

NOVAVAX INC  
Form 10-Q  
May 09, 2013

UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-Q

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

**For the quarterly period ended March 31, 2013**

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 20850**  
(Address of principal executive offices)

**(Zip code)**

**(240) 268-2000**

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Indicate by check mark whether the Registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the Registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes  No

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

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

Large accelerated filer <input type="checkbox"/>	Accelerated filer <input checked="" type="checkbox"/>	Non-accelerated filer <input type="checkbox"/>	Smaller reporting company <input type="checkbox"/>
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(Do not check if a smaller reporting company)

Indicate by check mark whether the Registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).  
Yes  No

The number of shares outstanding of the Registrant’s Common Stock, \$0.01 par value, was 152,464,007 as of April 30, 2013.

**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)

	March 31, 2013 (unaudited)	December 31, 2012
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 9,023	\$ 17,399
Short-term investments available-for-sale	35,256	26,712
Restricted cash	217	986
Accounts receivables	2,602	1,011
Unbilled receivables	1,571	1,570
Prepaid expenses	2,167	2,559
Other current assets	886	171
Total current assets	51,722	50,408
Investments available-for-sale	1,117	6,233
Property and equipment, net	11,617	11,456
Goodwill	33,141	33,141
Restricted cash	757	756
Other non-current assets	350	351
Total assets	\$ 98,704	\$ 102,345
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 2,173	\$ 3,228
Accrued expenses and other current liabilities	5,842	7,275
Deferred revenue	78	258
Current portion of capital lease	59	58
Current portion of notes payable	390	157
Warrant liability	267	267
Deferred rent	444	432
Total current liabilities	9,253	11,675
Deferred revenue	2,500	2,500
Non-current portion of capital lease	222	237
Non-current portion of notes payable	1,290	753
Deferred rent	7,871	6,940

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Total liabilities	21,136	22,105
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 151,700,247 shares issued and 151,244,817 shares outstanding at March 31, 2013 and 148,398,747 shares issued and 147,943,317 shares outstanding at December 31, 2012	1,517	1,484
Additional paid-in capital	446,191	438,939
Accumulated deficit	(368,159 )	(358,163 )
Treasury stock, 455,430 shares, cost basis	(2,450 )	(2,450 )
Accumulated other comprehensive income	469	430
Total stockholders' equity	77,568	80,240
Total liabilities and stockholders' equity	\$ 98,704	\$ 102,345

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

NOVAVAX, INC.

## STATEMENTS OF OPERATIONS

(in thousands, except per share information)

(unaudited)

	<b>For the Three Months Ended March 31,</b>	
	2013	2012
Revenue:		
Government contracts	\$ 3,441	\$ 4,642
Research and development collaborations	392	.
Total revenue	3,833	4,642
Costs and expenses:		
Cost of government contracts revenue	1,712	3,786
Research and development	9,432	5,338
General and administrative	2,694	2,985
Total costs and expenses	13,838	12,109
Loss from operations	(10,005 )	(7,467 )
Other income (expense):		
Interest income	48	33
Interest expense	(22 )	(3 )
Change in fair value of warrant liability	—	101
Loss from operations before income tax	(9,979 )	(7,336 )
Income tax expense	17	—
Net loss	\$ (9,996 )	\$ (7,336 )
Basic and diluted net loss per share	\$ (0.07 )	\$ (0.06 )
Basic and diluted weighted average number of common shares outstanding	148,448	120,558

## STATEMENTS OF COMPREHENSIVE LOSS

(in thousands)

(unaudited)

**For the Three Months  
Ended March 31,**

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	2013	2012
Comprehensive loss:		
Net loss	\$ (9,996 )	\$ (7,336 )
Unrealized gain on investments available-for-sale	39	144
Comprehensive loss	\$ (9,957 )	\$ (7,192 )

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

NOVAVAX, INC.

## STATEMENTS OF CASH FLOWS

(in thousands)

(unaudited)

	<b>For the Three Months Ended March 31,</b>	
	2013	2012
<b>Operating Activities:</b>		
Net loss	\$ (9,996 )	\$ (7,336 )
Reconciliation of net loss to net cash used in operating activities:		
Change in fair value of warrant liability	—	(101 )
Depreciation and amortization	449	404
Amortization of net premiums on investments	94	—
Gain on disposal of property and equipment	(17 )	—
Deferred rent	240	336
Non-cash stock-based compensation	483	587
Changes in operating assets and liabilities:		
Restricted cash	769	—
Accounts receivables	(1,591 )	240
Unbilled receivables	(1 )	427
Prepaid expenses and other assets	54	183
Accounts payable and accrued expenses	(1,590 )	(517 )
Deferred revenue	(180 )	—
Lease incentives received	703	1,557
Net cash used in operating activities	(10,583 )	(4,220 )
<b>Investing Activities:</b>		
Capital expenditures	(1,542 )	(772 )
Proceeds from disposal of property and equipment	51	—
Proceeds from maturities of investments	5,235	—
Purchases of investments	(8,718 )	(2,498 )
Net cash used in investing activities	(4,974 )	(3,270 )
<b>Financing Activities:</b>		
Principal payments of capital lease	(14 )	—
Principal payments of notes payable	(39 )	(13 )
Proceeds from notes payable	809	100
Restricted cash	(1 )	(755 )
Net proceeds from sales of common stock, net of offering costs of \$0.2 million and \$0.1 million, respectively	6,425	7,923
Proceeds from the exercise of stock options	1	4
Net cash provided by financing activities	7,181	7,259



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Net decrease in cash and cash equivalents	(8,376 )	(231 )
Cash and cash equivalents at beginning of period	17,399	14,104
Cash and cash equivalents at end of period	\$ 9,023	\$ 13,873
Supplemental disclosure of non-cash activities:		
Sale of common stock under the 2012 Sales Agreement not settled at quarter-end	\$ 376	\$ —
Property and equipment purchases included in accounts payable and accrued expenses	\$ 422	\$ 224
Deposit applied towards the purchase of laboratory equipment	\$ —	\$ 500
Supplemental disclosure of cash flow information:		
Cash payments of interest	\$ 20	\$ —

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

NOVAVAX, INC.

NOTES TO FINANCIAL STATEMENTS

March 31, 2013

(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 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 seasonal influenza, pandemic (H5N1) 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. Since the carrying value of the Company’s initial investment was nominal and there is no guarantee or commitment to provide future funding, the Company has not recorded any losses related to this investment.

Note 2 – Operations

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.

As a clinical-stage biopharmaceutical company, the Company has primarily funded its operations from proceeds through the sale of its common stock in equity offerings and under its At Market Issuance Sales Agreements and

revenue under its contract with the Department of Health and Human Services, Biomedical Advanced Research and Development Authority (“HHS BARDA”). Management regularly reviews the Company’s cash and cash equivalents and investments against its operating budget to ensure the Company will have sufficient working capital, and will continue to draw upon such available sources of capital to meet its operating needs.

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 March 31, 2013, statements of operations and statements of comprehensive loss for the three months ended March 31, 2013 and 2012 and the statements of cash flows for the three months ended March 31, 2013 and 2012 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, comprehensive loss 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, 2012.

### *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.

### Investments

Investments consist of commercial paper, corporate notes and an investment in one auction rate security. Classification of marketable securities between current and non-current is dependent upon the original maturity date at purchase. Those securities purchased with original maturities greater than 90 days, but less than one year are classified

as current and those with greater than one year are classified as non-current.

Interest and dividend income is recorded when earned and included in interest income. Premiums and discounts, if any, on 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 the Company's securities.

The Company has classified its investments as available-for-sale since the Company may need to liquidate these securities within the next year. The available-for-sale securities are carried at fair value and unrealized gains and losses on these securities, if determined to be temporary, are included in accumulated other comprehensive income (loss) in stockholders' equity. Investments 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 statement of operations.

## Restricted Cash

The Company's restricted cash includes payments received under the PATH agreement (See Note 7) until such time as the Company has paid for the work performed for the related Phase II RSV clinical trial. In addition, the Company's non-current 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.

## *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 15,722,925 shares and 14,383,567 shares at March 31, 2013 and 2012, respectively, are excluded from the computation, as their effect is antidilutive.

## *Reclassifications*

Within the March 31, 2012 statement of operations, certain expenses relating to patent and other costs of \$0.3 million have been reclassified from general and administrative expenses to research and development expenses. Also, within the March 31, 2012 statement of cash flows, additional lease incentives received of \$0.6 million recorded in the change in accounts payable and accrued expenses have been reclassified and are included in the change in lease incentives received. All of these reclassifications have been made to conform to current year presentation.

## **Note 4 – Fair Value Measurements**

The following table represents the Company's fair value hierarchy for its financial assets and liabilities measured at fair value on a recurring basis (in thousands):

	Fair Value at March 31, 2013			Fair Value at December 31, 2012		
	Level 1	Level 2	Level 3	Level 1	Level 2	Level 3
<u>Assets</u>						
Corporate debt securities and auction rate securities	\$ —	\$ 36,373	\$ —	\$ —	\$ 32,945	\$ —

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Total investments	\$ —	\$ 36,373	\$ —	\$ —	\$ 32,945	\$ —
Liabilities						
Warrant liabilities	\$ —	\$ —	\$ 267	\$ —	\$ —	\$ 267

During the three months ended March 31, 2013, the Company did not have any transfers between levels.

The following table provides a reconciliation of the beginning and ending balance of Level 3 assets and liabilities measured on a recurring basis for the three months ended March 31, 2013 (in thousands):

	<b>Fair Value Measurements of Warrants Using Significant Unobservable Inputs (Level 3)</b>	
Balance at December 31, 2012	\$	267
Change in fair value of Warrant liability		—
Balance at March 31, 2013	\$	267

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.

#### Note 5 – Investments

Investments classified as available-for-sale as of March 31, 2013 and December 31, 2012 were comprised of (in thousands):

	March 31, 2013				December 31, 2012			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Auction rate securities	\$ 1,175	\$ 459	\$	— \$ 1,634	\$ 1,175	\$ 409	\$	— \$ 1,584
Corporate debt securities	34,729	10		— 34,739	31,340	21		— 31,361
Total	\$35,904	\$ 469	\$	— \$ 36,373	\$32,515	\$ 430	\$	— \$ 32,945

#### Note 6 – 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 Company will seek approval at its 2013 annual meeting of stockholders to increase the number of shares of common stock available for issuance under the 2005 Plan by 4,000,000 shares. 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 as follows (in thousands):

	<b>Three Months Ended</b>	
	<b>March 31,</b>	
	2013	2012
Research and development	\$ 217	\$ 183
General and administrative	266	404
Total stock-based compensation expense	\$ 483	\$ 587

### *Stock Options Awards*

The following is a summary of option activity under the 2005 Plan and the 1995 Plan for the three months ended March 31, 2013:

	2005 Stock Incentive Plan		1995 Stock Option Plan	
	<b>Stock Options</b>	<b>Weighted-Average Exercise Price</b>	<b>Stock Options</b>	<b>Weighted-Average Exercise Price</b>
Outstanding at January 1, 2013	9,143,825	\$ 1.87	211,900	\$ 4.94
Granted	3,347,500	\$ 1.83	—	\$ —
Exercised	(1,500 )	\$ 0.56	—	\$ —
Canceled	(355,458 )	\$ 1.62	—	\$ —
Outstanding at March 31, 2013	12,134,367	\$ 1.87	211,900	\$ 4.94
Shares exercisable at March 31, 2013	4,442,548	\$ 2.18	211,900	\$ 4.94
Shares available for grant at March 31, 2013	2,760,319			

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>March 31,</b>	
	2013	2012
Weighted-average fair value of stock options granted	\$1.00	\$0.71
Risk-free interest rate	0.62%-1.34%	0.82%-1.54%
Dividend yield	0%	0%
Volatility	69.23%-73.72%	75.52%-80.48%

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Expected term (in years)	4.06-7.05	3.34-7.09
Expected forfeiture rate	0%-23.15%	0%-23.15%

The aggregate intrinsic value and weighted-average remaining contractual term of stock options outstanding as of March 31, 2013 was approximately \$6.6 million and 7.9 years, respectively. The aggregate intrinsic value and weighted-average remaining contractual term of stock options exercisable as of March 31, 2013 was approximately \$1.9 million and 6.0 years, respectively. The aggregate intrinsic value represents the total intrinsic value (the difference between the Company's closing stock price on the last trading day of the period and the exercise price, multiplied by the number of in-the-money options) that would have been received by the option holders had all option holders exercised their options on March 31, 2013. This amount is subject to change based on changes to the fair value of the Company's common stock. The aggregate intrinsic value of options exercised for the three months ended March 31, 2013 and 2012 was less than \$0.1 million.

***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 three months ended March 31, 2013:

	<b>Number of Shares</b>	<b>Per Share Weighted- Average Grant-Date Fair Value</b>
Outstanding at January 1, 2013	33,334	\$ 1.39
Restricted stock granted	—	\$ —
Restricted stock vested	—	\$ —
Restricted stock forfeited	—	\$ —
Outstanding at March 31, 2013	33,334	\$ 1.39

As of March 31, 2013, there was approximately \$5.1 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 1.7 years. This estimate does not include the impact of other possible stock-based awards that may be made during future periods.

Note 7 – U.S. Government Agreement and Collaborations

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

In February 2011, the Company was awarded a contract from HHS BARDA valued at \$97 million for the first three-year base-period, with an HHS BARDA option for an additional two-year period 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 allowable 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. An audit by the government of fiscal year 2011 has been initiated, but has not been completed as of the date of this filing. When the final determination of the allowable costs for any year has been made, revenue and billings may be adjusted accordingly; 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 recognized revenue of approximately \$3.3 million in the three months ended March 31, 2013, and has recognized approximately \$38 million in revenue since the inception of the contract.

Under certain circumstances, HHS BARDA reimbursements may be delayed or even potentially withheld. In March 2012, the Company decided to conduct a Phase II clinical trial of its quadrivalent seasonal influenza vaccine candidate ("205 Trial") under its existing U.S. investigational new drug application ("IND") for its trivalent seasonal influenza vaccine candidate as opposed to waiting to conduct this clinical trial under a new IND for its quadrivalent vaccine candidate ("Quadrivalent IND"). Based on the Company's discussions with HHS BARDA in 2012, the outside clinical trial costs for the 205 Trial may only be submitted for reimbursement to HHS BARDA and recorded as revenue by the Company after it submits the clinical trial data in a future Quadrivalent IND. The submission of the Quadrivalent IND is expected shortly before the Company initiates the next Phase II dose-confirmatory clinical trial, which has been delayed due to the development activity associated with improving the seroconversion rate of one of the four strains. The outside clinical trial costs of the 205 Trial conducted last year are expected to total approximately \$3.1 million, of which \$3.0 million was incurred from the inception of the clinical trial through March 31, 2013. These costs have been recorded as an expense and are included in cost of government contracts revenue.

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

In February 2011, the Company entered into a license agreement with 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 both its clinical development of the influenza VLP vaccines and a manufacturing facility to produce such vaccine 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 of 10% 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 (“PATH”) Clinical Development Agreement***

In July 2012, the Company entered into a clinical development agreement with 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 expires 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 elected to continue 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. The Company recognized revenue of approximately \$0.4 million in the three months ended March 31, 2013, and has recognized approximately \$1.7 million in revenue since the inception of the contract. 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 8 – 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 through June 2013 (“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 the Equipment Loan. During the three months ended March 31, 2013, the Company financed \$0.8 million at an interest rate of 12.1% with monthly principal payments of \$19,426 starting April 2013 (“2013 Funding”). Interest accrues on the outstanding balance until paid in full.

Aggregate future minimum principal payments on the Equipment Loan, including the 2013 Funding, at March 31, 2013 are as follows (in thousands):

Year	Amount
2013 (remainder)	\$ 293
2014	390
2015	390
2016	207
	\$ 1,280

#### Note 9 – 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 three months ended March 31, 2013 and 2012, the Company recorded as other income (expense) in its statements of operations a change in fair value of warrant liability of \$0 and \$0.1 million, respectively. As of March 31, 2013, the warrant liability recorded on the balance sheet was \$0.3 million and all Warrants remain outstanding as of that date.

#### Note 10 – Sales of Common Stock

In October 2012, the Company entered into an At Market Issuance Sales Agreement (“2012 Sales Agreement”), under which the Board of Directors of the Company (the “Board”) approved the Company’s sale of up to an aggregate of \$50 million in gross proceeds of its common stock. The shares of common stock are offered pursuant to a shelf registration statement filed with the SEC in 2010; in March 2013, the Company filed a new shelf registration statement for an aggregate value of \$200 million, which replaced the previous shelf registration statement. 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, absent any action by the Board to the contrary, to take any additional actions necessary to carry out the Board’s authorization of the issuance and sale of the common stock sold pursuant to the 2012 Sales Agreement. In doing so, the Committee is authorized to set the amount of shares to be sold, the period of time during which such sales may occur and the minimum sales price per share. During the three months ended March 31, 2013, the Company sold 3,300,000 shares at sales prices ranging from of \$2.06 – \$2.18 per share, resulting in \$6.4 million in net proceeds



(this amount excludes \$0.4 million received in the second quarter of 2013 for 0.2 million shares traded in late March 2013). Since March 31, 2013 through May 7, 2013, the Company has sold an additional 1.3 million shares resulting in \$3.2 million in net proceeds.

Note 11 – Manufacturing, Laboratory and Office Facility

The Company leases its new manufacturing, laboratory and office space in Gaithersburg, Maryland with rent payments for such space to the landlord commencing April 1, 2014. Under the terms of one lease agreement, the landlord provided the Company with a tenant improvement allowance of \$2.5 million and an additional tenant improvement allowance of \$3 million, such additional tenant improvement allowance is to be paid back to the landlord during the remainder of the term of such lease agreement through additional rent payments (collectively, the “Improvement Allowance”). The Company has been funded \$0.7 million in the three months ended March 31, 2013, and has been funded \$5.0 million in total under the Improvement Allowance. The Improvement Allowance is being amortized on a straight-line basis over the remaining term of the lease. The Company is currently considering its plans for the Rockville, Maryland facility.

## 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," "believe(s)," "will," "would," "may," "can," "anticipate(s)," "potential" and similar 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 differ materially 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 approximately the next 24 months;

- our expected 2013 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);

- our funding requirements and capital raising activity, including possible proceeds from our At Market Issuance Sales Agreement entered into in October 2012, and funding under the Improvement Allowance and Equipment Loan;

- 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 contracts with HHS BARDA, LG Life Sciences, Ltd. (LGLS) and PATH Vaccine Solutions (PATH), our planned clinical trials and regulatory filings, including receipt of accelerated approval status from the FDA, as necessary for our vaccine candidates;

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

our expectations that our multivalent seasonal influenza VLP vaccine could potentially address an unmet medical need in two vulnerable populations – children and the elderly;

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

our expectations regarding the development by the JV, in India, of a rabies vaccine, including a planned Phase I clinical trial in 2013, a seasonal or pandemic influenza vaccine, or a malaria vaccine;

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;

- 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.

Any or all of our forward-looking statements in this Quarterly Report may turn out to be inaccurate. These forward-looking statements may be affected by inaccurate assumptions or by known or unknown risks and uncertainties, including the risks, uncertainties and assumptions identified under Item 1A “Risk Factors” of the Company’s Annual Report on Form 10-K for the fiscal year ended December 31, 2012. In light of these risks, uncertainties and assumptions, the forward-looking events and circumstances discussed in this Quarterly Report may not occur as contemplated, and actual results could differ materially from those anticipated or implied by the forward-looking statements.

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), is a clinical-stage biopharmaceutical company focused on developing recombinant protein nanoparticle vaccines to address a broad range of infectious diseases. 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 seasonal influenza, pandemic influenza and RSV.

CPL Biologicals Private Limited (the JV), which is owned 20% by us and 80% by Cadila, was established to develop and manufacture certain vaccine candidates, biogeneric products and diagnostic products for the territory of India. The JV operates a state-of-the-art manufacturing facility for the production of influenza vaccine and other vaccine candidates. The JV is actively developing a number of vaccine candidates that were genetically engineered by Novavax. The JV’s seasonal influenza and pandemic influenza candidates began Phase I clinical trials in 2012. Also in 2012, the JV formed a new collaboration to develop a novel malaria vaccine in India with the International Centre for Genetic Engineering and Biotechnology. The JV’s rabies vaccine candidate is expected to begin a Phase I clinical trial in India in 2013. We continue to account for our investment in the JV using the equity method. Since the carrying

value of our initial investment 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:

<b>Program</b>	<b>Development Phase</b>	<b>Collaborator</b>
Seasonal Quadrivalent Influenza	Phase II	HHS BARDA/LGLS
Pandemic (H5N1) Influenza	Phase I	HHS BARDA/LGLS
RSV	Phase II	PATH <sup>1</sup>
Seasonal Trivalent Influenza	Phase I	JV
Pandemic (H1N1) Influenza	Phase I	JV
Rabies	Pre-clinical	JV

<sup>1</sup>PATH is collaborating with us on the Phase II clinical trial to develop our RSV vaccine to protect newborn infants in low-resource countries from RSV through maternal immunization, the top-line results of which were recently announced.

## **Influenza**

Novavax continues to use and reference accelerated approval seroconversion and seroprotection endpoints in developing its influenza vaccine candidates as described herein. The U.S. Food and Drug Administration, Center for Biologics Evaluation and Research (FDA) has published criteria for granting accelerated approval of a Biologics License Application (BLA, the biologic equivalent to a New Drug Application or NDA) for a new seasonal influenza vaccine. Under this guidance, developers that can demonstrate results that meet or exceed certain specified endpoint criteria in their clinical trials may, at the FDA's decision, be granted a license to market prior to conducting a traditional efficacy clinical trial. These criteria are based on demonstration of seroconversion rates (the proportion of subjects with a four-fold rise in hemagglutinin inhibition (HAI) titers or attaining titers of  $\geq 1:40$  from a negative baseline) that are  $\geq 40\%$  and  $\geq 30\%$  at the lower bound of the 95% confidence interval for adult populations under 65 years of age and those 65 years of age and older, respectively, and seroprotection rates (the proportion of subjects with HAI titers  $\geq 1:40$  post-vaccination) that are  $>70\%$  and  $>60\%$  at the lower bound of the 95% confidence interval for adult populations under 65 years of age and those 65 years of age and older, respectively. Accelerated approval may be available as long as there is a shortage of seasonal influenza vaccine relative to the total population recommended to receive the vaccine, a situation that persists. The FDA expects that developers seeking accelerated approval of a BLA will diligently conduct post marketing efficacy studies. The FDA has articulated the same immunogenicity criteria for accelerated approval of vaccines that address potential pandemic influenza strains. Because a controlled efficacy clinical trial of a pandemic vaccine candidate is not logistically or ethically possible, vaccine developers seeking accelerated approval will be required to provide evidence that a seasonal vaccine made by the same manufacturing process is efficacious. Thus, the demonstration of efficacy with a seasonal vaccine product provides a key link between the seasonal and pandemic programs.

### ***Seasonal Influenza Vaccine***

We believe that developing and commercializing a Novavax seasonal influenza vaccine is an important strategic goal and remains a viable opportunity. The Advisory Committee for Immunization Practices of the Center for Disease Control and Prevention (CDC) recommends that all persons aged six months and older should be vaccinated annually against seasonal influenza. In conjunction with these universal recommendations, attention from the 2009 influenza H1N1 pandemic has increased public health awareness of the importance of seasonal influenza vaccination, the market for which is expected to continue to grow worldwide in both developed and developing global markets.

There are currently two quadrivalent influenza vaccines licensed in the U.S., but in the coming years, additional seasonal influenza vaccines are expected to be produced and licensed within and outside of the U.S. in a quadrivalent

formulation (four influenza strains: two influenza A strains and two influenza B strains), as opposed to the current trivalent formulation (three influenza strains: two influenza A strains and one influenza B strain). With two distinct lineages of influenza B viruses circulating, governmental health authorities have advocated for the addition of a second influenza B strain to provide added coverage. Current estimates for seasonal influenza vaccines growth in the top seven markets (U.S., Japan, France, Germany, Italy, Spain and UK), show potential growth from the current market of approximately \$3.6 billion to \$4.7 billion over the next ten years<sup>1</sup>. Recombinant seasonal influenza vaccines, like the candidate we are developing, have an important advantage; once licensed for commercial sale, large quantities of vaccine can be quickly and cost-effectively manufactured without the use of either the live influenza virus or eggs.

<sup>1</sup> Market Forecasts: Seasonal Influenza Vaccines. Datamonitor (2012)

Top-line data from our most recent Phase II clinical trial for our quadrivalent influenza vaccine candidate were announced in July 2012. In that clinical trial, our quadrivalent VLP vaccine candidate demonstrated immunogenicity against all four viral strains based on HAI responses at day 21, and was also well-tolerated, as evidenced by the absence of any observed vaccine-related serious adverse events (SAEs) and an acceptable reactogenicity profile. Our vaccine candidate met the FDA accelerated approval seroprotection rates criterion for all four viral strains. The potential to fulfill the seroconversion rates criterion was demonstrated for three of the four viral strains. The fourth strain, B/Brisbane/60/08, despite fulfilling the seroprotection criterion, failed to demonstrate a satisfactory seroconversion rate. Our activities with respect to our seasonal influenza vaccine candidate have been, and are, focused on identifying the manufacturing process that will ensure consistent and enhanced immune responses in all strains. Over the last few quarters significant progress has been made and we expect to confirm our manufacturing process enhancements by mid-year 2013. During the second half of 2013, we expect to begin manufacturing product for our next Phase II clinical trial.

### ***Pandemic Influenza Vaccine***

In the aftermath of the 2009 H1N1 influenza pandemic, recognition of the potential devastation of a human influenza pandemic remains a key priority with both governmental health authorities and influenza vaccine manufacturers. In the U.S. alone, the 2009 H1N1 pandemic led to the production of approximately 126 million doses of monovalent (single strain) vaccine. Public health awareness and government preparedness for the next potential influenza pandemic are driving development of vaccines that can be quickly manufactured against a potentially threatening influenza strain. Industry and health experts have focused attention on developing a monovalent H5N1 influenza vaccine as a potential key defense of the next pandemic threat.

In October 2012, we reported positive results from two Phase I clinical trials of our pandemic (H5N1) vaccine candidate in combination with two different adjuvants, both of which are designed to improve the immunogenicity of vaccines at lower doses and thus provide antigen dose-sparing. The top-line data demonstrated safety and immunogenicity of varying dose-levels of the vaccine, with and without adjuvant, and further demonstrated statistically significant robust adjuvant effects on immune response.

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

HHS BARDA awarded us a contract in February 2011, which funds the development of both our seasonal and pandemic (H5N1) influenza vaccine candidates. The contract, valued at \$97 million for the first three-year base-period and \$82 million for an HHS BARDA optional two-year period, is a cost-plus-fixed-fee contract in which HHS BARDA reimburses us for allowable direct contract costs incurred plus allowable indirect costs and a fixed-fee earned in the ongoing clinical development and product scale-up of our multivalent seasonal and monovalent pandemic (H5N1) influenza vaccines. We recognized revenue of approximately \$3.3 million in the three months ended March 31, 2013, and have recognized approximately \$38 million in revenue since the inception of the contract.



In December 2012, HHS BARDA completed a contractually-defined in-process review (IPR) of our contract. This IPR was conducted by an inter-governmental-agency panel of experts from government agencies including HHS BARDA, FDA, CDC and the National Institutes of Health, who provided input on our progress during the contract base-period and plans for further development, including both near-term process development and manufacturing activities and longer-term clinical efforts. HHS BARDA subsequently notified us in January 2013 that the milestone decision had been made to continue to support our vaccine advanced development contract.

Under certain circumstances, HHS BARDA reimbursements may be delayed or even potentially withheld. As we have previously disclosed in our filings with the United States Securities and Exchange Commission (SEC), in March 2012, we decided to conduct a Phase II clinical trial of our quadrivalent seasonal influenza vaccine candidate (the 205 Trial) under our existing U.S. investigational new drug application (IND) for our trivalent seasonal influenza vaccine candidate as opposed to waiting to conduct this clinical trial under a new IND for our quadrivalent vaccine candidate (Quadrivalent IND). Based on our discussions with HHS BARDA in 2012, the outside clinical trial costs for the 205 Trial may only be submitted for reimbursement to HHS BARDA and recorded as revenue by us after we submit the clinical trial data in a future Quadrivalent IND. The submission of the Quadrivalent IND is expected shortly before we initiate the next Phase II dose-confirmatory clinical trial, which has been delayed due to the development activity associated with improving the seroconversion rate of one of the four strains. The outside clinical trial costs of the 205 Trial conducted last year are expected to total approximately \$3.1 million, of which \$3.0 million was incurred from the inception of the clinical trial through March 31, 2013. These costs have been recorded as an expense and are included in cost of government contracts revenue.

### ***LGLS License Agreement***

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 both its clinical development of the influenza VLP vaccines and a manufacturing facility to produce such vaccine 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 of 10% 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.

### **Respiratory Syncytial Virus (RSV)**

RSV is a widespread disease that causes infections of the lower respiratory tract. While RSV affects persons of all ages, it acutely impacts infants, young children, the elderly, and others with compromised immune systems. Current estimates indicate that RSV is responsible for over 30 million new acute lower respiratory infection episodes and between 150,000 and 200,000 deaths in children under five years old<sup>2</sup>. In the U.S., nearly all children become infected with RSV before they are two years old; it has been associated with 20% of hospitalizations and 15% of office visits for acute respiratory infection in young children. The World Health Organization (WHO) estimates that the global disease burden for RSV is 64 million cases. Because there is no approved prophylactic vaccine, the unmet need of an RSV vaccine has the potential to protect millions of patients from this far-reaching disease.

We are developing a vaccine candidate to prevent RSV and are looking at susceptible target populations that include the elderly, young children and infants who may receive protection through antibodies transferred from their mothers

who would be immunized during the last trimester of pregnancy. In October 2012, we initiated two separate dose-ranging clinical trials, one in women of child bearing age and the other in the elderly, which support our goals of developing a vaccine for maternal immunization of pregnant women and in elderly adults. In April 2013, we announced top-line data from the Phase II clinical trial in women of childbearing age that were similar to, or exceeded, immune responses seen in our Phase I clinical trial. That randomized, blinded, placebo-controlled Phase II clinical trial evaluated the safety and immunogenicity of two dose levels of our RSV vaccine candidate with and without an aluminum phosphate adjuvant with an enrollment of 330 women of childbearing age. We further reported:

- the clinical trial's protocol-specified objectives were accomplished;
- the vaccine candidate was generally well-tolerated with a similar safety profile as previously observed;
- the use of aluminum phosphate as an adjuvant enhanced both the single and two-dose regimen anti-F IgG responses;

<sup>2</sup> Nair, H., *et al.*, (2010) *Lancet*. 375:1545-1555

- the two-dose alum groups showed a 13 to 16-fold rise compared to a 6 to 10-fold rise in the non-alum groups;

- Antigen dose increases had a minimal impact on responses; and

Palivizumab-like antibody titers rose 8 to 9-fold, with four-fold rises in  $\geq 92\%$  of subjects in the two-dose alum-adjuvanted vaccine groups.

The second clinical trial was a randomized, blinded, placebo-controlled Phase I clinical trial that evaluated the safety and immunogenicity results of 220 enrolled elderly adults, 60 years of age and older, who received a single intramuscular injection of our RSV vaccine candidate (with and without an aluminum phosphate adjuvant) or placebo plus a single dose of licensed influenza vaccine or placebo at days 0 and 28. Top-line results from this Phase I clinical trial in the elderly are expected to be reported later in the first half of 2013. The design and timing of subsequent clinical trials will be determined after the data from both RSV clinical trials are analyzed.

Our expected path forward in maternal immunization would include a dose-confirmation clinical trial in women of child-bearing age. In parallel, and in consultation with the FDA, we would expect to initiate a reproductive toxicology study in rabbits to confirm the safety of our proposed formulation in advance of initiating a clinical trial in pregnant women.

### ***PATH Clinical Development Agreement***

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 (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 expires 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 elected to continue 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.

### **Rabies**

Rabies is a disease that causes acute encephalitis, or swelling of the brain, in warm-blooded animals including humans. The disease can be transmitted from one species of animal to another, such as from dogs to humans, most

commonly by a bite from an infected animal. For humans, rabies left untreated is almost invariably fatal. WHO has estimated that, when looking at the total cost associated with rabies, in many countries the cost of rabies post-exposure prophylaxis represents the highest healthcare expenditure<sup>3</sup>. In Asia and Africa, estimates show a combined 55,000 annual human deaths from endemic canine rabies, with annual treatment costs approaching \$600 million, although human deaths from rabies are likely to be grossly underreported in a number of countries, particularly in the youngest age groups. In India alone, 20,000 deaths are estimated to occur annually. Internal market data of vaccine manufacturers suggest that at the global level, 15 million or more people receive rabies prophylaxis annually, the majority of whom live in China and India. It is estimated that in the absence of post-exposure prophylaxis, about 327,000 persons would die from rabies in Africa and Asia each year. Marketed rabies vaccine is mostly used for post-exposure prophylaxis that requires generally between four and five administrations of vaccine. Pre-exposure prophylaxis is recommended for anyone who will be at increased risk to the rabies virus, including travelers with extensive outdoor exposure in rural high-risk areas<sup>4</sup>.

<sup>3</sup> WHO Technical Report Series (2004)

<sup>4</sup> Yousaf, *et al.* Virology Journal (2012) 9:50

The JV is currently developing a rabies vaccine candidate that we genetically engineered. The JV expects to initiate a Phase I clinical trial in India in 2013. Our objective is to develop a recombinant vaccine that can be administered as a pre-exposure prophylaxis for residents of certain higher-risk geographies, as well as travelers to such locations, and with the potential to provide post-exposure prophylaxis with fewer doses. Preliminary pre-clinical results have demonstrated that this vaccine candidate has the potential to successfully prevent the rabies virus from entering the central nervous system, thus preventing death.

### **Sales of Common Stock**

In October 2012, the Company entered into an At Market Issuance Sales Agreement (2012 Sales Agreement), under which the Board of Directors of the Company (the Board) approved the Company's sale of up to an aggregate of \$50 million in gross proceeds of its common stock. The shares of common stock are offered pursuant to a shelf registration statement filed with the SEC in 2010; in March 2013, the Company filed a new shelf registration statement for an aggregate value of \$200 million, which replaced the previous shelf registration statement. 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, absent any action by the Board to the contrary, to take any additional actions necessary to carry out the Board's authorization of the issuance and sale of the common stock sold pursuant to the 2012 Sales Agreement. In doing so, the Committee is authorized to set the amount of shares to be sold, the period of time during which such sales may occur and the minimum sales price per share. During the three months ended March 31, 2013, the Company sold 3,300,000 shares at sales prices ranging from of \$2.06 - \$2.18 per share, resulting in \$6.4 million in net proceeds (this amount excludes \$0.4 million received in the second quarter of 2013 for 0.2 million shares traded in late March 2013). Since March 31, 2013 through May 7, 2013, the Company has sold an additional 1.3 million shares resulting in \$3.2 million in net proceeds.

### ***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, 2012, 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 March 31, 2013 and 2012** (amounts in tables are presented in thousands, except per share information)

**Revenue:**

<b>Three Months Ended March 31,</b>			<b>Change</b>
<b>2013</b>	<b>2012</b>		<b>2012 to 2013</b>
Revenue:			
Total revenue	\$3,833	\$4,642	\$ (809 )

Revenue for the three months ended March 31, 2013 was \$3.8 million as compared to \$4.6 million for the same period in 2012, a decrease of \$0.8 million or 17%. Revenue for the three months ended March 31, 2013 and 2012 is primarily comprised of services performed under the HHS BARDA contract and, to a much lesser extent in 2013, the PATH clinical development agreement. The decrease in revenue is primarily due to the higher level of activity in the three months ended March 31, 2012 associated with our influenza clinical trials under the HHS BARDA contract as compared to the same period in 2013 when no similar clinical trials were initiated, partially offset by revenue under the PATH clinical development agreement in 2013.

For 2013, we expect a slight increase in revenue associated with our increased product development activities under the HHS BARDA contract to support the ultimate initiation of later-stage clinical trials of our seasonal influenza and pandemic (H5N1) influenza vaccine candidates.

**Costs and Expenses:**

<b>Three Months Ended March 31,</b>			<b>Change</b>
	<b>2013</b>	<b>2012</b>	<b>2012 to 2013</b>
Costs and Expenses:			
Cost of government contracts revenue	\$1,712	\$3,786	\$ (2,074 )
Research and development	9,432	5,338	4,094
General and administrative	2,694	2,985	(291 )
Total costs and expenses	\$13,838	\$12,109	\$ 1,729



***Cost of Government Contracts Revenue***

Cost of government contracts revenue includes 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 research contracts. Cost of government contracts revenue decreased to \$1.7 million for the three months ended March 31, 2013 from \$3.8 million for the same period in 2012, a decrease of \$2.1 million, or 55%. The decrease in cost of government contracts revenue is primarily related to the levels of activity associated with our influenza clinical trials previously mentioned, including the 205 Trial (see discussion of the 205 Trial in *HHS BARDA Contract for Recombinant Influenza Vaccines* above).

For 2013, we expect the cost of government contracts revenue to remain flat due to fewer clinical trials in 2013 as compared to 2012, offset by increased product development activities under the HHS BARDA contract.

***Research and Development Expenses***

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. In addition, indirect costs such as fringe benefits and overhead expenses, are also included in research and development expenses. Research and development expenses increased to \$9.4 million for the three months ended March 31, 2013 from \$5.3 million for the same period in 2012, an increase of \$4.1 million, or 77%. The increase in research and development expenses was primarily due to increased costs relating to our RSV clinical trials (an internally funded program at this time) and higher employee-related costs. For 2013, we expect a significant increase in research and development expenses primarily due to additional employee-related costs to support product development of RSV and other potential vaccine candidates.

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

We track our cost of government contracts 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 March 31, 2013, we had 114 employees dedicated to our research and development programs versus 86 employees as of March 31, 2012. 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 March 31 (in millions).

	2013	2012
Manufacturing	\$5.8	\$4.4
Vaccine Discovery	1.5	0.9
Clinical and Regulatory	3.8	3.8
Total cost of government contracts revenue and research and development expenses	\$11.1	\$9.1

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 clinical trials in order to focus our resources on more promising vaccine candidates. Completion of clinical trials may take several years or more, but the length of time can vary substantially depending upon the phase, size of clinical 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 clinical trials and the specific patient population;
- the number of sites included in the clinical trials;
- if clinical 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 decreased to \$2.7 million for the three months ended March 31, 2013 from \$3.0 million for the same period in 2012, a decrease of \$0.3 million, or 10%. The decrease in expenses was primarily due to lower employee-related costs and professional fees. For 2013, we expect general and administrative expenses to remain relatively flat.

### **Other Income (Expense):**

	<b>Three Months Ended March 31,</b>		
	<b>2013</b>	<b>2012</b>	<b>Change 2012 to 2013</b>
Other Income (Expense):			
Interest income	\$ 48	\$ 33	\$ 15
Interest expense	(22 )	(3 )	(19 )
Change in fair value of warrant liability	—	101	(101 )
Total other income (expense)	\$ 26	\$ 131	\$ (105 )

We had total other income of less than \$0.1 million for the three months ended March 31, 2013 compared to total other income of \$0.1 million for the same period in 2012. For the three months ended March 31, 2013, the change in fair value of the warrant liability resulted in a \$0.1 million decrease in total other income as compared to the same period in 2012. We will continue to mark the warrant liability to fair value at each reporting period until the warrants are either exercised or otherwise expire on July 31, 2013.

### **Net Loss:**

	<b>Three Months Ended March 31,</b>	
	<b>2013</b>	<b>2012</b>

**Change  
2012 to  
2013**

Net Loss:			
Net loss	\$(9,996 )	\$(7,336 )	\$(2,660 )
Net loss per share	\$(0.07 )	\$(0.06 )	\$(0.01 )
Weighted shares outstanding	148,448	120,558	27,890

Net loss for the three months ended March 31, 2013 was \$10.0 million, or \$0.07 per share, as compared to \$7.3 million, or \$0.06 per share, for the same period in 2012, an increased net loss of \$2.7 million. The increased net loss was primarily due to higher research and development spending, including increased costs relating to our RSV clinical trials and higher employee-related costs.

The increase in weighted average shares outstanding for the three months ended March 31, 2013 is primarily a result of sales of our common stock in the aggregate of 30,827,346 shares in 2012.

### **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 March 31, 2013, we had \$45.4 million in cash and cash equivalents and investments as compared to \$50.3 million as of December 31, 2012. These amounts consisted of \$9.0 million in cash and cash equivalents and \$36.4 million in investments as of March 31, 2013 as compared to \$17.4 million in cash and cash equivalents and \$32.9 million in investments at December 31, 2012.

The following table summarizes cash flows for the three months ended March 31, 2013 and 2012 (in thousands):

	<b>Three Months Ended</b>		
	<b>March 31,</b>		
	2013	2012	<b>Change 2012 to 2013</b>
Summary of Cash Flows:			
Net cash (used in) provided by:			
Operating activities	\$(10,583)	\$(4,220 )	\$ (6,363 )
Investing activities	(4,974 )	(3,270 )	(1,704 )
Financing activities	7,181	7,259	(78 )
Net decrease in cash and cash equivalents	(8,376 )	(231 )	(8,145 )
Cash and cash equivalents at beginning of period	17,399	14,104	3,295
Cash and cash equivalents at end of period	\$9,023	\$13,873	\$ (4,850 )

Net cash used in operating activities increased to \$10.6 million for the three months ended March 31, 2013 as compared to \$4.2 million for the same period in 2012, respectively. The increase in cash usage was primarily due to the timing of our customer and vendor payments and increased costs relating to our RSV clinical trials and higher employee-related costs.

During the three months ended March 31, 2013 and 2012, our investing activities consisted of purchases and maturities of investments and capital expenditures. In the three months ended March 31, 2013 and 2012, we primarily purchased investments to increase our rate of return on our investments. Capital expenditures for the three months ended March 31, 2013 and 2012 were \$1.5 million and \$0.8 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 2013, we expect our level of capital expenditures to decrease due to the expected completion of the scale-up work on our new manufacturing facility

Our financing activities consist primarily of sales of our common stock. We received net proceeds of \$6.4 million in the three months ended March 31, 2013 as compared to \$7.9 million in the same period of 2012 from the sale of our common stock through our At Market Issuance Sales Agreements.

In November 2011, we entered into lease agreements under which we lease our new manufacturing, laboratory and office space in Gaithersburg, Maryland with rent payments for such space to the landlord commencing April 1, 2014. Under the terms of the arrangement, the landlord provided 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 through additional rent payments. We were funded \$0.7 million in the three months ended March 31, 2013, and have been funded \$5.0 million in total under the Improvement Allowance.

In September 2012, we entered into a master security agreement, whereby we can borrow up to \$2.0 million to finance the purchases of equipment through June 2013 (Equipment Loan). We financed \$0.8 million in the three months ended March 31, 2013, and have financed \$1.3 million in total under the Equipment Loan.

We have entered into agreements with outside providers to support our clinical development. As of March 31, 2013, \$4.2 million remains unpaid on certain of these agreements in the event our outside providers complete their services in 2013. 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 (previously made), ongoing 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, with expected patent expiration in early 2022. 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 March 31, 2013 totaled \$5.7 million, of which no amounts were paid in the three months ended March 31, 2013. We do not expect to make a milestone payment to Wyeth in the next 12 months.

In connection with our JV with Cadila, we entered into a master services agreement, which we and Cadila amended first in July 2011, and subsequently in March 2013, in each case 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 2014, the amount of services provided by Cadila under the master services agreement is less than \$7.5 million, we 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 March 31, 2013, we have purchased \$1.3 million in services from Cadila pursuant to this agreement.

Based on our current cash and cash equivalents and investments, including our recent private equity offerings, anticipated revenue under the contract with HHS BARDA, possible proceeds from the sales of our common stock under our 2012 Sales Agreement and our current business operations, we believe we have adequate capital resources available to operate at planned levels for approximately the next 24 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 2012 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 2012 Sales Agreement, Improvement Allowance and Equipment Loan, 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 March 31, 2013, we had cash and cash equivalents of \$9.0 million, investments of \$36.4 million, of which \$35.3 million are short-term, and working capital of \$42.5 million.

Our exposure to market risk is primarily confined to our investment portfolio. As of March 31, 2013, our 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.

Interest and dividend income is recorded when earned and included in interest income. Premiums and discounts, if any, on 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 March 31, 2013. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship

of possible controls and procedures. Our disclosure controls and procedures are designed to provide reasonable assurance of achieving their control objectives. Based on the evaluation of our disclosure controls and procedures as of March 31, 2013, our Chief Executive Officer and Chief Financial Officer concluded that, as of such date, our disclosure controls and procedures were effective.

### **Changes in Internal Control over Financial Reporting**

Our management, including our Chief Executive Officer and Chief Financial Officer, has evaluated any changes in our internal control over financial reporting that occurred during the first quarter of 2013, and has concluded that there was no change that occurred during the first quarter of 2013 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, 2012.

**Item 6. Exhibits**

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

31.1\* Certification of Chief Executive Officer pursuant to Rule 13a-14(a) or 15d-14(e) of the Securities Exchange Act

31.2\* Certification of Chief Financial Officer pursuant to Rule 13a-14(a) or 15d-14(e) of the Securities Exchange Act

32.1\* Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

32.2\* Certification of Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

SIGNATURES

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

**NOVAVAX, INC.**

Date: May 9, 2013 By: /s/ Stanley C. Erck  
President and Chief Executive Officer  
and Director  
(Principal Executive Officer)

Date: May 9, 2013 By: /s/ Frederick W. Driscoll  
Vice President, Chief Financial Officer  
and Treasurer  
(Principal Financial and Accounting Officer)