

# Novavax Reports First Quarter 2018 Financial Results

GAITHERSBURG, Md., May 09, 2018 (GLOBE NEWSWIRE) -- Novavax, Inc., (Nasdaq:NVAX) today announced its financial results for the first quarter ended March 31, 2018.

## First Quarter and Subsequent Achievements:

### *RSV F Vaccine*

- In May 2018, Novavax reached enrollment of approximately 4,600 pregnant women in its Prepare™ Phase 3 clinical trial of its RSV F Vaccine for infants via maternal immunization. This milestone enables Novavax to initiate a prespecified interim efficacy analysis after approximately six months of follow-up of the last infant born to the approximately 4,600 women enrolled (including 3,000 actively vaccinated women). Completion of this analysis is expected in the first quarter of 2019. Since 2015, the Prepare trial is supported by an \$89 million grant from the Bill & Melinda Gates Foundation (BMGF).
- In April 2018, Novavax presented at the World Vaccine Congress on the status of its Phase 3 clinical trial of its RSV F Vaccine.

### *NanoFlu™*

- In April 2018, Novavax presented clinical data at the World Vaccine Congress from the Phase 1/2 clinical trial in older adults comparing trivalent formulations of NanoFlu to the market-leading licensed egg-based, high-dose influenza vaccine for older adults.
- In February 2018, Novavax reported positive top-line results from its Phase 1/2 clinical trial of its trivalent NanoFlu.

### *Corporate*

- In April 2018, Novavax completed an underwritten public offering of approximately 34.8 million shares of its common stock, including 4.5 million shares pursuant to the underwriters' option to purchase additional shares. The shares resulted in net proceeds of \$54 million.
- Effective on March 14, 2018, John J. Trizzino, former Senior Vice President, Commercial Operations since 2014, was promoted to Senior Vice President, Chief Business Officer and Chief Financial Officer.

### Anticipated Events:

- Initiation of the Phase 2 clinical trial of quadrivalent formulations of NanoFlu scheduled to begin in the third quarter of 2018.
- Top-line data from the Phase 2 NanoFlu trial and End of Phase 2 meeting with the FDA expected in the first quarter of 2019.
- Results of the Prepare Phase 3 interim efficacy analysis for our RSV F Vaccine expected in the first quarter of 2019.

### Summary

"We had an extremely productive first quarter, including making important advances in our two lead clinical vaccine programs. We are pleased to have reached the enrollment target for our Prepare Phase 3 RSV F Vaccine trial, which clears the path for following these most recent participants and their babies, and subsequently announcing top-line results of our planned interim efficacy analysis in the first quarter of 2019," said Stanley C. Erck, President and CEO of Novavax, Inc. "We also continue to make significant progress on NanoFlu and plan to initiate a Phase 2 clinical trial in the third quarter of 2018."

### Financial Results for the First Quarter Ended March 31, 2018

Novavax reported a net loss of \$46.4 million, or \$0.14 per share, for the first quarter of 2018, compared to a net loss of \$43.9 million, or \$0.16 per share, for the first quarter of 2017.

Novavax revenue in the first quarter of 2018 was \$9.7 million, compared to \$5.7 million in the same period in 2017. This 70% increase was driven by higher revenue recorded under the BMGF grant corresponding to the increased enrollment in the Prepare trial.

Research and development expenses increased 18% to \$44.5 million in the first quarter of 2018, compared to \$37.7 million for the same period in 2017. The increase was primarily due to increased development activities of the RSV F Vaccine for infants via maternal immunization.

Interest income (expense), net for the first quarter of 2018 was (\$2.9) million, compared to (\$3.0) million for the same period of 2017.

As of March 31, 2018, Novavax had \$164.2 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 first quarter of 2018 was \$66.1 million, compared to \$44.5 million for same period in 2017. The increase in cash usage was primarily due to approximately \$16 million of one-time payments, as well as the adoption of a new accounting standard that requires restricted cash to be included in the beginning and ending balances on the statements of cash flows, thus increasing Novavax' cash usage in the first quarter of 2018 and 2017 by approximately \$9 million and \$6 million, respectively. We expect our cash used in operating activities to significantly decrease for the subsequent quarters of 2018 as compared to the first quarter of 2018.

### Conference Call

Novavax management will host its quarterly conference call today at 4:30 p.m. ET. The dial-in number for the conference call is (877) 212-6076 (Domestic) or (707) 287-9331 (International), passcode 3687883. A replay of the conference call will be available starting at 7:30 p.m. ET on May 9, 2018 until 7:30 p.m. ET on May 16, 2018. To access the replay by telephone, dial (855) 859-2056 (Domestic) or (404) 537-3406 (International) and use passcode 3687883.

A webcast of the conference call can also be accessed via a link on the home page of the Novavax website at [www.novavax.com](http://www.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 9, 2018.

### 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.<sup>1</sup> In the U.S., RSV is the leading cause of hospitalization of infants.<sup>2</sup> Despite the induction of post-infection immunity, repeat infection and lifelong susceptibility to RSV is common.<sup>3</sup> 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 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.<sup>4</sup> 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.<sup>5</sup>

## About NanoFlu™

NanoFlu is a recombinant hemagglutinin (HA) protein nanoparticle influenza vaccine candidate 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 Novavax

Novavax, Inc. (Nasdaq:NVAX) is a clinical-stage biotechnology company committed to delivering novel products to prevent infectious diseases. Its RSV and influenza nanoparticle vaccine candidates are Novavax' most advanced clinical programs and are at the forefront of Novavax' efforts to improve global health. For more information, please visit [www.novavax.com](http://www.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](http://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.

1 <https://www.niaid.nih.gov/diseases-conditions/respiratory-syncytial-virus-rsv>

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

3 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>

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

5 Influenza Vaccines Forecasts. *Datamonitor* (2013)

## NOVAVAX, INC.

### CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(in thousands, except per share information)

(unaudited)

	Three Months Ended	
	March 31,	
	2018	2017
Revenue	\$ 9,653	\$ 5,680
Expenses:		
Research and development	44,514	37,654
General and administrative	8,652	8,852
Total expenses	53,166	46,506
Loss from operations	(43,513)	(40,826)
Interest income (expense), net	(2,872)	(3,039)
Other income (expense)	33	11
Net loss	\$ (46,352)	\$ (43,854)
Basic and diluted net loss per share	\$ (0.14)	\$ (0.16)
Basic and diluted weighted average number of common shares outstanding	336,972	274,178

SELECTED CONSOLIDATED BALANCE SHEET DATA  
(in thousands)

	March 31, 2018 (unaudited)	December 31, 2017
Cash and cash equivalents	\$ 113,402	\$ 106,307
Marketable securities	30,358	50,996
Total restricted cash	20,439	29,124
Total current assets	181,034	203,311
Working capital	136,130	129,636
Total assets	276,067	302,493
Notes payable	318,119	317,763
Total stockholders' deficit	(99,369)	) (101,732

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<https://ir.novavax.com/2018-05-09-Novavax-Reports-First-Quarter-2018-Financial-Results>