NOVAVAX INC
Form 8-K
May 10, 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): May 10, 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 FIRST QUARTER RESULTS

MALVERN, PA., May 10, 2005 – Novavax, Inc. (Nasdaq: NVAX), a specialty biopharmaceutical company, today announced its first quarter financial and operational results.

Recent Highlights
• Completed preclinical tests for seven new drug candidates utilizing Novavax's proprietary Micellar Nanoparticle (MNP) technology.
• Signed an agreement with Ranbaxy Laboratories to evaluate a new transdermal product formulated using MNP technology.
• Received funding from the National Institutes of Health (NIH) to develop a SARS vaccine using proprietary Virus-Like Particle (VLP) technology.
• Implemented a sales plan to lower costs and provide greater focus on higher prescribing obstetricians and gynecologists.
• Promoted Rahul Singhvi, Sc.D., to Senior Vice-President and Chief Operating Officer.
• Elected Gary C. Evans as Chairman of the Board of Directors.
• Announced an agreement with Cardinal Health, Inc. to reduce ESTRASORB® manufacturing costs.

Opportunities and Challenges
• Finalize ESTRASORB partnership.
• Address legacy product issues: wholesaler inventories, generic competition, and AVCTM Cream promotion opportunities.
• Complete additional new product partnership(s).
• Further reduce operating expenses.

"In the midst of a challenging business environment, we continue to accelerate new product development by completing preclinical trials for several new drug delivery candidates and to capitalize on our proprietary MNP technology," said Nelson M. Sims, President and CEO of Novavax. "We believe our proactive steps to strengthen our balance sheet, by better aligning expenses with future revenue, and the anticipated completion of an ESTRASORB partnership, will position Novavax to demonstrate improved performance for the remainder of 2005."

Financial Results
Total revenues for the three-month period ended March 31, 2005, were $1.0 million compared with total revenues of $3.2 million for the three-month period ended March 31, 2004. The primary reason for the decrease is approximately $1.0 million of backorders for our new prenatal vitamins introduced in late 2003 and shipped in the first quarter of 2004. In addition, we continue to experience generic competition on our prenatal vitamin line and greater than expected returns for Gynodiol® and AVC Cream. ESTRASORB sales for the three-month period ended March 31, 2005, were $0.3 million, a modest increase over the previous two quarters. ESTRASORB wholesaler inventories continued to decline in the first quarter and the company expects ex-factory sales to increase in the second quarter. There is no comparable three-month period from 2004, as the initial ESTRASORB product shipments occurred in June 2004.

Cost of sales for the three-month period ended March 31, 2005, were $2.0 million compared with $0.3 million for the three-month period ended March 31, 2004. Of the $2.0 million in cost of sales, $1.5 million was due to idle capacity costs at our manufacturing facility. The remaining $0.5 million is higher than the $0.3 million in 2004 due to ESTRASORB sales, which carry a higher cost of goods than our legacy products. Research and development costs for the three-month period ended March 31, 2005, were $1.2 million compared with $3.0 million for the three-month period ended March 31, 2004. The decrease is 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 expenses were $4.0 million for the three-month period ended March 31, 2005, compared with $2.8 million for the three-month period ended March 31, 2004. The change is primarily due to expenses to support the ESTRASORB launch. In March 2005, we restructured the sales force down to 40 positions to better align expenses with future revenues, thus our selling expenses will decrease in following quarters.

A decrease in normally recurring general and administrative expenses was offset by increases in the cost of our audit and Sarbanes-Oxley 404 compliance. As a result, total general and administrative costs were $2.1 million for the three-month period ended March 31, 2005, compared with $2.0 million for the three-month period ended March 31, 2004.

For the three-month period ended March 31, 2005, the company had a net loss of $8.9 million, or ($0.22) per share, compared with a net loss of $5.3 million, or ($0.15) per share, for the three-month period ended March 31, 2004. The first quarter net loss demonstrates an improvement over the fourth quarter of 2004.

As of March 31, 2005, the Company had $9.2 million in cash and cash-equivalents compared with $17.9 million at December 31, 2004.

The following measures have been taken, or are planned, to improve the Company's cash flow over the next few months:
• The sales force restructuring will reduce expenses by approximately $1.8 million per quarter.
• As announced on May 9, 2005, manufacturing costs will be reduced due to a new agreement with Cardinal Health, Inc., effective as of July. Together with other identified efficiencies beyond this agreement, additional savings exist.
• Marketing costs incurred for the ESTRASORB launch have been completed.

The Company has already reduced total expenses by nearly $2.6 million in the first quarter of 2005 compared with the fourth quarter of 2004. We believe that the impact from the combination of measures above will significantly reduce the quarterly reliance on cash reserves.

Pipeline Update
Novavax will continue to develop its pipeline products, specifically its proprietary MNP drug delivery and VLP biological platforms. The MNP platform is validated by virtue of the FDA approval of ESTRASORB. In our opinion MNP offers an attractive opportunity to capitalize on additional product development opportunities through the reformulation of approved pharmaceutical molecules in a topical delivery format. Seven new products have completed the animal blood level stage of preclinical testing. Once the results are evaluated, the Company will provide a market update on its clinical plan. For the first time the company has demonstrated that its MNP technology achieves blood levels in animal models for non-hormone products. This achievement could lead to a significant number of new product candidates.

Novavax's VLP biological platform uses recombinant protein technology to imitate the structure of a virus to provide protection without the risk of infection or disease. It is our belief that the VLP technology produces safe and effective vaccine products through an aseptic process that reduces contamination risk and produces high, cost-effective yields. Four VLP projects are currently in development, including projects for HIV/AIDS, SARS, pandemic flu and trivalent (seasonal) flu. Novavax is also working on E-selectin tolerogen for the prevention of secondary stroke with the National Institute of Neurological Disorders and Stroke.

Conference Call
The Company will hold a conference call to discuss its results at 8:30 a.m. (EDT) today, May 10, 2005. The call will be hosted by Mr. Nelson M. Sims, President and CEO. Mr. Sims will be joined by other senior management members to review the results, which will be followed by a question and answer session. The dial in number for the conference call is 1 (800) 866-5043.

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 May 10, 2005 at www.novavax.com. A replay of the conference call will also be available by telephone on May 10, 2005 through May 17, 2005. To access the replay, dial 1 (877) 289-8525 and enter reservation number 21123709#.

About Novavax, Inc.
Novavax, Inc. is a fully-integrated specialty biopharmaceutical company focused on the research, development and commercialization of products utilizing its proprietary drug delivery and vaccine technologies for large and growing markets, concentrating on areas of women's health and infectious diseases. Novavax currently sells, markets, and distributes a line of prescription pharmaceutical products and prenatal vitamins through its national sales force including its MNP based product, ESTRASORB, the first topical emulsion for estrogen therapy. Novavax's MNP technology involves the use of patented oil and water nanoemulsions that it believes can be used as vehicles for the topical delivery of a wide variety of drugs and other therapeutic products, including hormones. In addition, Novavax conducts research and development on preventative and therapeutic vaccines and proteins for a variety of infectious diseases, including HIV, influenza, SARS and E-selectin tolerogen for the prevention of stroke.

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 incorporated herein by reference. Statements made herein should be read in conjunction with Novavax's Form 10K. Copies of the filing may be obtained by contacting Novavax at 508 Lapp Road, Malvern, PA 19355 Tel 484-913-1200 or the SEC at www.sec.gov.

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.

May 10, 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	Consolidated Statements of Operations