

GAITHERSBURG, Md., Feb. 28, 2022 /PRNewswire/ --

- *NVX-CoV2373 is the first protein-based COVID-19 vaccine authorized in multiple major markets around the world, including the European Union, Australia, Canada, and Great Britain; authorizations granted by 12 regulatory agencies and emergency use listing from the WHO*
- *Additional filings for authorization under review, including in the United States*
- *Initiated vaccine shipments globally, with doses administered in the European Union, Australia, Indonesia and South Korea*
- *Expanded clinical body of evidence for NVX-CoV2373 across several studies, including:*
 - *82.5% overall protection against all COVID-19 infection in extended analysis of UK Phase 3 study*
 - *82% efficacy against Delta variant in PREVENT-19 pediatric expansion for adolescents aged 12 through 17*
 - *Broad cross-reactivity against Omicron and other variants following a 2-dose primary series, with increased immune responses after 6-month booster dose*
- *Developed Omicron-specific vaccine; GMP manufacturing ongoing with delivery expected toward the end of first quarter of 2022*
- *Full year 2022 total revenue guidance of between \$4 billion and \$5 billion*
- *Company to host conference call today at 4:30 p.m. ET*

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 fourth quarter and twelve months ended December 31, 2021.

"NVX-CoV2373 has now received regulatory authorizations globally, representing the potential to reach more than six billion lives. We are now delivering our vaccine around the world, with immunizations already happening in the European Union, Asia and Australia to meet the continued need to achieve high vaccination rates through primary immunization, boosting and protection of pediatric age groups," said Stanley C. Erck, President and Chief Executive Officer, Novavax. "We also remain focused on expanding access to our vaccine through additional regulatory filings and ongoing research to add to our robust body of clinical data. We are confident in NVX-CoV2373's potential as a vital vaccine option due to its reassuring safety profile and demonstrated efficacy against variants with the benefits of refrigerator-stable storage."

Fourth Quarter 2021 and Recent Highlights

Achieved Multiple Regulatory Authorizations Globally for COVID-19 Vaccine

- Nuvaxovid[™] was granted authorization (emergency, provisional, interim conditional or emergency use listing) in Great Britain, the European Union, the World Health Organization (WHO), Canada, Australia, United Arab Emirates, Singapore, and New Zealand; received Biologics License Application approval in South Korea with our partner, SK bioscience
- Covovax[™] was granted emergency use authorization in India, Indonesia, Philippines, Bangladesh, and emergency use listing from the WHO with our partner, Serum Institute of India (SII)

Completed Multiple Regulatory Submissions Globally for COVID-19 Vaccine

- Completed regulatory submissions for authorization for NVX-CoV2373 in the U.S. and Switzerland

- SII completed submission to South Africa, for NVX-CoV2373 to be marketed as Covovax
- Takeda Pharmaceutical Company Limited, our partner, completed submission to Japan for a New Drug Application

COVID-19 Vaccine Advanced Purchase Agreement

- Executed advance purchase agreement (APA) with Israel's Ministry of Health to supply a minimum of 5 million vaccine doses
 - Option to purchase an additional 5 million doses

COVID-19 Vaccine Manufacturing, Supply and Distribution

- Built manufacturing and robust supply network to support over 2 billion annual doses of capacity and initiated distribution of NVX-CoV2373 to begin fulfillment of our commitments
 - Expanded partnership with SII through new supply agreement
 - Reserved significant additional manufacturing capacity with SK bioscience to produce antigen, and SK bioscience acquired non-exclusive rights to sell to governments in Thailand and Vietnam
 - Entered into a contract manufacturing agreement with Mabion for the large-scale manufacturing of NVX-CoV2373 through 2026

COVID-19 Vaccine Clinical Development

- Announced data from extended analysis of our UK Phase 3 study demonstrating ongoing durability of protection against infection and disease
 - 82.5% vaccine efficacy in protection against all COVID-19 infection, both symptomatic and asymptomatic, as measured by PCR+ or anti-N seroconversion
 - 82.7% overall vaccine efficacy against disease over a 6-month data collection period (median of 101 days of surveillance)
 - 100% vaccine efficacy against severe disease
- Announced data from PREVENT-19 Phase 3 pediatric expansion in adolescents aged 12 through 17, achieving primary effectiveness endpoint and comparability to adult population
 - Adolescent neutralization responses ~1.5-fold higher than adults
 - 82% clinical efficacy against Delta variant
 - IgG and functional immune responses against variants were higher than in adults
 - Generally well-tolerated with no safety signals
 - Expect to supplement global regulatory filings in the first quarter of 2022
 - Expect to initiate a pediatric study in younger children in the second quarter of 2022
- Initiated PREVENT-19 Phase 3 booster study to evaluate safety and efficacy of a third dose of NVX-CoV2373
- Heterologous boosting data announced in COV-Boost Phase 2 Study, with NVX-CoV2373 demonstrating its ability to serve as a well-tolerated third dose to boost immune levels
- Announced immunologic cross-reactivity data from vaccine booster and adolescent studies to highlight potential utility of NVX-CoV2373 against Omicron variant (B.1.1.529)
 - Demonstrated broad IgG antibody cross-reactivity against Omicron and other circulating variants with primary 2-dose regimen

- Third dose at 6-months produced increased immune response showing 9.3-fold IgG rise and 14.8-fold functional ACE2 inhibition increase
- Ongoing PREVENT-19 Phase 3 pediatric expansion showed robust immune response 2-to-4-fold higher than adults against evaluated variants, including Omicron following primary 2-dose regimen
- Developed Omicron-specific vaccine with GMP manufacturing and lab-based assessments underway
 - Expect delivery toward the end of the first quarter of 2022

COVID-Influenza Combination Vaccine Clinical Development

- Ongoing Phase 1/2 trial for COVID-influenza combination vaccine
 - Data is expected in April 2022
 - Expect to initiate Phase 2 clinical trial for COVID-influenza combination vaccine and NanoFlu standalone in the second half of 2022

Publication Highlights

- Final analysis from PREVENT-19 Phase 3 trial in U.S. and Mexico published in the *New England Journal of Medicine*
- Final analysis from UK Phase 3 influenza co-administration sub-study published in *The Lancet Respiratory Medicine*
- Final analysis of COV-Boost study led by University of Southampton NHS published in *The Lancet*

Financial Results for the Three and Twelve Months Ended December 31, 2021

Novavax revenue for the fourth quarter and full year ended 2021 were \$222 million and \$1.1 billion, respectively, compared to \$280 million and \$476 million for the comparable periods in 2020. The increase to royalties and other revenue in the fourth quarter and full year 2021 was primarily the result of NVX-CoV2373 sales by our license partners to South Korea and Indonesia. The increase to full year 2021 grants revenue reflects the significant NVX-CoV2373 activities funded by both the U.S. government and the Coalition for Epidemic Preparedness Innovations.

Research and development expenses for the fourth quarter and full year ended 2021 were \$963 million and \$2.5 billion, respectively, compared to \$401 million and \$747 million for the comparable periods in 2020. The increase was primarily due to the development and manufacturing of NVX-CoV2373, including pre-launch inventory buildup in advance of regulatory authorizations.

General and administrative expenses for the fourth quarter and full year ended 2021 were \$84 million and \$298 million, respectively, compared to \$61 million and \$145 million for the comparable periods in 2020.

Net loss for the fourth quarter and full year ended 2021 were \$846 million and \$1.7 billion, respectively, compared to a net loss of \$178 million and \$418 million for the comparable periods in 2020.

As of December 31, 2021, Novavax had \$1.5 billion in cash, cash equivalents, marketable securities and restricted cash, compared to \$0.8 billion as of December 31, 2020.

Financial Guidance

Novavax expects to achieve full year 2022 total revenue of between \$4 billion 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 (877) 870-4263 (Domestic) or (412) 317-0790 (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, 2022 until 11:59 p.m. ET on March 7, 2022. To access the replay by telephone, dial (877) 344-7529 (Domestic) or (412) 317-0088 (International) and use passcode 2206365.

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 May 28, 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 NanoFlu

NanoFlu is a recombinant hemagglutinin (HA) protein nanoparticle influenza vaccine produced by Novavax in its SF9 insect cell baculovirus system. NanoFlu uses HA amino acid protein sequences that are the same as the recommended wild-type circulating virus HA sequences. NanoFlu contains Novavax' patented saponin-based Matrix-M adjuvant.

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

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 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 and connect with us on [Twitter](#), [LinkedIn](#), [Instagram](#) and [Facebook](#).

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, the timing for data for the ongoing Phase 1/2 trial for a COVID-influenza combination vaccine candidate and plans to initiate a Phase 2 clinical trial for a COVID-Influenza combination vaccine and NanoFlu standalone, the scope, timing and outcome of future regulatory filings and actions, including Novavax' plans to supplement global regulatory filings in the first quarter of 2022 and to supplement existing authorizations with data from additional manufacturing sites, 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 expected delivery 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, 2020 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,

	<u>2021</u>	2020	<u>2021</u>	2020
	(unaudited)			
Revenue:				
Grants	94,994	259,260	948,709	453,210
Royalties and other	127,206	20,399	197,581	22,388
Total revenue	222,200	279,659	1,146,290	475,598
Expenses:				
Research and development	962,957	401,199	2,534,508	747,027
General and administrative	84,214	61,313	298,358	145,290
Total expenses	1,047,171	462,512	2,832,866	892,317
Loss from operations	(824,971)	(182,853)	(1,686,576)	(416,719)
Interest income (expense), net	(4,835)	(3,737)	(19,763)	(14,131)
Other income (expense)	131	9,026	(8,197)	12,591
Net loss before income tax expense	(829,675)	(177,564)	(1,714,536)	(418,259)
Income tax expense	16,609	--	29,215	--
	\$	\$	\$	\$
Net loss	(846,284)	(177,564)	(1,743,751)	(418,259)
	\$	\$	\$	\$
Basic and diluted net loss per share	(11.18)	(2.70)	(23.44)	(7.27)
Basic and diluted weighted average number of common shares outstanding	75,670	65,725	74,400	57,554

SELECTED CONSOLIDATED BALANCE SHEET DATA
(in thousands)

	<u>December 31,</u> <u>2021</u>	<u>December 31,</u> <u>2020</u>
Cash and cash equivalents	\$ 1,515,116	\$ 553,398
Marketable securities	--	157,649
Total restricted cash	13,143	95,340
Total current assets	2,155,119	1,248,203
Working capital	(235,200)	668,531
Total assets	2,576,753	1,582,479
Convertible notes payable	323,458	322,035
Total stockholders' equity (deficit)	(351,673)	627,209

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<https://ir.novavax.com/2022-02-28-Novavax-Reports-Fourth-Quarter-and-Full-Year-2021-Financial-Results-and-Operational-Highlights>