Novavax Investor Relations

- *Received FDA EUA and CDC recommendation for NVX-CoV2373, marking the first protein-based COVID-19 vaccine authorized in the U.S. for adults; with immunizations underway*
- *Nuvaxovid™ and Covovax™ authorized for adults in 43 countries, with booster authorizations in Japan, Australia and New Zealand as well as, adolescent authorizations in the EU, Australia, India, Japan, and Thailand*
- *Over 73 million doses delivered globally to date*
- *Progressing variant program with top-line clinical data for Omicron expected near the end of the third quarter of 2022*
- *Adjusted revenue guidance to $2 billion to $2.3 billion*
- *Company to host conference call today at 4:30 p.m. ET*

GAITHERSBURG, Md., Aug. 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 second quarter ended June 30, 2022.

"We are pleased with our progress since the start of the second quarter, which importantly included delivering our vaccine to the U.S. market with immunizations underway," said Stanley C. Erck, President and Chief Executive Officer, Novavax. "With over 23 million doses delivered since the start of the third quarter, we are distributing our vaccine globally and have gained positive momentum as we move into the remainder of 2022 and into 2023. Through continued expansions to our label for adolescents and boosting and our vaccine's competitive product profile, we are confident it will play an important role in the long-term COVID-19 landscape."

**Second Quarter 2022 and Recent Highlights**

***Progressed COVID-19 Global Regulatory Strategy***

- Received Emergency Use Authorization (EUA) from United States (U.S.) Food and Drug Administration (FDA) with label expansion underway, marking first protein-based COVID-19 vaccine available for use domestically
    - Authorized for primary series in adults 18 and older with unanimous recommendation received from U.S. Centers for Disease Control and Prevention (CDC)
    - Planned submission for boosting data from PREVENT-19 Phase 3 trial in August of 2022
- Nuvaxovid or Covovax authorized in 43 countries for primary series in adults 18 and older, with additional label expansions received and underway in several geographies
    - Authorized for boosting in adults 18 and older in Japan, Australia and New Zealand
        - Nuvaxovid filings completed in the European Union (EU), Great Britain and Switzerland
    - Authorized for primary series in adolescents aged 12 through 17 in the EU, India, Australia, Japan and Thailand
        - Nuvaxovid filings completed to the World Health Organization (WHO), Great Britain, Canada, Switzerland, New Zealand and Taiwan
- Expect to file for authorization of Omicron-containing vaccine with U.S. FDA in the fourth quarter of 2022

***COVID-19 Vaccine Manufacturing and Distribution***

- Delivered over 73 million doses of Nuvaxovid and Covovax globally to date, including 23 million doses since the start of the third quarter 2022, reflecting strong momentum for the remainder of 2022
- Secured order from U.S. government for 3.2 million initial doses under existing agreements, with distribution underway
- Received approval from European Medicines Agency for SK bioscience to manufacture and supply the active substance in the Nuvaxovid COVID-19 vaccine to the EU
- Expanded partnership with SK bioscience to support manufacturing of Omicron-containing vaccine and to manufacture vaccine in prefilled syringes for commercial supply in 2023

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

- Ongoing development of Omicron BA.1 specific vaccine (NVX-CoV2515), Omicron BA.5 specific vaccine and bivalent format with prototype vaccine (NVX-CoV2373)

    - Announced positive preclinical boosting data for NVX-CoV2373, NVX-CoV2515, or bivalent formulation, demonstrating strong antibody levels
    - Ongoing Phase 3 strain change trial to assess safety and antibody responses following primary vaccination with mRNA vaccines; initial results expected near the end of the third quarter of 2022

- Initiated Phase 2b/3 Hummingbird global clinical trial in younger children aged six months through 11 years with initial results expected in the first quarter of 2023

    - Expected to enroll total 3,600 participants across nine countries, evaluating safety, effectiveness (immunogenicity) and efficacy of two doses of NVX-CoV2373, followed by a booster at least six months after primary vaccination in three age cohorts

- Advanced multiple studies evaluating homologous and heterologous boosting in adolescents for NVX-CoV2373

    - Completed administration of homologous third-dose booster for select participants in PREVENT-19 Phase 3 booster study in adolescents aged 12 through 17
    - Ongoing participation in University of Oxford's Com-COV3 Booster trial in adolescents aged 12 through 15 to evaluate heterologous boosting

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

- Announced initial results of CIC Phase 1/2 trial demonstrating robust immune response with both stand-alone influenza and CIC vaccine candidates

    - Phase 3 trial to evaluate efficacy on-track to be initiated in 2023

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

- **Total revenue** for the second quarter of 2022 was $186 million, compared to $298 million for the comparable period in 2021. Second quarter of 2022 total revenue includes $78 million of revenue comprised of $55 million of product sales from NVX-CoV2373 based on three million doses sold by Novavax and $23 million of royalties, milestone, and adjuvant sales to our license partners. Grant revenue of $108 million in the second quarter of 2022 compared to $272 million in the prior year resulted from a decrease in activity under our agreements with the U.S. government and with the Coalition for Epidemic Preparedness Innovations.
- **Cost of sales** for the second quarter of 2022 were $271 million. This includes $255 million related to excess, obsolete, or expired inventory and losses on firm purchase commitments under our third party supply agreements. The recognition of these costs were driven by a substantial reduction of our expected deliveries to COVAX and deferral of deliveries to other customers. 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 second quarter of 2022 were $290 million compared to $571 million for the comparable period in 2021. The decrease was primarily the result of lower clinical development activities for NVX-CoV2373, the capitalization of NVX-CoV2373 manufacturing costs and a net benefit from previously recognized embedded lease costs for manufacturing supply agreements during the second quarter of 2022.
- **Selling, general and administrative expenses** for the second quarter of 2022 were $108 million compared to $73 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 second quarter of 2022 was $510 million compared to $352 million for the comparable period in 2021.
- **Cash, cash equivalents, and restricted cash** were $1.4 billion as of June 30, 2022, compared to $1.5 billion as of December 31, 2021.

**Financial Guidance**

Revising full year 2022 total revenue guidance to $2 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 August 8, 2022 until 11:59 p.m. ET on August 15, 2022. To access the replay by telephone, dial (877) 344-7529

(Domestic) or (412) 317-0088 (International) and use passcode 9237495.

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

The 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, 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., European Commission and the WHO. The vaccine is currently under review by multiple regulatory agencies worldwide, including for additional indications and populations such as adolescents and as a booster. 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, and is also evaluating an Omicron strain-based vaccine (NVX-CoV2515) as well as a bivalent format Omicron-based / original strain-based vaccine. 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.

*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 strategic priorities for 2022, its operating plans and prospects, financial guidance, its position in the global COVID-19 market, its partnerships, the timing of clinical trial results, the ongoing development of NVX-CoV2373, NVX-CoV2515, a bivalent vaccine candidate and a

COVID-seasonal influenza investigational 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, the anticipated availability of Omicron-containing vaccine, 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 long-term 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 June 30, | |
|---|---|---|
| | **2022** | 2021 |
| | **(unaudited)** | |
| Revenue: | | |
| Product sales | **$ 55,455** | $ -- |
| Grants | **107,774** | 272,489 |
| Royalties and other | **22,696** | 25,528 |
| Total revenue | **185,925** | 298,017 |
| Expenses: | | |
| Cost of sales | **271,077** | -- |
| Research and development | **289,648** | 570,685 |
| Selling, general, and administrative | **108,160** | 73,161 |
| Total expenses | **668,885** | 643,846 |
| Income (loss) from operations | **(482,960)** | (345,829) |
| Other income (expense): | | |
| Interest income (expense) | **(6,234)** | (5,968) |
| Other income (expense) | **(19,873)** | 3,028 |
| Income (loss) before income tax expense | **(509,067)** | (348,769) |
| Income tax expense | **1,418** | 3,548 |
| Net income (loss) | **$ (510,485)** | $ (352,317) |
| Net income (loss) per share | | |
| Basic | **$ (6.53)** | $ (4.75) |
| Weighted average number of common shares outstanding | | |
| Basic | **78,143** | 74,118 |

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

| | June 30, 2022 | December 31, 2021 |
|---|---|---|

| | (unaudited) | |
|---|---|---|
| Cash and cash equivalents | $ 1,375,587 | $ 1,515,116 |
| Total restricted cash | 11,928 | 13,143 |
| Total current assets | 2,136,002 | 2,155,119 |
| Working capital | (20,237) | (235,200) |
| Total assets | 2,622,993 | 2,576,753 |
| Convertible notes payable* | 324,169 | 323,458 |
| Total stockholders' equity (deficit) | (416,950) | (351,673) |

* Included in current liabilities as of June 30, 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

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