

GAITHERSBURG, Md., Aug. 08, 2017 (GLOBE NEWSWIRE) -- Novavax, Inc. (Nasdaq:NVAX) today announced its financial results for the second quarter and six months ended June 30, 2017.

Second Quarter and Subsequent Achievements:

- Novavax' nanoparticle flu vaccine demonstrates superior immunogenicity and protection compared to market leader in preclinical challenge studies. In head-to-head comparison studies against Fluzone® High-Dose, Novavax' nanoparticle influenza vaccine with our proprietary Matrix-M™ adjuvant (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. Further details will be published in the near future in a peer-reviewed journal and presented at scientific conferences.
- Topline data from Phase 2 older adult safety and immunogenicity trial (E-205) demonstrated the benefit of adjuvanted formulations and two-dose regimens. Immunogenicity outcomes indicate both Matrix-M and aluminum phosphate adjuvants significantly increased the magnitude, duration and quality of the immune response relative to the RSV F antigen alone. All formulations and regimens were safe and well-tolerated.
- The Company announced the path forward for an adjuvanted RSV F protein recombinant nanoparticle vaccine (RSV F Vaccine) in older adults with plans to initiate a Phase 2 efficacy trial in 2018. This approach is driven by an observed 61% reduction in hospitalizations due to COPD exacerbations.
- 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 has grown from 16 sites in five countries in its first season of enrollment to 80 sites in 11 countries.
- Data from the second of two Phase 2 trials of its RSV F Vaccine candidate confirmed an overall reduction of infection of >50% in women of childbearing age, published in the journal *Vaccine*.

Anticipated 2017 Event:

- Initiation of a Phase 1/2 clinical trial of the Company's NanoFlu vaccine candidate in a head-to-head comparison to Fluzone High-Dose. Data from this trial should be available in the fourth quarter of 2017.

Summary

“Novavax has demonstrated considerable progress in our RSV F Vaccine program, highlighted by the continued strong execution of the Prepare trial, and the data from our recent trial in older adults, which confirmed the ability of the vaccine to generate robust immune responses and provided us with a development path forward,” said Stanley C. Erck, President and CEO. “We are also excited by the recent preclinical results of our nanoparticle influenza vaccine and look forward to Phase 1/2 clinical data in the fourth quarter of this year.”

Financial Results for the Three and Six Months Ended June 30, 2017

Novavax reported a net loss of \$44.5 million, or \$0.16 per share, for the second quarter of 2017, compared to

a net loss of \$79.4 million, or \$0.29 per share, for the second quarter of 2016. For the six months ended June 30, 2017, the net loss was \$88.3 million, or \$0.32 per share, compared to a net loss of \$156.6 million, or \$0.58 per share, for the same period in 2016.

Novavax revenue in the second quarter of 2017 increased 169% to \$6.7 million, compared to \$2.5 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 40% to \$39.3 million in the second quarter of 2017, compared to \$64.9 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 37% to \$8.9 million in the second quarter of 2017, compared to \$14.1 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 second quarter of 2017 was (\$3.0) million, compared to (\$2.8) million for the same period in 2016.

As of June 30, 2017, the company had \$187.3 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 six months of 2017 was \$69.4 million, compared to \$131.9 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 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 15614203. A replay of the conference call will be available starting at 7:30 p.m. ET on August 8, 2017 until 7:30 pm ET on August 15, 2017. To access the replay by telephone, dial (855) 859-2056 (Domestic) or (404) 537-3406 (International) and use passcode 15614203.

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 November 8, 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.

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 June 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.

NOVAVAX, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(in thousands, except per share information)

(unaudited)

	Three Months Ended		Six Months Ended	
	June 30,		June 30,	
	2017	2016	2017	2016
Revenue	\$ 6,732	\$ 2,505	\$ 12,412	\$ 6,723
Expenses:				
Research and development	39,263	64,904	76,916	133,856
General and administrative	8,940	14,099	17,793	24,627
Total expenses	48,203	79,003	94,709	158,483
Loss from operations	(41,471)	(76,498)	(82,297)	(151,760)
Interest income (expense), net	(2,993)	(2,842)	(6,032)	(4,799)
Other income (expense)	(1)	(11)	10	(44)
Net loss	\$ (44,465)	\$ (79,351)	\$ (88,319)	\$ (156,603)
Basic and diluted net loss per share	\$ (0.16)	\$ (0.29)	\$ (0.32)	\$ (0.58)
Basic and diluted weighted average number of common shares outstanding	283,444	270,760	278,836	270,469

SELECTED CONSOLIDATED BALANCE SHEET DATA

(in thousands)

June 30, December 31,

	2017	2016
	(unaudited)	
Cash and cash equivalents	\$ 75,793	\$ 144,353
Marketable securities	111,515	91,126
Total current assets	236,683	287,830
Working capital	169,892	221,424
Total assets	355,706	394,301
Total notes payable and capital lease obligation	317,051	316,376
Total stockholders' deficit	(59,062)	(5,546)

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