Novavax Investor Relations

- Filed regulatory submissions for EUA in India, Indonesia and the Philippines, in partnership with Serum Institute of India

- Demonstrated greater than 4-fold increase in neutralizing antibody levels versus peak responses after primary vaccination in 6-month booster study

- Cross-reactive functional antibodies to Delta (B.1.617.2) variant detected after primary vaccination series and increased more than 6-fold upon boosting at 6 months

- Finalized APA with European Commission to supply up to 200 million doses

- Demonstrated high efficacy across variants in PREVENT-19 Phase 3 trial

- Announced positive results from first clinical study of influenza vaccine and COVID-19 vaccine candidate administered simultaneously

- On track to achieve 100 million dose monthly capacity by the end of the third quarter and 150 million dose monthly capacity by the end of the fourth quarter

- Company to host conference call today at 4:30 p.m. ET

GAITHERSBURG, Md., Aug. 5, 2021 /PRNewswire/ -- Novavax, Inc. (NASDAQ: NVAX), a biotechnology company developing next-generation vaccines for serious infectious diseases, today announced its financial results and operational highlights for the second quarter ended June 30, 2021.

"We are highly encouraged by the filing of regulatory submissions in multiple markets, made in partnership with Serum Institute of India. We view these submissions as the first of many filings to come, which will allow NVX-CoV2373 to be made available at a global scale," said Stanley C. Erck, President and Chief Executive Officer, Novavax. "Our clinical successes over the second quarter reaffirm our confidence in NVX-CoV2373's differentiated efficacy profile. We continue to see the circulation of new variants and inequitable access to vaccine globally, demanding that we bring our COVID-19 vaccine to market as swiftly as possible."

Second Quarter 2021 and Recent Highlights

COVID-19 Vaccine Clinical and Non-Clinical Development

- Reported final analysis from PREVENT-19 U.S. and Mexico Phase 3 trial
    - Achieved primary efficacy endpoint with overall efficacy of 90.4% against mild, moderate, and severe disease
    - Demonstrated 100% protection against moderate and severe disease
    - Demonstrated 91.0% efficacy among high-risk populations
    - Demonstrated 92.6% efficacy against Variants of Concern/Variants of Interest (VoC/VoI) and 100% efficacy against variants not considered VoC/VoI
- Completed enrollment of pediatric expansion of PREVENT-19 Phase 3 trial
    - Enrolled 2,248 adolescents aged 12-17 across up to 75 sites in the U.S.

    - Blinded crossover expected to begin in August 2021 to ensure all participants have access to active vaccine

- Published results from late-stage South Africa Phase 2b and UK Phase 3 trials in *The New England Journal of Medicine*
- Completed UK Phase 3 crossover arms and initiated crossover studies in PREVENT-19 and South Africa Phase 2b trials to ensure all participants have access to active vaccine
- Advanced clinical development of booster studies of NVX-CoV2373

    - Reported 6-month booster data from U.S. and Australia Phase 2 trial

        - 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
        - Analysis of sera from primary series immunization showed cross-reactive functional antibodies to the Alpha (B.1.1.7), Beta (B.1.351), and Delta (B.1.617.2) variant strains, all of which increased 6- to 10-fold with a booster dose

- Participated in two UK Vaccines Taskforce-supported studies evaluating heterologous vaccination (Com-COV2) and heterologous boosting (CoV-Boost)

COVID-19 Vaccine Regulatory Pathway

- Filed regulatory submissions in partnership with Serum Institute of India Pvt. Ltd. (SII) for emergency use authorization in multiple markets

    - Submitted regulatory filings with the Drugs Controller General of India (DCGI) and regulatory agencies in Indonesia and the Philippines
    - Expect to file for Emergency Use Listing with the World Health Organization in August 2021

- Expect to complete regulatory filing with the UK Medicines and Healthcare products Regulatory Agency (MHRA) in the third quarter of 2021
- Expect to complete additional regulatory filings in other markets within weeks of MHRA filing, including with the European Medicines Agency (EMA), Australian Therapeutic Goods Administration, Health Canada, and New Zealand Medsafe
- Expect to submit for emergency use authorization to the U.S. Food and Drug Administration in the fourth quarter of 2021

COVID-19 Vaccine Manufacturing and Supply

- Collaborated with partners globally to progress toward anticipated manufacturing capacity

    - On track to achieve capacity of 100 million doses per month by the end of the third quarter of 2021 and 150 million doses per month by the end of the fourth quarter 2021
    - Initiated technology transfer at National Research Council of Canada Biologics Manufacturing Centre to produce NVX-CoV2373

- Expanded agreements globally to ensure equitable access to low-, middle-, and high-income countries

    - Entered into advance purchase agreement with Gavi, the Vaccine Alliance, to provide 1.1 billion doses to the COVAX Facility

        - Novavax to manufacture and distribute 350 million doses
        - SII to manufacture and distribute the remaining balance of the 1.1 billion doses to low- and middle-income countries

    - Finalized terms of advance purchase agreement with European Commission to supply up to 100 million doses with the option for an additional 100 million doses through 2023

        - Delivery of doses to begin following anticipated regulatory approval from EMA

NanoFlu™ / NVX-CoV2373 Combination Vaccine (qNIV/CoV2373)

- Announced preclinical data for qNIV/CoV2373 and expect to initiate Phase 1 clinical trial in Australia later this year

    - qNIV/CoV2373 induced strong functional antibodies, high levels of anti-S IgG, and neutralizing antibody titers
    - Preclinical data manuscript submitted for publication to a peer-reviewed journal and posted via the preprint server on bioRxiv.org

- Announced data from sub-study in UK Phase 3 trial, supporting co-administration of NVX-CoV2373 with influenza vaccination

    - 431 participants received approved seasonal influenza vaccine, while half of those participants were co-vaccinated with NVX-CoV2373
    - Co-administration did not negatively impact influenza immune response for any of the four influenza strains in the quadrivalent influenza vaccine
    - Confirmed efficacy trend of 87.5% against COVID-19
    - Data manuscript submitted for publication to a peer-reviewed journal and posted via the preprint server on medRxiv.org

Malaria Vaccine / Matrix-M™ Adjuvant Collaboration

- Ongoing clinical development for R21, the University of Oxford's malaria vaccine candidate formulated with Matrix-M™ adjuvant, in collaboration with SII

    - Phase 3 licensure trial underway in 4,800 participants, aged 5-36 months
    - Phase 2b clinical trial results demonstrated 77% efficacy and were published in *Preprints with The Lancet*

Financial Results for the Three Months Ended June 30, 2021

Novavax reported a net loss of $352 million, or $4.75 per share, for the second quarter of 2021, compared to a net loss of $18 million, or $0.30 per share, for the second quarter of 2020.

Novavax revenue in the second quarter of 2021 was $298 million, compared to $36 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 and Coalition for Epidemic Preparedness Innovations agreements.

Research and development expenses increased to $571 million in the second quarter of 2021, compared to $35 million in the same period in 2020. The increase was primarily due to the development of NVX-CoV2373.

General and administrative expenses increased to $73 million in the second quarter of 2021, compared to $18 million for the same period in 2020. The increase was primarily due to increased employee-related costs, stock-based compensation expenses, and professional fees supporting our NVX-CoV2373 program.

As of June 30, 2021, Novavax had $2.1 billion in cash, cash equivalents and restricted cash, compared to $806 million as of December 31, 2020. Net cash provided by operating activities for the first six months of 2021 was $807 million, compared to $93 million for the same period in 2020. The increase in cash provided was primarily due to $1.1 billion in payments under advance purchase agreements recorded as deferred revenue and the timing of payments to third parties.

Through utilization of At-the-Market (ATM) offerings during the first six months of 2021, Novavax raised net proceeds of $565 million.

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 (866) 652-5200 (Domestic) or (412) 317-6060 (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 5, 2021 until 7:30 p.m. ET on November 12, 2021. To access the replay by telephone, dial (877) 344-7529 (Domestic) or (412) 317-0088 (International) and use passcode 10158313.

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 12, 2021.

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. In preclinical studies, NVX-CoV2373 induced antibodies that blocked the binding of spike protein to cellular receptors and provided protection from infection and disease. It was generally well-tolerated and elicited robust antibody response in Phase 1/2 clinical testing.

NVX-CoV2373 is being evaluated in two pivotal Phase 3 trials: a trial in the U.K. that demonstrated efficacy of 96.4% against the original virus strain, 86.3% against the Alpha (B.1.1.7) variant and 89.7% efficacy overall; and the PREVENT-19 trial in the U.S. and Mexico that demonstrated 100% protection against moderate and severe disease and 90.4% efficacy overall. It is also being tested in two ongoing Phase 2 studies that began in August 2020: A Phase 2b trial in South Africa that demonstrated 55% efficacy overall in HIV-negative participants and 48.6% efficacy against a newly emerging escape variant first described in South Africa, and a Phase 1/2 continuation in the U.S. and Australia.

NVX-CoV2373 is stored and stable at 2°- 8°C, allowing the use of existing vaccine supply chain channels for its distribution. It is packaged in a ready-to-use liquid formulation in 10-dose vials.

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 SARSCoV-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 and will be advanced for regulatory submission. 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, the ongoing development of NVX-CoV2373 and other Novavax vaccine product candidates, timing of future regulatory filings and actions, anticipated manufacturing capacity, and future availability of NVX-CoV2373 at a global scale 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; 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	Six Months Ended

	June 30,		June 30,	
	2021	2020	**2021**	2020
Revenue	**$ 298,017**	$ 35,538	**$ 745,246**	$ 38,915
Expenses:				
Research and development	**570,685**	34,846	**1,163,356**	51,741
General and administrative	**73,161**	17,719	**136,351**	27,098
Total expenses	**643,846**	52,565	**1,299,707**	78,839
Loss from operations	**(345,829)**	(17,027)	**(554,461)**	(39,924)
Interest income (expense), net	**(5,599)**	(3,106)	**(10,076)**	(6,074)
Other income (expense)	**2,659**	2,612	**(3,934)**	2,613
Net loss before income tax expense	**(348,769)**	(17,521)	**(568,471)**	(43,385)
Income tax expense	**3,548**	--	**6,565**	--
Net loss	**$ (352,317)**	$ (17,521)	**$ (575,036)**	$ (43,385)
Basic and diluted net loss per share	**$ (4.75)**	$ (0.30)	**$ (7.82)**	$ (0.84)
Basic and diluted weighted average number of common shares outstanding	**74,118**	58,618	**73,580**	51,401

SELECTED CONSOLIDATED BALANCE SHEET DATA
(in thousands)

	June 30, 2021 (unaudited)	**December 31, 2020**
Cash and cash equivalents	**$ 2,074,880**	$ 553,398
Marketable securities	**--**	157,649
Total restricted cash	**47,859**	95,340
Total current assets	**2,354,992**	1,248,203
Working capital	**703,476**	668,531
Total assets	**2,749,587**	1,582,479
Notes payable	**322,746**	322,035
Total stockholders' equity	**745,562**	627,209

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https://ir.novavax.com/2021-08-05-Novavax-Reports-Second-Quarter-2021-Financial-Results-and-Operational-Highlights