

NOVAVAX INC  
Form 10-Q  
November 08, 2011

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 September 30, 2011

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 114,971,796 as of October 31, 2011.

---

NOVAVAX, INC.  
TABLE OF CONTENTS

	Page No.
<b>PART I. FINANCIAL INFORMATION</b>	
<b>Item 1.</b>	<b>Financial Statements</b>
	1
	Balance Sheets as of September 30, 2011 (unaudited) and December 31, 2010
	2
	Statements of Operations for the three and nine months ended September 30, 2011 and 2010 (unaudited)
	3
	Statements of Cash Flows for the nine months ended September 30, 2011 and 2010 (unaudited)
	4
	Notes to the Financial Statements (unaudited)
<b>Item 2.</b>	<b>Management's Discussion and Analysis of Financial Condition and Results of Operations</b>
	12
<b>Item 3.</b>	<b>Quantitative and Qualitative Disclosures about Market Risk</b>
	23
<b>Item 4.</b>	<b>Controls and Procedures</b>
	24
<b>PART II. OTHER INFORMATION</b>	
<b>Item 1.</b>	<b>Legal Proceedings</b>
	24
<b>Item 1A.</b>	<b>Risk Factors</b>
	24
<b>Item 5.</b>	<b>Other Information</b>
	24
<b>Item 6.</b>	<b>Exhibits</b>
	25
<b>SIGNATURES</b>	<b>26</b>

## PART I. FINANCIAL INFORMATION

## Item 1. Financial Statements

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

	September 30, 2011 (unaudited)	December 31, 2010
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 14,318	\$ 8,061
Short-term investments available-for-sale	5,286	23,615
Accounts receivables	17	54
Unbilled receivables	3,848	—
Prepaid expenses	2,392	1,342
Other current assets	392	265
Total current assets	26,253	33,337
Property and equipment, net	7,531	8,206
Goodwill	33,141	33,141
Other non-current assets	160	160
Total assets	\$ 67,085	\$ 74,844
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 2,395	\$ 3,572
Accrued expenses and other current liabilities	3,931	6,273
Current portion of notes payable	40	80
Deferred rent	375	341
Total current liabilities	6,741	10,266
Warrant liability	869	2,842
Deferred revenue	2,500	—
Non-current portion of notes payable	300	320
Deferred rent	2,078	2,366
Total liabilities	12,488	15,794
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 115,387,768 shares issued and 114,932,338 shares outstanding at September 30, 2011 and 111,492,014 shares issued and 111,036,584 shares outstanding at December 31, 2010	1,154	1,115
Additional paid-in capital	380,931	371,477
Notes receivable from former directors	—	(1,572 )
Accumulated deficit	(325,951 )	(310,292 )
Treasury stock, 455,430 shares, cost basis	(2,450 )	(2,450 )
Accumulated other comprehensive income	913	772

Total stockholders' equity	54,597	59,050
Total liabilities and stockholders' equity	\$ 67,085	\$ 74,844

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

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

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2011	2010	2011	2010
Revenue	\$ 5,008	\$ 175	\$ 8,843	\$ 292
Operating expenses:				
Research and development	6,239	7,870	17,237	23,226
General and administrative	2,737	2,844	8,926	8,528
Total operating expenses	8,976	10,714	26,163	31,754
Loss from operations	(3,968 )	(10,539 )	(17,320 )	(31,462)
Other income (expense):				
Interest income	22	50	106	138
Interest expense	(2 )	(2 )	(6 )	(6)
Change in fair value of warrant liability	736	133	1,973	1,771
Loss from operations before income tax	(3,212 )	(10,358 )	(15,247 )	(29,559)
Income tax (benefit) expense		(136 )	412	(136)
Net loss	\$ (3,212 )	\$ (10,222 )	\$ (15,659 )	\$ (29,423)
Basic and diluted net loss per share	\$ (0.03 )	\$ (0.10 )	\$ (0.14 )	\$ (0.29)
Basic and diluted weighted average number of common shares outstanding	115,107	107,092	113,053	102,683

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

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

	For the Nine Months Ended September 30,	
	2011	2010
<b>Operating Activities:</b>		
Net loss	\$(15,659 )	\$(29,423 )
Reconciliation of net loss to net cash used in operating activities:		
Change in fair value of warrant liability	(1,973 )	(1,771 )
Depreciation and amortization	1,197	991
Amortization of net premiums on short-term investments	317	134
Impairment of property and equipment	60	127
Loss of disposal of property and equipment	—	32
Deferred rent	(254 )	(206 )
Non-cash stock-based compensation	1,677	1,141
Changes in operating assets and liabilities:		
Accounts receivables	37	(341 )
Unbilled receivables	(3,848 )	—
Prepaid expenses and other current assets	(1,127 )	947
Accounts payable and accrued expenses	(3,687 )	1,468
Deferred revenue	2,500	(143 )
Net cash used in operating activities	(20,760 )	(27,044 )
<b>Investing Activities:</b>		
Capital expenditures	(414 )	(1,424 )
Proceeds from maturities of short-term investments	20,235	11,000
Purchases of short-term investments	(2,082 )	(27,545 )
Net cash provided by (used in) by investing activities	17,739	(17,969 )
<b>Financing Activities:</b>		
Principal payments of notes payable	(60 )	(66 )
Net proceeds from sales of common stock, net of offering costs of \$0.2 million and \$0.4 million, respectively	9,182	22,114
Proceeds from the exercise of stock options	156	423
Net cash provided by financing activities	9,278	22,471
Net increase (decrease) in cash and cash equivalents	6,257	(22,542 )
Cash and cash equivalents at beginning of period	8,061	38,757
Cash and cash equivalents at end of period	\$14,318	\$16,215
<b>Supplemental disclosure of non-cash activities:</b>		
Equipment purchases included in accounts payable	\$168	\$128
Settlement of notes receivable (See Note 9)	\$1,522	\$—

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





NOVAVAX, INC.  
NOTES TO FINANCIAL STATEMENTS  
September 30, 2011  
(unaudited)

Note 1 – Organization

Novavax, Inc. (the “Company”), is a clinical-stage biopharmaceutical company focused on developing novel and effective recombinant vaccines. These vaccines leverage the Company’s platform technology coupled with a single-use bioprocessing production system to develop virus-like particle (“VLP”) vaccines, as well as recombinant nanoparticle vaccines. VLPs are genetically engineered three-dimensional nanostructures that incorporate immunologically important recombinant proteins. The Company’s VLPs resemble the virus they were engineered to mimic, but lack the genetic material to replicate the virus and its single-use bioprocessing production technology uses insect cells rather than chicken eggs or mammalian cells. Similarly, recombinant nanoparticle vaccines are smaller in size than traditional VLPs, but the protein-based structures mimic key portions of the virus and their native configurations that are critical for induction of effective immunogenic responses. The Company’s current product targets include VLP vaccines against seasonal and pandemic (including H5N1) influenza and a recombinant nanoparticle vaccine against Respiratory Syncytial Virus (“RSV”).

In 2009, the Company formed a joint venture (the “JV”) with Cadila Pharmaceuticals Limited (“Cadila”) named CPL Biologicals Private Limited 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 September 30, 2011, the Company had cash and cash equivalents of \$14.3 million and short-term investments with a fair value of \$5.3 million.

The Company’s vaccine 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. The Company’s research and development efforts may not be successful and any potential vaccine candidates may not prove to be safe and effective in clinical trials. Even if developed, these vaccine candidates may not 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 is subject to significant risks including, but not limited to, manufacturing scale-up and market acceptance.

Based on the Company’s cash and cash equivalents and short-term investments balances as of September 30, 2011, anticipated revenue under the contract with the Department of Health and Human Services, Biomedical Advanced Research and Development Authority (“HHS BARDA”) that was awarded in February 2011, possible proceeds from sales of the Company’s common stock under its At Market Issuance Sales Agreement 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 vaccine candidates through clinical development, manufacturing and commercialization. The Company’s ability to generate revenue under the HHS BARDA contract is subject to its performance under the contract; its ability to raise funds under its At Market Issuance Sales Agreement is subject to both its business performance and market conditions. Further, the Company may seek additional capital through public or private equity offerings, debt financing, strategic alliance and licensing arrangements, 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 Market Issuance Sales Agreement, the Company has not secured any additional commitments for new financing, nor can the Company provide any assurance that financing will be available on commercially acceptable terms, if at all. If the Company is unable to perform under the HHS BARDA contract or 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 research and development programs, and/or downsize the organization, including its general and administrative infrastructure.

### Note 3 – Summary of Significant Accounting Policies

#### Basis of Presentation

The accompanying unaudited 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 balance sheet as of September 30, 2011, statements of operations for the three and nine months ended September 30, 2011 and 2010 and the statements of cash flows for the nine months ended September 30, 2011 and 2010 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”).

Results for any interim period are not necessarily indicative of results for any future interim period or for the entire year. The accompanying unaudited financial statements should be read in conjunction with the financial statements and notes thereto included in the Company’s Annual Report on Form 10-K for the year ended December 31, 2010.

#### Use of Estimates

The preparation of the 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 these estimates.

#### Fair Value Measurements

The Company adopted Accounting Standards Codification (“ASC”) Topic 820, Fair Value Measurements and Disclosures, for financial and non-financial assets and liabilities.

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 at fair market value on a recurring basis as of September 30, 2011 and December 31, 2010 are summarized below (in thousands):

	Fair Value at September 30, 2011			Fair Value at December 31, 2010		
	Level 1	Level 2	Level 3	Level 1	Level 2	Level 3
<b>Assets</b>						
Corporate debt and auction rate securities	\$—	\$5,286	\$—	\$—	\$23,615	\$—
<b>Total Short-term investments</b>	<b>\$—</b>	<b>\$5,286</b>	<b>\$—</b>	<b>\$—</b>	<b>\$23,615</b>	<b>\$—</b>
<b>Liabilities</b>						
Warrant liability	\$—	\$—	\$869	\$—	\$—	\$2,842

The following table summarizes the activity of Level 3 inputs measured on a recurring basis as of September 30, 2011 (in thousands):

	Fair Value Measurements of Warrants Using Significant Unobservable Inputs (Level 3)
Balance at December 31, 2010	\$ 2,842
Change in fair value of Warrant liability	(1,973 )
Balance at September 30, 2011	\$ 869

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

#### Short-Term Investments

Short-term investments at September 30, 2011 consist of investments in commercial paper and three auction rate securities. All marketable securities had original maturities greater than 90 days, but less than one year. The auction rate securities have a par value of \$5.1 million. 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, if determined to be temporary, on these securities 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 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 September 30, 2011 and December 31, 2010 were comprised of (in thousands):

	September 30, 2011			December 31, 2010			Fair Value
	Amortized	Gross	Gross	Amortized	Gross	Gross	

Edgar Filing: NOVAVAX INC - Form 10-Q

	Cost	Unrealized Gains	Unrealized Losses	Fair Value	Cost	Unrealized Gains	Unrealized Losses	
Auction rate securities	\$ 3,373	\$913	\$ —	\$ 4,286	\$ 3,373	\$773	\$ —	\$ 4,146
Corporate debt securities	1,000	—	—	1,000	19,470	—	(1 )	19,469
<b>Total</b>	<b>\$ 4,373</b>	<b>\$913</b>	<b>\$ —</b>	<b>\$ 5,286</b>	<b>\$ 22,843</b>	<b>\$773</b>	<b>\$ (1 )</b>	<b>\$ 23,615</b>

6

---

### 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 11,119,476 shares and 9,761,587 shares at September 30, 2011 and 2010, respectively, are excluded from the computation, as their effect is antidilutive.

### Comprehensive Income (Loss)

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, including unrealized gains (losses) on the Company's available-for-sale investments, was \$3.2 million and \$10.1 million for the three months ended September 30, 2011 and 2010, respectively. Total comprehensive loss, including unrealized gains (losses) on the Company's available-for-sale investments, was \$15.5 million and \$29.4 million for the nine months ended September 30, 2011 and 2010, respectively.

### Recent Accounting Pronouncements

In January 2010, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) 2010-06, Fair Value Measurements and Disclosures (Topic 820)—Improving Disclosures about Fair Value Measurements, which amends Topic 820 to add new requirements for disclosures about transfers into and out of Levels 1 and 2 and separate disclosures about purchases, sales, issuances and settlements related to Level 3 measurements. ASU 2010-06 also clarifies existing fair value disclosures about the level of disaggregation and about inputs and valuation techniques used to measure fair value. The ASU was effective for the first reporting period beginning after December 15, 2009, except for the requirements to provide the Level 3 activity of purchases, sales, issuances and settlements on a gross basis, which was effective for fiscal years beginning after December 15, 2010, and for interim periods within those fiscal years. Early adoption was permitted. The 2011 adoption for the requirement to provide the Level 3 activity did not have a material impact on the Company's financial statements.

In September 2009, ASU 2009-13, Revenue Recognition (Topic 605)—Multiple-Deliverable Revenue Arrangements, was issued and changed 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 became effective prospectively for multiple deliverable revenue arrangements entered into, or materially modified, on or after January 1, 2011. The adoption of this ASU did not have a material impact on the Company's 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 amended 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. ASU 2010-17 became effective prospectively for milestones achieved within research and development arrangements on or after January 1, 2011. The adoption of this ASU did not have a material

impact on the Company's financial statements.

7

---

In June 2011, the FASB issued ASU 2011-05, Comprehensive Income (Topic 220): Presentation of Comprehensive Income (“ASU 2011-05”). This guidance is intended to increase the prominence of other comprehensive income in financial statements by presenting it in either a single-statement or two-statement approach. This ASU is effective for the Company beginning January 1, 2012. The adoption of ASU 2011-05 will not have a material effect on the Company’s financial statements.

a. In September 2011, the FASB issued ASU 2011-08, Intangibles – Goodwill and Other (Topic 350): Testing Goodwill for Impairment (“ASU 2011-08”), to give both public and nonpublic entities the option to qualitatively determine whether they can bypass the two-step goodwill impairment test. Under the new guidance, if an entity chooses to perform a qualitative assessment and determines that it is more likely than not (a more than 50 percent likelihood) that the fair value of a reporting unit is less than its carrying amount, it would then perform Step 1 of the annual goodwill impairment test in ASC 350-20 and, if necessary, proceed to Step 2. Otherwise, no further evaluation would be necessary. The decision to perform a qualitative assessment is made at the reporting unit level, and an entity with multiple reporting units may utilize a mix of qualitative assessments and quantitative tests among its reporting units. The amended guidance is effective for interim and annual goodwill impairment tests performed for fiscal years beginning after December 15, 2011, although early adoption is permitted. The adoption of ASU 2011-08 will not have a material effect on the Company’s 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, approved in May 2005 and amended in June 2011 by the stockholders of the Company, currently authorizes the grant of equity awards for up to 14,312,192 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 1995 Plan has expired. Outstanding stock options remain in existence in accordance with their terms and no new awards will be made under the 1995 Plan.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2011	2010	2011	2010
Research and development	\$176	\$207	\$449	\$215
General and administrative	366	425	1,228	926
Total stock-based compensation expense	\$542	\$632	\$1,677	\$1,141



## Stock Options Awards

The following is a summary of option activity under the 2005 Plan and the 1995 Plan for the nine months ended September 30, 2011:

	2005 Stock Incentive Plan		1995 Stock Option Plan	
	Stock Options	Weighted-Average Exercise Price	Stock Options	Weighted-Average Exercise Price
Outstanding at January 1, 2011	5,214,794	\$ 2.34	579,850	\$ 4.97
Granted	3,122,400	\$ 2.19	—	\$ —
Exercised	(159,221 )	\$ 0.98	—	\$ —
Canceled	(927,305 )	\$ 2.48	(57,700 )	\$ 8.87
Outstanding at September 30, 2011	7,250,668	\$ 2.29	522,150	\$ 4.56
Shares exercisable at September 30, 2011	3,682,407	\$ 2.38	522,150	\$ 4.56
Shares available for grant at September 30, 2011	3,515,260			

The fair value of stock options granted was estimated at the date of grant using the Black-Scholes option-pricing model with the following assumptions:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2011	2010	2011	2010
Weighted-average fair value of stock options granted	\$0.78	\$1.43	\$1.19	\$1.47
Risk-free interest rate	0.48%-0.68%	1.11%-1.28%	0.48%-1.91%	1.11%-2.89%
Dividend yield	0%	0%	0%	0%
Volatility	75.86%-80.40%	97.79%-105.26%	73.28%-80.48%	97.79%-108.02%
Expected life (in years)	3.49-4.21	3.34-4.47	3.26-4.47	3.06-6.26
Expected forfeiture rate	0-23.15%	21.07%	0-23.15%	21.07%

The aggregate intrinsic value and weighted-average remaining contractual term of stock options outstanding as of September 30, 2011 was approximately \$0.7 million and 6.0 years, respectively. The aggregate intrinsic value and weighted-average remaining contractual term of stock options exercisable as of September 30, 2011 was approximately \$0.6 million and 5.7 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 September 30, 2011. 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 nine months ended September 30, 2011 and 2010 was \$0.2 million and \$0.3 million, respectively.

## Restricted Stock Awards

Under the 2005 Plan, the Company has granted restricted stock awards subject to certain performance-based and 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.

9

---

The following is a summary of restricted stock awards activity for the nine months ended September 30, 2011:

	Number of Shares	Per Share Weighted- Average Grant-Date Fair Value
Outstanding at January 1, 2011	56,666	\$ 2.47
Restricted stock granted	—	\$ —
Restricted stock vested	(53,333 )	\$ 2.30
Restricted stock forfeited	—	\$ —
Outstanding at September 30, 2011	3,333	\$ 5.21

As of September 30, 2011, there was approximately \$2.9 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 1.6 years. This estimate does not include the impact of other possible stock-based awards that may be made during future periods.

#### Note 5 – Warrant Liability

In July 2008, the Company completed a registered direct offering of 6,686,650 units, raising approximately \$17.5 million in net proceeds. Each unit consisted of one share of common stock and a warrant to purchase 0.5 shares of common stock (the “Warrants”) at a price of \$2.68 per unit. The Warrants represent the right to acquire an aggregate of 3,343,325 shares of common stock at an exercise price of \$3.62 per share and are exercisable between January 31, 2009 and July 31, 2013.

During the nine months ended September 30, 2011 and 2010, the Company recorded as other income in its statements of operations a change in fair value of warrant liability of \$2.0 million and \$1.8 million, respectively. As of September 30, 2011, the warrant liability recorded on the balance sheet was \$0.9 million and all Warrants remain outstanding as of that date.

#### Note 6 – At Market Issuance Sales Agreement

In March 2010, the Company entered into a sales agreement, 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. For the nine months ended September 30, 2011, the Company sold 4.0 million shares at an average sales price of \$2.34 per share, resulting in \$9.2 million in net proceeds. Since September 30, 2011 through November 7, 2011, the Company has not sold any additional shares.

#### Note 7 – License Agreement

In February 2011, the Company entered into a License Agreement with LG Life Sciences, Ltd. (“LGLS”) to develop, manufacture and commercialize influenza vaccines using the Company’s proprietary VLP technology exclusively in South Korea and non-exclusively in certain other emerging countries. The term of the License Agreement is expected to terminate in 2027. Payments to the Company under the License Agreement include an upfront payment, milestone payments of up to an aggregate value of \$2.5 million, reimbursements of certain development and product costs and royalty payments between ten and twenty percent from LGLS’s future commercial sales of influenza VLP vaccines.

The upfront payment has been deferred and will be recognized as revenue when certain obligations in the agreement are satisfied. Payments related to milestones deemed substantive under ASU 2010-17 will be recognized upon achievement of such events. Payments for milestones not deemed substantive will be recognized over the remaining term of the research and development period upon achievement of such milestone.

Note 8 – Master Services Agreement

In July 2011, the Company and Cadila extended the term by one year for which services can be provided by Cadila under its master services agreement. Under the recently revised terms, if, by March 2013, the amount of services provided by Cadila under the master services agreement is less than \$7.5 million, the Company will pay Cadila the portion of the shortfall amount that is less than or equal to \$2.0 million and 50% of the portion of the shortfall amount that exceeds \$2.0 million. Through September 30, 2011, the Company has purchased \$0.2 million in services from Cadila pursuant to this agreement.

Note 9 – Notes Receivable from Former Directors

In March 2010, the Company initiated 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 had each defaulted on outstanding notes due to the Company in the aggregate principal amount of \$1,572,000. In 2002, Mr. Kelly and Dr. O'Donnell executed notes with the Company as payment of the exercise price in connection with stock options to acquire Novavax Common Stock. In September 2011, the Company executed settlement agreements with both Mr. Kelly and Dr. O'Donnell, and in each case the lawsuit has been dismissed and the pledged shares of Common Stock were surrendered to the Company. As reflected on the Company's balance sheet, the remaining notes receivable were eliminated with a corresponding reduction in Common Stock and Additional Paid-In Capital as of September 30, 2011.





- 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 vaccine candidate may not prove to be safe and efficacious;
- decisions by regulatory agencies may delay or prevent our development programs or increase the costs of such programs;
- 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;
- RSV is a difficult disease to prevent and there is significant activity by many companies toward the development of a suitable vaccine;
  - we have not manufactured any of our vaccine candidates at a commercial scale;
  - 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;
- because of the unique and specialized nature of our technology, the regulatory requirements imposed on our clinical efforts, as well as other factors, we may not be able to fully utilize services that can be provided by Cadila as called for under the master services agreement;
  - risks associated with conducting business outside of the United States;
- the cost and our ability 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 financings or otherwise;
- our ability to meet the significant requirements of a federal government contractor, which includes having appropriate accounting, project tracking and earned-value management systems implemented and operational, under our contract with HHS BARDA; and
  - other factors referenced herein.





The Company assumes no obligation to update any such forward-looking statements, except as specifically required by law. We caution readers not to place considerable reliance on the forward-looking statements contained in this Quarterly Report.

## 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 and effective recombinant vaccines. These vaccines leverage our platform technology coupled with a single-use bioprocessing production system to develop virus-like particle (“VLP”) vaccines, as well as recombinant nanoparticle vaccines.

VLPs are genetically engineered three-dimensional nanostructures that incorporate immunologically important recombinant proteins. Our VLPs resemble the virus they were engineered to mimic, but lack the genetic material to replicate the virus and our single-use bioprocessing production technology uses insect cells rather than chicken eggs or mammalian cells. Similarly, recombinant nanoparticle vaccines are smaller in size than traditional VLPs, but the protein-based structures mimic key portions of the virus and their native configurations that are critical for induction of effective immunogenic responses. Our current product targets include VLP vaccines against seasonal and pandemic (including H5N1) influenza and a recombinant nanoparticle vaccine against Respiratory Syncytial Virus (RSV).

CPL Biologicals Private Limited (the JV), our joint venture formed in 2009 between us and Cadila, is 80% owned by Cadila and 20% is owned by us. The JV will develop and manufacture our pandemic and seasonal influenza vaccine candidates and Cadila’s biogeneric products and other diagnostic products for the territory of India. In June 2010, the JV opened its newly constructed state-of-the-art manufacturing facility, 100% funded by Cadila, to be used to produce pandemic and seasonal influenza vaccines, as well as other vaccine candidates. Because we do not control the JV, we account for our investment using the equity method. Since the carrying value of our contribution was nominal and there is no guarantee or commitment to provide future funding, we have not recorded nor do we expect to record losses related to this investment in the future.

A current summary of our significant research and development programs and status of development follows:

Program	Development Phase
Pandemic Influenza (H1N1)	Phase II (ended)
Pandemic Influenza (H5N1)	Phase II
Seasonal Influenza	Phase II
Respiratory Syncytial Virus (RSV)	Phase I

### Pandemic Influenza (H1N1)

In 2010, we completed our clinical trial of our H1N1 influenza VLP vaccine in Mexico in collaboration with Laboratorio Avi-Mex S.A. de C.V. and GE Healthcare. This randomized, blinded, placebo-controlled clinical trial was designed to evaluate the safety and immunogenicity of our H1N1 influenza VLP vaccine in healthy adults. We initially completed enrollment of stage-one and reported positive results on the vaccine’s safety and immunogenicity in the first 1,000 subjects. We initiated stage-two of the trial to evaluate the safety of the vaccine in a larger cohort and completed enrollment of more than 3,500 subjects. The 6-month safety evaluation of the subjects in the second-stage of the clinical trial was completed in September 2010, and no vaccine-related serious adverse events were reported. The positive final results of this trial were presented in February 2011 at the 7th World Health Organization Meeting on Evaluation of Pandemic Influenza Vaccines in Clinical Trials. These results are expected to support development of our H5N1 pandemic and seasonal influenza VLP vaccines in other countries, including the United States.



### Pandemic Influenza (H5N1)

In 2007, we released results from a pre-clinical study in which ferrets that received our H5N1 vaccine candidate were protected from a lethal challenge of the H5N1 virus. After filing an Investigational New Drug (IND) application, we initiated a Phase I/IIa clinical trial. We released interim data from the first portion of this clinical trial in December 2007. These interim results demonstrated that our pandemic influenza vaccine can generate a protective immune response. We conducted the second portion of the Phase I/IIa trial in 2008 to gather additional subject immunogenicity and safety data and determine a final dose through the completion of this clinical trial. In August 2008, we reported favorable results from this clinical trial, which demonstrated strong neutralizing antibody titers across all three doses tested. A final clinical study report was completed and the vaccine was well-tolerated at all dosages as compared with the placebo. No serious adverse events were reported. In February 2009, we announced that the vaccine induced robust hemagglutination inhibition (HAI) responses, which have been shown to be important for protection against influenza disease. In conjunction with our HHS BARDA contract, we have designed a detailed pandemic influenza vaccine clinical development plan. During the 36 month base-period, we expect to initiate multiple clinical trials, including a Phase I testing trial that is expected to begin in early 2012, utilizing Novavax's pandemic influenza VLP vaccine candidate with adjuvants (including Novavax's proprietary adjuvant) to prevent pandemic H5N1 influenza.

### Seasonal Influenza

In April 2010, we reported the final results of our Phase II trial in older adults (60 years or higher in age) in a dose-ranging study comparing our trivalent seasonal influenza VLP vaccine with a commercially available inactivated trivalent influenza vaccine (TIV). The results showed that the vaccine was both safe and immunogenic against the 2009-2010 seasonal influenza virus strains in older adults. The Center for Disease Control and Prevention (CDC) has indicated that currently approved seasonal influenza vaccines have shown to be only 30% to 70% effective in preventing hospitalization for pneumonia and influenza in older adults; however, we believe that our seasonal influenza VLP vaccine, formulated as a quadrivalent and delivering active neuraminidase, as well as hemagglutinin antigens, and mimicking a whole virus structure, may be able to offer improved efficacy. In March 2010, we released final results of the Phase II trial in healthy adults (18 to 49 years in age) immunized with our trivalent seasonal influenza VLP vaccine. The results showed the vaccine was well-tolerated and immunogenic. In conjunction with our HHS BARDA contract, we have designed a detailed seasonal influenza vaccine clinical development plan. During the 36 month base-period, we expect to initiate multiple Phase II dose-ranging and dose-confirmatory trials, with the first Phase II trial beginning in the first quarter of 2012, and a Phase III registration trial thereafter.

### Respiratory Syncytial Virus (RSV)

Our RSV vaccine candidate has completed a pre-clinical safety and efficacy study in cotton rats; the results of which were used to support an IND application that we filed with the FDA in September 2010. In December 2010, we began patient enrollment in our Phase I clinical trial to assess the safety, immunogenicity and tolerability of our RSV vaccine candidate. This blinded, placebo-controlled, escalating-dose study of healthy adults (18 to 49 years in age) was tested in a total of 150 subjects and interim top-line data from the trial was presented in October 2011 at the 5th Vaccine and ISV Annual Global Conference. The positive results showed that the vaccine was well tolerated, highly immunogenic and produced functional antibodies that neutralized RSV. With the conclusion of the Phase I trial, we will assess the safety and immunogenicity results and make a determination on the launch of a Phase II trial.

#### HHS BARDA Contract Award for Recombinant Influenza Vaccines

In September 2009, we responded to the HHS BARDA request for proposal (RFP) for a potential contract award for the advanced development of recombinant influenza vaccines. In February 2011, we were awarded a contract from HHS BARDA valued at \$97 million for the first 36 month base-period, with an HHS BARDA option for an additional period of 24 months valued at \$82 million, for a total contract value of up to \$179 million. The HHS BARDA contract award provides significant funding for our ongoing clinical development and product scale-up of our seasonal and pandemic influenza vaccine candidates. This is a cost-plus-fixed-fee contract in which HHS BARDA will reimburse us for direct contract costs incurred plus allowable indirect costs and a fee earned in the further development of our seasonal and pandemic H5N1 influenza vaccines. Billings under the contract will be based on approved provisional indirect billing rates, which permit recovery of fringe benefits, overhead and general and administrative expenses not exceeding certain limits. These indirect rates will be subject to audit by HHS BARDA on an annual basis. When the final determination of the allowable costs for any year has been made, revenue and billings may be adjusted accordingly.

#### License Agreement with LG Life Sciences, Ltd.

In February 2011, we entered into a licensing agreement with LG Life Sciences, Ltd. (LGLS) that allows LGLS to use our VLP technology to develop and commercially sell our influenza vaccines in South Korea and certain other emerging-market countries. LGLS received an exclusive license to our influenza VLP technology in South Korea and a non-exclusive license in the other specified countries. At its own cost, LGLS is responsible for funding its clinical development of the influenza VLP vaccines and completing a manufacturing facility in South Korea. We received an upfront payment and may receive potential milestone payments of up to an aggregate of value of \$2.5 million, reimbursements of certain development and product costs and royalty payments between ten and twenty percent from LGLS's future commercial sales of influenza VLP vaccines.

#### Critical Accounting Policies and Use of Estimates

There are no material changes to the Company's critical accounting policies as described in Item 7 of the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2010, as filed with the SEC, other than as mentioned below.

#### Revenue

We currently derive revenue from a cost-plus-fixed-fee contract in which HHS BARDA will reimburse us for direct contract costs incurred plus allowable indirect costs and a fee earned in the further development of our seasonal and pandemic H5N1 influenza vaccines. Revenue on this cost-plus-fixed-fee contract is recognized as costs are incurred plus allowable indirect costs and the fee earned. Billings under the contract will be based on approved provisional indirect billing rates, which permit recovery of fringe benefits, overhead and general and administrative expenses not exceeding certain limits. These indirect rates will be subject to audit by HHS BARDA on an annual basis. When the final determination of the allowable costs for any year has been made, revenue and billings may be adjusted accordingly.

#### Recent Accounting Pronouncements Not Yet Adopted

In June 2011, the FASB issued ASU 2011-05, Comprehensive Income (Topic 220): Presentation of Comprehensive Income ("ASU 2011-05"). This guidance is intended to increase the prominence of other comprehensive income in financial statements by presenting it in either a single-statement or two-statement approach. This ASU is effective for us beginning January 1, 2012. The adoption of ASU 2011-05 will not have a material effect on our financial

statements.

In September 2011, the FASB issued ASU 2011-08, Intangibles – Goodwill and Other (Topic 350): Testing Goodwill for Impairment (ASU 2011-08”), to give both public and nonpublic entities the option to qualitatively determine whether they can bypass the two-step goodwill impairment test. Under the new guidance, if an entity chooses to perform a qualitative assessment and determines that it is more likely than not (a more than 50 percent likelihood) that the fair value of a reporting unit is less than its carrying amount, it would then perform Step 1 of the annual goodwill impairment test in ASC 350-20 and, if necessary, proceed to Step 2. Otherwise, no further evaluation would be necessary. The decision to perform a qualitative assessment is made at the reporting unit level, and an entity with multiple reporting units may utilize a mix of qualitative assessments and quantitative tests among its reporting units. The amended guidance is effective for interim and annual goodwill impairment tests performed for fiscal years beginning after December 15, 2011, although early adoption is permitted. The adoption of ASU 2011-08 will not have a material effect on our financial statements.

16

---

## Results of Operations

The following is a discussion of the historical financial condition and results of operations of the Company and should be read in conjunction with the financial statements and notes thereto set forth in this Quarterly Report.

Three Months Ended September 30, 2011 and 2010 (amounts in tables are presented in thousands, except per share information)

## Revenue:

	Three Months Ended September 30,		Change 2010 to 2011
	2011	2010	
<b>Revenue:</b>			
Total revenue	\$ 5,008	\$ 175	\$ 4,833

Revenue for the three months ended September 30, 2011 was \$5.0 million and is comprised of services performed under the HHS BARDA contract. For 2011, we expect to generate significant revenue as we perform under the HHS BARDA contract.

## Operating Expenses:

	Three Months Ended September 30,		Change 2010 to 2011
	2011	2010	
<b>Operating Expenses:</b>			
Research and development	\$ 6,239	\$ 7,870	\$ (1,631 )
General and administrative	2,737	2,844	(107 )
Total operating expenses	\$ 8,976	\$ 10,714	\$ (1,738 )

## Research and Development Expenses

Research and development expenses decreased to \$6.2 million for the three months ended September 30, 2011 from \$7.9 million for the same period in 2010, a decrease of \$1.6 million, or 21%, primarily due to lower research and development spending in the three months ended September 30, 2011 to support our clinical trials related to our H1N1 and seasonal influenza vaccine candidates. The decrease is primarily a result of lower outside-testing costs (including outsourced clinical trial costs, sponsored research and consulting agreements), partially offset by higher employee-related costs.

We track our research and development expenses by the type of costs incurred in identifying, developing, manufacturing and testing vaccine candidates. We evaluate and prioritize our activities according to functional area and therefore believe that project-by-project information would not form a reasonable basis for disclosure to our investors. These expenses consist primarily of salaries and related expenses for personnel, costs associated with contract research and manufacturing organizations, manufacturing supplies and outside animal and pre-clinical testing. At September 30, 2011, we had 83 employees dedicated to our research and development programs.

Historically, we have not accounted for internal research and development expenses by project, since our employees work time is spread across multiple programs.



The following summarizes our research and development expenses by functional area for the three months ended September 30, 2011 (in millions).

Manufacturing	\$3.3
Vaccine Discovery	0.8
Clinical and Regulatory Affairs	2.1
Total research and development expenses	\$6.2

We do not provide forward-looking estimates of costs and time to complete our research programs due to the many uncertainties associated with vaccine development. As we obtain data from pre-clinical studies and clinical trials, we may elect to discontinue or delay trials in order to focus our resources on more promising vaccine candidates. Completion of trials may take several years or more, but the length of time can vary substantially depending upon the phase, size of trial, primary and secondary endpoints and the intended use of the vaccine candidate. The cost of clinical trials may vary significantly over the life of a project as a result of a variety of factors, including:

- the number of patients who participate in the trials;
- the number of sites included in the trials;
- if trial locations are domestic, international or both;
- the time to enroll patients;
- the duration of treatment and follow-up;
- the safety and efficacy profile of the vaccine candidate; and
- the cost and timing of, and the ability to secure, regulatory approvals.

As a result of these uncertainties, we are unable to determine with any significant degree of certainty, the duration and completion costs of our research and development projects or when, and to what extent, we will generate future cash flows from our research projects.

#### General and Administrative Expenses

General and administrative expenses were relatively flat at \$2.7 million for the three months ended September 30, 2011 compared to \$2.8 million for the same period in 2010.

#### Other Income (Expense):

	Three Months Ended September 30,			Change 2010 to 2011
	2011	2010		2011
Other Income (Expense):				
Interest income	\$ 22	\$ 50	\$ (28	)
Interest expense	(2 )	(2 )	—	
Change in fair value of warrant liability	736	133	603	

Total other income (expense)	\$ 756	\$ 181	\$ 575
------------------------------	--------	--------	--------

We had total other income of \$0.8 million for the three months ended September 30, 2011 compared to total other income of \$0.2 million for the same period in 2010, a change of \$0.6 million. For the three months ended September 30, 2011, the change in fair value of the warrant liability resulted in a \$0.6 million increase in total other income (expense) as compared to the same period in 2010.

## Income Tax:

	Three Months Ended September 30,		Change 2010 to 2011
	2011	2010	
<b>Income Tax:</b>			
Total income tax (benefit) expense	\$ —	\$ (136 )	\$ 136

Income tax benefit for the three months ended September 30, 2010 was \$(0.1) million. We recorded a deferred income tax provision related to a refundable income tax credit received.

## Net Loss:

	Three Months Ended September 30,		Change 2010 to 2011
	2011	2010	
<b>Net Loss:</b>			
Net loss	\$ (3,212 )	\$ (10,222 )	\$ 7,010
Net loss per share	\$ (0.03 )	\$ (0.10 )	\$ 0.07
Weighted shares outstanding	115,107	107,092	8,015

Net loss for the three months ended September 30, 2011 was \$3.2 million, or \$0.03 per share, as compared to \$10.2 million, or \$0.10 per share, for the same period in 2010, a decreased net loss of \$7.0 million, or 69%. The decrease in net loss was primarily due to revenue recognized under the HHS BARDA agreement, as well as lower research and development spending in the three months ended September 30, 2011.

The increase in weighted shares outstanding for the three months ended September 30, 2011 is primarily a result of sales of our common stock under our At Market Issuance Sales Agreement.

Nine Months Ended September 30, 2011 and 2010 (amounts in tables are presented in thousands, except per share information)

## Revenue:

	Nine Months Ended September 30,		Change 2010 to 2011
	2011	2010	
<b>Revenue:</b>			

Edgar Filing: NOVAVAX INC - Form 10-Q

Total revenue	\$ 8,843	\$ 292	\$ 8,551
---------------	----------	--------	----------

Revenue for the nine months ended September 30, 2011 was \$8.8 million and is comprised of services performed under the HHS BARDA contract.

19

---

## Operating Expenses:

	Nine Months Ended September 30,		Change 2010 to 2011
	2011	2010	2011
<b>Operating Expenses:</b>			
Research and development	\$ 17,237	\$ 23,226	\$ (5,989 )
General and administrative	8,926	8,528	398
Total operating expenses	\$ 26,163	\$ 31,754	\$ (5,591 )

## Research and Development Expenses

Research and development expenses decreased to \$17.2 million for the nine months ended September 30, 2011 from \$23.2 million for the same period in 2010, a decrease of \$6.0 million, or 26%, primarily due to lower research and development spending in the nine months ended September 30, 2011 to support our clinical trials related to our H1N1 and seasonal influenza vaccine candidates. The decrease is primarily a result of lower outside-testing costs (including outsourced clinical trial costs, sponsored research and consulting agreements).

The following summarizes our research and development expenses by functional area for the nine months ended September 30, 2011 (in millions).

Manufacturing	\$9.5
Vaccine Discovery	2.4
Clinical and Regulatory Affairs	5.3
Total research and development expenses	\$17.2

## General and Administrative Expenses

General and administrative expenses increased to \$8.9 million for the nine months ended September 30, 2011 from \$8.5 million for the same period in 2010, an increase of \$0.4 million, or 5%, primarily due to higher employee-related costs, including severance expenses, partially offset by lower professional fees.

## Other Income (Expense):

	Nine Months Ended September 30,		Change 2010 to 2011
	2011	2010	2011
<b>Other Income (Expense):</b>			
Interest income	\$ 106	\$ 138	\$ (32 )
Interest expense	(6 )	(6 )	—
Change in fair value of warrant liability	1,973	1,771	202
Total other income (expense)	\$ 2,073	\$ 1,903	\$ 170

We had total other income of \$2.1 million for the nine months ended September 30, 2011 compared to total other income of \$1.9 million for the same period in 2010, a change of \$0.2 million. For the nine months ended September

30, 2011, the change in fair value of the warrant liability resulted in a \$0.2 million increase in total other income (expense) as compared to the same period in 2010.

## Income Tax:

	Nine Months Ended September 30,		Change 2010 to 2011
	2011	2010	
<b>Income Tax:</b>			
Total income tax (benefit) expense	\$ 412	\$ (136 )	\$ (548 )

Income tax expense for the nine months ended September 30, 2011 was \$0.4 million compared to an income tax benefit of \$(0.1) million for the same period in 2010. In 2011, we incurred a foreign withholding tax related to a payment received in accordance with a license agreement. In 2010, we recorded a deferred income tax provision related to a refundable income tax credit received.

## Net Loss:

	Nine Months Ended September 30,		Change 2010 to 2011
	2011	2010	
<b>Net Loss:</b>			
Net loss	\$ (15,659 )	\$ (29,423 )	\$ 13,764
Net loss per share	\$ (0.14 )	\$ (0.29 )	\$ 0.15
Weighted shares outstanding	113,053	102,683	10,370

Net loss for the nine months ended September 30, 2011 was \$15.7 million, or \$0.14 per share, as compared to \$29.4 million, or \$0.29 per share, for the same period in 2010, a decreased net loss of \$13.8 million, or 47%. The decrease in net loss was primarily due to revenue recognized under the HHS BARDA agreement, as well as lower research and development spending to support our clinical trials for our H1N1 and seasonal influenza vaccine candidates in the nine months ended September 30, 2011.

The increase in weighted shares outstanding for the nine months ended September 30, 2011 is primarily a result of sales of our common stock under our At Market Issuance Sales Agreement.

## 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 patent claims and other intellectual property rights and manufacturing costs. We plan to continue to have multiple vaccine 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 scope, initiation, rate and progress of our pre-clinical studies and clinical trials and other research and development activities.

Edgar Filing: NOVAVAX INC - Form 10-Q

As of September 30, 2011, we had \$14.3 million in cash and cash equivalents and \$5.3 million in short-term investments as compared to \$8.1 million and \$23.6 million, respectively, at December 31, 2010. The following table summarizes cash flows for the nine months ended September 30, 2011 and 2010 (in thousands):

	Nine Months Ended September 30,		Change 2010 to 2011
	2011	2010	
<b>Summary of Cash Flows:</b>			
Net cash (used in) provided by:			
Operating activities	\$(20,760 )	\$(27,044 )	\$ 6,284
Investing activities	17,739	(17,969 )	35,708
Financing activities	9,278	22,471	(13,193 )
Net increase (decrease) in cash and cash equivalents	6,257	(22,542 )	28,799
Cash and cash equivalents at beginning of period	8,061	38,757	(30,696 )
Cash and cash equivalents at end of period	\$14,318	\$16,215	\$ (1,897 )

Net cash used in operating activities decreased to \$20.8 million as compared to \$27.0 million for the nine months ended September 30, 2011 and 2010, respectively. The decrease in cash usage was primarily due to a decreased net loss, partially offset by the timing of our customer and vendor payments.

During the nine months ended September 30, 2011 and 2010, our investing activities consisted primarily of purchases and maturities of short-term investments and capital expenditures. Capital expenditures for the nine months ended September 30, 2011 and 2010 were \$0.4 million and \$1.4 million, respectively.

During the nine months ended September 30, 2011 and 2010, our financing activity consisted primarily of \$9.2 million and \$22.1 million, respectively, in net proceeds from the sale of our common stock pursuant to our At Market Issuance Sales Agreement.

We have entered into agreements with outside clinical research organization providers to support our clinical development. As of September 30, 2011, \$1.0 million remains unpaid on certain of these agreements in the event our outside providers complete their services in 2011. 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, a subsidiary of Pfizer Inc (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; the license may be terminated by Wyeth only for cause and may be terminated by us only after we have provided ninety (90) days notice that we have absolutely and finally ceased activity, including through any affiliate or sublicense, related to the manufacturing, development, marketing or sale of products covered by the license. In May 2010, we amended the license, effective as of March 17, 2010, under which the parties agreed that we would not be obligated to make a milestone payment in the event our H1N1 pandemic vaccine candidate received regulatory approval in the country of Mexico, provided that we increase certain subsequent milestone payments. Payments under the agreement to Wyeth from 2007 through September 30, 2011 aggregated \$5.1 million. We do not expect to make a milestone payment to Wyeth in the next twelve months. 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 September 30, 2011, 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.

In connection with our JV with Cadila, we entered into a master services agreement, which we and Cadila amended in July 2011 to extend the term by one year for which services can be provided by Cadila under this agreement. Under the recently revised terms, if, by March 2013, the amount of services provided by Cadila under the master services agreement is less than \$7.5 million, the Company will pay Cadila the portion of the shortfall amount that is less than or equal to \$2.0 million and 50% of the portion of the shortfall amount that exceeds \$2.0 million. Through September 30, 2011, we have purchased \$0.2 million in services from Cadila pursuant to this agreement.

Based on our cash and cash equivalents and short-term investment balances as of September 30, 2011, anticipated revenue under the contract with HHS BARDA that was awarded in February 2011, possible proceeds from the sales of our common stock under our At 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. Our ability to generate revenue under the HHS BARDA contract is subject to our performance under the contract; our ability to raise funds under our At Market Sales Agreement is subject to both our business performance and market conditions. Further, we may 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 Market Sales Agreement, 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 perform under the HHS BARDA contract or 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 September 30, 2011, we had cash and cash equivalents of \$14.3 million, short-term investments of \$5.3 million and working capital of \$19.5 million.

Our exposure to market risk is primarily confined to our investment portfolio. As of September 30, 2011, our short-term investments were 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 when they mature and the proceeds are reinvested into new investments and, therefore, could impact our cash flows and results of operations.

We had previously invested in auction rate securities for short periods of time as part of our cash management program. Short-term investments at September 30, 2011 include investments in three auction rate securities with a par value of \$5.1 million and a fair value of \$4.3 million. At September 30, 2011, we have recorded \$0.9 million in unrealized gains on the auction rate securities included in other comprehensive income on the 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, has 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 September 30, 2011. 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 September 30, 2011, 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 third quarter of 2011, and has concluded that there was no change that occurred during the third quarter of 2011 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 initiated 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 had each defaulted on outstanding notes due to the Company in the aggregate principal amount of \$1,572,000. In 2002, Mr. Kelly and Dr. O'Donnell executed notes with the Company as payment of the exercise price in connection with stock options to acquire Novavax Common Stock. In September 2011, the Company executed settlement agreements with both Mr. Kelly and Dr. O'Donnell, and in each case the lawsuit has been dismissed and the shares of Common Stock were surrendered to the Company.

#### 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, 2010, as filed with the SEC.

#### Item 5. Other Information

None.

Item 6. Exhibits

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

- 10.1\* Amendment No. 1 to Master Services Agreement between Novavax, Inc. and Cadila Pharmaceuticals Limited dated July 27, 2011
- 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: November 8, 2011

By: /s/ Stanley C. Erck  
President and Chief Executive Officer  
and Director  
(Principal Executive Officer)

Date: November 8, 2011

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