

Novavax Investor Relations

GAITHERSBURG, Md., Nov. 07, 2017 (GLOBE NEWSWIRE) -- Novavax, Inc., (Nasdaq:NVAX) today announced its financial results for the third quarter and nine months ended September 30, 2017.

Third Quarter Achievements:

- Novavax initiated a Phase 1/2 clinical trial of its nanoparticle influenza vaccine candidate with its proprietary Matrix-M™ adjuvant (NanoFlu™) in older adults. The trial is a randomized, observer-blinded, active comparator-controlled trial in approximately 330 healthy older adults. The primary objective of the trial is to assess the safety and immunogenicity of two antigen concentrations (15 µg or 60 µg) of NanoFlu compared to a licensed influenza vaccine, Fluzone® High-Dose (Fluzone HD).
- Novavax reported that NanoFlu demonstrated superior immunogenicity and protection compared to the market leader in a preclinical challenge study. In a head-to-head comparison study against Fluzone HD, NanoFlu demonstrated significantly stronger and broader immune responses against matched and unmatched influenza strains, including a series of “drifted” strains evolved over more than a decade of influenza seasons. NanoFlu was also protective in an established challenge model against both a matched and a ten-year old unmatched strain. Data from this study was published in the journal *Vaccine*.
- The Prepare™ clinical trial for infants via maternal immunization, supported by an \$89 million grant from the Bill and Melinda Gates Foundation (BMGF), accelerated into the third global season of enrollment. Prepare’s global footprint is expected to grow from 16 sites in five countries in its first season of enrollment to over 90 sites in 12 countries in 2018.

Anticipated 2017 Event:

- Announce topline data from a Phase 1/2 clinical trial of the NanoFlu vaccine candidate in a head-to-head comparison with Fluzone HD before the end of 2017.

Summary

“We were very pleased to initiate and fully enroll the Phase 1/2 clinical trial of our NanoFlu vaccine candidate in older adults, following impressive results in preclinical challenge models. Given this timing, we are well positioned to announce data from the ongoing trial before the end of the year,” said Stanley C. Erck, President and CEO. “We also continue to make significant progress in our RSV F Vaccine program, highlighted by the continued execution of the Phase 3 Prepare trial for infants via maternal immunization. We are also evaluating plans to conduct a clinical trial for older adults in 2018.”

Financial Results for the Three and Nine Months Ended September 30, 2017

Novavax reported a net loss of \$44.6 million, or \$0.15 per share, for the third quarter of 2017, compared to a net loss of \$66.3 million, or \$0.24 per share, for the third quarter of 2016. For the nine months ended September 30, 2017, the net loss was \$132.9 million, or \$0.47 per share, compared to a net loss of \$222.9 million, or \$0.82 per share, for the same period in 2016.

Novavax revenue in the third quarter of 2017 was \$8.4 million, compared to \$3.2 million in the same period in 2016. This 158% increase was driven by higher revenue recorded under the BMGF grant of \$89 million.

Research and development expenses decreased 21% to \$41.9 million in the third quarter of 2017, compared to \$53.0 million for the same period in 2016. The decrease was primarily due to reduced activities related to the development of the RSV F Vaccine for older adults, other general R&D project-related expenses and lower employee-related costs.

General and administrative expenses decreased 40% to \$8.1 million in the third quarter of 2017, compared to \$13.6 million for the same period in 2016. The decrease was primarily due to lower professional fees for pre-commercialization activities and lower employee-related costs.

Interest income (expense), net for the third quarter of 2017 and 2016 was (\$3.0) million.

As of September 30, 2017, the company had \$172.6 million in cash, cash equivalents and marketable securities, compared to \$235.5 million as of December 31, 2016. Net cash used in operating activities for the first nine months of 2017 was \$106.6 million, compared to \$194.2 million for the same period in 2016. The decrease in cash usage was primarily due to decreased costs relating to our RSV F Vaccine and lower overall 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 2479419. A replay of the conference call will be available starting at 7:30 p.m. ET on November 7, 2017 until 7:30 pm ET on November 14, 2017. To access the replay by telephone, dial (855) 859-2056 (Domestic) or (404) 537-3406 (International) and use passcode 2479419.

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 February 7, 2018.

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.

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 Quarterly Report on Form 10-Q for the period ended September 30, 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.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(in thousands, except per share information)
(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
Revenue	\$ 8,352	\$ 3,231	\$ 20,764	\$ 9,954
Expenses:				
Research and development	41,862	52,983	118,779	186,839
General and administrative	8,118	13,556	25,911	38,183
Total expenses	49,980	66,539	144,690	225,022
Loss from operations	(41,628)	(63,308)	(123,926)	(215,068)
Interest income (expense), net	(2,989)	(2,957)	(9,021)	(7,756)
Other income (expense)	10	11	20	(33)
Net loss	\$ (44,607)	\$ (66,254)	\$ (132,927)	\$ (222,857)
Basic and diluted net loss per share	\$ (0.15)	\$ (0.24)	\$ (0.47)	\$ (0.82)
Basic and diluted weighted average number of common shares outstanding	296,435	271,064	284,767	270,669

SELECTED CONSOLIDATED BALANCE SHEET DATA
(in thousands)

	September 30, 2017 (unaudited)	December 31, 2016
Cash and cash equivalents	\$ 104,245	\$ 144,353
Marketable securities	68,321	91,126
Total current assets	225,995	287,830
Working capital	157,718	221,424
Total assets	334,077	394,301
Total notes payable and capital lease obligation	317,407	316,376
Total stockholders' deficit	(74,151)	(5,546)

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<https://ir.novavax.com/2017-11-07-Novavax-Reports-Third-Quarter-2017-Financial-Results>