Submission Data File

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All in to Protect **Global Health**

2022 ANNUAL REPORT

novavax

Novavax

A Message From Our CEO

April 18, 2023

To Our Shareholders,

2022 was a year of significant growth and learning for Novavax, as we executed the commercial launch of our COVID-19 vaccine, Nuvaxovid™,1. In our first year as a commercial-stage company, we faced significant challenges, but along the way we also learned valuable lessons about our business and the opportunities we have ahead. These lessons have given us important insight into how we can more effectively leverage our established infrastructure, technology platform, and capabilities. Through this, we intend to better position Novavax for success as we move forward and, importantly, build long-term value for our shareholders.

As we begin this new chapter of our journey, I am honored to lead Novavax, and I humbly accept the challenge of building on our past to create a path toward long-term success.

Our Opportunity and Focus on the Future

In 2023, we will maintain a strong focus on our three priorities that we shared during our fourth quarter and full year 2022 earnings call, which we believe are critical to both expanding our impact on global public health and delivering results for our stakeholders:

- **Priority #1: Deliver a competitive product for the upcoming fall 2023 vaccination season**
- **Priority #2: Reduce our rate of spend, manage our cash flow, and evolve our scale and structure**
- **Priority #3: Leverage our technology platform, our capabilities, and our portfolio of assets to drive additional value beyond Nuvaxovid alone**

Priority #1: Deliver a competitive product for the upcoming fall 2023 vaccination season

Our top near-term organizational focus is delivering a competitive product aligned with public health recommendations for the fall 2023 vaccination season. We continue to partner closely with regulatory authorities, including the U.S. Food and Drug Administration (FDA) and other regulatory agencies around the world, in order to support our readiness efforts in advance of further clarity on strain selection. We are also changing the way we work internally to optimize our chances for success. We recognize the significant opportunity ahead as the COVID-19 market begins to transition to a more traditional, commercial landscape in 2023, and these efforts are intended to best position us to capture this emerging opportunity and deliver our protein-based COVID-19 vaccine this fall.

Priority #2: Reduce our rate of spend, manage our cash flow, and evolve our scale and structure

Since the start of 2023, we have taken action to improve our financial position, including implementing measures across the organization to reduce and control our spend. In parallel, we are focusing our efforts and investments on our top business priorities that we believe will support our near-term success. To position the business for long-term value creation, we will also continue to evolve our scale and structure in ways that meaningfully improve our operational efficiency.

Priority #3: Leverage our technology platform, our capabilities, and our portfolio of assets to drive additional value beyond Nuvaxovid alone

Beyond our COVID-19 program, Novavax has an opportunity to unlock additional value across the company through our validated technology platform, portfolio of assets such as our Matrix-M™ adjuvant, and the fully integrated set of capabilities that we've established globally. As a team, we are exploring strategies to optimize the value of these promising assets and realize the full potential of the organization.

For the year ahead, our near-term priorities will guide our efforts as we aim to establish Novavax as one of the world's leading global vaccines companies over time.

I am appreciative of the many contributions that have brought Novavax to where we are today, including the dedication of our employees, trust of our customers, and the collaboration of our partners and their continued support of our mission.

To our shareholders, I thank you for your support and belief in our potential. Along this journey together, we intend to share both our successes and our challenges, and in all that we do, to remain committed to the highest standards of integrity.

John C. Jacobs
President and Chief Executive Officer

1. The trade name Nuvaxovid has not yet been approved by the U.S. FDA and is authorized as the Novavax COVID-19 Vaccine, Adjuvanted for emergency use by the FDA.

A Message From Our Chairman of the Board

April 18, 2023

To Our Shareholders,

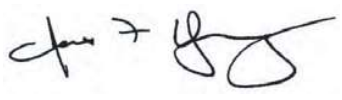
As a global vaccines company, Novavax is driven by a mission to protect the health of people everywhere. Our goal is always to leverage our proven technology platform and deliver innovative vaccines to those in need.

In 2022, we advanced this mission by expanding our global presence and building our commercial capabilities. Through this progress, we began to make our protein-based COVID-19 vaccine, Nuvaxovid[1], available in markets around the world.

As we look to the future, I'm pleased to welcome John Jacobs as our President and CEO. John will be instrumental in building on the strong foundation laid to date and shaping Novavax's path forward.

Since joining the company in early 2023, John has demonstrated a commitment to operational excellence and a deep appreciation for Novavax's mission. The organization has already taken important steps to narrow our focus, address the complexities of our business, and position Novavax for long-term success.

The Board looks forward to continuing to partner with John and the leadership team as we develop and execute our long-term strategy, with the aim of delivering significant value for our shareholders.



James F. Young, PhD
Chairman of the Board of Directors

1. The trade name Nuvaxovid has not yet been approved by the U.S. FDA and is authorized as the Novavax COVID-19 Vaccine, Adjuvanted for emergency use by the FDA.

Photo Credit:
Matt Feldman
Novavax Employee
United States

2022 in Review

In 2022, we began to lay the foundation to expand our fully integrated set of capabilities and bring to market our COVID-19 vaccine, Nuvaxovid[1]. We believe a diverse portfolio of vaccines available in the market is essential to best protect against serious infectious diseases. Throughout the year, we remained committed to making Nuvaxovid available as a differentiated, protein-based option within the portfolio of COVID-19 vaccines, which will continue to be a key focus moving forward.

COVID-19 Clinical

- Demonstrated our vaccine's **high efficacy, a durable and broad immune response, protection against infection,** and **well-characterized safety** and **reactogenicity profile**
- Evaluated our vaccine in **younger age groups** through multiple trials
- Demonstrated **variant strain change capabilities** through initial results from our Phase 3 COVID-19 Omicron trial

Pipeline

- Advanced **COVID-19-Influenza Combination** and **stand-alone influenza vaccine candidates** to Phase 2 trial

Regulatory

- Achieved regulatory authorizations for Nuvaxovid in **over 40 countries** to date, as well as Emergency Use Listing from the World Health Organization
- **Expanded label** for Nuvaxovid across multiple indications and ages
- **Advanced policy support** for Nuvaxovid to improve market access

1. The trade name Nuvaxovid has not yet been approved by the U.S. FDA and is authorized as the Novavax COVID-19 Vaccine, Adjuvanted for emergency use by the FDA.

Manufacturing

- Leveraged manufacturing and supply network for **vaccine distribution globally**
- Established internal drug substance manufacturing capabilities with European Medicines Agency approval received in 2023 for our own **state-of-the-art facility** in the Czech Republic, Novavax CZ

Commercial

- Developed **commercial presence** to support three priority markets: The Americas, Europe, and Asia-Pacific (APAC)
- Delivered **over 100 million doses** of our COVID-19 vaccine globally to date
- Achieved 2022 total revenue of **$2 billion** in Novavax's first year as a commercial-stage company

In the years ahead, we will continue to build on this foundation as we seek to solidify Nuvaxovid's role as an important, protein-based option among COVID-19 vaccines and position Novavax on a path toward long-term success.

Photo Credit:
Matt Feldman
Novavax Employee
United States

Establishing Our Commercial Presence

In 2022, we developed a global commercial presence to support three priority markets: The Americas, Europe, and APAC.

Americas Commercial Operations
Gaithersburg, Maryland, U.S.

1. The trade name Nuvaxovid has not yet been approved by the U.S. FDA and is authorized as the Novavax COVID-19 Vaccine, Adjuvanted for emergency use by the FDA.

With the goal of making Nuvaxovid[1] available around the world, we are building teams comprised of industry experts that have a deep understanding of how to best serve our customers, our consumers, and regulatory and policymaking bodies in their pursuit of protecting global health.

In the near-term, our efforts are focused on maintaining continuous access to our COVID-19 vaccine.

To establish our vaccine's role in the long-term COVID-19 market, we are educating key stakeholders on Nuvaxovid's differentiated product profile and building brand awareness.

We will continue to leverage this global commercial network in the years to come, ensuring we have the people and the capabilities in place to expand the reach of Nuvaxovid as a critical option to protect the health of people everywhere.

Expanding Our Impact

Throughout Novavax's history, our commitment to improving global public health has been at the core of all that we do.

With the transition of our business to a commercial-stage company in 2022, we believed it was imperative to build on our mission and pursue additional ways to serve the communities in which we work and live, and the world around us.

We are developing our long-term Environmental, Social, and Governance (ESG) strategy to expand Novavax's impact as a global corporate citizen.[1]

Access

Maximizing vaccine access and improving global health

- We innovate through R&D, business, and community partnerships to increase global access to vaccines that target serious infectious diseases

Governance

Meeting the highest standards of governance

- We are committed to operating with integrity, transparency, and accountability in all that we do as we pursue our important mission of protecting global public health

Environment

Mitigating our environmental impact

- We aim to operate in an environmentally sustainable manner that reduces our environmental impact

Diversity

Championing diversity, equity, and inclusion in our workforce

- We seek to build an empowering and diverse work culture, investing in our people to attract and retain the best talent and help our employees, referred to as SuperNovas, achieve their full potential

In 2023 and beyond, we will continue to advance our ESG initiatives, which will be instrumental in our ability to create long-term value for our shareholders, employees, and consumers.

1. For additional information on our ESG initiatives, please refer to page 39 of this annual report.

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, 2022

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	**22-2816046**
(State of incorporation)	*(I.R.S. Employer Identification No.)*
21 Firstfield Road, Gaithersburg, Maryland	**20878**
(Address of principal executive offices)	*(Zip Code)*

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

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

Title of each class	Trading Symbol	Name of each exchange on which registered
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 if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of the Registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☒

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	☒	Accelerated filer	☐
Non-accelerated filer	☐	Smaller reporting company	☐
Emerging growth company	☐		

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 Registrants common stock on June 30, 2022 on the Nasdaq Global Select Market) was approximately $4,010,000,000.

As of February 21, 2023, there were 86,173,245 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, 2022 in connection with the Registrant's 2023 Annual Meeting of Stockholders are incorporated by reference into Part III of this Annual Report on Form 10-K to the extent indicated herein.

NOVAVAX, INC.

TABLE OF CONTENTS

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).

NOTE REGARDING TRADEMARKS

Novavax™, Nuvaxovid™, Matrix-M™, Matrix™, 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 disclaimer under 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.
- Because our vaccine product development efforts depend on new and rapidly evolving technologies, we cannot be certain that our efforts will be successful.
- The regulatory and commercial success of our COVID-19 vaccine candidate, NVX-CoV2373, remains uncertain. While we have received provisional registration, conditional marketing authorization ("CMA"), or emergency use authorization ("EUA") for NVX-CoV2373 in a number of jurisdictions, we may be unable to obtain full regulatory approvals in the United States ("U.S.") or other jurisdictions or produce a successful vaccine in a timely manner, if at all.
- The emergence and transmissibility of variants of the SARS-CoV-2 virus, and the demand for bivalent vaccines, may affect market acceptance or sales of NVX-CoV2373, and our strategy to develop versions of our COVID-19 vaccine to protect against certain variants may not be successful.
- We are a biotechnology company and face significant risk in developing, manufacturing, and commercializing our products.
- Because we depend on third parties to conduct some of our laboratory testing and clinical trials, and a significant amount of our vaccine manufacturing and distribution, we may encounter delays in or lose some control over our efforts to develop and supply products.
- We are highly dependent on the commercial success of NVX-CoV2373, and even though we have received provisional registration, CMA, or EUA in certain jurisdictions for NVX-CoV2373, and even if we have products licensed in additional markets, our vaccine products may not be initially or ever profitable.
- The COVID-19 pandemic and associated governmental public health policies continue to evolve, which may have unpredictable effects on the prospects for commercial success of NVX-CoV2373.
- 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, influenza, and respiratory syncytial virus ("RSV") 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 ("FDA") licensure or foreign regulatory approvals necessary to sell our vaccine candidates.

- Our products might fail to meet their primary endpoints in clinical trials, meaning that we will not have the clinical data required to support full regulatory approvals.

- The regulatory pathway for NVX-CoV2373 is continually evolving, and may result in unexpected or unforeseen challenges.

- We have conducted, are conducting, and plan to conduct in the future, a number of clinical trials for NVX-CoV2373 at sites outside the U.S. and the FDA may not accept data from trials conducted in such locations.

- The later discovery of previously unknown problems with a product, manufacturer, or facility may result in restrictions, including withdrawal of a vaccine that had previously received regulatory approval in certain jurisdictions from the market.

- Our success depends on our ability to maintain the proprietary nature of our technology.

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

- Given our current cash position and cash flow forecast, and significant uncertainties related to 2023 revenue, funding from the U.S. government, and our pending arbitration with Gavi, substantial doubt exists regarding our ability to continue as a going concern through one year from the date that the financial statements included in this Annual Report were issued.

- Servicing our 5.00% convertible senior unsecured notes due 2027 (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 a biotechnology company that promotes improved health globally through the discovery, development, and commercialization of innovative vaccines to prevent serious infectious diseases. Our proprietary recombinant technology platform harnesses the power and speed of genetic engineering to efficiently produce highly immunogenic nanoparticle vaccines designed to address urgent global health needs.

Our vaccine candidates are genetically engineered nanostructures of conformationally correct recombinant proteins that mimic those found on natural pathogens. This technology enables the immune system to recognize target proteins and develop broadly protective antibodies. We believe that our vaccine technology may lead to the induction of a differentiated immune response that may be more efficacious than naturally occurring immunity or other vaccine approaches. Our vaccine candidates also incorporate our proprietary saponin-based Matrix-M™ adjuvant to enhance the immune response, stimulate higher levels of functional antibodies, and induce a cellular immune response.

We have developed and begun commercialization of a COVID-19 vaccine, NVX-CoV2373 ("Nuvaxovid™," "Covovax™," "Novavax COVID-19 Vaccine, Adjuvanted"), that has received approval, interim authorization, provisional approval, conditional marketing authorization ("CMA"), and emergency use authorization ("EUA") from multiple regulatory authorities globally for both adult and adolescent populations as a primary series and for both homologous and heterologous booster indications and are developing an influenza vaccine candidate, a COVID-19-Influenza Combination ("CIC") vaccine candidate, and additional vaccine candidates, including a COVID-19 variant strain-containing monovalent or bivalent formulation. In addition to COVID-19 and seasonal influenza, our other areas of focus include respiratory syncytial virus ("RSV") and malaria.

We were incorporated in 1987 under the laws of the State of Delaware. Our principal executive offices are located at 21 Firstfield 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, together with our proprietary Matrix-M™ adjuvant, is well suited for the development and commercialization of vaccine candidates targeting a broad scope of respiratory and other emerging infectious diseases at scale.

Recombinant Nanoparticle Vaccine Technology

Once a pathogenic threat has been identified, the genetic sequence encoding the antigen is selected for subsequent use in 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 proteins that are properly folded and modified—which can be critical for functional, protective immunity—as the vaccine antigen. Protein antigens are purified and organized around a polysorbate-based nanoparticle core, in a configuration that resembles their native presentation. 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 has been a key differentiator within our platform. This adjuvant has demonstrated 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 promotes the production of high affinity antibodies, an immune boosting response. This potent mechanism of action enables a lower dose of antigen required to achieve the desired immune response, and we believe thereby contributes 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 in a Phase 3 trial for R21, a malaria vaccine candidate created by the Jenner Institute, University of Oxford. The University of Oxford has partnered with Serum Institute of India Pvt. Ltd. ("SIIPL") for commercial development of R21 and has granted SIIPL a license for R21. We expect to manufacture and supply the Matrix-M™ adjuvant component of R21 to SIIPL, which represents a significant commercial opportunity for our adjuvant, pending possible licensure. We have commercial rights to sell and distribute the SIIPL-manufactured R21 in certain countries, primarily in the travelers' and military vaccine markets.

We are also supplying Matrix-M™ adjuvant for two Phase 1 vaccine trials led by National Institutes of Health teams, focused on Epstein-Barr virus and malaria transmission blocking.

NVX-CoV2373 Regulatory and Licensure

We have made substantial progress in advancing NVX-CoV2373 toward regulatory approvals. We have received authorizations in over 40 countries globally within the adult population, aged 18 and older, and the adolescent population, aged 12 through 17, for primary series and both homologous and heterologous booster indications. To date, we have received approval, interim authorization, provisional approval, CMA, and EUA for both adult and adolescent populations. We are working to continue to expand our label for heterologous boosting in adults, adolescents, and younger children, and achieve supportive policy recommendations enabling broad market access. We continue to work closely with governments, regulatory authorities, and non-governmental organizations in our commitment to facilitate equitable global access to our COVID-19 vaccine.

For the territories in which our vaccine has gained authorization, NVX-CoV2373 is marketed under the brand names (i) Nuvaxovid™ (SARS-CoV-2 rS Recombinant, adjuvanted), (ii) Covovax™ (manufacturing and commercialization by SIIPL), or (iii) Novavax COVID-19 Vaccine, Adjuvanted.

A summary of regulatory authorizations for NVX-CoV2373 through the date of filing this Annual Report on Form 10-K is presented below:

Country / Regulatory Authority	Authorizations	Vaccine Indication	Population	Marketed As
Australian Therapeutic Goods Administration	Provisional Registration	Primary	Adults & Adolescents	Nuvaxovid™
		Booster	Adults	
Directorate General of Drug Administration in Bangladesh[1]	EUA	Primary	Adults	Covovax™
Drugs Controller General of India[1]	EUA	Primary	Adults, Adolescents & ages 7 -11 years	Covovax™
		Booster	Adults	
European Commission, European Medicines Agency	CMA	Primary	Adults & Adolescents	Nuvaxovid™
		Booster	Adults	
Health Canada	Authorization	Primary	Adults & Adolescents	Nuvaxovid™
		Booster	Adults	
Israel Ministry of Health	Granted Import and Use Permit	Primary & Booster	Adults & Adolescents	Nuvaxovid™
Japan's Ministry of Healthy, Labour and Welfare[2]	Approval	Primary	Adults & Adolescents	Nuvaxovid™
		Booster	Adults	
Medicines and Healthcare products Regulatory Agency in Great Britain	CMA	Primary	Adults & Adolescents	Nuvaxovid™
		Booster	Adults	
National Agency of Drug and Food Control of the Republic of Indonesia[1]	EUA	Primary	Adults	Covovax™
New Zealand's Medsafe	Provisional Approval	Primary	Adults & Adolescents	Nuvaxovid™
		Booster	Adults	
Philippine Food and Drug Administration[1]	EUA	Primary	Adults	Covovax™
Singapore Health Sciences Authority	Interim Authorization	Primary	Adults	Nuvaxovid™
South African Health Products Regulatory Agency[1]	Full Product Registration	Primary	Adults	Covovax™
South Korea's Ministry of Food and Drug Safety[3]	Biologics License Application (BLA)	Primary	Adults & Adolescents	Nuvaxovid™
		Booster	Adults	
Switzerland's Swissmedic, the Swiss Agency for Therapeutic Products	CMA	Primary	Adults & Adolescents	Nuvaxovid™
		Booster	Adults	
Taiwan Food and Drug Administration	EUA	Primary	Adults & Adolescents	Nuvaxovid™
Thailand Food and Drug Administration[1]	EUA	Primary	Adults & Adolescents	Covovax™
U.S. Food and Drug Administration (FDA)	EUA	Primary	Adults & Adolescents	Novavax COVID-19 Vaccine, Adjuvanted
		Booster	Adults	
United Arab Emirates Ministry of Health Prevention	EUA	Primary	Adults & Adolescents	Nuvaxovid™
		Booster	Adults	
World Health Organization[1]	Emergency Use Listing (EUL)	Primary	Adults & Adolescents	Nuvaxovid™ / Covovax™
		Booster	Adults	

(1) Regulatory approval received in partnership with SIIPL.
(2) Regulatory manufacturing and marketing approval received by partner Takeda Pharmaceutical Company Limited ("Takeda").
(3) Regulatory approval received in partnership with SK bioscience, Co., Ltd. ("SK bioscience").

Below we highlight the fourth quarter 2022 and subsequent regulatory authorizations received through the date of this filing on Form 10-K.

In January 2023, our partner SK bioscience received expanded manufacturing and marketing approval from Korean Ministry of Food and Drug Safety ("KMFDS") for Nuvaxovid™ for use as a booster in adults aged 18 and older.

In December 2022, Health Canada approved a supplement to a New Drug Submission for Nuvaxovid™ as a primary series of two doses in adolescents aged 12 to 17 years.

In November 2022, the World Health Organization ("WHO") issued an updated EUL for Nuvaxovid™ as a primary series of two doses in adolescents aged 12 to 17 years and as a booster in adults aged 18 and older.

Additionally in November 2022, Health Canada granted expanded authorization for Nuvaxovid™ as a homologous booster in adults aged 18 and older.

Within the same month, the Medicines and Healthcare products Regulatory Agency in the United Kingdom ("U.K.") expanded CMA for Nuvaxovid™ as a homologous and heterologous booster dose after the primary series of Nuvaxovid™ or of an mRNA or adenoviral vector in adults aged 18 and older.

In October 2022, the U.S. FDA granted EUA to provide a first booster dose at least six months after completion of primary vaccination with an authorized or approved COVID-19 vaccine to adults aged 18 and older for whom an FDA-authorized mRNA bivalent COVID-19 booster vaccine is not accessible or clinically appropriate, and to adults aged 18 and older who elect to receive NVX-CoV2373 because they would otherwise not receive a booster dose of a COVID-19 vaccine.

We completed additional regulatory submissions in major markets for both adult and adolescent populations for primary and booster indications, and we are in active discussions with regulatory authorities regarding several of those submissions. We remain focused on expanding our label in multiple countries for NVX-CoV2373.

In February 2023, we had several additional regulatory submissions. We submitted an application to the U.S. FDA for expanded EUA of NVX-CoV2373 as a booster in adolescents aged 12 to 17 years. The application for expanded EUA is supported by data from the pediatric arm of our Phase 3 PREVENT-19 trial conducted in the U.S. We submitted an application to the European Medicines Agency ("EMA") for expanded CMA to include a booster in adolescents aged 12 to 17 years. We submitted an application to Taiwan's Food and Drug Administration for EUA in adults aged 18 and older. We submitted an application to Singapore's Health Sciences Authority for full BLA for primary series in adolescents aged 12 to 17 years and for a booster indication in adults aged 18 and older.

Advance Purchase Agreements ("APA")

We have entered into Advance Purchase Agreements ("APAs," also referred to as "supply agreements" throughout this Annual Report on Form 10-K) with the EC and 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 $2.1 billion in committed APAs anticipated for future delivery.

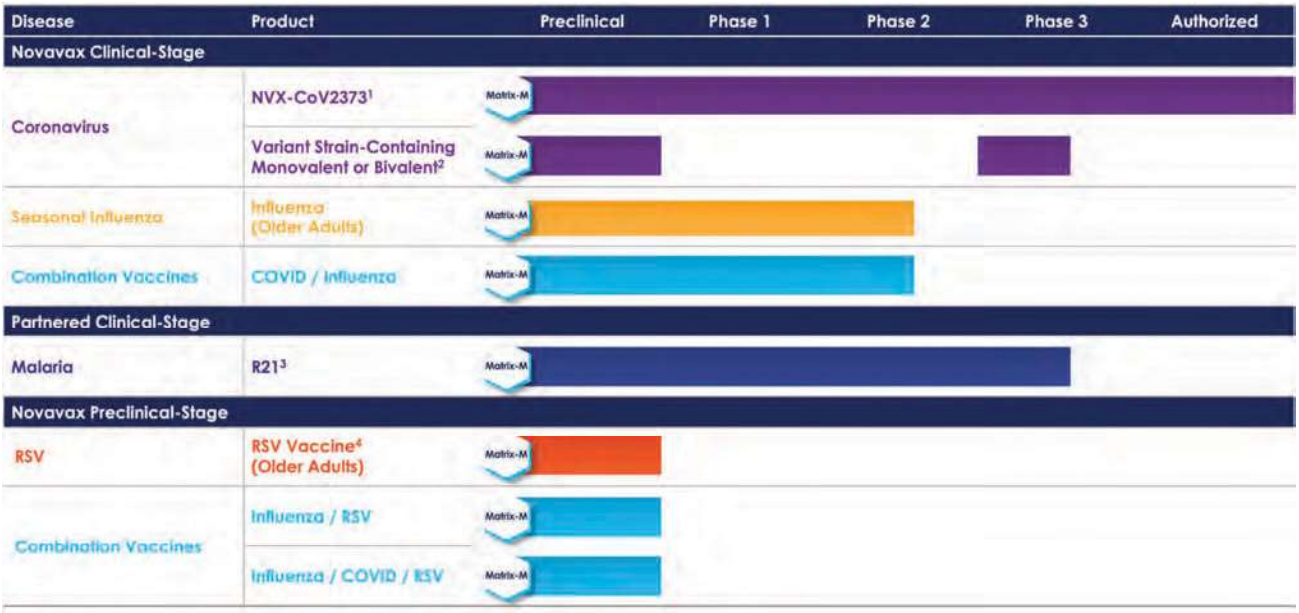
We have an APA with the EC, acting on behalf of various European Union member states to supply a minimum of 20 million and up to 100 million initial doses of NVX-CoV2373, with the option for the EC to purchase an additional 100 million doses up to a maximum aggregate of 200 million doses in one or more tranches through 2023. In 2022, we were notified by the EC that it was cancelling approximately 7 million doses of its prior commitment originally scheduled for delivery in the first and second quarters of 2022, in accordance with the APA, and reducing the order to approximately 63 million doses. In January 2023, we finalized a revised delivery schedule for the remaining 20 million committed doses under the APA that were originally scheduled for delivery during the first and second quarters of 2022 and are expected to be delivered in 2023.

In July 2022, we entered into an Amended and Restated SARS-CoV-2 Vaccine Supply Agreement (as amended on September 26, 2022, the "Amended and Restated UK Supply Agreement") with 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"), which amended and restated in its entirety the SARS-CoV-2 Vaccine Supply Agreement, dated October 22, 2020, between the parties (the "Original UK Supply Agreement"). Under the Original UK Supply Agreement, the Authority agreed to purchase 60 million doses of NVX-CoV2373 and made an upfront payment to us. 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 NVX-CoV2373, with the number of Conditional Doses contingent on, and subject to reduction based on, our timely achievement of supportive recommendations from the Joint Committee on Vaccination and Immunisation (the "JCVI") that is approved by the UK Secretary of State for Health, with respect to use of the vaccine for (a) the general adult population as part of a SARS-CoV-2 vaccine booster campaign in the United Kingdom or (b) the general adolescent population as part of a SARS-CoV-2 vaccine booster campaign in the United Kingdom or as a primary series SARS-CoV-2 vaccination, excluding where that recommendation relates only to one or more population groups comprising less than one million members in the United Kingdom. If the Authority does not purchase the Conditional Doses or the number of such Conditional Doses is reduced below 15 million doses of NVX-CoV2373, we would have to repay up to $225 million related to the upfront payment previously received from the Authority under the Original UK Supply Agreement. Under the Amended and Restated UK Supply Agreement, the Authority also has 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 yet made a supportive recommendation with respect to NVX-CoV2373, thereby triggering, under the terms of the Amended and Restated UK Supply Agreement, (i) a reduction of the number of Conditional Doses from 15 million doses to 7.5 million doses, which reduced number of Conditional Doses are contingent on, and subject to further reduction based on, our timely achievement by November 30, 2023 of a supportive recommendation from JCVI that is approved by the UK Secretary of State for Health as described in the paragraph above, and (ii) an obligation for us to repay $112.5 million related to the upfront payment previously received from the Authority under the Original UK Supply Agreement, which is reflected in our consolidated balance sheet as Other current liabilities, with the remaining upfront payment balance of $112.5 million reflected in current Deferred revenue.

Under the terms of an APA dated May 5, 2021, by and between the Company and Gavi, the Vaccine Alliance ("Gavi" and "the Gavi APA"), we received an upfront payment of $350.0 million from Gavi in 2021 and an additional payment of $350.0 million in the first quarter of 2022 related to our achieving EUL for NVX-CoV2373 by the WHO (the "Advance Payment Amount"). On November 18, 2022, we delivered written notice to Gavi to terminate the Gavi APA on the basis of Gavi's failure to procure the purchase of 350 million doses of NVX-CoV2373 from us as required by the Gavi APA. As of November 18, 2022, we had only received orders under the Gavi APA for approximately 2 million doses. On December 2, 2022, Gavi issued a written notice purporting to terminate the Gavi APA based on Gavi's contention that the Company repudiated the agreement and, therefore, materially breached the Gavi APA. Gavi also contends that, based on its purported termination of the Gavi APA, it is entitled to a refund of the Advance Payment Amount less any amounts that have been credited against the purchase price for binding orders placed by a buyer participating in the COVAX Facility. As of December 31, 2022, the remaining Gavi Advance Payment Amount of $697.4 million, pending resolution of the dispute with Gavi related to a return of the remaining Advance Payment Amount, was reclassified from Deferred revenue to Other current liabilities in our consolidated balance sheet. On January 24, 2023, Gavi filed a demand for arbitration with the International Court of Arbitration based on the claims described above. Our response is currently due by March 2, 2023. Arbitration is inherently uncertain, and while we believe that we are entitled to retain the remaining Advance Payment Amount received from Gavi, it is possible that we could be required to refund all or a portion of the remaining Advance Payment Amount from Gavi.

Product Pipeline



(1) Authorized in select geographies under trade names Novavax COVID-19 Vaccine, Adjuvanted; Covovax™; and Nuvaxovid™.
(2) Ongoing Phase 3 strain change trial.
(3) Ongoing Phase 3 trial for R21, a malaria candidate developed by the Jenner Institute, University of Oxford and formulated with Matrix-M™ adjuvant.
(4) Clinical development conducted in older adults with previous construct through Phase 3 trial.

Pipeline Overview

Our clinical pipeline encompasses vaccine candidates spanning multiple therapeutic areas, with our COVID-19 vaccine, NVX-CoV2373, as our lead product, which has received approval, interim authorization, provisional approval, CMA, or EUA for both adult and adolescent populations in over 40 countries. We advanced NVX-CoV2373 through two pivotal Phase 3 clinical trials that demonstrated high efficacy against both the original COVID-19 strain and commonly circulating COVID-19 variants, while maintaining a favorable safety profile. Beyond COVID-19, our clinical pipeline encompasses seasonal influenza and CIC vaccine, in addition to providing Matrix-M™ adjuvant for collaborations investigating the prevention of malaria.

We are developing our quadrivalent nanoparticle influenza vaccine ("qNIV") candidate, previously known as NanoFlu, which we advanced through a successful Phase 3 study published in September 2021, demonstrating the utility for a stand-alone influenza vaccine or for use in a combination vaccine. We have subsequently updated our qNIV for further development. We continue to progress in a Phase 2 trial our stand-alone influenza vaccine candidate, qNIV and our CIC vaccine candidate, which combines NVX-CoV2373 and our updated qNIV approach in a single formulation. In October 2022, we announced positive results from the Phase 1/2 CIC clinical trial demonstrating the CIC vaccine's ability to generate both antibody and polyfunctional CD4+ T-cell (lymphocytes that help coordinate the immune response) responses against severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) and homologous and heterologous influenza strains. In December 2022, we initiated a Phase 2 CIC dose-refinement trial that also includes further stand-alone updated qNIV evaluation.

In addition to COVID-19 and seasonal influenza, we remain interested in continuing the development of both our RSV Program for respiratory syncytial virus fusion (F) protein nanoparticle vaccine candidate ("RSV F Vaccine") and Matrix-M™ adjuvant collaborations for malaria. An ongoing Phase 3 trial is being conducted for R21, a malaria candidate, by our partner, the Jenner Institute, University of Oxford, which is formulated with our Matrix-M™ adjuvant.

We remain focused on expanding our NVX-CoV2373 vaccine label within the booster and adolescent market following global regulatory authorizations. We continue to evaluate vaccine efficacy through ongoing booster studies in our clinical trials and continued development of our COVID-19 variant strain containing monovalent or bivalent formulation. We expect to leverage these clinical insights to advance additional regulatory approvals of our COVID-19 vaccine for primary, booster, and pediatric indications globally, amidst the ongoing COVID-19 landscape.

Although our COVID-19, CIC, and influenza stand-alone vaccine candidates are our near-term priorities, our partner-led malaria candidates present strong opportunities for future development.

Coronavirus

NVX-CoV2373 Clinical Development

NVX-CoV2373 has progressed through multiple clinical trials, including a Phase 3 Lot Consistency Study, two Phase 3 pivotal efficacy trials, one Phase 3 Omicron boosting trial, one Phase 2b trial, and one Phase 1/2 trial, along with numerous others. We have expanded our clinical trials to evaluate heterologous and homologous boosting for populations spanning adults, adolescents, and children. Through our clinical development program, we established a dose of 5 micrograms of recombinant spike protein plus 50 micrograms of Matrix-M™ adjuvant. We continue to collect data that indicates a reassuring safety profile, and the induction robust cellular and humoral immune responses that were associated with high levels of efficacy in two independent Phase 3 studies.

A summary and status of our clinical development of NVX-CoV2373 by trial is as follows:

PREVENT-19 Phase 3 U.S. and Mexico

PREVENT-19 was a randomized, placebo-controlled, observer-blinded Phase 3 trial to evaluate the efficacy, safety, and immunogenicity of NVX-CoV2373 in 29,949 participants aged 18 years or older across 119 sites in the U.S. and Mexico. In the trial, NVX-CoV2373 achieved 90.4% efficacy overall, was generally well tolerated, and elicited a robust antibody response after the second dose. In December 2021, full results of the trial were published in *The New England Journal of Medicine*. In December 2021, we also initiated a PREVENT-19 Phase 3 boosting study.

In October 2022 at the World Vaccine Congress in Europe, we presented PREVENT-19 Phase 3 boosting data in both adults aged 18 years or older and adolescents aged 12 to 17 years, showing NVX-CoV2373 achieved its pre-specified immunologic endpoint.

In October 2022 at IDWeek, we presented additional data from the PREVENT-19 booster study, including an evaluation of the effect of age (18 to 64 years, and ≥ 65 years) and schedule on boosted immunologic response demonstrating significant boosting in all age groups. Booster doses were generally well tolerated, with mostly mild to moderate reactogenicity that was of short duration.

PREVENT-19 Phase 3 Pediatric Expansion

PREVENT-19 Pediatric Expansion was a randomized, placebo-controlled, observer-blinded study to evaluate the safety, effectiveness (immunogenicity), and efficacy of NVX-CoV2373 in 2,247 adolescents aged 12 to 17 years in 73 locations in the U.S., with an emphasis on ensuring well-balanced racial and ethnic representation among participants. Participants randomly received either the vaccine candidate or placebo in two doses, administered 21 days apart.

In October 2022 at the World Vaccine Congress in Europe, we presented PREVENT-19 Phase 3 pediatric expansion homologous boosting data, where a single boost dose was generally well tolerated and induced robust immune responses against prototype-strain as well as against Omicron BA.1, BA.2, and BA.5 subvariants. A third dose suggested benefit for the prevention of COVID-19 against contemporary variants such as Omicron. Additionally, booster doses were generally well tolerated, with mostly mild to moderate reactogenicity that was of short duration.

In April 2022, we announced initiation of PREVENT-19 Phase 3 booster study in adolescent trial participants with the booster dose administered at least 5 months after receipt of active vaccine.

In February 2022, we announced positive results from our Phase 3 PREVENT-19 pediatric expansion in adolescents. The results achieved their primary effectiveness endpoint and demonstrated 80% efficacy overall, with 82% clinical efficacy against the Delta variant. Immune responses were two-to-three-fold higher in adolescents than in adults against all variants studied. NVX-CoV2373 was well-tolerated with no safety signals identified.

Phase 2b/3 Hummingbird™ Trial

In August 2022, we initiated the Phase 2b/3 Hummingbird™ Global Clinical Trial to evaluate the safety, effectiveness (immunogenicity), and efficacy of two doses of NVX-CoV2373 in younger children aged 6 months to 11 years, followed by a booster at 6 months after the primary vaccination series. The trial is an age de-escalation trial and age groups will be tested sequentially to assess NVX-CoV2373 in infants (6 through 23 months of age), toddlers (2 to 5 years), and children (6 to 11 years). Enrollment is ongoing, expanding into the cohort aged 2- to 5-years in January 2023. The trial seeks to enroll 3,600 total participants in the U.S. and other countries.

Phase 3 Lot Consistency Study

In October 2022 at the World Vaccine Congress in Europe, we presented Lot Consistency data. The study achieved its primary endpoint showing that three lots of NVX-CoV2373 induced consistent immune responses in adults aged 18 to 49 years and demonstrated manufacturing consistency. Heterologous boosting responses for NVX-CoV2373 were consistent across participants who received primary vaccines from other approved U.S. FDA COVID-19 vaccines.

Phase 3 U.K.

In February 2022, we announced an extended analysis from our pivotal Phase 3 U.K. trial showing that a high level of efficacy for NVX-CoV2373 was maintained over a 6-month period of surveillance. The analysis showed vaccine efficacy of 82.5% in protection against all COVID-19 infection, both symptomatic and asymptomatic. These data were published in *Clinical Infectious Diseases* in October 2022 and build upon the final analysis of our Phase 3 U.K. trial, published in *The New England Journal of Medicine* in June 2021, which highlighted the robust safety and efficacy data for NVX-CoV2373 and demonstrated a vaccine efficacy of 89.7%.

Phase 2b South Africa

In May 2022, results from our Phase 2b South Africa trial were published in *The Lancet*, which highlighted safety and immunogenicity of two doses of NVX-CoV2373 in people living with and without HIV. The Phase 2b South Africa trial was a randomized, observer-blinded, placebo-controlled study that enrolled 4,419 participants. The results show that due to a lower observed antibody response in baseline SARS-CoV2 people living with HIV than compared to the HIV-negative participants, there is a need to investigate alternative dosing approaches, including potentially adding a third vaccine dose to the priming series.

Phase 2 South Africa

In February 2022, we initiated a Phase 2 South Africa trial evaluating the safety and immunogenicity of NVX-CoV2373 in adults aged 18 to 65 years, living with human immunodeficiency virus ("HIV"). The Phase 2 South Africa trial was a randomized, observer-blinded, placebo-controlled study that enrolled 360 participants living with HIV to evaluate different dosing regimens. Data are being evaluated to support extended primary vaccination schedules for immunocompromised adults.

NVX-CoV2373 Clinical Development Conducted by Partners

Phase 2/3 India

In January 2023, immunogenicity and safety results from SIIPL and India Council of Medical Research Phase 2/3 trial were published in *The Lancet* and in the preprint server for health sciences on *medRxiv*. This Phase 2/3 trial was expanded from adults to include a pediatric cohort. The trial was an observer-blind, randomized, controlled study in 920 total enrolled children aged 2 to 17 years and was found to be well tolerated and immunogenic.

Phase 1/2 Japan

In April 2022, Takeda reported primary data analysis of a Phase 1/2 clinical trial of NVX-CoV2373 in Japan. This placebo-controlled trial evaluated the immunogenicity and safety of NVX-CoV2373 in 200 participants aged 20 years and older. Primary data analysis demonstrated acceptable safety results and induced robust immune responses.

Phase 1/2 Boosting Study – Led by National Institute of Allergy and Infectious Diseases

In March 2022, we announced participation in an ongoing Phase 1/2 trial sponsored by the National Institute of Allergy and Infectious Diseases to evaluate safety, reactogenicity, and immunogenicity of delayed heterologous or homologous boosting regimens in participants who received a primary series of a COVID-19 vaccine which has received full approval or EUA from FDA. Participants will be given a third dose (greater than or equal to 12 weeks later) of either NVX-CoV2373 or one of three COVID-19 vaccines approved for use by the FDA. The full results are expected in 2023.

Phase 3 United Arab Emirates

In March 2022, we announced participation in a Phase 3 study in the United Arab Emirates to evaluate the safety and immunogenicity of a single booster dose of NVX-CoV2373 in approximately 1,000 adults aged 18 or older who have already been immunized with Sinopharm's inactive COVID-19 vaccine. Data from the head-to-head comparison is expected in 2023.

Phase 2 Com-COV3 Booster Trial – Led by University of Oxford

In May 2022, we announced our participation in University of Oxford's Phase 2 Com-COV3 vaccine trial where our COVID-19 vaccine, NVX-CoV2373 is one of two COVID-19 vaccines that are being studied as a third booster in approximately 380 adolescents aged 12 to 15 years.

Variant Strain-Containing Monovalent or Bivalent Vaccine Development

Our nanoparticle vaccine technology is purpose-built to rapidly address evolving infectious disease threats. As variants of COVID-19 emerge, we proactively evaluate NVX-CoV2373's ability to protect against variant strains and evaluate the potential need for variant-specific monovalent or bivalent vaccine constructs.

In January 2023, we participated in U.S. FDA Vaccine and Related Biological Products Advisory Committee's meeting, which resulted in a unanimous vote harmonizing vaccine strain composition of primary series and booster doses. Within the meeting we shared data demonstrating NVX-CoV2373, when used as a booster induces broad functional immune responses, including against forward drift variants. We intend to deliver an updated vaccine following FDA guidance on strain change.

COVID-19 Phase 3 Omicron Variant Strain Vaccine

In November 2022, we announced topline results from our Phase 3 boosting trial showing that our Omicron BA.1 vaccine candidate met the primary strain-change endpoint. We expect to advance group 2 of our Phase 3 Omicron boosting trial as part of our variant strategy to be ready for the fall season. Group 2 of the trial will build upon the first portion of our trial and will evaluate Omicron BA.5 vaccine in a monovalent and bivalent format in comparison to our monovalent prototype strain vaccine. These data will support regulatory filing authorization of a strain change. We expect to initiate part 2 of this study to evaluate our prototype vaccine compared to an Omicron BA.5 vaccine, as well as a bivalent containing prototype and Omicron BA.5 vaccine.

Phase 2 U.S. and Australia Homologous Booster Study – Including Variant Results

In August 2022, exploratory analysis results of our Phase 2 homologous booster study were published within *The Lancet Infectious Diseases*, which was a randomized study to assess a single booster of NVX-CoV2373 in 1,282 healthy adults aged 18 to 84 years. Overall, a single booster dose of NVX-CoV2373 administered approximately 6 months after the primary series induced substantial increases in humoral antibodies for both the prototype strain and all evaluated variants including Alpha, Delta, and Omicron (BA.1 and BA.2).

Additionally, immunogenicity data from a fourth homologous booster dose of NVX-CoV2373 was published as a letter in the *New England Journal of Medicine* in January 2023. The study showed that a fourth dose of NVX-CoV2373 enhanced immunogenicity without increasing reactogenicity. Antigenic cartography mapping demonstrated a broad response against contemporary SARS-CoV-2 variants after a fourth dose of NVX-CoV2373, indicating that updates to the vaccine composition may not be warranted for the evaluated variants. Additional data are forthcoming.

COVID-19 Vaccine Funding

We have secured critical funding from the U.S. government to support the development of NVX-CoV2373 for the U.S. population, including $1.8 billion from a partnership formerly known as Operation Warp Speed. In July 2020, we entered into a Project Agreement (the "Project Agreement") with Advanced Technology International, Inc. ("ATI"), the Consortium Management Firm acting on behalf of the Medical CBRN Defense Consortium in connection with the partnership. The partnership was among components of the U.S. Department of Health and Human Services and the U.S. Department of Defense working to accelerate the development, manufacturing, and distribution of COVID-19 vaccines, therapeutics, and diagnostics. The Project Agreement relates to the Base Agreement we entered into with ATI in June 2020 (the "Base Agreement," together with the Project Agreement, the "USG Agreement"). The original USG Agreement required us to conduct certain clinical, regulatory, and other activities, including a pivotal Phase 3 clinical trial to determine the safety and efficacy of NVX-CoV2373, and to manufacture and deliver to the U.S. government 100 million doses of the vaccine candidate. Funding under the USG Agreement is payable to us 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 is terminated prior to completion, we are entitled to be paid for work performed and costs or obligations incurred prior to termination and consistent with the terms of the USG Agreement. In July 2022, we entered into a modification to the USG Agreement that amended the terms of such agreement to provide for (i) an initial delivery to the U.S. government of approximately 3 million doses of NVX-CoV2373 and (ii) any additional manufacture and delivery to the U.S. government up to an aggregate of 100 million doses of NVX-CoV2373 contemplated by the original USG Agreement (inclusive of the initial batch of approximately 3 million doses) dependent on U.S. government demand, FDA guidance on strain selection, agreement between the parties on the price of such doses, and available funding. The 3 million initial doses were delivered in July 2022. In February 2023, we entered into a modification to the USG Agreement that amended the terms of such agreement to provide for additional deliveries to the U.S. government of up to 1.5 million doses of NVX-CoV2373. The performance period under the Project Agreement extends through 2023 to cover clinical trial activities, subject to early termination by the U.S. government or extension by mutual agreement of the parties.

Under the USG Agreement, we were originally entitled to receive funding of up to $1.75 billion to support certain activities related to the development of NVX-CoV2373 and the manufacture and delivery of the vaccine candidate to the U.S. government. In subsequent modifications, the USG Agreement was amended to increase the contract funding and ceiling to $1.8 billion, which allows us to make expenditures or incur obligations of up to $1.8 billion for support of the USG Agreement.

Our funding agreement with the Coalition for Epidemic Preparedness Innovations ("CEPI"), under which CEPI has agreed to provide funding of up to $399.5 million to us to support the development of NVX-CoV2373, provides up to $257.0 million in CEPI Grant Funding and up to $142.5 million in CEPI Forgivable Loan Funding, which are loans in the form of one or more forgivable no-interest term loans in order to prepay certain manufacturing activities and are not subject to restrictive or financial covenants. Payments received under the CEPI Forgivable Loan Funding are only repayable if NVX-CoV2373 manufactured by the contract manufacturing organization ("CMO") network funded by CEPI is sold to one or more third parties (which would have previously included, but is not limited to, any sales under our Gavi APA prior to its termination), and such sales cover our costs of manufacturing such vaccine, not including manufacturing costs funded by CEPI. The timing and amount of any loan repayments is currently uncertain.

A summary and status of our historical COVID-19 funding developments follows:

Funding Partner	Amount	Additional Details
CEPI	**$399.5 million**	• Entitled to received up to $399.5 million of funding to support the development of NVX-CoV2373 • To supply NVX-CoV2373 through the COVAX Facility
U.S. Department of Defense ("DoD")	**$45.7 million**	• Entitled to received up to $45.7 million of funding to support the development of NVX-CoV2373 • To manufacture and deliver up to 10 million doses of NVX-CoV2373 to the U.S. government • Contract term ended in December 2022
U.S. Government through USG Agreement	**$1.8 billion**	• Allotted $1.8 billion to support the development of NVX-CoV2373 • To manufacture and deliver up to 100 million doses of NVX-CoV2373 to the U.S. government

Seasonal Influenza

Influenza Program (Older Adults)

Influenza is a world-wide infectious disease with serious illness generally occurring in more susceptible populations such as children and older adults, but also occurring in the general population. According to a 2022 Fortune Business Insights research report forecast of influenza vaccines, the market for seasonal influenza vaccines is expected to grow from approximately $7.54 billion in 2022 to approximately $13.58 billion in 2029.

In October 2022 at the World Vaccine Congress in Europe, we reviewed key findings from the Phase 3 stand-alone qNIV candidate, previously referred to as NanoFlu, which met its primary immunogenicity endpoints. The final analysis of these results was previously published in September 2021, in *The Lancet Infectious Diseases*. The results demonstrated non-inferior immunogenicity to Fluzone® Quadrivalent against all four influenza virus strains included in the vaccine, while also showing both enhanced wild-type hemagglutination-inhibiting antibody responses against homologous strains (22-66% increased) and six heterologous A/H3N2 strains (34-46% increased) as compared to Fluzone® Quadrivalent. Additionally, qNIV showed potent induction of polyfunctional antigen-specific CD4+ T-cells against A(H3N2) and B/Victoria strains, with a 126–189% increase in various post vaccination cell-mediated immunity markers as compared to Fluzone® Quadrivalent.

Combination Vaccines

Our Influenza Program team remains focused on advancing combination vaccine candidates. With the ongoing development of Influenza Program, NVX-CoV2373, and our RSV Program, a strong rationale exists for developing combination respiratory vaccines designed to protect susceptible populations against these diseases.

COVID / Influenza Combination Vaccine

Phase 2 Clinical Trial of COVID-19-Influenza Combination Vaccine

In December 2022, we initiated a Phase 2 trial for CIC, which includes study arms for our stand-alone updated qNIV vaccine candidate. The dose-confirming trial will be conducted in two parts and will seek to enroll approximately 2,300 adults aged 50 to 80 years in Australia and New Zealand. The trial is randomized, observer-blinded with primary and secondary objectives of the study to assess the safety, tolerability, and immune responses to various formulations of the CIC and influenza vaccine candidates. As of January 2023, we completed enrollment of 1,500 participants. The initial results are expected mid-year 2023 with data informing the second part of the trial and future clinical development for both influenza stand-alone and CIC candidates.

Phase 1/2 Clinical Trial of COVID-19-Influenza Combination Vaccine

In October 2022 at the World Vaccine Congress in Europe, we announced additional positive results from Phase 1/2 CIC trial, which combines NVX-CoV2373 and our updated qNIV candidate. The results demonstrated CIC's ability to generate immune responses, including both antibody and polyfunctional CD4+ T-cell (lymphocytes that help coordinate the immune response) responses against an evolving SARS-CoV-2 virus, along with homologous and heterologous influenza strains. The CIC vaccine was well tolerated, and the safety and tolerability profile was consistent with the stand-alone NVX-CoV2373 prototype vaccine and quadrivalent influenza vaccine candidate reference formulations in the trial.

Respiratory Syncytial Virus ("RSV")

Currently, there is no approved RSV vaccine available to combat the estimated 64 million RSV infections and 160 thousand deaths that occur globally each year. Older adults (60 years and older) are at increased risk for RSV disease due in part to immunosenescence, the age-related decline in the human immune system. RSV infection can also lead to exacerbation of underlying co-morbidities such as chronic obstructive pulmonary disease, asthma, and congestive heart failure.

RSV Program (Older Adults)

Previous clinical development through a Phase 2 clinical trial demonstrated that our RSV Program for older adults with either aluminum phosphate or our proprietary Matrix-M™ adjuvant increased the magnitude, duration, and quality of the immune response versus the non-adjuvanted RSV F Vaccine. We continue to assess the preclinical development opportunities for our updated RSV vaccine for older adults.

Malaria

Malaria is a life-threatening disease caused by a parasite that infects mosquitos subsequently transmitted to humans. According to the 2022 WHO World Malaria Report, in 2021, there were an estimated 247 million malaria cases and 619 thousand deaths worldwide in 2021. We believe malaria has the potential to be preventable through the R21 vaccine candidate, which is being developed through several partner-led trials and is formulated with our Matrix-M™ adjuvant.

R21 - Malaria Vaccine

R21 is a malaria vaccine candidate created by the Jenner Institute, University of Oxford, and formulated with our Matrix-M™ adjuvant. The University of Oxford has granted SIIPL a license for R21. SIIPL has committed to manufacture at least 200 million doses per year of R21 after licensure, if granted. Additionally, SIIPL has rights to use Matrix-M™ adjuvant in R21 in regions where the disease is endemic and will pay royalties to us on its market sales of the vaccine. We will have commercial rights to sell and distribute the SIIPL-manufactured R21 in certain countries, primarily in the travelers' and military vaccine markets.

R21 Clinical Development

R21 is being evaluated in an ongoing Phase 3 trial being conducted by our partner, Jenner Institute, University of Oxford, for R21, a malaria candidate which is formulated using our Matrix-M™ adjuvant. In September 2022, positive results from an ongoing Phase 1/2b study were published in *The Lancet Infectious Diseases* reporting safety, immunogenicity, and efficacy results at 12 months following administration of a booster vaccination in children aged 5 to 17 years in Nanoro, Burkina Faso. A total of 409 children received a booster dose of R21 formulated with our Matrix-M™ adjuvant at 1 year following the primary three-dose regimen maintaining high efficacy against first and multiple episodes of clinical malaria, demonstrating 71% efficacy when formulated with 25 micrograms of Matrix-M™ adjuvant and 80% efficacy when formulated with 50 micrograms of Matrix-M™ adjuvant. The trial is continuing for a further 2 years to assess long-term follow-up of the participants and the value of further booster vaccinations.

License and Collaboration

Our commitment to partnering globally in efforts to end the COVID-19 pandemic is demonstrated through our partnership with SIIPL to supply NVX-CoV2373 to India and low- and middle-income countries. We have also partnered with both Takeda in Japan and SK bioscience in South Korea to expand our manufacturing and supply capabilities.

Licensee	Marketed Under	Territories
Serum Institute of India Private Limited	**Covovax™**	• India • COVAX Facility • The Philippines • Indonesia • South Africa • Bangladesh
Takeda Pharmaceutical Company Limited	**Nuvaxovid™**	• Japan • South Korea
SK bioscience Co., Ltd.	**Nuvaxovid™**	• South Korea[1]

(1) SK bioscience also has non-exclusive licenses in Thailand and Vietnam.

A summary of our license and collaboration agreements follows:

SIIPL

We previously granted exclusive and non-exclusive licenses to SIIPL under a supply and license agreement for the development, co-formulation, filling and finishing, registration, and commercialization of NVX-CoV2373. SIIPL agreed to purchase our Matrix-M™ adjuvant and we granted SIIPL a non-exclusive license to manufacture the antigen drug substance component of NVX-CoV2373 in SIIPL's licensed territory solely for use in the manufacture of NVX-CoV2373. We equally split the revenue from SIIPL's sale of NVX-CoV2373 in its licensed territory, net of agreed costs. We granted to SIIPL (i) an exclusive license in India during the agreement, and (ii) a non-exclusive license (a) during the "Pandemic Period" (as declared by the World Health Organization), in all countries other than specified countries designated by the World Bank as upper-middle or high-income countries, with respect to which we retains rights, and (b) after the Pandemic Period, in only those countries designated as low or middle-income by the World Bank. Following the Pandemic Period, we may notify SIIPL of any bona fide opportunities for us to license NVX-CoV2373 to a third party in such low- and middle-income countries and SIIPL would have an opportunity to match or improve such third-party terms, failing which, we would have the discretion to remove one or more non-exclusive countries from SIIPL's license. We also have a supply agreement with SIIPL and Serum Life Sciences Limited ("SLS") under which SIIPL and SLS will supply us with NVX-CoV2373 for commercialization and sale in certain territories, as well as a contract development manufacture agreement with SLS, under which SLS manufactures and supplies finished vaccine product to us using antigen drug substance and Matrix-M™ adjuvant supplied by us. In May and August 2022, we expanded our license and supply arrangements with SIIPL to include our proprietary COVID-19 variant antigen candidate(s), our quadrivalent influenza vaccine candidate, and our CIC vaccine candidate, so that SIIPL can manufacture and commercialize a vaccine targeting COVID-19 variants, including the Omicron subvariants, a quadrivalent influenza vaccine, and CIC vaccine, and supply such vaccines to us. In March 2020, we granted SIIPL a non-exclusive license for the use of Matrix-M™ adjuvant supplied by us to develop, manufacture, and commercialize R21, a malaria candidate developed by the Jenner Institute, University of Oxford.

Takeda

We have a collaboration and license agreement with Takeda under which we granted Takeda an exclusive license to develop, manufacture, and commercialize NVX-CoV2373 in Japan. Under the agreement, Takeda purchases Matrix-M™ adjuvant from us to manufacture doses of NVX-CoV2373 and we are entitled to receive 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 NVX-CoV2373. In September 2021, Takeda finalized an agreement with the Government of Japan's Ministry of Health, Labour and Welfare ("MHLW") for the purchase of 150 million doses of NVX-CoV2373. In February 2023, MHLW cancelled the remainder of doses under its agreement with Takeda. As a result, it is uncertain whether we will receive future payments from Takeda under the terms and conditions of our current collaboration and licensing agreement.

SK bioscience

We have a collaboration and license agreement with SK bioscience to manufacture and commercialize NVX-CoV2373 for sale to the governments of South Korea, Thailand, and Vietnam. SK bioscience pays a royalty in the low to middle double-digit range. Additionally, we have a manufacturing supply arrangement with SK bioscience under which SK bioscience supplies the antigen component of NVX-CoV2373 to us for use in the final drug product globally, including product distributed by the COVAX Facility, which was established to allocate and distribute vaccines equitably to participating countries and economies. In July 2022, we signed an additional agreement with SK bioscience for the technology transfer of our proprietary COVID-19 variant antigen materials so that SK bioscience can manufacture the drug substance targeting COVID-19 variants, including the Omicron subvariants. We also have an agreement with SK bioscience, pursuant to which it supplies us with our COVID-19 vaccine in a prefilled syringe.

Manufacturing and Supply

We are committed to discovering, developing, and commercializing innovative vaccines to prevent serious infectious diseases and are exploring a number of combination vaccine candidates, including a CIC vaccine, directly and by leveraging our strategic global partnerships. In 2021 and 2020, we established a global supply chain and worldwide partnerships to support the commercialization of NVX-CoV2373. In 2022, 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 NVX-CoV2373.

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 NVX-CoV2373

We manufacture the antigen component of NVX-CoV2373 at our Novavax CZ facility in the Czech Republic.

We have a supply agreement with SIIPL and SLS, an affiliate of SIIPL, for the manufacture of the antigen component of NVX-CoV2373 and the co-formulation, fill, and finishing of the finished vaccine product. In May and August 2022, we expanded our license and supply arrangements with SIIPL to include our proprietary COVID-19 variant antigen candidate(s), our quadrivalent influenza vaccine candidate, and our CIC vaccine candidate, so that SIIPL can manufacture and commercialize a vaccine targeting COVID-19 variants, including the Omicron subvariants, a quadrivalent influenza vaccine, and CIC vaccine, and supply such vaccines to us.

Additionally, we have a manufacturing supply arrangement with SK bioscience under which SK bioscience supplies us with the antigen component of NVX-CoV2373 for use in the final drug product globally. In July 2022, we signed an additional agreement with SK bioscience for the technology transfer of our proprietary COVID-19 variant antigen materials so that SK bioscience can manufacture the drug substance targeting COVID-19 variants, including the Omicron subvariants.

We have a partnership with FUJIFILM Diosynth Biotechnologies through an agreement for long-term commercial manufacturing of NVX-CoV2373, under which it manufactures the antigen component of NVX-CoV2373 at its Billingham, UK site.

We have an arrangement with the National Research Council of Canada ("NRCC") for the ongoing technology transfer for the production of NVX-CoV2373 at the NRCC's Biologics Manufacturing Centre. Engineering runs are currently underway at the facility and, once complete, process performance qualification and large-scale GMP production can begin.

Finished NVX-CoV2373

In addition to the supply agreement with SIIPL and SLS for the co-formulation, fill, and finishing of the finished vaccine product, we have a contract development manufacture agreement with SLS, pursuant to which SLS will manufacture and supply finished vaccine product to us using antigen drug substance and Matrix-M™ adjuvant supplied by us. We currently depend exclusively on SIIPL and SLS for co-formulation, filling, and finishing NVX-CoV2373. We also have an agreement with SK bioscience, pursuant to which it supplies us with our COVID-19 vaccine in a prefilled syringe.

Competition in COVID-19, Influenza, and RSV

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 such as enabling dose-sparing effects and refrigerator temperature storage when compared to other technologies creating a best-in-class vaccine, and is uniquely well suited for developing COVID-19, influenza, and RSV vaccines, as well as vaccines against a number of other infectious diseases.

A number of vaccine manufacturers, research institutions, and other organizations are developing 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. According to a coronavirus vaccine tracker published by *The New York Times*, updated as of August 31, 2022, there are 33 vaccines approved for limited or full use and 123 vaccines in clinical trials. Novavax is the first protein-based COVID-19 vaccine that received EUA by the FDA and a CMA by EMA in the European Union. As of February 2023, Novavax is one of four manufacturers that have a COVID-19 vaccine that has received EUA by the FDA, with the other manufacturers being Pfizer, Moderna, and Johnson & Johnson. As of February 2023, Pfizer and Moderna have received BLA approval by the FDA in the U.S. for their monovalent COVID-19 vaccines and received EUA by the FDA in the U.S. for their bivalent COVID-19 vaccines. Novavax and Johnson & Johnson have received EUA by the FDA in the U.S. for their monovalent vaccines. Based on NVX-CoV2373's 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 U.K. and U.S., we believe our vaccine candidate will continue to play an important role in addressing this global public health crisis.

A number of companies are selling vaccines for seasonal influenza employing both traditional (egg-based) and new vaccine technologies (cell-based). 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® and Flublok® manufactured by Sanofi and Fluad® 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 and/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 3 and Phase 1/2 trial results, we believe that our Influenza Program, our adjuvanted nanoparticle seasonal influenza product, could be as efficacious as, or more so than, current products or products being developed by our competitors.

Additionally, we believe that our platform is well suited for combination vaccines, for example influenza and COVID-19. Following our Phase 1/2 trial results, we are currently in a Phase 2 trial for our CIC and influenza standalone vaccine candidates to evaluate the safety and effectiveness (immunogenicity) of different formulations in adults aged 50 through 80. Other manufacturers, most notably Moderna and Pfizer, are in Phase 1/2 and Phase 1 clinical trials with COVID-19-influenza combination candidates.

There is currently no approved RSV vaccine for sale in the world; however, a number of vaccine manufacturers, academic institutions, and other organizations currently have, or have had, programs to develop such a vaccine. These groups are developing products to prevent disease caused by RSV using a variety of technology platforms, including viral vectors, nucleic acid ("RNA/DNA"), live attenuated chimeric, antigens or monoclonal antibodies ("Mab"), and competitive recombinant technologies. We continue to believe that our updated RSV F Vaccine candidate, which is a recombinant F-protein nanoparticle, is likely to be as effective as other RSV vaccine candidates or other products in development by our competitors. At this time, there are a number of companies and other organizations with vaccine candidates in late-stage clinical trials. In older adults, GSK, Pfizer, and Moderna have announced data from their Phase 3 studies, with GSK and Pfizer completing regulatory submission to the FDA in the U.S. with Prescription Drug User Fee Act ("PDUFA") dates in May 2023 and Moderna planning regulatory submission to the FDA in the first half of 2023. Janssen and Bavarian Nordic currently are in Phase 3 trials. In infants Pfizer announced Phase 3 data and completed regulatory submission to the FDA for their vaccine candidate via maternal immunization and have a PDUFA date in August 2023. Additionally, in infants, AstraZeneca / Sanofi partnered monoclonal antibody is approved in Europe and has a PDUFA date with the FDA in the U.S. in the third quarter of 2023, and Merck's monoclonal antibody is in Phase 3 trials.

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 for our technology and product candidates in the U.S. and abroad. The patent position of biotechnology and pharmaceutical firms generally is highly uncertain and involves 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;
- protect our trade secrets and know-how; and
- operate without infringing the intellectual property and proprietary rights of others.

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 550 U.S. and foreign patents and patent applications relating to vaccines and vaccine-related technologies.

Patents related to our Virus-Like Particle ("VLP") program include U.S. Patent No. 7,763,450, which covers, in part, the use of influenza gene sequences for high-yield production of consistent influenza VLP vaccines to protect against current and future seasonal and pandemic strains of influenza viruses. Corresponding European patent, European Patent No. 1644037 also covers this technology. U.S. Patent Nos. 8,080,255, 8,551,756, 8,506,967 and 8,592,197 are directed to methods of producing VLPs and inducing substantial immunity to an influenza virus infection by administering VLPs comprising HA and NA proteins, and our M1 protein derived from the avian influenza strain, A/Indonesia/5/05. Certain claims also encompass similar methods and compositions where the M1 protein is from a different strain of influenza virus than the influenza HA protein and the influenza NA protein. Related patent protection in Europe is provided by European Patent No. 2343084, which covers, in part, vaccine compositions containing VLPs that contain M1, HA, and NA proteins. Our VLP patent portfolio contains many other patents, including U.S. Patent Nos. 8,951,537, 8,992,939, 9,144,607, 9,050,290, 9,180,180, 9,381,239, 9,464,276, 9,474,799, and other patents in multiple ex-U.S. jurisdictions.

We also have been issued patents directed to other core programs, including our RSV and influenza programs. Issued patents directed to various aspects of the RSV program include U.S. Patent Nos. 8,715,692, 9,675,685, 9,731,000, 9,717,786, 10,022,437, 10,426,829, and 11,253,585. Additional patents in the family include EP237009 in Europe, as well as others throughout the world. Patents related to our rabies program include 9,724,405 and 10,086,065 in the U.S., and EP2635257 and EP3246019 in Europe. Related patents have been issued in other world markets. Issued patents in our influenza nanoparticle program include US Patent Nos. 11,364,294 and 11,278,612. In addition to our focus on vaccine programs, we also pursue patent protection for our Matrix Adjuvant program. Issued U.S. Patent Nos. 7,838,019, 9,205,147, 9,901,634, 8,821,881, and 10,729,764 provide examples of patents related to our Matrix Adjuvant program.

We pursue patents related to our COVID-19 vaccine program, including to NVX-CoV2373, our COVID-19 vaccine candidate. Issued U.S. Patent Nos. 10,953,089, 11,253,586, 11,541,112 provide examples of patents related to our COVID-19 program.

We also have four pending PCT applications directed to our COVID program (PCT/US2022/020974, PCT/US2022/080700, PCT/US2022/082331 and PCT/US2022/027465) and two pending PCT applications directed to our malaria program (PCT/US2022/078665 and PCT/US2022/080334).

We continue to prepare, file, and prosecute patent applications to provide broad and strong protection of our proprietary rights, including our RSV Program, our influenza nanoparticle program, our COVID-19 program, 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.

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 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 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 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 FDA licensure to market any new vaccine candidate, we expect to first submit an investigational new drug application ("IND") that explains to the 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 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 FDA. Following successful completion of all three phases of clinical development, a BLA can be submitted to the 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 FDA will only approve a BLA if the vaccine is demonstrated to be safe, pure, and potent. During the FDA's review of a BLA, the proposed manufacturing facility undergoes a pre-approval inspection during which the 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 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 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 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 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 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 Biden Administration has announced that it intends for the COVID-19 PHE, first declared in February 2020, to expire on May 11, 2023, that expiration will not terminate EUAs issued by the FDA.

In order to ensure continuing safety, the 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 FDA licensure for each product, each domestic manufacturing establishment must be registered with the FDA, is subject to 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 FDA or by corresponding regulatory agencies in their home country.

The EU and the U.K. 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 marketing authorization will eventually become unconditional. 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 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 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 FDA and the FDA may initiate review of sections of a Fast Track product's application before the application is complete. The FDA granted Fast Track Designation for NVX-CoV2373 in November 2020 and for NanoFlu, 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 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 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 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 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 June 2019, we announced that the FDA acknowledged that the accelerated approval pathway is available for NanoFlu.

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. 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 facility in Sweden. 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 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. For example, in March 2010, the U.S. Congress enacted the Patient Protection and Affordable Care Act and the Health Care and Education Reconciliation Act ("Healthcare Reform Act") which includes changes to the coverage and reimbursement of drug products under government health care programs. Under the Trump administration, there were several efforts to modify or repeal all or certain provisions of the Healthcare Reform Act, and some modifications were implemented. 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 Healthcare Reform Act was enacted. 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 due to subsequent legislative amendments contained in the Coronavirus Aid, Relief, and Economic Security Act, commonly referred to as the "CARES Act." In November 2020, the Centers for Medicare and Medicaid Services ("CMS") issued an interim final rule that seeks to lower prescription drug costs by paying no more for certain Medicare Part B drugs than the lowest price paid for such drugs in certain other countries (the "Most Favored Nation Rule"). Under the rule, the lower payment rates for affected drugs would be phased in over a period of four years, beginning in 2021. The rule has been challenged by industry associations on a number of grounds. On December 28, 2020, the U.S. District Court for the Northern District of California issued a nationwide preliminary injunction in Biotechnology Innovation Organization v. Azar, No. 3:20-cv-08603, which preliminarily enjoins CMS from implementing the Most Favored Nation Rule. Given this preliminary injunction, the Most Favored Nation Rule was not implemented on January 1, 2021 and will not be implemented without further rule-making. However, this interim final rule or any similar type of reference pricing regulation could potentially harm our business if expanded to include our products.

Recently, 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 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 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. Effective January 1, 2022, in advance of the calendar year 2022 Part D plan year, safe harbor protection will be eliminated for manufacturer rebates paid directly (or indirectly through a pharmacy benefit manager) to Part D prescription drug plans and Medicare Advantage prescription drug plans. Effective December 30, 2020, the Rebate Rule established two new safe harbors. The first new safe harbor protects price reductions paid by manufacturers to prescription drug plans (including prescription drug plans offered by Medicare Advantage organizations) and Medicaid managed care organizations, which are fully reflected at the point-of-sale. The second new safe harbor protects fair-market-value service fees paid to pharmacy benefit managers by manufacturers. 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 changes 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 to induce or encourage the prescription, recommendation, endorsement, purchase, supply, order, or use of medicinal products is prohibited. The provision of benefits or advantages to physicians is also governed by the national anti-bribery laws of EU Member States and the United Kingdom, such as the U.K. 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 is 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. 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 has been a recent trend of increased federal and state regulation of payments made to physicians and other healthcare providers. The Physician Payments Sunshine Act imposes annual reporting requirements on certain manufacturers of drugs, devices, biologics, and medical supplies for which payment is available under Medicare, Medicaid, or the Children's Health Insurance Program, with specific exceptions, for payments made by them to physicians (defined to include doctors, dentists, optometrists, podiatrists, and chiropractors) and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. Beginning in 2022, applicable manufacturers will also be required to report information related to payments and other transfers of value provided in the previous year to physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists, and certified nurse midwives.

Within the European Union and the United Kingdom, payments made to physicians must be publicly disclosed. 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 NVX-CoV2373 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. The current declaration will end on October 1, 2024, unless it is renewed. 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 HHS 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.

Human Capital

Employees

As of February 21, 2023, we have 1,992 full-time employees, of whom approximately 9% hold M.D. or Ph.D. degrees and approximately 21% hold other advanced degrees. Of our total workforce, approximately 63% of employees are engaged primarily in research, development, and manufacturing activities and approximately 37% of employees are engaged primarily in executive, business development, commercial, finance and accounting, legal, and administrative functions. Except for certain employees located in Sweden, 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.

To nurture, grow, and treat our employees fairly is an integral part of our culture. We are proud to have been recognized in the 2021 Top Workplaces USA list based on employee surveys. We believe this award reflects our investment in an exceptional work culture.

Employee Safety and Well-Being

Employee safety is our highest priority. As we moved through the pandemic in 2022, we continued to encourage employees who were able to work from home to do so. We have continued to follow all CDC guidelines related to COVID-19 safety. In addition, we implemented our Ways of Working guidelines, which allow employees the flexibility to work remotely either full time or in a hybrid manner to provide employees with continued flexibility based on business needs. We provide employees with updated information on COVID-19 through our COVID-19 Resources page on our intranet. This resource provides employees with information on COVID-19 safety, both inside and outside of the workplace. Resources on this site include our COVID-19 Protocols and Guide, our policies on face coverings and social distancing, a list of infection control measures, and mental wellness support resources.

Our 700 Quince Orchard office space located in Gaithersburg, Maryland received WELL Platinum certification in 2022. WELL is the leading tool for advancing health and well-being in buildings globally. As one of 35 WELL certified buildings in North America, this building will meet rigorous standards for materials selection, indoor air quality, and acoustics. In addition, our operations and policies contribute to earning high marks in all of the 10 WELL Concepts: Air, Water, Nourishment, Light, Movement, Thermal Comfort, Sound, Materials, Mind, and Community.

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 generous total rewards package includes competitive market pay and comprehensive benefits, including insurance to protect and maintain health; income protection through our short- and long-term disability programs; 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 help our employees lead healthier and happier lives. 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 for employees to access support for a variety of life events.

To assist employees with work/life balance, we offer a concierge service that helps employees with managing various personal tasks including finding and booking auto services; sourcing pet sitters and boarders; researching online and in-person tutors; suggesting community events; providing vacation ideas; finding and booking home cleaners, plumbers, HVAC, and landscaping services; finding and booking yoga, personal training sessions, and spin classes; suggesting nutritional meals and recipes; and researching day care center availability and ratings.

In addition, we offer every employee 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 2022, we held an Early Career Summit to engage, retain, and develop over 150 employees and college interns. The Summit provided a forum for this group to network, build relationships, and learn from Novavax leaders and one another.

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, videos were viewed and completed over 50,000 times by our employees. In addition, approximately 200 employees have participated in spot coaching. 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. 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 2023 Executive Development Program includes a diverse and global group of 34 employees. 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 tools to facilitate open and direct communication, including global forums with executives, employee surveys, and engagement through forums and committees. 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.

Diversity, Equity, and Inclusion

Our culture of diversity, equity, and inclusion ("DEI") helps us to create, develop, and leverage the strengths of our workforce to meet our growth objectives. We recently completed an evidence-based analysis of our current DEI state, resulting in a multi-year roadmap and strategy that will enable our mission, our people, and our best work. It is designed around three pillars:

- *Embed* DEI into our people decisions and processes.
- *Enable* our employees, who we refer to as our SuperNovas, to live our values and thrive in a culture of inclusion.
- *Equip* our leaders and SuperNovas with the understanding, capability, education, tools, and resources on DEI.

We started implementing our roadmap in 2022 and are making progress. We hired a DEI and Employee Engagement Manager who will facilitate and help focus our actions to build an inclusive workforce. We began acknowledging global DEI-related observances and we are investing in training to build an inclusive culture and develop our leaders to access different perspectives when generating ideas and decision making. The second annual Novavax Women's Leadership Forum was held and resulted in building networks, developing skills, sharing voices and ideas, and becoming agents of positive change for nearly 300 Novavax women. In 2022, we also made progress in increasing representation for women and minorities at the Executive level. We commenced and completed the reviews of three people processes, namely, Talent Acquisition, Promotion, and Performance Management. We also have intentionally incorporated DEI principles into our Novavax Leadership Model. We believe our multi-year DEI strategy and roadmap will enable us to continuously improve and excel.

Environmental, Social, and Governance

In addition to the DEI and human capital initiatives described above, we have several other Environmental, Social, and Governance ("ESG") related initiatives that are underway. These initiatives are centered around four focus areas including environmental sustainability, innovating for vaccine access and improving global health, empowering our employees, and governing responsibility. 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:

Environmental Sustainability

- Resource management and greenhouse gas ("GHG") reduction strategy with tracking and reporting GHG emissions
- Procurement approach that incorporates sustainability metrics into vendor evaluation rubrics
- Lease of approximately 170,000 square foot property in Gaithersburg, Maryland at 700 Quince Orchard Road that is designed with carbon-conscious initiatives in place such as a net zero parking structure
- Conserving water and monitoring energy use across multi-use leased and owned facilities
- Award of WELL certifications at multiple leased facilities
- Sustainable saponin sourcing with our partner Desert King, who is the key supplier of the *Quillaja saponaria* (Soapbark) tree found native to central Chile, used to produce our Matrix-M™ adjuvant

Innovating for Vaccine Access and Improving Global Health

- R21 malaria vaccine candidate, developed by the Jenner Institute, University of Oxford, and formulated with our Matrix-M™ adjuvant
- Vaccine access through community partnerships such as collaboration with representatives from Hip Hop Public Health, Anthem, and the CDC Foundation to host a discussion entitled "The Last Mile: Coming Together to Make Vaccines Make a Difference" at Aspen Ideas: Health
- Advocacy efforts to build a bureau of third-party organizations who are registered with the CDC to provide public commentary on behalf on Novavax, including National Health Council, Vaccinate your Families, and National Black Nurses Association
- Efforts focused on clinical trial diversity

Empowering our Employees

- Introduced an employee donation matching program to elevate Novavax' charitable contributions, collaborated with local community groups (Montgomery Country Community College, Fairfax Country SkillSource Center), and supported local non-profits

- Introduced a program to help build community and establish corporate values, and provide tuition and education reimbursement, access to professional coaching, and Executive Development programming for high-potential employees

Governing Responsibly

- In 2021, we hired a Head of Global Quality Assurance and Quality Control to focus on building quality control and functions of global technical quality, clinical quality, control systems, and compliance operations

- Policy 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")

- Hired a Chief Compliance Officer and published "The NovaCode," a robust handbook of written standards and business ethics policies

- Global hotline for reporting compliance concerns with established internal investigating protocols

- Establishment of a Strategic Compliance Governance Committee to help our partners comply with U.S. regulations

- Company-wide business ethics training, guidance, and raw materials review

- Standard operating procedures drafted to guide decision-making

- Robust cybersecurity standards, meeting elevated government contracting requirements

- Hired a Chief Safety Officer to build out a robust epidemiology benefit / risk group to better understand safety profiles of different vaccines

- Ongoing employee training for updated Safety Policy and Standards

Availability of Information

Our website address is 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.

We use our website (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) in the "Investors" or "News" sections. Accordingly, investors should monitor these portions of our website (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.
- Because our vaccine product development efforts depend on new and rapidly evolving technologies, our efforts may not succeed.
- The regulatory and commercial success of our COVID-19 vaccine candidate, NVX-CoV2373, remains uncertain. While we have received provisional registration, conditional marketing authorization, or emergency use authorization for NVX-CoV2373 in a number of jurisdictions, we may be unable to obtain full regulatory approvals in the U.S. or other jurisdictions or produce a successful vaccine in a timely manner, if at all.
- The emergence and transmissibility of variants of the SARS-CoV-2 virus, and the demand for bivalent vaccines, may affect market acceptance or sales of NVX-CoV2373, and our strategy to develop versions of our COVID-19 vaccine to protect against certain variants may not be successful.

- We are a biotechnology company and face significant risk in developing, manufacturing, and commercializing our products.

- Because we depend on third parties to conduct some of our laboratory testing and clinical trials, and a significant amount of our vaccine manufacturing and distribution, we may encounter delays in or lose some control over our efforts to develop and supply products.

- We are highly dependent on the commercial success of NVX-CoV2373, and even though we have received provisional registration, conditional marketing authorization, or emergency use authorization in certain jurisdictions for NVX-CoV2373, and even if we have products licensed in additional markets, our vaccine products may not be initially or ever profitable.

- The COVID-19 pandemic and associated governmental public health policies continue to evolve, which may have unpredictable effects on the prospects for commercial success of NVX-CoV2373.

- 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, influenza, and RSV and we may never see returns on the significant resources we are devoting to our vaccine candidates.

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

- Our products might fail to meet their primary endpoints in clinical trials, meaning that we will not have the clinical data required to support full regulatory approvals.

- The regulatory pathway for NVX-CoV2373 is continually evolving, and may result in unexpected or unforeseen challenges.

- We have conducted, are conducting, and plan to conduct in the future, a number of clinical trials for NVX-CoV2373 at sites outside the U.S. and the FDA may not accept data from trials conducted in such locations.

- The later discovery of previously unknown problems with a product, manufacturer, or facility may result in restrictions, including withdrawal of a vaccine that had previously received regulatory approval in certain jurisdictions from the market.

- Our success depends on our ability to maintain the proprietary nature of our technology.

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

- Given our current cash position and cash flow forecast, and significant uncertainties related to 2023 revenue, funding from the U.S. government, and our pending arbitration with Gavi, substantial doubt exists regarding our ability to continue as a going concern through one year from the date that the financial statements included in this Annual Report were issued.

- Servicing our 5.00% convertible senior unsecured notes due 2027 requires a significant amount of cash, and we may not have sufficient cash flow resources to pay our debt.

- Because our stock price has been and will likely continue to be highly volatile, the market price of our common stock may be lower or more volatile than expected.

- Litigation or regulatory investigations could have a material adverse impact on our results of operation and financial condition.

- We or the third parties upon whom we depend may be adversely affected by natural or man-made disasters or public health emergencies, such as the COVID-19 pandemic.

Risks Related to Our Financial Condition and Capital Requirements

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, 2022 was $4.3 billion. Our revenue and expenses fluctuate significantly from period to period. For most of our history our expenses have exceeded our revenue, which may occur during most periods in the foreseeable future. Our net losses for the last three fiscal years were $0.7 billion in 2022, $1.7 billion in 2021, and $0.4 billion in 2020.

Historically, our losses have resulted predominantly from research and development expenses for our vaccine candidates, manufacturing-related expenses, expenses associated with efforts to obtain regulatory approvals, costs related to protection of our intellectual property, and other general and administrative operating expenses, a significant portion of which have been noncash. Our expenses have exceeded our revenue since inception, and we believe our expenses will fluctuate over time, and may substantially increase in some years, as a result of continuing efforts to develop, test, manufacture, and make regulatory filings for our vaccine candidates, and commercialize NVX-CoV2373 and any other product candidates that receive requisite regulatory approvals.

As of the end of fiscal year 2022, our investment in the development and manufacture of NVX-CoV2373 has been substantial, and we expect such levels of investment to continue for the rest of 2023 and beyond, although the precise magnitude of our total investment will depend on the duration of the COVID-19 pandemic, the competitive landscape, the timing and results of our applications for regulatory approvals, the availability of funding, and whether and what booster shot protocols are recommended by governments, regulatory authorities, and healthcare providers. If we are unable to timely commercialize a vaccine against COVID-19 in sufficient jurisdictions, we likely would never recoup our investments. 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 NVX-CoV2373 and other potential vaccine candidates;
- conduct preclinical studies for other potential vaccine candidates;
- expand our global manufacturing and distribution capacity, and commercialize NVX-CoV2373; 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 NVX-CoV2373 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, and supply agreements (also sometimes referred to as advance purchase agreements) for NVX-CoV2373. Although we have entered into supply agreements for NVX-CoV2373 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 additional public or private equity or debt financings, as well as existing cash, potential collaborations, strategic alliances and marketing, distribution or licensing arrangements, funding from governmental and non-governmental funding entities, and potentially other sources. While we may continue to apply for contracts or grants from academic institutions, non-profit organizations and governmental entities, we may not be successful. Adequate additional funding may not be available to us on favorable terms, or at all. Furthermore, negative interpretations of clinical trial data or setbacks, or perceived setbacks, with respect to manufacturing ability and/or capacity or regulatory filing timelines for NVX-CoV2373 or our other vaccine candidates, as well as the competitive landscape posed by other COVID-19 vaccines, may impair our ability to raise additional financing on favorable terms, or at all. Additionally, under certain supply agreements, if we do not timely achieve requisite regulatory milestones for NVX-CoV2373 in the relevant jurisdictions, obtain supportive recommendations from governmental advisory committees, and/or achieve product volume or delivery timing obligations, purchasers may seek to terminate such agreements, reduce their purchase commitments, require us to refund all or some prepayments we have received, or renegotiate such agreements. If we cannot raise the additional funds required for our anticipated operations, 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 COVID-19 pandemic, the impact of increased interest rates, and inflation. In addition, our operations and performance may be affected by political or civil unrest or military action, including the ongoing conflict between Russia and Ukraine. Access to capital markets is critical to our ability to operate. Traditionally, biotechnology companies have funded their research and development expenditures by raising capital in the equity markets. Declines and uncertainties in these markets in the past have severely restricted raising new capital and have affected companies' ability to continue to expand or fund existing development, manufacturing, regulatory and commercialization efforts. We require significant capital for our current and expected operations. The general economic and capital market conditions, both in the U.S. and worldwide, have been volatile in the past and at times have adversely affected our access to capital and increased the cost of capital. The capital and credit markets may not be available to support future capital raising activity on favorable terms. If economic conditions decline, our future cost of equity or debt capital and access to the capital markets could be adversely affected. In addition, if we are unable to access the capital markets on favorable terms, our ability to execute our business plan as contemplated would be compromised. Moreover, we rely and intend to rely on third parties, including clinical research organizations, contract manufacturing organizations and other important vendors and consultants. Global economic conditions may result in a disruption or delay in the performance of our third-party contractors and suppliers. If such third parties are unable to adequately satisfy their contractual commitments to us in a timely manner, our business could be adversely affected.

Our existing funding and supply agreements do not assure success of our vaccine candidates or that we will be able to fully fund our vaccine candidates.

Our funding agreements with the U.S. government ("USG") and CEPI each reimburse a portion of the expenses associated with the development and commercialization of NVX-CoV2373. To the extent funding commitments in such agreements are conditioned on our meeting certain milestones or conditions, we may not ultimately receive the full amount of committed funds and may require additional funding to support our NVX-CoV2373 development and commercialization activities, and we may be unable to timely obtain additional funding. For example, in July 2021, in connection with funding from the USG partnership formerly known as Operation Warp Speed, the USG instructed us to prioritize alignment with the FDA on our analytic methods before conducting additional U.S. manufacturing, and the USG indicated that it would not fund additional U.S. manufacturing until such alignment was reached, which did not occur until June 2022. In February 2023, in connection with the execution of Modification 17 to the USG Agreement, the U.S. government indicated to us that the award may not be extended past its current period of performance. If the USG Agreement is not amended, as we had previously expected, then we may not receive all of the remaining $416 million in funding we had previously anticipated pursuant to the USG Agreement. The USG Agreement also includes provisions giving the USG termination rights based on a determination that the funded project will not produce beneficial results commensurate with the expenditure of resources and that termination would be in the USG's interest. Such a determination would result in the loss of funding under that agreement and could result in other actions by the USG. The CEPI funding agreement, meanwhile, provides CEPI certain "march-in" rights in the event of certain breaches of that agreement. Additionally, we have entered into, and plan to continue entering into, supply agreements (also sometimes referred to as advance purchase agreements) for NVX-CoV2373 that include prepayments from the purchasers to help fund our development and manufacture of the vaccine. Under certain supply agreements, if we do not timely achieve requisite regulatory milestones for NVX-CoV2373 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. In July 2022, following a delay in obtaining regulatory approval in the United Kingdom, for example, we entered into the Amended and Restated UK Supply Agreement, which amended and restated in its entirety the Original UK Supply Agreement, which reduced the volume of vaccine doses that the Authority is committed to purchase as compared to the Original UK Supply Agreement. As of November 30, 2022, the United Kingdom's Joint Committee on Vaccination and Immunisation had not yet made a supportive recommendation with respect to NVX-CoV2373, triggering, under the terms of the Amended and Restated UK Supply Agreement, a further reduction of the volume of vaccine doses that the Authority is committed to purchase, as well as an obligation of the Company to repay $112.5 million of an upfront payment previously received from the Authority. Additionally, following our notice to Gavi of termination of the Gavi APA, Gavi responded by providing us with its own purported termination of the Gavi APA, claiming that we are obligated to refund $697.4 million in advance payments previously received from Gavi. On January 31, 2023, Novavax received a Request for Arbitration from Gavi in respect of the dispute. Arbitration is inherently uncertain, and, while we believe that we are entitled to retain the advance payments received from Gavi, it is possible that we could be required to refund all or a portion of the advance payments from Gavi. As a result, our existing funding and supply agreements do not assure success of our vaccine candidates and may be insufficient to fully fund the development and commercialization of our vaccine candidates.

Risks Related to Product Development and Commercialization

Because our vaccine product development 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 products. Our development efforts and, if those are successful, commercialization of NVX-CoV2373 and our other vaccines 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 NVX-CoV2373 proves 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 candidate, NVX-CoV2373, remains uncertain. While we have received provisional registration, conditional marketing authorization or emergency use authorization for NVX-CoV2373 in a number of jurisdictions, we may be unable to obtain full regulatory approvals in the U.S. or other jurisdictions or produce a successful vaccine in a timely manner, if at all.

In response to the outbreak of COVID-19, we are pursuing the development and manufacture of our vaccine candidate, NVX-CoV2373. Even though we have reported positive data from Phase 1, 2 and 3 clinical trials, and we and our partners have received provisional registration, conditional marketing authorization, or emergency use authorization from the World Health Organization and in the U.S., Canada, Australia, New Zealand, the European Union ("E.U."), the United Kingdom, India, Indonesia, the Philippines, and Singapore, as well as full approval in South Korea, such results may not be sufficient to support regulatory submissions, authorizations and approvals, accelerated or otherwise, in any other relevant jurisdictions on our projected timelines, if at all.

Additionally, even though NVX-CoV2373 has received regulatory authorizations in certain jurisdictions and may receive further regulatory approval in others, successful commercialization depends on our ability to effectively scale up and maintain manufacturing capabilities at our own locations and those of our manufacturing partners and contractors. In May 2020, we acquired Novavax CZ (formerly Praha Vaccines, a.s.) including its vaccine manufacturing facility in Bohumil, Czech Republic and approximately 150 of its employees but we have yet to produce commercial batches or receive regulatory approval at this site. We also are actively entering into agreements with third parties to manufacture the antigen component of NVX-CoV2373 and our proprietary Matrix-M™ adjuvant, as well as to distribute NVX-CoV2373. Because of contractual restraints and the limited number of third-party manufacturers with the relevant expertise, required regulatory approvals and facilities to manufacture NVX-CoV2373 and its components at commercial scale, replacement of a manufacturer may be expensive and time-consuming and may cause interruptions in production. Manufacturing of NVX-CoV2373 and its components involves a complicated process that will require 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 NVX-CoV2373 in adequate quantities to address global demand.

We have limited experience with the commercial launch of vaccine products, and doing so in a pandemic environment with an urgent, critical global need creates additional challenges. In addition to scaling up our manufacturing capabilities, we need to develop global distribution channels and form partnerships with third parties worldwide, as well as hire, train and integrate additional management, administrative and sales and marketing personnel. Rapid and significant growth may strain our administrative and operational infrastructure, imposing significant additional responsibilities on our organization, and our efforts to establish and maintain these capabilities may not meet expectations as to timing, scale-up, reproducibility, yields, purity, cost, potency or quality. If we fail to successfully manage our growth and the increased complexity of our operations, our business, financial position, results of operations and prospects may be materially and adversely affected.

The emergence and transmissibility of variants of the SARS-CoV-2 virus, and the demand for bivalent vaccines, may affect market acceptance or sales of NVX-CoV2373, and our strategy to develop versions of our COVID-19 vaccine to protect against certain variants may not be successful.

Our prototype COVID-19 vaccine, NVX-CoV2373, was a monovalent vaccine developed based upon the genetic sequence of the SARS-CoV-2 virus that was first discovered in December 2019. As the SARS-CoV-2 virus continues to evolve, new strains of the virus, or those that are already in circulation, may prove more transmissible or cause more severe forms of COVID-19 disease than the predominant strains to date. For example, the Omicron and Delta variants have been observed to be more transmissible, or contagious, than previous variants.

NVX-CoV2373 may not be as effective in protecting against these or other future variant strains. Additionally, we expect the demand for bivalent vaccines to continue to increase, which may negatively impact the demand, particularly in the U.S., for NVX-CoV2373 and would likely require significant expenditures by the Company to successfully market a bivalent formulation, particularly in the U.S. NVX-CoV2373 may fail to achieve market acceptance or significant sales, despite gaining regulatory approval, provisional registration, conditional marketing authorization or emergency use authorization in a number of jurisdictions, including emergency use authorization the U.S., as demand for variant-specific or bivalent vaccines increases. We have several variant-specific vaccine candidates in development, including for Omicron subvariants, and bivalent formulations with NVX-CoV2373, and may develop others in the future. However, if these efforts are unsuccessful, these candidates do not receive regulatory approvals expeditiously, we are slower to develop variant-specific or bivalent vaccines than competitors, these vaccine candidates prove less effective than competitors' vaccines, or we are unable to successfully manufacture, distribute or market such vaccine candidates once approved, these shortcomings may lead to reputational harm, loss of market share, and adverse financial results.

Our 2023 revenue depends on our ability to successfully develop, manufacture, distribute, or market an updated monovalent or bivalent formulation of a vaccine candidate for COVID-19 for the fall 2023 COVID vaccine 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 has the potential to delay regulatory approval from the FDA for our vaccine candidate for the fall 2023 COVID vaccine season. In addition, in January 2023, the U.S. Vaccines and Related Biologics Products Advisory Committee ("VRBPAC") announced its intent to provide the industry with its strain protocol guidance in the second quarter of 2023 for the fall 2023 COVID vaccine season. To meet potential demand for fall 2023, we intend to begin manufacturing an updated COVID-19 variant strain-containing formulation prior to the availability of strain protocol guidance. If we begin manufacturing a formulation that is not consistent with the strain protocol guidance, we will not be able to deliver the appropriate vaccine to our customers in sufficient quantities for the fall 2023 COVID vaccine season and we will have incurred significant costs for a formulation that we will be unable to sell.

Further, counterparties to certain of our existing supply agreements may request variant-specific vaccines in place of NVX-CoV2373 and, depending on when we are able to offer 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 supply agreements. In addition, we may expend significant resources adapting NVX-CoV2373 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, NVX-CoV2373 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. 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 FDA, or a foreign equivalent, does not agree with our interpretation of the results, and we may face challenges when scaling-up the production process to commercial levels. Even after a product is approved and launched, general usage or post-marketing clinical trials may identify safety or other previously unknown problems with the product, or manufacturing issues may emerge, either of which may result in regulatory approvals being suspended, limited to narrow the scope of the approval, or revoked, which may otherwise prevent successful commercialization. Intense competition in the vaccine industry could also limit the successful commercialization of any products for which we receive commercial approval.

We will require approval from the FDA of any name we intend to use for our products regardless of whether we have secured a trademark registration from the USPTO. The FDA typically conducts a review of proposed product names, including an evaluation of potential for confusion with other product names. The FDA may object to any product name we submit if it believes the name inappropriately implies medical claims. If the 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 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 exclusively on SIIPL and SLS for co-formulation, filling, and finishing NVX-CoV2373. If SLS is unable to provide sufficient co-formulation, fill, and finish services to us, fails to meet regulatory requirements, or otherwise defaults on its obligations to us, we may not be able to obtain alternative co-formulation, fill, and finish services from other providers on acceptable terms in a timely manner or at all, which could prevent or delay delivery of customer orders, or otherwise negatively affect our business. Certain of our facilities are also contracted for defined time frames and through association with USG and CEPI, and we may not be able to access those facilities for sufficient periods of time to provide adequate supply.

We are responsible for confirming that each of our clinical trials is conducted in accordance with its general investigational plan and protocol. Moreover, the 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 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.

The results from the Prepare trial, including that ResVax failed to meet the primary endpoint of the trial, will likely create challenges, some of which may be significant, around further development of that vaccine.

While the Prepare results suggest that ResVax, the project name for the RSV vaccine candidate, is safe and is likely efficacious in more serious manifestations of RSV disease, the trial failed to achieve its primary clinical endpoint. Not achieving the primary clinical endpoint has been viewed negatively by our investors. Although the failure to achieve the primary endpoint in the trial is not evidence that the vaccine is ineffective, it means that regulatory agencies like the FDA and European Medicines Agency ("EMA") are likely to require additional clinical trial data prior to licensure. This development may be viewed negatively by our potential collaborators and partners, which may make future development of ResVax, and our other RSV F Vaccine candidates, more challenging.

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 trials, and for commercialization of NVX-CoV2373. However, we may not be able to obtain additional insurance coverage or maintain insurance coverage on commercially reasonable terms, at a reasonable cost or in sufficient amounts to protect us against losses due to liability. Furthermore, such insurance coverage and our resources may not be sufficient to satisfy all liabilities that result from product liability claims. A successful claim may prevent us from obtaining adequate product liability insurance in the future on commercially desirable terms, if at all. Even if a claim is not successful, defending such a claim would be time- consuming and expensive, may damage our reputation in the marketplace and would likely divert management's attention.

In addition, because we are developing NVX-CoV2373 in response to the outbreak of COVID-19, a global pandemic, we have received provisional registration, conditional marketing authorization or emergency use authorization from the World Health Organization and in the U.S., Canada, Australia, New Zealand, the E.U., the United Kingdom, India, Indonesia, the Philippines, and Singapore, as well as full authorization in South Korea, 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 other jurisdictions as well. Unexpected safety issues in these circumstances could lead to product liability claims and our existing insurance may not be adequate for such claims.

Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for our products;
- withdrawal of regulatory authorizations and approvals;
- voluntary or mandatory recalls of our products;
- necessity for additional nonclinical or clinical studies, changes in labeling, or changes to manufacturing processes, specifications and/or facilities;
- impairment of our business reputation and negative media attention;
- withdrawal of clinical trial participants;
- costs of related litigation;
- substantial monetary awards to participants or other claimants;
- loss of revenue; and
- inability to commercialize our vaccine candidates.

In the U.S., the PREP Act, when applicable, provides immunity for manufacturers from all claims under state or federal law for "loss" arising out of the administration or use of a "covered countermeasure." However, injured persons may still bring a suit for "willful misconduct" against the manufacturer under some circumstances. "Covered countermeasures" include security countermeasures and "qualified pandemic or epidemic products", including products intended to diagnose or treat pandemic or epidemic disease, such as pandemic vaccines, as well as treatments intended to address conditions caused by such products. For these immunities to apply, the Secretary of DHHS must invoke the PREP Act by issuing a declaration that a public health emergency or "credible risk" of a future public health emergency exists. Such a PREP Act declaration is separate from other declarations such as a PHE or EUA declaration and, among other things, defines the scope and duration of the PREP Act immunities. On March 17, 2020, the Secretary of DHHS issued a declaration under the PREP Act and has issued subsequent amendments thereto to provide liability immunity for activities related to certain countermeasures against the ongoing COVID-19 pandemic. The current declaration will end on October 1, 2024, 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 HHS 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 vaccines in sufficient quantities, at sufficient yields or are unable to obtain regulatory approvals for a manufacturing facility for our vaccines, 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 NVX-CoV2373, which is currently our only commercial product and source of product revenues. Completion of our clinical trials and commercialization of NVX-CoV2373 and our other vaccine candidates requires access to, or development of, facilities to effectively manufacture NVX-CoV2373 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 NVX-CoV2373, our efforts to establish and maintain manufacturing capabilities may not meet expectations as to timing, scale-up, reproducibility, yields, purity, cost, potency or quality. For example, we experienced delays in early 2023 in manufacturing our BA.5 clinical trial materials, which has the potential to delay regulatory approval from the FDA for our vaccine candidate for the fall 2023 COVID vaccine season. 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 NVX-CoV2373 and we have entered into third-party agreements for the components, as well as for commercial fill-finish manufacturing, for NVX-CoV2373. The antigen component of NVX-CoV2373 is currently being manufactured at Novavax CZ, as well as partnered manufacturing sites, including SIIPL in India and SK bioscience in Korea, and the Matrix-M™ adjuvant component of NVX-CoV2373 is currently being manufactured at Novavax AB, as well as other partnered manufacturing sites, including AGC Biologics in Europe. Challenges in manufacturing either the antigen component or the adjuvant, or issues in later manufacturing stages, could compromise production of NVX-CoV2373. Additionally, we currently depend exclusively on SIIPL and SLS for co-formulation, filling, and finishing NVX-CoV2373 and the loss of this supplier 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 NVX-CoV2373 could be negatively affected by many factors, including challenges in managing our commercial strategy, unanticipated changes in general market conditions or regulatory matters, and market demand for variant-specific COVID-19 vaccines, among others. If we underestimate our third-party manufacturing requirements, we may not be able to timely meet obligations under our customer supply agreements. Conversely, if we overestimate our third-party manufacturing requirements, we may end up with inventory levels in excess of customer demand that result in a portion of our inventory becoming obsolete or expiring, as well as inventory write-downs or write-offs, or we may need to cancel previously forecasted batches of product from our third-party manufacturers, which may result in material cancellation fees. In September 2022, for example, we entered into a Confidential Settlement Agreement and Release with FUJIFILM under which we are responsible for up to $185 million to FUJIFILM in connection with the termination of manufacturing activity. Additionally, in December 2022, we agreed to approximately $95 million in fees owed to AGC Biologics in connection with the cancellation of batches in 2022. If we are unable to accurately forecast demand for NVX-CoV2373 and the required services from third-party manufacturers, our results of operations could be materially harmed.

Manufacturing NVX-CoV2373 and our other vaccine candidates involves a complicated process with which we have limited experience. If we and our third-party manufacturers are unable to manufacture NVX-CoV2373 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 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 vaccines are in competition with other products for access to these third-party facilities and may be subject to delays in manufacture if third parties prioritize other products. We may not be able to enter into any necessary additional third-party manufacturing arrangements on acceptable terms, or on a timely basis. In addition, we have to enter into technical transfer agreements and share our know-how with the third-party manufacturers, which can be time-consuming and may result in delays.

Because of contractual restraints and the limited number of third-party manufacturers with the expertise, required regulatory approvals and facilities to manufacture bulk vaccines at commercial-scale, replacement of a manufacturer may be expensive and time-consuming and may cause interruptions in the production of our vaccine and negatively impact our ability to timely meet obligations under our customer supply agreements. We and our third-party manufacturers may also encounter production challenges related to:

- costs, scale up, and yields;
- shortages of raw materials and supplies;
- shipment delays or other supply chain disruptions
- quality control and assurance;
- contamination, lot consistency, potency, and purity;
- shortages of qualified personnel and other capacity constraints;
- compliance with strictly enforced and evolving federal, state and foreign regulations that vary in each country where products might be sold including nationalization or other territory restrictions placed on our owned and third-party manufacturing sites; and
- capital funding.

Delays or interruptions could have a material adverse effect on our business, financial condition, results of operations and cash flows.

We must identify vaccines for development with our technologies and establish successful third-party relationships.

The near and long-term viability of our vaccine candidates depend in part on our ability to successfully establish new strategic collaborations with pharmaceutical and biotechnology companies, non-profit organizations and government agencies. Establishing strategic collaborations and obtaining government funding is difficult and time-consuming. Potential collaborators may reject collaborations based upon their assessment of our financial, regulatory or intellectual property position or based on their internal pipelines; government agencies may reject contract or grant applications based on their assessment of public need, the public interest, our products' ability to address these areas, or other reasons beyond our expectations or control. Collaborators also may seek to modify or terminate relationships. Past success in establishing strategic collaborations with pharmaceutical and biotechnology companies, non-profit organizations and government agencies in the past is no guarantee of future success in entering into new relationships or in performing under existing relationships. If we fail to establish a sufficient number of collaborations or government relationships on acceptable terms, or fail to perform under collaborations or relationships to the satisfaction of counter-parties, we may not be able to commercialize our vaccine candidates or generate sufficient revenue to fund further research and development efforts.

The collaborations we have established or may establish may not result in the successful development or commercialization of any vaccine candidates for several reasons, including the fact that:

- we may not have the ability to control the activities of our partners and cannot provide assurance that they will fulfill their obligations to us, including with respect to the license, development and commercialization of vaccine candidates, in a timely manner or at all;
- such partners may not devote sufficient resources to our 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 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 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 lack of sales, marketing and distribution capabilities, significantly delay the commercialization of our vaccine candidates.

We are highly dependent on the commercial success of NVX-CoV2373, and even though we have received provisional registration, conditional marketing authorization or emergency use authorization in certain jurisdictions for NVX-CoV2373, and even if we have products licensed in additional markets, our vaccine products may not be initially or ever profitable.

We are highly dependent on the commercial success of NVX-CoV2373, which is currently our only commercial product and source of product revenues. Whether we make a profit from the sale of our vaccine products is dependent on a number of variables, including the costs we incur manufacturing, testing and releasing, packaging and shipping such vaccine product. Additionally, the CEPI funding agreement necessitates that we allocate a certain number of doses of NVX-CoV2373 to certain middle and lower income countries, and the Grant Agreement with the Bill and Melinda Gates Foundation necessitates that we commit to a specific amount of sales in certain specified middle and lower income countries, which may impact negatively our ability to generate profit. We cannot predict when, if at all, our approved vaccine products will be profitable to the Company, and, ultimately, we may never generate sufficient revenues from our products to reach or maintain profitability or sustain our anticipated levels of operations.

Even if we successfully commercialize any of our vaccine candidates, either alone or in collaboration, we face uncertainty with respect to pricing, third-party reimbursement and healthcare reform, all of which could be subject to change and could adversely affect any commercial success of our vaccine candidates.

Our ability to collect revenue from the commercial sale of our vaccines may depend on our ability, and that of any current or potential future collaboration partners or customers, to obtain and if obtained, maintain adequate levels of approval, coverage and reimbursement for such products from third-party payers such as:

- government health administration authorities such as the Advisory Committee for Immunization Practices of the Centers for Disease Control and Prevention;

- 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 prescribed product has not received appropriate clearances from the 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 pharmaceutical pricing or reimbursement rates for medical products, and while we have no current vaccines available for commercial sale other than subject to provisional registration, conditional marketing authorization or emergency use authorization in certain foreign jurisdictions, the impact of such reform could nevertheless adversely affect our business strategy, operations and financial results. For example, the Affordable Care Act ("ACA") contained several cost containment measures that could adversely affect our future revenue, including, for example, increased drug rebates under Medicaid for brand name prescription drugs, extension of Medicaid rebates to Medicaid managed care organizations, and extension of so-called 340B discounted pricing on pharmaceuticals sold to certain healthcare providers. Additional provisions of the healthcare reform laws that may negatively affect our future revenue and prospects for profitability include the assessment of an annual fee based on our proportionate share of sales of brand name prescription drugs to certain government programs, including Medicare and Medicaid. The ACA also established a Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 70% point-of-sale discounts off negotiated prices of applicable branded on drugs (including vaccines) to eligible beneficiaries during their coverage gap period (the so-called "donut hole"), as condition for the manufacturer's outpatient drugs to be covered under Medicare Part D. Other aspects of healthcare reform, such as expanded government enforcement authority and heightened standards that could increase compliance-related costs, could also affect our business.

Further, we face uncertainties because of occasional political, legislative, and administrative efforts to substantially modify or invalidate some or all of the provisions of the ACA. For example, in 2017, the Trump administration withheld the cost-sharing subsidies paid to ACA health insurance exchange plans serving low-income enrollees. The Tax Cut and Jobs Act ("TCJA") was also enacted at the end of 2017 and included provisions that affected healthcare insurance coverage and payment, such as the elimination of the tax penalty for individuals who do not maintain sufficient health insurance coverage beginning in 2019 (the so-called "individual mandate").

Through the American Rescue Plan Act of 2021, the Biden Administration increased subsidies for coverage purchased through ACA health insurance exchanges and extended eligibility for subsidies to higher income levels. On December 14, 2018, a U.S. District Court Judge in the Northern District of Texas ruled that the individual mandate is a critical and inseverable feature of the ACA, and therefore, because it was repealed as part of the TCJA, the remaining provisions of the ACA are invalid as well. On December 18, 2019, the U.S. Court of Appeals for the 5th Circuit ruled that the individual mandate was unconstitutional but remanded the case back to the District Court to determine whether the remaining provisions of the ACA are invalid as well. On March 2, 2020, the U.S. Supreme Court granted the petitions for writs of certiorari to review the case, and oral arguments were heard on November 10, 2020. On June 17, 2021, the U.S. Supreme Court dismissed the most recent judicial challenge to the ACA brought by several states without specifically ruling on the constitutionality of the ACA. Separately, President Biden issued an Executive Order to initiate a special enrollment period from February 15, 2021 through August 15, 2021 for purposes of obtaining health insurance coverage through the ACA marketplace. The Executive Order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA. On April 5, 2022, the Biden administration issued an Executive Order directing agencies "with responsibilities related to Americans' access to health coverage" to "review agency actions to identify ways to continue to expand the availability of affordable health coverage." It is also unclear how these and other healthcare reform measures of the Biden administration or other efforts, if any, to challenge, repeal or replace the ACA, will impact our business.

Other legislative changes have been proposed and adopted since the ACA was enacted. These changes include aggregate reductions to Medicare payments to providers of 2% per fiscal year pursuant to the Budget Control Act of 2011 and subsequent laws, which began in 2013 and, due to subsequent legislative amendments, will stay in effect through 2030 unless additional Congressional action is taken. In January 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several types of providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. New laws may result in additional reductions in Medicare and other healthcare funding, which may materially adversely affect customer demand and affordability for our products and, accordingly, the results of our financial operations. 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 USG, 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.

Even if we receive regulatory approvals for our vaccine candidates, including NVX-CoV2373, coverage and reimbursement may be subject to unique and changing regulatory policies. For example, under the ACA preventive care mandate, non-grandfathered group health plans and health insurance coverage offered in the individual or group market typically have at least one year before they must provide first-dollar coverage for a newly issued preventive care requirement or guideline. However, pursuant to the Coronavirus Aid, Relief, and Economic Security Act ("CARES Act"), non-grandfathered group health plans and health insurance coverage offered in the individual or group market must cover any qualifying coronavirus preventive service 15 business days after the United States Preventive Services Task Force, or Advisory Committee on Immunization Practices ("ACIP") designates such service as preventive. Further, third-party reimbursement for providers administering COVID-19 vaccines may affect market acceptance of NVX-CoV2373, if we receive regulatory approval. Currently, the CARES Act and its implementing regulations state that (i) providers that participate in the U.S. Centers for Disease Control and Prevention's COVID-19 Vaccination Program must administer a COVID-19 immunization regardless of an individual's ability to pay or health insurance coverage status, (ii) providers may not seek any reimbursement, including through balance billing, from an immunization recipient, (iii) coverage is required, without cost-sharing, for the administration of the immunization even if a third party, such as the federal government, pays for the cost of the immunization, and (iv) for the duration of the COVID-19 public health emergency (the "PHE"), private health insurance plans must cover COVID-19 immunizations and their administration even when provided by out-of-network providers. Even if we receive regulatory approvals for NVX-CoV2373, there is no guarantee that all payors will provide coverage and reimbursement for our product after the termination of the PHE, planned for May 11, 2023, nor can we guarantee that even if coverage is provided, the reimbursement amount will be high enough to allow us to establish or maintain pricing sufficient to realize a sufficient return on our investment. We cannot predict continued prevalence of COVID-19, whether herd immunity will be achieved (which would affect the need for future administration of COVID-19 vaccines), or whether NVX-CoV2373 will be effective against continuing mutations or variants of the SARS-CoV-2 virus.

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, the PHE expires, 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; starting 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.

We have limited marketing capabilities, and if we are unable to enter into collaborations with marketing partners or develop our own sales and marketing capability, we may not be successful in commercializing any approved products.

Although we have initiated commercialization of NVX-CoV2373, we currently have limited dedicated sales, marketing or distribution capabilities. As a result, we depend on collaborations with third parties that have established distribution systems and sales forces, including our collaboration with SIIPL, among others. To the extent that we enter into co-promotion or other licensing arrangements, 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 against emerging COVID-19 variants);
- the prevalence and severity of adverse side effects;
- whether our vaccines are differentiated from other vaccines;

- availability, relative cost and relative efficacy of alternative and competing treatments;
- the effectiveness of our marketing and distribution strategy;
- publicity concerning our products or competing products and treatments; and
- our ability to obtain sufficient third party insurance coverage or reimbursement.

If our vaccine candidates do not become widely accepted by physicians, patients, third-party payers and other members of the medical community as well as the relevant public health authorities responsible for scheduling immunizations, our business, financial condition and results of operations could be materially and adversely affected.

We may not be able to secure sufficient supplies of a key component of our adjuvant technology.

Because an important component of our adjuvant technology is extracted from a species of soap-bark tree (Quillaja saponaria) grown in Chile, we need long term access to quillaja extract with a consistent and sufficiently high quality. We need a secure supply of raw material, as well as back-up suppliers, or 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 SIIPL, 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 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. Recalls of any of our vaccine candidates would divert managerial and financial resources and have an adverse effect on our financial condition and results of operations. A recall announcement could harm our reputation with customers and negatively affect our sales, if any.

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., Johnson & Johnson, AstraZeneca, and Moderna, among others, compete in the vaccine market. In particular, these companies have greater experience and expertise in securing government contracts and grants to support their research and development efforts, conducting testing and clinical trials, obtaining regulatory approvals to market products, manufacturing such products on a broad scale and marketing approved products.

Regardless of the disease, smaller or early-stage companies and research institutions also may prove to be significant competitors, 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 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, influenza, and RSV 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 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. Many other companies, including AstraZeneca, Sinovac Biotech, and Sinopharm are in various stages of developing and obtaining marketing authorization for COVID-19 vaccine candidates. 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 satisfy a portion of the demand for initial vaccinations, and we no longer have access to that opportunity. In addition, COVID-19 vaccines approved prior to our vaccine may develop broad market acceptance that we are challenged to overcome. For example, in the U.S., the FDA granted a Biologics License Application ("BLA") in August 2021 to the Pfizer/BioNTech vaccine as a two-dose primary series for the prevention of COVID-19 in individuals 12 years of age and older, and in January 2022 to the Moderna vaccine as a two-dose primary series for the prevention of COVID-19 in individuals 18 years of age and older. The FDA amended the Pfizer-BioNTech emergency use authorization on September 22, 2021, and the Moderna emergency use authorization and Johnson & Johnson emergency use authorization on October 20, 2021, to authorize the use of a single booster dose for certain populations after completion of primary vaccination with any FDA-authorized or approved COVID-19 vaccine. The FDA then amended both of the Pfizer-BioNTech emergency use authorization and the Moderna emergency use authorization again on November 19, 2021, to authorize the use of such a single booster dose for all patients 18 years and older. The FDA has since amended the Pfizer-BioNTech emergency use authorization to authorize the use of the single booster dose for individuals 5 years and older and the Moderna emergency use authorization to authorize the use of the single booster dose for individuals 6 years and older and for individuals 6 months to 5 years who have received the primary Moderna vaccine series. The 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. 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 NVX-CoV2373, 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, and/or be less expensive or quicker to manufacture. Many competitors are working on new products and new generations of current products, intended to be more efficacious than those currently marketed. Our nanoparticle seasonal influenza vaccine candidate may not prove to be more efficacious than current products or 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.

We are also aware that there are multiple companies with active RSV vaccine programs at various stages of development. Thus, while there is no RSV vaccine currently on the market, there is likely to be significant and consistent competition as these active programs mature. Different RSV vaccines may work better for different segments of the population, so it may be difficult for a single RSV vaccine manufacturer to provide vaccines that are marketable to multiple population segments. Geographic markets are also likely to vary significantly, which may make it difficult to market a single RSV vaccine worldwide. Even if a manufacturer brings an RSV vaccine to license, it is likely that competitors will continue to work on new products that could be more efficacious and/or less expensive. Even if our RSV vaccine candidate is developed in the future and receives regulatory approval, it may not achieve significant sales if other, more effective vaccines under development by our competitors are also approved.

Risks Related to Regulatory and Compliance Matters

We may not succeed in obtaining full 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 FDA and regulatory authorities in other jurisdictions, including the EMA, the Czech Republic's State Institute for Drug Control (SUKL) with respect to our manufacturing facility in the Czech Republic and the Swedish Medical Products Agency (Läkemedelsverket, LV) with respect to our adjuvant product being developed in Sweden, as well as other country authorities into which active pharmaceutical ingredients and excipients are imported and/or manufactured by us or our sub-contracted manufacturers. In the U.S. and most foreign countries, we must complete rigorous preclinical testing and extensive clinical trials that demonstrate the safety and efficacy of a product in order to apply for regulatory approval to market the product. Additionally, we must demonstrate that our manufacturing facilities, processes and controls are adequate with respect to such product to assure safety, purity and potency and comply with applicable good manufacturing practice requirements. None of our vaccine candidates has yet gained full regulatory approval in the U.S., although NVX-CoV2373 has received provisional registration, conditional marketing authorization or emergency use authorization in the U.S., Canada, Australia, New Zealand, the E.U., the United Kingdom, India, Indonesia, the Philippines, and Singapore, and South Korea as well as EUL from the World Health Organization. We also have vaccine candidates in clinical trials and preclinical laboratory or animal studies.

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 FDA before our proposed investigational products may be marketed in the U.S. include:

- performance of preclinical (animal and laboratory) tests;
- submission to the 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 FDA inspection;

- submission to the FDA of a BLA or a NDA; and

- 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. 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 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 products on a timely basis or comply with our continuing regulatory obligations after approval is obtained.

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, certain of our APAs and supply agreements may be terminated by the counterparty if we do not timely achieve requisite regulatory approval for NVX-CoV2373 in the relevant jurisdictions under such agreements. 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 approval during the period of product development.

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.

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 the European Union, United Kingdom, India, Asia and many other non-U.S. jurisdictions, 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 FDA approval. The foreign regulatory approval process may include all of the risks associated with obtaining FDA approval. Additionally, regulatory authorities outside the U.S. might not accept data from trials conducted in other countries. Although NVX-CoV2373 has received provisional registration, conditional marketing authorization or emergency use authorization in a number of jurisdictions, we may not obtain regulatory approvals in other relevant jurisdictions on a timely basis, if at all. Approval by one regulatory agency does not ensure approval by regulatory agencies in other jurisdictions. However, a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in other jurisdictions, including approval by the FDA. The failure to obtain regulatory approval in foreign jurisdictions could harm our business.

The regulatory pathway for NVX-CoV2373 is continually evolving and may result in unexpected or unforeseen challenges.

The regulatory pathway for NVX-CoV2373 is evolving and failure by us to comply with any laws, rules and standards, some of which may not exist yet or are subject to interpretation and may be subject to change, could result in a variety of adverse consequences, including penalties, fines and delays in vaccine licensure. Efforts to comply with evolving laws, regulations and standards have resulted in, and are likely to continue to result in, increased general and administrative expenses and a diversion of management time and attention to regulatory compliance activities. For example, the rules, regulations and standards governing the USG Agreement are uncertain and may evolve as the program progresses. Such rules or standards may adversely affect our plans to develop NVX-CoV2373 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 FDA, the EMA, and the UK's Medicines and Healthcare Products Regulatory Agency ("MHRA") may make decisions more rapidly than is typical. Evolving or changing plans or priorities at the FDA or other regulatory bodies to whom we wish to apply for authorization, including based on new knowledge of COVID-19 and how the disease affects the human body, and new variants of the virus, may significantly affect the regulatory pathway for NVX-CoV2373. Results from clinical testing may raise new questions and require us to redesign proposed clinical trials, including revising proposed endpoints or adding new clinical trial sites or cohorts of subjects. In addition, the FDA's 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 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 NVX-CoV2373.

In addition, because the path to licensure of any vaccine against COVID-19 is unclear, we may have a widely used vaccine in circulation in certain countries as an investigational vaccine or a product authorized for temporary or emergency use prior to our receipt of full marketing approval. Unexpected safety issues in these circumstances could lead to significant reputational damage for Novavax 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 FDA for NVX-CoV2373, the 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 NVX-CoV2373 at sites outside the U.S. and the FDA may not accept data from trials conducted in such locations.

We have and are currently conducting several clinical trials of NVX-CoV2373 at sites outside the U.S., including a Phase 3 trial partially in Mexico, a Phase 3 trial in the U.K., a Phase 2b trial in South Africa, a Phase 1/2 trial partially in Australia, a Phase 2/3 trial in India, and a Phase 1/2 trial in Japan. Although the FDA may accept data from clinical trials conducted outside the U.S., acceptance of these data is subject to conditions imposed by the 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 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, 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 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 NVX-CoV2373.

The later discovery of previously unknown problems with a product, manufacturer or facility may result in restrictions, including withdrawal of a vaccine that had previously received regulatory approval in certain jurisdictions from the market.

Even after a product gains regulatory approval, the product and the manufacturer of the product will be subject to continuing regulatory review, including adverse event reporting requirements and prohibitions against promoting products for unapproved uses. Failure to comply with any post-approval requirements can, among other things, result in warning letters, product seizures, recalls, substantial fines, injunctions, suspensions or revocations of marketing authorizations or licenses, operating restrictions and criminal prosecutions. Any such enforcement actions, any unanticipated changes in existing regulatory requirements or the adoption of new requirements, or any safety issues that arise with any approved products, could adversely affect our ability to market products and generate revenue and thus adversely affect our ability to continue our business.

We also may be restricted or prohibited from marketing or manufacturing a product, even after obtaining product approval, if previously unknown problems with the product or its manufacture are subsequently discovered. We cannot provide assurance that newly discovered or developed safety issues will not arise following regulatory approval. With the use of any vaccine by a wide patient population, serious adverse events may occur from time to time that did not arise in the clinical trials of the product or that initially appeared to be unrelated to the vaccine itself and only with the collection of subsequent information were found to be causally related to the product. Any such safety issues could cause us to suspend or cease marketing of our approved products, possibly subject us to substantial liabilities, and adversely affect our ability to generate revenue and our financial condition.

Our ability to produce a successful vaccine may be curtailed by one or more government actions or interventions, which may be more likely during a global health crisis such as COVID-19.

Given the significant global impact of the COVID-19 pandemic, it is possible that one or more government entities may take actions, including under the USG under the Defense Production Act of 1950, as amended, that directly or indirectly have the effect of diminishing some of our rights or opportunities with respect to NVX-CoV2373, and the economic value of a COVID-19 vaccine to us could be limited. In addition, during a global health crisis, such as the COVID-19 pandemic, where the spread of a disease needs to be controlled, closed or heavily regulated national borders create challenges and delays in our development, production and distribution activities and may necessitate that we pursue strategies to develop, produce and distribute our vaccine candidates within self-contained national or international borders or with additional safety measures or checks in place, at potentially much greater expense and with longer timeframes for public distribution.

Inadequate funding for the 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 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. For example, average review times at the FDA have fluctuated in recent years as a result. In addition, government funding of the SEC and other government agencies on which our operations may rely, including those that fund research and development activities, is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other agencies may also slow the time necessary for new drugs to be reviewed and approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, the USG has shut down several times and certain regulatory agencies, such as the FDA and the SEC, have had to furlough employees and stop or slow the pace of critical activities. Equally, the move of the EMA to the Netherlands from London caused a significant loss of experienced staff and the UK's MHRA's loss of funding from the E.U. has caused a loss of funding and consequently of staff. If a prolonged government shutdown or slowdown of the relevant regulatory authority occurs, it could significantly impact the ability of that 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 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 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 FDA granted Fast Track Designation for NVX-CoV2373 in November 2020 and for NanoFlu, our recombinant quadrivalent seasonal influenza vaccine candidate, in January 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 FDA procedures. In addition, the 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 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 FDA has granted such designation for NVX-CoV2373 and NanoFlu, it may not actually result in faster clinical development or regulatory review or approval. Furthermore, such a designation does not increase the likelihood that NVX-CoV2373 or NanoFlu will receive marketing approval in the U.S.

Because we are subject to environmental, health and safety laws, we may be unable to conduct our business in the most advantageous manner.

We are subject to various laws and regulations relating to safe working conditions, laboratory and manufacturing practices, the experimental use of animals, emissions and wastewater discharges, and the use and disposal of hazardous or potentially hazardous substances used in connection with our research, including infectious disease agents. We also cannot accurately predict the extent of regulations that might result from any future legislative or administrative action. Any of these laws or regulations could cause us to incur additional expense or restrict our operations.

Our facilities in Maryland are subject to various local, state and federal laws and regulations relating to safe working conditions, laboratory practices, the experimental use of animals and the use and disposal of hazardous or potentially hazardous substances, including chemicals, microorganisms and various hazardous compounds used in connection with our research and development activities. In the U.S., these laws include the Occupational Safety and Health Act, the Toxic Test Substances Control Act and the Resource Conservation and Recovery Act. Similar national and local regulations govern our facilities in Sweden and the Czech Republic. 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 U.K. Bribery Act of 2010, or the Bribery Act, prohibits both domestic and international bribery, as well as bribery across both private and public sectors. An organization that fails to prevent bribery by anyone associated with the organization can be charged under the Bribery Act unless the organization can establish the defense of having implemented adequate procedures to prevent bribery.

Similarly, U.S. and similar worldwide trade laws, including economic sanctions, export laws, and customs laws, regulate our ability to conduct business with certain jurisdictions and counterparties, and regulate the ways in which we may export and import products around the world. In connection with these laws, various government agencies may require us to obtain export licenses, and may impose modifications to business practices, including requiring the cessation of business activities in or with countries, entities, and individuals targeted with sanctions. The breadth and dynamic nature of these laws and regulations may increase compliance costs, and may subject us to fines.

Novavax has 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 560 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.

Failure to obtain trademark registrations for proposed product names/brands, in the U.S. or abroad, may adversely impact our business.

Trademark registration to protect the trademarks for our proposed products will require approval from the USPTO in the U.S. and in trademark offices throughout the world in our key markets. The USPTO or a trademark office in a key international jurisdiction may refuse registration of any of our trademarks on a variety of potential grounds. If registration is not granted to one of our trademarks in the U.S. or in another key international jurisdiction, we may be required to adopt an alternative name for that proposed product. If we adopt an alternative name, we would 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 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 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 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 takes 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 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 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, as well as external opportunities, which include the acquisition, partnering and in-licensing of products, technologies and companies or the entry into strategic alliances and collaborations. The availability of high quality opportunities is limited, and we may fail to identify candidates that we and our stockholders consider suitable or complete transactions on terms that prove advantageous. In order to pursue such opportunities, we may require significant additional financing, which may not be available to us on favorable terms, if at all. Even if we are able to successfully identify and complete acquisitions, like our business combinations with Novavax CZ (formerly Praha Vaccines) and Novavax AB, strategic transactions involve many risks, including, among others, those related to diversion of management's attention from other business concerns, unanticipated expenses and liabilities, and increased complexity of our operations, which could prevent us from effectively exploiting acquired facilities, successfully integrating the acquired business and personnel, or fully realizing expected synergies.

To effectively manage our current and future potential growth, we will need to continue to enhance our operational, financial and management processes and to effectively expand, train and manage our employee base. Supporting our growth initiatives will require significant expenditures and management resources, including investments in research and development, manufacturing in-house and through third-party manufacturers and other areas of our business. If we do not successfully manage our growth and do not successfully execute our growth initiatives, then our business and financial results may be adversely impacted, and we may incur asset impairment or restructuring charges.

Given our current cash position and cash flow forecast, and significant uncertainties related to 2023 revenue, funding from the U.S. government, and our pending arbitration with Gavi, substantial doubt exists regarding our ability to continue as a going concern through one year from the date that the financial statements included in this Annual Report were issued.

Our management must evaluate whether there are conditions or events, considered in the aggregate, that raise substantial doubt about our ability to continue as a going concern within one year after the date the financial statements are issued. At December 31, 2022, we had $1.3 billion in cash and cash equivalents and restricted cash, of which $236.2 million was raised in December 2022 through concurrent sales of our common stock and issuance of our convertible senior unsecured notes that will mature on December 15, 2027 (the "2027 Notes"). On January 31, 2023, the Company funded the outstanding principal amount of $325.0 million on our convertible senior unsecured notes that matured on February 1, 2023 (the "2023 Notes"). During 2022, we incurred a net loss of $657.9 million and had net cash flows used in operating activities of $415.9 million.

While our current cash flow forecast for the one-year going concern look forward period estimates that we have sufficient capital available to fund operations, this forecast is subject to significant uncertainty, including as it relates to the following:

- 2023 Revenue: Our 2023 revenue depends on our ability to successfully develop, manufacture, distribute, or market an updated monovalent or bivalent formulation of a vaccine candidate for COVID-19 for the fall 2023 COVID vaccine season, which is inherently uncertain and subject to a number of risks, including regulatory approvals. We experienced delays in early 2023 in manufacturing our BA.5 clinical trial materials, which has the potential to delay regulatory approval from the FDA for our vaccine candidate for the fall 2023 COVID vaccine season. In addition, in January 2023, VRBPAC announced its intent to provide the industry with its strain protocol guidance in the second quarter of 2023 for the fall 2023 COVID vaccine season. To meet potential demand for fall 2023, we intend to begin manufacturing an updated COVID-19 variant strain-containing formulation prior to the availability of strain protocol guidance. If we begin manufacturing a formulation that is not consistent with the strain protocol guidance, we will not be able to deliver the appropriate vaccine to our customers in sufficient quantities for the fall 2023 COVID vaccine season and we will have incurred significant costs for a formulation that we will be unable to sell.

- Funding from the U.S. Government: Our USG Agreement will expire by its terms in December 2023. We had anticipated that the U.S. government would extend the USG Agreement until the full $1.8 billion authorized amount had been realized. In February 2023, in connection with the execution of Modification 17 to the USG Agreement, the U.S. government indicated to us that the award may not be extended past its current period of performance. If the USG Agreement is not amended, as we had previously expected, then we may not receive all of the remaining $416 million in funding we had previously anticipated pursuant to the USG Agreement.

- Pending Arbitration: On January 24, 2023, Gavi filed a demand for arbitration with the International Court of Arbitration regarding an alleged material breach by us of the Gavi APA. The outcome of that arbitration is inherently uncertain, and it is possible we could be required to refund all or a portion of the remaining advance payments of $697.4 million. See Note 3 and Note 18 to our consolidated financial statements in Part II, Item 8, "Financial Statements and Supplementary Data," of this Annual Report on Form 10-K for additional information related to the arbitration with Gavi.

Management believes that, given the significance of these uncertainties, substantial doubt exists regarding our ability to continue as a going concern through one year from the date that these financial statements are issued.

Our ability to fund Company operations is dependent upon revenue related to vaccine sales for our products and product candidates, if such product candidates receive marketing approval and are successfully commercialized; the resolution of certain matters, including whether, when, and how the dispute with Gavi is resolved; and management's plans, which include resolving the dispute with Gavi and may include raising additional capital through a combination of equity and debt financing, collaborations, strategic alliances, and marketing, distribution, or licensing arrangements. New financings may not be available to us on commercially acceptable terms, or at all. Also, any collaborations, strategic alliances, and marketing, distribution, or licensing arrangements may require us to give up some or all of our rights to a product or technology, which in some cases may be at less than the full potential value of such rights. In addition, the regulatory and commercial success of NVX-CoV2373 and our other vaccine candidates, including an influenza vaccine candidate, CIC vaccine candidate, or a COVID-19 variant strain-containing monovalent or bivalent formulation, remains uncertain. If we are unable to obtain additional capital, we will assess our capital resources and may be required to delay, reduce the scope of, or eliminate some or all of our operations, or downsize our organization, any of which may have a material adverse effect on our business, financial condition, results of operations, and ability to operate as a going concern.

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 and personally identifiable information. The secure maintenance of this information is critical to our operations and business strategy. Some of this information represents an attractive target of criminal attack by malicious third parties with a wide range of motives and expertise, including nation-states, organized criminal groups, "hacktivists," patient groups, disgruntled current or former employees and others. Our ongoing operating activities also depend on functioning information technology systems. Cyber attacks are of ever-increasing levels of sophistication, 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. In 2020, several domestic and foreign security agencies announced that government actors or government-affiliated actors were specifically targeting organizations engaging in COVID-19 vaccine development and research. Our profile as a recipient of funding under the USG Agreement and our development of NVX-CoV2373 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, 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 to our data and systems, including malware and computer viruses. Additionally, we partner with sites that store our clinical trial data. Attacks could have a material impact on our business, operations or financial results. Any access, disclosure or other loss of information, whether stored by us or our partners, or other cyberattack causing disruption to our business, including ransomware, could result in reputational, business, and competitive harms, significant costs related to remediation and strengthening our cyber defenses, legal claims or proceedings, government investigations, liability including under laws that protect the privacy of personal information, and increased insurance premium, all of which could adversely affect our business. 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 to us 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, 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 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 U.K., 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 U.K.'s Data Protection Act 2018. 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 are exposed to substantial penalties or litigation related to violations of existing or future data privacy laws and regulations.

Furthermore, the GDPR and UK GDPR impose strict restrictions surrounding the transfer of personal data to countries outside the EEA and the U.K., including to the U.S. In 2016, the EU and U.S. agreed to a transfer framework for data transferred from the European Union to the U.S., called the EU-US Privacy Shield. On July 16, 2020, however, the Court of Justice of the European Union issued a decision that declared the Privacy Shield framework invalid and raised questions about whether the European Commission's Standard Contractual Clauses ("SCCs"), an alternative to the Privacy Shield, can lawfully be used for cross-border data transfers. On June 4, 2021, the European Commission adopted new SCCs under the GDPR for personal data transfers outside of the EEA. Under this legal mechanism, we may have obligations to conduct transfer impact assessments for such cross-border data transfers and implement additional security measures. As we incorporate the new SCCs into our contractual arrangements, we may be required to expend significant resources to update our contractual arrangements and to comply with the new obligations. 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.

Privacy laws and regulations are also expanding in the U.S. The CCPA, which became effective January 1, 2020, substantially expands privacy obligations of many businesses, requiring new disclosures to California consumers, imposing new rules for collecting or using information about minors and affording consumers new 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, which is expected to increase risks related to data breach litigation. The California Privacy Rights Act ("CPRA"), which will become operational in 2023, expands on the CCPA, creating new consumer rights and protections, including the right to correct personal information, the right to opt out of the use of personal information in automated decision making, the right to opt out of "sharing" consumer's personal information for cross-context behavioral advertising, and the right to restrict use of and disclosure of sensitive personal information, including geolocation data to third parties. Similar restrictions are also included in the Virginia Consumer Data Protection Act ("VCDPA") and the Colorado Privacy Act ("CPA"), the first comprehensive state privacy statutes to follow the CCPA. We will need to evaluate and potentially update our privacy program to seek to comply with the CPRA, VCDPA, CPA and other US privacy laws, and we expect to incur additional expense in our effort to comply.

There is also a likelihood that other states will follow California, Colorado and Virginia in enacting more comprehensive privacy laws. Such legislation, if enacted, may add additional complexity, variation in requirements, restrictions and potential legal risk, and may require additional investment of resources in compliance programs, impact strategies, reduce the availability of previously useful data and result in increased compliance costs and/or changes in business practices and policies.

Collaborations and contracts of our wholly owned subsidiaries Novavax AB and Novavax CZ, with regional partners, such as SIIPL, 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 and Czech Republic-based Novavax CZ are wholly owned subsidiaries of Novavax, Inc. We also have entered into a supply and license agreement with SIIPL, 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, 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.

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, 2022 through December 31, 2022, the closing sale price of our common stock has been as low as $8.86 per share and as high as $142.90 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 NVX-CoV2373, 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 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.

The outbreak of COVID-19 may materially and adversely affect our business and our financial results.

The COVID-19 pandemic continues to present substantial global economic and public health challenges, which may materially and adversely impact our business, financial condition and results of operations. In response to COVID-19, various aspects of our business operations have been, and could continue to be, disrupted. We have implemented our Ways of Working guidelines, which allow employees the flexibility to work remotely either full time or in a hybrid manner to provide employees with continued flexibility based on business needs. Working remotely could increase our cybersecurity risk, create data accessibility concerns, and make us more susceptible to communication disruptions, any of which could adversely impact our business operations. Travel restrictions and other governmental measures may also 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. Furthermore, while some jurisdictions have phased out restrictions imposed on commercial activities at varying degrees, a resurgence of COVID-19, coupled with a potential surge in variant strains of COVID-19, in certain geographies could result in restrictions being reinstated.

Our clinical trials, whether planned or ongoing, may be affected by the COVID-19 pandemic. Study procedures (particularly any procedures that may be deemed non-essential), site initiation, participant recruitment and enrollment, participant dosing, shipment of our product candidates, distribution of clinical trial materials, study monitoring, site inspections and data analysis may be paused or delayed due to changes in hospital or research institution policies, federal, state or local regulations, prioritization of hospital and other medical resources toward efforts to treat or prevent COVID-19, or other reasons related to the pandemic. In addition, there could be a potential effect of COVID-19 to the operations of the FDA or other health authorities, which could result in delays of reviews and approvals, including with respect to our product candidates. Any prolongation or de-prioritization of our clinical trials or delay in regulatory review resulting from such disruptions could materially affect the development and study of our product candidates.

The trading prices for our common stock and that of other biopharmaceutical companies have been highly volatile due to the COVID-19 pandemic, especially as a result of investor concerns and uncertainty related to the impact of the outbreak on the economies of countries worldwide. These broad market and industry fluctuations, as well as general economic, political and market conditions, may negatively impact the market price of shares of our common stock.

The COVID-19 pandemic continues to rapidly evolve. The extent to which the outbreak impacts our business, preclinical studies and clinical trials will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the ultimate geographic spread of the disease, the emergence of variant strains, the duration of the pandemic, travel restrictions and social distancing in the U.S. and other countries, business closures or business disruptions and the effectiveness of actions taken in the U.S. and other countries to contain and treat the disease.

The United Kingdom's withdrawal from the European Union could result in increased regulatory and legal complexity, which may make it more difficult for us to do business in the UK and/or Europe and impose additional challenges in securing regulatory approval of our product candidates in the UK and/or Europe.

The United Kingdom's exit from the European Union as of January 31, 2020, with a transitional period up to December 31, 2020, commonly referred to as "Brexit", has caused political and economic uncertainty, including in the regulatory framework applicable to our operations and vaccine candidates in the United Kingdom and the European Union, and this uncertainty may persist for years. Brexit could, among other outcomes, disrupt the free movement of goods, services and people between the United Kingdom and the European Union, and result in increased legal and regulatory complexities, as well as potential higher costs of conducting business in Europe. As one of the Brexit consequences, the EMA has relocated from the United Kingdom to the Netherlands. This has led to a significant reduction of the EMA workforce, which has resulted and could further result in significant disruption and delays in its administrative procedures, such as granting clinical trial authorization or opinions for marketing authorization, disruption of importation and export of active substance and other components of new drug formulations, and disruption of the supply chain for clinical trial product and final authorized formulations. As the European Union granted conditional marketing authorization for NVX-CoV2373 after January 1, 2021, it is not grandfathered in the UK. We therefore must seek to obtain a separate marketing authorization for Great Britain or "GB" (England, Scotland and Wales while the European Union conditional marketing authorization continues to be applicable in Northern Ireland), increasing our regulatory burden. The GB product license for Nuvaxovid™ was granted on February 3, 2022, following a rigorous review of the safety, quality and effectiveness of this vaccine by the UK Medicines and Healthcare products Regulatory Agency and expert advice from the UK's independent scientific advisory body, the Commission on Human Medicines.

On September 22, 2022, the Department for Business, Energy & Industry Strategy published the Retained EU law (Revocation and Reform) Bill 2022 (the "Bill") and introduced it to the UK Parliament. The Bill seeks to provide a domestic law basis for amending or revoking over 2,400 well-established retained EU laws that operate across 21 sectors of the UK economy, including those concerning the life sciences industry, by December 31, 2023. The Bill will add further uncertainty to the future of medicines regulation and the potential regulatory burden that may arise in the U.K.

The cumulative effects of the disruption to the regulatory framework may add considerably to the development lead time to marketing authorization and commercialization of products in the European Union and/or the United Kingdom. It is possible that there will be increased regulatory complexities, which can disrupt the timing of our clinical trials and regulatory approvals. In addition, changes in, and legal uncertainty with regard to, national and international laws and regulations may present difficulties for our clinical and regulatory strategy. Any delay in obtaining, or an inability to obtain, any marketing approvals, as a result of Brexit or otherwise, would prevent us from commercializing our product candidates in the United Kingdom and/or the European Union and restrict our ability to generate revenues and achieve and sustain profitability.

In addition, as a result of Brexit, other European countries may seek to conduct referenda with respect to their continuing membership with the European Union. Given these possibilities and others we may not anticipate, as well as the absence of comparable precedent, it is unclear what financial, regulatory and legal implications the withdrawal of the United Kingdom from the European Union will have, how such withdrawal will affect us, and the full extent to which our business could be adversely affected.

We are increasingly a target for public scrutiny, and our business may be impacted by unfavorable publicity.

Given that COVID-19 represents an unprecedented urgent public health crisis, that we are developing NVX-CoV2373 as a COVID-19 vaccine candidate, and that we have received significant funding from the U.S. and foreign governments and other sources to support the development and potential commercialization of NVX-CoV2373, 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 NVX-CoV2373. 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 NVX-CoV2373 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 2. PROPERTIES

As of December 31, 2022, we leased approximately 53,000 square feet of office space in Gaithersburg, Maryland that serves as our corporate headquarters, and approximately 170,000 square feet of office space in Gaithersburg, Maryland ("700QO") that we currently use for office space and intend to also 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, 2022, we lease and own approximately 369,000 square feet of office and other space in the U.S., including our corporate headquarters and 700QO, and approximately 242,000 square feet of office and other space 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

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"). On January 26, 2022, the Maryland Court entered an order designating David Truong, Nuggehalli Balmukund Nandkumar, and Jeffrey Gabbert as co-lead plaintiffs in the Sinnathurai Action. The co-lead plaintiffs filed a consolidated amended complaint on March 11, 2022, alleging that the defendants made certain purportedly false and misleading statements concerning the Company's ability to manufacture NVX-CoV2373 on a commercial scale and to secure the NVX-CoV2373's regulatory approval. The amended complaint defines the purported class as those stockholders who purchased the Company's securities between February 24, 2021 and October 19, 2021. On April 25, 2022, defendants filed a motion to dismiss the consolidated amended complaint. On December 12, 2022, the Maryland Court issued a ruling granting in part and denying in part defendants' motion to dismiss. The Maryland Court dismissed all claims against two individual defendants and claims based on certain public statements challenged in the consolidated amended complaint. The Maryland Court denied the motion to dismiss as to the remaining claims and defendants, and directed the Company and other remaining defendants to answer within fourteen days. On December 27, 2022, the Company filed its answer and affirmative defenses.

After the Sinnathurai Action was filed, seven 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. 8:22-cv-00024-TDC (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.* (the "Mesa Action"), and (vii) *Sean Acosta v. Stanley C. Erck, et al.* (the "Acosta 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 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.

On July 21, 2022, the Maryland Court issued a memorandum opinion and order remanding the Kirst Action to state court. On December 6, 2022, the parties to the Kirst Action filed a stipulated schedule pursuant to which the plaintiffs were expected to file an amended complaint on December 22, 2022, and either (i) the parties would file a stipulated stay of the Kirst Action or (ii) the defendants would file a motion to stay the case by January 23, 2023. 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 February 24, 2023, the Court entered an order staying the Kirst Action until a final judgment in the Second Consolidated Derivative Action. The Company takes no position on whether the broader stay entered by the Court in the Kirst Action is likely to be modified to align with the parties' stipulation.

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, the court entered an order granting the parties' request to set a briefing schedule in connection with a motion to stay that defendants intended to file. Pursuant to the order, defendants filed a motion to stay on January 18, 2023. The plaintiff filed his opposition on February 8, 2023. Defendants filed their reply on February 22, 2023. On February 28, 2023, the court granted Defendants' motion to 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. The financial impact of this claim, as well as the claims discussed above, is not estimable.

On February 26, 2021, a Company stockholder named Thomas Golubinski filed a derivative complaint against members of the Company's board of directors and members of senior management in the Delaware Court, captioned Thomas Golubinski v. Richard H. Douglas, et al., No. 2021-0172-JRS. The Company is deemed a nominal defendant. Golubinski challenged equity awards made in April 2020 and in June 2020 on the ground that they were "spring-loaded," that is, made at a time when such board members or members of senior management allegedly possessed undisclosed positive material information concerning the Company. The complaint asserted claims for breach of fiduciary duty, waste, and unjust enrichment. The plaintiff sought an award of damages to the Company, an order rescinding both awards or requiring disgorgement, and an award of attorneys' fees incurred in connection with the litigation. On May 10, 2021, the defendants moved to dismiss the complaint in its entirety. On June 17, 2021, the Company's stockholders voted FOR ratification of the April 2020 awards and ratification of the June 2020 awards. Details of the ratification proposals are set forth in the Company's Definitive Proxy Statement filed on May 3, 2021. The results of the vote were disclosed in the Company's Current Report on Form 8-K filed on June 24, 2021. Thereafter, the plaintiff stipulated that, as a result of the outcome of the June 17, 2021 vote, the plaintiff no longer intends to pursue the lawsuit or any claim arising from the April 2020 and June 2020 awards. On August 23, 2021, the plaintiff filed a motion seeking an award of attorneys' fees and expenses, to which the defendants filed an opposition. On October 18, 2022, the Delaware Court denied the plaintiff's fee application in its entirety. Under a prior Delaware Court order, the case was automatically dismissed with prejudice upon denial of the plaintiff's fee application. On November 14, 2022, Golubinski filed a Notice of Appeal in the Supreme Court of the State of Delaware. The plaintiff / appellant filed his opening appellate brief on December 30, 2022. The Company filed its responsive brief on January 30, 2023 and the appellant filed his reply brief on February 14, 2023.

On March 29, 2022, Par Sterile Products, LLC ("Par") submitted a demand for arbitration against the Company with the American Arbitration Association, alleging that the Company breached certain provisions of the Manufacturing and Services Agreement (the "Par MSA") that the Company entered into with Par in September 2020 to provide fill-finish manufacturing services for NVX-CoV2373. The matter is at a preliminary stage and therefore the potential loss is not reasonably estimable. The parties are engaged in discovery and arbitration is scheduled for July 2023. While the Company maintains that no breach of the Par MSA has occurred and intends to vigorously defend the matter, if the final resolution of the matter is adverse to the Company, it could have a material impact on the Company's financial position, results of operations, or cash flows.

On November 18, 2022, the Company delivered written notice to Gavi to terminate the Gavi APA based on Gavi's failure to procure the purchase of 350 million doses of NVX-CoV2373 from the Company as required by the Gavi APA. As of November 18, 2022, the Company had only received orders under the Gavi APA for approximately 2 million doses. On December 2, 2022, Gavi issued a written notice purporting to terminate the Gavi APA based on Gavi's contention that the Company repudiated the agreement and, therefore, materially breached the Gavi APA. Gavi also contends that, based on its purported termination of the Gavi APA, it is entitled to a refund of the Advance Payment Amount less any amounts that have been credited against the purchase price for binding orders placed by a buyer participating in the COVAX Facility. As of December 31, 2022, the remaining Gavi Advance Payment Amount of $697.4 million, pending resolution of the dispute with Gavi related to a return of the remaining Advance Payment Amount, was reclassified from Deferred revenue to Other current liabilities in the Company's consolidated balance sheet. On January 24, 2023, Gavi filed a demand for arbitration with the International Court of Arbitration based on the claims described above. The Company's response is currently due by March 2, 2023. Arbitration is inherently uncertain, and while we believe that we are entitled to retain the remaining Advance Payment Amount received from Gavi, it is possible that we could be required to refund all or a portion of the remaining Advance Payment Amount from Gavi.

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

Item 4. MINE SAFETY DISCLOSURES

Not applicable.

PART II

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 137 stockholders of record as of February 21, 2023, 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

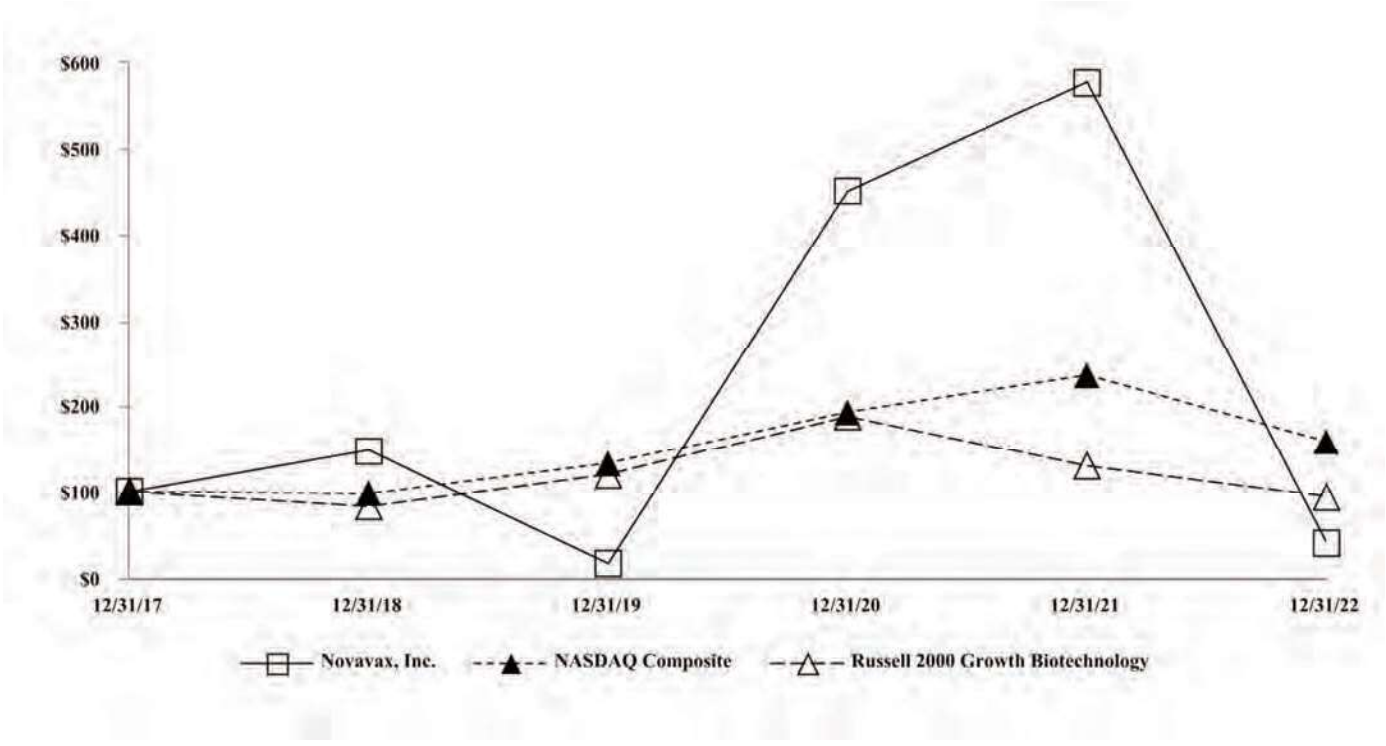
Information regarding our equity compensation plans, including both stockholder approved plans and non-stockholder approved plans, is included in Part III, Item 12 of this Annual Report on Form 10-K.

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, 2017 to December 31, 2022.

COMPARISON OF 5 YEAR CUMULATIVE RETURN*

Among Novavax Inc., the NASDAQ Composite index,
and the Russell2000 Growth Biotechnology Index



*$100 invested on 12/31/17 in stock or index, including reinvestment of dividends.
Fiscal year ending December 31.

Value of $100 invested on December 31, 2017 in stock or index, including reinvestment of dividends, for fiscal years ended:

	December 31,					
	2017	2018	2019	2020	2021	2022
Novavax, Inc.	$ 100	$ 148.39	$ 16.05	$ 449.64	$ 576.9	$ 41.45
NASDAQ Composite	$ 100	$ 97.16	$ 132.81	$ 192.47	$ 235.15	$ 158.65
Russell 2000 Growth Biotechnology	$ 100	$ 82.47	$ 120.36	$ 187.09	$ 130.2	$ 94.86

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 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, 2022; potential market sizes and demand for our product candidates; the efficacy, safety, and intended utilization of our 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 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 NVX-CoV2373 by us and our partners; our estimate of the number of individuals who may potentially be reached by NVX-CoV2373; our expectations with respect to the anticipated ongoing development and commercialization or licensure of NVX-CoV2373, ongoing development of COVID-19 variant strain-containing monovalent or bivalent formulation, efforts to expand the NVX-CoV2373 label worldwide as a booster, and to various age groups and geographic locations, and our seasonal quadrivalent influenza vaccine, previously known as NanoFlu; the expected timing, content, and outcomes of regulatory actions; funding from the U.S. government partnership formerly known as Operation Warp Speed under the USG Agreement, the U.S. Department of Defense ("DoD"), and CEPI; funding under our APAs and supply agreements and amendments to, termination of, 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; 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, challenges satisfying, alone or together with partners, various safety, efficacy, and product characterization requirements, including those related to process qualification and assay validation, necessary to satisfy applicable regulatory authorities, such as the FDA, the WHO, United Kingdom ("UK") Medicines and Healthcare Products Regulatory Agency, the European Medicines Agency, the Republic of Korea's Ministry of Food and Drug Safety, or Japan's Ministry of Health, Labour and Welfare; unanticipated challenges or delays in conducting clinical trials; difficulty obtaining scarce raw materials and supplies; resource constraints, including human capital and manufacturing capacity, constraints on the ability of Novavax to pursue planned regulatory pathways, alone or with partners, in multiple jurisdictions simultaneously, leading to staggering of regulatory filings, and potential regulatory actions; challenges meeting contractual requirements under agreements with multiple commercial, governmental, and other entities; 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 and at 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 NVX-CoV2373 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 biotechnology company that promotes improved health globally through the discovery, development, and commercialization of innovative vaccines to prevent serious infectious diseases. Our proprietary recombinant technology platform harnesses the power and speed of genetic engineering to efficiently produce highly immunogenic nanoparticle vaccines designed to address urgent global health needs.

Our vaccine candidates are genetically engineered nanostructures of conformationally correct recombinant proteins that mimic those found on natural pathogens. This technology enables the immune system to recognize the right target proteins from different angles and develop protective antibodies. We believe that our vaccine technology may lead to the induction of a differentiated immune response that may be more efficacious than naturally occurring immunity or other vaccine approaches. Our vaccine candidates also incorporate our proprietary saponin-based Matrix-M™ adjuvant to enhance the immune response and stimulate higher levels of functional antibodies and induce a cellular immune response.

We have developed a COVID-19 vaccine NVX-CoV2373 ("Nuvaxovid™," "Covovax™," "Novavax COVID-19 Vaccine, Adjuvanted") and are developing an influenza vaccine candidate, a COVID-19-Influenza Combination ("CIC") vaccine candidate, and additional vaccine candidates, including a COVID-19 variant strain-containing monovalent or bivalent formulation. NVX-CoV2373 has received approval, interim authorization, provisional approval, conditional marketing authorization ("CMA"), and emergency use authorization ("EUA") from multiple regulatory authorities globally for both adult and adolescent populations as a primary series and for both homologous and heterologous booster indications. In addition to COVID-19 and seasonal influenza, our other areas of focus include respiratory syncytial virus ("RSV") and malaria.

Business Highlights

Fourth Quarter 2022 and Recent Highlights

COVID-19 Vaccine Orders and Plans for the 2023 Fall Vaccination Season

- Delivered over 100 million doses of Nuvaxovid, Novavax's COVID-19 vaccine, globally to date
- Modified agreement with the U.S. government for up to 1.5 million additional doses of Novavax's COVID-19 vaccine for delivery in 2023
    - Agreement maintains the U.S. public's access to Novavax's COVID-19 vaccine and supports the development of smaller dose vials, strain selection in line with U.S. Food and Drug Administration (FDA) recommendations and a smooth transition to the commercial market
- Reaffirmed intent to deliver an updated mono- or bivalent strain vaccine for the 2023 fall vaccination season, consistent with public health recommendations
- Secured European Medicines Agency (EMA) and FDA approval of Nuvaxovid five-dose vial variation and EMA approval of the Company's Czech Republic facility to manufacture antigen and supply Nuvaxovid to the E.U.

COVID-19 Vaccine Clinical Development Program and Expanded Authorizations

- Presented data to the U.S. FDA Vaccine and Related Biological Products Advisory Committee demonstrating that when used as a booster, Novavax's COVID-19 vaccine induces broad functional immune responses, including for contemporary variants
- Announced topline results from Phase 3 COVID-19 Omicron BA.1 vaccine candidate, achieving the primary strain-change endpoint
    - Part 2 to evaluate our prototype vaccine compared to an Omicron BA.5 vaccine, as well as a bivalent containing prototype and Omicron BA.5 vaccine
- Expanded Nuvaxovid label in adult booster and adolescent primary series to enable broader uptake in the long-term commercial market

COVID-19-Influenza Combination (CIC) Vaccine Candidate Clinical Development

- Initiated Phase 2 dose-confirming trial to evaluate safety and immunogenicity of different formulations of CIC and influenza stand-alone vaccine candidates in adults aged 50 to 80 years, with topline results expected by mid-year 2023
- CIC Phase 2 trial includes additional study arms exploring alternate influenza stand-alone formulations

Financing Transactions

In December 2022, we completed a public offering of 7,475,000 shares of our common stock, including 975,000 shares of common stock that were issued upon the exercise in full of the option to purchase additional shares granted to the underwriters, at a price of $10.00 per share, resulting in net proceeds of $69.8 million. Concurrently with this public offering, we issued $175.3 million aggregate principal amount of 5.00% convertible senior unsecured notes due 2027 (the "2027 Notes"), including $25.3 million that was issued upon the exercise of the full option to purchase additional notes in a private placement to qualified institutional buyers pursuant to Rule 144A under the Securities Act of 1933, as amended. The 2027 Notes will mature on December 15, 2027, unless earlier converted, redeemed, or repurchased. We received $166.4 million in net proceeds from the issuance of the 2027 Notes after deducting the initial purchasers' fees and our offering expenses. See Note 11 to our consolidated financial statements in Part II, Item 8, "Financial Statements and Supplementary Data," of this Annual Report on Form 10-K for additional information related to the 2027 Notes.

In June 2021, we entered into an At Market Issuance Sales Agreement (the "June 2021 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. As of December 31, 2022, the remaining balance under the June 2021 Sales Agreement was approximately $318 million. During the years ended December 31, 2022 and 2021, we sold 2.2 million and 2.6 million, respectively, of shares of our common stock resulting in net proceeds of approximately $179 million and $565 million, respectively, under our various At Market Issuance Sales Agreements.

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 grant revenue, lease accounting, pre-launch inventory, inventory valuation, 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.

Grant Revenue Recognition

Our grant revenue primarily consists of funding under U.S. government contracts including the USG Agreement and the DoD Contract and was $382.9 million in 2022. We measure progress toward satisfaction of our grant performance obligations using an Estimate-at-Completion ("EAC") process, which is a cost-based input method that reviews and monitors the progress towards the completion of our performance obligation. 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 allowable 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, if significant, may impact the timing of revenue and fee recognition on our contracts. For our cost-reimbursable-plus-fixed-fee contracts, we recognize 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. Changes in estimates related to the EAC process are recognized in the period when such changes are made on a cumulative catch-up basis. We have not experienced any material difference as a result of change in estimate arising from the EAC process.

Lease Accounting

We enter into manufacturing supply agreements with CMOs and contract development and manufacturing organizations ("CDMOs") to manufacture our vaccine candidates. Certain of these manufacturing supply agreements include the use of identified manufacturing facilities and equipment that are controlled by us and for which we obtain substantially all the output and may qualify as an embedded lease. The evaluation of leases that are embedded in our 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, which generally is the use of a portion of the manufacturing facility; whether we have the right to direct the use of, and obtain substantially all of the benefit from, the identified asset; the term of the lease; and the fixed lease payments under the contract. Determining the lease commencement date may require judgment because the lease commencement date may be different than the inception date of the contract. We determine the non-cancellable lease term of our embedded leases based on the impact of certain expected milestones on our option to terminate the lease where we are reasonably certain to not exercise that option. For leases that have a lease term of more than 12 months at the lease commencement date, we recognize lease liabilities and corresponding right-of-use ("ROU") assets based on the present value of the fixed future payments over the lease term. We calculate the present value of future payments using the discount rate implicit in the lease, if available, or our incremental borrowing rate. In determining the lease period, we evaluate facts and circumstances that could affect the period over which we are reasonably certain to use the underlying asset while taking into consideration the non-cancelable period over which we have the right to use the underlying asset and any option period to extend or terminate the lease if we are reasonably certain to exercise the option. We use significant assumptions and judgment in evaluating our 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, and the term of embedded leases in our manufacturing supply agreements. As of December 31, 2022, we had total noncurrent ROU assets of $106.2 million, current lease liabilities of $44.1 million, and noncurrent lease liabilities of $81.3 million.

Pre-Launch Inventory

We capitalize raw materials and production costs as inventory when we determine that commercialization of a product is probable and have a present right to the economic benefit associated with the product. Our estimate of when commercialization is probable is based primarily on our experience with obtaining regulatory approval of comparable products. We began to capitalize inventory in 2022 and, as of December 31, 2022, we had approximately $30.6 million of commercial inventory that was expensed prior to approval.

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. We began to capitalize inventory in 2022. Subsequently, we recorded inventory write-downs of $447.6 million and losses on firm purchase commitments of inventory of $155.9 million to the extent the cost cannot be recovered based on estimates about future demand.

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 CMOs and 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 2022 and 2021

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, 2021, compared to the year ended December 31, 2020, 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, 2021.

Revenue

	2022	2021	Change
Revenue (in thousands):			
Product sales	$ 1,554,961	$ —	$ 1,554,961
Grants	382,921	948,709	(565,788)
Royalties and other	43,990	197,581	(153,591)
Total revenue	$ 1,981,872	$ 1,146,290	$ 835,582

Product sales

Product sales for 2022 were $1.6 billion as compared to no product sales for 2021. Product sales for 2022 related to revenue from commercial sales of NVX-CoV2373, which commenced in 2022. The geographic distribution of product sales in 2022 was as follows:

	2022
North America	$ 194,480
Europe	823,542
Rest of the world	536,939
Total product revenue	$ 1,554,961

Grants

We recognized grant revenue as follows:

	2022	2021	Change
Grant Revenue (in thousands)			
USG Agreement	$ 380,996	$ 788,953	$ (407,957)
U.S. DoD	1,925	21,683	(19,758)
CEPI	—	135,445	(135,445)
Other grant revenue	—	2,628	(2,628)
Total grant revenue	$ 382,921	$ 948,709	$ (565,788)

Grant revenue for 2022 was $382.9 million compared to $948.7 million for 2021, a decrease of $565.8 million. Grant revenue for 2022 primarily comprised revenue for services performed under the USG Agreement and grant revenue for 2021 primarily comprised revenue for services performed under the USG Agreement and the CEPI funding agreement. The decrease in revenue was primarily due to decreased development activities under the USG Agreement and our funding agreement with CEPI.

Royalties and Other

Royalties and other revenue for 2022 was $44.0 million as compared to $197.6 million for 2021, a decrease of $153.6 million. Royalties and other revenue primarily related to royalties under our licensing arrangements, and the decrease in revenue was due to lower sales-based royalties from our license partners.

Expenses:

	2022	2021	Change
Expenses (in thousands):			
Cost of sales	$ 902,639	$ —	$ 902,639
Research and development	1,235,278	2,534,508	(1,299,230)
Selling, general, and administrative	488,691	298,358	190,333
Total expenses	$ 2,626,608	$ 2,832,866	$ (206,258)

Cost of Sales

Cost of sales was $902.6 million, or 58% of product sales, for 2022, including expense of $603.5 million related to excess or obsolete inventory and losses on firm purchase commitments. Prior to receiving regulatory approval, we expensed manufacturing costs as research and development expenses. After receiving regulatory approval, we capitalize the costs of production for a particular supply chain when we determine that we have a present right to the economic benefit associated with the product. While we tracked the quantities of our manufactured vaccine product and components, we did not track pre-approval manufacturing costs and therefore the manufacturing cost of our pre-launch inventory produced prior to approval is not reasonably determinable. However, based on our expectations for future manufacturing costs to produce our vaccine product and components inventory, we estimate at December 31, 2022 we had approximately $30.6 million of commercial inventory that was expensed prior to approval. We expect to utilize the majority of our reduced-cost inventory through 2023. If inventory and pre-launch inventory sold in 2022 was valued at expected standard cost, including expenses related to excess and obsolete inventory and losses on firm purchase commitments, adjusted cost of sales for the period would have been approximately $1,067.4 million, or 69% of product sales, an adjustment of $164.8 million as compared to cost of sales recognized. The cost of sales as a percentage of product sales may fluctuate in the future as a result of changes to our customer pricing mix or standard costs.

Research and Development Expenses

Research and development expenses decreased to approximately $1.2 billion for 2022 as compared to $2.5 billion for 2021, a decrease of $1.3 billion. The decrease was primarily due to a decrease in development activities relating to coronavirus vaccines, including NVX-CoV2373, an Omicron BA.1 vaccine candidate, bivalent formulations, and CIC, as summarized in the table below (in thousands):

	2022	2021
Research and Development Expenses (in thousands):		
Coronavirus vaccines	$ 848,042	$ 2,245,935
Influenza vaccine	7,163	7,761
Other vaccine development programs	2,658	818
Total direct external research and development expense	857,863	2,254,514
Employee expenses	180,168	130,576
Stock-based compensation expense	66,565	86,928
Facility expenses	60,428	26,100
Other expenses	70,254	36,390
Total research and development expenses	$ 1,235,278	$ 2,534,508

Research and development expenses for coronavirus vaccines for 2022 and 2021 included a benefit of $201.4 million, inclusive of a $98.3 million benefit pursuant to the Fujifilm Settlement Agreement (see Note 4 to our consolidated financial statements in Part II, Item 8, "Financial Statements and Supplementary Data," of this Annual Report on Form 10-K), and an expense of $239.2 million, respectively, related to previously accelerated manufacturing costs for leases that we determined were embedded in multiple 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 2023, we expect research and development expenses to decrease as compared to 2022 as we continue to assess our manufacturing needs and modify our global manufacturing footprint consistent with our contractual obligations to supply, and anticipated demand for, NVX-CoV2373 and as additional manufacturing activities that were previously recognized as research and development expenses begin to meet the criteria for capitalization as inventory. We are gating funding for our potential Phase 3 research and development expenses related to our influenza and CIC vaccine candidates based on the assessment of our Phase 2 clinical trial results anticipated for mid 2023.

Selling, General, and Administrative Expenses

Selling, general, and administrative expenses increased to $488.7 million for 2022 from $298.4 million for 2021, an increase of $190.3 million. The increase in selling, general, and administrative expenses is primarily due to a $149.5 million increase in expenses related to the commencement of our commercial sales operations.

For 2023, our expected selling, general, and administrative expenses levels may vary depending on our ability to successfully develop, manufacture, distribute, or market an updated monovalent or bivalent formulation of a vaccine candidate for COVID-19 for the fall 2023 COVID vaccine season. Due to this uncertainty, we have announced our intention to reduce and control our operating spend to focus on key priorities and we will continue to evaluate our level of investment as the year progresses.

Other Expense, Net:

	2022	2021	Change
Other Expense, Net (in thousands):			
Interest expense	$ (19,880)	$ (21,127)	$ 1,247
Other income (expense)	10,969	(6,833)	17,802
Total other expense, net	$ (8,911)	$ (27,960)	$ 19,049

We had total net other expense of $8.9 million for 2022 compared to total net other expense of $28.0 million for 2021, a decrease of $19.0 million. During 2022 and 2021, other income (expense) was primarily related to foreign exchange rate activity.

Income Tax Expense:

During the years ended December 31, 2022 and 2021, we recognized $4.3 million and $29.2 million, respectively, of income tax expense related to federal and state income taxes and foreign withholding tax on royalties.

Net Loss:

	2022	2021	Change
Net Loss (in thousands, except per share information):			
Net loss	$ (657,939)	$ (1,743,751)	$ 1,085,812
Net loss per share, basic and diluted	$ (8.42)	$ (23.44)	$ 15.02
Weighted average shares outstanding, basic and diluted	78,183	74,400	3,783

Net loss for 2022 was $0.7 billion, or $8.42 per share, as compared to $1.7 billion, or $23.44 per share, for 2021, a decrease of $1.1 billion. The decrease in net loss was primarily due the commencement of commercial sales of NVX-CoV2373 in 2022 and a decrease in research and development expense, partially offset by the write-down of excess or obsolete inventory and losses on firm purchase commitments and decreased revenue under the USG Agreement.

The increase in weighted average shares outstanding for 2022 is primarily a result of sales of our common stock and common stock issued under our incentive programs.

Liquidity Matters and Capital Resources

Our future capital requirements depend on numerous factors including, but not limited to, revenue from our product sales and royalties under licensing arrangements with our strategic partners; funding and repayments under our grant agreements; our projected activities related to the development and commercial support of NVX-CoV2373 and variant 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 influenza vaccine candidate and potential combination vaccines candidates, which are in various stages of development.

We have entered into supply agreements, sometimes referred to as APAs, with the EC and various countries globally. We also have grant and license agreements. As of December 31, 2022, 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 $3 billion, which excludes amounts related to the Gavi APA and the reduction in doses related to the Amended and Restated UK Supply Agreement, as defined below. Failure to 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 payments or result in reduced future payments, which could adversely impact our ability to realize revenue from our unsatisfied performance obligations. The timing to fulfill performance obligations related to grant agreements will depend on the results of our research and development activities, including clinical trials, and delivery of doses. 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 the prototype NVX-CoV2373 vaccine under certain of our APAs. 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 NVX-CoV2373. Such upfront payments generally become non-refundable upon our achievement of certain development, regulatory, and commercial milestones.

In addition, we continue to assess our manufacturing needs and modify our global manufacturing footprint consistent with our contractual obligations to supply, and anticipated demand for, NVX-CoV2373, and, as a result, significant costs may be incurred. Pursuant to the Fujifilm Settlement Agreement (see Note 4 to our consolidated financial statements in Part II, Item 8, "Financial Statements and Supplementary Data," of this this Annual Report on Form 10-K), we are responsible for a Settlement Payment of up to $185.0 million to Fujifilm in connection with cancellation of manufacturing activity at FDBT under the Fujifilm CSA, of which $47.8 million, constituting the initial reservation fee under the Fujifilm CSA, was credited against the Settlement Payment on September 30, 2022.

We have an APA with the EC, acting on behalf of various European Union member states to supply a minimum of 20 million and up to 100 million initial doses of NVX-CoV2373, with the option for the EC to purchase an additional 100 million doses up to a maximum aggregate of 200 million doses in one or more tranches through 2023. In 2022, we were notified by the EC that it was cancelling approximately 7 million doses of its prior commitment originally scheduled for delivery in the first and second quarters of 2022, in accordance with the APA, and reducing the order to approximately 63 million doses. In January 2023, we finalized a revised delivery schedule for the remaining 20 million committed doses under the APA that were originally scheduled for delivery during the first and second quarters of 2022 and are expected to be delivered in 2023.

In July 2022, we entered into an Amended and Restated SARS-CoV-2 Vaccine Supply Agreement (as amended on September 26, 2022, the "Amended and Restated UK Supply Agreement") with 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"), which amended and restated in its entirety the SARS-CoV-2 Vaccine Supply Agreement, dated October 22, 2020, between the parties (the "Original UK Supply Agreement"). Under the Original UK Supply Agreement, the Authority agreed to purchase 60 million doses of NVX-CoV2373 and made an upfront payment to us. 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 NVX-CoV2373, with the number of Conditional Doses contingent on, and subject to reduction based on, our timely achievement of supportive recommendations from the Joint Committee on Vaccination and Immunisation (the "JCVI") that is approved by the UK Secretary of State for Health, with respect to use of the vaccine for (a) the general adult population as part of a SARS-CoV-2 vaccine booster campaign in the United Kingdom or (b) the general adolescent population as part of a SARS-CoV-2 vaccine booster campaign in the United Kingdom or as a primary series SARS-CoV-2 vaccination, excluding where that recommendation relates only to one or more population groups comprising less than one million members in the United Kingdom. If the Authority does not purchase the Conditional Doses or the number of such Conditional Doses is reduced below 15 million doses of NVX-CoV2373, we would have to repay up to $225.0 million related to the upfront payment previously received from the Authority under the Original UK Supply Agreement. Under the Amended and Restated UK Supply Agreement, the Authority also has 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 yet made a supportive recommendation with respect to NVX-CoV2373, thereby triggering, under the terms of the Amended and Restated UK Supply Agreement, (i) a reduction of the number of Conditional Doses from 15 million doses to 7.5 million doses, which reduced number of Conditional Doses are contingent on, and subject to further reduction based on, our timely achievement by November 30, 2023 of a supportive recommendation from JCVI that is approved by the UK Secretary of State for Health as described in the paragraph above, and (ii) an obligation for us to repay $112.5 million related to the upfront payment previously received from the Authority under the Original UK Supply Agreement, which is reflected in our consolidated balance sheet as Other current liabilities, with the remaining upfront payment balance of $112.5 million reflected in current Deferred revenue.

Under the terms of the Gavi APA, we received an upfront payment of $350.0 million from Gavi in 2021 and an additional payment of $350.0 million in the first quarter of 2022 related to our achieving EUL for NVX-CoV2373 by the WHO (the "Advance Payment Amount"). On November 18, 2022, we delivered written notice to Gavi to terminate the Gavi APA on the basis of Gavi's failure to procure the purchase of 350 million doses of NVX-CoV2373 from us as required by the Gavi APA. As of November 18, 2022, we had only received orders under the Gavi APA for approximately 2 million doses. On December 2, 2022, Gavi issued a written notice purporting to terminate the Gavi APA based on Gavi's contention that the Company repudiated the agreement and, therefore, materially breached the Gavi APA. Gavi also contends that, based on its purported termination of the Gavi APA, it is entitled to a refund of the Advance Payment Amount less any amounts that have been credited against the purchase price for binding orders placed by a buyer participating in the COVAX Facility. As of December 31, 2022, the remaining Gavi Advance Payment Amount of $697.4 million, pending resolution of the dispute with Gavi related to a return of the remaining Advance Payment Amount, was reclassified from Deferred revenue to Other current liabilities in our consolidated balance sheet. On January 24, 2023, Gavi filed a demand for arbitration with the International Court of Arbitration based on the claims described above. Our response is currently due by March 2, 2023. Arbitration is inherently uncertain, and while we believe that we are entitled to retain the remaining Advance Payment Amount received from Gavi, it is possible that we could be required to refund all or a portion of the remaining Advance Payment Amount from Gavi.

In July 2022, we entered into a modification to the USG Agreement that amended the terms of such agreement to provide for (i) an initial delivery to the U.S. government of approximately 3 million doses of NVX-CoV2373 and (ii) any additional manufacture and delivery to the U.S. government up to an aggregate of 100 million doses of NVX-CoV2373 contemplated by the original USG Agreement (inclusive of the initial batch of approximately 3 million doses) dependent on U.S. government demand, FDA guidance on strain selection, agreement between the parties on the price of such doses, and available funding. Additionally, in July 2022, we entered into a modification to our existing agreement with the DoD that amended the terms of such agreement to provide for the initial delivery of 0.2 million doses of NVX-CoV2373 after receipt of EUA approval from the FDA, with delivery of the remaining 9.8 million doses of NVX-CoV2373 contemplated by the original agreement subject to DoD demand and available funding. In February 2023, in connection with the execution of Modification 17 to the USG Agreement, the U.S. government indicated to us that the award may not be extended past its current period of performance. If the USG Agreement is not amended, as we had previously expected, then we may not receive all of the remaining $416 million in funding we had previously anticipated pursuant to the USG Agreement.

Our funding agreements currently include funding from CEPI in the form of one or more forgivable no interest term loans ("CEPI Forgivable Loan Funding"). Payments received under the CEPI Forgivable Loan Funding are only repayable if NVX-CoV2373 manufactured by the CMO network funded by CEPI is sold to one or more third parties (which would have previously included, but is not limited to, any sales under our Gavi APA prior to its termination), and such sales cover our costs of manufacturing such vaccine, not including manufacturing costs funded by CEPI. The timing and amount of any loan repayments is currently uncertain.

As of December 31, 2022, we had $1.3 billion in cash and cash equivalents and restricted cash as compared to $1.5 billion as of December 31, 2021. On January 31, 2023, we funded the outstanding principal amount of $325.0 million on the 2023 Notes, due February 1, 2023.

We funded our operations in 2022 with cash and cash equivalents, upfront payments under APAs, revenue from product sales, royalties under licensing arrangements with our strategic partners, and proceeds from the sale of common stock, together with revenue under the USG Agreement that support our NVX-CoV2373 vaccine development activities. We anticipate our future operations to be funded primarily by revenue from product sales, revenue under our USG Agreement, our cash and cash equivalents, and other potential funding sources.

The following table summarizes cash flows for 2022 and 2021:

	2022	2021	Change
Net cash (used in) provided by:			
Operating activities	$ (415,937)	$ 322,946	$ (738,883)
Investing activities	(92,985)	100,154	(193,139)
Financing activities	324,988	461,713	(136,725)
Effect on exchange rate on cash, cash equivalents, and restricted cash	4,520	(5,292)	9,812
Net increase in cash, cash equivalents, and restricted cash	(179,414)	879,521	(1,058,935)
Cash, cash equivalents, and restricted cash at beginning of year	1,528,259	648,738	879,521
Cash, cash equivalents, and restricted cash at end of year	$ 1,348,845	$ 1,528,259	$ (179,414)

Net cash used in operating activities was $415.9 million for 2022, as compared to cash provided by operating activities of $322.9 million in 2021. The decrease in cash from operating activities is primarily due to a decrease in upfront payments received under our APAs, timing of payments to vendors, and an increase in inventory production, partially offset by a reduction in our net loss.

Our investing activities primarily consisted of capital expenditures and, in 2021, $159.8 million in proceeds from maturities and sale of marketable securities, net of purchases. Capital expenditures for the years ended December 31, 2022 and 2021 were $89.1 million and $54.5 million, respectively.

Our financing activities consisted primarily of sales of our common stock, issuance of our 2027 Notes, payments of finance lease liabilities, and exercises of stock-based awards. In 2022, we received net proceeds of approximately $179 million and $70 million from the sale of shares of common stock through our At Market Issuance Sales Agreements and a public offering at $10.00 per share, respectively. In addition, we received net proceeds of $166.4 million during 2022 through the issuance of our 2027 Notes (see Note 11 to the accompanying consolidated financial statements). In 2021, we received net proceeds of approximately $565 million from the sale of shares of common stock through our At Market Issuance Sales Agreements.

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. At December 31, 2022, we had $1.3 billion in cash and cash equivalents and restricted cash, of which $236.2 million was raised in December 2022 through concurrent sales of our common stock and issuance of our 2027 Notes. On January 31, 2023, the Company funded the outstanding principal amount of $325.0 million on the 2023 Notes. During 2022, we incurred a net loss of $657.9 million and had net cash flows used in operating activities of $415.9 million.

While our current cash flow forecast for the one-year going concern look forward period estimates that we have sufficient capital available to fund operations, this forecast is subject to significant uncertainty, including as it relates to 2023 revenue, funding from the U.S. government, and pending arbitration. Our 2023 revenue depends on our ability to successfully develop, manufacture, distribute, or market an updated monovalent or bivalent formulation of a vaccine candidate for COVID-19 for the fall 2023 COVID vaccine season, which is inherently uncertain and subject to a number of risks, including regulatory approval. See "Risk Factors—Risks Related to Product Development and Commercialization—The emergence and transmissibility of variants of the SARS-CoV-2 virus, and the demand for bivalent vaccines, may affect market acceptance or sales of NVX-CoV2373, and our strategy to develop versions of our COVID-19 vaccine to protect against certain variants may not be successful." In February 2023, in connection with the execution of Modification 17 to the USG Agreement, the U.S. government indicated to us that the award may not be extended past its current period of performance, which may result in us not receiving all of the remaining $416 million in funding we had previously anticipated. See "Risk Factors—Risks Related to Our Financial Condition and Capital Requirements—Our existing funding and supply agreements do not assure success of our vaccine candidates or that we will be able to fully fund our vaccine candidates." On January 24, 2023, Gavi filed a demand for arbitration with the International Court of Arbitration regarding an alleged material breach by us of the Gavi APA. The outcome of that arbitration is inherently uncertain, and it is possible we could be required to refund all or a portion of the remaining Advance payment Amount of $697.4 million. See Note 3 and Note 18 to our consolidated financial statements in Part II, Item 8, "Financial Statements and Supplementary Data," of this Annual Report on Form 10-K for additional information related to the arbitration with Gavi. Management believes that, given the significance of these uncertainties, substantial doubt exists regarding our ability to continue as a going concern through one year from the date that these financial statements are issued.

Our ability to fund Company operations is dependent upon revenue related to vaccine sales for our products and product candidates, if such product candidates receive marketing approval and are successfully commercialized; the resolution of certain matters, including whether, when, and how the dispute with Gavi is resolved; and management's plans, which include resolving the dispute with Gavi and may include raising additional capital through a combination of equity and debt financing, collaborations, strategic alliances, and marketing, distribution, or licensing arrangements. New financings may not be available to us on commercially acceptable terms, or at all. Also, any collaborations, strategic alliances, and marketing, distribution, or licensing arrangements may require us to give up some or all of our rights to a product or technology, which in some cases may be at less than the full potential value of such rights. In addition, the regulatory and commercial success of NVX-CoV2373 and our other vaccine candidates, including an influenza vaccine candidate, CIC vaccine candidate, or a COVID-19 variant strain-containing monovalent or bivalent formulation, remains uncertain. If we are unable to obtain additional capital, we will assess our capital resources and may be required to delay, reduce the scope of, or eliminate some or all of our operations, or downsize our organization, any of which may have a material adverse effect on our business, financial condition, results of operations, and ability to operate as a going concern.

Contractual Obligations

The following table summarizes our contractual obligations as of December 31, 2022 (in thousands):

Contractual Obligations:	Total	Less than One Year	1 – 3 Years	3 – 5 Years	More than 5 Years
Operating leases	$ 74,853	$ 18,182	$ 29,354	$ 14,791	$ 12,526
Finance leases obligation	74,837	29,153	5,680	5,968	34,036
Convertible notes[1]	500,250	325,000	—	175,250	—
Contractual obligations recognized as of December 31, 2022	649,940	372,335	35,034	196,009	46,562
Purchase commitments[2]	560,638	560,638	—	—	—
Facilities lease agreement[3]	56,109	3,397	7,050	7,407	38,255
Total contractual obligations	$ 1,266,687	$ 936,370	$ 42,084	$ 203,416	$ 84,817

(1) We had $325.0 million of 3.75% convertible senior unsecured notes due February 1, 2023, which we repaid in full. In 2022, we issued $175.3 million of 5.00% convertible senior unsecured notes due in 2027. See "Note 11—Long-term Debt" included in our Notes to Consolidated Financial Statements for additional information related to our convertible notes.

(2) This amount primarily represents our non-cancelable fixed payment obligations under certain CMO, CDMO, and lab 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, 2022, 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 in our consolidated balance sheets.

(3) This relates to the lease of floor space at 700 Quince Orchard that had not commenced as of December 31, 2022 (see Note 10 to the consolidated financial statements).

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, Pound Sterling, 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 decline of stockholders' equity (deficit) of approximately $18.2 million as of December 31, 2022.

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, which historically has been classified as available-for-sale. 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-43.

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, as of the Evaluation Date, such controls and procedures were effective at the reasonable assurance level.

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, 2022. In making this assessment, our management used the criteria set forth in the 2013 Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on its assessment, our management has determined that, as of December 31, 2022, our internal controls over financial reporting are effective based on those criteria.

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 any changes in our internal control over financial reporting that occurred during the quarterly period ended December 31, 2022 and has concluded that there was no change that occurred during the quarterly period ended December 31, 2022 that materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. OTHER INFORMATION

None.

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 2023 Annual Meeting of Stockholders scheduled to be held in June 2023 (the "2023 Proxy Statement"). We expect to file the 2023 Proxy Statement within 120 days after the close of the fiscal year ended December 31, 2022.

Item 11. EXECUTIVE COMPENSATION

We incorporate herein by reference the information required by this item concerning executive compensation to be contained in the 2023 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 2023 Proxy Statement.

The following table provides our equity compensation plan information as of December 31, 2022. 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 14 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[1]	6,151,589	$47.11	4,501,492
Equity compensation plans not approved by security holders	N/A	N/A	N/A

(1) Includes our 2015 Stock Incentive Plan, 2005 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.

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 2023 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 2023 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

(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 treatment has been granted for portions of exhibits marked with a double asterisk (**).

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 Number	Description
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 3.1 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 June 24, 2021 (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 Appendix C 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))
10.7††	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 No. 000-26770))
10.8††	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))
10.9††	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))
10.10††	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))
10.11††	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))
10.12††	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))
10.13††	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))
10.14††	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))
10.15††	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))

10.16††	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))
10.17††	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))
10.18††*	Employment Agreement between the Company and John C. Jacobs, dated as of January 5, 2023
10.19††	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))
10.20††*	Consulting and Advisory Agreement between the Company and Stanley C. Erck, dated as of January 5, 2023
10.21††	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))
10.22††	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))
10.23††	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))
10.24††	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))
10.25††	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))
10.26††	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 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))
10.27††	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))
10.28††	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))
10.29	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))
10.30	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))
10.31	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))
10.32	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))
10.33	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))

10.34	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))
10.35^	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))
10.36^	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))
10.37^	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 8, 2022 (File No. 000-26770))
10.38^	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 8, 2022 (File No. 000-26770))
10.39^	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 8, 2022 (File No. 000-26770))
10.40^	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))
10.41^	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))
10.42^	Statement of Work No. 1 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 10.40 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))
10.43^	Change Order No. 1 to Statement of Work No. 1 to Collaboration and Exclusive License Agreement between the Company and SK bioscience Company Limited, dated as of March 31, 2022 (Incorporated by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2022, filed on May 9, 2022 (File No. 000-26770))
10.44^	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))
10.45**	Global Access Commitments Agreement between Bill & Melinda Gates Foundation and the Company, dated as of September 25, 2015 (Incorporated by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2015, filed on November 9, 2015 (File No. 000-26770))
10.46^	Asset Purchase Agreement between Company and Paragon Bioservices, Inc., dated June 26, 2019 (Incorporated by reference to Exhibit 10.3 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2019, filed on August 7, 2019 (File No. 000-26770))
10.47^	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))

10.48^	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))
10.49^	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))
10.50^	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))
10.51^	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)
10.52^	Advance Purchase Agreement, dated August 16, 2021, between the Company, Novavax CZ and the European Commission (Incorporated by reference to Exhibit 10.8 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))
10.53^	Base Agreement between the Company and Advanced Technology International, dated June 25, 2020 (Incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2020 (File No. 000-26770))
10.54^	Modification No. 01 to Base Agreement between the Company and Advanced Technology International, dated as of March 23, 2022 (Incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2022, filed on May 9, 2022 (File No. 000-26770))
10.55^	Modification No. 02 to Base Agreement between the Company and Advanced Technology International, dated as of August 2, 2022 (Incorporated by reference to Exhibit 10.3 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))
10.56^*	Modification No. 03 to Base Agreement between the Company and Advanced Technology International, dated as of November 30, 2022
10.57^	Undefinitized Project Agreement No. 1 between the Company and Advanced Technology International, dated July 6, 2020 (Incorporated by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2020 (File No. 000-26770))
10.58^	Modification No. 01 to Undefinitized Project Agreement No. 1 between the Company and Advanced Technology International, dated July 9, 2020 (Incorporated by reference to Exhibit 10.3 to the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2020 (File No. 000-26770))
10.59^	Modification No. 02 to Undefinitized Project Agreement No. 01, entered into September 10, 2020, between the Company and Advanced Technology International (Incorporated by reference to Exhibit 10.41 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))
10.60^	Modification No. 03 to Undefinitized Project Agreement No. 01, entered into September 18, 2020, between the Company and Advanced Technology International (Incorporated by reference to Exhibit 10.42 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))
10.61^	Modification No. 04 to Undefinitized Project Agreement No. 01, entered into December 23, 2020, between the Company and Advanced Technology International (Incorporated by reference to Exhibit 10.43 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^	Modification No. 05 to Undefinitized Project Agreement No. 01, dated January 12, 2021, between the Company and Advanced Technology International (Incorporated by reference to Exhibit 10.44 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))
10.63^	Modification No. 06 to Undefinitized Project Agreement No. 01, entered into January 19, 2021, between the Company and Advanced Technology International (Incorporated by reference to Exhibit 10.45 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))
10.64^	Modification No. 07 to Undefinitized Project Agreement No. 01, dated April 23, 2021, between the Company and Advanced Technology International (Incorporated by reference to Exhibit 10.6 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))
10.65^	Modification No. 08 to Undefinitized Project Agreement No. 01, dated June 4, 2021, between the Company and Advanced Technology International (Incorporated by reference to Exhibit 10.7 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))
10.66^	Modification No. 09 to Undefinitized Project Agreement No. 01, dated July 16, 2021, between the Company and Advanced Technology International (Incorporated by reference to Exhibit 10.5 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))
10.67^	Modification No. 10 to Undefinitized Project Agreement No. 01, dated August 6, 2021, between the Company and Advanced Technology International (Incorporated by reference to Exhibit 10.6 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))
10.68^	Modification No. 11 to Undefinitized Project Agreement No. 01, dated August 26, 2021, between the Company and Advanced Technology International (Incorporated by reference to Exhibit 10.7 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))
10.69^	Modification No. 12 to Undefinitized Project Agreement No. 01, dated December 20, 2021, between the Company and Advanced Technology International (Incorporated by reference to Exhibit 10.64 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))
10.70^	Modification No. 13 to Undefinitized Project Agreement No. 01, dated February 1, 2022, between the Company and Advanced Technology International (Incorporated by reference to Exhibit 10.65 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))
10.71^	Modification No. 14 to Undefinitized Project Agreement No. 01, dated July 1, 2022, between the Company and Advanced Technology International (Incorporated by reference to Exhibit 10.4 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))
10.72^	Modification No. 15 to Undefinitized Project Agreement No. 01, dated August 9, 2022, between the Company and Advanced Technology International (Incorporated by reference to Exhibit 10.5 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))
10.73^	Modification No. 16 to Undefinitized Project Agreement No. 01, dated September 9, 2022, between the Company and Advanced Technology International (Incorporated by reference to Exhibit 10.6 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))
10.74^	Amendment of Solicitation/Modification of Contract, Modification No. 6, dated as of July 29, 2022, between the Company and the U.S. Department of Defense Joint Program Executive Office for Chemical, Biological, Radiological and Nuclear Defense (Incorporated by reference to Exhibit 10.7 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))
10.75	Series A Convertible Preferred Subscription Agreement, dated June 15, 2020, between the Company and RA Capital Healthcare Fund, L.P. (Incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed June 19, 2020 (File No. 000-26770))

10.76	Restated Funding Agreement, entered into on May 11, 2020, between the Company and the Coalition for Epidemic Preparedness Innovations (Incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2020 (File No. 000-26770))
10.77^	Amendment Number 1 to the iPDP and Budget of the Outbreak Response Funding Agreement (Step 2), entered into on November 2, 2020, between the Company and the Coalition for Epidemic Preparedness Innovations (Incorporated by reference to Exhibit 10.56 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))
10.78^	Settlement Agreement, dated September 30, 2022, between the Company and FUJIFILM Diosynth Biotechnologies UK Limited, FUJIFILM Diosynth Biotechnologies Texas, LLC, and FUJIFILM Diosynth Biotechnologies USA, Inc. (Incorporated by reference to Exhibit 10.8 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))
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))
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
101	The following financial information from our Annual Report on Form 10-K for the year ended December 31, 2022, formatted in Extensible Business Reporting Language (XBRL): (i) the Consolidated Balance Sheets as of December 31, 2022 and 2021, (ii) the Consolidated Statements of Operations for the three years in the period ended December 31, 2022, (iii) the Consolidated Statements of Comprehensive Loss for the three years in the period ended December 31, 2022, (iv) the Consolidated Statements of Changes in Stockholders' Equity (Deficit) for the three years in the period ended December 31, 2022, (v) the Consolidated Statements of Cash Flows for the three years in the period ended December 31, 2022, and (vi) the Notes to Consolidated Financial Statements.
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 28, 2023

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
/s/ John C. Jacobs John C. Jacobs	President and Chief Executive Officer and Director (Principal Executive Officer)	February 28, 2023
/s/ James P. Kelly James P. Kelly	Executive Vice President, Chief Financial Officer, and Treasurer (Principal Financial and Accounting Officer)	February 28, 2023
/s/ James F. Young James F. Young	Chairman of the Board of Directors	February 28, 2023
/s/ Gregg H. Alton Gregg H. Alton	Director	February 28, 2023
/s/ Richard H. Douglas Richard H. Douglas	Director	February 28, 2023
/s/ Rachel K. King Rachel K. King	Director	February 28, 2023
/s/ Margaret G. McGlynn Margaret G. McGlynn	Director	February 28, 2023
/s/ David M. Mott David M. Mott	Director	February 28, 2023
/s/ Richard J. Rodgers Richard J. Rodgers	Director	February 28, 2023

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Years ended December 31, 2022, 2021, and 2020

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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, 2022 and 2021, the related consolidated statements of operations, comprehensive loss, changes in stockholders' equity (deficit), and cash flows for each of the three years in the period ended December 31, 2022, 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, 2022 and 2021, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2022, 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, 2022, 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 28, 2023 expressed an unqualified opinion thereon.

The Company's Ability to Continue as a Going Concern

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 2 to the financial statements, the Company has suffered recurring losses from operations, has a working capital deficiency, and has stated that substantial doubt exists about the Company's ability to continue as a going concern. Management's evaluation of the events and conditions and management's plans regarding these matters are also described in Note 2. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

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 matter communicated below is a matter arising from the current period audit of the financial statements that was communicated or required to be communicated to the audit committee and that: (1) relates to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective or complex judgments. The communication of the critical audit matter 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 matter below, providing a separate opinion on the critical audit matter or on the account or disclosures to which it relates.

Inventory Excess and Obsolescence Reserve

Description of the Matter

As of December 31, 2022, the Company had $36.7 million of inventory. As disclosed in Note 2, inventories are stated at the lower of cost or net realizable value. The Company assesses its inventory levels each reporting period and writes down inventory that is either expected to be at risk of expiration prior to sale, or for which there are inventory quantities in excess of expected requirements. For the year ended December 31, 2022, inventory write-downs were $447.6 million and losses on firm purchase commitments were $155.9 million.

Auditing management's estimates for excess and obsolete inventory involved subjective auditor judgment because the estimates rely on a number of factors that are affected by market and economic conditions outside the Company's control. In particular, the obsolete and excess inventory calculations are sensitive to significant assumptions, including the expected demand for the Company's products, assumptions about the vaccine's life cycle, the effect on demand of competitive products and the Company's purchase commitments.

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 Company's excess and obsolete inventory reserve process including management's review of the significant assumptions described above and controls over the completeness and accuracy of the information used to develop the estimate.

Our substantive audit procedures included, among others, evaluating methodologies, assumptions and data utilized in the analysis for inventory expected to be at risk for expiration or excess. We evaluated purchase commitments or alternative uses, compared forecasted demand to historical trends, compared actual inventory levels to forecasted demand requirements and evaluated the sensitivity of sales forecast assumptions on the amount of inventory reserves recorded.

/s/ Ernst & Young LLP

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

Tysons, Virginia
February 28, 2023

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, 2022, 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, Novavax, Inc. (the Company) maintained, in all material respects, effective internal control over financial reporting as of December 31, 2022, based on the COSO criteria.

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, 2022 and 2021, the related consolidated statements of operations, comprehensive loss, changes in stockholders' equity (deficit), and cash flows for each of the three years in the period ended December 31, 2022, and the related notes and our report dated February 28, 2023 expressed an unqualified opinion that included an explanatory paragraph regarding the Company's ability to continue as a going concern.

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* included 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 28, 2023

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

	Year Ended December 31,		
	2022	**2021**	**2020**
Revenue:			
Product sales	$ 1,554,961	$ —	$ —
Grants	382,921	948,709	453,210
Royalties and other	43,990	197,581	22,388
Total revenue	1,981,872	1,146,290	475,598
Expenses:			
Cost of sales	902,639	—	—
Research and development	1,235,278	2,534,508	747,027
Selling, general, and administrative	488,691	298,358	145,290
Total expenses	2,626,608	2,832,866	892,317
Loss from operations	(644,736)	(1,686,576)	(416,719)
Other income (expense):			
Interest expense	(19,880)	(21,127)	(15,145)
Other income (expense)	10,969	(6,833)	13,605
Loss before income tax expense	(653,647)	(1,714,536)	(418,259)
Income tax expense	4,292	29,215	—
Net loss	$ (657,939)	$(1,743,751)	$ (418,259)
Net loss per share:			
Basic and diluted	$ (8.42)	$ (23.44)	$ (7.27)
Weighted average number of common shares outstanding:			
Basic and diluted	78,183	74,400	57,554

CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS
(in thousands)

	Year Ended December 31,		
	2022	**2021**	**2020**
Net loss	$ (657,939)	$(1,743,751)	$ (418,259)
Other comprehensive income (loss):			
Net unrealized gains (losses) on marketable securities available-for-sale, net of reclassifications	—	(9)	9
Foreign currency translation adjustment	(5,024)	(8,368)	19,523
Other comprehensive income (loss)	(5,024)	(8,377)	19,532
Comprehensive loss	$ (662,963)	$(1,752,128)	$ (398,727)

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

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

	December 31,	
	2022	**2021**
ASSETS		
Current assets:		
Cash and cash equivalents	$ 1,336,883	$ 1,515,116
Restricted cash	10,303	11,490
Accounts receivable	82,375	454,993
Inventory	36,683	8,872
Prepaid expenses and other current assets	237,147	164,648
Total current assets	1,703,391	2,155,119
Property and equipment, net	294,247	225,741
Right of use asset, net	106,241	40,123
Goodwill	126,331	131,479
Other non-current assets	28,469	24,291
Total assets	$ 2,258,679	$ 2,576,753
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current liabilities:		
Accounts payable	$ 216,517	$ 127,050
Accrued expenses	591,158	673,731
Deferred revenue	370,137	1,422,944
Current portion of finance lease liabilities	27,196	130,533
Convertible notes payable	324,881	—
Other current liabilities	930,055	36,061
Total current liabilities	2,459,944	2,390,319
Deferred revenue	179,414	172,528
Convertible notes payable	166,466	323,458
Non-current finance lease liabilities	31,238	—
Other non-current liabilities	55,695	42,121
Total liabilities	2,892,757	2,928,426
Commitments and contingencies (Note 18)		
Preferred stock, $0.01 par value, 2,000,000 shares authorized at December 31, 2022 and 2021; no shares issued and outstanding at December 31, 2022 and 2021	—	—
Stockholders' equity (deficit):		
Common stock, $0.01 par value, 600,000,000 shares authorized at December 31, 2022 and 2021; and 86,806,554 shares issued and 86,039,923 shares outstanding at December 31, 2022 and 76,433,151 shares issued and 75,841,171 shares outstanding at December 31, 2021	868	764
Additional paid-in capital	3,737,979	3,351,967
Accumulated deficit	(4,275,889)	(3,617,950)
Treasury stock, 766,631 shares, cost basis at December 31, 2022 and 591,980 shares, cost basis at December 31, 2021	(90,659)	(85,101)
Accumulated other comprehensive loss	(6,377)	(1,353)
Total stockholders' equity (deficit)	(634,078)	(351,673)
Total liabilities and stockholders' equity (deficit)	$ 2,258,679	$ 2,576,753

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

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

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Treasury Stock	Accumulated Other Comprehensive Income (Loss)	Total Stockholders' Equity (Deficit)
	Shares	Amount					
Balance at December 31, 2019	**32,399,352**	**$ 324**	**$ 1,260,551**	**$ (1,431,801)**	**$ (2,583)**	**$ (12,508)**	**$ (186,017)**
Preferred stock beneficial conversion feature	—	—	24,139	(24,139)	—	—	—
Conversion of preferred stock	4,388,850	44	199,778	—	—	—	199,822
Stock-based compensation	—	—	128,035	—	—	—	128,035
Stock issued under incentive programs	2,168,725	22	44,447	—	(39,223)	—	5,246
Issuance of common stock, net of issuance costs of $11,416	32,393,438	324	878,526	—	—	—	878,850
Unrealized gain on marketable securities	—	—	—	—	—	9	9
Foreign currency translation adjustment	—	—	—	—	—	19,523	19,523
Net loss	—	—	—	(418,259)	—	—	(418,259)
Balance at December 31, 2020	**71,350,365**	**714**	**2,535,476**	**(1,874,199)**	**(41,806)**	**7,024**	**627,209**
Stock-based compensation	—	—	183,626	—	—	—	183,626
Stock issued under incentive programs	2,503,819	24	68,032	—	(43,295)	—	24,761
Issuance of common stock, net of issuance costs of $7,292	2,578,967	26	564,833	—	—	—	564,859
Unrealized gain on marketable securities	—	—	—	—	—	(9)	(9)
Foreign currency translation adjustment	—	—	—	—	—	(8,368)	(8,368)
Net loss	—	—	—	(1,743,751)	—	—	(1,743,751)
Balance at December 31, 2021	**76,433,151**	**764**	**3,351,967**	**(3,617,950)**	**(85,101)**	**(1,353)**	**(351,673)**
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 $7,216	9,672,398	97	249,133	—	—	—	249,230
Foreign currency translation adjustment	—	—	—	—	—	(5,024)	(5,024)
Net loss	—	—	—	(657,939)	—	—	(657,939)
Balance at December 31, 2022	**86,806,554**	**$ 868**	**$ 3,737,979**	**$ (4,275,889)**	**$ (90,659)**	**$ (6,377)**	**$ (634,078)**

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

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

	Year Ended December 31,		
	2022	**2021**	**2020**
Operating Activities:			
Net loss	$ (657,939)	$ (1,743,751)	$ (418,259)
Reconciliation of net loss to net cash used in operating activities:			
Depreciation and amortization	29,054	12,661	4,885
Right-of-use assets expensed, net of credits received	18,104	144,433	245,861
Non-cash stock-based compensation	130,300	183,626	128,035
Provision for excess and obsolete inventory	447,597	—	—
Other items, net	(21,903)	(7,641)	(15,080)
Changes in operating assets and liabilities:			
Inventory	(477,801)	(8,872)	—
Accounts receivable, prepaid expenses, and other assets	249,166	(183,393)	(422,689)
Accounts payable, accrued expenses, and other liabilities	913,399	600,326	163,161
Deferred revenue	(1,045,914)	1,325,557	271,545
Net cash provided by (used in) operating activities	(415,937)	322,946	(42,541)
Investing Activities:			
Capital expenditures	(89,056)	(54,501)	(54,473)
Internal-use software	(3,929)	(2,985)	(149)
Acquisition of Novavax CZ, net of cash acquired	—	—	(165,516)
Purchases of marketable securities	—	(2,167)	(363,202)
Proceeds from maturities of marketable securities	—	159,807	205,562
Net cash provided by (used in) investing activities	(92,985)	100,154	(377,778)
Financing Activities:			
Net proceeds from sale of preferred stock	—	—	199,822
Net proceeds from sales of common stock	249,230	564,859	875,623
Proceeds from issuance of convertible notes	175,250	—	—
Payments of costs related to issuance of convertible notes	(5,258)	—	—
Net proceeds from the exercise of stock-based awards	(639)	24,761	5,382
Finance lease payments	(93,595)	(127,907)	(96,065)
Net cash provided by financing activities	324,988	461,713	984,762
Effect of exchange rate on cash, cash equivalents, and restricted cash	4,520	(5,292)	2,115
Net increase in cash, cash equivalents, and restricted cash	(179,414)	879,521	566,558
Cash, cash equivalents, and restricted cash at beginning of year	1,528,259	648,738	82,180
Cash, cash equivalents, and restricted cash at end of year	$1,348,845	$ 1,528,259	$ 648,738
Supplemental disclosure of non-cash activities:			
Sale of common stock under the Sales Agreement not settled at year-end	$ —	$ —	$ 3,227
Capital expenditures included in accounts payable and accrued expenses	$ 17,665	$ 10,338	$ 9,255
Right-of-use assets from new lease agreements	$ 91,855	$ 179,210	$ 247,599
Supplemental disclosure of cash flow information:			
Cash interest payments, net of amounts capitalized	$ 18,035	$ 19,428	$ 13,705
Cash paid for income taxes	$ 17,980	$ 12,606	$ —

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

Note 1 – Organization

Novavax, Inc. ("Novavax," and together with its wholly owned subsidiaries, the "Company") is a biotechnology company that promotes improved health globally through the discovery, development, and commercialization of innovative vaccines to prevent serious infectious diseases. The Company's COVID-19 vaccine NVX-CoV2373 ("Nuvaxovid™," "Covovax™," "Novavax COVID-19 Vaccine, Adjuvanted"); influenza vaccine candidate; COVID-19-Influenza Combination ("CIC") vaccine candidate; and additional vaccine candidates, including for Omicron subvariants and bivalent formulations with prototype vaccine ("NVX-CoV2373"), are genetically engineered nanostructures of conformationally correct recombinant proteins critical to disease pathogenesis and may elicit differentiated immune responses, which may be more efficacious than naturally occurring immunity or other vaccine approaches. NVX-CoV2373 and the Company's other vaccine candidates incorporate the Company's proprietary Matrix-M™ adjuvant to enhance the immune response and stimulate higher levels of functional antibodies and induce a cellular immune response. The Company has announced data from its ongoing PREVENT-19 study supporting the use of NVX-CoV2373 for homologous boosting in adults and adolescents aged 12 through 17. Additional findings in Phase 3 COVID-19 Omicron (study 311) trial showed utility of the prototype vaccine as a heterologous booster, inducing broad immune responses against contemporary Omicron variants.

As of December 31, 2022, the Company had received approval, interim authorization, provisional approval, conditional marketing authorization, and emergency use authorization ("EUA") from multiple regulatory authorities globally for NVX-CoV2373 for both adult and adolescent populations as a primary series and for both homologous and heterologous booster indications.

The Company commenced commercial shipments of NVX-CoV2373 doses under the name "Novavax COVID-19 Vaccine, Adjuvanted" and the brand name "Nuvaxovid™" in 2022.

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. At December 31, 2022, the Company had $1.3 billion in cash and cash equivalents and restricted cash, of which $236.2 million was raised in December 2022 through concurrent sales of common stock and issuance of the Company's convertible senior unsecured notes that will mature on December 15, 2027 (see Notes 11 and 13). On January 31, 2023, the Company funded the outstanding principal amount of $325.0 million on the Company's convertible senior unsecured notes that matured on February 1, 2023. During 2022, the Company incurred a net loss of $657.9 million and had net cash flows used in operating activities of $415.9 million.

While the Company's current cash flow forecast for the one-year going concern look forward period estimates that there will be sufficient capital available to fund operations, this forecast is subject to significant uncertainty, including as it relates to 2023 revenue, funding from the U.S. government, and pending arbitration. The Company's 2023 revenue depends on its ability to successfully develop, manufacture, distribute, or market an updated monovalent or bivalent formulation of a vaccine candidate for COVID-19 for the fall 2023 COVID vaccine season, which is inherently uncertain and subject to a number of risks, including regulatory approval. In February 2023, in connection with the execution of Modification 17 to the USG Agreement (as defined in Note 3), the U.S. government indicated to the Company that the award may not be extended past its current period of performance. If the USG Agreement is not amended, as the Company's management had previously expected, then the Company may not receive all of the remaining $416 million in funding that was previously anticipated pursuant to the USG Agreement. On January 24, 2023, Gavi, the Vaccine Alliance ("Gavi") filed a demand for arbitration with the International Court of Arbitration regarding an alleged material breach by the Company of the Company's advance purchase agreement with Gavi ("the Gavi APA"). The outcome of that arbitration is inherently uncertain, and it is possible the Company could be required to refund all or a portion of the remaining advance payments of $697.4 million (see Note 3 and Note 18). Management believes that, given the significance of these uncertainties, substantial doubt exists regarding the Company's ability to continue as a going concern through one year from the date that these financial statements are issued.

The Company's ability to fund Company operations is dependent upon revenue related to vaccine sales for its products and product candidates, if such product candidates receive marketing approval and are successfully commercialized; the resolution of certain matters, including whether, when, and how the dispute with Gavi is resolved; and management's plans, which include resolving the dispute with Gavi and may include raising additional capital through a combination of equity and debt financing, collaborations, strategic alliances, and marketing, distribution, or licensing arrangements. New financings may not be available to the Company on commercially acceptable terms, or at all. Also, any collaborations, strategic alliances, and marketing, distribution, or licensing arrangements may require the Company to give up some or all of its rights to a product or technology, which in some cases may be at less than the full potential value of such rights. In addition, the regulatory and commercial success of NVX-CoV2373 and the Company's other vaccine candidates, including an influenza vaccine candidate, CIC vaccine candidate, or a COVID-19 variant strain-containing monovalent or bivalent formulation, remains uncertain. If the Company is unable to obtain additional capital, the Company will assess its capital resources and may be required to delay, reduce the scope of, or eliminate some or all of its operations, or downsize its organization, any of which may have a material adverse effect on its business, financial condition, results of operations, and ability to operate as a going concern.

Reclassifications

Certain amounts reported in prior periods have been reclassified to conform to current period financial statement presentation. These reclassifications have no material effect on previously reported financial position, cash flows, or results of operations.

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. Estimates are used for, but not limited to, revenue recognition, inventory, research and development expenses, stock-based compensation, useful lives of long-lived assets, leases, and income taxes. 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 Accounting Standards Codification ("ASC") Topic 606, *Revenue from Contracts with Customers (Topic 606)* ("ASC 606"), or are contributions subject to the guidance in ASC Topic 958-605, *Not-for-Profit Entities – Revenue Recognition* ("ASC 958-605"). 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. The Company recognizes contribution revenue within the scope of ASC 958-605 when the funder-imposed conditions have been substantially met. Contributions are recorded as deferred revenue until the period in which research and development activities are performed that satisfy the funder-imposed conditions.

Product Sales

Product sales are associated with the Company's NVX-CoV2373 supply agreements, sometimes referred to as advance purchase agreements ("APAs"), with various international governments. The Company recognizes revenue from product sales 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. If an APA includes a term that may have the effect of decreasing the price per dose of previously delivered shipments, the Company constrains the price until it is probable that a significant reversal in revenue recognized will not occur.

Grants

Grant revenue includes both revenue from government contracts and grants from organizations such as the Coalition for Epidemic Preparedness Innovations ("CEPI"). 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 and other arrangements to advance the clinical development and manufacturing of NVX-CoV2373.

Under the 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 NVX-CoV2373 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.

The Company's other funding agreements currently include funding from CEPI in the form of a grant ("CEPI Grant Funding") and one or more forgivable no interest term loans ("CEPI Forgivable Loan Funding"). Under the Company's grant funding arrangements, including the CEPI arrangement, the Company is primarily entitled to reimbursement for costs that support development related activities of NVX-CoV2373. The Company analyzed these other funding arrangements and determined that they are not within the scope of ASC 606 as they do not provide a direct economic benefit to the grantor. Payments received under the grant funding arrangements are considered conditional contributions under the scope of ASC 958-605 and are recorded as deferred revenue until the period in which such research and development activities are actually performed in a manner that satisfies the funder-imposed conditions. Payments received under the CEPI Forgivable Loan Funding are only repayable if NVX-CoV2373 manufactured by the contract manufacturing organization ("CMO") network funded by CEPI is sold to one or more third parties (which would have previously included, but is not limited to, any sales under the Company's Gavi APA prior to its termination), and such sales cover the Company's costs of manufacturing such vaccine, not including manufacturing costs funded by CEPI. As the financial risk remains with CEPI, the Company determined that the use of the funds from the CEPI agreement is outside the scope of ASC Topic 470, *Debt*. The research and development risk was considered substantive, such that it was not probable that the development would be successful at the inception of the contract. Therefore, the Company concluded that ASC Topic 730, *Research and Development* ("ASC 730") was considered applicable and most appropriate. Given the financial risk associated with the research and development activities lies with CEPI because repayment of any funds provided by CEPI depends solely on the results of the research and development activities having future economic benefit, the Company has accounted for the obligation under the CEPI Forgivable Loan Funding as a contract to perform research and development for others. The Company has determined that payments received under these agreements should be recorded as revenue under ASC 958-605 rather than a reduction to research and development expenses. This is consistent with the Company's policy of presenting such amounts as revenue. In reaching this determination, the Company considered a number of factors, including whether it is principal under the arrangement, and whether the arrangement is significant to, and part of, the Company's core operations. The Company will record revenue as it performs the contractual research and development services.

Payments received in advance related to arrangements where revenue is recognized under ASC 958-605 that are related to future performance are deferred and recognized as revenue when the research and development activities are performed. Such cash payments are restricted as to their use and are reflected in Restricted cash until expenditures contemplated in the funding agreements are incurred.

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 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 standalone selling price basis. It develops assumptions that require judgment to determine the standalone 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.

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"), 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 $84.0 million and $8.9 million during the years ended December 31, 2022 and 2021, 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 generally 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 approximate fair value due to their short-term nature.

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. As of December 31, 2022 and 2021, the restricted cash balances (both current and non-current) consisted primarily of payments under the CEPI funding agreements.

Accounts Receivable

The Company recognizes amounts due from customers as accounts receivable when its right to payment is unconditional. The Company evaluates outstanding receivables to assess collectability, with consideration given to 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. 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.

The Company's accounts receivable arise from revenue arrangements with customers in different countries. The Company's revenue is primarily due to product sales, grants made by government-sponsored and private 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,	
	2022	2021	2020	2022	2021
European Commission	40%	*	*	10%	*
Government of Australia	21%	*	*	*	*
Government of Canada	10%	*	*	*	*
Government of Israel	*	*	*	21%	*
Gavi, the Vaccine Alliance	*	*	*	*	77%
U.S. government[(1)]	19%	71%	46%	46%	*
CEPI	*	12%	47%	*	*
SK bioscience, Co., Ltd.	*	14%	*	*	*

*Amounts represent less than 10%

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

The Company currently depends exclusively on a single supplier for co-formulation, filling, and finishing NVX-CoV2373. 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 730 if they do not have an alternative future use, in research and development projects or otherwise.

The Company uses significant 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*. The Company calculates the estimated fair value of a long-lived asset or asset group using the income approach. Impairment losses are recognized when the sum of expected future cash flows is less than the asset's or asset group's carrying value.

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 the development of recombinant vaccines, it operates as a single operating segment and has one reporting unit. The Company primarily utilizes the market approach and, if considered necessary, the income approach to determine if it has an impairment of its goodwill. The market approach is based on market value of invested capital. To ensure that the Company's capital stock is the appropriate measurement of fair value, the Company considers factors such as its trading volume, diversity of investors, and analyst coverage. If considered necessary, the income approach is used to corroborate the results of the market approach. Goodwill impairment may exist if the carrying value of the reporting unit exceeds its estimated fair value. 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.

At October 1, 2022 and 2021, the fair value of the Company's single reporting unit was substantially higher than its carrying value, resulting in no impairment to goodwill as of October 1, 2022 and 2021.

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.

During the years ended December 31, 2022 and 2021, the Company recognized $4.3 million and $29.2 million, respectively, primarily in income tax expense related to foreign withholding tax on royalties. During the year ended December 31, 2020, the Company recognized no income tax expense.

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, primarily convertible notes, stock options, SARs, and unvested RSUs. As of December 31, 2022, the Company's 2027 Notes and 2023 Notes (see Note 11) would have been convertible into approximately 16.4 million shares of the Company's common stock assuming the common stock price is equal to or greater than $12.50 and $136.20, respectively. These shares, after giving effect to the add back of interest expense and unamortized discounts and debt issuance costs on the Notes and any shares due to the Company upon settlement of its capped call transactions, are excluded from the computation, as their effect is antidilutive under the if-converted method.

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 $(6.4) million and $(1.4) million at December 31, 2022 and 2021, respectively. The aggregate foreign currency transaction gains and losses resulting from the conversion of the transaction currency to functional currency were $(2.5) million, $(5.3) million, and $9.6 million for the years ended December 31, 2022, 2021, and 2020 respectively, which are reflected in Other income (expense).

Segment Information

The Company manages its business as one operating segment: the development of recombinant vaccines. The Company does not operate separate lines of business with respect to its vaccine candidates. Accordingly, the Company does not have separately reportable segments as defined by ASC Topic 280, *Segment Reporting*.

Recent Accounting Pronouncements

Not Yet Adopted

In June 2016, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 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 ASU is effective for the Company beginning on January 1, 2023. Management has evaluated the effect of the guidance and its implementation will not have a material impact on the Company's consolidated financial statements.

Adopted

In August 2020, the FASB issued ASU No. 2020-06, *Debt—Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging—Contracts in Entity's Own Equity (Subtopic 815-40): Accounting for Convertible Instruments and Contracts in an Entity's Own Equity* ("ASU 2020-06"), which simplified the accounting for certain financial instruments with characteristics of liabilities and equity, including certain convertible instruments and contracts in an entity's own equity. Specifically, the new standard removed the separation models required for convertible debt with cash conversion features and convertible instruments with beneficial conversion features. It also removed certain settlement conditions that are currently required for equity contracts to qualify for the derivative scope exception and simplified the diluted earnings per share calculation for convertible instruments. The Company adopted ASU 2020-06 on January 1, 2022 using a modified retrospective approach, which did not have a material impact on the Company's consolidated financial statements.

Note 3 – Revenue

The Company's accounts receivable included $53.8 million and $419.7 million related to amounts that were billed to customers and $28.6 million and $35.3 million related to amounts which had not yet been billed to customers as of December 31, 2022 and 2021, respectively. During the years ended December 31, 2022 and 2021, changes in the Company's accounts receivables, deferred revenue, and allowance for doubtful accounts balances were as follows (in thousands):

	Balance, Beginning of Period	Additions	Deductions	Balance, End of Period
Accounts receivable:				
Year ended December 31, 2022	$ 454,993	$ 1,768,457	$ (2,127,240)	$ 96,210
Year ended December 31, 2021	262,012	2,432,268	(2,239,287)	454,993
Allowance for doubtful accounts:				
Year ended December 31, 2022	—	(13,835)[1]	—	(13,835)
Year ended December 31, 2021	—	—	—	—
Deferred revenue[2]:				
Year ended December 31, 2022	1,595,472	46,908	(1,092,829)[3]	549,551
Year ended December 31, 2021	273,228	1,598,152	(275,908)	1,595,472

(1) Bad debt expense was $13.8 million in the year ended December 31, 2022 and there was no bad debt expense in the years ended December 31, 2021 and 2020.
(2) Amount is comprised of $0.4 billion, $1.4 billion, and $0.3 billion current Deferred revenue and $179.4 million, $172.5 million, and no non-current Deferred revenue as of December 31, 2022, 2021, and 2020 respectively.
(3) Deductions from Deferred revenue include the following: $273.8 million that was realized in Revenue and $819.0 million, including $697.4 million related to the Advance Payment Amount (as described below) at issue in the Gavi arbitration and $112.5 million related to the Amended and Restated UK Supply Agreement, that was reclassified to Other current liabilities, as described below. In the fourth quarter of 2022, the Company recognized revenue of $41.9 million related to a change in estimate attributed to changes in constraint of variable consideration.

The aggregate amount of the transaction price allocated to performance obligations that were unsatisfied (or partially unsatisfied), excluding amounts related to sales-based royalties, was approximately $3 billion as of December 31, 2022, which excludes amounts related to the Company's APA ("the Gavi APA") with Gavi, the Vaccine Alliance ("Gavi") and the reduction in doses related to the Amended and Restated UK Supply Agreement, as defined below. 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 payments or result in reduced future payments, which could adversely impact the Company's ability to realize revenue from its unsatisfied performance obligations. The timing to fulfill performance obligations related to grant agreements will depend on the results of the Company's research and development activities, including clinical trials, and delivery of doses. 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 in place of the prototype NVX-CoV2373 vaccine under certain of the Company's APAs. The remaining unfilled performance obligations not related to grant agreements or APAs are expected to be fulfilled in less than one year.

Under the terms of the Gavi APA and a separate purchase agreement between Gavi and Serum Institute of India Pvt. Ltd. ("SIIPL"), 1.1 billion doses of NVX-CoV2373 were to be made available to countries participating in the COVAX Facility. The Company expected to manufacture and distribute 350 million doses of NVX-CoV2373 to countries participating under the COVAX Facility. Under a separate purchase agreement with Gavi, SIIPL was expected to manufacture and deliver the balance of the 1.1 billion doses of NVX-CoV2373 for low- and middle-income countries participating in the COVAX Facility. The Company expected to deliver doses with antigen and adjuvant manufactured at facilities directly funded under the Company's funding agreement with CEPI, with initial doses supplied by SIIPL and Serum Life Sciences Limited ("SLS") under a supply agreement. The Company expected to supply significant doses that Gavi would allocate to low-, middle- and high-income countries, subject to certain limitations, utilizing a tiered pricing schedule and Gavi could prioritize such doses to low- and middle- income countries, at lower prices. Additionally, the Company could provide additional doses of NVX-CoV2373, to the extent available from CEPI funded manufacturing facilities, in the event that SIIPL could not materially deliver expected vaccine doses to the COVAX Facility. Under the agreement, the Company received an upfront payment of $350.0 million from Gavi in 2021 and an additional payment of $350.0 million in the first quarter of 2022 related to the Company's achieving EUL for NVX-CoV2373 by the WHO (the "Advance Payment Amount").

On November 18, 2022, the Company delivered written notice to Gavi to terminate the Gavi APA on the basis of Gavi's failure to procure the purchase of 350 million doses of NVX-CoV2373 from the Company as required by the Gavi APA. As of November 18, 2022, the Company had only received orders under the Gavi APA for approximately 2 million doses. On December 2, 2022, Gavi issued a written notice purporting to terminate the Gavi APA based on Gavi's contention that the Company repudiated the agreement and, therefore, materially breached the Gavi APA. Gavi also contends that, based on its purported termination of the Gavi APA, it is entitled to a refund of the Advance Payment Amount less any amounts that have been credited against the purchase price for binding orders placed by a buyer participating in the COVAX Facility. As of December 31, 2022, the remaining Gavi Advance Payment Amount of $697.4 million, pending resolution of the dispute with Gavi related to a return of the remaining Advance Payment Amount, was reclassified from Deferred revenue to Other current liabilities in the Company's consolidated balance sheet. On January 24, 2023, Gavi filed a demand for arbitration with the International Court of Arbitration based on the claims described above. The Company's response is currently due by March 2, 2023. Arbitration is inherently uncertain, and while the Company believes that it is entitled to retain the remaining Advance Payment Amount received from Gavi, it is possible that it could be required to refund all or a portion of the remaining Advance Payment Amount from Gavi.

Product Revenue

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

	Year Ended December 31, 2022
North America	$ 194,480
Europe	823,542
Rest of the world	536,939
Total product revenue	$ 1,554,961

The Company has an APA with the European Commission ("EC") acting on behalf of various European Union member states to supply a minimum of 20 million and up to 100 million initial doses of NVX-CoV2373, with the option for the EC to purchase an additional 100 million doses up to a maximum aggregate of 200 million doses in one or more tranches, through 2023. Under the terms of the APA, the Company agreed to manufacture the vaccine in facilities located in the European Union and ensure continued efficacy of the vaccine against variants of the SARS-CoV-2 virus. Pursuant to the terms of the APA, the Company is prohibited from supplying NVX-CoV2373 to any third party if such delivery would impede or limit the fulfillment of the Company's obligations to the European Commission under the APA, except with respect to the Company's obligations under the Gavi APA. In 2022, the Company was notified by the EC that it was cancelling approximately 7 million doses of its prior commitment originally scheduled for delivery in the first and second quarters of 2022, in accordance with the APA, and reducing the order to approximately 63 million doses. In January 2023, the Company finalized a revised delivery schedule for the remaining 20 million committed doses under the APA that were originally scheduled for delivery during the first and second quarters of 2022 and are expected to be delivered in 2023.

In July 2022, the Company entered into an Amended and Restated SARS-CoV-2 Vaccine Supply Agreement (as amended on September 26, 2022, the "Amended and Restated UK Supply Agreement") with 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"), which amended and restated in its entirety the SARS-CoV-2 Vaccine Supply Agreement, dated October 22, 2020, between the parties (the "Original UK Supply Agreement"). Under the Original UK Supply Agreement, the Authority agreed to purchase 60 million doses of NVX-CoV2373 and made an upfront payment to the Company. 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 NVX-CoV2373, with the number of Conditional Doses contingent on, and subject to reduction based on, the Company's timely achievement of supportive recommendations from the Joint Committee on Vaccination and Immunisation (the "JCVI") that is approved by the UK Secretary of State for Health, with respect to use of the vaccine for (a) the general adult population as part of a SARS-CoV-2 vaccine booster campaign in the United Kingdom or (b) the general adolescent population as part of a SARS-CoV-2 vaccine booster campaign in the United Kingdom or as a primary series SARS-CoV-2 vaccination, excluding where that recommendation relates only to one or more population groups comprising less than one million members in the United Kingdom. If the Authority does not purchase the Conditional Doses or the number of such Conditional Doses is reduced below 15 million doses of NVX-CoV2373, the Company would have to repay up to $225.0 million related to the upfront payment previously received from the Authority under the Original UK Supply Agreement. Under the Amended and Restated UK Supply Agreement, the Authority also has 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 yet made a supportive recommendation with respect to NVX-CoV2373, thereby triggering, under the terms of the Amended and Restated UK Supply Agreement, (i) a reduction of the number of Conditional Doses from 15 million doses to 7.5 million doses, which reduced number of Conditional Doses are contingent on, and subject to further reduction based on, the Company's timely achievement by November 30, 2023 of a supportive recommendation from JCVI that is approved by the UK Secretary of State for Health as described in the paragraph above, and (ii) an obligation of the Company to repay $112.5 million related to the upfront payment previously received from the Authority under the Original UK Supply Agreement, which is reflected in Other current liabilities, with the remaining upfront payment balance of $112.5 million reflected in current Deferred revenue.

Grants

The Company recognized grant revenue as follows (in thousands):

	Year Ended December 31,		
	2022	2021	2020
USG Agreement	$ 380,996	$ 788,953	$ 204,727
U.S. DoD	1,925	21,683	12,519
CEPI	—	135,445	223,158
Other grant revenue	—	2,628	12,806
Total grant revenue	$ 382,921	$ 948,709	$ 453,210

U.S. Government

In July 2020, the Company entered into a Project Agreement (the "Project Agreement") with Advanced Technology International, Inc. ("ATI"), the Consortium Management Firm acting on behalf of the Medical CBRN Defense Consortium in connection with the partnership formerly known as Operation Warp Speed. Operation Warp Speed was a partnership among components of the U.S. Department of Health and Human Services and the U.S. Department of Defense working to accelerate the development, manufacturing, and distribution of COVID-19 vaccines, therapeutics, and diagnostics. The Project Agreement relates to the Base Agreement the Company entered into with ATI in June 2020 (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 NVX-CoV2373, and to manufacture and deliver to the U.S. government 100 million doses of the vaccine candidate. Funding under the USG Agreement is 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 is 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. In July 2022, the Company entered into a modification to the USG Agreement that amended the terms of such agreement to provide for (i) an initial delivery to the U.S. government of approximately 3 million doses of NVX-CoV2373 and (ii) any additional manufacture and delivery to the U.S. government up to an aggregate of 100 million doses of NVX-CoV2373 contemplated by the original USG Agreement (inclusive of the initial batch of approximately 3 million doses) dependent on U.S. government demand, FDA guidance on strain selection, agreement between the parties on the price of such doses, and available funding. The 3 million initial doses were delivered in July 2022. The performance period under the Project Agreement extends through 2023 to cover clinical trial activities, subject to early termination by the U.S. government or extension by mutual agreement of the parties.

Under the USG Agreement, the Company was originally entitled to funding of up to $1.75 billion to support certain activities related to the development of NVX-CoV2373 and the manufacture and delivery of the vaccine candidate to the U.S. government. In subsequent modifications, the Company's USG Agreement was amended to increase the contract funding and ceiling to $1.8 billion, which allows the Company to make expenditures or incur obligations of up to $1.8 billion for support of the USG Agreement. As of December 31, 2022, the Company had recognized $1.4 billion in revenue related to the USG Agreement since the inception of the contract, leaving $0.4 billion remaining to spend.

U.S. Department of Defense

In June 2020, the Company entered into a letter contract that was later amended in January 2021 (the "DoD Contract") with the DoD Joint Program Executive Office for Chemical, Biological, Radiological and Nuclear Defense ("JPEO-CRBND-EB"), under which JPEO-CRBND-EB agreed to provide funding of up to $45.7 million to the Company to support the manufacture of NVX-CoV2373. The Company is authorized to make expenditures or incur obligations up to the full amount of the funding.

Under the DoD Contract, the Company originally expected to deliver 10 million doses of NVX-CoV2373 to the DoD. The 10 million doses of NVX-CoV2373 could be used in Phase 2/3 clinical trials or under an EUA, if approved by the FDA. Pursuant to the DoD Contract, after NVX-CoV2373 is approved by the FDA, the DoD is entitled to most-favored customer status for a period of five years from the award of the DoD Contract, meaning that the Company cannot give any comparable commercial client in the United States more favorable pricing than the DoD under similar transactional circumstances. In July 2022, the Company modified its existing agreement with the DoD and delivered 0.2 million doses of NVX-CoV2373 after receipt of EUA approval from the FDA, with delivery of the remaining 9.8 million doses of NVX-CoV2373 contemplated by the original agreement subject to DoD demand and available funding. The term of the DoD Contract expired in December 2022.

Coalition for Epidemic Preparedness Innovations

In May 2020, the Company entered into a restated funding agreement which was amended in November 2020 with CEPI, under which CEPI agreed to provide funding of up to $399.5 million to the Company to support the development of NVX-CoV2373. The agreement provides up to $257.0 million in CEPI Grant Funding and up to $142.5 million in CEPI Forgivable Loan Funding, which are loans in the form of one or more forgivable no-interest term loans in order to prepay certain manufacturing activities and are not subject to restrictive or financial covenants. As of December 31, 2022 and 2021, the Company had recognized total revenue related to CEPI of $358.6 million, with the unused amounts primarily related to CEPI Forgivable Loan Funding. Payments received under the CEPI Forgivable Loan Funding are only repayable if NVX-CoV2373 manufactured by the CMO network funded by CEPI is sold to one or more third parties (which would have previously included, but is not limited to, any sales under the Company's Gavi APA prior to its termination), and such sales cover the Company's costs of manufacturing such vaccine, not including manufacturing costs funded by CEPI. The timing and amount of any loan repayments is currently uncertain.

Royalties and Other

For the years ended December 31, 2022 and 2021, the Company recognized $9.0 million and $178.6 million, respectively, in revenue related to sales-based royalties, which is reflected in Royalties and other revenue. For the years ended December 31, 2022 and 2020, the Company recognized $20.0 million upon the sale of NVX-CoV2373 in Japan and $20.0 million related to a development milestone payment, respectively.

Note 4 – Collaboration and License Agreements

Serum Institute

The Company has granted SIIPL exclusive and non-exclusive licenses for the development, co-formulation, filling and finishing, registration, and commercialization of NVX-CoV2373. SIIPL agreed to purchase the Company's Matrix-M™ adjuvant and the Company granted SIIPL a non-exclusive license to manufacture the antigen drug substance component of NVX-CoV2373 in SIIPL's licensed territory solely for use in the manufacture of NVX-CoV2373. The Company and SIIPL equally split the revenue from SIIPL's sale of NVX-CoV2373 in its licensed territory, net of agreed costs. The Company granted to SIIPL (i) an exclusive license in India during the agreement and (ii) a non-exclusive license (a) during the "Pandemic Period" (as declared by the WHO) in all countries other than specified countries designated by the World Bank as upper-middle or high-income countries, with respect to which the Company retains rights, and (b) after the Pandemic Period, in only those countries designated as low or middle-income by the World Bank. Following the Pandemic Period, the Company may notify SIIPL of any bona fide opportunities for the Company to license NVX-CoV2373 to a third party in such low and middle-income countries and SIIPL would have an opportunity to match or improve such third-party terms, failing which, the Company would have the discretion to remove one or more non-exclusive countries from SIIPL's license. The Company also has a supply agreement with SIIPL and SLS under which SIIPL and SLS supply the Company with NVX-CoV2373 for commercialization and sale in certain territories, as well as a contract development manufacture agreement with SLS, under which SLS manufactures and supplies finished vaccine product to the Company using antigen drug substance and Matrix-M™ adjuvant supplied by the Company. In May and August 2022, the Company expanded its license and supply arrangements with SIIPL to include its proprietary COVID-19 variant antigen candidate(s), its quadrivalent influenza vaccine candidate, and its CIC vaccine candidate, so that SIIPL can manufacture and commercialize a vaccine targeting COVID-19 variants, including the Omicron subvariants, a quadrivalent influenza vaccine, and CIC vaccine, and supply such vaccines to the Company. In March 2020, the Company granted SIIPL a non-exclusive license for the use of Matrix-M™ adjuvant supplied by the Company to develop, manufacture, and commercialize R21, a malaria candidate developed by the Jenner Institute, University of Oxford.

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 NVX-CoV2373 in Japan. Under the agreement, Takeda purchases Matrix-M™ adjuvant from the Company to manufacture doses of NVX-CoV2373 and the Company is entitled to receive 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 NVX-CoV2373. In September 2021, Takeda finalized an agreement with the Government of Japan's Ministry of Health, Labour and Welfare ("MHLW") for the purchase of 150 million doses of NVX-CoV2373. In February 2023, MHLW cancelled the remainder of doses under its agreement with Takeda. As a result, it is uncertain whether the Company will receive future payments from Takeda under the terms and conditions of their current collaboration and licensing agreement. For the years ended December 31, 2022 and 2020, the Company recognized $20.0 million upon the sale of NVX-CoV2373 in Japan and $20.0 million related to a development and commercial milestone payment, respectively, which are included in Royalties and other revenue on the consolidated statements of operations.

SK bioscience, Co., Ltd.

The Company has a collaboration and license agreement with SK bioscience, Co., Ltd. ("SK bioscience") to manufacture and commercialize NVX-CoV2373 for sale to the governments of South Korea, Thailand, and Vietnam. SK bioscience finalized an APA with the Korean government to supply 40 million doses of NVX-CoV2373 to the Republic of Korea beginning in 2021. SK bioscience pays a royalty in the low to middle double-digit range. Additionally, the Company has a manufacturing supply arrangement with SK bioscience under which SK bioscience supplies the Company with the antigen component of NVX-CoV2373 for use in the final drug product globally, including product to be distributed by the COVAX Facility, which was established to allocate and distribute vaccines equitably to participating countries and economies. In July 2022, the Company signed an additional agreement with SK bioscience for the technology transfer of the Company's proprietary COVID-19 variant antigen materials so that SK bioscience can manufacture the drug substance targeting COVID-19 variants, including the Omicron subvariants. The companies also signed an agreement to manufacture and supply NVX-CoV2373 in a prefilled syringe.

Other Supply Agreements

On September 30, 2022, 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 "Fujifilm Settlement Agreement") regarding amounts due to Fujifilm in connection with the termination of manufacturing activity at FDBT under the Commercial Supply Agreement (the "Fujifilm CSA") dated August 20, 2021 and Master Services Agreement dated June 30, 2020 and associated statements of work (the "Fujifilm MSA") by and between the Company and Fujifilm. The Fujifilm MSA and Fujifilm CSA established the general terms and conditions applicable to Fujifilm's manufacturing and supply activities related to NVX-CoV2373 under the associated statements of work.

Pursuant to the Fujifilm Settlement Agreement, the Company is responsible for payment of up to $185.0 million (the "Settlement Payment") to Fujifilm in connection with cancellation of manufacturing activity at FDBT under the Fujifilm CSA, of which (i) $47.8 million, constituting the initial reservation fee under the Fujifilm CSA, was credited against the Settlement Payment on September 30, 2022 and (ii) the remaining balance is to be paid in four equal quarterly installments of $34.3 million each beginning March 31, 2023. As of December 31, 2022, the remaining payment of $137.2 million was reflected in Accrued expenses. Under the Fujifilm Settlement Agreement, Fujifilm is required to use commercially reasonable efforts to mitigate the losses associated with the vacant manufacturing capacity caused by the termination of manufacturing activities at FDBT under the Fujifilm CSA, and the final two quarterly installments will be mitigated by any replacement revenue achieved by Fujifilm between July 1, 2023 and December 31, 2023. The Settlement Payment is less than amounts previously recognized as embedded lease expense and reflected in Research and development expense from FDBT manufacturing activity under the Fujifilm CSA prior to the Fujifilm Settlement Agreement and accordingly, during the year ended December 31, 2022, the Company recorded a benefit of $98.3 million as Research and development expense (see Note 10).

Except with respect to certain limited activities agreed upon by the parties, the Fujifilm MSA terminated with respect to all activities in FDBU and FDBT on October 21, 2022 and the impact of the termination was determined in accordance with the provisions of the Fujifilm MSA. The terms and conditions of the Fujifilm MSA and Fujifilm CSA will remain in full force and effect with respect to the ongoing activities at FDBK. In addition, the Company and Fujifilm mutually released all claims relating to (i) the cancellation of batches to be manufactured at FDBT under the Fujifilm MSA or Fujifilm CSA, (ii) FDBT facility idle time in 2022, (iii) failure to complete product performance qualification testing of batches manufactured by Fujifilm by December 2021, and (iv) any obligation by Fujifilm to reserve capacity or manufacture batches at FDBT for the benefit of the Company under the Fujifilm MSA or Fujifilm CSA.

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, NVX-CoV2373, and, as a result, 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 in 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,		
	2022	2021	2020
Cash and cash equivalents	$ 1,336,883	$ 1,515,116	$ 553,398
Restricted cash current	10,303	11,490	93,880
Restricted cash non-current[1]	1,659	1,653	1,460
Cash, cash equivalents, and restricted cash	$ 1,348,845	$ 1,528,259	$ 648,738

(1) Classified as Other non-current assets as of December 31, 2022 and 2021.

Note 6 – 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, 2022			Fair Value at December 31, 2021		
	Level 1	Level 2	Level 3	Level 1	Level 2	Level 3
Assets						
Money market funds[1]	$ 398,834	$ —	$ —	$ 361,822	$ —	$ —
Government-backed securities[1]	—	296,000	—	—	266,250	—
Corporate debt securities[1]	—	—	—	—	790,672	—
Agency securities[1]	—	104,536	—	—	—	—
Total cash equivalents	$ 398,834	$ 400,536	$ —	$ 361,822	$ 1,056,922	$ —
Liabilities						
3.75% Convertible notes due 2023	$ —	$ 322,111	$ —	$ —	$ 447,509	$ —
5.00% Convertible notes due 2027	—	172,789	—	—	—	—
Total convertible notes payable	$ —	$ 494,900	$ —	$ —	$ 447,509	$ —

(1) All investments are classified as Cash and cash equivalents as of December 31, 2022 and 2021, 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, 2022 and 2021, the Company did not have any transfers between Levels.

The amount in the Company's consolidated balance sheets for accounts payable and accrued expenses approximates its fair value due to its short-term nature.

Note 7 – Inventory

Inventory consisted of the following (in thousands):

	December 31,	
	2022	2021
Raw materials	$ 13,912	$ 8,872
Semi-finished goods	21,410	—
Finished goods	1,361	—
Total inventory	$ 36,683	$ 8,872

Inventory write-downs as a result of excess, obsolescence, expiry, or other reasons, and losses on firm purchase commitments are recorded as a component of Cost of sales in the consolidated statements of operations. For the year ended December 31, 2022, inventory write-downs were $447.6 million and losses on firm purchase commitments were $155.9 million. There were no inventory write-downs or losses on firm purchase commitments during 2021 or 2020. 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, 2022
Balance at January 1, 2022	$ —
Charged to Cost of sales, including impairments	447,597
Other additions	—
Deductions	(79,214)
Balance at December 31, 2022	$ 368,383

Note 8 – Goodwill

The change in the carrying amounts of goodwill was as follows (in thousands):

	Year Ended December 31,	
	2022	2021
Beginning balance	$ 131,479	$ 135,379
Currency translation adjustments	(5,148)	(3,900)
Ending balance	$ 126,331	$ 131,479

Note 9 – Acquisition of Novavax CZ

On May 27, 2020 (the "Acquisition Date"), the Company entered into a Share Purchase Agreement (the "Deed") by and among Novavax AB, the Company's wholly-owned Swedish subsidiary (the "Buyer"), and De Bilt Holdings B.V., Poonawalla Science Park B.V., and Bilthoven Biologicals B.V. and, solely as guarantors, each of Serum International B.V. and the Company. Pursuant to the terms and conditions of the Deed, the Buyer acquired all the issued and outstanding shares of Novavax CZ (formerly, Praha Vaccines a.s.), a vaccine manufacturing company (the "Acquisition"). The assets of Novavax CZ acquired as part of the Acquisition include a biologics manufacturing facility and associated assets in Bohumil, Czech Republic and will be used by the Company to expand its manufacturing capacity.

Allocation of Purchase Price to Assets Acquired and Liabilities Assumed

The Company has accounted for the Acquisition as a business combination using the acquisition method of accounting, with the Company as the acquirer. The acquisition method requires the Company to record the assets acquired and liabilities assumed at fair value. The amount by which the purchase price exceeds the fair value of net assets acquired is recorded as goodwill. The Company completed the appraisal process necessary to assess the fair values of the assets acquired and liabilities assumed to determine the amount of goodwill to be recognized as of the Acquisition Date. The final determination of the fair value of all assets and liabilities was completed in 2020 and is presented in the table below.

The table below summarizes the final allocation of the purchase price based upon the fair values of assets acquired and liabilities assumed (in thousands):

	May 27, 2020
Prepaid expense and other current assets	$ 326
Property and equipment	96,739
Goodwill	70,662
Accounts payable	(1,193)
Accrued expenses	(205)
Other non-current liabilities	(813)
Purchase price, net of cash acquired	$ 165,516

The fair value of the assets acquired and liabilities assumed was determined using market and cost valuation methodologies. The fair value measurements were based on significant unobservable inputs that were developed by the Company using publicly available information, market participant assumptions, and cost and development assumptions. Because of the use of significant unobservable inputs, the fair value measurements represent a Level 3 measurement as defined in ASC 820. The market approach is a valuation technique that uses prices and other relevant information generated by market transactions involving identical or comparable assets, liabilities, or a group of assets or liabilities. The cost approach estimates value by determining the current cost of replacing an asset with another of equivalent utility. The cost to replace a given asset reflects the estimated reproduction or replacement cost for the property, less an allowance for loss in value due to depreciation.

The cost approach was the primary approach used to value fixed assets, including the real property. Fixed assets are depreciated on a straight-line basis over their expected remaining useful lives, ranging from four years to 25 years.

The Company recorded $70.7 million in goodwill related to the Acquisition representing the purchase price that was in excess of the fair value of the assets acquired and liabilities assumed. The goodwill generated from the Acquisition is not expected to be deductible for U.S. federal income tax purposes. The goodwill recognized is attributable to intangible assets that do not qualify for separate recognition, such as the assembled workforce of Novavax CZ.

Current assets and current liabilities were recorded at their contractual or historical acquisition amounts, which approximate their fair value.

Impact to Financial Results for the Year Ended December 31, 2020

The results of operations from Novavax CZ have been included in the consolidated financial statements since the Acquisition Date. As a result, the consolidated financial results for the year ended December 31, 2020 does not reflect a full twelve months of Novavax CZ results. From the Acquisition Date through December 31, 2020, Novavax CZ did not recognize any revenue and recorded a net loss from operations of $11.3 million.

The Company incurred approximately $2.7 million of costs related to the Acquisition in the year ended December 31, 2020, which are included within general and administrative expenses in the consolidated statements of operations.

Supplemental Pro Forma Financial Information (Unaudited)

The unaudited pro forma financial information below gives effect to the Acquisition as if it had occurred as of January 1, 2019. The pro forma financial information is presented for informational purposes only and is not necessarily indicative of the results of operations that would have been achieved had the Acquisition been consummated as of that time. The unaudited pro forma financial information combines the historical results of operations of the Company and Novavax CZ and reflects the application of certain pro forma adjustments (in thousands, except per share amounts):

	Year Ended December 31, 2020
Revenue	$ 475,598
Net loss	(419,896)
Basic and diluted net loss per share	$ (7.04)

Pro forma adjustments include the recognition of depreciation expense based on the Acquisition Date fair value and remaining useful lives of Novavax CZ fixed assets (net of historical depreciation expense) and the elimination of costs related to the Acquisition, which are non-recurring in nature.

Note 10 – Leases

The Company has embedded leases related to multiple manufacturing supply agreements with CMOs and CDMOs to manufacture NVX-CoV2373, as well as operating leases for its research and development and manufacturing facilities, corporate headquarters and offices, and certain equipment.

During the years ended December 31, 2022 and 2021, 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, 2022, the Company recognized ROU assets and a corresponding long-term operating lease liability on the remeasurement of modified supply agreements. During the year ended December 31, 2021, for leases that were previously determined to represent short-term embedded leases, modifications did not result in a change in lease classification.

During 2022 and 2021, as a result of new or modified leases, the Company recognized ROU assets, net of credits on modifications, of $18.6 million and $144.4 million, respectively, for its finance leases and long-term operating leases embedded in CMO and CDMO manufacturing supply agreements. The Company expensed the ROU assets since they related to research and development activities for the development of NVX-CoV2373 for which the Company did not have an alternative future use.

During 2022 and 2021, the Company entered into and extended various facility lease agreements related to research and development facilities and office space. During 2020, the Company entered into a lease agreement for the premises located at 700 Quince Orchard Road, Gaithersburg, Maryland ("700QO"). The lease is for approximately 170,000 square feet of space that the Company intends to use for manufacturing, research and development, and offices. The term of the lease is 15 years with options to extend the lease that have not been recognized in the ROU asset. The lease provides for an annual base rent of $5.8 million that is subject to future rent increases and obligates the Company to pay building operating costs. During the year ended December 31, 2022, the Company obtained the right to direct the use of, and obtain substantially all of the benefit from, certain floors located at the premises and recognized an ROU asset and related lease obligation of $73.2 million as lease commencement for accounting purposes had occurred. As of December 31, 2022 and 2021, the Company had incurred $49.0 million and $36.4 million, respectively, related to tenant improvement costs to be recognized as a ROU asset. The Company anticipates that it will incur additional tenant improvement costs, net of a landlord contribution of $9.8 million, through 2023 to bring the remainder of the building to the condition necessary for its intended use.

As of December 31, 2022, facility leases, excluding the 700QO lease, have expirations that range from approximately three to nine 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.

Supplemental balance sheet information related to leases as of December 31, 2022 and 2021 was as follows (in thousands, except weighted-average remaining lease term and discount rate):

Lease Assets and Liabilities	Classification	December 31, 2022	December 31, 2021
Assets:			
ROU assets, operating, net	Right of use asset, net	$ 36,384	$ 40,123
ROU assets, finance, net	Right of use asset, net	69,857	—
Total non-current ROU assets		$ 106,241	$ 40,123
Liabilities:			
Current portion of operating lease liabilities	Other current liabilities	$ 16,867	$ 30,983
Current portion of finance lease liabilities	Current portion of finance lease liabilities	27,196	130,533
Total current lease liabilities		$ 44,063	$ 161,516
Non-current portion of operating lease liabilities	Other non-current liabilities	$ 50,085	$ 39,116
Non-current portion of finance lease liabilities	Non-current finance lease liabilities	31,238	—
Total non-current lease liabilities		$ 81,323	$ 39,116
Weighted-average remaining lease term (years):			
Operating leases		4.6	5.0
Finance leases		8.3	3.7
Weighted-average discount rate:			
Operating leases		6.4%	6.0%
Finance leases		5.4%	5.2%

Lease expense for the operating and short-term leases for the years ended December 31, 2022, 2021, and 2020 was as follows (in thousands):

	Year Ended December 31, 2022	2021	2020
Operating lease expense	$ 6,903	$ 37,027	$ 2,462
Short-term lease expense	94,726	468,210	66,805
Variable lease expense	6,836	116,435	4,854
Finance lease expense:			
ROU assets expensed	$ 7,759	$ 112,528	$ 242,009
Interest expense	1,472	7,241	3,097
Total finance lease expense	$ 9,231	$ 119,769	$ 245,106

Supplemental cash flow information related to leases for the year ended December 31, 2022, 2021, and 2020 was as follows (in thousands):

	Year Ended December 31, 2022	2021	2020
Cash paid for amounts included in the measurement of lease liabilities:			
Operating cash flows used in operating leases	$ 190,158	$ 203,991	$ 63,634
Operating cash flows used in finance leases	1,472	7,241	3,097
Financing cash flows used in finance leases	93,595	127,907	96,065
ROU assets obtained in exchange for operating lease obligations	$ 30,675	$ 66,682	$ 5,590
ROU assets obtained in exchange for finance lease obligations	73,240	112,528	242,009

As of December 31, 2022, maturities of lease liabilities were as follows (in thousands):

Year	Amount
2023	$ 47,335
2024	24,589
2025	10,446
2026	10,509
2027	10,250
Thereafter	46,562
Total minimum lease payments	149,691
Less: imputed interest	(24,305)
Total lease liabilities	$ 125,386

Note 11 – Long-Term Debt

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

	December 31,	
	2022	2021
Current portion:		
3.75% Convertible notes due 2023	$ 325,000	$ —
Unamortized debt issuance costs	(119)	—
Total current convertible notes payable	$ 324,881	$ —
Non-current portion:		
5.00% Convertible notes due 2027	$ 175,250	$ —
3.75% Convertible notes due 2023	—	325,000
Unamortized debt issuance costs	(8,784)	(1,542)
Total non-current convertible notes payable	$ 166,466	$ 323,458

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

	Year Ended December 31,		
	2022	2021	2020
Coupon interest	$ 12,542	$ 12,188	$ 12,188
Amortization of debt issuance costs	1,497	1,424	1,424
Total interest expense on convertible notes payable	$ 14,039	$ 13,612	$ 13,612

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 (see Note 13). 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 (see Note 13). 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 815-40, *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, 2022.

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 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 concurrent common stock offering, as well as cash on hand.

The 2023 Notes were issued pursuant to an indenture dated January 29, 2016 (the "2023 Indenture") between the Company and the trustee. The Company received $315.0 million in net proceeds from the offering after deducting underwriting fees and offering expenses. The 2023 Notes bore cash interest at a rate of 3.75%, payable on February 1 and August 1 of each year. The 2023 Notes were not redeemable prior to maturity and were convertible into shares of the Company's common stock. As a result of the Company's one-for-twenty reverse stock split in 2019 and pursuant to Section 14.04(a) of the 2023 Indenture, the 2023 Notes were initially convertible into approximately 2,385,800 shares of the Company's common stock based on the initial conversion rate of 7.3411 shares of the Company's common stock per $1,000 principal amount of the 2023 Notes. This represents an initial conversion price of approximately $136.20 per share of the Company's common stock, representing an approximate 22.5% conversion premium based on the last reported sale price of the Company's common stock of $111.20 per share on January 25, 2016. In addition, the holders of the 2023 Notes may have required the Company to repurchase the 2023 Notes at par value plus accrued and unpaid interest following the occurrence of a Fundamental Change (as described in the 2023 Indenture). If a holder of the 2023 Notes converted upon a Make-Whole Adjustment Event (as described in the 2023 Indenture), they may have been eligible to receive a make-whole premium through an increase to the conversion rate up to a maximum of 8.9928 shares per $1,000 principal amount of 2023 Notes (subject to other adjustments as described in the 2023 Indenture).

The 2023 Notes are accounted for in accordance with ASC 470-20, *Debt with Conversion and Other Options* ("ASC 470-20") and ASC 815-40. Under ASC 815-40, to qualify for equity classification (or non-bifurcation, if embedded) the instrument (or embedded feature) must be both (1) indexed to the issuer's stock and (2) meet the requirements of the equity classification guidance. Based upon the Company's analysis, it was determined the 2023 Notes do contain embedded features indexed to its own stock, but do not meet the requirements for bifurcation, and therefore do not need to be separately accounted for as an equity component. Since the embedded conversion feature meets the equity scope exception from derivative accounting, and also since the embedded conversion option does not need to be separately accounted for as an equity component under ASC 470-20, the proceeds received from the issuance of the convertible debt were recorded as a liability on the consolidated balance sheets.

In connection with the issuance of the 2023 Notes, the Company also paid $38.5 million, including expenses, to enter into privately negotiated capped call transactions with certain financial institutions (the "capped call transactions"). The capped call transactions expired by their terms on January 27, 2023. The capped call transactions were generally expected to reduce the potential dilution upon conversion of the 2023 Notes in the event that the market price per share of the Company's common stock, as measured under the terms of the capped call transactions, was greater than the strike price of the capped call transactions, which initially corresponded to the conversion price of the 2023 Notes, and was subject to anti-dilution adjustments generally similar to those applicable to the conversion rate of the 2023 Notes. The cap price of the capped call transactions was initially $194.60 per share, which represented a premium of approximately 75% based on the last reported sale price of the Company's common stock of $111.20 per share on January 25, 2016, and was subject to certain adjustments under the terms of the capped call transactions. If, however, the market price per share of the Company's common stock, as measured under the terms of the capped call transactions, exceeded the cap price, there would nevertheless have been dilution upon conversion of the 2023 Notes to the extent that such market price exceeded the cap price. The Company evaluated the capped call transactions under ASC 815-10, *Derivatives and Hedging – Overall* and determined that they should be accounted for as a separate transaction and that the capped call transactions would be classified as an equity instrument.

The Company incurred approximately $10.0 million of debt issuance costs in 2016 relating to the issuance of the 2023 Notes, which were recorded as a reduction to the 2023 Notes on the consolidated balance sheet. The $10.0 million of debt issuance costs was amortized and recognized as additional interest expense over the seven-year contractual term of the 2023 Notes on a straight-line basis, which approximated the effective interest rate method. The Company also incurred $0.9 million of expenses related to the capped call transactions, which were recorded as a reduction to additional paid-in-capital.

Note 12 – Preferred Stock

In June 2020, the Company entered into a redeemable Series A Convertible Preferred Stock Subscription Agreement, pursuant to which the Company agreed to issue and sell in a private placement 438,885 shares of its newly designated redeemable Series A Convertible Preferred Stock, par value $0.01 per share ("Preferred Stock"), at a purchase price of $455.70 per share, for total gross proceeds of $200.0 million. During the fourth quarter of 2020, all outstanding shares of Preferred Stock were converted and the Company issued 4,388,850 shares of common stock, par value $0.01 per share, and reclassified $199.8 million from Preferred stock to Additional paid-in capital. The Company recognized a beneficial conversion feature of approximately $24.1 million at the time of issuance of the Preferred Stock that was recorded in Additional paid-in capital and Accumulated deficit as the Preferred Stock issuance was contingently redeemable and convertible at any time at the option of the holder.

Note 13 – Stockholders' Equity

In December 2022, the Company completed a public offering of 7,475,000 shares of its common stock, including 975,000 shares of common stock that were issued upon the exercise in full of the option to purchase additional shares granted to the underwriters, at a price of $10.00 per share resulting in net proceeds, net of offering costs of $4.9 million, of approximately $70 million. The Company completed this public offering concurrent with the issuance of the 2027 Notes (see Note 11).

In June 2021, the Company entered into an At Market Issuance Sales Agreement (the "June 2021 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. As of December 31, 2022, the remaining balance available under the June 2021 Sales Agreement was approximately $318 million. During the years ended December 31, 2022, 2021, and 2020, the Company sold 2.2 million, 2.6 million, and 32.4 million, respectively, of shares of its common stock resulting in net proceeds of approximately $179 million, $565 million, and $877 million, respectively, under its various At Market Issuance Sales Agreements.

Note 14 – Stock-Based Compensation

Equity Plans

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 14.8 million shares of common stock under equity awards granted under the 2015 Plan, which includes an increase of 2.4 million shares approved for issuance under the 2015 Plan at the Company's 2022 annual meeting of stockholders. All such shares authorized for issuance under the 2015 Plan have been reserved. The 2015 Plan will expire on March 4, 2025. As of December 31, 2022, there were 3.8 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 2015 Plan permits and the 2005 Plan permitted the grant of stock options (including incentive stock options), restricted stock, SARs, and RSUs. In addition, under the 2015 Plan, unrestricted stock, stock units, and performance awards may be granted. Stock options and SARs generally have a maximum term of 10 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 stock options are generally subject to vesting over periods ranging from 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,		
	2022	2021	2020
Cost of sales	$ 1,032	$ —	$ —
Research and development	66,565	86,928	55,955
Selling, general, and administrative	62,703	96,698	72,080
Total stock-based compensation expense	$ 130,300	$ 183,626	$ 128,035

Total stock-based compensation capitalized and included in inventory as of December 31, 2022 was $1.7 million. There was no stock-based compensation capitalized and included in inventory as of December 31, 2021.

As of December 31, 2022, there was approximately $171 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 1.1 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, 2022. 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, 2022, 2021, and 2020 was $21.4 million, $453.8 million, and $187.3 million, respectively.

Stock Options and Stock Appreciation Rights

The following is a summary of stock options and SARs activity under the 2015 Plan and the 2005 Plan for the year ended December 31, 2022:

	2015 Plan		2005 Plan	
	Stock Options	Weighted-Average Exercise Price	Stock Options	Weighted-Average Exercise Price
Outstanding at January 1, 2022	3,635,837	$ 42.60	68,225	$ 109.52
Granted	633,626	$ 65.32	—	$ —
Exercised	(134,222)	$ 15.64	(3,000)	$ 31.10
Canceled	(81,951)	$ 90.83	(1,500)	$ 121.00
Outstanding at December 31, 2022	4,053,290	$ 46.07	63,725	$ 112.94
Shares exercisable at December 31, 2022	2,892,161	$ 39.58	63,725	$ 112.94

The fair value of stock options granted under the 2015 Plan was estimated at the date of grant or the date upon which the 2015 Plan was approved by the Company's stockholders for certain stock options granted in 2020 and 2019 using the Black-Scholes option-pricing model with the following assumptions:

	Year Ended December 31,		
	2022	2021	2020
Weighted average Black-Scholes fair value of stock options and SARs granted	$55.32	$158.02	$80.48
Risk-free interest rate	1.4%-4.3%	0.5%-1.3%	0.2%-1.5%
Dividend yield	—%	—%	—%
Volatility	120.5%-140.1%	124.7%-142.0%	116.0%-152.2%
Expected term (in years)	4.0-6.3	4.1-6.1	3.9-7.6

The total aggregate intrinsic value and weighted-average remaining contractual term of stock options and SARs outstanding under the 2015 Plan and 2005 Plan as of December 31, 2022 was approximately $3 million and 7.1 years, respectively. The total aggregate intrinsic value and weighted-average remaining contractual term of stock options and SARs exercisable under the 2015 Plan and 2005 Plan as of December 31, 2022 was approximately $2 million and 6.6 years, respectively.

Restricted Stock Units

The following is a summary of RSU activity for the year ended December 31, 2022:

	Number of Shares	Per Share Weighted-Average Fair Value
Outstanding and unvested at January 1, 2022	819,828	$ 116.70
Restricted stock units granted	1,882,987	$ 48.51
Restricted stock units vested	(505,009)	$ 89.77
Restricted stock units forfeited	(163,232)	$ 99.58
Outstanding and unvested at December 31, 2022	2,034,574	$ 61.65

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 1.1 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 1.65 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, 2022, there were 0.7 million shares available for issuance under the ESPP.

The ESPP is considered compensatory for financial reporting purposes. As such, the fair value of ESPP shares was estimated at the date of grant using the Black-Scholes option-pricing model with the following assumptions:

	Year Ended December 31,		
	2022	2021	2020
Range of Black-Scholes fair values of ESPP shares granted	$23.59-$79.74	$83.47-$238.85	$2.57-$92.67
Risk-free interest rate	0.6%-3.3%	0.1%-0.2%	0.2%-2.6%
Dividend yield	—%	—%	—%
Volatility	103.0%-142.9%	114.9%-159.4%	66.6%-189.7%
Expected term (in years)	0.5-2.0	0.5-2.0	0.5-2.0

Note 15 – 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 $6.0 million, $3.4 million, and $0.9 million in 2022, 2021, and 2020, 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 this plan were $2.4 million, $1.7 million, and $1.0 million in 2022, 2021, and 2020, respectively.

Note 16 – Other Financial Information

Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consist of the following at December 31 (in thousands):

	December 31,	
	2022	2021
Prepaid expenses	$ 160,773	$ 120,029
Other current assets	76,374	44,619
Prepaid expenses and other current assets	$ 237,147	$ 164,648

Property and Equipment, net

Property and equipment is comprised of the following at December 31 (in thousands):

	December 31,	
	2022	2021
Land and buildings	$ 101,342	$ 83,534
Machinery and equipment	134,809	119,998
Leasehold improvements	18,895	10,282
Computer hardware	4,927	2,612
Construction in progress	81,566	35,114
	341,539	251,540
Less: accumulated depreciation	(47,292)	(25,799)
Property and equipment, net	$ 294,247	$ 225,741

As of December 31, 2022 and 2021, approximately $170.0 million and $164.0 million, respectively, of net assets used in operations were located in the Czech Republic. Depreciation expense was approximately $29.1 million, $12.5 million, and $4.3 million for the years ended December 31, 2022, 2021, and 2020, respectively.

Accrued Expenses

Accrued expenses consist of the following at December 31 (in thousands):

	December 31,	
	2022	2021
Employee benefits and compensation	$ 52,569	$ 38,419
Research and development accruals	468,214	577,100
Other accrued expenses	70,375	58,212
Accrued expenses	$ 591,158	$ 673,731

Other Current Liabilities

Other current liabilities consist of the following at December 31 (in thousands):

	December 31,	
	2022	2021
Refunds to customers	$ 210,362	$ —
Other current liability related to Gavi (see Note 3 and Note 18)	697,384	—
Other current liabilities	22,309	36,061
Total other current liabilities	$ 930,055	$ 36,061

Note 17 – Income Taxes

The Company's income (loss) from operations before income tax provision (benefit) by jurisdiction for the years ended December 31 are as follows (in thousands):

	Year Ended December 31,		
	2022	2021	2020
Domestic	$ (712,183)	$ (1,633,016)	$ (455,253)
Foreign	58,536	(81,520)	36,994
Loss before income tax expense	$ (653,647)	$ (1,714,536)	$ (418,259)

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

	Year Ended December 31,		
	2022	2021	2020
Domestic	$ 1,300	$ —	$ —
State and local	503	—	—
Foreign	2,489	29,215	—
Total current income tax expense	$ 4,292	$ 29,215	$ —

During the years ended December 31, 2022, 2021, and 2020, the Company recognized $4.3 million, $29.2 million, and no federal, state, and foreign current income tax expense. The foreign income tax expense is primarily related to foreign withholding tax on royalties. The Company recognized no deferred income tax expense during the years listed above due to a full valuation allowance.

A reconciliation of the provision for income tax 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,		
	2022	2021	2020
Statutory federal tax rate	21 %	21 %	21 %
State income taxes, net of federal benefit	2 %	6 %	3 %
Research and development and other tax credits	1 %	1 %	— %
Non-deductible expenses	(1) %	(2) %	(4) %
Non-cash stock-based compensation	(1) %	4 %	7 %
U.S. taxation of foreign operations	(3) %	— %	— %
Foreign tax expense	— %	(1) %	— %
Other	2 %	(1) %	(1) %
Change in tax rate	(20) %	— %	5 %
Change in valuation allowance	(2) %	(30) %	(31) %
Income tax provision	(1) %	(2) %	— %

As of December 31, 2022, the Company has available federal, state, and foreign net operating losses of $2.0 billion, $0.9 billion, and $29.1 million, respectively, that may be applied against future taxable income in the respective jurisdiction. The federal net operating losses of $2.0 billion can be carried forward indefinitely, although limited to 80% of annual taxable income. State net operating losses of $0.4 billion have various expiration dates between 2028 and 2042. The remaining state net operating losses of $0.5 billion can be carried forward indefinitely. Approximately $15.1 million of the foreign net operating losses will begin to expire in 2024 through 2027. The remaining $14.0 million of foreign net operating losses can be carried forward indefinitely. The Company also has research tax credits of $46.0 million that will begin to expire in 2030 through 2052. Utilization of the domestic net operating loss carryforwards and research tax credits may be subject to an annual limitation due to potential ownership changes of the Company. As of December 31, 2022, the Company does not expect such limitation, if any, to impact the use of these domestic 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 foreign jurisdictions such as 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 2022. The returns in Sweden are subject to examination from 2016 through 2022 and the returns for the Czech Republic are subject to examination from 2019 through 2022.

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

	December 31,	
	2022	2021
Deferred tax assets:		
Federal and state net operating loss carryforward	$ 479,134	$ 845,731
Foreign net operating loss carryforward	5,752	25,625
Research tax credits	45,560	44,618
Lease liability	27,625	52,852
Deferred revenue	195,049	20,262
Inventory reserve	213,076	—
Non-cash stock-based compensation	27,599	24,698
Original discount interest	—	1,729
Capitalized research costs	49,309	—
Other	13,695	11,801
Gross deferred tax assets	1,056,799	1,027,316
Valuation allowance	(1,020,123)	(1,015,333)
Total deferred tax assets	$ 36,676	$ 11,983
Deferred tax liabilities:		
ROU assets	(23,330)	(10,071)
Fixed assets	(11,587)	—
Intangibles	(1,055)	(1,034)
Other	(704)	(878)
Total deferred tax liabilities	$ (36,676)	$ (11,983)
Net deferred tax assets (liabilities)	$ —	$ —

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 asset. The Company concluded that realization of its net deferred tax assets is not more-likely-than-not to be realized as of December 31, 2022 and 2021. The valuation allowance increased by $4.8 million and $510.5 million for the years ended December 31, 2022 and 2021, respectively.

On a periodic basis, the Company reassesses the valuation allowance on its deferred income tax assets, weighing positive and negative evidence to assess the recoverability. In 2022, the Company reassessed the valuation allowance and considered negative evidence, including its cumulative losses over the three years ended December 31, 2022 and the substantial doubt about the Company's ability to continue as a going concern through one year from the date that these financial statements are issued, and positive evidence, including its regulatory authorizations for and commercial sales of NVX-CoV2373. After assessing both the negative and positive evidence, the Company concluded that it should maintain the valuation allowance on its net operating losses, credits, and its other deferred tax assets as of December 31, 2022. The release of the valuation allowance, as well as the exact timing and the amount of such release, continue to be subject to, among other things, the Company's level of profitability, revenue growth, clinical program progression, and expectations regarding future profitability. The Company's total net deferred tax asset balance subject to the valuation allowance was $1.1 billion and $1.0 billion as of December 31, 2022 and 2021, respectively.

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, 2022, 2021, and 2020 is as follows (in thousands):

	Year Ended December 31,		
	2022	2021	2020
Unrecognized tax benefits balance at January 1,	$ 11,154	$ 8,766	$ —
Additions for tax positions of current year	1,260	4,158	1,413
Additions for tax positions of prior years	807	—	7,353
Reductions for tax positions of prior year	(8,027)	(1,770)	—
Settlements of tax positions of prior years	—	—	—
Unrecognized tax benefits balance at December 31,	$ 5,194	$ 11,154	$ 8,766

The Company's policy is to recognize interest and penalties related to income tax matters in income tax expense. As of December 31, 2022 and 2021, the Company had no accruals for interest or penalties related to income tax matters. The total amount of unrecognized tax benefits that, if recognized, could affect the effective tax rate was $5.2 million and $11.2 million as of December 31, 2022 and 2021, respectively. However, the Company maintains a full valuation allowance as of December 31, 2022 and 2021 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, 2022, the Company does not expect a significant change in the recorded unrecognized tax benefits reserve 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.

Note 18 – Commitment and Contingencies

Legal Matters

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"). On January 26, 2022, the Maryland Court entered an order designating David Truong, Nuggehalli Balmukund Nandkumar, and Jeffrey Gabbert as co-lead plaintiffs in the Sinnathurai Action. The co-lead plaintiffs filed a consolidated amended complaint on March 11, 2022, alleging that the defendants made certain purportedly false and misleading statements concerning the Company's ability to manufacture NVX-CoV2373 on a commercial scale and to secure the NVX-CoV2373's regulatory approval. The amended complaint defines the purported class as those stockholders who purchased the Company's securities between February 24, 2021 and October 19, 2021. On April 25, 2022, defendants filed a motion to dismiss the consolidated amended complaint. On December 12, 2022, the Maryland Court issued a ruling granting in part and denying in part defendants' motion to dismiss. The Maryland Court dismissed all claims against two individual defendants and claims based on certain public statements challenged in the consolidated amended complaint. The Maryland Court denied the motion to dismiss as to the remaining claims and defendants, and directed the Company and other remaining defendants to answer within fourteen days. On December 27, 2022, the Company filed its answer and affirmative defenses.

After the Sinnathurai Action was filed, seven 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. 8:22-cv-00024-TDC (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.* (the "Mesa Action"), and (vii) *Sean Acosta v. Stanley C. Erck, et al.* (the "Acosta 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 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.

On July 21, 2022, the Maryland Court issued a memorandum opinion and order remanding the Kirst Action to state court. On December 6, 2022, the parties to the Kirst Action filed a stipulated schedule pursuant to which the plaintiffs were expected to file an amended complaint on December 22, 2022, and either (i) the parties would file a stipulated stay of the Kirst Action or (ii) the defendants would file a motion to stay the case by January 23, 2023. 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 February 24, 2023, the Court entered an order staying the Kirst Action until a final judgment in the Second Consolidated Derivative Action. The Company takes no position on whether the broader stay entered by the Court in the Kirst Action is likely to be modified to align with the parties' stipulation.

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, the court entered an order granting the parties' request to set a briefing schedule in connection with a motion to stay that defendants intended to file. Pursuant to the order, defendants filed a motion to stay on January 18, 2023. The plaintiff filed his opposition on February 8, 2023. Defendants filed their reply on February 22, 2023. On February 28, 2023, the court granted Defendants' motion to 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. The financial impact of this claim, as well as the claims discussed above, is not estimable.

On February 26, 2021, a Company stockholder named Thomas Golubinski filed a derivative complaint against members of the Company's board of directors and members of senior management in the Delaware Court, captioned Thomas Golubinski v. Richard H. Douglas, et al., No. 2021-0172-JRS. The Company is deemed a nominal defendant. Golubinski challenged equity awards made in April 2020 and in June 2020 on the ground that they were "spring-loaded," that is, made at a time when such board members or members of senior management allegedly possessed undisclosed positive material information concerning the Company. The complaint asserted claims for breach of fiduciary duty, waste, and unjust enrichment. The plaintiff sought an award of damages to the Company, an order rescinding both awards or requiring disgorgement, and an award of attorneys' fees incurred in connection with the litigation. On May 10, 2021, the defendants moved to dismiss the complaint in its entirety. On June 17, 2021, the Company's stockholders voted FOR ratification of the April 2020 awards and ratification of the June 2020 awards. Details of the ratification proposals are set forth in the Company's Definitive Proxy Statement filed on May 3, 2021. The results of the vote were disclosed in the Company's Current Report on Form 8-K filed on June 24, 2021. Thereafter, the plaintiff stipulated that, as a result of the outcome of the June 17, 2021 vote, the plaintiff no longer intends to pursue the lawsuit or any claim arising from the April 2020 and June 2020 awards. On August 23, 2021, the plaintiff filed a motion seeking an award of attorneys' fees and expenses for $1.5 million, to which the defendants filed an opposition. On October 18, 2022, the Delaware Court denied the plaintiff's fee application in its entirety. Under a prior Delaware Court order, the case was automatically dismissed with prejudice upon denial of the plaintiff's fee application. On November 14, 2022, Golubinski filed a Notice of Appeal in the Supreme Court of the State of Delaware. The plaintiff / appellant filed his opening appellate brief on December 30, 2022. The Company filed its responsive brief on January 30, 2023 and the appellant filed his reply brief on February 14, 2023.

On March 29, 2022, Par Sterile Products, LLC ("Par") submitted a demand for arbitration against the Company with the American Arbitration Association, alleging that the Company breached certain provisions of the Manufacturing and Services Agreement (the "Par MSA") that the Company entered into with Par in September 2020 to provide fill-finish manufacturing services for NVX-CoV2373. The matter is at a preliminary stage and therefore the potential loss is not reasonably estimable. The parties are engaged in discovery and arbitration is scheduled for July 2023. While the Company maintains that no breach of the Par MSA has occurred and intends to vigorously defend the matter, if the final resolution of the matter is adverse to the Company, it could have a material impact on the Company's financial position, results of operations, or cash flows.

On November 18, 2022, the Company delivered written notice to Gavi to terminate the Gavi APA based on Gavi's failure to procure the purchase of 350 million doses of NVX-CoV2373 from the Company as required by the Gavi APA. As of November 18, 2022, the Company had only received orders under the Gavi APA for approximately 2 million doses. On December 2, 2022, Gavi issued a written notice purporting to terminate the Gavi APA based on Gavi's contention that the Company repudiated the agreement and, therefore, materially breached the Gavi APA. Gavi also contends that, based on its purported termination of the Gavi APA, it is entitled to a refund of the Advance Payment Amount less any amounts that have been credited against the purchase price for binding orders placed by a buyer participating in the COVAX Facility. As of December 31, 2022, the remaining Gavi Advance Payment Amount of $697.4 million, pending resolution of the dispute with Gavi related to a return of the remaining Advance Payment Amount, was reclassified from Deferred revenue to Other current liabilities in the consolidated balance sheet. On January 24, 2023, Gavi filed a demand for arbitration with the International Court of Arbitration based on the claims described above. The Company's response is currently due by March 2, 2023. Arbitration is inherently uncertain, and while the Company believes that it is entitled to retain the remaining Advance Payment Amount received from Gavi, it is possible that the Company could be required to refund all or a portion of the remaining Advance Payment Amount from Gavi.

The Company is also involved in various legal proceedings arising in the normal course of business. Although the outcomes of these legal proceedings are inherently difficult to predict, management does not expect the resolution of these legal proceedings to have a material adverse effect on the Company's 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. A number of these arrangements are within the scope of lease accounting (see Note 10). 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, 2022, 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, 2022, the Company had no non-cancelable purchase commitments with a remaining term of more than one year.

Note 19 – Subsequent Events

On January 5, 2023, the Board of Directors of the Company approved the appointment of John C. Jacobs, as President and Chief Executive Officer and a member of the Board, effective as of January 23, 2023. Mr. Jacobs succeeded Stanley C. Erck, who provided the Board with notice on January 5, 2023 of his decision to retire as President and Chief Executive Officer and as a member of the Board, in each case effective as of January 23, 2023.

On January 24, 2023, Gavi filed a demand for arbitration with the International Court of Arbitration based on claims stemming from the Gavi APA. Arbitration is inherently uncertain, and while the Company believes that it is entitled to retain the remaining Advance Payment Amount received from Gavi, it is possible that it could be required to refund all or a portion of the remaining Advance Payment Amount from Gavi (see Note 3 and Note 18).

On January 31, 2023, the Company funded the outstanding principal amount of $325.0 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.

Leadership

Board of Directors

John C. Jacobs
President and Chief Executive Officer, Director

James F. Young, PhD
Chairman of the Board of Directors

Gregg H. Alton, JD
Director

Richard H. Douglas, PhD
Director

Rachel K. King
Director

Margaret G. McGlynn, R. Ph.
Director

David M. Mott
Director

Richard J. Rodgers, MBA
Director

Executive Leadership Team

John C. Jacobs
President and Chief Executive Officer, Director

Filip Dubovsky, MD
President, Research and Development

Rick Crowley
Executive Vice President, Chief Operations Officer

John A. Herrmann III, JD
Executive Vice President, Chief Legal Officer and Corporate Secretary

Jill Hoyt
Executive Vice President, Chief Human Resources Officer

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

John J. Trizzino
Executive Vice President, Chief Commercial Officer and Chief Business Officer

Troy Morgan, JD
Senior Vice President, Chief Compliance Officer

Corporate Information

Annual Meeting
June 15, 2023 at 8:30 a.m. EDT
Live virtual webcast link: www.virtualshareholdermeeting.com/NVAX2023

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.
21 Firstfield Road
Gaithersburg, MD 20878

Market Information
Novavax is traded on the NASDAQ Global Select Market under "NVAX"

We never rest in our quest to protect the health of people everywhere.