NOVAVAX INC
Form 8-K
August 09, 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): August 9, 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 9.01 Financial Statements and Exhibits.

FOR IMMEDIATE RELEASE
NASDAQ symbol: NVAX

NOVAVAX ANNOUNCES SECOND QUARTER RESULTS

MALVERN, PA., August 9, 2005 – Novavax, Inc. (Nasdaq: NVAX), a specialty biopharmaceutical company, today announced its second quarter financial and operational results.

Highlights:
• Improved second quarter 2005 results with an increase in revenue and a decrease in expenses over the first quarter 2005.
• Announced favorable results from preclinical tests for seven additional compounds utilizing the Company's proprietary micellar nanoparticle (MNP) technology.
• Completed preclinical testing of a pandemic (avian) influenza virus-like particle (VLP) vaccine.
• Continued business development efforts for potential co-development/licensing arrangements with a number of different companies.
• Significantly reduced ESTRASORB® manufacturing costs, effective July 1, 2005.
• Raised $4,000,000 in an equity offering completed in early July.
• Elected Gary C. Evans as Chairman of the Board of Directors.

"In conjunction with the senior management changes announced today and the significant progress achieved with the MNP pipeline after the launch and commercialization of our primary product, ESTRASORB, Novavax has successfully begun our transition from a company predominantly focused on one product to a developer of multiple products. The speed and the risk profile of our MNP product development model, based on the delivery of FDA approved compounds and our rigorous target selection process, provides partnership and licensing opportunities throughout the development process. It is this product development model, and our ability to advance candidates through clinical development, that will be critical to positioning Novavax for long-term growth," said Gary C. Evans, Chairman of the Board of Directors of Novavax.

ESTRASORB Update
While the overall sales of ESTRASORB are lower than the Company's original expectations, the sales of ESTRASORB have improved and more than doubled in the second quarter compared to the first quarter. The Company continues to pursue a potential partner to assist in the marketing and promotion of ESTRASORB to physicians and consumers.

Financial Results
Total revenues for the three-month period ended June 30, 2005, were $2.3 million compared with total revenues of $3.0 million for the same period last year. The variance is primarily due to the initial shipment of $1.5 million of ESTRASORB stock in preparation of the product launch during the three-month period ended June 30, 2004. However, sales of all products increased when compared to the first quarter of 2005, and in total increased by $1.2 million. Contract research and development revenues rose 49% over the same period last year, primarily due to the successful achievement of the first milestone of a new contract.

For the six-month period ended June 30, 2005, total revenues were $3.3 million compared with $6.2 million for the corresponding six-month period last year. Contributing to the variance in total revenue was a high level of backorders for the Company's prenatal vitamins introduced in late 2003 and shipped in the first quarter of 2004, the effects of generic competition on the Company's prenatal vitamins, and the completion of a major research contract in 2004.

Cost of sales for the three-month period ended June 30, 2005, were $2.0 million compared with $1.5 million for the three-month period ended June 30, 2004. Of the $2.0 million cost of sales, $1.0 million was due to idle plant capacity costs at our ESTRASORB manufacturing facility, which was operating at higher production levels at this time last year. The remaining $1.0 million in cost of sales is a decrease from the comparable figure of $1.5 million for the same period in 2004.

Cost of sales for the six-month period ended June 30, 2005, were $4.0 million compared with $1.8 million for the same six-month period last year. The variance in cost of sales over the six-month period is due primarily to idle plant capacity costs at the Company's ESTRASORB manufacturing facility during the first six months of 2005 compared with 2004.

Research and development costs for the three-month period ended June 30, 2005, were $1.4 million compared with $1.2 million for the three-month period ended June 30, 2004. Research and development costs for the six-month period ended June 30, 2005 were $2.6 million compared with $4.3 million for the same six-month period last year. The difference in research and development costs over the current six-month period is primarily due to manufacturing start-up costs during the 2004 period being accounted for in the research and development category until April 2004. Since April 2004, manufacturing costs have been included in the cost of sales and inventory category.

Selling and marketing costs were $1.8 million for the three-month period ended June 30, 2005, compared with $5.6 million for the same period

last year. The decrease in expenses is primarily a result of higher costs to support the commercial launch of ESTRASORB in the second quarter of 2004. The remaining portion of the variance is due to the sales force restructuring initiated in March 2005. Selling and marketing expenses were $5.9 million for the six-month period ended June 30, 2005, compared with $8.3 million for the same six-month period last year.

Total general and administrative costs were $2.3 million for the three-month period ended June 30, 2005, compared with $2.1 million for the three-month period ended June 30, 2004. The difference is primarily due to costs associated with increased business development activity, which were partially offset by other cost saving measures implemented during late 2004 and 2005. Total general and administrative costs were $4.4 million for the six-month period ended June 30, 2005, compared with $4.1 million for the six-month period ended June 30, 2004.

For the three-month period ended June 30, 2005, the Company had a net loss of $5.7 million, or ($0.14) per share, compared with a net loss of $7.7 million, or ($0.22) per share, for the same three-month period last year. This represents a 26% improvement over the same period last year and a 36% improvement compared with the first quarter of 2005. For the six-month period ended June 30, 2005, the Company had a net loss of $14.6 million, or ($0.37) per share, compared with a net loss of $13.0 million, or ($0.37) per share, for the three-month period ended June 30, 2004.

As of June 30, 2005, the Company had $4.4 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 gross proceeds of $4.0 million which on a proforma basis increased our cash position to approximately $8.0 million. The Company anticipates its cash requirements for the remainder of the year will be significantly lower than during the first half.

Outlook
Novavax is focused on the expansion of its new product portfolio, having recently added several new candidates utilizing the proprietary MNP technology platform. The Company continues to work with partners on product candidates in both drug delivery and biologics.

Conference Call
The Company will hold a conference call to discuss its results at 8:30 a.m. (EDT) on August 9, 2005. The call will be hosted by Mr. Gary C. Evans, Chairman of the Board of Directors of Novavax. Mr. Evans will be joined by Dr. Rahul Singhvi and other senior management to review the results, which will be followed by a question and answer session. The dial in number for the conference call is 1 (866) 250-4877.

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 August 9, 2005 at www.novavax.com. A replay of the conference call will also be available by telephone on August 9, 2005 through August 16, 2005. To access the replay, dial 1 (877) 289-8525 and enter reservation number 21133334#.

About Novavax, Inc.
Novavax, Inc. is a specialty biopharmaceutical company focused on the research, development and commercialization of products utilizing its proprietary drug delivery and biological technologies for large and growing markets. Novavax currently markets and distributes a line of prescription pharmaceutical products, including ESTRASORB®, its topical emulsion for estrogen therapy, and prenatal vitamins.

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, including an ESTRASORB® licensing agreement; 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 contained in Novavax's annual report on Form 10K for the year ended December 31, 2004 and quarterly report on Form 10Q for the quarter ended March 31, 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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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.

August 9, 2005

By: Dennis W. Genge

Name: Dennis W. Genge
Title: Vice President and Chief Financial Officer

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Exhibit Index

Exhibit No.	Description
99.1	Exhibit 1