Novavax Reports First Quarter 2019 Financial Results

May 2, 2019

GAITHERSBURG, Md., May 02, 2019 (GLOBE NEWSWIRE) -- Novavax, Inc., (Nasdaq: NVAX) today announced its financial results and operational highlights for the first quarter ended March 31, 2019.

First Quarter 2019 and Subsequent Operational Highlights

ResVax™ Program

- In February 2019, Novavax announced top-line data from the Prepare™ trial, which was designed to determine the efficacy of ResVax™ against medically significant respiratory syncytial virus (RSV)-positive lower respiratory tract infection (LRTI) in infants. ResVax is the first RSV vaccine to demonstrate efficacy in infants.

- In April 2019, Novavax presented additional results at the World Vaccine Congress in Washington, D.C. from the Prepare trial of ResVax. Although the Prepare trial results did not meet the pre-specified primary efficacy endpoint, it demonstrated efficacy against RSV LRTI hospitalizations, a pre-specified secondary endpoint. RSV LRTI hospitalization is not only an important indication of the severity of RSV disease in infants, it also reflects a significant economic burden to global health systems.

NanoFlu™ Program

- In January 2019, Novavax announced positive top-line results of its Phase 2 clinical trial of NanoFlu comparing various quadrivalent formulations, with or without Novavax' Matrix-M™ adjuvant, with two U.S.-licensed influenza vaccines in older adults. These results show that NanoFlu with Matrix-M generated enhanced immune responses compared to the unadjuvanted formulation, and importantly, showed superior hemagglutination inhibition antibody (HAI) responses against wild-type A(H3N2) viruses, including drifted strains, when compared to Fluzone® High-Dose, the leading flu vaccine in older adults.

Key Upcoming Events

- Meet with the FDA, European regulatory agencies, and potentially other national regulatory agencies during the second and third quarters, to assess opportunities for submission of marketing applications for ResVax.
- Reach agreement with the FDA during the third quarter of 2019 on a proposed Phase 3 clinical trial design for NanoFlu utilizing accelerated approval criteria for licensure.
- Present ResVax Phase 3 clinical trial data at the 37th Annual Meeting of the European Society for Paediatric Infectious Diseases (ESPID) on May 7, 2019.

Financial Results for the First Quarter Ended March 31, 2019

Novavax reported a net loss of $43.2 million, or $0.11 per share, for the first quarter of 2019, compared to a net loss of $46.4 million, or $0.14 per share, for the first quarter of 2018.

Novavax revenue in the first quarter of 2019 was $4.0 million, compared to $9.7 million in the same period in 2018. This 59% decrease was driven by the completion of enrollment of the Prepare trial in the second quarter of 2018.

Research and development expenses decreased 20% to $35.5 million in the first quarter of 2019, compared to $44.5 million for the same period in 2018. This decrease was primarily due to decreased development activities, including lower clinical trial costs, of ResVax.

General and administrative expenses were flat at $8.7 million in the first quarter of 2019, compared to the same period of 2018.

Interest income (expense), net was ($3.0) million in the first quarter of 2019, compared to ($2.9) million for the same period of 2018.

As of March 31, 2019, Novavax had $108.7 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 quarter of 2019 was $50.6 million, compared to $66.1 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 5394082. A replay of the conference call will be available starting at 7:30 p.m. ET on May 2, 2019 until 7:30 p.m. ET on May 9, 2019. To access the replay by telephone, dial (855) 859-2056 (Domestic) or (404) 537-3406 (International) and use passcode 5394082.

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 August 2, 2019.

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. Estimated annual hospitalizations are 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. In February 2019, Novavax announced top-line data from Prepare™, a global Phase 3 clinical trial in 4,636 pregnant women, at least 3,000 of whom have received the vaccine, and their infants. Prepare is supported by an $89.1 million grant from the Bill & Melinda Gates Foundation (BMGF).

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 2012-13 season to $5.3 billion by the 2021-22 season.

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 protein amino acid sequences that are the same as the recommended wild-type circulating virus HA sequences. NanoFlu contains Novavax' patented saponin-based Matrix-M adjuvant, which is potent and well- stimulates both high quality and durable antibody responses as well as multifunctional CD4 and CD8 T-cell responses. In January 2019, Novavax announced positive top-line data from its Phase 2 clinical trial in older adults of quadrivalent formulations of NanoFlu in 1,375 healthy older adults across clinical sites in the U.S.

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 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. Its two priority programs are ResVax™, its RSV vaccine for infants via maternal immunization, and NanoFlu™, its quadrivalent influenza nanoparticle vaccine. Novavax' 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 March 31, 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)

Revenue

Expenses:
Research and development
General and administrative
Total expenses
Loss from operations
Interest income (expense), net
Other income (expense)
Net loss

Basic and diluted net loss per share
Basic and diluted weighted average
number of common shares outstanding

SELECTED CONSOLIDATED BALANCE SHEET DATA
(in thousands)

March 31,
2019

	(unaudited)
Cash and cash equivalents	97,711
Marketable securities	2,484
Total restricted cash	8,488
Total current assets	123,394
Working capital	91,898
Total assets	221,319
Notes payable	319,543
Total stockholders' deficit	(150,583)

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