also, during the years ended December 31, 2024 and 2023, the Company recorded impairment charges of \$3.8 million and \$6.1 million, respectively, in Cost of sales related to embedded lease agreements with CMOs for production capacity in excess of production needs. Inventory reserves for write-downs are relieved when the inventory is disposed of through scrap or sale. Activity in the reserve for excess and obsolete inventory was as follows (in thousands):

	Year Ended December 31,	
	2024	2023
Beginning balance	\$ 266,059	\$ 368,383
Charged to Cost of sales, including impairments	20,970	72,441
Other additions	14,381	65,049
Deductions	(209,386)	(239,814)
Ending balance	<u>\$ 92,024</u>	<u>\$ 266,059</u>

Other additions include receipts of inventory previously recorded as losses on firm purchase commitments.

#### Note 9 – Goodwill

The Company has one reporting unit, which has a negative carrying amount as of December 31, 2024 and 2023. The change in the carrying amounts of goodwill was as follows (in thousands):

	Year Ended December 31,	
	2024	2023
Beginning balance	\$ 127,454	\$ 126,331
Goodwill allocated to disposition of Novavax CZ assets (See Note 19)	(12,371)	—
Currency translation adjustments	(7,605)	1,123
Ending balance	<u>\$ 107,478</u>	<u>\$ 127,454</u>

#### Note 10 – Leases

The Company has embedded leases related to multiple manufacturing supply agreements with CMOs and CMOS to manufacture COVID-19 Vaccine, as well as operating and finance leases for its research and development and manufacturing facilities, corporate headquarters and offices. During the year ended December 31, 2024, the Company continued to align its global manufacturing footprint as a result of its ongoing assessment of manufacturing needs consistent with its contractual obligations related to the supply, and anticipated demand for, its COVID-19 Vaccine.

During the years ended December 31, 2024 and 2023, the Company modified certain of its CMO and CDMO agreements that had previously been determined to represent embedded leases and, in accordance with its policy, the Company remeasured and reallocated the remaining consideration under the contracts and reassessed the lease classification as of the effective dates of the respective modifications. During the year ended December 31, 2024 and 2023, as a result of new or modified leases, the Company recognized ROU assets, net of credits on modifications, and a corresponding lease liability of \$4.0 million and \$6.8 million, respectively, for its long-term operating lease embedded in CMO and CDMO manufacturing supply agreements. Also, during the year ended December 31, 2024 and 2023, the Company recorded an impairment charge of \$3.8 million and \$6.1 million, respectively, in Cost of sales related to embedded lease agreements with CMO for production capacity in excess of production needs.

During the year ended December 31, 2023, the Company obtained the right to direct the use of, and obtain substantially all of the benefit from, the remaining floors located at the premises and recognized a ROU asset and related lease obligation of \$96.5 million as the lease commencement dates for accounting purposes had occurred for such remaining floors. The lease obligation was reduced by \$73.4 million for prepaid rent and prior costs incurred on behalf of the landlord during 2023. As of December 31, 2024, facility leases, including the 700QO lease, have expirations that range from approximately one to twelve years, some of which include options to extend the lease term. The facility leases contain provisions for future rent increases and obligate the Company to pay building operating costs.

During the year ended December 31, 2023, the Company recorded an impairment charge of \$5.9 million related to ROU facility leases used for research and development, manufacturing and offices space that are impacted by the Restructuring Plan. No impairment charge related to facility leases was recorded during the year ended December 31, 2024.

Supplemental balance sheet information related to leases as of December 31, 2024 and 2023 was as follows (in thousands, except weighted-average remaining lease term and discount rate):

Lease Assets and Liabilities	Classification	December 31,	
		2024	2023
Assets:			
ROU assets, operating, net	Right of use asset, net	\$ 21,846	\$ 24,985
ROU assets, finance, net	Right of use asset, net	139,739	160,233
Total non-current ROU assets		\$ 161,585	\$ 185,218
Liabilities:			
Current portion of operating lease liabilities	Other current liabilities	\$ 10,094	\$ 22,977
Current portion of finance lease liabilities	Current portion of finance lease liabilities	7,009	5,142
Total current lease liabilities		\$ 17,103	\$ 28,119
Non-current portion of operating lease	Other non-current liabilities	\$ 22,958	\$ 28,577
Non-current portion of finance lease liabilities	Non-current finance lease liabilities	53,726	55,923
Total non-current lease liabilities		\$ 76,684	\$ 84,500
Weighted-average remaining lease term (years):			
Operating leases		4.3	3.9
Finance leases		10.7	11.6
Weighted-average discount rate:			
Operating leases		6.4 %	6.0 %
Finance leases		9.0 %	8.9 %

Lease expense for the operating and short-term leases for the years ended December 31, 2024, 2023, and 2022 was as follows (in thousands):

	Year Ended December 31,		
	2024	2023	2022
Operating lease expense	\$ 9,005	\$ 6,929	\$ 6,903
Short-term lease expense (benefit <sup>(1)</sup> )	(26,619)	(48,009)	94,726
Variable lease expense	6,831	10,292	6,836
Finance lease expense:			
ROU assets expensed	\$ 11,737	\$ 12,876	\$ 7,759
Interest expense	5,697	2,605	1,472
Total finance lease expense	<u>\$ 17,434</u>	<u>\$ 15,481</u>	<u>\$ 9,231</u>

- (1) During the year ended December 31, 2024 and 2023, the Company recognized a short-term lease benefit of \$26.6 million and \$48.0 million, respectively, due to gains on the settlement of manufacturing supply agreements with CMOs and CDMOs that included embedded leases.



Supplemental cash flow information related to leases for the year ended December 31, 2024, 2023, and 2022 was as follows (in thousands):

	Year Ended December 31,		
	2024	2023	2022
Cash paid for amounts included in the measurement of lease liabilities:			
Operating cash flows used in operating leases	\$ 63,673	\$ 101,297	\$ 190,158
Operating cash flows used in finance leases	5,697	2,605	1,472
Financing cash flows used in finance leases	3,994	27,345	93,595
ROU assets obtained in exchange for operating lease obligations	\$ 3,987	\$ —	\$ 30,675
ROU assets obtained in exchange for finance lease obligations	3,664	103,299	73,240
As of December 31, 2024, maturities of lease liabilities were as follows (in thousands):			
Year	Operating		Finance
2025	10,855		12,187
2026	7,006		7,570
2027	7,225		7,736
2028	7,431		7,905
2029	3,682		7,596
Thereafter	1,404		55,025
Total minimum lease payments	37,603		98,019
Less: imputed interest	4,551		37,284
Total lease liabilities	\$ 33,052		\$ 60,735

#### Note 11 – Long-Term Debt

The Company's long-term debt consisted of the following (in thousands):

	December 31,	
	2024	2023
Non-current portion:		
5.00% Convertible notes due 2027	\$ 175,250	\$ 175,250
Unamortized debt issuance costs	(5,566)	(7,234)
Total convertible notes payable	\$ 169,684	\$ 168,016

Interest expense incurred in connection with the convertible notes payable consisted of the following (in thousands):

	Year Ended December 31,		
	2024	2023	2022
Coupon interest	\$ 8,762	\$ 9,779	\$ 12,542
Amortization of debt issuance costs	1,668	1,689	1,497
Total interest expense on convertible notes payable	\$ 10,430	\$ 11,468	\$ 14,039

#### 2027 Convertible Notes

In December 2022, the Company issued \$175.3 million aggregate principal amount of convertible senior unsecured notes that will mature on December 15, 2027 (the "2027 Notes"), unless earlier converted, redeemed, or repurchased. The 2027 Notes were issued in a private placement to qualified institutional buyers pursuant to Rule 144A under the Securities Act of 1933, as amended, and pursuant to an indenture dated December 20, 2022 (the "2027 Indenture") between the Company and The Bank of New York Mellon Trust Company, N.A., as trustee. Concurrently with the issuance of the 2027 Notes, the Company completed a public offering of shares of its common stock. The Company received \$166.4 million in net proceeds from the issuance of the 2027 Notes after deducting the initial purchasers' fees and the Company's offering expenses. The 2027 Notes bear cash interest at a rate of 5.00% per year, payable semiannually in arrears on June 15 and December 15 of each year, beginning on June 15, 2023.

The 2027 Notes are convertible at the option of the holders at any time prior to the close of business on the business day immediately preceding September 15, 2027, only under the following circumstances: (1) during any calendar quarter commencing after the calendar quarter ending on March 31, 2023 (and only during such calendar quarter), if the last reported sale price of the Company's common stock for at least 20 trading days (whether or not consecutive) during a period of 30 consecutive trading days ending on, and including, the last trading day of the immediately preceding calendar quarter is greater than or equal to 130% of the conversion price for the 2027 Notes on each applicable trading day; (2) during the five business day period after any ten consecutive trading day period (the "measurement period") in which the trading price (as defined in the 2027 Indenture) per \$1,000 principal amount of the 2027 Notes for each trading day of the measurement period was less than 98% of the product of the last reported sale price of the Company's common stock and the conversion rate for the 2027 Notes on each such trading day; (3) if the Company calls such 2027 Notes for redemption, at any time prior to the close of business on the scheduled trading day immediately preceding the redemption date, but only with respect to the 2027 Notes called (or deemed called) for redemption; and (4) upon the occurrence of specified corporate events as set forth in the 2027 Indenture. On or after September 15, 2027, until the close of business on the business day immediately preceding the maturity date (December 15, 2027), holders of the 2027 Notes may convert all or any portion of their 2027 Notes at any time, regardless of the foregoing conditions. Upon conversion, the Company may satisfy its conversion obligation by paying or delivering, as the case may be, cash, shares of the Company's common stock, or a combination of cash and shares of the Company's common stock, at the Company's election, in the manner and subject to the terms and conditions provided in the 2027 Indenture.

The conversion rate for the 2027 Notes will initially be 80.0000 shares of the Company's common stock per \$1,000 principal amount of 2027 Notes, which is equivalent to an initial conversion price of \$12.50 per share of common stock. The initial conversion price of the 2027 Notes represents a conversion premium of 25% of the public offering price in the Company's concurrent common stock offering that closed on December 20, 2022. The conversion rate for the 2027 Notes is subject to adjustment under certain circumstances in accordance with the terms of the 2027 Indenture. In addition, following certain corporate events that occur prior to the maturity date of the 2027 Notes or if the Company delivers a notice of redemption in respect of the 2027 Notes, the Company will, under certain circumstances, increase the conversion rate of the 2027 Notes for a holder who elects to convert its 2027 Notes (or any portion thereof) in connection with such a corporate event or convert its 2027 Notes called (or deemed called) for redemption during the related redemption period (as defined in the 2027 Indenture), as the case may be.

The Company may not redeem the 2027 Notes prior to December 22, 2025. The Company may redeem for cash all or any portion of the 2027 Notes, at its option, on or after December 22, 2025, if the last reported sale price of the common stock has been at least 130% of the conversion price for the 2027 Notes then in effect for at least 20 trading days (whether or not consecutive) during any 30 consecutive trading day period (including the last trading day of such period) ending on, and including, the trading day immediately preceding the date on which the Company provides notice of redemption at a redemption price equal to 100% of the principal amount of the 2027 Notes to be redeemed, plus accrued and unpaid interest, to, but excluding, the redemption date. If the Company redeems less than all the outstanding 2027 Notes, at least \$50 million aggregate principal amount of 2027 Notes must be outstanding and not subject to redemption as of the date of the relevant notice of redemption. No sinking fund is provided for the 2027 Notes.

If the Company undergoes a Fundamental Change (as defined in the 2027 Indenture), holders may require, subject to certain conditions and exceptions as set forth in the 2027 Indenture, the Company to repurchase for cash all or any portion of their 2027 Notes at a Fundamental Change repurchase price equal to 100% of the principal amount of the 2027 Notes to be repurchased, plus accrued and unpaid interest, to, but excluding, the Fundamental Change repurchase date. If a holder of the 2027 Notes converted upon a Make-Whole Fundamental Change (as described in the 2027 Indenture), they may be eligible to receive a make-whole premium through an increase to the conversion rate up to a maximum of 20.0000 shares per \$1,000 principal amount of 2027 Notes (subject to other adjustments as described in the 2027 Indenture).

In accounting for the issuance of the 2027 Notes, the Company determined that the scope exceptions provided under ASC Topic 815-40, *Derivatives and Hedging – Contracts in Entity's Own Equity* ("ASC 815-40") apply to all but one of the conversion features embedded in the 2027 Notes. This remaining conversion feature, which is associated with a Fundamental Change of the Company, was determined to have a de minimis value as of December 31, 2024, and 2023.

The initial purchasers' fees and the Company's issuance costs related to the 2027 Notes totaled \$8.8 million, which were recorded as a reduction to the 2027 Notes on the consolidated balance sheet. The \$8.8 million of debt issuance costs is being amortized and recognized as additional interest expense over the five-year contractual term of the 2027 Notes using an effective interest rate of 6.2%.

## **2023 Convertible Notes**

In 2016, the Company issued \$325 million aggregate principal amount of convertible senior unsecured notes that matured on February 1, 2023 (the "2023 Notes"). The 2023 Notes were senior unsecured debt obligations and were issued at par. The Company funded the outstanding principal amount of \$325 million on the 2023 Notes, due February 1, 2023, and the indenture governing the 2023 Notes was subsequently satisfied and discharged in accordance with its terms. The Company's related "capped call transactions" expired by their terms on January 27, 2023. The Company repaid the outstanding principal amount of \$325 million together with accrued but unpaid interest on the maturity date. The repayment was funded by the issuance of the 2027 Notes and the common stock offering, as well as cash on hand.

## **Note 12 – Stockholders' Deficit**

In August 2023, the Company entered into an At Market Issuance Sales Agreement (the "August 2023 Sales Agreement"), which allows it to issue and sell up to \$500 million in gross proceeds of shares of its common stock, and terminated its then-existing At Market Issuance Sales agreement entered in June 2021 (the "June 2021 Sales Agreement"). During the year ended December 31, 2024, the Company sold 12.2 million shares of its common stock under its August 2023 Sales Agreement, resulting in net proceeds of approximately \$188 million. As of December 31, 2024, the remaining balance available under the August 2023 Sales Agreement was approximately \$51 million.

In May 2024, the Company also entered into the Sanofi Subscription Agreement, pursuant to which the Company sold and issued to Sanofi, in a private placement, 6.9 million shares of the Company's common stock, par value \$0.01 per share at a price of \$10.00 per share, for aggregate gross proceeds to the Company of \$68.8 million.

During the year ended December 31, 2023, the Company sold 38.3 million shares of its common stock under its August 2023 Sales Agreement and 7.9 million shares of its common stock under its June 2021 Sales Agreement, resulting in net proceeds of approximately \$321 million, of which \$6.9 million was included in Prepaid expenses and other current assets as of December 31, 2023 and received in cash in January 2024.

In August 2023, pursuant to the SK Subscription Agreement, the Company agreed to sell and issue to SK 6.5 million shares of the Company's common stock at a price of \$13.00 per share (the "Shares") in a Private Placement for aggregate gross proceeds to the Company of approximately \$84.5 million. The Company recognized the Shares at the settlement date fair value of \$46.5 million. The closing of the Private Placement occurred on August 10, 2023.

## **Note 13 – Stock-Based Compensation**

### ***Equity Plans***

In January 2023, the Company established the 2023 Inducement Plan (the "2023 Inducement Plan"), which provides for the granting of share-based awards to individuals who were not previously employees, or following a bona fide period of non-employment, as an inducement material to such individuals entering into employment with the Company. The Company reserved 1.0 million shares of common stock for grants under the 2023 Inducement Plan. As of December 31, 2024, there were 0.1 million shares available for issuance under the 2023 Inducement Plan.

The 2015 Stock Incentive Plan, as amended ("2015 Plan"), was approved at the Company's annual meeting of stockholders in June 2015. Under the 2015 Plan, equity awards may be granted to officers, directors, employees, and consultants of and advisors to the Company and any present or future subsidiary.

The 2015 Plan authorizes the issuance of up to 27.5 million shares of common stock under equity awards granted under the 2015 Plan. All such shares authorized for issuance under the 2015 Plan have been reserved. The 2015 Plan will expire on March 30, 2033. As of December 31, 2024, there were 11.1 million shares available for issuance under the 2015 Plan.

The Amended and Restated 2005 Stock Incentive Plan ("2005 Plan") expired in February 2015 and no new awards may be made under such plan, although awards will continue to be outstanding in accordance with their terms.

The 2023 Inducement Plan and the 2015 Plan permit, and the 2005 Plan permitted, the grant of stock options (including incentive stock options), restricted stock, stock appreciation rights ("SARs"), and restricted stock units ("RSUs"). In addition, under the 2023 Inducement Plan and the 2015 Plan, unrestricted stock, stock units, and performance awards may be granted. Stock

options and SARs generally have a maximum term of ten years and may be or were granted with an exercise price that is no less than 100% of the fair market value of the Company's common stock at the time of grant. Grants of share-based awards are generally subject to vesting over periods ranging from one to one to four years.

The Company recorded stock-based compensation expense in the consolidated statements of operations as follows (in thousands):

	Year Ended December 31,		
	2024	2023	2022
Cost of sales	\$ 3,431	\$ 3,417	\$ 1,032
Research and development	20,868	41,211	66,565
Selling, general, and administrative	23,853	40,729	62,703
Total stock-based compensation expense	\$ 48,152	\$ 85,357	\$ 130,300

During the year ended December 31, 2023 and 2022, total stock-based compensation capitalized in inventory was \$0.5 million and \$1.7 million, respectively. No stock-based compensation was capitalized in inventory during the year ended December 31, 2024.

As of December 31, 2024, there was approximately \$43 million of total unrecognized compensation expense related to unvested stock options, SARs, RSUs, and the ESPP. This unrecognized non-cash compensation expense is expected to be recognized over a weighted-average period of approximately 1.2 years and will be allocated between cost of sales, research and development, and general and administrative expenses accordingly. This estimate does not include the impact of other possible stock-based awards that may be made during future periods.

The aggregate intrinsic value represents the total intrinsic value (the difference between the Company's closing stock price on the last trading day of the period and the exercise price, multiplied by the number of in-the-money stock options and SARs) that would have been received by the holders had all stock option and SARs holders exercised their stock options and SARs on December 31, 2024. This amount is subject to change based on changes to the closing price of the Company's common stock. The aggregate intrinsic value of stock options and SARs exercises and vesting of RSUs for the years ending December 31, 2024, 2023, and 2022 was approximately \$13 million, \$5 million, and \$21 million, respectively.

### **Stock Options and Stock Appreciation Rights**

The following is a summary of stock options and SARs activity under the 2023 Inducement Plan, 2015 Plan and the 2005 Plan for the year ended December 31, 2024:

	2023 Inducement Plan		2015 Plan		2005 Plan	
	Stock Options	Weighted-Average Exercise Price	Stock Options & SARs	Weighted-Average Exercise Price	Stock Options	Weighted-Average Exercise Price
Outstanding at January 1, 2024	422,800	\$ 10.67	4,787,042	\$ 38.10	58,275	\$ 119.79
Granted	64,150	\$ 9.01	769,891	\$ 7.96	—	\$ —
Exercised	—	—	(414,234)	\$ 7.71	—	\$ —
Canceled	—	—	(1,646,647)	\$ 42.99	(58,275)	\$ 119.79
Outstanding at December 31, 2024	486,950	\$ 10.45	3,496,052	\$ 32.75	—	\$ —
Shares exercisable at December 31, 2024	189,061	\$ 10.82	2,248,656	\$ 43.77	—	\$ —

The fair value of stock options granted under the 2023 Inducement Plan and the 2015 Plan was estimated at the date of grant using the Black-Scholes option-pricing model with the following assumptions:

	Year Ended December 31,		
	2024	2023	2022
Weighted average Black-Scholes fair value of stock options and SARs granted	\$5.94	\$7.00	\$55.32
Risk-free interest rate	4.1%-4.3%	3.5%-4.8%	1.4%-4.3%
Dividend yield	—%	—%	—%
Volatility	104.4%-121.8%	120.4%-140.3%	120.5%-140.1%
Expected term (in years)	3.8-6.3	3.9-6.4	4.0-6.3

The total aggregate intrinsic value and weighted-average remaining contractual term of stock options and SARs outstanding under the 2023 Inducement Plan and 2005 Plan as of December 31, 2024 was less than \$3.2 million and 7.0 years, respectively. The total aggregate intrinsic value and weighted-average remaining contractual term of stock options and SARs exercisable under the 2023 Inducement Plan and 2005 Plan as of December 31, 2024 was less than \$1.0 million and 5.9 years, respectively.

### **Restricted Stock Units**

The following is a summary of RSU activity for the year ended December 31, 2024:

	2023 Inducement Plan		2015 Plan	
	Number of Shares	Per Share Weighted-Average Fair Value	Number of Shares	Per Share Weighted-Average Fair Value
Outstanding and unvested at January 1, 2024	363,990	\$ 10.66	3,714,870	\$ 19.43
Restricted stock units granted	42,770	\$ 9.01	4,545,824	\$ 5.72
Restricted stock units vested	(121,331)	\$ 10.66	(1,326,868)	\$ 24.95
Restricted stock units forfeited	—	\$ —	(1,375,184)	\$ 13.88
Outstanding and unvested at December 31, 2024	285,429	\$ 10.42	5,558,642	\$ 8.27

### **Employee Stock Purchase Plan**

The ESPP was approved at the Company's annual meeting of stockholders in June 2013. The ESPP currently authorizes an aggregate of 2.2 million shares of common stock to be purchased, and the aggregate amount of shares will continue to increase 5% on each anniversary of its adoption up to a maximum of 3.5 million shares. The ESPP allows employees to purchase shares of common stock of the Company at each purchase date through payroll deductions of up to a maximum of 15% of their compensation, at 85% of the lesser of the market price of the shares at the time of purchase or the market price on the beginning date of an option period (or, if later, the date during the option period when the employee was first eligible to participate). At December 31, 2024, there were 1.0 million shares available for issuance under the ESPP.

### **Note 14 – Employee Benefits**

The Company maintains a defined contribution 401(k) retirement plan, pursuant to which employees may elect to contribute up to 100% of their compensation on a tax deferred basis up to the maximum amount permitted by the Internal Revenue Code of 1986, as amended. The Company matches 100% of the first 3% of the participants' deferral, and 50% on the next 2% of the participants' deferral, up to a potential 4% Company match. The Company's matching contributions to the 401(k) plan vest immediately. Under its 401(k) plan, the Company has recorded expense of \$5.5 million, \$7.0 million, and \$6.0 million in 2024, 2023, and 2022, respectively.

The Company's foreign subsidiaries have pension plans under local tax and labor laws and are obligated to make contributions to the plan. Contributions and other expenses related to these plans were \$2.6 million, \$3.0 million, and \$2.4 million in 2024, 2023, and 2022, respectively.

## Note 15 – Other Financial Information

### ***Prepaid Expenses and Other Current Assets***

Prepaid expenses and other current assets consist of the following as of (in thousands):

	December 31,	
	2024	2023
Prepaid expenses	\$ 56,276	\$ 70,297
Other current assets	21,888	155,726
Prepaid expenses and other current assets	<u>\$ 78,164</u>	<u>\$ 226,023</u>

### ***Property and Equipment, net***

Property and equipment is comprised of the following as of (in thousands):

	December 31,	
	2024	2023
Land and buildings	\$ 14,945	\$ 102,916
Machinery and equipment	61,498	148,243
Leasehold improvements	66,886	48,310
Computer hardware	4,728	5,114
Construction in progress	39,513	76,156
	187,570	380,739
Less: accumulated depreciation	(49,157)	(74,968)
Property and equipment, net	<u>\$ 138,413</u>	<u>\$ 305,771</u>

On December 30, 2024, the Company sold approximately \$135 million of property and equipment, net, representing the Company's biologics manufacturing campus and other moveable assets and equipment located in the Czech Republic (see note 19). Depreciation expense was approximately \$48 million, \$41 million, and \$29 million for the years ended December 31, 2024, 2023, and 2022, respectively.

### ***Accrued Expenses***

Accrued expenses consist of the following as of (in thousands):

	December 31,	
	2024	2023
Employee benefits and compensation	\$ 60,350	\$ 55,952
Gross-to-net deductions	18,821	20,616
U.S. product sales returns accrual	58,259	82,506
Research and development accruals	37,847	131,027
Other accrued expenses	35,888	104,567
Accrued expenses	<u>\$ 211,165</u>	<u>\$ 394,668</u>



**Other Current Liabilities**

Other current liabilities consist of the following as of (in thousands):

	<b>December 31,</b>	
	<b>2024</b>	<b>2023</b>
Refunds due to APA customers	\$ 87,901	\$ 142,165
Due to UK Authority (see Note 3)	36,357	—
Due to Gavi (see Note 3)	85,000	696,390
Other current liabilities	10,338	22,853
<b>Total other current liabilities</b>	<b>\$ 219,596</b>	<b>\$ 861,408</b>

**Note 16 – Income Taxes**

The Company's income (loss) before income tax expense by jurisdiction is as follows (in thousands):

	<b>Year Ended December 31,</b>		
	<b>2024</b>	<b>2023</b>	<b>2022</b>
Domestic	\$ (261,909)	\$ (628,984)	\$ (712,183)
Foreign	85,294	85,953	58,536
<b>Loss before income tax expense</b>	<b>\$ (176,615)</b>	<b>\$ (543,031)</b>	<b>\$ (653,647)</b>

Significant components of the current and deferred income tax expense (benefit) are as follows (in thousands):

	<b>Year Ended December 31,</b>		
	<b>2024</b>	<b>2023</b>	<b>2022</b>
Current:			
Domestic	\$ —	\$ (1,300)	\$ 1,300
State and local	43	(157)	503
Foreign	12,264	1,445	2,489
<b>Total current income tax expense (benefit)</b>	<b>12,307</b>	<b>(12)</b>	<b>4,292</b>
Deferred:			
Foreign	(1,423)	2,043	—
<b>Total income tax expense</b>	<b>\$ 10,884</b>	<b>\$ 2,031</b>	<b>\$ 4,292</b>

A reconciliation of income tax expense to the amount computed by applying the U.S. federal statutory tax rate to the Company's effective tax rate is as follows:

	Year Ended December 31,					
	2024		2023		2022	
Statutory federal tax rate	21	%	21	%	21	%
State income taxes, net of federal benefit	3	%	1	%	2	%
Research and development and other tax credits	—	%	—	%	1	%
Non-deductible expenses	—	%	—	%	(1)	%
Non-cash stock-based compensation	(9)	%	(1)	%	(1)	%
U.S. taxation of foreign operations	(3)	%	(4)	%	(3)	%
Cancellation of indebtedness	—	%	(1)	%	—	%
Deferred tax asset write down	(13)	%	—	%	—	%
Non-US tax credits	—	%	4	%	—	%
Other	(6)	%	—	%	2	%
Change in tax rate	8	%	—	%	(20)	%
Change in valuation allowance	(7)	%	(20)	%	(2)	%
Income tax expense	(6)	%	—	%	(1)	%

As of December 31, 2024, the Company has available federal and state net operating losses of \$2.4 billion, \$785.1 million, respectively, that may be applied against future taxable income in the respective jurisdiction. The federal net operating losses of \$2.4 billion can be carried forward indefinitely, with all but \$9.6 million, which expires in 2037, limited to use equal to 80% of future annual federal taxable income. State net operating losses of \$434.1 million have various expiration dates between 2030 and 2044. The remaining state net operating losses of \$351.0 million can be carried forward indefinitely. The Company also has federal research tax credits of \$51.3 million that will expire from 2025 through 2045 and a state research tax credit of \$1.2 million that will expire from 2040 through 2042. Utilization of the federal and state net operating loss carryforwards and research tax credits may be subject to an annual limitation due to potential future ownership changes of the Company. As of December 31, 2024, the Company does not expect such limitation, if any, to impact the use of its net operating losses and research tax credits.

The Company files income tax returns in the U.S. federal jurisdiction and in various states, as well as in multiple foreign jurisdictions including Sweden and the Czech Republic. The Company has U.S. federal and state net operating losses and credit carryforwards that are subject to examination from 2002 through 2024. The returns in Sweden are subject to examination from 2016 through 2024 and the returns for the Czech Republic are subject to examination from 2019 through 2024.

The significant components of the Company's deferred tax assets and liabilities as of December 31 were as follows (in thousands):

	December 31,	
	2024	2023
Deferred tax assets:		
Federal and state net operating loss carryforward	\$ 551,261	\$ 550,272
Research tax credits	51,343	51,878
Lease liability	21,567	25,207
Deferred revenue	314,121	266,392
Inventory reserve	36,546	79,386
Allowance for sales returns	13,397	20,756
Non-cash stock-based compensation	22,376	30,727
Capitalized research costs	152,046	132,500
Foreign tax credit carryforward	—	18,679
Other	15,150	10,996
Gross deferred tax assets	1,177,807	1,186,793
Valuation allowance	(1,135,559)	(1,128,941)
Total deferred tax assets	\$ 42,248	\$ 57,852
Deferred tax liabilities:		
ROU assets	\$ (37,159)	\$ (41,456)
Fixed assets	(4,492)	(17,160)
Intangibles	(999)	(1,279)
Total deferred tax liabilities	\$ (42,650)	\$ (59,895)
Net deferred tax liabilities	\$ (402)	\$ (2,043)

The Company has evaluated the positive and negative evidence bearing upon the realization of its deferred tax assets, including its history of significant losses in every year since inception and, in accordance with U.S GAAP, has fully reserved the net deferred tax assets. The Company concluded that realization of its net deferred tax assets is not more-likely-than-not to be realized as of December 31, 2024 and 2023. The valuation allowance increased by \$6.6 million and \$108.8 million for the years ended December 31, 2024 and 2023, respectively, due to the pretax book losses recognized during these years.

The net deferred tax liability of \$0.4 million and \$2.0 million at December 31, 2024 and 2023, respectively, is included within other non-current liabilities on the accompanying consolidated balance sheet.

The Company recognizes the effect of an income tax position when it is more likely than not, based on the technical merits, that the income tax position will be sustained upon examination. A reconciliation of the beginning and ending amounts of unrecognized tax benefits in the year ended December 31, 2024, 2023, and 2022 is as follows (in thousands):

	Year Ended December 31,		
	2024	2023	2022
Unrecognized tax benefits balance at January 1	\$ 4,237	\$ 5,194	\$ 11,154
Additions for tax positions of current year	—	271	1,260
Additions for tax positions of prior years	—	—	807
Reductions for tax positions of prior year	(137)	(1,228)	(8,027)
Unrecognized tax benefits balance at December 31,	\$ 4,100	\$ 4,237	\$ 5,194

The Company's policy is to recognize interest and penalties related to income tax matters in income tax expense. As of December 31, 2024 and 2023, the Company had no accruals for interest or penalties. The total amount of unrecognized tax benefits that, if recognized, could affect the effective tax rate was \$4.1 million and \$4.2 million as of December 31, 2024 and 2023, respectively. However, the Company maintains a full valuation allowance as of December 31, 2024 and 2023 and the recognition of any unrecognized tax benefits would be offset with a change in the valuation allowance and therefore there would be no income statement impact. As of December 31, 2024, the Company does not expect a significant change in the recorded unrecognized tax benefits liability balance during the next twelve months. The unrecognized tax benefits are presented in the financial statements as a reduction to the deferred tax assets for all periods.

In 2021, the Organization for Economic Cooperation and Development ("OECD") developed guidance on Base Erosion and Profit Shifting ("BEPS") Pillar Two Model Rules ("Pillar Two"), which addresses corporate tax planning strategies used by some large multinational corporations to shift profits from higher-tax jurisdictions to lower-tax jurisdictions or zero-tax locations. This guidance imposes a 15% minimum tax on the earnings of large multinational corporations. Pillar Two is effective in 2024 for the jurisdictions in which the Company operates. The Company does not expect these rules to have a significant impact on its effective tax rate or its consolidated financial statements.

## **Note 17 – Commitment and Contingencies**

### ***Legal Matters***

#### **Stockholder Litigation**

On November 12, 2021, Sothinathan Sinnathurai filed a purported securities class action in the U.S. District Court for the District of Maryland (the "Maryland Court") against the Company and certain members of senior management, captioned Sothinathan Sinnathurai v. Novavax, Inc., et al., No. 8:21-cv-02910-TDC (the "Sinnathurai Action"). The parties ultimately negotiated a settlement, which the Maryland Court approved on May 23, 2024. The Maryland Court closed the Sinnathurai Action on May 24, 2024. Upon the Maryland Court's final approval, the Company relieved the \$47 million estimated settlement liability within Accrued expenses and the \$47 million estimated insurance recovery within Prepaid expenses and other current assets on the consolidated balance sheet.

After the Sinnathurai Action was filed, eight derivative lawsuits were filed: (i) Robert E. Meyer v. Stanley C. Erck, et al., No. 8:21-cv-02996-TDC (the "Meyer Action"), (ii) Shui Shing Yung v. Stanley C. Erck, et al., No. 8:21-cv-03248-TDC (the "Yung Action"), (iii) William Kirst, et al. v. Stanley C. Erck, et al., No. C-15-CV-21-000618 (the "Kirst Action"), (iv) Amy Snyder v. Stanley C. Erck, et al., No. 8:22-cv-01415-TDC (the "Snyder Action"), (v) Charles R. Blackburn, et al. v. Stanley C. Erck, et al., No. 1:22-cv-01417-TDC (the "Blackburn Action"), (vi) Diego J. Mesa v. Stanley C. Erck, et al., No. 2022-0770-NAC (the "Mesa Action"), (vii) Sean Acosta v. Stanley C. Erck, et al., No. 2022-1133-NAC (the "Acosta Action"), and (viii) Jared Needelman v. Stanley C. Erck, et al., No. C-15-CV-23-001550 (the "Needelman Action"). The Meyer, Yung, Snyder, and Blackburn Actions were filed in the Maryland Court. The Kirst Action was filed in the Circuit Court for Montgomery County, Maryland, and shortly thereafter removed to the Maryland Court by the defendants. The Needelman Action was also filed in the Circuit Court for Montgomery County, Maryland. The Mesa and Acosta Actions were filed in the Delaware Court of Chancery (the "Delaware Court"). The derivative lawsuits name members of the Company's board of directors and certain members of senior management as defendants. The Company is deemed a nominal defendant. The plaintiffs assert derivative claims arising out of substantially the same alleged facts and circumstances as the Sinnathurai Action. Collectively, the derivative complaints assert claims for breach of fiduciary duty, insider selling, unjust enrichment, violation of federal securities law, abuse of control, waste, and mismanagement. Plaintiffs seek declaratory and injunctive relief, as well as an award of monetary damages and attorneys' fees.

On February 7, 2022, the Maryland Court entered an order consolidating the Meyer and Yung Actions (the "First Consolidated Derivative Action"). The plaintiffs in the First Consolidated Derivative Action filed their consolidated derivative complaint on April 25, 2022. On May 10, 2022, the Maryland Court entered an order granting the parties' request to stay all proceedings and deadlines pending the earlier of dismissal or the filing of an answer in the Sinnathurai Action. On June 10, 2022, the Snyder and Blackburn Actions were filed. On October 5, 2022, the Maryland Court entered an order granting a request by the plaintiffs in the First Consolidated Derivative Action and the Snyder and Blackburn Actions to consolidate all three actions and appoint co-lead plaintiffs and co-lead and liaison counsel (the "Second Consolidated Derivative Action"). The co-lead plaintiffs in the Second Consolidated Derivative Action filed a consolidated amended complaint on November 21, 2022. On February 10, 2023, defendants filed a motion to dismiss the Second Consolidated Derivative Action. The plaintiffs filed their opposition to the motion to dismiss on April 11, 2023. Defendants filed their reply brief in further support of their motion to dismiss on May 11, 2023. On August 21, 2023, the court entered an order granting in part and denying in part the motion to dismiss. On September 5, 2023, the

Company filed an Answer to the consolidated amended complaint. On September 6, 2023, the court entered an order granting the individual defendants an extension of time to file their answer until November 6, 2023. On October 6, 2023, the Board of Directors of the Company formed a Special Litigation Committee (“SLC”) with full and exclusive power and authority of the Board to, among other things, investigate, review, and analyze the facts and circumstances surrounding the claims asserted in the pending derivative actions, including the claims that remain following the court’s order on the motion to dismiss in the Second Consolidated Derivative Action. On November 7, 2023, the court entered an order granting the parties’ request to stay the Second Consolidated Derivative Action for up to six months from the date of entry of the order, and, on April 15, 2024, the court entered a further order extending the stay until June 6, 2024. On June 7, 2024, the court entered another order extending the stay until August 5, 2024. On August 19, 2024, the court entered another order extending the stay until November 4, 2024, to allow the SLC and the parties to continue then-ongoing mediation efforts. On November 1, 2024, the parties notified the court that a settlement in principle had been reached and requested the stay to be extended until the definitive settlement agreement was filed. On November 22, 2024, the SLC filed its Unopposed Motion for Preliminary Approval of Derivative Settlement, Approval of Form and Manner of Notice, and Setting Hearing Date on Final Approval of Settlement and supporting documents. Under the terms of the proposed settlement, individual defendants Erck and Herrmann agreed to pay or cause their insurers to pay \$6.8 million to Novavax in exchange for a release of claims. In addition, Novavax and its Board of Directors agreed to adopt and implement certain governance provisions identified in the settlement stipulation. On December 12, 2024, the court entered an order granting preliminary approval of the derivative settlement and setting a date for a hearing on the final approval of the settlement. The hearing for final consideration of the proposed settlement is presently scheduled to be held on March 7, 2025 at 9:30 a.m. EST at the United States District Court for the District of Maryland, Southern Division, 650 Cherrywood Lane, Greenbelt, MD 20770.

***A copy of the settlement agreement, together with the Notice, can be found on the “Investor Hub” section of Novavax’s website. The date and time of the final fairness hearing may change. Any updates to the date or time of the final fairness hearing can also be found on the “Investor Hub” section of Novavax’s website or on the Maryland Court’s website. The contents of Novavax’s website are not incorporated by reference into this Annual Report on Form 10-K and you should not consider information provided on Novavax’s website to be part of this Annual Report on Form 10-K.***

The Kirst Action was filed on December 28, 2021, and the defendants immediately removed the case to the Maryland Court. On July 21, 2022, the Maryland Court issued a memorandum opinion and order remanding the Kirst Action to state court. The plaintiffs filed an amended complaint on December 30, 2022. On January 23, 2023, defendants filed a motion to stay the Kirst action. On February 22, 2023, the parties in the Kirst Action filed for the Court’s approval of a stipulation staying the Kirst Action pending the resolution of defendants’ motion to dismiss in the Second Consolidated Derivative Action. On March 22, 2023, the Court entered the parties’ stipulated stay of the Kirst Action pending resolution of the motion to dismiss in the Second Consolidated Derivative Action.

On August 30, 2022, the Mesa Action was filed. On October 3, 2022, the Delaware Court entered an order granting the parties’ request to stay all proceedings and deadlines in the Mesa Action pending the earlier of dismissal of the Sinnathurai Action or the filing of an answer to the operative complaint in the Sinnathurai Action. On January 9, 2023, following the ruling on the motion to dismiss the Sinnathurai Action, the Delaware Court entered an order granting the Mesa Action parties’ request to set a briefing schedule in connection with a motion to stay by defendants. On February 28, 2023, the court granted the defendants’ motion and stayed the Mesa Action pending the entry of a final, non-appealable judgment in the Second Consolidated Derivative Action. On August 31, 2023, the Mesa plaintiffs filed a motion to lift the stay in the Mesa Action. On October 6, 2023, the Company filed an opposition to plaintiff’s motion to lift the stay. Plaintiff filed his reply on October 17, 2023. On December 27, 2023, the parties filed a letter informing the Court that the Second Consolidated Derivative Action had been stayed for a period of six months and asked the Court to stay further proceedings in the Mesa Action until expiration of that stay.

On December 7, 2022, the Acosta Action was filed. On February 6, 2023, defendants accepted service of the complaint and summons in the Acosta Action. On March 9, 2023, the court entered an order granting the parties’ request to stay the Acosta Action pending the entry of a final, non-appealable judgment in the Second Consolidated Derivative Action. On October 13, 2023, the parties filed, and the Delaware Court entered, a stipulated order providing that (i) if the Delaware Court declines to lift the stay in the Mesa Action, the Acosta Action will also remain stayed, and (ii) if the Delaware Court lifts the stay in the Mesa Action, the stay in the Acosta Action will also be lifted.

On April 17, 2023, the Needelman Action was filed. On July 12, 2023, the parties filed a stipulation and proposed order to stay the Needelman Action pending the Maryland Court’s decision on the motion to dismiss in the Second Consolidated Derivative Action. The court entered that order on July 17, 2023.

On November 30, 2023, the court entered an order consolidating the Kirst and Needelman Actions. On December 14, 2023, the parties filed a stipulation (i) extending the plaintiffs' deadline to file a consolidated complaint until January 29, 2024, and (ii) otherwise staying all other proceedings in the case (including the defendants' deadline to respond to the consolidated complaint) until February 12, 2024. On May 3, 2024, the plaintiffs filed a consolidated complaint. On May 14, 2024, the parties filed a stipulation staying the action until June 6, 2024. On July 12, 2024, the court entered an order staying the action until August 5, 2024. On September 24, 2024, the court entered another order staying the action until November 4, 2024. On November 4, 2024, the parties filed a stipulation requesting a status conference with the court and further requesting that the action remain stayed until such status conference takes place. To date, the court has not scheduled a status conference.

The financial impact of the First Consolidated Derivative action is described above and is dependent on the court's approval of the settlement. The financial impact of the Mesa, Kirst and Needleman Actions referenced above are not estimable.

The Company is also involved in various other legal proceedings arising in the normal course of business. Although the outcomes of these other legal proceedings are inherently difficult to predict, the Company does not expect the resolution of these other legal proceedings to have a material adverse effect on its financial position, results of operations, or cash flows.

### ***Purchase Commitments***

The Company has entered into agreements in the normal course of business with CMOs and CDMOs supplying the Company with production capabilities, and with vendors for preclinical studies, clinical trials, and other goods or services. Certain agreements provide for termination rights subject to termination fees. Under such agreements, the Company is contractually obligated to make payments to vendors, mainly to reimburse them for their estimated unrecoverable expenses. The exact amount of such obligations are dependent on the timing of termination and the terms of the relevant agreement, and cannot be reasonably estimated. As of December 31, 2024, most of these agreements were active ongoing arrangements and the Company expects to receive value from these arrangements in the future. The Company recognizes fees related to obligations for terminated contracts where such fees are reasonably estimable. The Company did not accrue obligations that were not reasonably estimable. As of December 31, 2024, the Company had \$2.8 million of non-cancelable purchase commitments with a remaining term of more than one year.

### **Note 18 – Restructuring**

The restructuring charge recorded by the Company consisted of the following (in thousands):

	<b>Year Ended December 31,</b>		
	<b>2024</b>	<b>2023</b>	<b>2022</b>
Severance and employee benefit costs	\$ 12,829	\$ 4,503	\$ —
Impairment of assets	4,132	10,081	—
<b>Total Restructuring charge <sup>(1)</sup></b>	<b>\$ 16,961</b>	<b>\$ 14,584</b>	<b>\$ —</b>

- (1) Restructuring charges of \$1.0 million, \$2.4 million and \$13.6 million are included in Cost of sales, Research and development and Selling, general, and administrative expenses, respectively, in the Consolidated Statements of Operations for 2024. Restructuring charges of \$0.5 million, \$2.3 million and \$11.5 million are included in Cost of sales, Research and development and Selling, general, and administrative expenses, respectively, in the Consolidated Statements of Operations for 2023. These charges reflect substantially all expected restructuring charges under the Restructuring Plan. No restructuring charges were recorded during 2022.

### ***Severance and employee benefit costs***

Employees affected by the reduction in force under the Restructuring Plan are entitled to receive severance payments and certain termination benefits. The Company recorded a severance and termination benefit cost in full for employees who were notified of their termination during the year ended December 31, 2024 and had no requirements for future service. The Company paid \$9.8 million for severance and employee benefit costs during the year ended December 31, 2024 and \$3.1 million remaining liability for the severance and employee benefit costs is included in Accrued expenses in the Company's consolidated balance sheet as of December 31, 2024. The Company recorded and fully paid a severance and employee benefit costs of \$4.5 million during the year ended December 31, 2023. There were no severance and employee benefit costs during the year ended December 31, 2022.



### ***Impairment of long-lived assets***

In connection with the Restructuring Plan, the Company evaluated its long-lived assets for impairment including certain leased laboratory and office spaces located in Gaithersburg, Maryland. The evaluation is subject to judgment and actual results may vary from the estimates, resulting in potential future adjustments to amounts recorded. During the year ended December 31, 2024 and 2023, the Company recorded an impairment charge of \$4.1 million and \$10.1 million, respectively, related to the impairment of long-lived assets, including \$5.9 million related to ROU assets for facility leases in 2023. There were no impairment charges recorded during the year ended December 31, 2022.

### **Note 19 – Disposition of Assets**

On December 30, 2024, Novavax CZ a.s. ("CZ"), a wholly-owned subsidiary of the Company, completed the sale of its biologics manufacturing campus located at Bohumil, Czech Republic (the "Facility") to Novo Nordisk Production Czech s.r.o. (the "Purchaser"), pursuant to an asset purchase agreement, dated as of December 3, 2024 (the "Asset Purchase Agreement"). Under the Asset Purchase Agreement, CZ sold, transferred and assigned to the Purchaser: (i) land and properties that comprise the Facility, as well as certain moveable assets and equipment located at the Facility (the "Transferred Assets"); (ii) contracts related to the operation and management of the Transferred Assets (the "Transferred Contracts"); and (iii) certain employees providing services related to the Transferred Assets (the "Transferred Employees").

The total purchase price for the sale was \$202.6 million and the assumption by the Purchaser of liabilities (on a look-forward basis) pertaining to the Transferred Assets, Transferred Contracts and Transferred Employees. On the closing date, the Company received a cash payment of \$180 million, net of the initial payment of \$10 million made in October 2024 and \$10 million placed in an escrow account to be released to the Company on the date which is 12 months following the closing date (subject to adjustment for any claims the Purchaser may have against the Seller under the Asset Purchase Agreement). Pursuant to the terms of the Asset Purchase Agreement, the Company was also reimbursed \$2.6 million, subject to adjustments, for costs incurred in continuing to operate and maintain the Transferred Assets, Transferred Contracts and Transferred Employees between December 3, 2024 and the completion of the sale.

The Company recognized a gain on the sale of \$51.9 million, which has been reflected in Other income in the Company's consolidated income statement for the year ended December 31, 2024. No gain on sale was recognized in the year ended December 2023 and 2022. The disposition qualified as the sale of a business pursuant to ASC Topic 805, *Business Combinations*, and therefore, the Company allocation goodwill of \$12.4 million to the sale on a relative fair value basis.

### **Note 20 – Segment Reporting**

The Company manages its business as one reportable operating segment, in-house early-stage R&D to build a pipeline of high-value assets using its proven technology along with seeking to enter into partnerships to drive value creation for its assets. The Company has determined its reportable operating segment based on the management approach, which considers the internal organization and reporting used by the Company's CODM to make decisions about allocating resources and assessing the Company's performance. The Company's CODM uses consolidated single-segment net loss as reported in the Consolidated Statements of Operations to evaluate performance, forecast future period financial results, allocate resources, and set incentive targets.

The table below summarizes the significant expense categories regularly reviewed by the CODM (in thousands):

	Year Ended December 31,		
	2024	2023	2022
Revenue	\$ 682,162	\$ 983,705	\$ 1,981,872
Cost of sales	202,739	343,768	902,639
Research and development expenses:			
Direct coronavirus vaccines <sup>(1)</sup>	122,445	413,448	848,042
Direct other vaccine development programs <sup>(1)</sup>	4,632	3,241	9,821
Employee and benefit expenses	163,728	210,589	246,733
Facility and other research and development expenses <sup>(2)</sup>	100,364	110,224	130,682
Selling, general, and administrative expense	337,185	468,946	488,691
Other segment income (expense) <sup>(3)</sup>	61,432	21,449	(13,203)
Net loss	<u>\$ (187,499)</u>	<u>\$ (545,062)</u>	<u>\$ (657,939)</u>

(1) Direct research and development expenses are comprised primarily of costs paid to third parties for clinical and product development activities.

(2) Facility and other research and development expenses consist of indirect costs incurred in support of overall research and development activities and non-specific programs, such as overhead costs, information technology and facility-based expenses not allocated to a specific program.

(3) Other segment income (expense) includes interest expense, gain on disposition of Novavax CZ assets, income tax expense, and other income.

Total revenue by the Company's customer's or collaboration partner's geographic location was as follows (in thousands):

	Year Ended December 31,		
	2024	2023	2022
United States	\$ 522,535	\$ 443,894	\$ 382,921
Rest of North America	4,462	13,388	194,480
Europe	96,143	271,964	826,829
Rest of the world	59,022	254,459	577,642
Total revenue	<u>\$ 682,162</u>	<u>\$ 983,705</u>	<u>\$ 1,981,872</u>

Total long-lived assets of the Company by geographic location were as follows (in thousands):

	December 31,	
	2024	2023
United States	\$ 295,879	\$ 328,915
Europe	4,119	162,074
Total long-lived assets	<u>\$ 299,998</u>	<u>\$ 490,989</u>

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## Board of Directors

### **John C. Jacobs**

President and Chief Executive Officer,  
Director

### **Margaret G. McGlynn, RPh**

Chairman of the Board of Directors  
Former President, Merck Vaccines and  
Infectious Diseases, and Merck Inc.

### **Gregg H. Alton, JD**

Director  
Former Interim Chief Executive Officer and  
Chief Patent Officer, Gilead Sciences

### **Richard H. Douglas, PhD**

Director  
Former Senior Vice President, Corporate  
Development, Genzyme Corporation

### **Rachel K. King**

Director  
Founder and former Chief Executive Officer,  
GlycoMimetics, Inc.

### **David Mott**

Director  
Private Investor, Mott Family Capital

### **Charles W. Newton**

Director  
Chief Financial Officer, Lyell Immunopharma

### **Richard J. Rodgers, MBA**

Director  
Former Executive Vice President and  
Chief Financial Officer, TESARO, Inc.

### **John Shiver, PhD**

Director  
Head of Research and Development,  
Vibrant Biomedicines

## Executive Leadership Team

### **John C. Jacobs**

President and Chief Executive Officer,  
Director

### **John J. Trizzino**

President, Chief Operating Officer

### **Mark Casey**

Executive Vice President, Chief Legal Officer

### **Rick Crowley**

Executive Vice President, Chief Operations Officer

### **Ruxandra Draghia-Akli, MD, PhD**

Executive Vice President,  
Head of Research & Development

### **James P. Kelly**

Executive Vice President,  
Chief Financial Officer and Treasurer

### **Elaine O'Hara**

Executive Vice President, Chief Strategy Officer

### **Silvia Taylor**

Executive Vice President,  
Chief Corporate Affairs and Advocacy Officer

### **Henrietta Ukwu, MD**

Executive Vice President, Chief Regulatory Officer

### **Ian Watkins**

Executive Vice President, Chief Human Resources Officer

### **Troy Morgan, JD**

Senior Vice President,  
Deputy General Counsel & Chief Compliance Officer

### **Robert Walker, MD**

Senior Vice President, Chief Medical Officer

## Corporate Information

### Annual Meeting

June 20, 2025 at 8:30 a.m. EDT

Live virtual webcast link: [www.virtualshareholdermeeting.com/NVAX2025](http://www.virtualshareholdermeeting.com/NVAX2025)

### Independent Registered Public Accounting Firm

Ernst & Young, LLP

1775 Tysons Boulevard

McLean, VA 22102

### Transfer Agent

Computershare, Inc.

250 Royall Street

Canton, MA 02021

### Novavax Corporate Headquarters

Novavax, Inc.

700 Quince Orchard Road

Gaithersburg, MD 20878

### Market Information

Novavax is traded on the NASDAQ Global Select Market under “NVAX”

By leveraging **our science, our technology and our people**,  
we will **innovate and collaborate** to tackle the world's  
most significant health challenges

