Novavax Reports Fourth Quarter and Full Year 2020 Financial Results and Operational Highlights

March 1, 2021

GAITHERSBURG, Md., March 01, 2021 (GLOBE NEWSWIRE) -- 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 fourth quarter and twelve months ended December 31, 2020.

“Novavax continues to make significant strides towards bringing NVX-CoV2373, our COVID-19 vaccine candidate, to market,” said Stanley C. Erck, President and Chief Executive Officer of Novavax. “With positive efficacy results, including against evolving variant strains, NVX-CoV2373 offers a highly unique profile, including the ability to ship and store the vaccine at traditional refrigerated temperatures. We believe these attributes support emergency use authorization and have initiated dialogue with regulators to pursue appropriate regulatory authorization. In addition, we have secured agreements for the delivery of approximately 300 million doses of NVX-CoV2373. In our efforts to provide fair and equitable access to our vaccine around the world, we are proud to partner with the Serum Institute of India to jointly supply 1.1 billion doses of NVX-CoV2373 to Gavi through the COVAX Facility. We continue to work tirelessly to make final commercial preparations in advance of delivering our product across the globe.”

Fourth Quarter 2020 and Recent Highlights

COVID-19 Program

- Commenced regulatory process for authorization for NVX-CoV2373
    - Rolling submission initiated with the UK Medicines and Healthcare products Regulatory Agency; potential to file for authorization in the UK by early second quarter 2021
    - Engaged in ongoing dialogue with US Food and Drug Administration (FDA) through submissions to our open investigational new drug application, with potential for EUA filing in the second quarter of 2021
    - Rolling reviews initiated with:
        - European Medicines Agency
        - Health Canada
        - Australian Therapeutic Goods Administration
        - Medsafe New Zealand
- Reported positive top-line data from Phase 3 UK clinical trial
    - Observed 95.6% efficacy against the original strain of COVID-19 and 85.6% against the UK variant strain
        - Overall primary endpoint met with a vaccine efficacy of 89.3%
    - Generally well-tolerated with a reassuring safety profile
    - Trial included 15,000 participants between 18-84 years of age, including 27 percent over the age of 65
- Reported successful Phase 2b South Africa efficacy study
    - Observed 60% efficacy for HIV-negative portion of study population (94% of study participants were HIV-negative)
    - Demonstrated clinically meaningful protection from South Africa escape variant, which accounted for 93% of sequenced cases
    - Achieved primary efficacy endpoint in overall trial population of 49.4%
    - Trial included 4,404 participants, including 245 medically stable, HIV-positive participants
    - Supported in part by a $15 million grant from Bill & Melinda Gates Foundation (BMGF)
- Completed enrollment in pivotal PREVENT-19 Phase 3 efficacy trial in the US and Mexico
    - 30,000 participants enrolled in two-to-one study design, with highly diverse population
        - 20% Latin American, 12% African American, 6% Native American, 5% Asian American and 13% adults over the age of 65
    - Interim data expected in the second quarter of 2021 dependent on the overall COVID-19 attack rate
    - Blinded crossover protocol, ensuring all participants are provided active vaccine, submitted to the FDA
    - Trial design harmonized to align with other Phase 3 clinical studies supported by the U.S. government
- Ongoing clinical development of NVX-CoV2373
    - 6-month boost dose as part of Phase 1/2 clinical trial in the US and Australia
- Developing variant strain vaccines as standalone and bivalent candidates

    - Evaluation of candidates ongoing in non-human primates
    - Planning clinical evaluation of variant vaccine candidates in mid-2021

- Secured cumulative funding of over $2 billion to date through US government, CEPI and BMGF for development of NVX-CoV2373
    - US government funding through partnership formerly known as Operation Warp Speed increased up to $1.75 billion
    - Coalition for Epidemic Preparedness Innovations (CEPI) funding up to $400 million

- Increased projected global manufacturing capacity to over 2 billion annualized doses when at full-capacity, expected to occur in mid-2021
    - Approximately one billion doses to be manufactured by Serum Institute of India Private Limited (SIIPL)
- Completed collaborations for global manufacturing, commercialization and distribution 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
    - Advanced joint commitment with SIIPL for the equitable access of 1.1 billion doses of NVX-CoV2373 for distribution by the COVAX Facility
    - Reached Memorandum of Understanding with Canadian government for plans to produce NVX-CoV2373 at the National Research Council's Biologics Manufacturing Centre in Montreal
    - 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

- Secured agreements for approximately 200 million doses of NVX-CoV2373
    - Government of Canada to be supplied 52 million doses with an option for up to an additional 24 million
    - UK government to be supplied 60 million doses
    - Commonwealth of Australia to be supplied 51 million doses with an option for up to an additional 10 million
    - Government of New Zealand to be supplied 11 million doses
    - Government of Switzerland to be supplied 6 million doses

NanoFlu™ Program

- Continued to advance NanoFlu program, including exploration of a combined NanoFlu/NVX-CoV2373 vaccine that could be used in a post-pandemic setting

Corporate Highlights

- Appointed three individuals with extensive pharmaceutical industry experience to Novavax' Board of Directors
    - Gregg Alton, J.D.
        - Brings extensive industry experience, including more than 20 years at Gilead Pharmaceuticals, serving in an array of leadership roles including Chief Executive Officer and Chief Patient Officer
    - Margie McGlynn, R. Ph.
        - Brings extensive pharmaceutical industry, vaccine and non-profit experience, including more than two decades at Merck; held roles of increasing responsibility, including President of Merck Vaccines and Infectious Diseases and President, US Hospital and Specialty Products Division
    - David Mott
        - Brings more than three decades of global management, board and investment experience across numerous biopharmaceutical companies, including previously having served as President and Chief Executive Officer of MedImmune

Financial Results for the Three and Twelve Months Ended December 31, 2020

Novavax reported a net loss of $177.6 million, or $2.70 per share, for the fourth quarter of 2020, compared to a net loss of $31.8 million, or $1.13 per share, for the fourth quarter of 2019. For the twelve months ended December 31, 2020, the net loss was $418.3 million, or $7.27 per share, compared to a net loss of $132.7 million, or $5.51 per share, for the same period in 2019.

Novavax revenue in the fourth quarter of 2020 was $279.7 million, compared to $8.8 million in the same period in 2019. The significant increase in revenue was comprised of revenue for services performed under the CEPI agreement and participation in OWS.

Research and development expenses increased to $401.2 million in the fourth quarter of 2020, compared to $29.3 million in the same period in 2019. The increase was primarily due to increased development activities relating to NVX-CoV2373 and increased employee-related costs, including stock-based compensation expense.

General and administrative expenses increased to $61.3 million in the fourth quarter of 2020, compared to $8.2 million for the same period in 2019. The increase was primarily due to increased employee-related costs, primarily stock-based compensation expense, and increased professional fees to support of our NVX-CoV2373 program.

As of December 31, 2020, Novavax had $806.4 million in cash, cash equivalents, marketable securities and restricted cash, compared to $82.2 million as of December 31, 2019. Net cash used in operating activities for the twelve months of 2020 was $42.5 million, compared to $136.6 million for same period in 2019.

Through utilization of At-the-market (ATM) offerings, Novavax raised net proceeds of $428 million and $874 million during the three and twelve months of 2020, respectively. In addition, in the second quarter of 2020, Novavax received gross proceeds of $200 million upon entering into an agreement to sell Series A Convertible preferred stock, convertible into 4,388,850 shares of common stock, to an investment fund affiliated with RA Capital Management (RA Capital) in a private placement. There shares were converted to common stock in the fourth quarter of 2020.

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) 212-6076 (Domestic) or (707) 287-9331 (International), passcode 3797013. A replay of the conference call will be available starting at 7:30 p.m. ET on March 1, 2021 until 7:30 p.m. ET on March 8, 2021. To access the replay by telephone, dial (855) 859-2056 (Domestic) or (404) 537-3406 (International) and use passcode 3797013.

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 June 1, 2021.

About NVX-CoV2373

NVX-CoV2373 is a protein-based vaccine candidate engineered from the genetic sequence 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 block binding of the spike protein to cellular receptors and provided protection from infection and disease. It was generally well-tolerated and elicited robust antibody response numerically superior to that seen in human convalescent sera in Phase 1/2 clinical testing. NVX-CoV2373 is currently being evaluated in two pivotal Phase 3 trials: a trial in the U.K that demonstrated 89.3 percent overall efficacy and 95.6 percent against the original strain in a post-hoc analysis, and the PREVENT-19 trial in the U.S. and Mexico that began in December. It is also being tested in two ongoing Phase 2 studies that began in August: A Phase 2b trial in South Africa that demonstrated 50-60 percent efficacy against newly emerging escape variants, and a Phase 1/2 continuation in the U.S. and Australia.

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)

	Three Months End December 31, 2020 (unaudited)
Revenue	$ 279,659
Expenses:	
Research and development	401,199
Gain on sale of assets	--
General and administrative	61,313
Total expenses	462,512
Loss from operations	(182,853
Interest income (expense), net	(3,737
Other income (expense)	9,026
Net loss	$ (177,564
Basic and diluted net loss per share	$ (2.70
Basic and diluted weighted average number of common shares outstanding	65,725

SELECTED CONSOLIDATED BALANCE SHEET DATA
(in thousands)

Cash and cash equivalents
Marketable securities
Total restricted cash
Total current assets
Working capital
Total assets

Notes payable
Total stockholders’ equity (deficit)

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