

NOVAVAX INC
Form 10-Q
May 10, 2010

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

Form 10-Q

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended March 31, 2010

OR

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from to .

Commission File No. 0-26770

NOVAVAX, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

22-2816046
(I.R.S. Employer
Identification No.)

9920 Belward Campus Drive, Rockville, MD
(Address of principal executive offices)

20850
(Zip code)

(240) 268-2000

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 has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes No

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

Large accelerated filer Accelerated filer Non-accelerated filer Smaller reporting company

(Do not check if a smaller reporting company)

Edgar Filing: NOVAVAX INC - Form 10-Q

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 the Registrant's Common Stock, \$0.01 par value, was 100,488,543 as of April 30, 2010.

NOVAVAX, INC.
TABLE OF CONTENTS

		Page No.
PART I. FINANCIAL INFORMATION		
Item 1.	Financial Statements	
	Consolidated Balance Sheets as of March 31, 2010 (unaudited) and December 31, 2009	1
	Consolidated Statements of Operations for the three months ended March 31, 2010 and 2009 (unaudited)	2
	Consolidated Statements of Cash Flows for the three months ended March 31, 2010 and 2009 (unaudited)	3
	Notes to the Consolidated Financial Statements (unaudited)	4
Item 2.	Management's Discussion and Analysis of Financial Condition and Results of Operations	10
Item 3.	Quantitative and Qualitative Disclosures about Market Risk	15
Item 4.	Controls and Procedures	16
PART II. OTHER INFORMATION		
Item 1.	Legal Proceedings	16
Item 1A.	Risk Factors	16
Item 6.	Exhibits	17
SIGNATURES		18

PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

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

	March 31, 2010 (unaudited)	December 31, 2009
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 14,575	\$ 38,757
Short-term investments available-for-sale	18,313	4,193
Accounts and other receivables	231	258
Prepaid expenses and other current assets	698	1,295
Total current assets	33,817	44,503
Property and equipment, net	8,259	7,801
Goodwill	33,141	33,141
Other non-current assets	160	160
Total assets	\$ 75,377	\$ 85,605
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 5,474	\$ 2,098
Accrued expenses and other current liabilities	3,326	5,417
Current portion of notes payable	80	80
Deferred revenue	61	150
Deferred rent	292	282
Total current liabilities	9,233	8,027
Non-current portion of notes payable	380	406
Deferred rent	2,625	2,707
Total liabilities	12,238	11,140
Commitments and contingences	—	—
Stockholders' equity:		
Preferred stock, \$0.01 par value, 2,000,000 shares authorized; no shares issued and outstanding	—	—
Common stock, \$0.01 par value, 200,000,000 shares authorized; and 100,753,640 shares issued and 100,286,543 shares outstanding at March 31, 2010 and 100,717,890 shares issued and 100,262,460 shares outstanding at December 31, 2009	1,008	1,007
Additional paid-in capital	350,957	350,810
Notes receivable from former directors	(1,572)	(1,572)
Accumulated deficit	(285,562)	(274,150)
Treasury stock, 467,097 and 455,430 shares at March 31, 2010 and December 31, 2009, respectively, cost basis	(2,450)	(2,450)
Accumulated other comprehensive income	758	820
Total stockholders' equity	63,139	74,465

Total liabilities and stockholders' equity	\$	75,377	\$	85,605
--	----	--------	----	--------

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

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

	For the Three Months Ended March 31,	
	2010	2009
Revenue	\$ 110	\$ 21
Operating expenses:		
Research and development	9,029	4,266
General and administrative	2,535	2,892
Total operating expenses	11,564	7,158
Loss from continuing operations	(11,454)	(7,137)
Other income (expense):		
Interest income	44	104
Interest expense	(2)	(437)
Impairment of short-term investments	—	(879)
Net loss	\$ (11,412)	\$ (8,349)
Basic and diluted net loss per share	\$ (0.11)	\$ (0.12)
Basic and diluted weighted average number of common shares outstanding	100,188	68,692

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

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

	For the Three Months Ended March 31,	
	2010	2009
Operating Activities:		
Net loss:	\$ (11,412)	\$ (8,349)
Reconciliation of net loss to net cash used in operating activities:		
Depreciation and amortization	296	294
Amortization of debt discount	—	103
Amortization of deferred financing costs	—	64
Loss on disposal of property and equipment	—	29
Deferred rent	(72)	(66)
Non-cash stock-based compensation	84	497
Impairment of short-term investments	—	879
Changes in operating assets and liabilities:		
Accounts and other receivables	27	216
Prepaid expenses and other current assets	597	(152)
Accounts payable and accrued expenses	1,189	(242)
Deferred revenue	(89)	—
Net cash used in operating activities	(9,380)	(6,727)
Investing Activities:		
Capital expenditures	(658)	(63)
Proceeds from disposal of property and equipment	—	6
Proceeds from maturities of short-term investments	—	125
Purchases of short-term investments	(14,182)	—
Net cash (used in) provided by investing activities	(14,840)	68
Financing Activities:		
Principal payments of notes payable	(26)	(807)
Net proceeds from sales of common stock	—	122
Proceeds from the exercise of stock options	64	35
Net cash provided by (used in) financing activities	38	(650)
Net decrease in cash and cash equivalents	(24,182)	(7,309)
Cash and cash equivalents at beginning of period	38,757	26,938
Cash and cash equivalents at end of period	\$ 14,575	\$ 19,629
Supplemental disclosure of non-cash activities:		
Equipment purchases included in accounts payable	\$ 96	\$ 47
Supplemental disclosure of cash flow information:		
Cash interest payments	\$ —	\$ 523

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

NOVAVAX, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
March 31, 2010

Note 1 – Organization

Novavax, Inc. (the “Company”), is a clinical-stage biopharmaceutical company focused on developing novel, highly potent recombinant vaccines. These vaccines leverage the Company’s virus-like-particle (“VLP”) platform technology coupled with a unique disposable production technology. VLPs are genetically engineered three-dimensional nanostructures which incorporate immunologically important lipids and recombinant proteins. The Company’s VLPs resemble the virus, but lack the genetic material to replicate the virus and its proprietary production technology uses insect cells rather than chicken eggs or mammalian cells. The Company’s current product targets include vaccines against pandemic influenza (including H5N1 and H1N1 pandemic strains), seasonal influenza, Respiratory Syncytial Virus (“RSV”) and Varicella Zoster Virus (“VZV”), which causes shingles.

In 2009, the Company formed a joint venture with Cadila Pharmaceuticals Ltd. (“Cadila”), named CPL Biologicals Private Limited (the “JV”), to develop and manufacture vaccines, biological therapeutics and diagnostics in India. The Company owns 20% of the JV and Cadila owns the remaining 80%.

Note 2 – Liquidity Matters

Since its inception, the Company has incurred, and continues to incur, significant losses from operations. At March 31, 2010, the Company had cash and cash equivalents of \$14.6 million and short-term investments with a fair value of \$18.3 million.

The Company’s vaccine product candidates currently under development 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 product candidates will prove to be safe and effective in clinical trials. Even if developed, there can be no assurance that these vaccine product candidates would receive regulatory approval or be successfully introduced and marketed at prices that would permit the Company to operate profitably. The commercial launch of any vaccine product candidate is subject to certain risks including, but not limited to, manufacturing scale-up and market acceptance.

Based on the Company’s cash, cash equivalents and short-term investment balances as of March 31, 2010, anticipated proceeds from sales of the Company’s Common Stock under the At the Market Sales Agreement with McNicoll, Lewis & Vlak LLC and its current business operations, the Company believes it will have adequate capital resources available to operate at planned levels for at least the next twelve months. Additional capital will be required in the future to develop its product candidates through clinical development, manufacturing and commercialization. The Company will seek additional capital through further public or private equity offerings, debt financing, additional strategic alliance and licensing arrangements, non-dilutive government contracts, collaborative arrangements, or some combination of these financing alternatives. Any capital raised by an equity offering, whether public or private, will likely be substantially dilutive to the existing stockholders and any licensing or development arrangement may require the Company to give up rights to a product or technology at less than its full potential value. Other than the Company’s At the Market Sales Agreement, it has not secured any additional commitments for new financing nor can the Company provide any assurance that new financing will be available on commercially acceptable terms, if at all. If the Company is unable to obtain additional capital, it will assess its capital resources and will likely be required to delay, reduce the scope of, or eliminate one or more of its product research and development programs, downsize the organization, or reduce its general and administrative infrastructure.

Note 3 – Summary of Significant Accounting Policies

Basis of Presentation

The accompanying unaudited consolidated financial statements have been prepared in accordance with United States Generally Accepted Accounting Principles (“GAAP”) for interim financial information and the instructions to Form 10-Q and Article 10 of Regulation S-X. The consolidated balance sheet as of March 31, 2010, consolidated statements of operations for the three months ended March 31, 2010 and 2009 and the consolidated statements of cash flows for the three months ended March 31, 2010 and 2009 are unaudited, but include all adjustments (consisting of normal recurring adjustments) that the Company considers necessary for a fair presentation of the financial position, operating results and cash flows, respectively, for the periods presented. Although the Company believes that the disclosures in these financial statements are adequate to make the information presented not misleading, certain information and footnote information normally included in financial statements prepared in accordance with GAAP have been condensed or omitted pursuant to the rules and regulations of the United States Securities and Exchange Commission (“SEC”).

The accompanying consolidated financial statements include the accounts of the Company and its wholly owned subsidiary, Fielding Pharmaceutical Company. All significant intercompany accounts and transactions have been eliminated in consolidation.

Results for any interim period are not necessarily indicative of results for any future interim period or for the entire year. The accompanying unaudited consolidated financial statements should be read in conjunction with the consolidated financial statements and notes thereto included in the Company’s Annual Report on Form 10-K for the year ended December 31, 2009.

Use of Estimates

The preparation of the consolidated financial statements in conformity with GAAP 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 revenue and expenses during the reporting period. Actual results could differ materially from those estimates.

Fair Value Measurements

The Company adopted ASC 820, Fair Value Measurements and Disclosures, for financial assets and liabilities on January 1, 2008. The Company adopted ASC 820 for non-financial assets and liabilities on January 1, 2009.

ASC 820 discusses valuation techniques, such as the market approach (comparable market prices), the income approach (present value of future income or cash flow) and the cost approach (cost to replace the service capacity of an asset or replacement cost). The statement utilizes a fair value hierarchy that prioritizes the inputs to valuation techniques used to measure fair value into three broad levels. The following is a brief description of those three levels:

- Level 1: Observable inputs such as quoted prices (unadjusted) in active markets for identical assets or liabilities.
- Level 2: Inputs other than quoted prices that are observable for the asset or liability, either directly or indirectly. These include quoted prices for similar assets or liabilities in active markets and quoted prices for identical or similar assets or liabilities in markets that are not active.
 - Level 3: Unobservable inputs that reflect the reporting entity’s own assumptions.

Financial assets and liabilities measured a fair market value on a recurring basis as of March 31, 2010 are summarized below (in thousands):

Assets	Fair Value Measurement at				Fair Value
	March 31, 2010 using Fair Value Hierarchy				
	Level 1	Level 2	Level 3		
Cash and cash equivalents	\$ 14,575	\$ —	\$ —	\$ —	\$ 14,575
Short-term investments	—	18,313	—	—	18,313
Total	\$ 14,575	\$ 18,313	\$ —	\$ —	\$ 32,888

The amounts in the Company's consolidated balance sheet for accounts and other receivables, accounts payable and notes payable approximate fair value due to their short-term nature.

Short-Term Investments

Short-term investments at March 31, 2010 consist of investments in commercial paper, corporate notes and three auction rate securities. The Company has classified these securities as available-for-sale since the Company may need to liquidate these securities within the next year. The available-for-sale securities are carried at fair value and unrealized gains and losses on these securities, if determined to be temporary, are included in accumulated other comprehensive income (loss) in stockholders' equity. Investments available for sale are evaluated periodically to determine whether a decline in value is "other-than-temporary." The term "other-than-temporary" is not intended to indicate a permanent decline in value. Rather, it means that the prospects for a near term recovery of value are not necessarily favorable, or that there is a lack of evidence to support fair values equal to, or greater than, the carrying value of the security. Management reviews criteria, such as the magnitude and duration of the decline, as well as the Company's ability to hold the securities until market recovery, to predict whether the loss in value is other-than-temporary. If a decline in value is determined to be other-than-temporary, the value of the security is reduced and the impairment is recorded in the consolidated statements of operations. The specific identification method is used in computing realized gains and losses on sale of the Company's securities.

Short-term investments classified as available-for-sale as of March 31, 2010 were comprised of (in thousands):

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Auction rate securities	\$ 3,373	\$ 766	\$ —	\$ 4,139
Corporate debt securities	14,182	—	(8)	14,174
Total	\$ 17,555	\$ 766	\$ (8)	\$ 18,313

Net Loss per Share

Net loss per share is computed using the weighted average number of shares of common stock outstanding. All outstanding warrants, stock options and unvested restricted stock awards totaling 9,485,967 shares and 10,132,185 shares at March 31, 2010 and 2009, respectively, are excluded from the computation, as their effect is anti-dilutive.

Comprehensive Income (Loss)

The Company accounts for comprehensive income (loss) as prescribed by ASC 220, Comprehensive Income. Comprehensive income (loss) is the total net income (loss) plus all changes in equity during the period except those changes resulting from investment by and distribution to owners. Total comprehensive loss was \$11.5 million and \$8.3 million for the three months ended March 31, 2010 and 2009, respectively.

Recent Accounting Pronouncements Not Yet Adopted

In September 2009, ASU 2009-13, Revenue Recognition (Topic 605)—Multiple-Deliverable Revenue Arrangements, was issued and will change the accounting for multiple-deliverable arrangements to enable vendors to account for products or services (deliverables) separately rather than as a combined unit. Specifically, this guidance amends the criteria in Subtopic 605-25, Revenue Recognition—Multiple-Element Arrangements, for separating consideration in multiple-deliverable arrangements. This guidance establishes a selling price hierarchy for determining the selling price of a deliverable, which is based on: (a) vendor-specific objective evidence; (b) third-party evidence; or (c) estimates. This guidance also eliminates the residual method of allocation and requires that arrangement consideration be allocated at the inception of the arrangement to all deliverables using the relative selling price method. In addition, this guidance significantly expands required disclosures related to a vendor’s multiple-deliverable revenue arrangements. ASU 2009-13 is effective prospectively for revenue arrangements entered into or materially modified in fiscal years beginning on or after June 15, 2010, with early adoption permitted. The impact of ASU 2009-13 on the Company’s consolidated financial statements will depend on the nature and terms of its revenue arrangements entered into or materially modified after the adoption date. However, based on the Company’s current customer arrangements, the Company does not believe the adoption of this ASU will have a material impact on its consolidated financial statements.

In March 2010, ASU 2010-17, Revenue Recognition—Milestone Method (Topic 605): Milestone Method of Revenue Recognition—a consensus of the FASB Emerging Issues Task Force, was issued and will amend the accounting for revenue arrangements under which a vendor satisfies its performance obligations to a customer over a period of time, when the deliverable or unit of accounting is not within the scope of other authoritative literature and when the arrangement consideration is contingent upon the achievement of a milestone. The amendment defines a milestone and clarifies whether an entity may recognize consideration earned from the achievement of a milestone in the period in which the milestone is achieved. This amendment is effective for fiscal years beginning on or after June 15, 2010, with early adoption permitted. The amendment may be applied retrospectively to all arrangements or prospectively for milestones achieved after the effective date. The Company does not believe the adoption of this ASU will have a material impact on its consolidated financial statements.

Note 4 – Stock-Based Compensation

Under the Company’s stock-based compensation plan, the 2005 Stock Incentive Plan (the “2005 Plan”), equity awards may be granted to officers, directors, employees, consultants and advisors to the Company and any present or future subsidiary. The 2005 Plan currently authorizes the grant of equity awards for up to 11,312,192 shares of Common Stock, which included, at the time of approval of the 2005 Plan, a maximum 5,746,468 shares of Common Stock subject to stock options outstanding under the Company’s 1995 Stock Option Plan (the “1995 Plan”) that may revert to and become issuable under the 2005 Plan, if such options should expire or otherwise terminate unexercised. The term of the Company’s previous stock-based compensation plan, the 1995 Plan, has expired. Outstanding stock options remain in existence in accordance with their terms; however, no new awards will be made under the 1995 Plan. The Company’s 1995 Director Stock Option Plan (the “1995 Director Plan”) has expired and no stock options under this plan remain outstanding at March 31, 2010.

The Company recorded stock-based compensation expense in the consolidated statements of operations as follows (in thousands):

	Three Months Ended March 31,	
	2010	2009
Research and development	\$ (69)	\$ 179
General and administrative	153	318

Total stock-based compensation expenses	\$	84	\$	497
---	----	----	----	-----

7

During the three months ended March 31, 2010, the stock-based compensation benefit of (\$0.1) million is due to the reversal of previously recognized expense for unvested stock options that were cancelled due to employees leaving the Company.

Stock Options Awards

The following is a summary of option activity under the 2005 Plan, the 1995 Plan and the 1995 Director Plan for the three months ended March 31, 2010:

	2005 Stock Incentive Plan		1995 Stock Option Plan		1995 Director Stock Option Plan	
	Stock Options	Weighted-Average Exercise Price	Stock Options	Weighted-Average Exercise Price	Stock Options	Weighted-Average Exercise Price
Outstanding at January 1, 2010	4,878,675	\$ 2.38	1,086,319	\$ 5.72	30,000	\$ 5.63
Granted	1,018,250	\$ 2.36	—	\$ —	—	\$ —
Exercised	(35,750)	\$ 1.78	—	\$ —	—	\$ —
Canceled	(468,383)	\$ 2.45	(386,469)	\$ 7.25	(30,000)	\$ 5.63
Outstanding at March 31, 2010	5,392,792	\$ 2.37	699,850	\$ 4.90	—	\$ —
Shares exercisable at March 31, 2010	2,836,534	\$ 2.24	699,850	\$ 4.90	—	\$ —
Shares available for grant at March 31, 2010	2,590,849					

The fair value of the stock options granted for the three months ended March 31, 2010 and 2009 was estimated at the date of grant using the Black-Scholes option-pricing model with the following assumptions:

	Three Months Ended March 31,	
	2010	2009
Weighted average fair value of options granted	\$1.62	\$0.39
Risk-free interest rate	1.46%-2.89%	1.56%-2.27%
Dividend yield	0%	0%
Volatility	99.53%-107.83%	85.68%-95.08%
Expected life (in years)	3.11-6.26	4.00-6.29
Expected forfeiture rate	21.07%	21.96%

The aggregate intrinsic value and weighted-average remaining contractual term of stock options outstanding as of March 31, 2010 was approximately \$2.3 million and 6.6 years, respectively. The aggregate intrinsic value and weighted-average remaining contractual term of stock options exercisable as of March 31, 2010 was approximately \$1.6 million and 5.0 years, respectively. The aggregate intrinsic value represents the total intrinsic value (the difference between the Company's closing stock price on the last trading day of the period and the exercise price, multiplied by the number of in-the-money options) that would have been received by the option holders had all option holders exercised their options on March 31, 2010. This amount is subject to change based on changes to the fair value of the Company's common stock. The aggregate intrinsic value of options exercised for the three months ended March 31, 2010 and 2009 was \$0.1 million and \$38,573, respectively.

Restricted Stock Awards

Under the 2005 Plan, the Company has granted restricted stock awards subject to certain performance- or time-based vesting conditions which, if not met, would result in forfeiture of the shares and reversal of any previously recognized related stock-based compensation expense.

8

The following is a summary of restricted stock awards activity for the three months ended March 31, 2010:

	Number of Shares	Per Share Weighted- Average Grant-Date Fair Value
Outstanding at January 1, 2010	90,000	\$ 3.04
Restricted stock granted	—	\$ —
Restricted stock vested	(28,333)	\$ 2.77
Restricted stock forfeited	(11,667)	\$ 2.77
Outstanding at March 31, 2010	50,000	\$ 3.26

As of March 31, 2010, there was approximately \$2.8 million of total unrecognized compensation expense (net of estimated forfeitures) related to unvested options and restricted stock awards. This unrecognized compensation expense is expected to be recognized over a weighted-average period of 1.8 years. This estimate does not include the impact of other possible stock-based awards that may be made during future periods.

Note 5 – At the Market Sales Agreement

On March 15, 2010, the Company terminated its previous At the Market Sales Agreements entered into in 2009 with Wm Smith & Co. and entered into a new sales agreement with McNicoll, Lewis & Vlak LLC, as sales agent, under which the Company may sell an aggregate of \$50 million in gross proceeds of its Common Stock. The Company's Board of Directors has authorized the sale of up to 25 million shares of the Company's Common Stock pursuant to this agreement. The shares of Common Stock are being offered pursuant to a shelf registration statement filed with the SEC.

Note 6 – Related Party Transactions

Mr. Lambert, the Company's former Executive Chairman of the Board of Directors, had a consulting agreement with the Company, pursuant to which he assisted the Company with issues regarding the development and commercialization of its vaccine product candidates and assisted with business development predominantly in the international markets. During the three months ended March 31, 2010, the Company paid Mr. Lambert \$41,398 for these services. On March 8, 2010, Mr. Lambert's consulting agreement expired by its original terms.

Item 2. Management’s Discussion and Analysis of Financial Condition and Results of Operations

Certain statements contained herein or as may otherwise be incorporated by reference herein constitute “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements include, but are not limited to, statements relating to future funding requirements and capital raising activity, financial or business performance, conditions or strategies and other financial and business matters, including expectations regarding operating expenses, use of cash, and clinical developments and anticipated milestones, including a Department of Health and Human Services (HHS), Biomedical Advanced Research and Development Authority (BARDA) contract and seeking approval in Mexico, and include words such as “expect(s)”, “intends”, “plans”, “seeks”, “estimates”, “could”, “should”, “feel(s)”, “believe(s)”, “will”, “would”, “may”, “can”, “anticipate”, and similar expressions or the negative of these terms, are based upon management’s current expectations and beliefs. Such forward-looking statements are not guarantees of future performance, 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.

Factors that may cause actual results to differ materially from the results discussed in the forward-looking statements or historical experience include, among other things, the following:

- our ability to progress any product candidates into pre-clinical studies or clinical trials;
- the scope, initiation, rate and progress of our pre-clinical studies and clinical trials and other research and development activities;
- clinical trial results;
- even with positive data from pre-clinical studies or clinical trials, the product candidate may not prove to be safe and efficacious;
- regulatory approval is needed before any vaccines can be sold in or outside the United States and, to date, no governmental authority has approved any of our vaccine candidates for sale;
- influenza is seasonal in nature, and if approval or commercial launch after approval is not timely in relation to the influenza season, we may not be able to manufacture or sell our influenza vaccines on terms favorable to us until the next influenza season, if at all;
 - we have not manufactured any of our vaccine candidates at a commercial level;
 - we utilize a unique manufacturing process and the scale-up of that process may prove difficult and/or costly;
 - our dependence on third parties to manufacture and distribute our vaccines;
 - risks associated with conducting business outside of the United States;
- the cost of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights;
- competition for clinical resources and patient enrollment from drug candidates in development by other companies with greater resources and visibility;
- our ability to enter into future collaborations with industry partners and the terms, timing and success of any such collaboration;
- our ability to obtain adequate financing in the future through product licensing, co-promotional arrangements, public or private equity or debt financing or otherwise;
 - the inability to win any government grants, including BARDA, in a timely manner or at all; and
 - other factors referenced herein.

The Company assumes no obligation to update any such forward-looking statements, except as specifically required by law.

Overview

Novavax, Inc., a Delaware corporation (“Novavax,” the “Company,” “we,” or “us”), was incorporated in 1987, and is a clinical-stage biopharmaceutical company focused on developing novel, highly potent recombinant vaccines. These vaccines leverage our virus-like-particle (VLP) platform technology coupled with a unique disposable production technology.

VLPs are genetically engineered three-dimensional nanostructures which incorporate immunologically important lipids and recombinant proteins. Our VLPs resemble the virus, but lack the genetic material to replicate the virus and our proprietary production technology uses insect cells rather than chicken eggs or mammalian cells. Our current product targets include vaccines against pandemic influenza (including the H5N1 and H1N1 pandemic strains), seasonal influenza, Respiratory Syncytial Virus (RSV) and Varicella Zoster Virus (VZV), which causes shingles.

We are conducting a two-stage clinical trial of our 2009 H1N1 influenza VLP vaccine in Mexico in collaboration with Laboratorio Avi-mex S.A. de C.V. and GE Healthcare. The randomized blinded, placebo-controlled clinical trial will evaluate the safety and immunogenicity of our 2009 H1N1 influenza VLP vaccine in healthy adults. We completed enrollment of the first stage and reported positive results on the vaccine's safety and immunogenicity in the first 1,000 subjects. Due to the favorable results from the first stage, we initiated the second stage of the trial to evaluate the safety of the vaccine in a larger cohort and completed enrollment of more than 3,500 subjects. The primary safety results from the second stage of the trial are expected later in 2010. All of the results will be used to pursue possible registration of our 2009 H1N1 influenza VLP vaccine in the country of Mexico. These data are also expected to support development of our pandemic and seasonal influenza VLP vaccines in other countries, including the United States.

In March 2010, we released final results of the Phase II trial in healthy adults immunized with our trivalent seasonal influenza VLP vaccine. The results showed the vaccine was well-tolerated and immunogenic. In November 2009, we completed enrollment of a Phase II trial of our trivalent seasonal influenza VLP vaccine in older adults (60 years or higher in age) in a dose-ranging study comparing Novavax's trivalent seasonal influenza VLP vaccine with a commercially available inactivated trivalent influenza vaccine (TIV). In April 2010, we reported our vaccine was both safe and immunogenic against the 2009-2010 seasonal influenza virus strains in adults 60 years or higher in age.

We have also developed vaccine candidates for both RSV and VZV. We completed a pre-clinical safety and efficacy study of our RSV vaccine in cotton rats; the results of which will be used to support an Investigational New Drug (IND) application, which we expect to file in 2010. Our VZV vaccine candidate induced antibody and T-cell responses and we plan on moving forward with further pre-clinical development in 2010.

HHS has determined our BARDA proposal to provide recombinant influenza vaccines and manufacturing capabilities for pandemic preparedness is in the competitive range for award of an advanced development contract. We submitted our proposal in September 2009 in response to United States Government RFP solicitation number HHS BARDA-09-32 for the advanced development of recombinant influenza vaccines in a U.S.-based manufacturing facility.

Our vaccine product candidates currently under development 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 our research and development efforts will be successful or that any potential product candidates will prove to be safe and effective in clinical trials. Even if developed, these vaccine product candidates may not receive regulatory approval or be successfully introduced and marketed at prices that would permit us to operate profitably. The commercial launch of any vaccine product candidate is subject to certain risks including, but not limited to, manufacturing scale-up and market acceptance. No assurance can be given that we can generate sufficient product revenue to become profitable or generate positive cash flow from operations at all or on a sustained basis. We continue to fund our operations through the sales of our Common Stock. We terminated our previous At the Market Sales Agreements entered into in 2009 with Wm Smith & Co. and entered into a new sales agreement with McNicoll, Lewis & Vlak LLC, as sales agent, under which we may sell an aggregate of \$50 million in gross proceeds of our Common Stock. Our Board of Directors has authorized the sale of up to 25 million shares of our Common Stock pursuant to this agreement.

Recent Accounting Pronouncements Not Yet Adopted

In September 2009, ASU 2009-13, Revenue Recognition (Topic 605)—Multiple-Deliverable Revenue Arrangements, was issued and will change the accounting for multiple-deliverable arrangements to enable vendors to account for products or services (deliverables) separately rather than as a combined unit. Specifically, this guidance amends the criteria in Subtopic 605-25, Revenue Recognition—Multiple-Element Arrangements, for separating consideration in multiple-deliverable arrangements. This guidance establishes a selling price hierarchy for determining the selling price of a deliverable, which is based on: (a) vendor-specific objective evidence; (b) third-party evidence; or (c) estimates. This guidance also eliminates the residual method of allocation and requires that arrangement consideration be allocated at the inception of the arrangement to all deliverables using the relative selling price method. In addition, this guidance significantly expands required disclosures related to a vendor's multiple-deliverable revenue arrangements. ASU 2009-13 is effective prospectively for revenue arrangements entered into or materially modified in fiscal years beginning on or after June 15, 2010 with early adoption permitted. The impact of ASU 2009-13 on our consolidated financial statements will depend on the nature and terms of our revenue arrangements entered into or materially modified after the adoption date. However, based on our current customer arrangements, we do not believe the adoption of this ASU will have a material impact on our consolidated financial statements.

In March 2010, ASU 2010-17, Revenue Recognition—Milestone Method (Topic 605): Milestone Method of Revenue Recognition—a consensus of the FASB Emerging Issues Task Force, was issued and will amend the accounting for revenue arrangements under which a vendor satisfies its performance obligations to a customer over a period of time, when the deliverable or unit of accounting is not within the scope of other authoritative literature and when the arrangement consideration is contingent upon the achievement of a milestone. The amendment defines a milestone and clarifies whether an entity may recognize consideration earned from the achievement of a milestone in the period in which the milestone is achieved. This amendment is effective for fiscal years beginning on or after June 15, 2010, with early adoption permitted. The amendment may be applied retrospectively to all arrangements or prospectively for milestones achieved after the effective date. We do not believe the adoption of this ASU will have a material impact on its consolidated financial statements.

Results of Operations for the Three Months Ended March 31, 2010 and 2009 (amounts in tables are presented in thousands, except per share information)

The following is a discussion of the historical consolidated financial condition and results of operations of the Company and its wholly owned subsidiary and should be read in conjunction with the consolidated financial statements and notes thereto set forth in this Quarterly Report on Form 10-Q. Additional information concerning factors that could cause actual results to differ materially from those in our forward-looking statements is contained from time to time in our SEC filings.

Revenue:

	Three Months Ended March 31		
	2010	2009	Change 2009 to 2010
Revenue:			
Total revenue	\$ 110	\$ 21	\$ 89

Revenue for the three months ended March 31, 2010 was \$0.1 million as compared to less than \$0.1 million for the same period in 2009. Revenue is comprised of services performed under contracts with United States government

agencies.

12

Operating Expenses:

	Three Months Ended March 31		Change 2009 to 2010
	2010	2009	
Operating Expenses:			
Research and development	\$ 9,029	\$ 4,266	\$ 4,763
General and administrative	2,535	2,892	(357)
Total operating expenses	\$ 11,564	\$ 7,158	\$ 4,406

Research and Development Expenses

Research and development expenses increased to \$9.0 million for three months ended March 31, 2010 from \$4.3 million for the same period in 2009, an increase of \$4.7 million, or 112%, primarily due to higher research and development spending to support our clinical trials related to our H1N1 and seasonal influenza product candidates. The increase is primarily a result of increased outside-testing costs (including outsourced clinical trial costs, sponsored research and consulting agreements) of \$4.0 million.

General and Administrative Expenses

General and administrative expenses decreased to \$2.5 million for the three months ended March 31, 2010 from \$2.9 million for the same period in 2009, a decrease of \$0.4 million, or 12%, primarily due to lower professional service fees.

Other Income (Expense):

	Three Months Ended March 31		Change 2009 to 2010
	2010	2009	
Other Income (Expense):			
Interest income	\$ 44	\$ 104	\$ (60)
Interest expense	(2)	(437)	435
Impairment of short-term investments	—	(879)	879
Total other income (expense)	\$ 42	\$ (1,212)	\$ 1,254

We had total other income of less than \$0.1 million for the three months ended March 31, 2010 compared to total other expense of \$1.2 million for the same period in 2009, a change of \$1.3 million. Interest expense decreased \$0.4 million to less than \$0.1 million for the three months ended March 31, 2010 from \$0.4 million for the same period in 2009 as a result of the payment of our convertible notes in 2009. In the three months ended March 31, 2009, we recorded an impairment of \$0.9 million relating to our auction rate securities.

Net Loss:

Three Months Ended
March 31

Edgar Filing: NOVAVAX INC - Form 10-Q

	2010	2009	Change 2009 to 2010
Net Loss:			
Net loss	\$ (11,412)	\$ (8,349)	\$ (3,063)
Net loss per share	\$ (0.11)	\$ (0.12)	\$ 0.01
Weighted shares outstanding	100,188	68,692	31,496

Net loss for the three months ended March 31, 2010 was \$11.4 million, or \$0.11 per share, as compared to \$8.3 million, or \$0.12 per share, for the same period in 2009, an increased net loss of \$3.1 million. The increased net loss was primarily due to higher research and development spending to support our clinical trials related to our H1N1 and seasonal influenza product candidates, partially offset by reduced total other income (expense) in the three months ended March 31, 2010.

The increase in weighted shares outstanding for the three months ended March 31, 2010 is primarily a result of sales of our Common Stock in the aggregate of 27.9 million shares through direct stock offerings, an underwritten public offering and our previous At the Market Sales Agreement in 2009.

Liquidity Matters and Capital Resources

Our future capital requirements depend on numerous factors including, but not limited to, the commitments and progress of our research and development programs, the progress of pre-clinical and clinical testing, the time and costs involved in obtaining regulatory approvals, the costs of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights and manufacturing costs. We plan to continue to have multiple vaccine product candidates in various stages of development and we believe our research and development, as well as general and administrative expenses and capital requirements will fluctuate depending upon the timing of certain events, such as the scope, initiation, rate and progress of our pre-clinical studies and clinical trials and other research and development activities.

As of March 31, 2010, we had \$14.6 million in cash and cash equivalents and \$18.3 million in short-term investments as compared to \$38.8 million and \$4.2 million, respectively, at December 31, 2009. The following table summarizes cash flows for the three months ended March 31, 2010 and 2009 (in thousands):

	Three Months Ended		
	March 31		Change 2009 to 2010
	2010	2009	
Summary of Cash Flows:			
Net cash (used in) provided by:			
Operating activities	\$ (9,380)	\$ (6,727)	\$ (2,653)
Investing activities	(14,840)	68	(14,908)
Financing activities	38	(650)	688
Net decrease in cash and cash equivalents	(24,182)	(7,309)	(16,873)
Cash and cash equivalents at beginning of period	38,757	26,938	11,819
Cash and cash equivalents at end of period	\$ 14,575	\$ 19,629	\$ (5,054)

Net cash used in operating activities increased to \$9.4 million for the three months ended March 31, 2010 from \$6.7 million for the same period in 2009, primarily due to our increased loss, resulting primarily from our higher research and development spending to support our clinical trials related to our H1N1 and seasonal influenza product candidates.

During the three months ended March 31, 2010 and 2009, our investing activities consisted primarily of purchases of short-term investments and capital expenditures. Capital expenditures for the three months ended March 31, 2010 and 2009 were \$0.7 million and \$0.1 million, respectively. The increase in capital expenditures was primarily due to the purchase of laboratory equipment relating to our manufacturing scale-up. We purchased short-term investments in the three months ended March 31, 2010 to increase our rate of return on our funds. For 2010, as compared to 2009, we expect our level of capital expenditures to increase modestly.

The increase in our financing activities is primarily due to the payment of our convertible notes in 2009.

We have entered into agreements with outside clinical research organization providers to support our clinical development. As of March 31, 2010, \$7.9 million remains unpaid on certain of these agreements in the event our outside providers complete their services in 2010. However, under the terms of the agreements, we have the option to terminate, but we would be obligated to pay the provider(s) for all costs incurred through the effective date of termination.

We have licensed certain rights from Wyeth Holdings Corporation (Wyeth) and the University of Massachusetts Medical School (UMMS). The Wyeth license, which provides for an upfront payment, annual license fees, milestone payments and royalties on any product sales, is a non-exclusive, worldwide license to a family of patent applications covering VLP technology for use in human vaccines in certain fields of use. Payments under the agreement to Wyeth from 2007 through March 31, 2010 aggregated \$5.1 million. Based on the clinical and commercial milestones, which could possibly occur through early 2011, we would make a milestone payment to Wyeth of \$4 million in the next twelve months. However, it is difficult to predict at this time whether such milestones will be achieved through early 2011. The UMMS license, which provides for milestone payments and royalties on product sales, is an exclusive worldwide license of VLP technology to develop VLP vaccines for the prevention of any viral diseases in humans. As of March 31, 2010, our payments made to UMMS in the aggregate are not material. Also, we believe that all payments under the UMMS agreement will not be material in the next twelve months.

Based on our cash, cash equivalents and short-term investment balances as of March 31, 2010, anticipated proceeds from the sale of our Common Stock under the At the Market Sales Agreement and our current business operations, we believe we will have adequate capital resources available to operate at planned levels for at least the next twelve months. Additional capital will be required in the future to develop our product candidates through clinical development, manufacturing and commercialization. We will seek additional capital through further public or private equity offerings, debt financing, additional strategic alliance and licensing arrangements, non-dilutive government contracts, collaborative arrangements, or some combination of these financing alternatives. Any capital raised by an equity offering will likely be substantially dilutive to the existing stockholders and any licensing or development arrangement may require us to give up rights to a product or technology at less than its full potential value. Other than our At the Market Sales Agreement with McNicoll, Lewis & Vlak LLC, we have not secured any additional commitments for new financing nor can we provide any assurance that new financing will be available on commercially acceptable terms, if at all. If we are unable to obtain additional capital, we will assess our capital resources and will likely be required to delay, reduce the scope of, or eliminate one or more of our product research and development programs, downsize our organization, or reduce our general and administrative infrastructure.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

The primary objective of our investment activities is to preserve our capital until it is required to fund operations while at the same time maximizing the income we receive from our investments without significantly increasing risk. As of March 31, 2010, we had cash and cash equivalents of \$14.6 million, short-term investments of \$18.3 million and working capital of \$24.6 million.

Our exposure to market risk is confined to our investment portfolio. As of March 31, 2010, our short-term investments are classified as available-for-sale. We do not believe that a change in the market rates of interest would have any significant impact on the realizable value of our investment portfolio. Changes in interest rates may affect the investment income we earn on our investments and, therefore, could impact our cash flows and results of operations.

Short-term investments at March 31, 2010 consist of investments in commercial paper, corporate notes and three auction rate securities. We had previously invested in auction rate securities for short periods of time as part of our cash management program. The auction rate securities have a par value of \$5.1 million and a fair value of \$4.1 million. In 2009, we recorded an other-than-temporary impairment charge of \$1.3 million related to these securities,

which was partially offset by realized gains of \$0.8 million relating to redemptions of several auction rate securities. At March 31, 2010, we have \$0.8 million in unrealized gains on the auction rate securities in other comprehensive income on the consolidated balance sheet. These investments are classified within current assets because we may need to liquidate these securities within the next year to fund our ongoing operations.

Interest and dividend income is recorded when earned and included in interest income. Premiums and discounts, if any, on short-term investments are amortized or accreted to maturity and included in interest income. The specific identification method is used in computing realized gains and losses on sale of our securities.

We are headquartered in the United States where we conduct the vast majority of our business activities. Accordingly, we have not had any material exposure to foreign currency rate fluctuations.

We do not have material debt and, as such, do not believe that we are exposed to any material interest rate risk as a result of our borrowing activities.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Our management, with the assistance of our Chief Executive Officer and Chief Financial Officer, have reviewed and evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended) as of March 31, 2010. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Our disclosure controls and procedures are designed to provide reasonable assurance of achieving their control objectives. Based on the evaluation of our disclosure controls and procedures as of March 31, 2010, our Chief Executive Officer and Chief Financial Officer concluded that, as of such date, our disclosure controls and procedures were effective.

Changes in Internal Control over Financial Reporting

Our management, including our Chief Executive Officer and Chief Financial Officer, has evaluated any changes in our internal control over financial reporting that occurred during the first quarter of 2010, and has concluded that there was no change that occurred during the first quarter of 2010 that materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings

In March 2010, we instituted legal proceedings against Mr. Mitch Kelly in the state of New York and Dr. Denis O'Donnell in the Commonwealth of Massachusetts for collection of their respective indebtedness due to the Company. Mr. Kelly and Dr. O'Donnell are former directors of the Company that have outstanding notes due to the Company in the aggregate principal amount of \$1,572,000. Both notes are currently in default.

Item 1A. Risk Factors

There are no material changes to the Company's risk factors as described in Item 1A of the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2009, as filed with the SEC, other than as mentioned below.

We may not be awarded a contract with HHS BARDA.

Although we have been notified by HHS BARDA that our response to United States Government RFP solicitation number HHS BARDA-09-32 for a contract award for the advanced development of recombinant influenza vaccines is within the competitive range for award consideration, there can be no assurance that we will win a contract with HHS BARDA. A contract with HHS BARDA would also be attractive to our competitors, so we anticipate there to be significant competition in the competitive range for this contract, potentially from companies that have more experience, capital and human resources and overall capabilities than us. In addition, HHS BARDA may elect to limit a contract or to not award any contract to us for a number of potential reasons including, but not limited to: concerns resulting from unsatisfactory on-site inspections or subsequent technical or business discussions; safety or efficacy issues not seen to date may be encountered before HHS BARDA makes its decision; we have not yet manufactured, or relied on third parties to manufacture, any vaccines at a commercial scale; and HHS BARDA may elect to contract with multiple companies that may or may not include us, and even if we were included in a contract, the amount of the contract could be comparatively smaller than we currently anticipated.

Item 6. Exhibits

Exhibits marked with a single asterisk (*) are filed herewith.

Exhibits marked with a double plus sign (††) refer to management contracts, compensatory plans or arrangements.

- 10.11†† Severance Agreement of James Robinson dated February 1, 2010 (Incorporated by reference to Exhibit 10.11 to the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2009, filed March 16, 2010)
- 10.19†† Form of Indemnity Agreement, entered into between the Company and its directors and officers (Incorporated by reference to Exhibit 10.19 to the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2009, filed March 16, 2010)
- 10.38 At Market Issuance Sales Agreement, dated March 15, 2010, by and between Novavax, Inc. and McNicoll, Lewis and Vlak, LLC (Incorporated by reference to Exhibit 10.38 to the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2009, filed March 16, 2010)
- 10.47*†† Severance Agreement of Raymond J. Hage dated April 7, 2010
- 31.1* Certification of Chief Executive Officer pursuant to Rule 13a-14(a) or 15d-14(e) of the Securities Exchange Act
- 31.2* Certification of Chief Financial Officer pursuant to Rule 13a-14(a) or 15d-14(e) of the Securities Exchange Act
- 32.1* Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
- 32.2* Certification of Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

NOVAVAX, INC.

Date: May 10, 2010

By: /s/ Rahul Singhvi
President and Chief Executive Officer
and Director
(Principal Executive Officer)

Date: May 10, 2010

By: /s/ Frederick W. Driscoll
Vice President, Chief Financial Officer
and Treasurer
(Principal Financial and Accounting Officer)