

GAITHERSBURG, Md., May 08, 2017 (GLOBE NEWSWIRE) -- Novavax, Inc., (Nasdaq:NVAX) today announced its financial results for the first quarter ended March 31, 2017.

First Quarter Achievements:

- Enrollment continued during the second global season in the RSV Phase 3 Prepare™ clinical trial for infants via maternal immunization. Enrollment in the first quarter of 2017 transitioned from the northern hemisphere to southern hemisphere sites in Argentina, Australia, Chile, New Zealand and South Africa. The second season of enrollment has benefitted greatly from the establishment of the operational infrastructure and experience from the first global season, resulting in material increases in enrollment and enhanced momentum as we move towards the third global season of enrollment.
- Initiation of a randomized, observer-blinded, multi-arm, dose-ranging Phase 2 clinical trial, in one and two dose formulations, both with and without adjuvants, of its RSV F Vaccine in older adults (60 years of age and older). The trial will evaluate safety and immunogenicity of these formulations in older adults as measured by serum microneutralization titers against RSV/A and RSV/B, palivizumab competing antibodies (“PCA”) and anti-F IgG.

Anticipated 2017 Events:

- Announce top-line data from the Phase 2 safety and immunogenicity clinical trial of the RSV F vaccine in older adults in the next 90 days.
- File revised study documents and conduct an informational analysis of the Prepare trial that would provide an indication of the RSV F Vaccine’s potential efficacy against the trial’s primary endpoint before the end of the year.
- Initiate a Phase 1 clinical trial of the Company’s recombinant seasonal influenza vaccine candidate before the end of the year.
- Initiate a Phase 1 clinical trial of the Company’s Zika vaccine candidate before the end of the year.

Summary

“We continued to make significant progress in the execution of our two key clinical trials of our RSV F vaccine for both infant via maternal immunization and in older adults. We look forward to reporting important clinical data from our older adult trial in the next 90 days. We’ve also been in discussion with the FDA about conducting an informational analysis of the Prepare trial that would provide an indication of our vaccine’s potential efficacy. From these discussions, we believe we can conduct this analysis in late 2017,” said Stanley C. Erck, President and CEO. “In addition, we are seeing the continued adoption and use of our proprietary adjuvant, Matrix-M, in a number of internal and partnered programs.”

Financial Results for the Three Months Ended March 31, 2017

Novavax reported a net loss of \$43.9 million, or \$0.16 per share, for the first quarter of 2017, compared to a net loss of \$77.3 million, or \$0.29 per share, for the first quarter of 2016.

Novavax revenue in the first quarter of 2017 increased 35% to \$5.7 million, compared to \$4.2 million for the same period in 2016, primarily due to increased revenue recorded under the BMGF grant relating to our

ongoing Prepare clinical trial.

Research and development expenses decreased 45% to \$37.7 million in the first quarter of 2017, compared to \$69.0 million for the same period in 2016. The decrease was primarily due to reduced costs associated with the clinical trials and development activities of our RSV F Vaccine and lower employee-related costs.

General and administrative expenses decreased 16% to \$8.9 million in the first quarter of 2017, compared to \$10.5 million for the same period in 2016. The decrease was primarily due to lower professional fees for pre-commercialization activities.

Interest income (expense), net for the first quarter of 2017 was (\$3.0) million, compared to (\$1.9) million for the same period in 2016.

As of March 31, 2017, the company had \$211.2 million in cash and cash equivalents and marketable securities compared to \$235.5 million as of December 31, 2016. Net cash used in operating activities for the first quarter of 2017 was \$38.6 million, compared to \$69.8 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 employee-related costs.

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 15607801. A replay of the conference call will be available starting at 7:30 p.m. ET on May 8, 2017 until 7:30 pm ET on May 15, 2017. To access the replay by telephone, dial (855) 859-2056 (Domestic) or (404) 537-3406 (International) and use passcode 15607801.

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 through the "Investor Info"/"Events" tab on the Novavax website until July 3, 2017.

About Novavax

Novavax, Inc. (Nasdaq:NVAX) is a clinical-stage biotechnology company committed to delivering novel products to prevent a broad range of infectious diseases. Our recombinant nanoparticles and Matrix-M™ adjuvant technology are the foundation for groundbreaking innovation that improves global health through safe and effective vaccines. Additional information about Novavax is available on the Company's website, novavax.com.

About RSV

Respiratory syncytial virus (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.¹ In the U.S., RSV is the leading cause of hospitalization of infants, and globally, is second only to malaria as a cause of death in children under 1 year of age.^{2 3} Despite the induction of post-infection immunity, repeat infection and lifelong susceptibility to RSV is common. Currently, there is no approved RSV vaccine available.^{4 5}

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, 2016 and the Report on Form 10-Q for the period ended March 31, 2017, both 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.

1 Nair, H. *et al.* Global burden of acute lower respiratory infections due to respiratory syncytial virus in young children: a systematic review and meta-analysis. *Lancet*, 2010; 375: 1545-1555.

2 Hall, C.B. *et al.* Respiratory Syncytial Virus-Associated hospitalizations Among Children Less Than 24 Months of Age. *Pediatrics*, 2013; 132(2): E341-348.

3 Oxford Vaccine Group: <http://www.ovg.ox.ac.uk/rsv>

4 Glezen, W.P. *et al.* Risk of primary infection and reinfection with respiratory syncytial virus. *Am J Dis Child*, 1986; 140:543-546.

5 Glenn GM, *et al.* Modeling maternal fetal RSV F vaccine induced antibody transfer in guinea pigs. *Vaccine*, 2015; In press. <http://dx.doi.org/10.1016/j.vaccine.2015.08.039>.

NOVAVAX, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(in thousands, except per share information)

(unaudited)

	Three Months Ended	
	March 31,	
	2017	2016
Revenue	\$ 5,680	\$ 4,218
Expenses:		
Research and development	37,654	68,952
General and administrative	8,852	10,528
Total expenses	46,506	79,480
Loss from operations	(40,826)	(75,262)
Interest income (expense), net	(3,039)	(1,957)
Other income (expense)	11	(33)
Net loss	\$ (43,854)	\$ (77,252)

Basic and diluted net loss per share	\$ (0.16)	\$ (0.29)
Basic and diluted weighted average number of common shares outstanding	274,178	270,179

SELECTED CONSOLIDATED BALANCE SHEET DATA

(in thousands)

	March 31, 2017 (unaudited)	December 31, 2016
Cash and cash equivalents	\$ 95,847	\$ 144,353
Marketable securities	115,331	91,126
Total current assets	258,449	287,830
Working capital	201,951	221,424
Total assets	361,504	394,301
Total notes payable and capital lease obligation	316,714	316,376
Total stockholders' deficit	(29,099)	(5,546)

Contact:

Investor Relations

Novavax, Inc. Andrea N. Flynn, Ph.D.

Associate Director, Investor Relations

ir@novavax.com

240-268-2000

Westwicke Partners John Woolford john.woolford@westwicke.com

443-213-0506

Media

Russo Partners, LLC David Schull Todd Davenport, Ph.D.

david.schull@russopartnersllc.com

212-845-4271

<https://ir.novavax.com/2017-05-08-Novavax-Reports-First-Quarter-2017-Financial-Results>