Novavax Reports Second Quarter 2016 Financial Results

August 9, 2016

GAITHERSBURG, Md., Aug. 09, 2016 (GLOBE NEWSWIRE) -- Novavax, Inc., (Nasdaq:NVAX) today announced its financial results for the second quarter and six months ended June 30, 2016.

Novavax Second Quarter Achievements:

- Announced a new seasonal combination respiratory vaccine program. Novavax demonstrated the ability to combine the RSV F and influenza nanoparticle vaccines, bringing together a vaccine approach that induces broadly neutralizing antibodies against both influenza and RSV. Novavax' program was unveiled at the New Approaches to Vaccines for Human and Veterinary Tropical Diseases Keystone Symposia in Cape Town, South Africa in June 2016.

- Continued execution of Resolve™, a pivotal Phase 3 trial of our RSV F Vaccine in older adults (60 years of age and older). The Resolve trial 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. The Prepare trial 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. The Prepare trial is supported by a grant of up to $89 million from the Bill & Melinda Gates Foundation (BMGF).

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 between now and year end.

Summary

"This is an incredibly exciting time for Novavax, as we near the announcement of Phase 3 data for our RSV F Vaccine in older adults. Our regulatory expertise, manufacturing operations, and strong balance sheet, in conjunction with the pre-commercialization activities we have initiated, leave us very well-positioned to execute on this opportunity," said Stanley C. Erck, President and CEO. "We also continue 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."

Financial Results for the Three and Six Months Ended June 30, 2016

Novavax reported a net loss of $79.4 million, or $0.29 per share, for the second quarter of 2016, compared to a net loss of $20.6 million, or $0.08 per share, for the second quarter of 2015. For the six months ended June 30, 2016, the net loss was $156.6 million, or $0.58 per share, compared to a net loss of $45.0 million, or $0.18 per share, for the same period in 2015.

Novavax revenue in the second quarter of 2016 decreased 82% to $2.5 million, compared to $14.0 million for the same period in 2015. Lower revenue under the BARDA contract of $13.6 million is the primary driver of this decrease. The decline in BARDA revenue in the second quarter of 2016 is the result of the one-time recognition of $7.7 million in revenue in the second quarter of 2015, and the recent advances in the Company's seasonal influenza nanoparticle program which

resulted in the wind-down of VLP influenza activities under the BARDA contract. This decrease in BARDA revenue was partially offset by $1.7 million in revenue recorded under the BMGF grant relating to our ongoing Prepare clinical trial.

Research and development expenses increased 134% to $64.9 million in the second quarter of 2016, compared to $27.7 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 99% to $14.1 million in the second quarter of 2016, compared to $7.1 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 second quarter of 2016 includes $3.0 million of interest expense relating to the Company's Convertible Senior Notes.

As of June 30, 2016, the Company had $366.4 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 six months of 2016 was $131.9 million, compared to $42.8 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.

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 59901631. 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 August 9, 2016 until midnight August 16, 2016. To access the replay by telephone, dial (855) 859-2056 (Domestic) or (404) 537-3406 (International) and use passcode 59901631. 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.

NOVAVAX, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(in thousands, except per share information)

	For the Three Months	For the Six Months

	Ended June 30, 2016	2015	Ended June 30, 2016	2015
	(unaudited)		(unaudited)	
Revenue	$ 2,505	$ 13,996	$ 6,723	$ 23,872
Expenses:				
Research and development	64,904	27,729	133,856	56,076
General and administrative	14,099	7,088	24,627	12,931
Total expenses	79,003	34,817	158,483	69,007
Loss from operations	(76,498)	(20,821)	(151,760)	(45,135)
Interest income (expense), net	(2,842)	108	(4,799)	194
Other income (expense)	(11)	72	(44)	(70)
Net loss	$ (79,351)	$ (20,641)	$ (156,603)	$ (45,011)
Basic and diluted net loss per share	$ (0.29)	$ (0.08)	$ (0.58)	$ (0.18)
Basic and diluted weighted average number of common shares outstanding	270,760	268,083	270,469	254,727

SELECTED CONSOLIDATED BALANCE SHEET DATA
(in thousands)

	June 30, 2016	December 31, 2015
	(unaudited)	
Cash and cash equivalents	$ 89,395	$ 93,108
Marketable securities	276,967	137,548
Total current assets	419,981	287,257
Working capital	338,103	210,763
Total assets	525,004	386,038
Total notes payable and capital lease obligations	315,849	503
Total stockholders’ equity	110,117	292,669

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