# Novavax Reports Third Quarter 2022 Financial Results and Operational Highlights

November 8, 2022

- *Achieved total revenue for the third quarter of $735 million*
- *Delivered over 94 million doses of NVX-CoV2373 globally to date*
- *Authorized as a booster for adults in the U.S., E.U., and additional markets*
- *Authorized as a primary series for adolescents aged 12 – 17 years in U.S., EU, Japan, and additional markets*
- *Announced data about our prototype's broad immune response against circulating variants when used as a booster*
- *Initiated NVX-CoV2373 Phase 2b/3 study in children 6 months through 11 years of age*
- *Refining full year 2022 total revenue guidance to approximately $2.0 billion*
- *Company to host conference call today at 4:30 p.m. ET*

GAITHERSBURG, Md., Nov. 8, 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 third quarter ended September 30, 2022.

"Our progress in the third quarter continued as we successfully expanded our COVID-19 vaccine's label, achieved policy recommendations globally and expanded our body of clinical evidence supporting the differentiated benefit of our vaccine technology," said Stanley C. Erck, President and Chief Executive Officer, Novavax. "New data that we announced today reaffirms the broad immune responses of NVX-CoV2373 against circulating variants. Additionally, based on our most recent Phase 1/2 trial results for our COVID-19-Influenza Combination (CIC) vaccine candidate, we look forward to initiating our Phase 2 clinical trial by the end of this year."

**Third Quarter 2022 and Recent Highlights**

***Expanded COVID-19 Vaccine in Adult Population Aged 18 and Older***

- Nuvaxovid™ booster authorized for emergency use in the U.S., European Union (EU), Switzerland, United Arab Emirates (UAE) and New Zealand, with submissions completed to World Health Organization (WHO), as well as in Great Britain and South Korea
    - Recommendations provided by U.S. Centers for Disease Control and Prevention (CDC), E.U.'s Committee for Medicinal Products for Human Use and Switzerland's Federal Office of Public Health
- Nuvaxovid granted import and use permit in Israel for primary series and as a booster
- Covovax™ granted full product registration in South Africa for primary series

***Expanded COVID-19 Vaccine in Adolescent Population Aged 12 Through 17***

- Nuvaxovid primary series authorized for emergency use in the U.S., EU, Japan, Great Britain, Australia, South Korea, Taiwan, Switzerland, Thailand, UAE and New Zealand, with submissions completed to WHO and in Singapore
    - Recommendation provided by U.S. CDC
- Nuvaxovid granted import and use permit in Israel for primary series and as a booster

***COVID-19 Vaccine Manufacturing and Supply***

- Delivered over 94 million doses of NVX-CoV2373 globally to date
- Completed submission to add Novavax Czech Republic as an EU manufacturing site
- Solidified manufacturing and supply network ensuring capacity to support ongoing global demand

***COVID-19 Clinical Development Program***

- Announced topline results from Phase 3 Boosting Trial for Omicron BA.1 vaccine candidate (NVX-CoV2515), meeting the primary strain-change endpoint and reaffirming that prototype vaccine induces broadly cross-reactive responses, suggesting utility against current and future variants

- PREVENT-19 Phase 3 NVX-CoV2373 homologous booster data support benefits against variants
    - Following a single homologous booster dose, adult participants demonstrated increased anti-spike IgG levels and increased functional antibody levels measured by hACE2 receptor inhibition against Omicron BA.1, BA.2 and BA.5 variants, approximating levels observed in our Phase 3 efficacy studies
    - Robust booster responses were consistent between younger (less than 65 years of age) and older (greater than 65 years of age) adults, and independent of whether the booster dose was administered eight or 11 months after the primary series, offering further evidence of broad utility and duration of response with NVX-CoV2373
    - Adolescent participants following a single booster dose demonstrated neutralizing titers were 2.7-fold higher than those seen with primary vaccination and a broad antibody response against Omicron BA.1, BA.2 and BA.5 variants

- Demonstrated NVX-CoV2373 induced consistent immune responses when boosted on top of mRNA or AD26 vaccines, and achieved primary endpoint of Lot Consistency study for adults aged 18 through 49, demonstrating a consistent manufacturing process
    - When used as a heterologous boost (after either 2 or 3 doses of mRNA OR 1 or 2 doses of AD26) NVX-CoV2373 generated antibody levels previously found to be related to efficacy in the PREVENT-19 Phase 3 trial

- Initiated Phase 2b/3 Hummingbird global clinical trial for NVX-CoV2373 in younger children aged six months through 11 years, enrolling the sentinel cohort in the first group aged six through 11 years in the U.S.
    - Based on initial supportive safety and tolerability data analyzed by an independent Safety and Monitoring Committee, progressed to recruiting the full age cohort

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

- Announced positive cellular immunity results of CIC Phase 1/2 trial following initial results announced in April, demonstrating ability to generate immune responses, including both antibody and polyfunctional CD4+ T-cell responses, against SARS-CoV-2 and homologous and heterologous influenza strains
    - Generated robust antibody responses against both prototype and Omicron BA.1 strains of SARS-CoV-2 and influenza antigens
    - Safety and tolerability profile was consistent with standalone NVX-CoV2373 prototype vaccine and quadrivalent influenza vaccine candidate
    - Phase 2 trial expected to begin by the end of 2022

***Corporate Highlights***

- Strengthened corporate leadership with appointment of a new board member and executive promotions
    - Rick Rodgers appointed to Board of Directors
    - Silvia Taylor promoted to Executive Vice President, Chief Communications Officer
    - Henrietta Ukwu, M.D. promoted to Executive Vice President, Chief Regulatory Officer

**Financial Results for the Three Months Ended September 30, 2022**

- **Total revenue** for the third quarter of 2022 was $735 million, compared to $179 million for the comparable period in 2021. Third quarter of 2022 total revenue includes $628 million of revenue comprised of $626 million of product sales from NVX-CoV2373 based on the sale of 35 million doses sold by Novavax and $2 million of royalties, milestone and adjuvant sales to our license partners. Grant revenue of $106 million in the third quarter of 2022 compared to $135 million in the prior year resulted from a decrease in activity under our agreements with the Coalition for Epidemic Preparedness Innovations.

- **Cost of sales** for the third quarter of 2022 were $435 million. This includes $249 million related to excess, obsolete, or expired inventory and losses on firm purchase commitments under our third-party supply agreements. 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. Cost of sales valued at expected standard costs, including expenses related to excess and obsolete inventory, would have been approximately $444 million.

- **Research and development expenses** for the third quarter of 2022 were $304 million compared to $408 million for the comparable period in 2021. The decrease was primarily the result of a $98 million benefit from the settlement of a manufacturing agreement.

- **Selling, general and administrative expenses** for the third quarter of 2022 were $123 million compared to $78 million for the comparable period in 2021. The increase in the period was the result of activities in support of the commercialization of NVX-CoV2373.

- **Net loss** for the third quarter of 2022 was $169 million compared to a net loss of $322 million for the comparable period in 2021.

- **Cash, cash equivalents, and restricted cash** were $1.3 billion as of September 30, 2022, compared to $1.5 billion as of December 31, 2021.

**Financial Guidance**

Refining full year 2022 total revenue guidance, to approximately $2.0 billion, the low end of the previous guidance of $2.0 to $2.3 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 November 8, 2022 until 11:59 p.m. ET on November 15, 2022. To access the replay by telephone, dial (877) 344-7529 (Domestic) or (412) 317-0088 (International) and use passcode 3408655.

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 February 8, 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 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. The vaccine was created using Novavax' recombinant nanoparticle technology to generate antigen derived from the coronavirus spike 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.

The 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 the vaccine worldwide. Existing authorizations leverage Novavax' manufacturing partnership with Serum Institute of India, 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. The Novavax COVID-19 vaccine has received authorization from multiple regulatory authorities globally, including the U.S. Food and Drug Administration, the European Commission, and the WHO. The vaccine is currently under review by multiple regulatory agencies worldwide, including for additional populations and indications such as adolescents and as a booster. In addition to its COVID-19 vaccine, Novavax is also currently evaluating its CIC vaccine candidate in a Phase 1/2 clinical trial, its quadrivalent influenza investigational vaccine candidate, and an Omicron strain-based vaccine candidate (NVX-CoV2515) as well as a bivalent format Omicron-based / original strain-based 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?and connect with us on LinkedIn.

**Forward-Looking Statements**

Statements herein relating to the future of Novavax, its strategic priorities for end of 2022, its operating plans and prospects, financial guidance, its position in the global COVID-19 market, its partnerships, the timing of clinical trials, the ongoing development of NVX-CoV2373, NVX-CoV2515, a bivalent vaccine candidate, a quadrivalent influenza investigational vaccine candidate and Novavax' CIC vaccine candidate, the scope, timing and outcome of future regulatory filings and actions, Novavax' plans to supplement existing authorizations with data from the additional manufacturing sites in Novavax' global supply chain, additional worldwide authorizations of NVX-CoV2373 for use in adults and adolescents and as a booster, the role that Novavax' COVID-19 vaccine will play in the evolving COVID-19 landscape, and the efficacy, safety, intended utilization and expected administration of NVX-CoV2373 and Novavax' other vaccine candidates 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; the emergence of variants of the SARS-CoV-2 virus that may negatively impact market acceptance or anticipated sales of NVX-CoV-2373; 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 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 September 30, | |
|---|---|---|
| | **2022** | 2021 |
| | **(unaudited)** | |

| | | |
|---|---|---|
| Revenue: | | |
| Product sales | **$ 626,091** | $ -- |
| Grants | **106,273** | 135,007 |
| Royalties and other | **2,213** | 43,837 |
| Total revenue | **734,577** | 178,844 |
| Expenses: | | |
| Cost of sales | **434,593** | -- |
| Research and development | **304,297** | 408,195 |
| Selling, general, and administrative | **122,876** | 77,793 |
| Total expenses | **861,766** | 485,988 |
| Income (loss) from operations | **(127,189)** | (307,144) |
| Other income (expense): | | |
| Interest income (expense) | **(4,169)** | (5,182) |
| Other income (expense) | **(34,783)** | (4,064) |
| Income (loss) before income tax expense | **(166,141)** | (316,390) |
| Income tax expense | **2,472** | 6,041 |
| Net income (loss) | **$ (168,613)** | $ (322,431) |
| | | |
| Net income (loss) per share | | |
| Basic and diluted | **$ (2.15)** | $ (4.31) |
| Weighted average number of common shares outstanding | | |
| Basic and diluted | **78,274** | 74,745 |

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

| | **September 30, 2022** | **December 31, 2021** |
|---|---|---|
| | **(unaudited)** | |
| Cash and cash equivalents | **$ 1,280,581** | **$ 1,515,116** |
| Total restricted cash | **12,441** | **13,143** |
| Total current assets | **1,759,965** | **2,155,119** |
| Working capital | **92,004** | **(235,200)** |
| Total assets | **2,267,437** | **2,576,753** |
| Convertible notes payable* | **324,525** | **323,458** |
| Total stockholders' deficit | **(565,985)** | **(351,673)** |

* Included in current liabilities as of September 30, 2022 and non-current liabilities as of December 31, 2021


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