

NOVAVAX INC
Form 8-K
November 08, 2005

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of Earliest Event Reported):

November 8, 2005

Novavax, Inc.

(Exact name of registrant as specified in its charter)

Delaware

0-26770

22-2816046

(State or other jurisdiction
of incorporation)

(Commission
File Number)

(I.R.S. Employer
Identification No.)

508 Lapp Road, Malvern, Pennsylvania

19355

(Address of principal executive offices)

(Zip Code)

Registrant's telephone number, including area code:

484-913-1200

Not Applicable

Former name or former address, if changed since last report

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
 - Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
 - Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
 - Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))
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Item 2.02 Results of Operations and Financial Condition.

FOR IMMEDIATE RELEASE NASDAQ symbol: NVAX

NOVAVAX ANNOUNCES
THIRD QUARTER 2005 FINANCIAL RESULTS

MALVERN, PA., November 8, 2005 – Novavax, Inc. (Nasdaq: NVAX), today announced its third quarter financial and operational results.

Recent Significant Events at Novavax include:

- Completed \$18.0 million Equity Capital Raise at \$4.30 per share (November)
- Total of \$22.0 million of new equity capital raised in 2005

- Completed new License Agreement on ESTRASORB® with Esprit Pharma Inc. for North American distribution (October)
- Minimum \$12.5 million in mandatory payments over next twelve months (received \$2.0 million at closing - \$8.0 million due prior to December 31, 2005 and \$2.5 million due in October 2006)
- Double digit royalty on all ESTRASORB sales
- Significant future milestone payments
- Novavax maintains product manufacturing, and international markets outside of North America

- Converted \$6 million of outstanding convertible notes to equity (October)
- Reduced convertible notes outstanding to \$29.0 million
- Reduced annual interest expense by \$285,000
- Bond holders cannot "Put" remaining convertible notes to the Company until July 2007

- Sold non-core products/inventory to Pharmelle LLC for \$2.5 million (September)
- Potential future royalties if product sales exceed certain pre-determined levels

- Continued reduction in monthly burn rate during the third quarter

Commenting on the third quarter operating results, Dr. Rahul Singhvi President and Chief Executive Officer stated, "We are aggressively transitioning Novavax from a specialty pharmaceutical company to a product development company leveraging our proprietary technologies. To that end, we have achieved several major goals in the past few months. We completed a licensing deal for ESTRASORB with Esprit Pharma Inc. that placed the product in the hands of a strong women's health commercial franchise and brought cash into the company. We also monetized several of our non-core products for an additional \$2.5 million. We continued our goal of further reducing our monthly burn rate by continuing to tighten our business operations, focusing our activities on the Company's core technologies, and eliminating the sales force organization. In addition, Novavax announced progress on its Avian Flu vaccine initiative. Given the increased global public health risk associated with Avian Flu, the Company and its Board of Directors has made a strategic decision to focus significant resources to develop this vaccine. We believe that our vaccine, based on recombinant virus-like particle technology, currently offers a compelling solution to address an avian flu pandemic."

Third Quarter Financial Results

Total revenues for the three-month period ended September 30, 2005, were \$1.9 million compared with total revenues of (\$11) thousand for the same period last year. The variance is primarily due to a non-recurring reserve of \$1.3 million which was recorded in 2004 for potential returns of our vitamin products which had been negatively impacted by generic competition. In addition product sales of Gynodiol®, AVC™ and ESTRASORB all increased from the third quarter 2004 levels. For the nine-month period ended September 30, 2005, total revenues were \$5.1 million compared with \$6.2 million for the corresponding nine-month period last year.

Cost of product sold for the three-month period ended September 30, 2005, was \$1.1 million compared with \$364 thousand for the three-month period ended September 30, 2004. This years cost of product sold includes an idle capacity charge of \$400 thousand which was not required last year as we were in full production with ESTRASORB. In addition, 2005 product sales were higher which accounts for the remaining increase in cost of sales. Cost of sales for the nine-month period ended September 30, 2005, were \$5.1 million compared with \$2.1 million for the same nine-month period in 2004. The 2005 charges include \$2.9 million of idle capacity costs.

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Research and development costs for the three-month period ended September 30, 2005, were \$1.2 million compared with \$1.6 million for the three-month period ended September 30, 2004. Research and development costs for the nine-month period ended September 30, 2005 were \$3.8 million compared with \$5.8 million for the same nine-month period last year. The difference in research and development costs over the current nine-month period was primarily due to manufacturing start-up costs in 2004 that were accounted for in the research and development category until production began in April 2004. We expect research and development costs to increase as we progress on the development of other products in our pipeline.

Selling and marketing costs were reduced to \$930 thousand for the three-month period ended September 30, 2005, compared with \$8.9 million for the same period last year. The decrease of \$8.0 million was primarily due to the prior investment in the ESTRASORB marketing launch in 2004 as well as elimination of our sales force over the past year and the decision to discontinue any further marketing efforts. Selling and marketing expenses were \$6.8 million for the nine-month period ended September 30, 2005, compared with \$17.3 million for the same nine-month period last year. The \$10.5 million decrease is due to the same reasons as noted for the quarterly variance.

Total general and administrative costs were \$1.7 million for the three-month period ended September 30, 2005, compared with \$1.9 million for the three-month period ended September 30, 2004. The \$200 thousand difference is primarily due to the receipt of a \$400 thousand grant received from the Commonwealth of Pennsylvania related to the Company's relocation of its corporate offices last year offset by an increase in business development costs. Total general and administrative costs were \$6.1 million for the nine-month period ended September 30, 2005, compared with \$6.0 million for the nine-month period ended September 30, 2004.

For the three-month period ended September 30, 2005, the Company had a net loss of \$2.7 million, or (\$0.06) per share, compared with a net loss of \$2.7 million, or (\$0.07) per share, for the same three-month period last year. Even though revenues increased over last year and expenses decreased substantially, in 2004 we recorded a one time gain of \$11.2 million on the redemption of convertible notes. For the nine-month period ended September 30, 2005, the Company had a net loss of \$17.3 million, or (\$0.42) per share, compared with a net loss of \$15.6 million, or (\$0.43) per share, for the nine-month period ended September 30, 2004.

As of September 30, 2005, the Company had \$6.9 million in cash and cash-equivalents compared with \$17.9 million at December 31, 2004. Subsequent to the end of the quarter, the Company completed an equity offering raising net proceeds of approximately \$17.0 million and entered into an ESTRASORB licensing agreement which will add \$10.3 to cash by the end of the year. Taking these two transactions into account, on a proforma basis, our cash position would be approximately \$34.2 million. The Company anticipates its cash requirements for the fourth quarter will be significantly lower than the average of the first nine months of the year.

Conference Call

The Company will hold a conference call to discuss its financial results at 10:00 a.m. (EST) on November 8, 2005. The call will be hosted by Mr. Gary C. Evans, Chairman and Dr. Rahul Singhvi, President and CEO of Novavax. Other participants on the call will include senior management of Novavax. A question and answer session will follow the financial results overview. The dial in number for the conference call is (800) 561-2693, pass code 74329370.

A live audio webcast of the conference call will be available through <http://www.novavax.com>. Please connect to this website at least 15 minutes prior to the conference call to ensure adequate time for any software download that may be needed to hear the webcast. A replay of the webcast will be available for 90 days starting on November 9, 2005 at www.novavax.com. A replay of the conference call will also be available by telephone on November 9, 2005 through November 16, 2005. To access the replay, dial (888) 286-8010 and enter pass code 73997800 followed by the number sign.

About Novavax, Inc.

Novavax, Inc. is a product development company focused on the research, development and commercialization of products utilizing its proprietary drug delivery and biological technologies for large and growing markets. Novavax's drug delivery technologies include the micellar nanoparticle (MNP) technology which is the basis for the development of its first FDA-approved product, ESTRASORB®. In addition to MNP, Novavax drug delivery technologies include Novasomes® (paucillamellar non-phospholipid liposomes) and Sterisomes® (subcutaneous depot injection) technologies. Novavax's vaccine technologies include its virus like particle (VLP) manufacturing technology utilizing the baculovirus expression system in insect cells as well as novel vaccine adjuvants based on Novasomes and dendrimer technologies.

Statements made in this press release that state Novavax's or management's intentions, hopes, beliefs, expectations, or predictions of the future are forward-looking statements. Forward-looking statements include but are not limited to statements regarding usage of cash, product sales, future product development and related clinical trials and future research and development, including FDA approval. Novavax's actual results could differ materially from those expressed in such forward-looking statements. Such forward-looking statements involve known and unknown risks, uncertainties and other factors which may cause the actual results, performance or achievements of the Company, or industry results, to be materially different from those expressed or implied by such forward-looking statements. Such factors include, among other things, the following: general economic and business conditions; ability to enter into future collaborations with industry partners, competition; unexpected changes in technologies and technological advances; ability to obtain rights to technology; ability to obtain and enforce patents; ability to commercialize and manufacture products; ability to establish and maintain commercial-scale manufacturing capabilities; results of clinical studies; progress of research and development activities; business abilities and judgment of personnel; availability of qualified personnel; changes in, or failure to comply with, governmental regulations; the ability to obtain adequate financing in the future through product licensing, co-promotional arrangements, public or private equity financing or otherwise; and other factors referenced herein. Additional information is

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contained in Novavax's annual report on Form 10K for the year ended December 31, 2004 and quarterly reports on Form 10Q for the quarters ended March 31, 2005 and June 30, 2005, incorporated herein by reference. Statements made herein should be read in conjunction with Novavax's annual and quarterly reports filed with the SEC. Copies of these filings may be obtained by contacting Novavax at 508 Lapp Road, Malvern, PA 19355 Tel 484-913-1200 or the SEC at www.sec.gov.

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For Further Information Contact:

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Email: khamilton@novavax.com

Item 9.01 Financial Statements and Exhibits.

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SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Novavax, Inc.

November 8, 2005

By: Dennis W. Genge

Name: Dennis W. Genge

Title: Vice President and Chief Financial Officer

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Exhibit Index

<u>Exhibit No.</u>	<u>Description</u>
99.1	Consolidated Statements of Operations