Novavax Reports Third Quarter 2019 Financial Results

November 7, 2019

GAITHERSBURG, Md., Nov. 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 third quarter and nine months ended September 30, 2019.

“The recent initiation of our pivotal NanoFlu Phase 3 clinical trial in older adults represents an important milestone toward gaining approval for our novel vaccine candidate,” said Stanley C. Erck, President and Chief Executive Officer of Novavax. “Enrollment in the trial is complete and we are well positioned to deliver top-line clinical trial data in the first quarter of 2020. For ResVax, discussions with potential partners and other stakeholders are ongoing to determine the best path forward to protect vulnerable infants against RSV, for which there is currently no vaccine.”

Third Quarter 2019 and Subsequent Operational Highlights

NanoFlu™ Program

- Novavax initiated a pivotal Phase 3 clinical trial for NanoFlu, its recombinant quadrivalent seasonal influenza vaccine candidate, and completed enrollment of 2,652 healthy older adults across 19 U.S. clinical sites. The primary objective of the randomized, observer-blinded, active-controlled trial is to demonstrate non-inferior immunogenicity as measured by hemagglutination inhibition (HAI) titers of vaccine homologous influenza strains and safety compared against a licensed vaccine, Fluzone® Quadrivalent.

- Top-line results from this Phase 3 clinical trial are expected in the first quarter of 2020 and would support a subsequent U.S. biologics license application (BLA) and licensure of NanoFlu using the U.S. Food and Drug Administration’s (FDA) accelerated approval pathway.

- On September 19, 2019, a Presidential Executive Order was issued that mandates the modernization of influenza vaccines for the benefit of U.S. national security and public health. This Executive Order reinforces the strategic value of the NanoFlu program in particular because, as a non-egg based vaccine formulated using recombinant nanoparticle technology and combined with a safe and potent adjuvant, NanoFlu has all the characteristics of the better influenza vaccine mandated by the Order. The full Executive Order is available here.

ResVax™ Program

- The FDA and the European Medicines Agency (EMA) have both recommended that Novavax conduct an additional Phase 3 clinical trial to confirm the efficacy of ResVax. Novavax is in continuing discussions with both global regulatory authorities and with potential partners to explore the opportunity to bring ResVax to market globally.

- Novavax presented additional efficacy and safety findings from the program at the Infectious Diseases Society for Obstetrics and Gynecology (IDSOG) Annual meeting in August and at the World Vaccine Congress - Europe last week. The presentations included new observations based on the recently completed analyses of the 1-year safety data, including a 56.9% (95% CI 34.5, 71.7%) reduction in the incidence of serious adverse events (SAEs) diagnosed as pneumonia, with confirmation by chest x-ray, that extended through the first year of life.

Ebola™ Program

- *The Journal of Infectious Diseases*published a peer-reviewed manuscript detailing the positive results from Novavax’ Phase 1 clinical trial in healthy adults of the Ebola virus glycoprotein vaccine candidate. Additional details of the manuscript are available here.

Corporate

- Novavax and Catalent Biologics closed the transaction 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 has begun to provide process development and manufacturing services for specified Novavax programs.

Financial Results for the Three and Nine Months Ended September 30, 2019

Share and per share data have been restated to reflect the reverse stock split that was completed in May 2019.

Novavax reported a net loss of $18.0 million, or $0.74 per share, for the third quarter of 2019, compared to a net loss of $44.6 million, or $2.33 per share, for the third quarter of 2018. For the nine months ended September 30, 2019, the net loss was $100.9 million, or $4.43 per share, compared to a net loss of $135.4 million, or $7.42 per share, for the same period in 2018. The 2019 net losses include a gain of $9.0 million recorded as a result of the Catalent transaction.

Novavax revenue in the third quarter of 2019 was $2.5 million, compared to $7.7 million in the same period in 2018. This 68% 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 55% to $18.6 million in the third quarter of 2019, compared to $41.3 million in the same period in 2018. This decrease was primarily due to decreased development activities of ResVax, lower employee-related costs and other cost savings due to the Catalent transaction.

General and administrative expenses slightly decreased to $7.9 million in the third quarter of 2019, compared to $8.3 million for the same period in 2018.

Interest income (expense), net for the third quarter of 2019 was ($3.1) million, compared to ($2.7) million for the same period of 2018.

As of September 30, 2019, Novavax had $75.9 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 nine months of 2019 was $112.9 million, compared to $139.6 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 5956098. A replay of the conference call will be available starting at 7:30 p.m. ET on November 7, 2019 until 7:30 p.m. ET on November 14, 2019. To access the replay by telephone, dial (855) 859-2056 (Domestic) or (404) 537-3406 (International) and use passcode 5956098.

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 February 7, 2020.

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 September 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 September 30,	
	2019	2018

Revenue	$ 2,507	$ 7,735
Expenses:		
Research and development	18,611	41,326
Gain on Catalent transaction	(9,016)	--
General and administrative	7,899	8,309
Total expenses	17,494	49,635
Loss from operations	(14,987)	(41,900
Interest income (expense), net	(3,061)	(2,651
Other income (expense)	5	(19
Net loss	$ (18,043)	$ (44,570
Basic and diluted net loss per share	$ (0.74)	$ (2.33
Basic and diluted weighted average number of common shares outstanding	24,327	19,116

SELECTED CONSOLIDATED BALANCE SHEET DATA
(in thousands)

	September 30, 2019 (unaudited)
Cash and cash equivalents	$ 71,167
Marketable securities	--
Total restricted cash	4,763
Total current assets	89,022
Working capital	67,447
Total assets	164,810
Notes payable	320,255
Total stockholders' deficit	(189,838)

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