Novavax Reports Second Quarter 2019 Financial Results

August 7, 2019

GAITHERSBURG, Md., Aug. 07, 2019 (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 second quarter and six months ended June 30, 2019.

“We made important clinical and strategic progress this quarter, particularly in advancing NanoFlu, our next-generation flu vaccine candidate,” said Stanley C. Erck, President and Chief Executive Officer of Novavax. “The agreement reached with the FDA on our NanoFlu Phase 3 clinical trial design will allow us to leverage the accelerated approval pathway. We are now well-positioned to deliver top-line Phase 3 data in the first quarter of 2020.”

Second Quarter 2019 and Subsequent Operational Highlights

NanoFlu™ Program

- Novavax received input from the U.S. Food and Drug Administration (FDA) on its End-of Phase 2 questions and reached agreement on the Phase 3 clinical trial design, enabling Novavax to conduct a non-inferiority immunogenicity clinical trial against a licensed quadrivalent comparator. These data would support the future biologics license application and licensure of NanoFlu via the accelerated approval pathway.

ResVax™ Program

- Novavax continues to receive input from global regulatory agencies to solicit input on possible pathways to licensure for ResVax. In Europe, we will seek formal scientific advice this fall from the European Medicines Agency (EMA). In the U.S., the FDA recommended that Novavax conduct an additional Phase 3 clinical trial to confirm efficacy against medically significant RSV disease.

- Novavax presented key efficacy and safety findings at the World Vaccine Congress in Washington, D.C. and at the Annual Meeting of the European Society for Pediatric Infectious Diseases (ESPID) in Ljubljana, Slovenia from the Prepare trial of ResVax. Additional details on these presentations are available on our website.

Corporate

- Novavax and Catalent Biologics entered into an arrangement under which Catalent purchased Novavax’ manufacturing equipment and related assets for approximately $18 million, assumed the property leases to two Novavax product development and manufacturing facilities and hired approximately 100 of Novavax’ manufacturing and quality employees. In addition, Catalent will also provide long-term process development and manufacturing services for specified Novavax programs.

- Effective May 10, 2019, Novavax completed a reverse stock split of its issued and outstanding common stock at a ratio of 1-for-20.

Financial Results for the Three and Six Months Ended June 30, 2019

Share and per share information have been restated to reflect the reverse stock split described above.

Novavax reported a net loss of $39.6 million, or $1.69 per share, for the second quarter of 2019, compared to a net loss of $44.5 million, or $2.37 per share, for the second quarter of 2018. For the six months ended June 30, 2019, the net loss was $82.8 million, or $3.77 per share, compared to a net loss of $90.8 million, or $5.10 per share, for the same period in 2018.

Novavax revenue in the second quarter of 2019 was $3.4 million, compared to $10.8 million in the same period in 2018. This 69% decrease was driven by the completion of enrollment of participants in the Prepare trial in the second quarter of 2018.

Research and development expenses decreased 32% to $30.4 million in the second quarter of 2019, compared to $44.5 million for the same period in 2018. This decrease was primarily due to decreased development activities of ResVax.

General and administrative expenses increased 17% to $9.6 million in the second quarter of 2019, compared to $8.2 million for the same period in 2018. The increase was primarily due to higher professional fees and recent stockholders meetings.

Interest income (expense), net for the second quarter of 2019 was ($2.9) million, compared to ($2.6) million for the same period of 2018.

As of June 30, 2019, Novavax had $78.2 million in cash, cash equivalents, marketable securities and restricted cash, compared to $103.9 million as of December 31, 2018. Net cash used in operating activities for the first six months of 2019 was $80.6 million, compared to $106.0 million for same period in 2018.

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 3193866. A replay of the conference call will be available starting at 7:30 p.m. ET on August 7, 2019 until 7:30 p.m. ET on August 14, 2019. To access the replay by telephone, dial (855) 859-2056 (Domestic) or (404) 537-3406 (International) and use passcode 3193866.

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 "Investor Info"/"Events" tab on the Novavax website. A replay of the webcast will be available on the Novavax website until November 7, 2019.

About Influenza

Influenza is a world-wide infectious disease that causes illness in humans with symptoms ranging from mild to life-threatening or even death. Serious illness occurs not only in susceptible populations such as infants, young children and older adults, but also in the general population largely because of infection by continuously evolving strains of influenza which can evade the existing protective antibodies in humans. An estimated one million deaths globally each year are attributed to influenza. Current estimates for seasonal influenza vaccine growth in the top seven markets (U.S., Japan, France, Germany, Italy, Spain and UK), show a potential increase from approximately $3.2 billion in 2015 to $5.3 billion by 2025.

About NanoFlu™ and Matrix-M™

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, which 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.

About Accelerated Approval

Accelerated approval may be granted for certain biological products that have been studied for their safety and effectiveness in treating serious or life-threatening illnesses and that provide meaningful therapeutic benefit over existing treatments. Such an approval will be based on adequate and well-controlled clinical trials establishing that the biological product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit. For seasonal influenza vaccines, the hemagglutination inhibition (HAI) antibody response may be an acceptable surrogate marker of activity that is reasonably likely to predict clinical benefit. To be considered for accelerated approval, a biologics license application for a new seasonal influenza vaccine should include results from one or more well-controlled studies designed to meet immunogenicity endpoints and a commitment to conduct confirmatory post-marketing studies of clinical effectiveness in preventing influenza.

About RSV in Infants

Globally, RSV (respiratory syncytial virus) is the leading viral cause of severe lower respiratory tract disease in infants and young children. It is the second leading cause of death in children under one year of age. Estimated annual hospitalizations of 1.4 million and an estimated 27,300 in-hospital deaths were due to RSV acute lower respiratory infection in children under six months of age. RSV results in a total global economic burden of $6.2 billion annually.

In the U.S., RSV is the leading cause of hospitalization of infants, with estimated annual hospitalizations of up to 76,000. While RSV can impact all infants, babies under six months of age are among those at highest risk, as approximately 77% of all first-year RSV infections occur before six months. In the U.S., the total economic burden is $2.7 billion annually.

About ResVax™

ResVax is an RSV fusion (F) protein recombinant nanoparticle vaccine with aluminum phosphate as an adjuvant. It is being developed to protect infants from RSV disease via maternal immunization, which may offer the best method of protection

from RSV disease in infants through the first months of life. ResVax is being evaluated in Prepare™, a global Phase 3 clinical trial in 4,636 pregnant women, at least 3,000 of whom received the vaccine, and their infants. Prepare is supported by an $89.1 million grant from the Bill & Melinda Gates Foundation (BMGF).

About Novavax

Novavax, Inc. (Nasdaq:NVAX), is a late-stage biotechnology company that drives improved health globally through the discovery, development, and commercialization of innovative vaccines to prevent serious infectious diseases. ResVax™, its RSV vaccine for infants via maternal immunization, is the only vaccine in a Phase 3 clinical program and is designed to prevent severe lower respiratory tract infection which is the second leading cause of death in children under one year of age worldwide. Novavax is also advancing NanoFlu™, its quadrivalent influenza nanoparticle vaccine, to address key factors that can lead to the poor effectiveness of currently approved flu vaccines. Novavax is a leading innovator of recombinant vaccines; its proprietary recombinant technology platform combines the power and speed of genetic engineering to efficiently produce a new class of highly immunogenic nanoparticles addressing 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, 2018, and Quarterly Report on Form 10-Q for the period ended June 30, 2019, as filed with the Securities and Exchange Commission (SEC). We caution investors not to place considerable reliance on the 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 June 30, 2019
Revenue	$ 3,357
Expenses:	
Research and development	30,417
General and administrative	9,606
Total expenses	40,023
Loss from operations	(36,666
Interest income (expense), net	(2,929
Other income (expense)	(8
Net loss	$ (39,603
Basic and diluted net loss per share	$ (1.69
Basic and diluted weighted average number of common shares outstanding	23,473

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' deficit	

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