Novavax Reports First Quarter 2016 Financial Results

May 4, 2016

GAITHERSBURG, Md., May 04, 2016 (GLOBE NEWSWIRE) -- Novavax, Inc., (Nasdaq:NVAX) a clinical-stage vaccine company focused on the discovery, development and commercialization of recombinant nanoparticle vaccines and adjuvants, today announced its financial results for the first quarter ended March 31, 2016.

Novavax First Quarter Achievements:

- Continued execution of Resolve™, a pivotal Phase 3 trial of our RSV F Vaccine in older adults (60 years of age and older). Resolve is a randomized, observer-blinded, placebo-controlled trial in 11,850 older adults at 60 sites in the United States. The primary efficacy objective is the prevention of moderate-severe RSV-associated lower respiratory tract disease, as defined by the presence of multiple lower respiratory tract symptoms. Enrollment was completed in the fourth quarter of 2015.

- Ongoing execution of a Phase 2 rollover clinical trial of our RSV F Vaccine in 1,330 older adults. The trial is a randomized, observer-blinded, placebo-controlled rollover trial designed to enroll from the population of older adults who participated in the prior Phase 2 trial. The primary endpoints of the trial will evaluate safety and serum anti-F IgG antibody concentrations in response to immunization with our RSV F Vaccine. Enrollment was completed in the fourth quarter of 2015.

- Expanded enrollment of Prepare™, a pivotal Phase 3 trial of our RSV F Vaccine in healthy pregnant women, to multiple international sites to take advantage of the RSV season in the southern hemisphere. Prepare is a randomized, observer-blinded, placebo-controlled trial. The primary objective is to determine the efficacy of maternal immunization with our RSV F Vaccine against symptomatic RSV lower respiratory tract infection with hypoxemia in infants through the first 90 days of life. Prepare is supported by a grant of up to $89 million from the Bill & Melinda Gates Foundation (BMGF).

- Issued a total of $325 million Convertible Senior Notes, resulting in net proceeds of $276.5 million. The Notes' initial conversion price of approximately $6.81 per common share represents a 22.5% premium to Novavax' common stock on January 25, 2016, the day the Notes were issued. In conjunction with the issuance of the Notes, the Company entered into capped call transactions with an initial cap price of $9.73 per share. The capped call will serve to reduce dilution from issuance of shares upon conversion at prices greater than the Notes' conversion price of $6.81.

- Appointed Bob Darius to Senior Vice President, Quality Operations and promoted Gregory M. Glenn, M.D., to President, Research & Development, Amy B. Fix to Senior Vice President, Regulatory Affairs, Louis F. Fries III, M.D., to Senior Vice President and Chief Medical Officer, and Iksung Cho to Vice President, Biostatistics.

2016 Anticipated Events:

- Announce top-line data from Resolve, the Phase 3 pivotal RSV F Vaccine trial in older adults in the third quarter of 2016; and

- Announce top-line data from the Phase 2 RSV F Vaccine rollover trial in older adults in the second half of 2016.

Summary

"During the first quarter, we continued to successfully execute on our two ongoing pivotal Phase 3 trials of our RSV F Vaccine. We also raised $325 million in a successful Convertible Senior Notes offering, which strengthens Novavax' balance sheet ahead of data from the pivotal Phase 3 Resolve clinical trial," said Stanley C. Erck, President and CEO. "We are pleased to see significant interest from a number of multinational, world-class vaccine companies seeking potential partnership and commercialization rights to our RSV F Vaccine franchise outside of North America. We remain well positioned to announce value creating data from the Resolve trial and the Phase 2 rollover trial in older adults in 2016."

Financial Results for the Three Months Ended March 31, 2016

Novavax reported a net loss of $77.3 million, or $0.29 per share, for the first quarter of 2016, compared to a net loss of $24.4 million, or $0.10 per share, for the first quarter of 2015.

Novavax revenue in the first quarter of 2016 decreased 57% to $4.2 million, compared to $9.9 million for the same period in 2015. Lower revenue under the HHS BARDA contract of $7.3 million is the primary driver of this decrease. The lower HHS BARDA revenue is the result of a lower level of activity in the three months ended March 31, 2016, as compared to the same period in 2015, along with a one-time revenue recognition of $3.1 million in the first quarter of 2015. This decrease in HHS BARDA revenue was partially offset by $1.6 million in revenue recorded under the BMGF grant relating to our ongoing Prepare clinical trial.

Research and development expenses increased 143% to $69.0 million in the first quarter of 2016, compared to $28.3 million for the same period in 2015. The increase in research and development expenses was primarily due to increased costs associated with the clinical trials and development activities of our RSV F Vaccine and higher employee-related costs, including non-cash stock-based compensation.

General and administrative expenses increased 80% to $10.5 million in the first quarter of 2016, compared to $5.8 million for the same period in 2015. The increase was primarily due to higher employee-related costs, including non-cash stock-based compensation expense, and professional fees for pre-commercialization activities, as compared to the same period in 2015.

Interest income (expense), net for the first quarter of 2016 includes $2.1 million of interest expense relating the Company's Convertible Senior Notes offering.

As of March 31, 2016, the company had $433.9 million in cash and cash equivalents and marketable securities compared to $230.7 million as of December 31, 2015. Net cash used in operating activities for the first quarter of 2016 was $69.8 million, compared to $30.5 million for same period in 2015. The increase in cash usage was primarily due to increased costs relating to our RSV F Vaccine, higher employee-related costs and timing of vendor payments. As previously mentioned, Novavax completed a $325 million Convertible Senior Notes offering in the first quarter of 2016.

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 95870834. 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 conference call will be available starting at 7:00 p.m. on May 4, 2016 until midnight May 11, 2016. To access the replay by telephone, dial (855) 859-2056 (Domestic) or (404) 537-3406 (International) and use passcode 95870834. The replay will also be available as a webcast and can be found on the "Investor Info"/"Events" on the Novavax website.

About Novavax

Novavax, Inc. (Nasdaq:NVAX) is a clinical-stage vaccine 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.

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, 2015 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.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(in thousands, except per share information)

	Three Months Ended March 31,	
	2016	2015
	(unaudited)	
Revenue	$ 4,218	$ 9,877
Expenses:		
Research and development	68,952	28,347
General and administrative	10,528	5,843
Total expenses	79,480	34,190
Loss from operations	(75,262)	(24,313)
Interest income (expense), net	(1,957)	85
Other expense	(33)	(142)
Net loss	$ (77,252)	$ (24,370)
Basic and diluted net loss per share	$ (0.29)	$ (0.10)
Basic and diluted weighted average number of common shares outstanding	270,179	241,223

SELECTED CONSOLIDATED BALANCE SHEET DATA
(in thousands)

	March 31, 2016	December 31, 2015
	(unaudited)	
Cash and cash equivalents	$ 132,225	$ 93,108
Marketable securities	301,642	137,548
Total current assets	484,595	287,257
Working capital	413,544	210,763
Total assets	592,507	386,038
Total notes payable and capital lease obligation	315,614	503
Total stockholders' equity	185,433	292,669

Contact:

Novavax, Inc.Barclay A. Phillips
SVP, Chief Financial Officer and Treasurer

Andrea N. Flynn, Ph.D.
Associate Director, Investor Relations

ir@novavax.com
240-268-2000

Russo Partners, LLCDavid SchullTodd Davenport, Ph.D.

david.schull@russopartnersllc.comtodd.davenport@russopartnersllc.com

212-845-4271