Novavax Provides Corporate Update and Report of Fourth Quarter and Year-End 2017 Financial Results

March 14, 2018

GAITHERSBURG, Md., March 14, 2018 (GLOBE NEWSWIRE) -- Novavax, Inc., (Nasdaq:NVAX) today provided a corporate update and announced its financial results for the fourth quarter and twelve months ended December 31, 2017.

“During this last quarter we collected our most significant results to date from our two lead vaccine programs,” said Stanley C. Erck, President and CEO, Novavax, Inc. “This progress gives us enhanced focus and momentum to execute under these programs for the remainder of 2018 and beyond.”

NanoFlu Program Update:

In late February 2018, the Company announced positive top-line results from its Phase 1/2 clinical trial in 330 older adults of its NanoFlu recombinant influenza vaccine, which includes its proprietary Matrix-M™ adjuvant, compared to the leading licensed egg-based, high-dose influenza vaccine for older adults (IIV3-HD). Key findings from the trial show that Novavax’ trivalent NanoFlu vaccine induced significantly higher hemagglutination inhibition (HAI) antibody responses against homologous A-type strains as well as against historic and forward-drifted H3N2 strains. Based on the strength of these trial results, the Company submitted a related manuscript to a peer-reviewed medical journal and is planning to present the data at the World Vaccine Congress meeting on April 4, 2018.

“This influenza season in the Northern Hemisphere has resulted in a serious public health epidemic, largely because of the H3N2 flu strain and the inability of current vaccines to provide adequate protection, particularly to older adults and other vulnerable populations,” said Gregory M. Glenn, M.D., President of Research and Development. “Our NanoFlu vaccine’s head-to-head performance against IIV3-HD demonstrated that it has the potential to address two primary confounding factors related to poor vaccine efficacy: virus drift and vaccine mutation resulting from egg-based manufacturing. With these findings, we are able to initiate manufacturing and clinical operations activities to support our next step, a Phase 2 trial of a quadrivalent formulation of our NanoFlu vaccine, scheduled to begin in the third quarter of this year.”

RSV F Vaccine Maternal Immunization Program Update:

In December 2017, the Company completed a successful informational analysis of the Phase 3 Prepare™ clinical trial of its RSV F Vaccine for infants via maternal immunization. The analysis of data from 1,307 infants in the per-protocol population indicate an observed vaccine efficacy in the range of between 45% and 100%. The Company anticipates that it will reach approximately 4,600 participants, including approximately 3,000 actively vaccinated mothers, in the second quarter of 2018, which will enable an interim efficacy analysis with results reported in early 2019. This program continues to be funded under an $89 million grant from the Bill and Melinda Gates Foundation (BMGF), and has been granted Fast Track designation by the U.S. Food and Drug Administration (FDA).

“The results of our informational analysis this December significantly increased the likelihood of success of our RSV F Vaccine program for infants via maternal immunization,” added Mr. Erck. “With over 4,000 current participants, we are very close to triggering the interim efficacy analysis, the positive results of which would form the basis of our Biologics License Application filing with the FDA. Providing protection to newborns from respiratory syncytial virus, one of the most prevalent and damaging diseases to which they are exposed during their first months of life, has important global public health implications.”

Financial Results for the Three and Twelve Months Ended December 31, 2017

Novavax reported a net loss of $50.8 million, or $0.16 per share, for the fourth quarter of 2017, compared to a net loss of $57.1 million, or $0.21 per share, for the fourth quarter of 2016. For the twelve months ended December 31, 2017, the net loss was $183.8 million, or $0.63 per share, compared to a net loss of $280.0 million, or $1.03 per share, for the same period in 2016.

Novavax revenue in the fourth quarter of 2017 was $10.4 million, compared to $5.4 million in the same period in 2016. This 93% increase was driven by higher revenue recorded under the BMGF grant of $89 million.

Research and development expenses decreased 3% to $49.7 million in the fourth quarter of 2017, compared to $51.1 million for the same period in 2016. The decrease was primarily due to reduced development activities of our RSV F Vaccine for older adults, partially offset by increased developemtnt activities of our RSV F Vaccine for infants via maternal immunization.

Interest income (expense), net for the fourth quarter of 2017 and 2016 was ($3.1) million.

As of December 31, 2017, the company had $157.3 million in cash, cash equivalents and marketable securities, compared to $235.5 million as of December 31, 2016. Net cash used in operating activities for the full year 2017 was $138.7 million, compared to $255.5 million for same period in 2016. The decrease in cash usage was primarily due to decreased costs relating to our RSV F Vaccine and lower overall employee-related costs.

Conference Call

Novavax management will host its quarterly conference call today at 5:00 p.m. ET. The dial-in number for the conference call is (877) 212-6076 (Domestic) or (707) 287-9331 (International), passcode 6472939. A replay of the conference call will be available starting at 7:30 p.m. ET on March 14, 2018 until 8:30 pm ET on March 21, 2018. To access the replay by telephone, dial (855) 859-2056 (Domestic) or (404) 537-3406 (International) and use passcode 6472939.

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 June 14, 2018.

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 each year are attributed to influenza.1 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 2025.2

About the Phase 1/2 Clinical Trial

Novavax conducted a randomized, observer-blind, comparator-controlled trial of NanoFlu vaccine (in two trivalent formulations: 45µg or 180µg total HA) against IIV3-HD in 330 healthy adults aged 60 years or older. Vaccine immunogenicity was measured by HAI and neutralization antibody responses against a panel of vaccine-homologous, and historically and forward-drifted, influenza virus strains.

About NanoFlu™ and Matrix M™

NanoFlu vaccine is a recombinant hemagglutinin (HA) protein nanoparticle influenza vaccine candidate produced by Novavax in its SF9 insect cell baculovirus system. NanoFlu vaccine uses HA amino acid protein sequences that are substantially the same as wild-type circulating virus HA sequences. NanoFlu vaccine 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 RSV

RSV is the most common cause of lower respiratory tract infections and the leading viral cause of severe lower respiratory tract disease in infants and young children worldwide, with estimated annual infection and mortality rates of 64 million and 160,000, respectively.3 In the US, RSV is the leading cause of hospitalization of infants.4 Despite the induction of post-infection immunity, repeat infection and lifelong susceptibility to RSV is common.5 Currently, there is no approved RSV vaccine available.

About RSV F Vaccine for Infants via Maternal Immunization

Novavax is developing a vaccine that targets the fusion protein, or F-protein, of the RSV virus. The F-protein has highly conserved amino acid sequences, called antigenic sites, which are the target of neutralizing antibodies and are believed to be ideal vaccine targets. Novavax’ genetically engineered novel F-protein antigen exposes a range of these antigenic sites, and can evoke immune responses to them in human vaccine recipients. In a previous Phase 2 clinical trial of the RSV F Vaccine, which assessed the transplacental transfer of maternal antibodies induced by the vaccine, immunized women demonstrated

meaningful fold rises in anti-F IgG, palivizumab-competing antibodies and microneutralization titers. In addition, infants' antibody levels at delivery averaged 90-100% of the mothers' levels, indicating efficient transplacental transfer of antibodies from mother to infant.

About the U.S. Food and Drug Administration's (FDA) Fast Track Program

The Fast Track Drug Development Program was established under the FDA Modernization Act of 1997. A Fast Track designation is intended for products that treat serious or life-threatening diseases or conditions, and that demonstrate the potential to address unmet medical needs for such diseases or conditions. The program is intended to facilitate development and expedite review of drugs to treat serious and life-threatening conditions so that an approved product can reach the market expeditiously. Specifically, Fast Track designation facilitates meetings to discuss all aspects of development to support licensure and it provides the opportunity to submit sections of a BLA on a rolling basis as data become available, which permits the FDA to review modules of the BLA as they are received instead of waiting for the entire BLA submission. In addition, priority review (six month review versus standard ten month review) is a potential benefit that may be available to Novavax' RSV F vaccine in the future.

About Novavax

Novavax, Inc. (Nasdaq:NVAX) is a clinical-stage biotechnology company committed to delivering novel products to prevent infectious diseases. Our RSV and influenza nanoparticle vaccine candidates are Novavax' most advanced clinical programs and are at the forefront of the Company's efforts to improve global health. Additional information about Novavax is available on the Company's website, novavax.com.

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, 2017 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.
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NOVAVAX, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(in thousands, except per share information)

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2017 (unaudited)	2016	2017	2016
Revenue	$ 10,412	$ 5,399	$ 31,176	$ 15,35
Expenses:				
Research and development	49,657	51,100	168,435	237,939
General and administrative	8,540	8,344	34,451	46,527
Total expenses	58,197	59,444	202,886	284,466
Loss from operations	(47,785)	(54,045)	(171,710)	(269,11
Interest income (expense), net	(3,105)	(3,066)	(12,126)	(10,822
Other income (expense)	47	2	67	(31)

Net loss	$ (50,843)	$ (57,109)	$ (183,769)	$ (279,9
Basic and diluted net loss per share	$ (0.16)	$ (0.21)	$ (0.63)	$ (1.03)
Basic and diluted weighted average number of common shares outstanding	316,119	271,200	292,669	270,802

SELECTED CONSOLIDATED BALANCE SHEET DATA
(in thousands)

	December 31, 2017	December 31, 2016
Cash and cash equivalents	$ 106,307	$ 144,353
Marketable securities	50,996	91,126
Total current assets	203,311	287,830
Working capital	129,636	221,424
Total assets	302,493	394,301
Total notes payable and capital lease obligation	317,763	316,376
Total stockholders' deficit	(101,732)	(5,546)

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1 Resolution of the World Health Assembly (2003) WHA56.19.28

2 Influenza Vaccines Forecasts. Datamonitor (2013)

3 https://www.niaid.nih.gov/diseases-conditions/respiratory-syncytial-virus-rsv

4 Leader S. Pediatr Infect Dis J. 2002 Jul;21(7):629-32

5 PLOS. "How immunity to respiratory syncytial virus develops in childhood, deteriorates in adults." ScienceDaily. 21 April 2016. https://www.sciencedaily.com/releases/2016/04/160421145747.htm