

NOVAVAX INC  
Form 10-Q  
November 09, 2012

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  
X ACT OF 1934**

**For the quarterly period ended September 30, 2012**

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**



**NOVAVAX, INC.**

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**PART I. FINANCIAL INFORMATION****Item 1. Financial Statements****NOVAVAX, INC.****BALANCE SHEETS**

(in thousands, except share and per share information)

	September 30, 2012 (unaudited)	December 31, 2011
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 10,738	\$ 14,104
Short-term investments available-for-sale	17,672	4,205
Restricted cash	838	—
Accounts receivables	2,469	1,965
Unbilled receivables	1,725	1,836
Prepaid expenses	2,807	2,441
Other current assets	235	1,558
Total current assets	36,484	26,109
Property and equipment, net	9,815	6,857
Goodwill	33,141	33,141
Restricted cash	756	—
Other non-current assets	350	469
Total assets	\$ 80,546	\$ 66,576
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 2,203	\$ 2,645
Accrued expenses and other current liabilities	6,031	4,528
Deferred revenue	803	—
Current portion of capital lease	57	—
Current portion of notes payable	157	20
Warrant liability	769	—
Deferred rent	421	386
Total current liabilities	10,441	7,579
Deferred revenue	2,500	2,500
Non-current portion of capital lease	252	—
Non-current portion of notes payable	793	300

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Warrant liability	—	368
Deferred rent	5,184	1,980
Total liabilities	19,170	12,727
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 136,003,676 shares issued and 135,548,246 shares outstanding at September 30, 2012 and 117,480,867 shares issued and 117,025,437 shares outstanding at December 31, 2011	1,360	1,175
Additional paid-in capital	411,558	383,948
Accumulated deficit	(350,128 )	(329,656 )
Treasury stock, 455,430 shares, cost basis	(2,450 )	(2,450 )
Accumulated other comprehensive income	1,036	832
Total stockholders' equity	61,376	53,849
Total liabilities and stockholders' equity	\$ 80,546	\$ 66,576

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

NOVAVAX, INC.

## STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

(in thousands, except per share information)

(unaudited)

	<b>For the Three Months</b>		<b>For the Nine Months</b>	
	<b>Ended September 30,</b>		<b>Ended September 30,</b>	
	<b>2012</b>	<b>2011</b>	<b>2012</b>	<b>2011</b>
Revenue:				
Government contracts	\$ 5,583	\$ 5,008	\$ 17,328	\$ 8,843
Research and development collaboration	182		182	
Total revenue	5,765	5,008	17,510	8,843
Costs and expenses:				
Cost of government contracts revenue	3,838	2,190	12,740	3,763
Research and development	6,395	4,049	16,649	13,474
General and administrative	2,381	2,737	8,291	8,926
Total costs and expenses	12,614	8,976	37,680	26,163
Loss from operations	(6,849 )	(3,968 )	(20,170 )	(17,320 )
Other income (expense):				
Interest income	39	22	111	106
Interest expense	(6 )	(2 )	(12 )	(6 )
Change in fair value of warrant liability	(401 )	736	(401 )	1,973
Loss from operations before income tax	(7,217 )	(3,212 )	(20,472 )	(15,247 )
Income tax expense				412
Net loss	\$ (7,217 )	\$ (3,212 )	\$ (20,472 )	\$ (15,659 )
Basic and diluted net loss per share	\$ (0.05 )	\$ (0.03 )	\$ (0.16 )	\$ (0.14 )
Basic and diluted weighted average number of common shares outstanding	134,178	115,107	127,246	113,053

	<b>For the Three Months</b>		<b>For the Nine Months</b>	
	<b>Ended September 30,</b>		<b>Ended September 30,</b>	
	<b>2012</b>	<b>2011</b>	<b>2012</b>	<b>2011</b>
Comprehensive loss:				
Net loss	\$ (7,217 )	\$ (3,212 )	\$ (20,472 )	\$ (15,659 )
Unrealized gain on short-term investments available-for-sale	96	3	204	141

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Comprehensive loss \$ (7,121 ) \$ (3,209 ) \$ (20,268 ) \$ (15,518 )

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



NOVAVAX, INC.

## STATEMENTS OF CASH FLOWS

(in thousands)

(unaudited)

	<b>For the Nine Months</b>	
	<b>Ended September 30,</b>	
	2012	2011
Operating Activities:		
Net loss	\$(20,472 )	\$(15,659 )
Reconciliation of net loss to net cash used in operating activities:		
Change in fair value of warrant liability	401	(1,973 )
Depreciation and amortization	1,216	1,197
Amortization of net premiums on short-term investments	—	317
Impairment of property and equipment	—	60
Gain on disposal of property and equipment	(26 )	—
Deferred rent	436	(254 )
Non-cash stock-based compensation	1,668	1,677
Changes in operating assets and liabilities:		
Accounts receivables	(504 )	37
Unbilled receivables	111	(3,848 )
Prepaid expenses and other assets	(271 )	(1,127 )
Accounts payable and accrued expenses	(304 )	(3,687 )
Deferred revenue	803	2,500
Lease incentives received	2,803	—
Net cash used in operating activities	(14,139 )	(20,760 )
Investing Activities:		
Capital expenditures	(2,202 )	(414 )
Proceeds from disposal of property and equipment	318	
Proceeds from maturities of short-term investments	2,500	20,235
Purchases of short-term investments	(15,763 )	(2,082 )
Net cash (used in) provided by investing activities	(15,147 )	17,739
Financing Activities:		
Principal payments of capital lease	(90 )	—
Principal payments of notes payable	(20 )	(60 )
Proceeds from notes payable	650	—
Restricted cash	(1,594 )	—
Net proceeds from sales of common stock, net of offering costs of \$0.4 million and \$0.2 million, respectively	26,925	9,182
Proceeds from the exercise of stock options	49	156

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Net cash provided by financing activities	25,920	9,278
Net (decrease) increase in cash and cash equivalents	(3,366 )	6,257
Cash and cash equivalents at beginning of period	14,104	8,061
Cash and cash equivalents at end of period	\$ 10,738	\$ 14,318
Supplemental disclosure of non-cash activities:		
Equipment acquired under a capital lease	\$ 399	\$ —
Deposit applied towards the purchase of laboratory equipment	\$ 500	\$ —
Property and equipment purchases included in accounts payable and accrued expenses	\$ 1,365	\$ 168
Settlement of notes receivable	\$ —	\$ 1,522

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

NOVAVAX, INC.

NOTES TO FINANCIAL STATEMENTS

September 30, 2012

(unaudited)

Note 1 – Organization

Novavax, Inc. (the “Company”) is a clinical-stage biopharmaceutical company focused on developing recombinant protein nanoparticle vaccines to address a broad range of infectious diseases. The Company’s goal is to become a profitable vaccine company that is aggressively driving towards development, licensure and commercialization of an important portfolio of vaccines worldwide. The Company’s technology platform is based on proprietary recombinant vaccine technology that includes virus-like particles (“VLPs”) and recombinant protein micelle vaccines combined with a single-use bioprocessing production system. These vaccine candidates are genetically engineered three-dimensional nanostructures that incorporate immunologically important recombinant proteins. The Company’s product pipeline targets a variety of infectious diseases and its vaccine candidates are currently in or have completed clinical trials that target pandemic (H5N1) influenza, seasonal influenza and respiratory syncytial virus (“RSV”).

In 2009, the Company formed a joint venture with Cadila Pharmaceuticals Limited (“Cadila”) named CPL Biologicals Private Limited (the “JV”) to develop and manufacture vaccines, biological therapeutics and diagnostics in India. The JV is owned 20% by the Company and 80% by Cadila. The Company accounts for its investment in the JV using the equity method.

Note 2 – Liquidity Matters

The Company’s vaccine candidates currently under development will require significant additional research and development efforts that include 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.

Since its inception, the Company has incurred, and continues to incur, significant losses from operations. At September 30, 2012, the Company had cash and cash equivalents of \$10.7 million and short-term investments with a

fair value of \$17.7 million. In October 2012, the Company raised \$27 million through the sale of common stock to institutional investors (See Note 12).

Based on the Company's current cash and cash equivalents and short-term investments, including its recent private equity offering, 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 has adequate capital resources available to operate at planned levels that fund the Company beyond 2013. Additional capital will be required in the future to develop its vaccine candidates through clinical development, manufacturing and commercialization. The Company's ability to obtain such additional capital is subject to various factors:

generating revenue under the HHS BARDA contract is subject to the Company's performance under the contract, including its ability to collect on delayed reimbursement situations, such as the 205 Trial costs described in Note 5 below; and

raising 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, 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 Market Issuance Sales Agreement, Equipment Loan (See Note 7) and Improvement Allowance (See Note 10), 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, 2012, statements of operations for the three and nine months ended September 30, 2012 and 2011 and the statements of cash flows for the nine months ended September 30, 2012 and 2011 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, 2011.

##### ***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 applies 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, 2012 and December 31, 2011 are summarized below (in thousands):

	Fair Value at September 30, 2012			Fair Value at December 31, 2011		
	Level 1	Level 2	Level 3	Level 1	Level 2	Level 3
<b>Assets</b>						
Corporate debt and auction rate securities	\$ —	\$ 17,672	\$ —	\$ —	\$ 4,205	\$ —
<b>Liabilities</b>						
Warrant liability	\$ —	\$ —	\$ 769	\$ —	\$ —	\$ 368

The following table summarizes the activity of Level 3 inputs measured on a recurring basis as of September 30, 2012 (in thousands):

**Fair Value Measurements of  
Warrants Using Significant  
Unobservable Inputs**

	<b>(Level 3)</b>	
Balance at December 31, 2011	\$	368
Change in fair value of Warrant liability		401
Balance at September 30, 2012	\$	769

The amounts in the Company's balance sheet for accounts receivables, unbilled receivables and accounts payable approximate fair value due to their short-term nature. Based on borrowing rates available to the Company, the fair value of capital lease and notes payable approximates their carrying value.

## Short-Term Investments

Short-term investments at September 30, 2012 consist of investments in commercial paper, corporate notes 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, 2012 and December 31, 2011 were comprised of (in thousands):

	September 30, 2012				December 31, 2011			
	<b>Amortized Cost</b>	<b>Gross Unrealized Gains</b>	<b>Gross Unrealized Losses</b>	Fair Value	<b>Amortized Cost</b>	<b>Gross Unrealized Gains</b>	<b>Gross Unrealized Losses</b>	Fair Value
Auction rate securities	\$3,373	\$ 1,032	\$ —	\$ 4,405	\$3,373	\$ 832	\$ —	\$ 4,205
Corporate debt securities	13,263	4	—	13,267	—	—	—	—
Total	\$16,636	\$ 1,036	\$ —	\$ 17,672	\$3,373	\$ 832	\$ —	\$ 4,205

#### Restricted Cash

The Company's noncurrent restricted cash with respect to its new manufacturing, laboratory and office space in Gaithersburg, Maryland functions as collateral for letters of credit, which serve as security deposits for the duration of the leases. In addition, the Company's restricted cash includes payments received under the PATH agreement (See Note 5) until such time the Company has paid for the work performed for the related Phase II RSV clinical trial.

#### *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 12,951,625 shares and 11,119,476 shares at September 30, 2012 and 2011, respectively, are excluded from the computation, as their effect is antidilutive.

#### *Revenue Recognition*

The Company performs research and development for U.S. Government agencies and other collaborators under cost reimbursable and fixed price contracts, including license and clinical development agreements. The Company recognizes revenue under research contracts when a contract has been executed, the contract price is fixed and determinable, delivery of services or products has occurred and collection of the contract price is reasonably assured. Payments received in advance of work performed are recorded as deferred revenue and losses on contracts, if any, are recognized in the period in which they become known.

Under cost reimbursable contracts, the Company is reimbursed and recognizes revenue as allowable costs are incurred plus a portion of the fixed-fee earned. The Company considers fixed-fees under cost reimbursable contracts to be earned in proportion to the allowable costs incurred in performance of the work as compared to total estimated contract costs, with such costs incurred representing a reasonable measurement of the proportional performance of the work completed. Under its HHS BARDA contract, certain activities must be pre-approved by HHS BARDA in order for their costs to be deemed allowable direct costs. Direct costs incurred under cost reimbursable contracts are recorded as cost of government contracts revenue. The Company's government contracts, including its HHS BARDA contract, provide the U.S. government (or agency) the ability to terminate the contract for convenience or to terminate for default if the Company fails to meet its obligations as set forth in the statement of work. The Company believes that if the government were to terminate one of its contracts for convenience, including the HHS BARDA contract, the costs incurred through the effective date of such termination and any settlement costs resulting from such termination would be allowable costs. Payments to the Company under cost reimbursable contracts with agencies of the U.S. Government, including its contract with HHS BARDA, are provisional payments subject to adjustment upon annual audit by the government. No such audit has been completed as of September 30, 2012; however, management believes that revenue for periods subject to audit has been recorded in amounts that are expected to be realized upon final audit and settlement.

The Company's collaborative research and development agreements may include an upfront payment, payments for research and development services, milestone payments and royalties. Agreements with multiple deliverables are evaluated to determine if the deliverables can be divided into more than one unit of accounting. A deliverable can generally be considered a separate unit of accounting if both of the following criteria are met: (1) the delivered item(s) has value to the customer on a stand-alone basis; and (2) if the arrangement includes a general right of return relative to the delivered item(s), delivery or performance of the undelivered item(s) is considered probable and substantially in control of the Company. Deliverables that cannot be divided into separate units are combined with other units of accounting, as appropriate. Consideration received is allocated among the separate units of accounting based on the relative selling price method. Deliverables under these arrangements typically include rights to intellectual property, research and development services and involvement by the parties in steering committees. Historically, deliverables under the Company's collaborative research and development agreements have been deemed to have no stand-alone value and as a result been treated as a single unit of accounting. In addition, the Company analyzes its contracts and collaborative agreements to determine whether the payments received should be recorded as revenue or as a reduction to research and development expenses. In reaching this determination, management considers a number of factors, including whether the Company is principal under the arrangement, and whether the arrangement is significant to, and part of, the Company's core operations. Historically, payments received under its contracts and collaborative agreements have been recognized as revenue since the Company acts as a principal in the arrangement, and the activities are core to its operations.

When the performance under a fixed price contract can be reasonably estimated, revenue for fixed price contracts is recognized under the proportional performance method and earned in proportion to the contract costs incurred in performance of the work as compared to total estimated contract costs. Costs incurred under fixed price contracts represent a reasonable measurement of proportional performance of the work. Direct costs incurred under collaborative research and development agreements are recorded as research and development expenses. If the performance under a fixed price contract cannot be reasonably estimated, the Company recognizes the revenue on a straight-line basis over the contract term.

Revenue associated with upfront payments under arrangements is recognized over the contract term or when all obligations associated with the upfront payment have been satisfied.

Revenue from the achievement of research and development milestones, if deemed substantive, is recognized as revenue when the milestones are achieved, and the milestone payments are due and collectible. If not deemed substantive, the Company would recognize such milestone as revenue upon its achievement on a straight-line basis over the remaining expected term of the research and development period. Milestones are considered substantive if all of the following conditions are met: (1) the milestone is non-refundable; (2) there is substantive uncertainty of achievement of the milestone at the inception of the arrangement; (3) substantive effort is involved to achieve the milestone and such achievement relates to past performance; and (4) the amount of the milestone appears reasonable in relation to the effort expended and all of the deliverables and payment terms in the arrangement.

### ***Recent Accounting Pronouncements***

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 was effective for the Company beginning January 1, 2012. This presentation requirement was adopted January 1, 2012 and is reflected on the accompanying statements of operations and comprehensive loss for the periods ended September 30, 2012 and 2011.

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 was effective for interim and annual goodwill impairment tests performed for fiscal years beginning after December 15, 2011, although early adoption was permitted. The adoption of ASU 2011-08 on January 1, 2012 did not have a material effect on the Company’s financial statements.

#### Note 4 – Stock-Based Compensation

The Company has granted equity awards under several plans. Under 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 2007, June 2011 and June 2012 by the Company’s stockholders, currently authorizes the grant of equity awards for up to 18,312,192 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.

Under the 2005 Plan and the 1995 Plan, incentive stock options, having a maximum term of 10 years, can be or were granted at no less than 100% of the fair value of the Company’s common stock at the time of grant and are generally exercisable over periods ranging from six months to four years. There is no minimum exercise price for non-statutory stock options.

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

	<b>Three Months Ended</b>		<b>Nine Months Ended</b>	
	<b>September 30,</b>		<b>September 30,</b>	
	2012	2011	2012	2011
Research and development	\$ 219	\$ 176	\$ 638	\$ 449
General and administrative	274	366	1,030	1,228

Total stock-based compensation expense \$ 493      \$ 542      \$ 1,668      \$ 1,677

*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, 2012:

	2005 Stock Incentive Plan		1995 Stock Option Plan	
	<b>Weighted-</b>		<b>Weighted-</b>	
	<b>Average</b>		<b>Average</b>	
	<b>Stock</b>	<b>Exercise</b>	<b>Stock</b>	<b>Exercise</b>
	<b>Options</b>	<b>Price</b>	<b>Options</b>	<b>Price</b>
Outstanding at January 1, 2012	7,412,746	\$ 2.22	474,650	\$ 4.38
Granted	3,483,000	\$ 1.29	—	\$ —
Exercised	(80,784	) \$ 0.61	—	\$ —
Canceled	(1,546,562	) \$ 2.26	(184,750	) \$ 4.01
Outstanding at September 30, 2012	9,268,400	\$ 1.88	289,900	\$ 4.59
Shares exercisable at September 30, 2012	3,503,043	\$ 2.38	289,900	\$ 4.59
Shares available for grant at September 30, 2012	5,559,536			

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:

	<b>Three Months Ended</b>		<b>Nine Months Ended</b>	
	<b>September 30,</b>		<b>September 30,</b>	
	2012	2011	2012	2011
Weighted-average fair value of stock options granted	\$1.09	\$0.78	\$0.71	\$1.19
Risk-free interest rate	0.55%	0.48%-0.68%	0.55%-1.54%	0.48%-1.91%
Dividend yield	0%	0%	0%	0%
Volatility	76.60%-76.71%	75.86%-80.40%	75.47%-80.48%	73.28%-80.4%
Expected term (in years)	4.24	3.49-4.21	3.34-7.09	3.26-4.47
Expected forfeiture rate	0%-23.15%	0%-23.15%	0%-23.15%	0%-23.15%

The aggregate intrinsic value and weighted-average remaining contractual term of stock options outstanding as of September 30, 2012 was approximately \$4.6 million and 7.7 years, respectively. The aggregate intrinsic value and weighted-average remaining contractual term of stock options exercisable as of September 30, 2012 was approximately \$1.0 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, 2012. 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, 2012 and 2011 was less than \$0.1 million and \$0.2 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.

The following is a summary of restricted stock awards activity for the nine months ended September 30, 2012:

**Per Share**

**Weighted-**

**Average**

**Number of Grant-Date**

	<b>Shares</b>	<b>Fair Value</b>
Outstanding at January 1, 2012	53,333	\$ 1.63
Restricted stock granted	—	\$ —
Restricted stock vested	3,333	\$ 5.21
Restricted stock forfeited	—	\$ —
Outstanding at September 30, 2012	50,000	\$ 1.39

As of September 30, 2012, there was approximately \$3.6 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 – U.S. Government Agreement and Collaborations

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

In February 2011, the Company was awarded a contract from HHS BARDA valued at \$97 million for the 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 the Company's ongoing clinical development and product scale-up of both its seasonal and pandemic (H5N1) influenza vaccine candidates. This is a cost-plus-fixed-fee contract in which HHS BARDA will reimburse the Company for direct contract costs incurred plus allowable indirect costs and a fixed-fee earned in the further development of its multivalent seasonal and monovalent pandemic (H5N1) influenza vaccines. Billings under the contract are 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 are 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. Since the inception of the contract and during the nine months ended September 30, 2012, the Company has recognized revenue of approximately \$31.6 million and \$16.9 million, respectively.

Under certain circumstances HHS BARDA reimbursements may be delayed or even potentially withheld. In March 2012, the Company decided to conduct its Phase II dose-ranging clinical trial of its trivalent and quadrivalent seasonal influenza vaccine candidates (the "205 Trial") under its existing U.S. investigational new drug application ("IND") for its trivalent seasonal influenza vaccine candidate ("Trivalent IND") as opposed to waiting to conduct the 205 Trial under a new IND for its quadrivalent vaccine candidate ("Quadrivalent IND"). In July 2012, the Company reported that it expected to launch its next quadrivalent Phase II clinical trial in 2013 rather than in the second half of 2012; similarly, the filing of the Quadrivalent IND, which the Company had previously indicated was expected in the second half of 2012 will also be delayed. Based on discussions between HHS BARDA and the Company, because the 205 Trial includes its quadrivalent seasonal influenza vaccine candidate, the outside clinical trial costs for the 205 Trial will only be submitted for reimbursement to HHS BARDA and recorded as revenue by the Company after it submits the 205 Trial data to its Quadrivalent IND. Until then, the outside clinical trial costs of the 205 Trial will be expensed and included in cost of government contracts revenue. The financial impact of this delay in revenue recognition is based on the outside clinical trial costs of the 205 Trial that are expected to total approximately \$3.1 million, of which \$2.8 million was incurred through September 30, 2012.

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

In February 2011, the Company entered into a license agreement with LG Life Sciences, Ltd. ("LGLS") that allows LGLS to use the Company's technology to develop and commercially sell influenza vaccines exclusively in South Korea and non-exclusively in certain 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. Under

the license agreement, the Company is obligated to provide LGLS with information and materials related to the manufacture of the licensed products, provide on-going project management and regulatory support and conduct clinical trials of its influenza vaccines in order to obtain FDA approval in the U.S. The term of the license agreement is expected to terminate in 2027. Payments to the Company under the license agreement include an upfront payment of \$2.5 million, reimbursements of certain development and product costs, payments related to the achievement of certain milestones and royalty payments at a rate between 10% and 20% from LGLS's future commercial sales of influenza VLP vaccines, which royalty rate is subject to reduction if certain timelines for regulatory licensure are not met. The upfront payment has been deferred and will be recognized when the previously mentioned obligations in the agreement are satisfied, which may not occur until the end of the term of the agreement. Payments for milestones under the agreement will be recognized on a straight-line basis over the remaining term of the research and development period upon achievement of such milestone. Any royalties under the agreement will be recognized as earned.

***PATH Vaccine Solutions***

In July 2012, the Company entered into a clinical development agreement with PATH Vaccine Solutions (“PATH”) to develop its vaccine candidate to protect against RSV through maternal immunization in low-resource countries (the “RSV Collaboration Program”). The Company was awarded approximately \$2.0 million by PATH for initial funding under the agreement to partially support its Phase II dose-ranging clinical trial in women of childbearing age, which was launched in October 2012. The agreement would expire July 31, 2013, unless the Company and PATH decide to continue the RSV Collaboration Program. The Company retains global rights to commercialize the product and has made a commitment to make the vaccine affordable and available in low-resource countries. To the extent PATH has continued to fund 50% of the Company’s external clinical development costs for the RSV Collaboration Program, but the Company does not continue development, the Company would then grant PATH a fully-paid license to its RSV vaccine technology for use in pregnant women in such low-resource countries. During the three months ended September 30, 2012, the Company recognized revenue of approximately \$0.2 million under the agreement. Revenue under this arrangement is being recognized under the proportional performance method and earned in proportion to the contract costs incurred in performance of the work as compared to total estimated contract costs. Costs incurred under this agreement represent a reasonable measurement of proportional performance of the work.

**Note 6 – Capital Lease**

In August 2012, the Company leased equipment under a capital lease with an effective interest rate of 6.5% with an advance payment and monthly payments of \$6,325 starting August 2012 and over the next 59 months. The capital lease is recorded at the present value of the future minimum lease payments. Future minimum capital lease payments under the capital lease agreement at September 30, 2012 are as follows (in thousands):

	Amount
2012	\$ 12
2013	76
2014	76
2015	76
2016	76
2017	44
	360
Less amounts representing interest	(51 )
Present value of net minimum lease payments	309
Less current portion of capital lease	(57 )
Non-current portion of capital lease	\$ 252

**Note 7 – Notes Payable**

In September 2012, the Company entered into a Master Security Agreement with General Electric Capital Corporation (“GE”), whereby the Company can borrow up to \$2.0 million to finance the purchases of equipment (“Equipment Loan”). Each Equipment Loan bears interest at the three-year U.S. Government treasury rate plus 11.68%, provided that the rate shall not be less than 12.1%, and is to be repaid over forty-two (42) months. GE will maintain a security interest in all equipment financed under this facility. During the three months ended September 30, 2012, the Company financed \$0.5 million at an interest rate of 12.1% with monthly principal payments of \$13,089 starting October 2012. Interest accrues on the outstanding balance until paid in full.

Aggregate future minimum principal payments on the GE Equipment Loan at September 30, 2012 are as follows (in thousands):

Year	Amount
2012	\$ 39
2013	157
2014	157
2015	157
2016	40
	\$ 550

#### Note 8 – 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, 2012 and 2011, the Company recorded as other income (expense) in its statements of operations and comprehensive loss a change in fair value of warrant liability of (\$0.4) million and \$2.0 million, respectively. As of September 30, 2012, the warrant liability recorded on the balance sheet was \$0.8 million and all Warrants remain outstanding as of that date.

#### Note 9 – Sales of Common Stock

The Board of Directors of the Company (the “Board”) has appointed a standing Finance Committee (the “Committee”) to assist the Board with its responsibilities to monitor, provide advice to senior management of the Company and approve all capital raising activities. The Committee has been authorized by the Board to approve all At Market Issuance sales transactions. In doing so, the Committee sets the amount of shares to be sold, the period of time during which such sales may occur and the minimum sales price per share. In September 2012, the Company entered into an At Market Issuance Sales Agreement, under which the Company may sell an aggregate of \$50 million in gross proceeds of its common stock. This agreement replaces the previous sales agreement entered in March 2010, which also allowed for the sale of an aggregate of \$50 million in gross proceeds of its common stock, but had recently met its limitation on sales of shares. The shares of common stock are being offered pursuant to a shelf registration statement previously filed with the SEC. For the nine months ended September 30, 2012, the Company sold 8.4 million shares at an average sales price of \$1.70 per share, resulting in \$14.0 million in net proceeds; this amount

excludes \$0.8 million received in early 2012 for 0.7 million shares traded in late December 2011. Since entering into the March 2010 sales agreement through November 7, 2012, the Company has sold 24,957,715 shares of its common stock and received gross proceeds of \$49.9 million. No sales have occurred under the September 2012 sales agreement.

In May 2012, the Company sold 10,000,000 shares of its common stock to two affiliates of RA Capital Management, LLC at a price of \$1.22 per share, resulting in \$12.1 million in net proceeds. The shares were offered under an effective shelf registration statement previously filed with the SEC.

#### Note 10 – Manufacturing, Laboratory and Office Facility

In November 2011, the Company entered into lease agreements, under which the Company leases its new manufacturing, laboratory and office space in Gaithersburg, Maryland. The lease agreements provide that, among other things, as of January 1, 2012, the Company sublease from the current facility tenant, and subsequently lease directly from the landlord, approximately 74,000 total square feet, with rent payments for such space to the landlord commencing April 1, 2014. Under the terms of the arrangement, the Landlord will provide the Company with a tenant improvement allowance of \$2.5 million and an additional tenant improvement allowance of \$3 million (collectively, the "Improvement Allowance"). The additional tenant improvement allowance is to be paid back to the Landlord over the remaining term of the lease agreement with an effective interest rate of 8.0%. During the nine months ended September 30, 2012, the Company was funded \$2.8 million under the Improvement Allowance. In addition, the Company purchased laboratory equipment under an agreement with the then current facility tenant. The Company is currently renovating the new facility and has started remarketing the Rockville, Maryland facility, which lease term ends January 31, 2017.

Note 11 – Master Services Agreement with Cadila

In connection with the JV with Cadila, the Company entered into a master services agreement, which the Company 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 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, 2012, the Company has purchased \$0.4 million in services from Cadila pursuant to this agreement. The Company plans to explore with Cadila ways to potentially reduce its financial obligation and/or extend the time period during which the Company could utilize such services. The Company can provide no assurance, however, that these efforts will be successful. If the Company fails to negotiate a change in this arrangement, the Company expects that it will be obligated to spend a significant portion of its available cash and cash equivalents to pay Cadila for our shortfall in services purchased.

**Note 12 – Subsequent Events**

In October 2012, the Company sold 12,385,321 shares of its common stock to two affiliates of RA Capital Management, LLC, three affiliates of Camber Capital Management LLC and three affiliates of Ayer Capital Management LLC at a price of \$2.18 per share, resulting in approximately \$26.9 million in net proceeds. The shares were offered under an effective shelf registration statement previously filed with the SEC.

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

Certain statements contained or incorporated by reference herein constitute forward-looking statements. In some cases, these statements can be identified by the use of forward-looking terminology such as "expect(s)," "intends," "plans," "seeks," "estimates," "could," "should," "feel(s)," "believe(s)," "will," "would," "may," "can," "anticipate(s)," "potential" and expressions or the negative of these terms. Such forward-looking statements are subject to risks and uncertainties that 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.

Forward-looking statements in this Quarterly Report on Form 10-Q include, without limitation, statements regarding:

- potential benefits, regulatory approval and commercialization of our vaccine candidates;

- our expectation that we will have adequate capital resources available to operate at planned levels for at least the next twenty-four months;

- our expected 2012 capital expenditures;

- our expectations for future revenue under the contract with the Department of Health and Human Services, Biomedical Advanced Research and Development Authority (HHS BARDA) and funding requirements and capital raising activity, including possible proceeds from our At Market Issuance Sales Agreement and funding under the Loan Agreement and Improvement Allowance;

- our expectations on financial or business performance, conditions or strategies and other financial and business matters, including expectations regarding operating expenses, use of cash, and the fluctuations in expenses and capital requirements associated with pre-clinical studies, clinical trials and other research and development activities;

- our expectations on clinical development and anticipated milestones, including under contracts with HHS BARDA, LG Life Sciences and PATH, our planned clinical trials and regulatory filings as necessary for our vaccine candidates;

- our expectations that our product candidates will prove to be safe and effective;



our expectations that our multivalent seasonal influenza virus-like particle (VLP) vaccine could potentially address an unmet medical need in older adults or children;

our expectation that our monovalent pandemic (H5N1) influenza vaccine could potentially be developed without an adjuvant for population segments that are sensitive to adjuvant use;

our expectations that our RSV vaccine could potentially address unmet medical needs;

our expectation that we will utilize the amount of services that is required to be provided by Cadila Pharmaceuticals Limited (Cadila) under the master services agreement and our ability to reduce our financial obligation and/or extend the period during which we could utilize such services;

our expectations regarding payments to Wyeth Holdings Corporation, a subsidiary of Pfizer Inc. (Wyeth);

our expectations concerning payments under existing license agreements; 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 recombinant protein nanoparticle vaccines to address a broad range of infectious diseases. Our goal is to become a profitable vaccine company that is aggressively driving towards development, licensure and commercialization of an important portfolio of vaccines worldwide.

Our technology platform is based on proprietary recombinant vaccine technology that includes VLPs and recombinant protein micelle vaccines combined with a single-use bioprocessing production system. Our vaccine candidates are genetically engineered three-dimensional nanostructures that incorporate immunologically important recombinant proteins. Our product pipeline targets a variety of infectious diseases and our vaccine candidates are currently in or have completed clinical trials that target pandemic (H5N1) influenza, seasonal influenza and respiratory syncytial virus (RSV).

CPL Biologicals Private Limited (the JV), our joint venture formed in 2009 between us and Cadila, of which 20% is owned by us and 80% is owned by Cadila. The JV will develop and manufacture our pandemic (H5N1) influenza 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 (H5N1) and seasonal influenza vaccines, as well as other vaccine candidates. The JV is actively developing a rabies vaccine candidate that was genetically engineered by Novavax; it recently completed initial pre-clinical immunogenicity studies on this vaccine candidate and is now complete with pre-clinical toxicology studies. 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 (H1N1) Influenza	Phase II (ended)
Pandemic (H5N1) Influenza	Phase I
Seasonal Influenza	Phase II
Respiratory Syncytial Virus (RSV)	Phase II
Rabies (through JV)	Pre-clinical

***HHS BARDA Contract Award for 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 both our seasonal and pandemic (H5N1) 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 fixed-fee earned in the further development of our multivalent seasonal and monovalent pandemic (H5N1) influenza vaccines.

Under certain circumstances HHS BARDA reimbursements may be delayed or even potentially withheld. In March 2012, we decided to conduct our Phase II dose-ranging clinical trial of our trivalent and quadrivalent seasonal influenza vaccine candidates (the 205 Trial) under our existing U.S. investigational new drug application (IND) for our trivalent seasonal influenza vaccine candidate (Trivalent IND) as opposed to waiting to conduct the 205 Trial under a new IND for our quadrivalent vaccine candidate (Quadrivalent IND). In July 2012, we reported that we expected to launch our next quadrivalent Phase II clinical trial in 2013 rather than in the second half of 2012; similarly, the filing of the Quadrivalent IND, which we had previously indicated was expected in the second half of 2012 will also be delayed. Based on our discussions with HHS BARDA, because the 205 Trial includes our quadrivalent seasonal influenza vaccine candidate, the outside clinical trial costs for the 205 Trial will only be submitted for reimbursement to HHS BARDA and recorded as revenue by us after we submit the 205 Trial data to our Quadrivalent IND. Until then, the outside clinical trial costs of the 205 Trial will be expensed and included in cost of government contracts revenue. The financial impact of this delay in revenue recognition is based on the outside clinical trial costs of the 205 Trial that are expected to total approximately \$3.1 million, of which \$2.8 million was incurred through September 30, 2012.

### ***Pandemic (H1N1) Influenza***

In 2009 and 2010, we dedicated significant resources to demonstrate our ability to develop a recombinant monovalent VLP vaccine against H1N1 influenza, which had been declared a pandemic. We produced a non-cGMP H1N1 VLP vaccine candidate within 3 weeks after the genetic sequence of the novel H1N1 influenza virus was announced and manufactured a cGMP vaccine candidate within 11 weeks of the announcement. We conducted a Phase II clinical trial in Mexico, in collaboration with Laboratorio Avi-Mex S.A. de C.V. and GE Healthcare; we published the final data results in 2011 and presented at the World Health Organization (WHO) Meeting for the Evaluation of Pandemic Influenza Vaccines in Clinical Trials. Our results showed that our H1N1 VLP influenza vaccine exceeded the immunogenicity criteria for seasonal influenza vaccine licensure at all dose levels, including the lowest 5µg dose and that a single administration of the VLP vaccine induced high levels of hemagglutination-inhibition (HAI) titers in subjects without pre-existing detectable immunity to H1N1 influenza. Although H1N1 influenza is no longer considered a pandemic and is being addressed as an active strain in the determination of ongoing seasonal influenza strains, we nevertheless expect that the data from our H1N1 clinical trials will be used to support our pandemic (H5N1) and seasonal influenza VLP vaccine programs in the U.S. and in other countries.

### ***Pandemic (H5N1) Influenza***

We have made significant progress in the development of our monovalent pandemic influenza vaccine that targets the H5N1 influenza strain. In 2007, we released results from an important 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 IND, 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 (H5N1) 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. The vaccine was well-tolerated at all dose levels as compared with placebo, and no serious adverse events were reported. The vaccine also induced robust HAI responses, which have been shown to be important for protection against influenza disease. In conjunction with our HHS BARDA contract, in May 2012, we launched two Phase I trials of our H5N1 vaccine candidate in combination with several alternative adjuvant candidates. These trials were designed to evaluate the safety and tolerability of the vaccines in the presence and absence of adjuvants; the ability of VLP vaccine antigens with and without adjuvants to generate antibody levels that fulfill the FDA's criteria for accelerated approval, and the ability of these vaccines to provide an expanded number of doses and possible cross-protection against other virus strains to the U.S. population. In October 2012, we reported positive results from these clinical trials. The data from the trials demonstrated the safety and immunogenicity of varying dose-levels of the vaccine, with and without adjuvant, and further demonstrated that statistically significant robust adjuvant effects on the immune responses were achieved. The vaccine safety was acceptable with no vaccine-related serious adverse events observed. Notably, in both trials the unadjuvanted vaccine elicited HAI titers  $\geq 40$  in  $>82\%$  of subjects at a dose of 45  $\mu\text{g}$ , which would fulfill FDA criteria for accelerated approval.

### *Seasonal Influenza*

We are actively developing our multivalent VLP vaccine that targets the seasonal influenza virus. In April 2010, we reported the final results of our Phase II trial in older adults (60 years of age or older) in a dose-ranging study comparing our seasonal trivalent (three strain) 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 CDC has indicated that currently approved seasonal influenza vaccines may be suboptimally effective in preventing hospitalization for pneumonia and influenza in older adults; however, we believe that some features of our seasonal influenza VLP vaccine have the potential to offer improved efficacy.

In March 2012, we initiated the 205 Trial. We developed a quadrivalent formulation of our seasonal influenza vaccine candidate as many influenza vaccine manufacturers move from trivalent to quadrivalent formulations, an industry move that has been acknowledged by WHO and the FDA. In July 2012, topline results for the 205 Trial were reported and demonstrated that the quadrivalent VLP vaccine candidate achieved its primary endpoints of safety and immunogenicity. The VLP vaccine candidate demonstrated immunogenicity against all four viral strains based on HAI responses at day 21, was also well-tolerated with no vaccine-related serious adverse events observed and reactogenicity was considered acceptable. We also announced that a secondary endpoint of the study was to evaluate the potential of the VLP vaccine candidate to fulfill the FDA Center for Biologics Evaluation and Research (CBER) criteria for accelerated approval, specifically by meeting certain seroconversion rates and seroprotection rates. The VLP vaccine candidate met the FDA seroprotection rates for all four viral strains; however, the seroconversion rates were met by three of the four viral strains. The fourth virus, B/Brisbane/60/08, despite fulfilling the seroprotection rates, failed to meet the seroconversion rates. In addition, we also compared the immunogenicity of the VLP vaccine candidate against that of a licensed TIV produced in eggs. In general, the results showed the comparator TIV to reach higher levels of HAI than our VLP vaccine candidate. Finally, we reported that we are evaluating further process development and assay refinements that we believe will further improve the immunogenicity profile of the VLP vaccine candidate and will delay the start of our next Phase II trial until 2013. The timing of the launch of our Phase III registration will be coordinated with the completion of the aforementioned Phase II trial launch in 2013.

### *Respiratory Syncytial Virus (RSV)*

We have developed a recombinant nanoparticle vaccine to prevent RSV. In pre-clinical studies, we have demonstrated positive results in models designed to test the safety and efficacy of our RSV vaccine candidate. In December 2010, we initiated a blinded, placebo-controlled, dose-escalating Phase I trial to assess the safety and tolerability of aluminum phosphate-adjuvanted and unadjuvanted formulations of our RSV vaccine candidate. A secondary objective of the study was to evaluate total and neutralizing anti-RSV antibody responses and assess the impact of the adjuvant. The study enrolled 150 healthy adults 18 to 49 years old who were allocated to six cohorts that included four dose levels of vaccine. The primary safety findings were local pain and tenderness at the site of injection, the majority of which were mild in nature with no dose-related increase observed. There were no observed vaccine-related serious

adverse events or trends for related systemic side effects. The antibody response to the RSV F protein was significantly increased compared to placebo ( $p < 0.001$ ) in all groups and increased by 19-fold in the highest-dose adjuvant group at day 60. A significant dose-response pattern was observed. High rates of seroconversion were seen at all doses including a rate of 100% at the highest-dose-adjuvant group. In October 2012, we initiated two separate dose-ranging clinical trials, one in women of child bearing age and the other in elderly adults. The first trial is a randomized, blinded, placebo-controlled Phase II trial that will evaluate the immunogenicity and safety of two dose levels of our RSV vaccine candidate with and without aluminum phosphate as an adjuvant, enrolling 330 women of childbearing age. Top-line data is expected to be reported in first quarter of 2013. The second trial is a randomized, blinded, placebo-controlled Phase I trial that will evaluate the immunogenicity and safety of two doses of our RSV vaccine candidate, also with and without aluminum phosphate as an adjuvant, enrolling 220 elderly adults. Top-line results are expected to be reported in the first half of 2013.

***License Agreement with LG Life Sciences, Ltd. (LGLS)***

In February 2011, we entered into a license agreement with LGLS that allows LGLS to use our 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 reimbursements of certain development and product costs, payments related to the achievement of certain milestones and royalty payments at a rate between 10% and 20% from LGLS's future commercial sales of influenza VLP vaccines, which royalty rate is subject to reduction if certain timelines for regulatory licensure are not met.

***Clinical Development Agreement with PATH Vaccine Solutions (PATH)***

In July 2012, we entered into a clinical development agreement with PATH to develop our vaccine candidate to protect against RSV through maternal immunization in low-resource countries (the "RSV Collaboration Program"). We were awarded approximately \$2.0 million by PATH for initial funding under the agreement to partially support our Phase II dose-ranging clinical trial in women of childbearing age as described above. The agreement would expire July 31, 2013, unless we and PATH decide to continue the RSV Collaboration Program. We retain global rights to commercialize the product and have made a commitment to make the vaccine affordable and available in low-resource countries. To the extent PATH has continued to fund 50% of our external clinical development costs for the RSV Collaboration Program, but we do not continue development, we would then grant PATH a fully-paid license to our RSV vaccine technology for use in pregnant women in such low-resource countries.

***Sales of Common Stock***

In October 2012, the Company sold 12,385,321 shares of its common stock to two affiliates of RA Capital Management, LLC (RA Capital), three affiliates of Camber Capital Management LLC and three affiliates of Ayer Capital Management LLC at a price of \$2.18 per share, resulting in approximately \$26.9 million in net proceeds. The shares were offered under an effective shelf registration statement previously filed with the SEC.

The Board of Directors of the Company (the "Board") has appointed a standing Finance Committee (the "Committee") to assist the Board with its responsibilities to monitor, provide advice to senior management of the Company and approve all capital raising activities. The Committee has been authorized by the Board to approve all At Market Issuance sales transactions. In doing so, the Committee sets the amount of shares to be sold, the period of time during



which such sales may occur and the minimum sales price per share. In September 2012, the Company entered into an At Market Issuance Sales Agreement, under which the Company may sell an aggregate of \$50 million in gross proceeds of its common stock. This agreement replaces the previous sales agreement entered in March 2010, which also allowed for the sale of an aggregate of \$50 million in gross proceeds of its common stock, but had recently met its limitation of sales of shares. 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, 2012, the Company sold 8.4 million shares at an average sales price of \$1.70 per share, resulting in \$14.0 million in net proceeds; this amount excludes \$0.8 million received in early 2012 for 0.7 million shares traded in late December 2011. Since entering into the March 2010 sales agreement through November 7, 2012, the Company has sold 24,957,715 shares of its common stock and received gross proceeds of \$49.9 million. No sales have occurred under the September 2012 sales agreement.

In May 2012, we sold 10,000,000 shares of our common stock to two affiliates of RA Capital at a price of \$1.22 per share, resulting in \$12.1 million in net proceeds. The shares were offered under an effective shelf registration statement previously filed with the SEC.

***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, 2011, as filed with the SEC.

***Recent Accounting Pronouncements Not Yet Adopted***

We have considered the applicability and impact of all Financial Accounting Standards Board’s Accounting Standards Updates (ASUs). Recently issued ASUs were evaluated and determined to be not applicable in this Quarterly Report.

**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, 2012 and 2011** (amounts in tables are presented in thousands, except per share information)

**Revenue:**

<b>Three Months Ended</b>		
<b>September 30,</b>		
		<b>Change</b>
2012	2011	<b>2011 to</b>
		<b>2012</b>
Revenue:		
Total revenue	\$5,765	\$5,008
		\$ 757

Revenue for the three months ended September 30, 2012 was \$5.8 million as compared to \$5.0 million for the same period in 2011, an increase of \$0.8 million or 15%. Revenue for 2012 and 2011 is primarily comprised of services performed under the HHS BARDA contract that was awarded in February 2011. The increase in revenue relates to increased costs associated with our product development activities and clinical trials performed under the HHS BARDA contract.

Revenue for the three months ended September 30, 2012 was negatively impacted due to the Company electing to conduct the 205 Trial without immediate HHS BARDA reimbursement of its outside clinical trial costs, which are expected to total approximately \$3.1 million, of which \$0.4 million was incurred during the three months ended September 30, 2012 (see discussion of the 205 Trial in *Management's Discussion and Analysis of Financial Condition and Results of Operations—Overview* on page 17). In July 2012, we reported that we expected to launch our next quadrivalent Phase II clinical trial in 2013 rather than in the second half of 2012; similarly, the filing of the Quadrivalent IND, which we had previously indicated was expected in the second half of 2012 will also be delayed. Until then, we will not record revenue associated with the outside clinical trial costs of our 205 Trial and such costs will be expensed and included in cost of government contracts revenue. For 2012, we expect to generate significant revenue from conducting multiple clinical trials, ongoing process development and the manufacture of clinical materials under the HHS BARDA contract.

**Costs and Expenses:**

	Three Months Ended September 30,		<b>Change 2011 to 2012</b>
	2012	2011	
Costs and Expenses:			
Cost of government contracts revenue	\$3,838	\$2,190	\$1,648
Research and development	6,395	4,049	2,346
General and administrative	2,381	2,737	(356 )
Total costs and expenses	\$12,614	\$8,976	\$3,638

***Cost of Government Contracts Revenue***

Cost of government contracts revenue was \$3.8 million for the three months ended September 30, 2012 as compared to \$2.2 million for the same period in 2011, an increase of \$1.6 million, primarily due to increased costs associated with our product development activities and clinical trials performed under the HHS BARDA contract that was awarded in February 2011. These costs include direct costs of salaries, laboratory supplies, consultants and subcontractors and other direct costs associated with our process development, manufacturing, clinical, regulatory and quality assurance activities under government research contracts.

Cost of government contracts revenue for the three months ended September 30, 2012 includes \$0.4 million of direct clinical trial costs of our 205 Trial (see discussion of the 205 Trial in *Management's Discussion and Analysis of Financial Condition and Results of Operations—Overview* on page 17). For 2012, we expect a significant increase in the cost of government contracts revenue from conducting multiple clinical trials, ongoing process development and the manufacture of clinical materials under the HHS BARDA contract.

***Research and Development Expenses***

Research and development expenses were \$6.4 million for the three months ended September 30, 2012, as compared to \$4.0 million for the same period in 2011, an increase of \$2.3 million or 58%, primarily due to increased costs relating to our RSV clinical trials, higher employee-related costs and expenses associated with our new manufacturing facility. Research and development expenses include salaries, laboratory supplies, consultants and subcontractors and other expenses associated with our process development, manufacturing, clinical, regulatory and quality assurance activities for internally funded programs and our collaboration agreements. In addition, indirect costs, such as fringe benefits and overhead expenses, are also included in research and development expenses. For 2012, we expect a

continued increase in research and development expenses primarily due to two anticipated clinical trials in RSV (an internally funded program at this time), higher employee-related costs and expenses associated with our new manufacturing facility.

***Costs and Expenses by Functional Area***

We track our cost of contract revenue and 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. At September 30, 2012, we had 98 employees dedicated to our research and development programs versus 83 employees as of September 30, 2011. Historically, we did not account for internal research and development expenses by project, since our employees work time is spread across multiple programs and our internal manufacturing clean-room facility produces multiple vaccine candidates.

The following summarizes our cost of government contracts revenue and research and development expenses by functional area for the three months ended September 30 (in millions).

	2012	2011
Manufacturing	\$5.0	\$3.3
Vaccine Discovery	0.9	0.8
Clinical & Regulatory	4.3	2.1
Total cost of government contracts revenue and research and development expenses	\$10.2	\$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 \$2.4 million for the three months ended September 30, 2012 as compared to \$2.7 million for the same period in 2011, a decrease of \$0.4 million or 13%. The decrease in expenses was primarily due to lower professional fees, partially offset by non-cash expenses associated with our new office facility. For 2012, we expect a slight decrease in general and administrative expenses primarily due to lower employee-related costs, including severance expenses, partially offset by non-cash expenses associated with our new office facility that we leased along with our new manufacturing facility.

**Other Income (Expense):**

	<b>Three Months Ended</b>		
	<b>September 30,</b>		
	<b>2012</b>	<b>2011</b>	<b>Change 2011 to 2012</b>
Other Income (Expense):			
Interest income	\$39	\$22	\$17
Interest expense	(3 )	(2 )	(1 )
Change in fair value of warrant liability	(401)	736	(1,137)
Total other income (expense)	\$(365)	\$756	\$(1,121)

We had total other expense of \$0.4 million for the three months ended September 30, 2012 compared to total other income of \$0.8 million for the same period in 2011, a change of \$1.1 million. We are required to calculate the fair value of our warrant liability at each reporting period. For the three months ended September 30, 2012 as compared to the same period in 2011, the change in the fair value of the warrant liability resulted in a \$1.1 million decrease in total other income.

**Net Loss:**

	<b>Three Months Ended</b>		
	<b>September 30,</b>		
	<b>2012</b>	<b>2011</b>	<b>Change 2011 to 2012</b>
Net Loss:			
Net loss	\$(7,217 )	\$(3,212 )	\$(4,005 )
Net loss per share	\$(0.05 )	\$(0.03 )	\$(0.02 )
Weighted shares outstanding	134,178	115,107	19,071

Net loss for the three months ended September 30, 2012 was \$7.2 million, or \$0.05 per share, as compared to \$3.2 million, or \$0.03 per share, for the same period in 2011, an increased net loss of \$4.0 million, or 125%. The increase in net loss is primarily due to higher research and development costs and lower other income relating to the change in fair value of our warrant liability.



The increase in weighted shares outstanding for the three months ended September 30, 2012 is primarily a result of sales of our common stock under our At Market Issuance Sales Agreement and to RA Capital.

**Nine Months Ended September 30, 2012 and 2011** (amounts in tables are presented in thousands, except per share information)

**Revenue:**

<b>Nine Months Ended</b>			
<b>September 30,</b>			<b>Change</b>
<b>2012</b>	<b>2011</b>		<b>2011 to</b>
			<b>2012</b>
Revenue:			
Total revenue	\$17,510	\$8,843	\$8,667

Revenue for the nine months ended September 30, 2012 was \$17.5 million as compared to \$8.8 million for the same period in 2011, an increase of \$8.7 million or 98%. Revenue for 2012 and 2011 is primarily comprised of services performed under the HHS BARDA contract that was awarded in February 2011. The increase in revenue relates to increased costs associated with our product development activities and clinical trials performed under the HHS BARDA contract.

Revenue for the nine months ended September 30, 2012 was negatively impacted due to the Company electing to conduct the 205 Trial without immediate HHS BARDA reimbursement of its outside clinical trial costs, which are expected to total approximately \$3.1 million, of which \$2.8 million was incurred through September 30, 2012 (see discussion of the 205 Trial in *Management's Discussion and Analysis of Financial Condition and Results of Operations—Overview* on page 17). In July 2012, we reported that we expected to launch our next quadrivalent Phase II clinical trial in 2013 rather than in the second half of 2012; similarly, the filing of the Quadrivalent IND, which we had previously indicated was expected in the second half of 2012 will also be delayed. Until then, we will not record revenue associated with the outside clinical trial costs of our 205 Trial and such costs will be expensed and included in cost of government contracts revenue.

### **Costs and Expenses:**

	<b>Nine Months Ended</b>		
	<b>September 30,</b>		
	2012	2011	<b>Change 2011 to 2012</b>
Costs and Expenses:			
Cost of government contracts revenue	\$12,740	\$3,763	\$8,977
Research and development	16,649	13,474	3,175
General and administrative	8,291	8,926	(635 )
Total costs and expenses	\$37,680	\$26,163	\$11,517

### ***Cost of Government Contracts Revenue***

Cost of government contracts revenue was \$12.7 million for the nine months ended September 30, 2012 as compared to \$3.8 million for the same period in 2011, an increase of \$9.0 million, primarily due to increased costs associated with our product development activities and clinical trials performed under the HHS BARDA contract that was awarded in February 2011. These costs include direct costs of salaries, laboratory supplies, consultants and subcontractors and other direct costs associated with our process development, manufacturing, clinical, regulatory and quality assurance activities under government research contracts.

Cost of government contracts revenue for the nine months ended September 30, 2012 includes \$2.6 million of direct clinical trial costs of our 205 Trial (see discussion of the 205 Trial in *Management's Discussion and Analysis of Financial Condition and Results of Operations—Overview* on page 17).

***Research and Development Expenses***

Research and development expenses were \$16.6 million for the nine months ended September 30, 2012 as compared to \$13.5 million for the same period in 2011, an increase of \$3.2 million or 24%, primarily due to higher employee-related costs and expenses associated with our new manufacturing facility, partially offset by higher RSV clinical trial costs in 2011. Research and development expenses include salaries, laboratory supplies, consultants and subcontractors and other expenses associated with our process development, manufacturing, clinical, regulatory and quality assurance activities for internally funded programs and our collaboration agreements. In addition, indirect costs, such as fringe benefits and overhead expenses, are also included in research and development expenses.

***Costs and Expenses by Functional Area***

The following summarizes our cost of government contracts revenue and research and development expenses by functional area for the nine months ended September 30 (in millions).

	2012	2011
Manufacturing	\$14.2	\$9.5
Vaccine Discovery	2.5	2.4
Clinical & Regulatory	12.7	5.3
Total cost of government contracts revenue and research and development expenses	\$29.4	\$17.2

***General and Administrative Expenses***

General and administrative expenses were \$8.3 million for the nine months ended September 30, 2012 as compared to \$8.9 million for the same period in 2011, a decrease of \$0.6 million or 7%. The decrease in expenses was primarily due to lower employee-related costs, including severance expenses, partially offset by non-cash expenses associated with our new office facility.

**Other Income (Expense):**

	<b>Nine Months Ended</b>		
	<b>September 30,</b>		<b>Change</b>
	2012	2011	<b>2011 to 2012</b>
Other Income (Expense):			
Interest income	\$111	\$106	\$5
Interest expense	(12 )	(6 )	(6 )
Change in fair value of warrant liability	(401)	1,973	(2,374)
Total other income (expense)	\$(302)	\$2,073	\$(2,375)

We had total other expense of \$0.3 million for the nine months ended September 30, 2012 compared to total other income of \$2.1 million for the same period in 2011, a change of \$2.4 million. We are required to calculate the fair value of our warrant liability at each reporting period. For the nine months ended September 30, 2012 as compared to the same period in 2011, the change in fair value of the warrant liability resulted in a \$2.4 million decrease in total other income.

**Income Tax:**

**Nine Months  
Ended**

**September 30,**

**Change**

**2012 2011 2011 to**

**2012**

Income Tax:

Total income tax expense \$—\$412 \$ (412 )

Income tax expense for the nine months ended September 30, 2011 was \$0.4 million. We incurred a foreign withholding tax related to a payment received in accordance with a license agreement.

Net Loss:**Nine Months Ended****September 30,**

	2012	2011	<b>Change 2011 to 2012</b>
Net Loss:			
Net loss	\$(20,472 )	\$(15,659 )	\$(4,813 )
Net loss per share	\$(0.16 )	\$(0.14 )	\$(0.02 )
Weighted shares outstanding	127,246	113,053	14,193

Net loss for the nine months ended September 30, 2012 was \$20.5 million, or \$0.16 per share, as compared to \$15.7 million, or \$0.14 per share, for the same period in 2011, an increased net loss of \$4.8 million, or 31%. The increase in net loss is primarily due to higher research and development costs and lower other income relating to the change in the fair value of our warrant liability.

The increase in weighted shares outstanding for the nine months ended September 30, 2012 is primarily a result of sales of our common stock under our At Market Issuance Sales Agreement and to RA Capital.

**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 vaccines and products in various stages of development, and we believe our operating 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 September 30, 2012, we had \$28.4 million in cash and cash equivalents and short-term investments as compared to \$18.3 million as of December 31, 2011, which consists of \$10.7 million in cash and cash equivalents and \$17.7 million in short-term investments as of September 30, 2012 as compared to \$14.1 million and \$4.2 million, respectively, at December 31, 2011. The following table summarizes cash flows for the nine months ended September 30, 2012 and 2011 (in thousands):

	Nine Months Ended September 30,		<b>Change 2011 to 2012</b>
	2012	2011	
Summary of Cash Flows:			
Net cash (used in) provided by:			
Operating activities	\$(14,139)	\$(20,760)	\$6,621
Investing activities	(15,147)	17,739	(32,886)
Financing activities	25,920	9,278	16,642
Net (decrease) increase in cash and cash equivalents	(3,366 )	6,257	(9,623 )
Cash and cash equivalents at beginning of period	14,104	8,061	6,043
Cash and cash equivalents at end of period	\$10,738	\$14,318	\$(3,580 )

Net cash used in operating activities decreased to \$14.1 million for the nine months ended September 30, 2012 as compared to \$20.8 million for the same period in 2011, respectively. The decrease in cash usage was primarily due to the timing of our vendor payments and funds received under our Improvement Allowance.

During the nine months ended September 30, 2012 and 2011, our investing activities included purchases and maturities of short-term investments and capital expenditures. In the nine months ended September 30, 2012, we primarily purchased short-term investments to increase our rate of return on our investments. In the same period in 2011, we primarily utilized our short-term investments to fund operations and increase our cash balances. Capital expenditures for the nine months ended September 30, 2012 and 2011 were \$2.2 million and \$0.4 million, respectively. The increase in capital expenditures was primarily due to purchase of laboratory equipment and tenant improvements relating to our new manufacturing facility. For 2012, we expect our level of capital expenditures to increase in connection with the scale-up of our new manufacturing facility.

The increase in our financing activities consists primarily of increased sales of our common stock. We received net proceeds of \$26.9 million in the nine months ended September 30, 2012 as compared to \$9.2 million in the same period of 2011 from the sale of our common stock to RA Capital and through our At Market Issuance Sales Agreement.

In November 2011, we entered into lease agreements, under which we lease our new manufacturing, laboratory and office space in Gaithersburg, Maryland. The lease agreements provide that, among other things, as of January 1, 2012, we sublease from the current facility tenant, and subsequently lease directly from the landlord, approximately 74,000 total square feet, with rent payments for such space to the landlord commencing April 1, 2014. Under the terms of the arrangement, the Landlord will provide us with a tenant improvement allowance of \$2.5 million and an additional tenant improvement allowance of \$3 million (collectively, the Improvement Allowance). The additional tenant improvement allowance is to be paid back to the Landlord over the remaining term of the lease agreement with an effective interest rate of 8.0%. During the nine months ended September 30, 2012, the Company was funded \$2.8 million. In addition, we purchased laboratory equipment under an agreement with the then current facility tenant and are currently renovating the new facility.

We have entered into agreements with outside providers to support our clinical development. As of September 30, 2012, \$8.0 million remains unpaid on certain of these agreements in the event our outside providers complete their services in 2012. However, under the terms of the agreements, we have the option to terminate for convenience pursuant to notification, but we would be obligated to pay the provider for all costs incurred through the effective date of termination.

We have licensed certain rights from Wyeth. 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; 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. Payments under the agreement to Wyeth from 2007 through September 30, 2012 totaled \$5.5 million, of which \$0.4 million was paid in the nine months ended September 30, 2012. We do not expect to make a milestone payment to Wyeth 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 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, 2012, we have purchased \$0.4 million in services from Cadila pursuant to this agreement. We plan to explore with Cadila ways to potentially reduce our financial obligation and/or extend the time period during which we could utilize such



services. We can provide no assurance, however, that these efforts will be successful. If we fail to negotiate a change in this arrangement, we expect that we will be obligated to spend a significant portion of our available cash and cash equivalents to pay Cadila for our shortfall in services purchased.

Based on our current cash and cash equivalents and short-term investments, including our recent private equity offering, 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 Issuance Sales Agreement and our current business operations, we believe we have adequate capital resources available to operate at planned levels for at least the next twenty-four months. Additional capital will be required in the future to develop our vaccine candidates through clinical development, manufacturing and commercialization. Our ability to obtain such additional capital is subject to various factors:

generating revenue under the HHS BARDA contract is subject to our performance under the contract, including our ability to collect on delayed reimbursement situations, such as the 205 Trial costs; and

raising funds under our At Market Issuance 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 Issuance Sales Agreement, Equipment Loan and Improvement Allowance, 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, and/or downsize our organization, including 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, 2012, we had cash and cash equivalents of \$10.7 million, short-term investments of \$17.7 million and working capital of \$26.0 million.

Our exposure to market risk is primarily confined to our investment portfolio. As of September 30, 2012, 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.

In 2007, we invested in auction rate securities as part of our cash management program. Short-term investments at September 30, 2012 are comprised of investments in commercial paper, corporate notes and three auction rate securities with a par value of \$5.1 million and a fair value of \$4.4 million. At September 30, 2012, we have recorded \$1.0 million in unrealized gains on the auction rate securities included in accumulated 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 the sale of our securities.

We are headquartered in the U.S. 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, 2012. 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, 2012, 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 2012, and has concluded that there was no change that occurred during the third quarter of 2012 that materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

## **PART II. OTHER INFORMATION**

#### **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, 2011, as filed with the SEC.

**Item 6. Exhibits**

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

- At Market Issuance Sales Agreement, dated October 1, 2012, by and between Novavax, Inc. and MLV & Co.
- 10.1 LLC (Incorporated by reference to Exhibit 1.1 to the Company's Current Report on Form 8-K, filed October 2, 2012)
  - 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 9, 2012 By: /s/ Stanley C. Erck  
President and Chief  
Executive Officer  
and Director  
(Principal Executive  
Officer)

Date: November 9, 2012 By: /s/ Frederick W. Driscoll  
Vice President, Chief  
Financial Officer and  
Treasurer  
(Principal Financial and  
Accounting Officer)