

NOVAVAX INC
Form 10-Q
August 14, 2006

UNITED STATES SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549
FORM 10-Q

QUARTERLY REPORT UNDER SECTION 13 or 15(d) OF THE SECURITIES EXCHANGE
ACT OF 1934

For Quarterly Period Ended June 30, 2006

Commission File No. 0-26770

NOVAVAX, INC.

(Exact name of registrant as specified in its charter)

Delaware

22-2816046

(State or other jurisdiction of
incorporation or organization)

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

508 Lapp Road, Malvern, PA

19355

(Address of principal executive offices)

(Zip code)

(484) 913-1200

(Registrant's telephone number, including area code)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer. See definition of "accelerated filer and large accelerated filer" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer Accelerated filer Non-accelerated filer

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).

Yes No

The number of shares outstanding of each of the issuer's classes of common stock, as of the latest practicable date:

Shares of Common Stock Outstanding at August 9, 2006: 61,528,693

NOVAVAX, INC.
Form 10-Q
For the Quarter Ended June 30, 2006
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Part I. Financial Information
Item 1. Financial Statements

NOVAVAX, INC.
CONSOLIDATED BALANCE SHEETS
(in thousands, except share and per share information)

	June 30, 2006 (unaudited)	December 31, 2005
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 78,601	\$ 31,893
Accounts and other receivables, net of allowance for doubtful accounts of \$325 and \$429 as of June 30, 2006 and December 31, 2005, respectively	3,825	3,571
Inventory	757	800
Prepaid expenses and other current assets	1,306	1,347
Total current assets	84,489	37,611
Property and equipment, net	10,761	11,589
Goodwill	33,141	33,141
Other intangible assets, net	1,044	1,110
Other non-current assets	1,141	931
Total assets	\$ 130,576	\$ 84,382
LIABILITIES and STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable	\$ 780	\$ 1,426
Accrued expenses	2,813	2,597
Current portion of notes payable	386	715
Facility exit costs	54	138
Total current liabilities	4,033	4,876
Convertible notes	22,000	29,000
Deferred rent	144	176
Non-current portion of notes payable	569	678
Stockholders equity:		
Preferred stock, \$.01 par value, 2,000,000 shares authorized; no shares issued and outstanding		
Common stock, \$.01 par value, 100,000,000 shares authorized; 61,784,738 shares issued and 61,536,871 outstanding at June 30, 2006, and 50,259,494 issued and 50,005,646 outstanding at December 31, 2005	618	503
Additional paid-in capital	260,400	195,361
Unearned compensation		(425)

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Notes receivable from directors	(1,032)	(1,480)
Accumulated deficit	(153,800)	(141,894)
Treasury stock, 247,867 shares at June 30, 2006 and 253,848 shares at December 31, 2005, cost basis	(2,356)	(2,413)
Total stockholders' equity	103,830	49,652
Total liabilities and stockholders' equity	\$ 130,576	\$ 84,382

The accompanying notes are an integral part of these consolidated financial statements.

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NOVAVAX, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS
(in thousands, except share and per share information)
(unaudited)

	Three months ended		Six months ended	
	June 30,		June 30,	
	2006	2005	2006	2005
Revenues:				
Net product sales	\$ 378	\$ 1,889	\$ 1,097	\$ 2,608
Contract research and development	403	426	877	669
Royalties, milestone and licensing fees	58		168	
Total revenues	839	2,315	2,142	3,277
Operating costs and expenses:				
Cost of products sold	1,161	2,027	2,394	4,006
Excess inventory costs over market	677		992	
Research and development	3,401	1,377	5,433	2,599
Selling and marketing	28	1,844	66	5,901
General and administrative	2,610	2,292	5,330	4,413
Total operating costs and expenses	7,877	7,540	14,215	16,919
Loss from operations	(7,038)	(5,225)	(12,073)	(13,642)
Interest income / (expense), net	627	(491)	167	(960)
Net loss	\$ (6,411)	\$ (5,716)	\$ (11,906)	\$ (14,602)
Basic and diluted loss per share	\$ (.10)	\$ (.14)	\$ (.21)	\$ (.37)
Basic and diluted weighted average number of common shares outstanding	61,465,003	39,553,876	56,891,602	39,553,876

The accompanying notes are an integral part of these consolidated financial statements.

NOVAVAX, INC.
CONSOLIDATED STATEMENTS OF STOCKHOLDERS EQUITY
For the Three Months Ended March 31, 2006 and June 30, 2006
(in thousands, except share information)
(unaudited)

	Common Stock		Additional	Notes	Accumulated	Treasury	Total	
	Shares	Amount	Paid-in Capital	Unearned Compensation From Directors	Deficit	Stock	Stockholders Equity	
Balance, December 31, 2005	50,259,494	\$ 503	\$ 195,361	\$ (425)	\$ (1,480)	\$ (141,894)	\$ (2,413)	\$ 49,652
Netted unearned compensation against additional paid in capital in accordance with SFAS No. 123R			(425)	425				
Non-cash compensation costs for stock options			825					825
Exercise of stock options	158,750	1	797					798
Conversion of convertible debt	1,294,564	13	7,055					7,068
Restricted stock issued as compensation	155,000	2						2
Non-cash compensation cost for amortization of restricted stock			208					208
Treasury stock issued in lieu of payment of services rendered			(32)			57		25
Sales of common stock	9,803,180	98	57,902					58,000
Financing costs incurred to raise additional capital			(1,978)					(1,978)
Net loss					(5,495)			(5,495)
Balance, March 31, 2006	61,670,988	\$ 617	\$ 259,713	\$ (1,480)	\$ (147,389)	\$ (2,356)	\$ 109,105	

Non-cash compensation costs for stock options			420					420
Non-cash compensation cost for amortization of restricted stock			129					129
Restricted stock issued as compensation	60,000	1						1
Exercise of stock options	53,750		179					179
Financing costs incurred to raise additional capital			(41)					(41)
Reclassification due to change in status of a director					448			448
Net loss						(6,411)		(6,411)
Balance, June 30, 2006	61,784,738	\$ 618	\$ 260,400	\$	\$ (1,032)	\$ (153,800)	\$ (2,356)	\$ 103,830

The accompanying notes are an integral part of these consolidated financial statements.

NOVAVAX, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS
(in thousands)
(unaudited)

	Six months ended	
	June 30,	
	2006	2005
Operating Activities:		
Net loss	\$ (11,906)	\$ (14,602)
Reconciliation of net loss to net cash used in operating activities:		
Amortization	66	431
Depreciation	1,437	1,426
Provision for bad debts	(104)	12
Retirement of capital assets	46	42
Amortization of deferred financing costs	417	206
Deferred rent	(32)	(1)
Non-cash expense for services	25	
Non-cash stock compensation	1,585	15
Changes in operating assets and liabilities:		
Trade accounts receivable	(150)	(318)
Inventory	43	2,063
Prepaid expenses and other assets	(41)	440
Accounts payable and accrued expenses	(362)	(2405)
Facility exit costs	(84)	(85)
Other non-current assets	(97)	38
Net cash used in operating activities	(9,157)	(12,738)
Investing Activities:		
Capital expenditures	(655)	(80)
Net cash used in investing activities	(655)	(80)
Financing Activities:		
Principal payments of notes payable	(438)	(616)
Net proceeds from sales of common stock	55,981	
Proceeds from the exercise of stock options	977	
Net cash provided by/(used in) financing activities	56,520	(616)
Net change in cash and cash equivalents	46,708	(13,434)
Cash and cash equivalents at beginning of period	31,893	17,876
Cash and cash equivalents at end of period	\$ 78,601	\$ 4,442

Non-cash transactions:

Conversion of convertible debt and accrued interest to common stock	\$ 7,068	\$
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Cash Interest Payments:

Cash interest payments	\$ 778	\$ 862
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The accompanying notes are an integral part of these consolidated financial statements.

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NOVAVAX, INC.
NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS
(unaudited)

1. Organization

Novavax, Inc., a Delaware corporation (Novavax or the Company), was incorporated in 1987, and is a biopharmaceutical company focused on creating differentiated, value-added vaccines that leverage the Company's proprietary virus-like particle (VLP) technology utilizing the baculovirus expression system in insect cells, as well as developing novel vaccine adjuvants based on Novasomes[®]. The Company is developing vaccines against the H5N1, H9N2 and other subtypes of avian influenza with pandemic potential and against human seasonal influenza as well as other viral diseases. The Company also has developed a drug delivery platform using micellar nanoparticle (MNP) technology, which was the basis for the development of its first Food and Drug Administration-approved product, ESTRASORB[®]. In October 2005, the Company entered into License and Supply Agreements for ESTRASORB. Under the agreements, the Company will continue to manufacture ESTRASORB and the licensee, Esprit Pharma, Inc., (Esprit), which was granted an exclusive license to sell ESTRASORB in North America.

In April 2006, the Company entered into a License and Development Agreement and a Supply Agreement with Esprit to co-develop, supply and commercialize the Company's MNP testosterone medicine for the treatment of female hypoactive sexual desire disorder. Esprit was granted exclusive rights to market the product in North America.

The products currently under development or in clinical trials by the Company will require significant additional research and development efforts, including extensive pre-clinical and clinical testing and regulatory approval, prior to commercial use. There can be no assurance that the Company's research and development efforts will be successful or that any potential products will prove to be safe and effective in clinical trials. Even if developed, these products may not receive regulatory approval or be successfully introduced and marketed at prices that would permit the Company to operate profitably. The Company also recognizes that the commercial launch of any product is subject to certain risks including, but not limited to, manufacturing scale-up and market acceptance. No assurance can be given that the Company can generate sufficient product revenue to become profitable or generate positive cash flow from operations at all or on a sustained basis.

NOVAVAX, INC.
NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS
(unaudited)

The consolidated financial statements of Novavax for the three months and six months ended June 30, 2006 and 2005, are unaudited. These financial statements reflect all adjustments which, in the opinion of management, are necessary for a fair presentation of the results of operations for the interim periods presented. All such adjustments are of a normal recurring nature. These interim results are not necessarily indicative of the results to be expected for the fiscal year ending December 31, 2006.

Certain information in footnote disclosures normally included in financial statements prepared in accordance with generally accepted accounting principles has been condensed or omitted pursuant to the rules and regulations of the Securities and Exchange Commission, although the Company believes the disclosures are adequate to make the information presented not misleading. We suggest that these consolidated financial statements be read in conjunction with the audited consolidated financial statements and the notes thereto in the Company's Annual Report on Form 10-K for the year ended December 31, 2005.

2. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying consolidated financial statements include the accounts of the Company and its wholly-owned subsidiary. All significant inter-company accounts and transactions have been eliminated in consolidation.

Use of Estimates

The preparation of the consolidated financial statements in conformity with accounting principles generally accepted in the United States requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

NOVAVAX, INC.
NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS
(unaudited)

Revenue Recognition

The Company recognizes revenue in accordance with the provisions of Staff Accounting Bulletin No. 104, *Revenue Recognition* (SAB No. 104). For product sales, revenue is recognized when all of the following criteria are met: persuasive evidence of an arrangement exists, delivery has occurred, the seller's price to the buyer is fixed or determinable and collectibility is reasonably assured. The Company recognizes these sales, net of allowances for returns, rebates and chargebacks. A large part of the Company's product sales is to Esprit or to distributors who resell the products to their respective customers. The Company provides rebates to members of certain buying groups who purchase from the Company's distributors, to distributors that sell to their customers at prices determined under a contract between the Company and the customer, and to state agencies that administer various programs such as the federal Medicaid and Medicare. Rebate amounts are usually based upon the volume of purchases or by reference to a specific price for a product. The Company estimates the amount of the rebate that will be paid, and records the liability as a reduction of revenue when the Company records its sale of the products. Settlement of the rebate generally occurs from three to 12 months after sale. The Company regularly analyzes the historical rebate trends and makes adjustments to recorded reserves for changes in trends and terms of rebate programs. In a similar manner, the Company estimates amounts for returns based on historical trends, distributor inventory levels, product prescription data and generic competition and makes adjustments to the recorded reserves based on such information.

Under the terms of an Asset Purchase Agreement with Pharmelle, LLC, the Company no longer has responsibility for rebates or returns related to AVC Cream and Suppositories, NovaNatal and NovaStart. Under the License and Supply Agreements with Esprit, as of January 20, 2006, the Company no longer had responsibility for rebates related to ESTRASORB or for returns related to ESTRASORB sales made subsequent to October 19, 2005.

A roll-forward of the sales return allowances is as follows:

	(in thousands) (unaudited)
Balance, December 31, 2005	\$ 282
Provision for 2006 sales	7
Additional provision for 2004 sales	34
Returns received from 2004 sales	(113)
 Balance, March 31, 2006	 \$ 210
Provision for 2006 sales	6
Additional provision for 2004 sales	105
Additional provision for 2005 sales	93
Returns received from 2004 sales	(77)
 Balance, June 30, 2006	 \$ 337

NOVAVAX, INC.
NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS
(unaudited)

Revenue Recognition (continued):

The shipping and handling costs the Company incurs are included in cost of products sold in its statements of operations.

For upfront payments and licensing fees related to contract research or technology, the Company follows the provisions of SAB No. 104 in determining if these payments and fees represent the culmination of a separate earnings process or if they should be deferred and recognized as revenue earned over the life of the related agreement. Milestone payments are recognized as revenue upon achievement of contract-specified events and when there are no remaining performance obligations.

Revenue earned under research contracts is recognized per the terms and conditions of such contracts for reimbursement of costs incurred and defined milestones. Revenue earned under a drug development contract is recognized in proportion to the work performed.

Inventories

Inventories consist of raw materials, work-in-process and finished goods, and are priced at the lower of cost or market, using the first-in-first-out method, and were as follows:

	June 30, 2006 (unaudited)	December 31, 2005
(amounts in thousands)		
Raw materials	\$ 232	\$ 358
Work-in-process		38
Finished goods	525	404
	\$ 757	\$ 800

During the year ended December 31, 2005, the Company implemented Statement of Financial Accounting Standard No. 151, *Inventory Costs - an amendment of ARB No. 43, Chapter 4* (SFAS No. 151). Under SFAS No. 151, the Company allocates fixed production overhead costs to inventories based on the anticipated normal capacity of its manufacturing facility at the time. Included in cost of products sold for the three months and six months ended June 30, 2006 is \$728,000, or \$(.01) per share, and \$1,128,000, or \$(.02) per share, respectively, of idle capacity costs, which amounts represent the excess of fixed production overhead costs over that allocated to inventories.

During the three months and six months ended June 30, 2006, \$677,000 and \$992,000, respectively, of inventory costs in excess of market value were included in the accompanying consolidated statement of operations related to the Supply Agreement with Esprit. Under the terms of this agreement, the Company sold ESTRASORB at a price which was below its manufacturing costs for the product during the first half of 2006.

NOVAVAX, INC.
NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS
(unaudited)

Inventories (continued):

It is most likely the Company will continue to manufacture ESTRASORB at a loss until production volumes increase or it enters into additional contract manufacturing agreements with third parties to more fully utilize its manufacturing facility's capacity. The facility is able to accommodate much greater production than its current schedule, which, if more fully utilized, would offset the fixed costs related to the manufacturing process and facility. In addition, the Company is negotiating revisions to its agreements for packaging costs of ESTRASORB as well as its fixed lease costs for the manufacturing facility. If these negotiations result in higher packaging or lease costs to the Company, it may have a material adverse impact on future financial results.

Net Loss per Share

Basic loss per share is computed by dividing the net loss (the numerator) by the weighted average number of common shares outstanding (the denominator) during the period. Shares issued during the period and shares reacquired during the period are weighted for the portion of the period that they were outstanding. The computation of diluted loss per share is similar to the computation of basic loss per share except that the denominator is increased to include the number of additional common shares that would have been outstanding if the dilutive potential common shares had been issued (e.g. upon exercise of stock options). Potentially dilutive common shares are not included in the computation of diluted earnings per share if they are anti-dilutive. Net loss per share as reported was not adjusted for potential common shares, as they are anti-dilutive.

Property and Equipment

Property and equipment are recorded at cost. Depreciation of furniture, fixtures and equipment is provided under the straight-line method over the estimated useful lives of the assets, generally three to ten years. Amortization of leasehold improvements is provided over the shorter of the estimated useful lives of the improvements or the term of the respective lease. Repairs and maintenance costs are expensed as incurred.

NOVAVAX, INC.
NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS
(unaudited)

Property and Equipment (continued):

Property and equipment is comprised of the following:

	June 30, 2006 (unaudited)	As of December 31,2005
	(amounts in thousands)	
Machinery and equipment	\$ 11,765	\$ 11,275
Leasehold improvements	6,248	6,201
Computer software and hardware	344	320
	18,357	17,796
Less accumulated depreciation	(7,596)	(6,207)
	\$ 10,761	\$ 11,589