Novavax Reports First Quarter 2021 Financial Results and Operational Highlights

May 10, 2021

GAITHERSBURG, Md., May 10, 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 first quarter ended March 31, 2021.

"Novavax made great strides over the first quarter to pave the path for our COVID-19 vaccine candidate, NVX-CoV2373, notably achieving statistically significant efficacy across our Phase 3 UK and Phase 2bSouth Africa trials," said Stanley C. Erck, President and Chief Executive Officer, Novavax. "In parallel, we have secured additional manufacturing and supply agreements, expanding our global supply chain to over 10 countries. In the coming months, we look forward to delivering on critical milestones, including announcing final data from our PREVENT-19 Phase 3 trial, completing our regulatory submissions, evaluating NVX-CoV2373 in younger populations and continuing to develop our booster strategy to address the evolving COVID-19 pandemic. As we continue our dialogue with regulatory authorities for authorization, we remain committed to promptly delivering our vaccine globally, ensuring equitable access and expansive distribution."

First Quarter 2021 and Recent Highlights

COVID-19 Clinical Development

- Reported final efficacy analysis from UK Phase 3 trial and complete analysis from South Africa Phase 2b trial, expanding upon previously reported interim results
    - Demonstrated 100% protection against severe disease
    - Confirmed 96.4% efficacy against original strain of COVID-19 and 86.3% efficacy against B.1.1.7 variant strain in UK Phase 3 trial
    - Demonstrated efficacy of 88.9% in adults over the age of 65 and efficacy of 90.9% in adults with high-risk medical comorbidities in UK Phase 3 trial
    - Demonstrated efficacy of 55.4% among HIV-negative participants in South Africa Phase 2b trial, with the vast majority of cases due to the B.1.351 escape variant
    - South Africa Phase 2b results published in the *New England Journal of Medicine*
    - UK Phase 3 results submitted for publication to peer-reviewed journal and posted to medRxiv.org

- Completed successful enrollment of 30,000 participants for PREVENT-19; final analysis to be reported in the second quarter of 2021

- Initiated pediatric expansion of PREVENT-19 to evaluate efficacy, safety and immunogenicity of NVX-CoV2373 in adolescents
    - Enrolling up to 3,000 adolescent participants aged 12-17 across up to 75 sites in the U.S.
    - Blinded crossover expected to begin six months after initial set of vaccinations

- Initiated crossovers and progressed booster studies of NVX-CoV2373
    - Initiated crossovers in PREVENT-19, UK Phase 3 and South Africa Phase 2b trials to ensure all trial participants have access to active vaccine
    - Completed 6-month booster doses in the U.S. and Australia Phase 2 study with immunology results expected in the third quarter of 2021
    - Com-COV2 Phase 2 clinical trial conducted by University of Oxford and UK Vaccines Taskforce
        - NVX-CoV2373 is one of four COVID-19 vaccines administered during trial to evaluate combined vaccine regimens in 1,050 participants
        - Top-line data expected in the third quarter of 2021

- Advanced development of variant strain vaccines into preclinical studies
    - Preclinical data from study of B.1.351 variant strain vaccine candidate showed strong antibody response and functional immune response in non-human primates when boosted one year after receiving NVX-CoV2373
    - Expect to initiate clinical evaluation of one or more candidates

- Successful collaboration on partner-initiated trials to advance clinical developmentof NVX-CoV2373
    - Takeda completed enrollment of 200 participants in Phase 1/2 clinical trial in Japan
    - Serum Institute of India (Serum Institute) completed enrollment of initial cohort in Phase 2/3 clinical trial in India, with total study including 1,600 participants

COVID-19 Manufacturing and Supply

- Secured additional manufacturing capacity for NVX-CoV2373 globally, with continued progress toward achieving full manufacturing capacity
    - Anticipated capacity revised to 100 million doses per month by the end of the third quarter of 2021, with remainder of capacity expected to come online in the fourth quarter to support 150 million doses per month
    - Reached agreement in principle with GSK to support 'fill and finish' manufacturing of up to 60 million doses of NVX-CoV2373 for use in the UK
    - Established manufacturing presence in Canada through Memorandum of Understanding with Canadian government to produce NVX-CoV2373 at National Research Council's Biologics Manufacturing Centre

- Advanced purchase agreements globally, ensuring equitable access to low, middle and high income countries
    - Finalized advance purchase agreement with Government of Canada to supply 52 million doses with an option for up to an additional 24 million doses
    - Finalized 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 to participants of the COVAX Facility
        - Serum Institute to manufacture and distribute remaining balance of the 1.1 billion doses to low- and middle-income countries

- Furthered existing partnerships to expand global access of NVX-CoV2373
    - Finalized exclusive license agreement with Takeda for the development, manufacturing and commercialization of NVX-CoV2373
        - Takeda to manufacture over 250 million doses of NVX-CoV2373 annually
        - Takeda in discussions with Government of Japan to potentially purchase 150 million doses of NVX-CoV2373
    - Expanded existing partnership with SK bioscience to include license agreement for the manufacturing and commercialization of NVX-CoV2373
        - SK bioscience to supply 40 million doses to the Republic of Korea

COVID-19 Regulatory Pathway

- Progressed regulatory processes for authorization of NVX-CoV2373 with multiple regulatory agencies globally
    - Intend to file for authorization with the U.S. Food and Drug Administration (FDA), the UK Medicines and Healthcare products Regulatory Agency (MHRA) and the European Medicines Agency (EMA) in Europe in the third quarter of 2021
    - Rolling reviews initiated with regulatory authorities, including Health Canada, Australian Therapeutic Goods Administration, New Zealand Medsafe, MHRA and EMA
    - SK bioscience initiated regulatory submission process in collaboration with Novavax to the Republic of Korea's Ministry of Food and Drug Safety

Combination Vaccine

- NanoFlu™/NVX-CoV2373 combination vaccine candidate induced protective responses in preclinical studies
    - Preclinical data manuscript submitted for publication to a peer-reviewed journal and posted on bioRxiv.org
    - Expect to initiate clinical evaluation later this year

Malaria R21 Vaccine / Matrix-M™ Adjuvant Collaboration

- Phase 2b clinical trial results for the University of Oxford's malaria vaccine candidate (R21), including Matrix-M™ adjuvant, published in *Preprints with The Lancet*
    - Trial included 450 participants aged 5-17 months in Burkina Faso
    - Demonstrated high efficacy of 77% when using 5 micrograms of antigen and 50 micrograms of Matrix-M adjuvant
    - Novavax to manufacture and supply Matrix-M adjuvant to Serum Institute for use in R21

    - Serum Institute has rights to use the vaccine, comprised of R21 with Matrix-M adjuvant, in endemic regions, while Novavax will have rights to sell and distribute the vaccine in travelers' and military vaccine markets

- Phase 3 licensure trial underway in 4,800 participants, aged 5-36 months, across four countries in Africa to evaluate the safety and efficacy of R21

Corporate Highlights

- Strengthened corporate leadership with executive management promotions and hiring
    - Gale E. Smith, Ph.D. promoted to Senior Vice President, Discovery and Preclinical Research and Chief Scientist
    - Madelyn 'Lyn' Caltabiano, Ph.D. as Senior Vice President, Global Program Management
    - Troy Morgan, J.D. as Senior Vice President, Chief Compliance Officer
    - Henrietta Ukwu, M.D. as Senior Vice President, Chief Regulatory and Quality Officer

Financial Results for the Three Months Ended March 31, 2021

Novavax reported a net loss of $223 million, or $3.05 per share, for the first quarter of 2021, compared to a net loss of $26 million, or $0.58 per share, for the first quarter of 2020.

Novavax revenue in the first quarter of 2021 was $447 million, compared to $3 million in the same period in 2020. This significant 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 $593 million in the first quarter of 2021, compared to $17 million in the same period in 2020. The significant increase was primarily due to the development of NVX-CoV2373.

General and administrative expenses increased to $63 million in the first quarter of 2021, compared to $9 million for the same period in 2020. The increase was primarily due to increased employee-related costs, stock-based compensation expenses, and supporting our NVX-CoV2373 program.

As of March 31, 2021, Novavax had $2 billion in cash, cash equivalents, marketable securities and restricted cash, compared to $806 million as of December 31, 2020. Net cash provided by operating activities for the first three months of 2021 was $663 million, compared to net cash used in operating activities of $23 million for same period in 2020. The increase in cash provided was primarily due to $772 million 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 quarter 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 May 10, 2021 until 11:59 p.m. ET on May 17, 2021. To access the replay by telephone, dial (877) 344-7529 (Domestic) or (412) 317-0088 (International) and use passcode 10155684.

A webcast of the conference call can also be accessed on the Novavax website at https://ir.novavax.com/events. A replay of the webcast will be available on the Novavax website until August 10, 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 adjuvanted with Novavax' patented saponin-based Matrix-M™ 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 100% protection against severe disease, efficacy of 96.4% against the original virus strain, 86.3% against the B.1.1.7/501Y.V1 variant and 89.7% overall; and the PREVENT-19 trial in the U.S. and Mexico that began in December 2020. 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 100% protection against severe disease 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™

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 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 and the ongoing development of its vaccine and adjuvant products are forward-looking statements. Novavax cautions that these forward-looking statements are subject to numerous risks and uncertainties, which could cause actual results to differ materially from those expressed or implied by such statements. These risks and uncertainties include those identified under the heading "Risk Factors" in the Novavax Annual Report on Form 10-K for the year ended December 31, 2020, 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 sec.gov, 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 March 31,	
	2021	**2020**
Revenue	**$ 447,229**	$ 3,377
Expenses:		

Research and development	**592,671**	16,895
General and administrative	**63,190**	9,379
Total expenses	**655,861**	26,274
Loss from operations	**(208,632)**	(22,897)
Interest income (expense), net	**(4,477)**	(2,967)
Other income (expense)	**(6,593)**	--
Net loss before income tax expense	**$ (219,702)**	$ (25,864)
Income tax expense	**3,017**	--
Net loss	**$ (222,719)**	$ (25,864)
Basic and diluted net loss per share	**$ (3.05)**	$ (0.58)
Basic and diluted weighted average number of common shares outstanding	**73,035**	44,421

SELECTED CONSOLIDATED BALANCE SHEET DATA
(in thousands)

	March 31, 2021	**December 31, 2020**
	(unaudited)	
Cash and cash equivalents	**$ 1,995,482**	$ 553,398
Marketable securities	**2,250**	157,649
Total restricted cash	**33,588**	95,340
Total current assets	**2,246,784**	1,248,203
Working capital	**1,038,229**	668,531
Total assets	**2,608,366**	1,582,479
Notes payable	**322,390**	322,035
Total stockholders' equity	**1,039,127**	627,209

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