Novavax Reports Third Quarter 2020 Financial and Operational Results

November 9, 2020

GAITHERSBURG, Md., Nov. 09, 2020 (GLOBE NEWSWIRE) -- Novavax, Inc. (NASDAQ: NVAX), a late-stage biotechnology company developing next-generation vaccines for serious infectious diseases, today announced its financial results and operational highlights for the third quarter ended September 30, 2020.

“Novavax continued to deliver remarkable progress this quarter, with our most notable achievement being the initiation of a 15,000-person pivotal Phase 3 trial in the U.K. of NVX-CoV2373, our COVID-19 vaccine candidate,” said Stanley C. Erck, President and Chief Executive Officer of Novavax. “With multiple clinical trials ongoing worldwide, we expect initial efficacy data potentially by early first quarter 2021. In the U.S., we made significant progress in large-scale manufacturing and expect to launch a pivotal Phase 3 trial by the end of November. We also announced a newly formed team to lead the NanoFlu program to licensure in the U.S. and look forward to providing updates as the team finalizes its strategy.”

Third Quarter 2020 and Recent Highlights

COVID-19 Program

- Secured funding for late-stage clinical development of NVX?CoV2373
    - U.S. Government funding through Operation Warp Speed (OWS) up to $1.6 billion
    - Coalition for Epidemic Preparedness Innovations (CEPI) funding increased up to a total of $399 million
    - Cumulative $2 billion funding to date through OWS, CEPI and Department of Defense (DoD)

- Advanced ongoing clinical trials for NVX?CoV2373
    - Phase 3 clinical trial in the United Kingdom (U.K.) initiated
        - Trial expanded to 15,000 participants with full enrollment expected by the end of November
        - Enrollment approximately 9,000 participants, over 60% as of today
        - Event-driven interim data expected as soon as early first quarter 2021
    - Pivotal Phase 3 clinical trial in the U.S. expected to begin by end of November
        - U.S. Food and Drug Administration granted Fast Track designation
        - Conducted with support from the U.S. Government through OWS
        - Enrollment of up to 30,000 participants in the U.S. and Mexico, with proportional representation among diverse populations most vulnerable to COVID-19 distributed across race/ethnicity, age and those living with co-morbidities
    - Phase 2b clinical trial in South Africa initiated
        - Includes two cohorts, one in healthy adults and one in medically stable, HIV-positive adults, to allow for evaluation across a diverse, representative study population
        - Trial expanded to approximately 4,404 participants
        - Enrollment over 50% as of today
        - Supported in part by a $15 million grant from Bill & Melinda Gates Foundation
    - Phase 2 portion of Phase 1/2 clinical trial in the U.S. and Australia initiated
        - Enrollment completed with 1,288 healthy volunteers
        - Presented favorable preliminary reactogenicity data during the CDC Advisory Committee on Immunization Practices meeting

- Published Phase 1 data in *The New England Journal of Medicine* from the Phase 1/2 clinical trial of NVX?CoV2373 in healthy adults 18-59 years of age in September 2020

- Completed collaborations for global development, manufacture, supply and commercialization of NVX?CoV2373 with:
    - Australian Federal Government to be supplied 40 million doses
        - Novavax to supply doses beginning as early as the first half of 2021
    - Government of Canada to be supplied up to 76 million doses
    - U.K. Government for the purchase of 60 million doses and support for the Phase 3 clinical trial to assess the efficacy in the U.K. population

        - Novavax to supply doses beginning as early as the first quarter of 2021
    - SK bioscience for development and supply in global markets including the COVAX Facility
        - Signed letter of intent with Republic of Korea's Ministry of Health and Welfare
        - SK bioscience to manufacture the vaccine antigen component for use in the final drug product
    - AGC Biologics for manufacture of Matrix-M™ adjuvant in Copenhagen, Denmark and Seattle, Washington in the U.S.
    - Takeda Pharmaceutical Company Limited for development, manufacture and commercialization in Japan
        - Novavax to receive payments based on achievement of certain development and commercial milestones
        - Novavax shares in proceeds from vaccine sales
    - Serum Institute of India (SII) for development and commercialization in India and low- and middle-income countries
        - Novavax and SII will split revenue from sale of product, net of agreed costs
        - SII to manufacture the antigen component
    - FUJIFILM Diosynth Biotechnologies (FDB) to manufacture bulk drug substance in North Carolina, Texas and in the U.K.
- Increased manufacturing capacity of NVX-CoV2373 to over two billion doses annually, when all planned capacity has been brought online anticipated by mid-2021

NanoFlu™ Program

- Formed a leadership team to advance NanoFlu to regulatory licensure and accelerate all activities required to file a biologics licensing application (BLA), including exploration of a combined NanoFlu/NVX-CoV2373 vaccine that could be used in a post-pandemic setting.
    - Russell (Rip) Wilson, J.D./M.B.A., to Executive Vice President and NanoFlu General Manager
- Published Phase 2 data in *Clinical Infectious Diseases*

Corporate

- Strengthened corporate leadership with additional executive management promotions and hiring
    - Gregory F. Covino as Chief Financial Officer
    - John J. Trizzino as Chief Commercial Officer and Chief Business Officer
    - Filip Dubovsky, M.D. to Executive Vice President, Chief Medical Officer
    - Biegie Lee to Senior Vice President, Chief Information Officer
    Click here to read today's leadership announcement
- Appointed Gregg Alton, J.D. to Novavax' Board of Directors
    - Provides extensive industry experience, including more than 20 years at Gilead Pharmaceuticals in an array of leadership roles across a portfolio of responsibilities
- Expanded facilities to support global vaccine development
    - 170,000 square feet in Gaithersburg, Maryland for manufacturing, research and development, and general operational purposes
    - 9.7-acre parcel of land in Gaithersburg, Maryland to develop in the future to accommodate growth

Financial Results for the Three and Nine Months Ended September 30, 2020

Novavax reported a net loss of $197.3 million, or $3.21 per share, for the third quarter of 2020, compared to a net loss of $18.0 million, or $0.74 per share, for the third quarter of 2019. For the nine months ended September 30, 2020, the net loss was $240.7 million, or $4.39 per share, compared to a net loss of $100.9 million, or $4.43 per share, for the same period in 2019.

Novavax revenue in the third quarter of 2020 was $157.0 million, compared to $2.5 million in the same period in 2019. This significant increase was due to increased development activities relating to NVX-CoV2373 under the CEPI agreement, participation in OWS and the DOD contract.

Research and development expenses increased to $294.1 million in the third quarter of 2020, compared to $18.6 million in the same period in 2019. The increase was primarily due to increased development activities relating to NVX-CoV2373, including an expense of $187.2 million associated with its manufacturing supply agreements for NVX-CoV2373. Of the $187.2 million expense, approximately $122 million was non-cash in the period, and is based on Novavax' determination that certain supply agreements contain an embedded lease under U.S. accounting principles. Given that determination, Novavax recognized a financing lease liability and a right-of-use (ROU) asset. As Novavax is in the research and development phase of its vaccine development, the ROU asset was expensed in the third quarter, as it did not have an alternative use. Research and development expenses also increased due to increased employee-related costs, primarily stock-

based compensation expense.

General and administrative expenses increased to $56.9 million in the third quarter of 2020, compared to $7.9 million for the same period in 2019. This increase was primarily due to increased employee-related costs, primarily stock-based compensation expenses, and increased professional fees relating to the integration of Novavax CZ and supporting our NVX-CoV2373 program.

As of September 30, 2020, Novavax had $571.6 million in cash, cash equivalents, marketable securities and restricted cash, compared to $82.2 million as of December 31, 2019. Net cash provided by operating activities for the first nine months of 2020 was $86.0 million, compared to net cash used in operating activities of $112.9 million for same period in 2019.

Through utilization of At-the-market (ATM) offerings during the third quarter of 2020, Novavax raised net proceeds of $53.3 million and $445.6 million since the beginning of the year. In addition, in the second quarter of 2020, Novavax entered 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. Novavax received gross proceeds of $200 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 (877) 212-6076 (Domestic) or (707) 287-9331 (International), passcode 8059421. A replay of the conference call will be available starting at 7:30 p.m. ET on November 9, 2020 until 7:30 p.m. ET on November 16, 2020. To access the replay by telephone, dial (855) 859-2056 (Domestic) or (404) 537-3406 (International) and use passcode 8059421.

A webcast of the conference call can also be accessed via a link on the home page of the Novavax website (novavax.com) or through the “For Investors”/“Events” tab on the Novavax website. A replay of the webcast will be available on the Novavax website until February 9, 2021.

About NVX-CoV2373

NVX-CoV2373 is a 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 contains 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 cannot replicate, nor can it cause COVID-19. In preclinical trials, NVX-CoV2373 demonstrated induction of antibodies that block binding of spike protein to receptors targeted by the virus, a critical aspect for effective vaccine protection. In the Phase 1 portion of its Phase 1/2 clinical trial, NVX-CoV2373 was generally well-tolerated and elicited robust antibody responses numerically superior to that seen in human convalescent sera. NVX-CoV2373 is also being evaluated in a Phase 3 trial in the U.K. and two ongoing Phase 2 studies that began in August; a Phase 2b trial in South Africa, and a Phase 1/2 continuation in the U.S. and Australia. Novavax has secured $2 billion in funding for its global coronavirus vaccine program, including up to $399 million in funding from the Coalition for Epidemic Preparedness Innovations (CEPI) and almost $1.7 billion from the U.S. government.

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 late-stage biotechnology company that promotes improved health globally through the discovery, development, and commercialization of innovative vaccines to prevent serious infectious diseases.?Novavax?is currently conducting multiple clinical trials for NVX-CoV2373, its vaccine candidate against the virus that causes COVID-19, including a pivotal Phase 3 clinical trial in the United Kingdom to evaluate the efficacy, safety and immunogenicity in individuals aged 18-84 years of age. NanoFlu™, its quadrivalent influenza nanoparticle vaccine, met all primary objectives

in its pivotal Phase 3 clinical trial in older adults. Both candidate vaccines incorporate Novavax' proprietary saponin-based Matrix-M™ adjuvant to enhance the immune response and stimulate high levels of neutralizing antibodies.?Novavax?is a leading innovator of recombinant vaccines; its proprietary recombinant technology platform combines the power and speed of genetic engineering to efficiently produce highly immunogenic nanoparticles in order to address urgent global health needs.

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, 2019, and Quarterly Report on Form 10-Q for the period ended September 30, 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 September 30,	
	2020	2019
Revenue	$ 157,024	$ 2,507
Expenses:		
Research and development	294,087	18,611
Gain on Catalent transaction	--	(9,016
General and administrative	56,879	7,899
Total expenses	350,966	17,494
Loss from operations	(193,942)	(14,987
Interest income (expense), net	(4,320)	(3,061
Other income (expense)	952	5
Net loss	$ (197,310)	$ (18,043
Basic and diluted net loss per share	$ (3.21)	$ (0.74
Basic and diluted weighted average number of common shares outstanding	61,554	24,327

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)	

Contacts:

Investors
Erika Trahan
ir@novavax.com
240-268-2022

Media
Brandzone/KOGS Communication
Edna Kaplan
kaplan@kogspr.com
617-974-8659