Novavax Reports Third Quarter 2015 Financial Results

November 9, 2015

GAITHERSBURG, Md., Nov. 09, 2015 (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 third quarter and nine months ended September 30, 2015.

Novavax Third Quarter and Subsequent Achievements

- Announced positive top-line data from a Phase 2 clinical trial of its RSV F-protein recombinant nanoparticle vaccine candidate (RSV F Vaccine) in older adults (60 years of age and older). The vaccine was well-tolerated and fulfilled the Company's expectations on the primary, secondary and exploratory objectives of the trial. The trial is the first to demonstrate efficacy of an active RSV immunization in any clinical trial population.

- Announced positive top-line data from a Phase 2 clinical trial of its RSV F Vaccine to protect infants via maternal immunization. Significant anti-F, PCA and microneutralizing antibody responses were elicited in mothers and efficient antibody transfer from mothers to infants was observed.

- Announced that it has been awarded a grant of up to $89 million by the Bill & Melinda Gates Foundation to support development of the RSV F Vaccine Phase 3 clinical trial in pregnant women. This grant will also support regulatory licensing efforts, providing a path to WHO prequalification. Upon licensure, Novavax has agreed to make the RSV F Vaccine affordable and accessible to people in the developing world.

- Announced positive top-line data from a Phase 1 clinical trial of its RSV F Vaccine in healthy children two to six years of age. All RSV F Vaccine formulations and regimens were well-tolerated and highly immunogenic.

- Commenced enrollment in a Phase 2 rollover clinical trial of its RSV F Vaccine in older adults. The trial is a randomized, observer-blinded, placebo-controlled rollover trial designed to enroll the same 1600 older adults who participated in the recently concluded prior Phase 2 trial.

- Announced positive top-line data from a Phase 2 trial of its recombinant quadrivalent seasonal influenza virus-like particle candidate (Quadrivalent Seasonal Influenza VLP). The trial, funded in whole or part with Federal funds from the Company’s contract with the Department of Health and Human Services, Biomedical Advanced Research and Development Authority (HHS BARDA) (Contract No. HHSO 100201100012C), demonstrated that the Quadrivalent Seasonal Influenza VLP vaccine candidate was well-tolerated with no vaccine-related serious adverse events. The trial met its immunogenicity targets and demonstrated potential to meet the Center for Biological Evaluation and Research (CBER) criteria for accelerated approval.

- Delivered positive top-line data from a Phase 1 clinical trial of its Ebola virus glycoprotein (GP) recombinant nanoparticle vaccine (Ebola GP Vaccine) candidate adjuvanted with Matrix-M™. The trial demonstrated that the adjuvanted Ebola GP Vaccine was highly immunogenic, well-tolerated and resulted in significant antigen dose-sparing.

- Hosted its 3rd Annual Analyst and Investor Meeting.

Today’s Announcement

- Initiation of a Phase 3 trial of the RSV F Vaccine in older adults

Near-term Anticipated Events

- Initiation of a Phase 3 trial of the RSV F Vaccine to protect infants via maternal immunization, contingent upon discussions with regulatory authorities

Summary

“The initiation of the first Phase 3 trial of our RSV F Vaccine in older adults underscores our accomplishments to date and positions the company to bring the first RSV vaccine to market. Our recent data announcements demonstrate the safety and

robust immunogenicity of the RSV F Vaccine across all three target populations: older adults; infants via maternal immunization; and pediatrics," said Gregory Glenn, M.D., Senior Vice President, Research and Development. "Our Phase 2 trial of the RSV F Vaccine in older adults was the first to demonstrate efficacy of an active RSV immunization in any clinical trial population. In addition, data from pregnant women in their third trimester provided an important safety data and proof-of-concept for maternal immunization, with a high level of transplacental antibody transfer."

"During the third quarter, we delivered positive results from five key clinical programs including our RSV F Vaccine for older adults, infants via maternal immunization and pediatrics, as well as our Seasonal Influenza Vaccine, and our Ebola GP Vaccine. These results, coupled with today's initiation of our Phase 3 trial of our RSV F Vaccine in older adults, demonstrate Novavax' ability to successfully advance our clinical stage programs along aggressive timelines," said Stanley C. Erck, President and CEO. "With successful phase 2 results, and consistent execution, the Company is well-positioned to begin our second phase 3 trial in pregnant women in the first quarter of 2016."

Financial Results for the Three and Nine Months Ended September 30, 2015

Novavax reported a net loss of $33.1 million, or $0.12 per share, for the third quarter of 2015, compared to a net loss of $19.7 million, or $0.08 per share, for the third quarter of 2014. For the nine months ended September 30, 2015, the net loss was $78.1 million, or $0.30 per share, compared to a net loss of $51.4 million, or $0.23 per share, for the same period in 2014.

Novavax revenue in the third quarter of 2015 decreased 21% to $6.5 million, compared to $8.2 million for the same period in 2014. This decrease results from a lower level of development activities under the HHS BARDA contract in the third quarter of 2015 as compared to the same period in 2014.

The cost of government contracts revenue in the third quarter of 2015 decreased 32% to $2.7 million, compared to $4.0 million for the same period in 2014. The decrease in cost of government contracts revenue was associated with a lower level of development activities under the HHS BARDA contract in the third quarter of 2015 as compared to the same period in 2014.

Research and development expenses increased 45% to $27.9 million in the third quarter of 2015, compared to $19.2 million for the same period in 2014. The increase in research and development expenses was driven by activities relating to the RSV Vaccine and higher employee-related expenses, including non-cash stock-based compensation, tied to the continued growth of the company.

General and administrative expenses increased 90% to $9.1 million in the third quarter of 2015, compared to $4.8 million for the same period in 2014. The increase in general and administrative expenses resulted from increased employee-related expenses, including non-cash stock-based compensation, tied to the continued growth of the company and professional fees for pre-commercialization activities.

As of September 30, 2015, the company had $290.2 million in cash and cash equivalents and marketable securities compared to $168.1 million as of December 31, 2014. Net cash used in operating activities for the nine months of 2015 was $71.3 million, compared to $47.2 million for the same period in 2014. The factors contributing to the change in operating cash usage were primarily due to increased costs relating to our RSV F Vaccine, Ebola GP Vaccine and higher employee-related expenses, as well as the timing of customer and vendor payments.

Conference Call

Novavax management will host its quarterly conference call today at 8:00 a.m. EST. The dial-in number for the conference call is 877-212-6076 (U.S. or Canada) or 707-287–9331 (International). 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 11:00 a.m. on November 9, 2015 until midnight November 16, 2015. To access the replay by telephone, dial 855-859-2056 (Domestic) or 404-537-3406 (International) and use passcode 70778771. 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, 2014 and our Quarterly Reports on Form 10-Q for the quarters ended March 31, 2015 and June 30, 2015, 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 September 30,		Nine Months Ended September 30,	
	2015 (unaudited)	2014	2015 (unaudited)	2014
Revenue	$ 6,525	$ 8,214	$ 30,397	$ 23,935
Costs and expenses:				
Cost of government contracts revenue	2,747	4,027	8,054	12,150
Research and development	27,917	19,219	78,686	48,940
General and administrative	9,060	4,757	21,991	14,871
Total costs and expenses	39,724	28,003	108,731	75,961
Loss from operations	(33,199)	(19,789)	(78,334)	(52,026)
Interest income (expense), net	130	81	324	10
Other income (expense)	(51)	(19)	(121)	?
Realized gains on marketable securities	?	?	?	615
Net loss	$ (33,120)	$ (19,727)	$ (78,131)	$ (51,401)
Basic and diluted net loss per share	$ (0.12)	$ (0.08)	$ (0.30)	$ (0.23)
Basic and diluted weighted average number of common shares outstanding	269,554	238,304	259,703	221,578

SELECTED CONSOLIDATED BALANCE SHEET DATA
(in thousands)

	September 30, 2015 (unaudited)	December 31, 2014
Cash and cash equivalents	$ 138,144	$ 32,335
Marketable securities	152,042	135,721

Total current assets	310,102	188,158
Working capital	285,229	154,042
Total assets	404,634	276,002
Total notes payable and capital lease obligation	664	1,173
Total stockholders’ equity	367,016	229,618

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