Novavax Reports Third Quarter 2021 Financial Results and Operational Highlights

November 4, 2021

GAITHERSBURG, Md., Nov. 4, 2021 /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, 2021.

"We are excited by the significant progress made over the quarter, including our landmark milestone of gaining the first regulatory approval for our COVID-19 vaccine," said Stanley C. Erck, President and Chief Executive Officer, Novavax. "With additional regulatory submissions around the world, we are prepared to deliver our vaccine globally. We believe the highly encouraging results from our six-month booster study complement the strong efficacy demonstrated by NVX-CoV2373 to date, and we remain confident that our vaccine will serve as an important tool to fight COVID-19 in the years to come."

Third Quarter 2021 and Recent Highlights

COVID-19 Vaccine Regulatory Pathway

- Received emergency use authorization (EUA) from National Agency of Drug and Food Control of the Republic of Indonesia, in partnership with Serum Institute of India Pvt. Ltd. (SII)
    - NVX-CoV2373 to be marketed by SII under the brand name COVOVAX™
- Novavax completed multiple regulatory submissions
    - U.K. Medicines and Healthcare products Regulatory Agency (MHRA) for conditional marketing authorization
    - Australia Therapeutic Goods Administration (TGA) for provisional approval
    - Health Canada for authorization
    - New Zealand Medsafe for provisional approval
    - World Health Organization (WHO) for emergency use listing (EUL)
    - European Medicines Agency (EMA) (submitted all final data and modules)
- SII, our licensee, completed multiple regulatory submissions for our COVID-19 vaccine
    - Drugs Controller General of India (DCGI) and the Philippines for EUA
    - WHO for EUL
- Expect to submit the complete regulatory package to the U.S. FDA by the end of 2021

COVID-19 Vaccine Advanced Purchase Agreements

- Executed advance purchase agreement with European Commission to supply a minimum of 20 million doses and up to 100 million initial doses
    - Option to purchase an additional 100 million doses through 2023

COVID-19 Vaccine Manufacturing and Supply

- Achieved capacity of 100 million doses per month as of the end of the third quarter of 2021, on track to achieve capacity of 150 million doses per month by the end of the fourth quarter of 2021, and expect to have capacity in excess of 2 billion annual doses in 2022
- Collaborated with licensed manufacturers to enable distribution of NVX-CoV2373 globally
    - Expanded partnership with SII through a supply agreement
    - Takeda Pharmaceutical Company Limited finalized agreement with government of Japan's Ministry of Health, Labour and Welfare for purchase of 150 million doses, with anticipated distribution in 2022

COVID-19 Vaccine Clinical Development

- Completed crossover arms in U.K. Phase 3, South Africa Phase 2b, PREVENT-19 Phase 3, and pediatric expansion of PREVENT-19 trials
- Ongoing pediatric expansion of PREVENT-19 Phase 3 trial
    - Completed enrollment of 2,248 adolescents aged 12-17 years across up to 75 sites in the U.S.

    - Expect to have a regulatory package available for global submission in the first quarter of 2022
- Advanced booster study in the Phase 2 portion of U.S. and Australia Phase 1/2 trial
    - Data from 6-month booster study demonstrated positive results
        - Wild-type neutralizing antibodies increased more than 4-fold versus primary vaccination series
        - Cross-reactive functional antibodies to the Delta (B.1.617.2) variant strain detected after primary vaccination series and increased more than 6-fold following boosting
    - Initiated twelve-month booster dose for select participants following completion of 6-month booster study

Combination Vaccine

- Completed enrollment of Phase 1/2 clinical trial for COVID-NanoFlu™ combination vaccine in Australia across 10 sites
    - Enrolled 642 healthy adults aged 50 to 70 years
    - Evaluating the safety, tolerability and immune response of a COVID-NanoFlu combination vaccine formulated with Matrix-M™ adjuvant
    - Data is expected in the first half of 2022

Publication Highlights

- Final analysis from multiple Phase 3 trials accepted by a peer-reviewed journal and posted via the preprint server on medRxiv.org
    - PREVENT-19 U.S. and Mexico study
    - U.K. influenza co-administration sub-study
- Final analysis from pivotal Phase 3 clinical trial for NanoFlu™ published in *The Lancet Infectious Diseases*
- Final analysis from Phase 2 Australia and U.S. dosing regimen study published in *PLOS Medicine*

Corporate Highlights

- Strengthened corporate leadership with executive hiring and promotions
    - Jim Kelly as Executive Vice President, Chief Financial Officer and Treasurer
    - Denny Kim, M.D. as Senior Vice President, Chief Safety Officer
    - Marco Cacciuttolo, Ph.D. promoted to Senior Vice President, Process and Analytical Development
    - Raburn Mallory, M.D. promoted to Senior Vice President, Head of Clinical Development

Financial Results for the Three Months Ended September 30, 2021

Novavax reported a net loss of $322.4 million, or $4.31 per share, for the third quarter of 2021, compared to a net loss of $197.3 million, or $3.21 per share, for the third quarter of 2020.

Novavax revenue in the third quarter of 2021 was $178.8 million, compared to $157.0 million in the same period in 2020. This increase was due to increased development activities relating to NVX-CoV2373 for services performed under the U.S. government agreement and royalties under Novavax' licensing agreements.

Research and development expenses increased to $408.2 million in the third quarter of 2021, compared to $294.1 million in the same period in 2020. The increase was primarily due to the development and manufacturing for NVX-CoV2373.

General and administrative expenses increased to $77.8 million in the third quarter of 2021, compared to $56.9 million for the same period in 2020. The increase was primarily due to costs associated supporting our NVX-CoV2373 program.

As of September 30, 2021, Novavax had $1.9 billion in cash, cash equivalents and restricted cash, compared to $0.8 billion as of December 31, 2020. The increase in cash provided was primarily due to $1.2 billion in payments under advance purchase agreements recorded as deferred revenue and $565 million net proceeds raised through utilization of At-the-market (ATM) offerings during the first quarter of 2021.

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 November 4, 2021 until 11:59 p.m. ET on November 11, 2021. To access the replay by telephone, dial (877) 344-7529 (Domestic) or (412) 317-0088 (International) and use passcode 10161242.

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 4, 2022.

About NVX-CoV2373

NVX-CoV2373 is a protein-based vaccine candidate 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 microgram antigen and 50 microgram 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.

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 combines the power and speed of genetic engineering to efficiently produce highly immunogenic nanoparticles designed to address urgent global health needs. Novavax is conducting late-stage clinical trials for NVX-CoV2373, its vaccine candidate against SARS-CoV-2, the virus that causes COVID-19. NanoFlu™, its quadrivalent influenza nanoparticle vaccine, met all primary objectives in its pivotal Phase 3 clinical trial in older adults. Both 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 and LinkedIn.

Forward-Looking Statements

Statements herein relating to the future of Novavax, its operating plans and prospects, its partnerships, the ongoing development of NVX-CoV2373, COVID-NanoFlu™ combination vaccine and other Novavax vaccine product candidates, including the timing of anticipated clinical trial results, the scope, timing and outcome of future regulatory filings and actions, the anticipated manufacturing capacity for Novavax' COVID-19 vaccine, the preparedness of Novavax to deliver vaccine doses, and the anticipated role that NVX-CoV2373 will play in fighting COVID-19 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 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)
(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	**2021**	2020
Revenue	**$ 178,844**	$ 157,024	**$ 924,090**	$ 195,939
Expenses:				
Research and development	**408,195**	294,087	**1,571,551**	345,828
General and administrative	**77,793**	56,879	**214,144**	83,977
Total expenses	**485,988**	350,966	**1,785,695**	429,805
Loss from operations	**(307,144)**	(193,942)	**(861,605)**	(233,866)
Interest income (expense), net	**(4,852)**	(4,320)	**(14,928)**	(10,394)
Other income (expense)	**(4,394)**	952	**(8,328)**	3,565
Net loss before income tax expense	**(316,390)**	(197,310)	**(884,861)**	(240,695)
Income tax expense	**6,041**	--	**12,606**	--
Net loss	**$ (322,431)**	$ (197,310)	**$ (897,467)**	$ (240,695)
Basic and diluted net loss per share	**$ (4.31)**	$ (3.21)	**$ (12.13)**	$ (4.39)
Basic and diluted weighted average number of common shares outstanding	**74,745**	61,554	**73,972**	54,810

SELECTED CONSOLIDATED BALANCE SHEET DATA
(in thousands)

	September 30, 2021	**December 31, 2020**
	(unaudited)	
Cash and cash equivalents	**$ 1,936,998**	$ 553,398
Marketable securities	**--**	157,649
Total restricted cash	**9,828**	95,340
Total current assets	**2,174,181**	1,248,203
Working capital	**420,766**	668,531
Total assets	**2,565,941**	1,582,479
Notes payable	**323,102**	322,035
Total stockholders' equity	**461,336**	627,209

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