Novavax Reports Fourth Quarter and Year-End 2014 Financial Results

February 26, 2015

GAITHERSBURG, Md., Feb. 26, 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 fourth quarter and twelve months ended December 31, 2014.

Corporate Highlights

Fourth Quarter and Subsequent Achievements:

RSV

- Initiated a Phase 2 clinical trial of its RSV F-Protein nanoparticle vaccine candidate (RSV F Vaccine) in 1,600 elderly adults (≥60 years of age);
- Received the U.S. Food and Drug Administration's (FDA) Fast Track Designation of our RSV F Vaccine for protection of infants via maternal immunization, which, among other advantages, provides the potential for priority review (shorter Biologics License Application review) that could result in improved timeline to licensure;
- Initiated enrollment in a Phase 1 clinical trial of our RSV F Vaccine in healthy children, the first study of this vaccine candidate to be conducted in a pediatric population; and
- Presented new positive data from the first clinical study of our RSV F Vaccine in women of childbearing age at the 8th Vaccine & ISV Congress, showing 50% reduction in infection in the vaccinated women relative to placebo. This data suggests that the vaccine may be efficacious in future clinical testing.

Influenza

- Initiated a randomized, observer-blinded, dose-ranging Phase 2 clinical trial of our recombinant quadrivalent seasonal influenza virus-like particle (VLP) vaccine candidate (Seasonal Influenza VLP) in 400 healthy adults. This trial is being conducted under our contract with the U.S. Department of Health and Human Services, Biomedical Advanced Research and Development Authority (BARDA) (Contract No. HHSO 100201100012C) for the development of Novavax' recombinant vaccines to address seasonal influenza and influenza strains with pandemic potential; and
- Received the FDA's Fast Track Designation of our Pandemic H7N9 Influenza VLP vaccine candidate (Pandemic H7N9 VLP) with Matrix-M™ adjuvant, which recognizes the public health risks of the H7N9 strain and may allow for an improved timeline to licensure via the potential for accelerated approval and priority review.

Ebola

- Initiated a novel Ebola Glycoprotein (GP) recombinant nanoparticle vaccine candidate (EBOV GP Vaccine) program based on the currently circulating Makona strain (previously referred to as the Guinea strain) of Ebola virus;
- Presented positive pre-clinical results at the 8th Vaccine & ISV Congress of our EBOV GP Vaccine with Matrix-M adjuvant, showing seroprotective antibodies and cross-neutralization to a previously circulating Ebola virus strain;
- Announced significant immunogenicity and efficacy data demonstrating the EBOV GP Vaccine is the first subunit Ebola GP-based vaccine to provide protection in non-human primates. Non-human primates received two injections of a 5µg dose of the EBOV GP Vaccine with Matrix-M adjuvant. As expected, the challenge was lethal for the control animal whereas, in sharp contrast, 100% of the immunized animals were protected; and
- Initiated a randomized, observer-blinded, dose-ranging Phase 1 clinical trial of our EBOV GP Vaccine in Australia to evaluate the safety and immunogenicity of the vaccine, with and without Matrix-M adjuvant, in 230 healthy adults between 18 and 50 years of age.

2015 Anticipated Events:

- Announce top-line data from the Phase 1 clinical trial our EBOV GP Vaccine in mid-2015;
- Announce top-line data from the Phase 2 clinical trial of our Seasonal Influenza VLP in the second quarter of 2015;
- Announce top-line data from the Phase 2 clinical trial of our RSV F Vaccine in healthy women in their third trimester of pregnancy in the third quarter of 2015;
- Announce top-line data from the Phase 2 clinical trial of our RSV F Vaccine in elderly adults in the third quarter of 2015;

and

- Announce top-line data from the Phase 1 clinical trial of our RSV F Vaccine in healthy pediatrics in late 2015 or in the first half of 2016.

"We have initiated five clinical trials within the last six months, including advancing both our RSV and seasonal influenza programs into Phase 2 clinical trials, while introducing our new Ebola vaccine into the clinic," said Stanley C. Erck, President and Chief Executive Officer of Novavax. "These achievements underscore the strength of our vaccine technology, capability of our manufacturing platform and experience of our leadership team. We look forward to carrying this momentum through 2015, with important clinical data readouts expected in our RSV, seasonal influenza and Ebola programs."

Financial Results for the Three and Twelve Months Ended December 31, 2014

Novavax reported a net loss of $31.5 million, or $0.13 per share, for the fourth quarter of 2014, compared to a net loss of $14.1 million, or $0.07 per share, for the fourth quarter of 2013. For the twelve months ended December 31, 2014, the net loss was $82.9 million, or $0.37 per share, compared to a net loss of $52.0 million, or $0.31 per share for 2013.

Novavax revenue in the fourth quarter of 2014 decreased 23% to $6.7 million, compared to $8.7 million for the same period in 2013. Revenue for the full year 2014 increased 47% to $30.7 million, compared to $20.9 million in 2013. The increase in the full year revenue results from the Phase 1/2 clinical trial of our H7N9 pandemic influenza vaccine candidate with Matrix-M and activities relating to the preparation and initiation of the Phase 2 clinical trial of our Seasonal Influenza VLP; both programs are funded under our contract with HHS BARDA.

The cost of government contracts revenue in the fourth quarter of 2014 increased 9% to $2.8 million, compared to $2.6 million for the same period in 2013. For the full year 2014, cost of government contracts revenue increased 82% to $15.0 million, compared to $8.2 million in 2013. The increase in costs for the full year 2014 were associated with the Phase 1/2 clinical trial of our H7N9 pandemic influenza candidate with Matrix-M adjuvant and activities relating to the preparation and initiation of the Phase 2 clinical trial of our Seasonal Influenza VLP; both programs are funded under our contract with HHS BARDA.

Research and development expenses increased 87% to $30.5 million in the fourth quarter of 2014, compared to $16.3 million for the same period in 2013. For the full year 2014, research and development expenses increased 58% to $79.4 million, compared to $50.3 million in 2013. The increase in research and development expenses for the full year 2014 is driven by activities relating to the preparation and initiation of three RSV F Vaccine candidate clinical trials in 2014, the initiation of our Ebola vaccine candidate program and higher employee-related expenses tied to the continued growth of the company.

General and administrative expenses increased 24% to $5.1 million in the fourth quarter of 2014, compared to $4.1 million for the same period in 2013. For the full year 2014, general and administrative expenses increased 34% to $19.9 million, compared to $14.8 million in 2013. The increase in general and administrative expenses for the full year 2014 resulted from increased employee-related expenses tied to the continued growth of the company.

As of December 31, 2014, the company had $168.1 million in cash and cash equivalents and marketable securities compared to $133.1 million as of December 31, 2013. Net cash used in operating activities for 2014 was $67.0 million, compared to $45.4 million for 2013. The factors contributing to the change in cash usage were primarily due to increased costs relating to our RSV F Vaccine candidate and higher employee-related costs, as well as the timing of vendor payments.

Conference Call

Novavax management will host its quarterly conference call today at 4:30 p.m. EDT. 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 7:30 p.m. on February 26, 2015 until midnight March 5, 2015. To access the replay by telephone, dial 855-859-2056 (Domestic) or 404-537-3406 (International) and use passcode 89629680. 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, to be 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 STATEMENTS OF OPERATIONS

(in thousands, except per share information)

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2014	**2013**	**2014**	**2013**
	(unaudited)			
Revenue	**$ 6,724**	$ 8,748	**$ 30,659**	$ 20,915
Costs and expenses:				
Cost of government contracts revenue	**2,837**	2,602	**14,987**	8,222
Research and development	**30,495**	16,319	**79,435**	50,308
General and administrative	**5,056**	4,080	**19,928**	14,819
Total costs and expenses	**38,388**	23,001	**114,350**	73,349
Loss from operations	**(31,664)**	(14,253)	**(83,691)**	(52,434)
Interest income (expense), net	**118**	10	**129**	27
Other income, net	**—**	192	**—**	182
Realized gains on marketable securities	**—**	**—**	**615**	**—**
Change in fair value of warrant liability	**—**	—	**—**	267
Loss from operations before income tax expense	**(31,546)**	(14,051)	**(82,947)**	(51,958)
Income tax expense	—	3	—	25
Net loss	**$ (31,546)**	$ (14,054)	**$ (82,947)**	$ (51,983)
Basic and diluted net loss per share	**$ (0.13)**	$ (0.07)	**$ (0.37)**	$ (0.31)
Basic and diluted weighted average number of common shares outstanding	**238,519**	208,538	**225,848**	169,658

SELECTED BALANCE SHEET DATA

(in thousands)

	December 31, 2014	December 31, 2013
Cash and cash equivalents	**$ 32,335**	$ 119,471
Marketable securities	**135,721**	13,597
Total current assets	**188,158**	145,001
Working capital	**154,042**	126,879
Total assets	**276,002**	235,125
Total notes payable and capital lease obligations	**1,173**	2,184
Total stockholders' equity	**229,618**	203,234

CONTACT: Barclay A. Phillips
SVP, Chief Financial Officer and Treasurer
Novavax, Inc.
240-268-2000

Novavax logo

Novavax, Inc.