

Novavax Reports Fourth Quarter and Full Year 2022 Financial Results and Operational Highlights

February 28, 2023

- *Achieved revenues in fourth quarter 2022 of \$357 million and full year 2022 of \$2.0 billion*
- *Appointed John C. Jacobs as President and Chief Executive Officer*
- *Updated U.S. government agreement to include up to 1.5 million additional doses of Novavax's COVID-19 vaccine for delivery in 2023*
- *Expanded Nuvaxovid™ label in adult booster and adolescent primary series*
- *Initiated Phase 2 trial of COVID-19-Influenza Combination and stand-alone influenza vaccine candidates*
- *Company to host conference call today at 4:30 p.m. ET*

GAITHERSBURG, Md., Feb. 28, 2023 /PRNewswire/ -- Novavax, Inc. (Nasdaq: NVAX), a global company advancing protein-based vaccines with its novel Matrix-M™ adjuvant, today announced its financial results and operational highlights for the fourth quarter and twelve months ended December 31, 2022.

"I am excited to be joining Novavax at this important time in the company's history," said John C. Jacobs, President and Chief Executive Officer, Novavax. "Much has been achieved over the past three years, and based on the foundation that has been laid to date, I believe that Novavax has significant potential for a bright future."

"Over the past few weeks, the management team and I have identified three near-term priorities that we believe are essential to our success this year and beyond: 1) to deliver a competitive product for the upcoming 2023 fall vaccination season; 2) to reduce our rate of spend, manage our cash flow, and evolve our scale and structure; and 3) to leverage our technology platform, our capabilities and our portfolio of assets to drive additional value beyond Nuvaxovid alone. We believe that if we succeed in executing against these priorities, we will position the company well for long-term success."

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

Corporate Highlights

- Appointed John C. Jacobs, President and Chief Executive Officer and a member of the Board of Directors, following the retirement of Stanley C. Erck, who served as President and Chief Executive Officer for 12 years
- Appointed Elaine O'Hara, Chief Strategy Officer, joining the organization to focus on business and corporate development, portfolio strategy and alliance management
- Reorganized executive leadership team to better align internal resources and operate more efficiently; key changes include:
 - Filip Dubovsky, Executive Vice President, assumes the role of President, Research & Development (R&D) following the retirement of Gregory M. Glenn, MD. Dr. Glenn will move into a consulting role as a strategic R&D advisor
 - Silvia Taylor, Executive Vice President, promoted to Chief Corporate Affairs and Advocacy Officer with expanded responsibilities for government affairs, policy and advocacy, in addition to her communications role
 - Troy Morgan, Chief Compliance Officer, remains in role and now reports directly to John C. Jacobs to elevate the company's focus on compliance
 - Jim Kelly, Chief Financial Officer, assumes responsibility for investor relations
- Strengthened Board of Directors with appointment of Rick Rodgers, adding extensive biopharmaceutical experience and financial leadership
- Raised \$250 million in concurrent convertible senior notes and common stock offerings

Fourth Quarter and Full Year 2022 Financial Results

- **Total revenue** for the fourth quarter 2022 was \$357 million and reflects 61% growth compared to \$222 million in the same period in 2021. Total revenue for the full year 2022 was \$1.9 billion and reflects 73% growth compared to \$1.1 billion in the same period in 2021. The growth in each period is the result of Nuvaxovid product sales that offset a decline in Grants, Royalties and Other Revenue and reflects the transition of Novavax to a commercial stage company.
- **Cost of sales** for the fourth quarter and full year 2022 were \$182 million and \$903 million, respectively. These periods included \$99 million and \$604 million, respectively, related to excess, obsolete, or expired inventory and losses on firm purchase commitments under our third-party supply agreements.
- **Research and development expenses** for the fourth quarter of 2022 were \$258 million as compared to \$963 million in the same period in 2021. Research and development expenses for the full year 2022 were \$1.2 billion compared to \$2.5 billion in the same period in 2021. The decrease in both periods was primarily due to a decrease in development activities relating to coronavirus vaccines and an increased amount of manufacturing network costs capitalized to inventory that previously were expensed to research and development.
- **Selling, general and administrative expenses** for the fourth quarter of 2022 were \$162 million compared to \$84 million for the same period in 2021. Selling, general and administrative expenses for the full year 2022 were \$489 million compared to \$298 million for the same period in 2021. Expenses in both periods increased due to the commencement of commercial sales operations in support of Novavax's COVID-19 vaccine program.
- **Net loss** for the fourth quarter 2022 was \$182 million as compared to a net loss of \$846 million in the same period in 2021. Net loss for the full year 2022 was \$658 million compared to a net loss of \$1.7 billion in the same period in 2021.
- **Cash, cash equivalents, and restricted cash** were \$1.3 billion as of December 31, 2022, compared to \$1.5 billion as of December 31, 2021. In December 2022, Novavax raised \$250 million gross proceeds in concurrent equity and convertible securities offerings. In January 2023, Novavax funded the maturity of its \$325 million convertible notes.

Financial Framework

In 2023, Novavax intends to focus the organization to align our investments and activities with our top priority of delivering an updated Covid-19 vaccine consistent with public health recommendations for strain composition for the 2023 fall vaccination season. To maximize our opportunities and mitigate the significant risks and uncertainties of the COVID-19 market, our goal is to reduce spend, extend our cash runway and operate efficiently to best position the company to deliver long-term growth.

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. Given 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.

The accompanying condensed consolidated financial statements have been prepared assuming Novavax will continue as a going concern. A more detailed discussion of Novavax's liquidity position and risk related thereto will be set forth in Novavax's Annual Report on Form 10-K that will be filed with the SEC.

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 February 28, 2023 until 11:59 p.m. ET on March 7, 2023. To access the replay by telephone, dial (877) 344-7529 (Domestic) or (412) 317-0088 (International) and use passcode 1137418.

A webcast of the conference call can also be accessed on the Novavax website at novavax.com/events. A replay of the webcast will be available on the Novavax website until May 28, 2023.

Trade Name in the U.S.

The trade name Nuvaxovid™ has not yet been approved by the U.S. Food and Drug Administration.

About Nuvaxovid™ (NVX-CoV2373)

Novavax's COVID-19 vaccine is a protein-based vaccine made by creating copies of the surface spike protein of SARS-CoV-2 that causes COVID-19. With Novavax's unique recombinant nanoparticle technology, the non-infectious spike protein serves as the antigen that primes the immune system to recognize the virus, while Novavax's Matrix-M™ adjuvant enhances and broadens the immune response. The vaccine is packaged as a ready-to-use liquid formulation and is stored at 2° to 8°C, enabling the use of existing vaccine supply and cold chain channels.

About Matrix-M™ Adjuvant

When added to vaccines, Novavax's patented saponin-based Matrix-M adjuvant enhances the immune system response, making it broader, and more durable. The Matrix-M adjuvant stimulates the entry of antigen-presenting cells at the injection site and enhances antigen presentation in local lymph nodes.

About the COVID-19-Influenza Combination (CIC) Vaccine Candidate Phase 2 Trial

The COVID-19-Influenza Combination (CIC) Vaccine Candidate Phase 2 Trial is a dose-confirming, randomized, observer-blinded trial evaluating the safety and effectiveness (immunogenicity) of different formulations of the CIC and influenza vaccine candidates in adults aged 50 through 80. The trial will assess a CIC vaccine comprised of Novavax's recombinant protein-based COVID-19 vaccine, quadrivalent influenza vaccine candidate, and patented saponin-based Matrix-M adjuvant. Primary and secondary objectives of the study are to assess the safety, tolerability, and immune responses to various formulations of the CIC and influenza vaccine candidates. The Phase 2 dose-confirmation trial will be conducted in two parts. The first part seeks to enroll a total of approximately 1,500 participants in Australia and New Zealand. Initial results are expected mid-year 2023. These data will inform the phase 3 trials for both influenza stand-alone and COVID-19-influenza combination vaccine candidates.

About Novavax

Novavax, Inc. (Nasdaq: NVAX) promotes improved health by discovering, developing and commercializing innovative vaccines to protect against serious infectious diseases. Novavax, a global company based in Gaithersburg, Md., U.S., offers a

differentiated vaccine platform that combines a recombinant protein approach, innovative nanoparticle technology and Novavax's patented Matrix-M adjuvant to enhance the immune response. Focused on the world's most urgent health challenges, Novavax is currently evaluating vaccines for COVID-19, influenza, and COVID-19 and influenza combined. Please visit novavax.com and [LinkedIn](#) for more information.

Forward-Looking Statements

Statements herein relating to the future of Novavax, its near term priorities including delivering an updated vaccine for the 2023 fall vaccination season, streamlining its investment and organizational structure and building value for Novavax from its technology platform and Matrix-M adjuvant, its operating plans, objectives and prospects, including Novavax's ability to continue as a going concern within one year after the issuance date of the financial statements for the year ended December 31, 2022, its anticipated strategic plan, its future financial or business performance, conditions or strategies, its partnerships, the timing of clinical trial results, the ongoing development of NVX-CoV2373, and a bivalent or monovalent Omicron-based / original strain based vaccine, the CIC investigational vaccine candidate, a quadrivalent influenza investigational vaccine candidate, the scope, timing and outcome of future and pending regulatory filings and actions and additional worldwide authorizations of NVX-CoV2373 for use in adults and adolescents and as a booster, 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; 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; unanticipated challenges or delays in conducting clinical trials; challenges meeting contractual requirements under agreements with multiple commercial, governmental, and other entities; manufacturing delays or challenges, including as a result of the timing of the anticipated regulatory requirements for the fall 2023 vaccination season; the loss of future funding from the U.S. government; the potential for an unfavorable outcome in disputes, including the pending arbitration with Gavi; 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's Annual Report on Form 10-K for the year ended December 31, 2021 and subsequent Quarterly Reports on Form 10-Q, 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 and 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 December 31,		Twelve Months Ended December 31,	
	2022	2021	2022	2021
	(unaudited)			
Revenue:				
Product sales	287,787	--	1,554,961	--
Grants	69,573	94,994	382,921	948,709
Royalties and other	39	127,206	43,990	197,581
Total revenue	357,399	222,200	1,981,872	1,146,290
Expenses:				
Cost of sales	181,765	--	902,639	--
Research and development	257,850	962,957	1,235,278	2,534,508
Selling, general and administrative	161,663	84,214	488,691	298,358
Total expenses	601,278	1,047,171	2,626,608	2,832,866
Income (loss) from operations	(243,879)	(824,971)	(644,736)	(1,686,576)
Interest expense	(4,601)	(5,138)	(19,880)	(21,127)
Other income (expense)	63,971	434	10,969	(6,833)
Income (loss) before income tax expense	(184,509)	(829,675)	(653,647)	(1,714,536)
Income tax expense (benefit)	(2,260)	16,609	4,292	29,215
Net income (loss)	\$ (182,249)	\$ (846,284)	\$ (657,939)	\$ (1,743,751)

Basic net income (loss) per share	<u><u>\$ (2.28)</u></u>	<u><u>\$ (11.18)</u></u>	<u><u>\$ (8.42)</u></u>	<u><u>\$ (23.44)</u></u>
Basic weighted average				
Number of common shares outstanding	<u><u>79,822</u></u>	<u><u>75,670</u></u>	<u><u>78,183</u></u>	<u><u>74,400</u></u>

SELECTED CONSOLIDATED BALANCE SHEET DATA
(in thousands)

	<u>December 31,</u> <u>2022</u>	<u>December 31,</u> <u>2021</u>
Cash and cash equivalents	\$ 1,336,883	\$ 1,515,116
Total restricted cash	11,962	13,143
Total current assets	1,703,391	2,155,119
Working capital	(756,553)	(235,200)
Total assets	2,258,679	2,576,753
Convertible notes payable*	491,347	323,458
Total stockholders' equity (deficit)	(634,078)	(351,673)

*Included in current and noncurrent liabilities as of December 31, 2022 and non-current liabilities as of December 31, 2021.

Contacts:

Investors

Erika Schultz | 240-268-2022

ir@novavax.com

Media

Ali Chartan or Giovanna Chandler | 202-709-5563

media@novavax.com

SOURCE Novavax, Inc.

Image not found or type unknown