Novavax Reports Fourth Quarter and Year-End 2018 Financial Results

March 18, 2019

Company to Host Conference Call Today at 4:30 p.m. ET

GAITHERSBURG, Md., March 18, 2019 (GLOBE NEWSWIRE) -- Novavax, Inc. (Nasdaq: NVAX) today announced its financial results and operational highlights for the fourth quarter and twelve months ended December 31, 2018.

“In 2018, we committed to focus on our two lead programs, ResVax™ and Nanoflu™, and reflecting on last year’s activities, I am proud to say we have achieved significant results for both,” said Stanley C. Erck, President and CEO of Novavax, Inc. “Although we were disappointed to miss the primary endpoint of our Prepare trial, ResVax is the first RSV vaccine to demonstrate efficacy for the prevention of RSV disease in a Phase 3 clinical trial. In addition, the successful Phase 2 results for our NanoFlu vaccine provide an opportunity to now confirm with the FDA the use of accelerated approval for licensure. We are now prepared to make meaningful advances on these programs during 2019.”

Fourth Quarter 2018 and Subsequent Operational Highlights

ResVax ™ Program

- In February 2019, Novavax announced top-line data from the Prepare trial, which was initiated in December 2015 to determine the efficacy of ResVax against medically significant RSV-positive lower respiratory tract infection (LRTI) in infants. Although the Prepare trial results did not meet the pre-specified primary efficacy endpoint, they demonstrate efficacy against a secondary objective (RSV LRTI hospitalizations). In addition, other pre-specified exploratory endpoints and post-hoc analyses highlight ResVax’ potential to improve global health against serious RSV disease.

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

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

Financial Results for the Three and Twelve Months Ended December 31, 2018

Novavax reported a net loss of $49.3 million, or $0.13 per share, for the fourth quarter of 2018, compared to a net loss of $50.8 million, or $0.16 per share, for the fourth quarter of 2017. For the twelve months ended December 31, 2018, the net loss was $184.7 million, or $0.50 per share, compared to a net loss of $183.8 million, or $0.63 per share, for the same period in 2017.

Novavax revenue in the fourth quarter of 2018 was $6.1 million, compared to $10.4 million in the same period in 2017. This 41% 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 13% to $43.4 million in the fourth quarter of 2018, compared to $49.7 million for the same period in 2017. This decrease was primarily due to decreased development activities of ResVax and lower employee-related costs, partially offset by increased development activities of NanoFlu.

General and administrative expenses increased 8% to $9.2 million in the fourth quarter of 2018, compared to $8.5 million for the same period in 2017. The increase was primarily due to higher professional fees.

Interest income (expense), net for the fourth quarter of 2018 was ($2.8) million, compared to ($3.1) million for the same period of 2017.

As of December 31, 2018, Novavax had $103.9 million in cash, cash equivalents, marketable securities and restricted cash, compared to $186.4 million as of December 31, 2017. Net cash used in operating activities for the fourth quarter of 2018 was $45.3 million, compared to $43.4 million for

same period in 2017.

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 9559037. A replay of the conference call will be available starting at 7:30 p.m. ET on March 18, 2019 until 7:30 p.m. ET on March 25, 2019. To access the replay by telephone, dial (855) 859-2056 (Domestic) or (404) 537-3406 (International) and use passcode 9559037.

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 18, 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.[1] It is the second leading cause of death in children under one year of age.[2] 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.[3] 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.[4] Estimated annual hospitalizations are up to 76,000.[5,6] 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.[7] 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.[8]

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[1] Nair, H., et al. (2010) Lancet. 375:1545-1555

[2] Losano R., et al. (2012/Dec15) Lancet. 380: 2095

[3] Ting S/Nair H. Lancet. 2017/Sep2;390:946

[4] Leader S., et al. (2003) J Pediatr. 143: S127

[5] Hall CB. N Engl J Med 2009;360:588

[6] CDC-Stockman LJ. Pediatr Infect Dis J 2012;31:5

[7] Resolution of the World Health Assembly. (2003) WHA56.19.28

[8] Influenza Vaccines Forecasts. Datamonitor (2013)

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 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)

	Three Months Ended December 31,		Twelve Months Ended December 31	
	2018	**2017**	**2018**	**2017**
	(unaudited)			
Revenue	**$ 6,127**	$ 10,412	**$ 34,288**	$ 31,176
Expenses:				
Research and development	**43,415**	49,657	**173,797**	168,435
General and administrative	**9,224**	8,540	**34,409**	34,451
Total expenses	**52,639**	58,197	**208,206**	202,886
Loss from operations	**(46,512)**	(47,785)	**(173,918)**	(171,710)
Interest income (expense), net	**(2,819)**	(3,105)	**(10,938)**	(12,126)
Other income (expense)	**(3)**	47	**108**	67
Net loss	**$ (49,334)**	$ (50,843)	**$ (184,748)**	$ (183,769)
Basic and diluted net loss per share	**$ (0.13)**	$ (0.16)	**$ (0.50)**	$ (0.63)
Basic and diluted weighted average number of common shares outstanding	**383,171**	316,119	**369,757**	292,669

SELECTED CONSOLIDATED BALANCE SHEET DATA
(in thousands)

	December 31, 2018	December 31, 2017
Cash and cash equivalents	**$ 70,154**	$ 106,307
Marketable securities	**21,980**	50,996
Total restricted cash	**11,805**	29,124
Total current assets	**119,276**	203,311
Working capital	**73,737**	129,636
Total assets	**207,978**	302,493
Notes payable	**319,187**	317,763
Total stockholders' deficit	**(167,935)**	(101,732)

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