

# Novavax Reports First Quarter 2022 Financial Results and Operational Highlights

May 9, 2022

- Achieved revenue of \$704 million and net income of \$203 million highlighting the first profitable quarter as a commercial stage company
- Reiterating full year 2022 total revenue guidance of between \$4 and \$5 billion
- Continued label expansion including primary, booster and adolescent authorizations and new shipments of Nuvaxovid™ into European Union, Canada, South Korea, Australia, Thailand, Singapore and New Zealand
- Submitted request for EUA to U.S. FDA for NVX-CoV2373, with FDA Advisory Committee meeting scheduled for June 7<sup>th</sup>
- Announced positive Phase 1/2 results of COVID-19-Influenza Combination vaccine candidate confirming feasibility of approach
- Company to host conference call today at 4:30 p.m. ET

GAITHERSBURG, Md., May 9, 2022 /PRNewswire/ -- Novavax, Inc. (NASDAQ: NVAX), a biotechnology company dedicated to developing and commercializing next-generation vaccines for serious infectious diseases, today announced its financial results and operational highlights for the first quarter ended March 31, 2022.

"Novavax has been successful in launching our protein-based COVID-19 vaccine worldwide and executing on our plans for ongoing label expansions for pediatrics and homologous and heterologous boosting. Reinforced by our first profitable quarter, with \$704 million in revenue, we are continuing our robust commercial rollout." said Stanley C. Erck, President and Chief Executive Officer, Novavax. "Importantly, as new variants have emerged, we have progressed our strategy to be ready to address the dynamic environment and continue development beyond COVID-19 with our COVID-19-Influenza Combination vaccine candidate."

## First Quarter 2022 and Recent Highlights

### *Expanded Worldwide Authorizations for COVID-19 Primary and Booster Vaccination in Adult Population Aged 18+*

- Received manufacturing and marketing approval with our partner Takeda Pharmaceutical Company Limited, in Japan for Nuvaxovid for primary, heterologous and homologous boosting indications
- Granted authorization (emergency use, provisional, interim or conditional) for Nuvaxovid in Great Britain, Canada, Australia, Switzerland, Singapore and New Zealand
- Received full regulatory approval for Nuvaxovid in South Korea with our partner SK bioscience, becoming the first protein-based vaccine approved in South Korea
- Granted emergency use authorization (EUA) for Covovax™ with our partner the Serum Institute of India Pvt. Ltd. (SII) in Thailand and Bangladesh
- Submitted request for EUA to U.S. FDA and, with SII, filed for EUA in South Africa
  - FDA scheduled Vaccines and Related Biological Products Advisory Committee (VRBPAC) meeting for June 7<sup>th</sup>

### *Progressed COVID-19 Vaccine Regulatory Pathway for Children Aged 12-17 Years*

- Granted EUA for adolescents in India with SII for Covovax
- Submitted requests for authorization for Nuvaxovid in adolescents to the European Union, Great Britain, Australia and New Zealand
- Filed for approval of Nuvaxovid with SK bioscience, for adolescents in South Korea
- Additional global submissions planned throughout the second quarter of 2022

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

- Announced initial results of CIC Phase 1/2 trial, combining NVX-CoV2373 and quadrivalent influenza vaccine candidate
  - Immune response confirmed in stand-alone influenza vaccine candidate and CIC vaccine candidate with potential path forward for both
  - Demonstrated combined formulation has potential to reduce total antigen amount by up to 50% overall

- Expect to begin CIC Phase 2 trial by the end of 2022

### ***COVID-19 Vaccine Supply and Distribution***

- Delivered Nuvaxovid globally to European Union, Canada, Australia, Thailand, Singapore and New Zealand and with SK bioscience to South Korea

### ***COVID-19 Vaccine Clinical Development***

- UK Phase 3 study demonstrated ongoing durability of protection against infection and disease in long term follow-up (median of 101 days)
  - 82.5% efficacy in protection against all COVID-19 infection, as measured by PCR+ or anti-N seroconversion
  - 82.7% overall efficacy against disease
  - 100% efficacy against severe disease
- Continued rapid development and assessment of strain change, including Omicron-specific clinical studies with topline readout expected in third quarter of 2022
  - Evaluating benefit of Omicron-specific (BA.1 and BA.2) or bivalent vaccine compared to current prototype, with first doses expected this month
- Progressed South Africa Phase 2 study with ongoing administration in participants to evaluate a three-dose regimen and different dosing schedules in -immunocompromised participants, providing flexibility to national delivery programs
  - Topline results expected in fourth quarter of 2022
- Progressed PREVENT-19 Phase 3 study in adolescents aged 12-17 years
  - Achieved primary effectiveness endpoint and demonstrated comparability to adult population
  - Demonstrated 80% overall clinical efficacy and 82% efficacy against Delta variant
  - Vaccine was generally well-tolerated and safety profile was consistent with previous studies
  - Initiated booster study to evaluate safety and immunogenicity of a third dose
- Continued clinical trials in younger age groups to build on positive pediatric data
  - Expect to initiate PREVENT-19 Phase 3 trial in younger age groups (5-11 years) by third quarter of 2022
  - SII generated positive data from Phase 2/3 India study in children ages 2-17 years showing robust immune responses with favorable reactogenicity profiles
- Announced participation in Phase 1/2 heterologous booster study sponsored by National Institute of Allergy and Infectious Diseases
  - Evaluating safety, reactogenicity and immunogenicity of heterologous boosters in approximately 180 individuals aged 18 years or older
  - Topline results expected later this year and full results in 2023
- Announced participation in Phase 3 study in the United Arab Emirates evaluating boost with NVX-CoV2373 in participants who were immunized with an inactive COVID-19 vaccine in individuals aged 18 years or older

### **Financial Results for the Three Months Ended March 31, 2022**

- **Total revenue** for the first quarter of 2022 was \$704 million, compared to \$447 million for the comparable period in 2021. First quarter of 2022 total revenue includes \$605 million of revenue comprised of \$586 million of product sales from NVX-CoV2373 based on 31 million doses sold by Novavax and \$19 million of royalties and adjuvant sales to our license partners. Grant revenue of \$99 million in the first quarter of 2022 compared to \$447 million in the prior year resulted from a decrease in funding under our agreements with the U.S. government and with the Coalition for Epidemic Preparedness Innovations.
- **Cost of sales** for the first quarter of 2022 were \$15 million and 3% of product sales in the period. During 2021 and prior to receipt of regulatory authorizations for NVX-CoV2373, certain manufacturing costs were expensed to research and development that would otherwise have been capitalized to inventory.
- **Research and development expenses** for the first quarter of 2022 were \$383 million compared to \$593 million for the comparable period in 2021. The decrease was primarily the result of lower clinical development activities for NVX-CoV2373 and the capitalization of NVX-CoV2373 manufacturing costs during the first quarter of 2022.
- **Selling, general and administrative expenses** for the first quarter of 2022 were \$96 million compared to \$63 million for the comparable period in 2021. The increase in the period was the result of activities in support of the commercial launch of NVX-CoV2373.
- **Net income** for the first quarter of 2022 was \$203 million compared to a net loss of \$223 million for the comparable period in 2021.
- **Cash, cash equivalents, and restricted cash** were \$1.6 billion as of March 31, 2022, compared to \$1.5 billion as of December 31, 2021. Through sales of Novavax common stock pursuant to at-the-market (ATM) offerings during the first quarter of 2022, Novavax raised net proceeds of \$179 million.

## **Financial Guidance**

Novavax continues to expect to achieve its full year 2022 total revenue of between \$4 and \$5 billion. Total revenue reflects all sources, including product sales of Nuvaxovid by Novavax, grants revenue, royalties and other revenue.

## **Conference Call**

Novavax will host its quarterly conference call today at 4:30 p.m. ET. The dial-in numbers for the conference call are (833) 974-2381 (Domestic) or (412) 317-5774 (International). Participants will be prompted to request to join the Novavax, Inc. call. A replay of the conference call will be available starting at 7:30 p.m. ET on May 9, 2022 until 11:59 p.m. ET on May 16, 2022. To access the replay by telephone, dial (877) 344-7529 (Domestic) or (412) 317-0088 (International) and use passcode 9339969.

A webcast of the conference call can also be accessed on the Novavax website at [novavax.com/events](https://www.novavax.com/events). A replay of the webcast will be available on the Novavax website until August 9, 2022.

## **About NVX-CoV2373**

NVX-CoV2373 is a protein-based vaccine engineered from the genetic sequence of the first strain of SARS-CoV-2, the virus that causes COVID-19 disease. NVX-CoV2373 was created using Novavax' recombinant nanoparticle technology to generate antigen derived from the coronavirus spike (S) protein and is formulated with Novavax' patented saponin-based Matrix-M™ adjuvant to enhance the immune response and stimulate high levels of neutralizing antibodies. NVX-CoV2373 contains purified protein antigen and can neither replicate, nor can it cause COVID-19.

Novavax' COVID-19 vaccine is packaged as a ready-to-use liquid formulation in a vial containing ten doses. The vaccination regimen calls for two 0.5 ml doses (5 mcg antigen and 50 mcg Matrix-M adjuvant) given intramuscularly 21 days apart. The vaccine is stored at 2°- 8° Celsius, enabling the use of existing vaccine supply and cold chain channels. Use of the vaccine should be in accordance with official recommendations.

Novavax has established partnerships for the manufacture, commercialization and distribution of NVX-CoV2373 worldwide. Existing authorizations leverage Novavax' manufacturing partnership with Serum Institute of India (SII), the world's largest vaccine manufacturer by volume. They will later be supplemented with data from additional manufacturing sites throughout Novavax' global supply chain.

## **About Matrix-M™ Adjuvant**

Novavax' patented saponin-based 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.

## **About Novavax' Influenza Program**

Novavax' influenza vaccine, previously known as NanoFlu, is a quadrivalent recombinant hemagglutinin (HA) protein nanoparticle influenza vaccine produced by Novavax in its SF9 insect cell baculovirus system. The influenza vaccine uses HA amino acid protein sequences that are the same as the recommended wild-type circulating virus HA sequences, and contains Novavax' patented saponin-based Matrix-M adjuvant. This investigational candidate was evaluated during a controlled phase 3 trial conducted during the 2019-2020 influenza season.

## **About Novavax**

Novavax, Inc. (Nasdaq: NVAX) 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 proprietary recombinant technology platform harnesses the power and speed of genetic engineering to efficiently produce highly immunogenic nanoparticles designed to address urgent global health needs. NVX-CoV2373, the company's COVID-19 vaccine, has received conditional authorization from multiple regulatory authorities globally, including the European Commission and the World Health Organization. The vaccine is also under review by multiple regulatory agencies worldwide. In addition to its COVID-19 vaccine, Novavax is also currently evaluating a COVID-seasonal influenza combination vaccine candidate in a Phase 1/2 clinical trial, which combines NVX-CoV2373 and NanoFlu\*, its quadrivalent influenza investigational vaccine candidate. These vaccine candidates incorporate Novavax' proprietary saponin-based Matrix-M™ adjuvant to enhance the immune response and stimulate high levels of neutralizing antibodies.

For more information, visit [www.novavax.com](https://www.novavax.com) and connect with us on [Twitter](#), [LinkedIn](#), [Instagram](#) and [Facebook](#).

\*NanoFlu? identifies a recombinant hemagglutinin (HA) protein nanoparticle influenza vaccine candidate produced by Novavax. This investigational candidate was evaluated during a controlled phase 3 trial conducted during the 2019-2020 influenza season.

## Forward-Looking Statements

Statements herein relating to the future of Novavax, its operating plans and prospects, its partnerships, financial guidance, the timing of clinical trial results, the ongoing development of NVX-CoV2373, including Novavax' plans to initiate a pediatric study in Q2 2022, a COVID-19-Influenza combination vaccine candidate, including plans to initiate a Phase 2 clinical trial by the end of 2022, the scope, timing and outcome of future regulatory filings and actions, including Novavax' upcoming FDA Advisory Committee meeting and including Novavax' plans for additional global submissions throughout the second quarter of 2022, the potential impact of Novavax and NVX-CoV2373 in addressing vaccine access, controlling the pandemic and protecting populations, including the potential reach of NVX-CoV2373, the efficacy, safety and intended utilization of NVX-CoV2373 and COVID-19-Influenza combination vaccine candidate, and expected administration of NVX-CoV2373, including a Omicron-specific vaccine, are forward-looking statements. Novavax cautions that these forward-looking statements are subject to numerous risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statements. These 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; unanticipated challenges or delays in conducting clinical trials; difficulty obtaining scarce raw materials and supplies; resource constraints, including human capital and manufacturing capacity, on the ability of Novavax to pursue planned regulatory pathways; challenges meeting contractual requirements under agreements with multiple commercial, governmental, and other entities; and those other risk factors identified in the "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" sections of Novavax' Annual Report on Form 10-K for the year ended December 31, 2021, as filed with the Securities and Exchange Commission (SEC). We caution investors not to place considerable reliance on forward-looking statements contained in this press release. You are encouraged to read our filings with the SEC, available at [www.sec.gov](http://www.sec.gov) and [www.novavax.com](http://www.novavax.com), for a discussion of these and other risks and uncertainties. The forward-looking statements in this press release speak only as of the date of this document, and we undertake no obligation to update or revise any of the statements. Our business is subject to substantial risks and uncertainties, including those referenced above. Investors, potential investors, and others should give careful consideration to these risks and uncertainties.

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

	Three Months Ended	
	2022	2021
	March 31,	
	2022	2021
	(unaudited)	
Revenue:		
Product sales	\$ 585,628	\$ --
Grants	99,301	446,893
Royalties and other	19,042	336
Total revenue	<u>703,971</u>	<u>447,229</u>
Expenses:		
Cost of sales	15,204	--
Research and development	383,483	592,671
Selling, general, and administrative	95,992	63,190
Total expenses	<u>494,679</u>	<u>655,861</u>
Income (loss) from operations	209,292	(208,632)
Other income (expense):		
Interest income (expense)	(4,876)	(4,839)
Other income (expense)	1,654	(6,231)
Income (loss) before income tax expense	206,070	(219,702)
Income tax expense	2,662	3,017
Net income (loss)	<u>\$ 203,408</u>	<u>\$ (222,719)</u>

Net income (loss) per share		
Basic	\$ 2.66	\$ (3.05)
Diluted	\$ 2.56	\$ (3.05)
Weighted average number of common shares outstanding		
Basic	76,457	73,035
Diluted	80,711	73,035

**SELECTED CONSOLIDATED BALANCE SHEET DATA**  
(in thousands)

	March 31, 2022 (unaudited)	December 31, 2021
Cash and cash equivalents	\$ 1,570,954	\$ 1,515,116
Total restricted cash	13,146	13,143
Total current assets	2,347,405	2,155,119
Working capital	86,400	(235,200)
Total assets	2,834,875	2,576,753
Convertible notes payable*	323,814	323,458
Total stockholders' equity (deficit)	65,324	(351,673)

\* Included in current liabilities as of March 31, 2022 and non-current liabilities as of December 31, 2021

**Contacts:**

Investors

Alex Delacroix | 240-268-2022

[ir@novavax.com](mailto:ir@novavax.com)

Media

Alison Chartan | 240-720-7804

[media@novavax.com](mailto:media@novavax.com)

SOURCE Novavax, Inc.

Image not found or type unknown