

NOVAVAX INC  
Form 10-Q  
November 06, 2014

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, 2014**

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** **22-2816046**  
(State or other jurisdiction of (I.R.S. Employer  
incorporation or organization) Identification No.)

**20 Firstfield Road, Gaithersburg, MD 20878**  
(Address of principal executive offices) (Zip code)

**(240) 268-2000**

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

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

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

The number of shares outstanding of the Registrant's Common Stock, \$0.01 par value, was 238,477,974 as of October 31, 2014.



**NOVAVAX, INC.**

**TABLE OF CONTENTS**

<b><u>PART I. FINANCIAL INFORMATION</u></b>		<b>Page No.</b>
Item 1.	<u>Consolidated Financial Statements</u>	
	<u>Consolidated Balance Sheets as of September 30, 2014 (unaudited) and December 31, 2013</u>	1
	<u>Unaudited Consolidated Statements of Operations and Unaudited Consolidated Statements of Comprehensive Loss for the three and nine months ended September 30, 2014 and 2013</u>	2
	<u>Unaudited Consolidated Statements of Cash Flows for the nine months ended September 30, 2014 and 2013</u>	3
	<u>Notes to the Consolidated Financial Statements (unaudited)</u>	4
Item 2.	<u>Management’s Discussion and Analysis of Financial Condition and Results of Operations</u>	16
Item 3.	<u>Quantitative and Qualitative Disclosures about Market Risk</u>	32
Item 4.	<u>Controls and Procedures</u>	32
<b><u>PART II. OTHER INFORMATION</u></b>		
Item 1A.	<u>Risk Factors</u>	33
Item 6.	<u>Exhibits</u>	33
	<b><u>SIGNATURES</u></b>	34



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

(in thousands, except share and per share information)

	September 30, 2014 (unaudited)	December 31, 2013
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 34,473	\$ 119,471
Short-term investments available-for-sale	143,617	13,597
Restricted cash	—	1,417
Accounts receivable – billed	2,859	1,911
Account receivable – unbilled	4,233	4,988
Prepaid expenses	6,395	3,044
Other current assets	402	573
Total current assets	191,979	145,001
Investments available-for-sale	12,189	—
Property and equipment, net	17,492	14,251
Intangible assets, net	13,763	16,250
Goodwill	56,174	58,707
Restricted cash	758	757
Other non-current assets	159	159
Total assets	\$ 292,514	\$ 235,125
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 2,975	\$ 5,985
Accrued expenses and other current liabilities	13,712	10,411
Deferred revenue	3	271
Current portion of capital leases	89	108
Current portion of notes payable	795	877
Deferred rent	1,061	470

Edgar Filing: NOVAVAX INC - Form 10-Q

Total current liabilities	18,635	18,122
Deferred revenue	2,500	2,500
Non-current portion of capital leases	150	195
Non-current portion of notes payable	571	1,004
Deferred rent	7,609	8,502
Other non-current liabilities	1,399	1,568
Total liabilities	30,864	31,891
Commitments and contingencies	—	—
Stockholders' equity:		
Preferred stock, \$0.01 par value, 2,000,000 shares authorized; no shares issued and outstanding	—	—
as of September 30, 2014 and December 31, 2013, respectively		
Common stock, \$0.01 par value, 300,000,000 shares authorized; 238,913,904 shares issued and 238,458,474 shares outstanding at September 30, 2014 and 209,110,744 shares issued and 208,655,314 shares outstanding at December 31, 2013	2,389	2,091
Additional paid-in capital	727,369	612,900
Accumulated deficit	(461,547 )	(410,146)
Treasury stock, 455,430 shares, cost basis at both September 30, 2014 and December 31, 2013	(2,450 )	(2,450 )
Accumulated other comprehensive income (loss)	(4,111 )	839
Total stockholders' equity	261,650	203,234
Total liabilities and stockholders' equity	\$ 292,514	\$ 235,125

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

NOVAVAX, INC.

## CONSOLIDATED STATEMENTS OF OPERATIONS

(in thousands, except per share information)

(unaudited)

	<b>For the Three Months</b>		<b>For the Nine Months</b>	
	<b><u>Ended September 30,</u></b>		<b><u>Ended September 30,</u></b>	
	2014	2013	2014	2013
Revenue:				
Government contracts	\$7,504	\$4,268	\$20,217	\$10,985
Research and development collaborations	710	534	3,718	1,182
Total revenue	8,214	4,802	23,935	12,167
Costs and expenses:				
Cost of government contracts revenue	4,027	2,276	12,150	5,619
Research and development	19,219	13,948	48,940	33,989
General and administrative	4,757	3,857	14,871	10,740
Total costs and expenses	28,003	20,081	75,961	50,348
Loss from operations	(19,789 )	(15,279 )	(52,026 )	(38,181 )
Other income (expense):				
Interest income	128	53	160	149
Interest expense	(47 )	(64 )	(150 )	(132 )
Other income (expense)	(19 )	(10 )		(10 )
Change in fair value of warrant liability				267
Realized gains on investments			615	
Loss from operations before income tax	(19,727 )	(15,300 )	(51,401 )	(37,907 )
Income tax expense				22
Net loss	\$(19,727 )	\$(15,300 )	\$(51,401 )	\$(37,929 )
Basic and diluted net loss per share	\$(0.08 )	\$(0.09 )	\$(0.23 )	\$(0.24 )
Basic and diluted weighted average number of common shares outstanding	238,304	168,537	221,578	156,555



**CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS****(in thousands)****(unaudited)**

	<b>For the Three Months</b>		<b>For the Nine Months</b>	
	<b><u>Ended September 30,</u></b>		<b><u>Ended September 30,</u></b>	
	2014	2013	2014	2013
Net loss	\$(19,727)	\$(15,300)	\$(51,401)	\$(37,929)
Other comprehensive income (loss):				
Net unrealized gains (losses) on investments available-for-sale	(54 )	(33 )	(28 )	174
Reclassification adjustment for gains included in net loss			(615 )	
Foreign currency translation adjustment	(2,764 )	509	(4,307 )	509
Other comprehensive income (loss)	(2,818 )	476	(4,950 )	683
Comprehensive loss	\$(22,545)	\$(14,824)	\$(56,351)	\$(37,246)

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

NOVAVAX, INC.

## CONSOLIDATED STATEMENTS OF CASH FLOWS

(in thousands)

(unaudited)

	<b>For the Nine Months Ended September 30,</b>	
	2014	2013
Operating Activities:		
Net loss	\$(51,401 )	\$(37,929 )
Reconciliation of net loss to net cash used in operating activities:		
Change in fair value of warrant liability	—	(267 )
Depreciation and amortization	2,995	1,636
Amortization of net premiums on investments	106	326
Loss on disposal of property and equipment	(13 )	(37 )
Deferred rent	(302 )	678
Non-cash stock-based compensation	4,583	1,784
Realized gains on investments	(615 )	—
Changes in operating assets and liabilities:		
Restricted cash	1,417	862
Accounts receivable – billed	(999 )	(291 )
Accounts receivable – unbilled	755	(1,624 )
Prepaid expenses and other assets	(3,348 )	639
Accounts payable and accrued expenses	(164 )	623
Deferred revenue	(260 )	(199 )
Lease incentives received	—	703
Net cash used in operating activities	(47,246 )	(33,096 )
Investing Activities:		
Capital expenditures	(4,877 )	(4,762 )
Proceeds from disposal of property and equipment	39	83
Net cash received from Novavax AB acquisition	—	3,034
Proceeds from sales and maturities of investments	18,440	23,630
Purchases of investments	(160,782)	(14,754 )
Net cash (used in) provided by investing activities	(147,180)	7,231
Financing Activities:		
Principal payments on capital leases	(58 )	(54 )
Principal payments on notes payable	(505 )	(305 )
Proceeds from notes payable	—	1,450
Changes in restricted cash	(1 )	(1 )
Cash paid with the Novavax AB acquisition	(171 )	—

Edgar Filing: NOVAVAX INC - Form 10-Q

Net proceeds from sales of common stock, net of offering costs of \$7.1 million and \$6.1 million, respectively	107,896	128,659
Proceeds from the exercise of stock options and employee stock purchases	2,288	1,194
Net cash provided by financing activities	109,449	130,943
Effect of exchange rate on cash and cash equivalents	(21 )	16
Net (decrease) increase in cash and cash equivalents	(84,998 )	105,094
Cash and cash equivalents at beginning of period	119,471	17,399
Cash and cash equivalents at end of period	\$34,473	\$122,493
Supplemental disclosure of non-cash activities:		
Commons stock issued in connection with the Novavax AB acquisition	\$	\$41,942
Property and equipment purchases included in accounts payable and accrued expenses	\$999	\$407
Supplemental disclosure of cash flow information:		
Cash payments of interest	\$143	\$120

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

NOVAVAX, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

September 30, 2014

(unaudited)

Note 1 – Organization

Novavax, Inc. (“Novavax,” and together with its wholly owned subsidiary, “Novavax AB” (formerly known as Isconova AB), the “Company”) is a clinical-stage biopharmaceutical company focused on the discovery, development and commercialization of recombinant nanoparticle vaccines and adjuvants. The Company’s product pipeline targets a variety of infectious diseases with vaccine candidates currently in clinical development for respiratory syncytial virus (“RSV”), seasonal influenza and pandemic influenza. The Company has additional pre-clinical stage programs in a variety of infectious diseases, including Middle East Respiratory Syndrome (“MERS”) and the Ebola virus disease (“EVD”).

**Note 2 – Operations**

The Company’s vaccine candidates currently under development, some of which include adjuvants, will require significant additional research and development efforts that include extensive pre-clinical and clinical testing, and regulatory approval prior to commercial use.

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 revenue under its contract with the Department of Health and Human Services, Biomedical Advanced Research and Development Authority (“HHS BARDA”) and, to a lesser degree, revenue under its contract with Path Vaccine Solutions (“PATH”). Management regularly reviews the Company’s cash and cash equivalents and investments against its operating budget and forecast to monitor the sufficiency of the Company’s working capital, and anticipates continuing to draw upon available sources of capital to meet its product development activities.

Note 3 – Summary of Significant Accounting Policies

***Basis of Presentation***

The accompanying unaudited consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP") for interim financial information and the instructions to Form 10-Q and Article 10 of Regulation S-X. The consolidated balance sheet as of September 30, 2014, the consolidated statements of operations and the consolidated statements of comprehensive loss for the three and nine months ended September 30, 2014 and 2013 and the consolidated statements of cash flows for the nine months ended September 30, 2014 and 2013 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 consolidated financial statements are adequate to make the information presented not misleading, certain information and footnote information normally included in consolidated financial statements prepared in accordance with U.S. GAAP have been condensed or omitted as permitted under the rules and regulations of the United States Securities and Exchange Commission ("SEC").

The unaudited consolidated financial statements include the accounts of Novavax, Inc. and its wholly owned subsidiary, Novavax AB. All intercompany accounts and transactions have been eliminated in consolidation.

The accompanying unaudited consolidated financial statements are presented in U.S. dollars. The translation of assets and liabilities to U.S. dollars is made at the exchange rate in effect at the consolidated balance sheet date, while equity accounts are translated at historical rates. The translation of statement of operations data is made at the average exchange rate in effect for the period. The translation of operating cash flow data is made at the average exchange rate in effect for the period, and investing and financing cash flow data is translated at the exchange rate in effect at the date of the underlying transaction. Translation gains and losses are recognized as a component of other comprehensive income (loss) in the accompanying consolidated statements of comprehensive loss and accumulated other comprehensive income (loss) in the accompanying consolidated balance sheets. The foreign currency translation adjustment balance included in accumulated other comprehensive loss was \$4.1 million at September 30, 2014.

The accompanying unaudited consolidated 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, 2013. Results for this or any interim period are not necessarily indicative of results for any future interim period or for the entire year. The Company operates in one business segment.

#### *Use of Estimates*

The preparation of consolidated financial statements in conformity with U.S. 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 consolidated financial statements and the reported amounts of revenue and expenses during the reporting period. Actual results could differ materially from these estimates.

#### Cash and Cash Equivalents

Cash and cash equivalents consist of highly liquid investments with maturities of three months or less from the date of purchase. Cash and cash equivalents consist of the following at (in thousands):

	September 30, 2014	December 31, 2013
Cash	\$ 3,737	\$ 4,251
Money market funds	20,736	100,049
Government-backed security	10,000	
Corporate debt securities		15,171
Cash and cash equivalents	\$ 34,473	\$ 119,471

Cash equivalents are recorded at cost plus accrued interest, which approximate fair value due to their short-term nature.

### ***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

At September 30, 2014, investments consist of asset-backed securities, commercial paper and corporate notes. Classification of marketable securities between current and non-current is dependent upon the maturity date at the balance sheet date.

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. 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 statements of operations.

## Restricted Cash

The Company's restricted cash includes payments received under the PATH agreement (See Note 10) until such time as the Company has paid for the work performed under the agreement. In addition, the Company's non-current restricted cash with respect to its 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.

## 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 or 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 U.S. government. An audit by the U.S. government of fiscal years 2011 and 2012 was completed in the first quarter of 2014, which resulted in no significant adjustments. An audit of fiscal year 2013 has been initiated, but has not been completed as of the date of this filing. Management believes that revenue for periods not yet audited has been recorded in amounts that are expected to be realized upon final audit and settlement. When the final determination of the allowable costs for any year has been made, revenue and billings may be adjusted accordingly in the period that the adjustments are known.

The Company's collaborative research and development agreements may include upfront payments, 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 and treated as one unit of accounting. 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 have 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 the 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 such a contract 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.

### ***Net Loss per Share***

Net loss per share is computed using the weighted average number of shares of common stock outstanding. All outstanding stock options and unvested restricted stock awards totaling 17,018,180 and 12,157,634 at September 30, 2014 and 2013, respectively, are excluded from the computation, as their effect is antidilutive.

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

In May 2014, the Financial Accounting Standards Board issued ASU 2014-09, *Revenue from Contracts with Customers (Topic 606)* (“ASU 2014-09”), which supersedes nearly all existing revenue recognition guidance under Topic 605, *Revenue Recognition*. The new standard requires a company to recognize revenue when it transfers goods and services to customers in an amount that reflects the consideration that the company expects to receive for those goods or services. ASU 2014-09 defines a five-step process that includes identifying the contract with the customer, identifying the performance obligations in the contract, determining the transaction price, allocating the transaction prices to the performance obligations in the contract and recognizing revenue when (or as) the entity satisfies the performance obligations. ASU 2014-09 will be effective for the Company on January 1, 2017. The Company is evaluating the potential impact that ASU 2014-09 will have on its consolidated financial position and results of operations.

### **Note 4 – Acquisition Novavax AB**

During the second quarter of 2014, the Company completed its purchase of the remaining 0.5% shares outstanding from the holders of such securities of Novavax AB. As a result, Novavax AB is now a wholly owned subsidiary of Novavax. The results of Novavax AB’s operations have been included in the consolidated financial statements since the acquisition date, July 31, 2013. Due to new information obtained in the first quarter of 2014 about facts and circumstances that existed at the acquisition date regarding certain accrued contingencies related to its pre-existing contractual rights and obligations, the Company reduced the carrying value of its goodwill retrospectively as of the acquisition date related to the acquisition by \$0.8 million from \$26.2 million to \$25.4 million, which represents the purchase price paid in the acquisition that was in excess of the fair value of the assets acquired and liabilities assumed. The goodwill generated from the acquisition is not deductible for income tax purposes.

### **Note 5 – 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):

Assets	Fair Value at September 30, 2014			Fair Value at December 31, 2013		
	Level 1	Level 2	Level 3	Level 1	Level 2	Level 3
Auction rate security	\$	\$	\$	\$1,790	\$	\$
Money market funds	20,736			100,049		
Government-backed security		10,000				
Asset-backed securities		50,300				
Corporate debt securities		105,506			26,978	
Total cash equivalents and investments	\$20,736	\$165,806	\$	\$101,839	\$26,978	\$

During the nine months ended September 30, 2014, the Company did not have any transfers between levels.

The amounts in the Company's consolidated balance sheet for accounts receivable – billed, accounts receivable – unbilled 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 leases and notes payable approximates their carrying value.

**Note 6 – Investments**

Marketable securities classified as available-for-sale as of September 30, 2014 and December 31, 2013 were comprised of (in thousands):

	September 30, 2014				December 31, 2013			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Auction rate security	\$—	\$ —	\$ —	\$—	\$1,175	\$ 615	\$ —	\$1,790
Asset-backed securities	50,316	—	(16 )	50,300	\$—	\$ —	\$ —	\$—
Corporate debt securities	105,517	21	(32 )	105,506	11,806	1	—	11,807
Total	\$155,833	\$ 21	\$ (48 )	\$155,806	\$12,981	\$ 616	\$ —	\$13,597

As of September 30, 2014, the Company held securities in an unrealized loss position with a fair value of approximately \$106 million. All of these securities have been in a continuous unrealized loss position for less than one year. The Company has determined that the decline in fair value of these investments is temporary as the Company does not intend to sell these securities and it is not likely that the Company will be required to sell the securities before the recovery of their amortized cost basis.

The following table summarizes maturities of the Company's marketable securities as of September 30, 2014:

	Marketable Securities	
	Amortized Cost	Fair Value
Less than one year	\$143,634	\$143,617
Due in year two	12,199	12,189
Total	\$155,833	\$155,806

The Company's investments in asset-backed securities have effective maturity dates of less than one year and greater than one year and accordingly, have been included in both short-term investments available-for-sale and investments available-for-sale, respectively, on the consolidated balance sheets.

In January 2014, the Company sold its auction rate security and received proceeds of \$1.8 million resulting in a realized gain of \$0.6 million.

**Note 7 – Goodwill and Other Intangible Assets**

*Goodwill*

The changes in the carrying amounts of goodwill for the nine months ended September 30, 2014 and 2013 were as follows (in thousands):

	Nine Months Ended September 30,	
	2014	2013
Beginning balance after retroactive adjustment	\$58,707	\$33,141
Goodwill resulting from acquisition of business	—	25,298
Currency translation and other adjustments	(2,533 )	320
Ending balance	\$56,174	\$58,759

**Identifiable Intangible Assets**

Identifiable intangible, all of which are finite-lived, assets consisted of the following as of September 30, 2014 (in thousands):

	Gross Carrying Amount	Accumulated Amortization	Intangible Assets, Net
Proprietary adjuvant technology	\$ 10,279	\$ (600	) \$ 9,679
Collaboration agreements	4,641	(557	) 4,084
Total identifiable intangible assets	\$ 14,920	\$ (1,157	) \$ 13,763

Amortization expense for the nine months ended September 30, 2014 was \$0.8 million.

Estimated amortization expense for existing intangible assets for the remainder of 2014 and for each of the five succeeding years ending December 31 will be as follows (in thousands):

<u>Year</u>	Amount
2014 (remainder)	\$ 248
2015	991
2016	991
2017	991
2018	991
2019	991

**Note 8 – Stockholders’ Equity**

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 potentially available pursuant to a shelf registration statement filed with the SEC in March 2013, which replaced the previous shelf registration statement filed in 2010. The Board’s standing Finance Committee (the “Finance Committee”) assists with the Board’s responsibilities to monitor, provide advice to senior management of the Company and approve capital raising activities that are not otherwise approved by the Board. The Finance 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 pursuant to the 2012 Sales Agreement. In doing so, the Finance 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. As of September 30, 2014, the Company had approximately \$15 million available under the 2012 Sales Agreement. The most recent sales that occurred under the 2012 Sales Agreement were on September 10, 2013.

In June 2014, the Company completed a public offering of 28,750,000 shares of its common stock, including 3,750,000 shares of common stock that were issued upon the exercise in full of an option to purchase additional shares granted to the underwriters, at a price of \$4.00 per share resulting in net proceeds of approximately \$108 million.

## **Note 9 – Stock-Based Compensation**

### *Stock Options*

The Company has granted equity awards under several plans, two of which remain active. Under the Amended and Restated 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 most recently in June 2014 by the Company’s stockholders, currently authorizes the grant of equity awards for up to 26,312,192 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 expire or otherwise terminate unexercised. The Company received approval at its 2014 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 and no new awards will be made under the 1995 Plan; however, outstanding stock options remain in existence in accordance with their terms.



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.

Since the 2005 Plan expires in the first quarter of 2015, the Company intends to adopt a 2015 stock incentive plan and submit it for approval to its stockholders at the 2015 annual meeting of stockholders.

***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, 2014:

	<b>2005 Stock Incentive Plan</b>		<b>1995 Stock Option Plan</b>	
	<b>Stock Options</b>	<b>Weighted-Average Exercise Price</b>	<b>Stock Options</b>	<b>Weighted-Average Exercise Price</b>
Outstanding at January 1, 2014	11,788,100	\$ 1.87	188,150	\$ 5.04
Granted	5,985,500	\$ 5.48	—	\$ —
Exercised	(524,912 )	\$ 1.90	(32,450 )	\$ 4.81
Canceled	(268,775 )	\$ 3.17	(149,100)	\$ 5.76
Outstanding at September 30, 2014	16,979,913	\$ 3.12	6,600	\$ 2.21
Shares exercisable at September 30, 2014	6,265,762	\$ 2.01	6,600	\$ 2.21
Shares available for grant at September 30, 2014	4,896,344			

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2014	2013	2014	2013
Weighted-average Black-Scholes fair value of stock options granted	\$1.92	\$1.41	\$2.41	\$1.02
Risk-free interest rate	1.43%-1.51%	1.12%-1.36%	1.24%-2.22%	0.54%-1.36%

Edgar Filing: NOVAVAX INC - Form 10-Q

Dividend yield	0%	0%	0%	0%
Volatility	52.75%-54.25%	56.75%-62.51%	52.47%-67.93%	55.81%-73.72%
Expected term (in years)	4.10-4.27	4.25	4.04-6.96	3.98-7.05
Expected forfeiture rate	14.18%-16.33%	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, 2014 was approximately \$25.8 million and 7.8 years, respectively. The aggregate intrinsic value and weighted-average remaining contractual term of stock options exercisable as of September 30, 2014 was approximately \$14.0 million and 6.2 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, 2014. This amount is subject to change based on changes to the closing price of the Company's common stock. The aggregate intrinsic value of options exercised for the nine months ended September 30, 2014 and 2013 was \$1.8 million and \$0.3 million, respectively.

Stock options issued to non-employees are measured at their estimated fair value. Stock-based compensation expense is recognized when services are rendered; however, the expense may fluctuate with changes in the fair value of the underlying common stock, until the award is vested. The Company recorded \$0.3 million and less than \$0.1 million in stock-based compensation expense related to stock options granted to non-employees in the nine months ended September 30, 2014 and 2013, respectively.

### ***Employee Stock Purchase Plan***

In 2013, the Company adopted an Employee Stock Purchase Plan (the “ESPP”), which authorized an aggregate of 2,000,000 shares of common stock to be purchased, which will increase 5% on each anniversary of its adoption up to a maximum of 3,000,000 shares. The ESPP allows employees to purchase shares of common stock of the Company at each purchase date through payroll deductions of up to a maximum of 15% of their compensation, at 85% of the lesser of the market price of the shares at the time of purchase or the market price on the beginning date of an option period (or, if later, the date during the option period when the employee was first eligible to participate). At September 30, 2014, there were 1,619,202 shares available for issuance under the ESPP.

The ESPP is considered compensatory for financial reporting purposes. As such, the fair value of ESPP shares was estimated at the date of grant using the Black-Scholes option-pricing model with the following assumptions:

	Three Months Ended September 30, 2014	Nine Months Ended September 30, 2014
Range of Black-Scholes fair values of ESPP shares granted	\$0.97-\$2.08	\$0.78-\$2.08
Risk-free interest rate	0.05%-0.24%	0.04%-0.24%
Dividend yield	0%	0%
Volatility	51.10%-67.57%	50.80%-67.57%
Expected term (in years)	0.5-1.5	0.5-1.5
Expected forfeiture rate	5%	5%

Stock-based compensation related to the ESPP for the three and nine months ended September 30, 2014 was \$0.2 million and \$0.5 million, respectively.

### ***Restricted Stock Awards***

The following is a summary of restricted stock awards activity for the nine months ended September 30, 2014:

	<b>Number of Shares</b>	<b>Per Share Weighted- Average Grant-Date <u>Fair Value</u></b>
Outstanding and Unvested at January 1, 2014	16,667	\$ 1.39
Restricted stock granted	15,000	\$ 4.48
Restricted stock vested	—	\$ —
Restricted stock forfeited	—	\$ —
Outstanding and Unvested at September 30, 2014	31,667	\$ 2.85

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

	<b>Three Months Ended <u>September 30,</u></b>		<b>Nine Months Ended <u>September 30,</u></b>	
	2014	2013	2014	2013
Research and development	\$780	\$316	\$1,955	\$829
General and administrative	911	347	2,628	955
Total stock-based compensation expense	\$1,691	\$663	\$4,583	\$1,784

As of September 30, 2014, there was approximately \$13.3 million of total unrecognized compensation expense (net of estimated forfeitures) related to unvested options, ESPP and restricted stock awards. This unrecognized compensation expense is expected to be recognized over a weighted-average period of 1.5 years. This estimate does not include the impact of other possible stock-based awards that may be made during future periods.

Note 10 – U.S. Government Agreement, Joint Venture 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, which base-period was extended in February 2014 by seven months to September 2014, with an HHS BARDA option for an additional two-year period valued at \$79 million. In September 2014, HHS BARDA exercised the option-period under the contract, which extends the contract for an additional two years, until September 2016, and allocated \$70 million (of the original \$79 million option-period funding) to the option-period in addition to any funding remaining from the original \$97 million base-period funding. 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 influenza vaccine candidates. This is a cost-plus-fixed-fee contract in which HHS BARDA reimburses the Company for allowable direct contract costs, allowable indirect costs and a fixed-fee earned in the development of the Company's multivalent seasonal and monovalent pandemic influenza vaccine candidates. HHS BARDA originally directed the Company to develop its monovalent pandemic influenza vaccine against the A(H5N1) strain. In February 2014, the Company amended its contract with HHS BARDA to prioritize its development efforts on a monovalent pandemic influenza vaccine against the A(H7N9) strain with a Phase 1/2 clinical trial using its H7N9 candidate and Matrix-M adjuvant, data from which were reported by the Company in the third quarter of 2014. In October 2014, the Company announced that the U.S. Food & Drug Administration ("FDA") had granted "Fast Track" designation to its H7N9 vaccine candidate adjuvanted with Matrix-M. HHS BARDA has also indicated that, while not a current

development priority, the Company's H5N1 vaccine program remains a viable potential development opportunity under the contract. Billings under the contract are based on approved provisional indirect billing rates, which permit recovery of fringe benefits, overhead and general and administrative expenses that may be subject to certain limits. These indirect rates are subject to audit by HHS BARDA on an annual basis. An audit by the U.S government of fiscal years 2011 and 2012 was completed in the first quarter of 2014, which resulted in no significant adjustments. Management believes that revenue for periods not yet audited has been recorded in amounts that are expected to be realized upon final audit and settlement. When the final determination of the allowable costs for any year has been made, revenue and billings may be adjusted accordingly in the period that the adjustments are known. The Company recognized revenue of \$7.5 million and \$20.0 million in the three and nine months ended September 30, 2014, respectively, and has recognized approximately \$72 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 2 clinical trial of its quadrivalent seasonal influenza vaccine candidate in Australia ("205 Trial") under appropriate local regulatory authorization. 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 205 Trial data in a quadrivalent investigational new drug application ("Quadrivalent IND"), and those costs are approved by HHS BARDA. The outside clinical trial costs of the 205 Trial conducted in 2012 totaled \$2.9 million. These costs have been recorded as an expense in the period incurred as a cost of government contracts revenue. FDA acceptance of the Quadrivalent IND is expected shortly before initiation of the next Phase 2 dose-confirmatory clinical trial, which is expected to begin later in the fourth quarter of 2014.

***CPL Biologicals Private Limited (“CPLB”) Joint Venture***

In 2009, the Company formed a joint venture with Cadila Pharmaceuticals Limited (“Cadila”) named CPL Biologicals Private Limited (“CPLB”) to develop and manufacture vaccines, biological therapeutics and diagnostics in India. CPLB is owned 20% by the Company and 80% by Cadila. The Company accounts for its investment in CPLB using the equity method. CPLB has incurred losses since its inception; however, the Company has not recorded any losses related to this investment because the carrying value of the Company’s initial investment was nominal and the Company has no obligation or commitment to provide future funding.

***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 vaccines 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 license agreement is scheduled to terminate in 2027. Payments to the Company under the license agreement include an upfront payment of \$2.5 million (received in 2011), reimbursements of certain development and product costs, payments related to the achievement of certain milestones and royalty payments in the high single digits from LGLS’s future commercial sales of influenza VLP vaccines, if any. 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 would 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 would be recognized as earned.

***PATH Clinical Development Agreement***

In July 2012, the Company entered into a clinical development agreement with PATH to develop its RSV F-protein nanoparticle vaccine candidate (“RSV F vaccine candidate”) to protect against RSV through maternal immunization in low-resource countries (the “RSV Collaboration Program”). Under the RSV Collaboration Program, the Company has been awarded \$5.8 million, including \$3.5 million in funding pursuant to a December 2013 amendment to partially support the Company’s Phase 2 dose-ranging clinical trial in 720 women of childbearing age, which was launched in October 2013. 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 elects 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 technology for its RSV F vaccine candidate for use in pregnant women in such low-resource countries. The Company and PATH are currently discussing further development under the RSV Collaboration Program. The Company recognized revenue of \$0.1 million and \$2.0 million in the three and nine months ended September 30, 2014, respectively, and has recognized \$5.8 million in revenue since the inception of 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 services being performed.



Note 11 – Master Services Agreement with Cadila

The Company and Cadila entered into a master services agreement pursuant to which the Company may request services from Cadila in the areas of biologics research, pre-clinical development, clinical development, process development, manufacturing scale-up and general manufacturing related services in India. In each of July 2011, March 2013 and March 2014, the Company and Cadila amended the master services agreement 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 31, 2015, the amount of services provided by Cadila 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, 2014, the Company has purchased \$4.9 million in services from Cadila pursuant to this agreement, which includes services provided, since the beginning of 2013, by CPLB to the Company on behalf of Cadila pursuant to an October 2013 amendment authorizing such CPLB services. During the nine months ended September 30, 2014, the Company purchased \$1.8 million in services from Cadila pursuant to this agreement, \$0.8 million of which were provided by CPLB on behalf of Cadila. The Company has recognized as expense the entire amount related to CPLB as the Company has not recorded any equity income (loss) of CPLB (see Note 10).

Note 12 – License agreement with Wyeth Holding Corporation

In July 2007, the Company entered into an agreement to license certain rights from Wyeth Holding Corporation, a subsidiary of Pfizer Inc. (“Wyeth”). The Wyeth license, which provides for an upfront payment (previously made), ongoing annual license fees, sublicense payments, payments on certain milestone development activities 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. At present, the Company’s influenza VLP vaccine programs, both seasonal and pandemic, are the only programs to which the Wyeth license applies. The license may be terminated by Wyeth only for cause and may be terminated by the Company only after it has provided ninety (90) days’ notice that the Company has 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, 2014 totaled \$6.4 million. The Company is currently in discussions with Wyeth to potentially amend the agreement and reduce the milestone payment owed as a result of CPLB’s initiation of a Phase 3 clinical trial for a monovalent H1N1 seasonal influenza VLP vaccine candidate in the third quarter of 2014. Such milestone payment is only owed once and the Company would not be required to make another payment if it or any of its affiliates initiate an additional Phase 3 clinical trial in a seasonal influenza VLP vaccine candidate. The \$3.0 million milestone has been accrued for on the consolidated balance sheet at September 30, 2014 and recorded as a research and development expense in the three months ended September 30, 2014.

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

Any statements in the discussion below and elsewhere in this report, about expectations, beliefs, plans, objectives, assumptions or future events or performance of Novavax, Inc. (Novavax, and together with its wholly owned subsidiary, Novavax AB (formerly known as Isconova AB), the "Company," "we" or "us") are not historical facts and are forward-looking statements. Such forward-looking statements include, without limitation, statements with respect to our expectations regarding future revenue and expense levels; potential market sizes and demand for our product candidates; the efficacy, safety and intended utilization of our product candidates; the development of our clinical-stage product candidates and our recombinant vaccine and adjuvant technologies; the future development of our product candidates; the conduct, timing and results of clinical trials; plans for and potential timing of regulatory filings; reimbursement by Department of Health and Human Services, Biomedical Advanced Research and Development Authority (HHS BARDA); the potential modification to our license agreement with Wyeth; our available cash resources and the availability of financing generally, plans regarding partnering activities, business development initiatives and the adoption of stock incentive plans, and other factors referenced herein. You generally can identify these forward-looking statements by the use of words or phrases such as "believe," "may," "could," "will," "would," "possible," "can," "estimate," "continue," "ongoing," "consider," "anticipate," "intend," "seek," "plan," "project," "expect," "assume" or the negative of these terms, or other comparable terminology, although not all forward-looking statements contain these words.

Any or all of our forward-looking statements in this Quarterly Report may turn out to be inaccurate or materially different than actual results. Among the factors that could cause actual results to differ materially from those indicated in the forward-looking statements are risks and uncertainties inherent in our business including, without limitation, the progress, timing or success of our clinical trials; difficulties or delays in development, testing, GMP manufacturing and scale-up, obtaining regulatory approval for producing and marketing our product candidates; regulatory developments in the U.S. or in foreign jurisdictions; decisions by regulatory authorities and HHS BARDA; risks associated with our reliance on collaborations for the development and commercialization of our product candidates; unexpected adverse side effects or inadequate efficacy of our product candidates that could delay or prevent product development or commercialization, or that could result in recalls or product liability claims; our ability to attract and retain key scientific, management or operational personnel; the size and growth potential of the markets for our product candidates and our ability to serve those markets; the scope and validity of patent protection for our product candidates; competition from other pharmaceutical or biotechnology companies; our ability to establish and maintain strategic collaborations or to otherwise obtain additional financing to support our operations on commercially reasonable terms; successful administration of our business and financial reporting capabilities; and risks identified under Item 1A "Risk Factors" of the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2013. In light of these risks and uncertainties, forward-looking events and circumstances discussed in this Quarterly Report may not occur as indicated in forward-looking statements, and actual results could differ materially from those anticipated or implied by the forward-looking statements. We, therefore, caution readers not to place undue reliance on such forward-looking statements contained in this Quarterly Report.

We cannot guarantee future results, events, levels of activity, performance or achievement. We undertake no obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, unless required by law.

## Overview

We are a clinical-stage biopharmaceutical company focused on the discovery, development and commercialization of recombinant protein nanoparticle vaccines and adjuvants. Our vaccine technology platform is based on proprietary recombinant nanoparticle vaccine technology that includes both virus-like particle vaccines (“VLPs”) and nanoparticle vaccines. In each case, these vaccine candidates are genetically engineered three-dimensional nanostructures that incorporate immunologically important proteins. Our vaccine product pipeline targets a variety of infectious diseases with candidates currently in clinical development for respiratory syncytial virus (“RSV”), seasonal influenza and pandemic influenza. We have additional pre-clinical stage programs in a variety of infectious diseases, including Middle East Respiratory Syndrome (MERS) and the Ebola virus disease (EVD).

Through our Swedish wholly owned subsidiary, Novavax AB, we are also developing proprietary immune-stimulating saponin-based adjuvants, which we expect to utilize in conjunction with our pandemic influenza vaccine candidates and potentially with other vaccine candidates that may benefit from such an adjuvant. Our Matrix™ adjuvant technology utilizes selected quillaja fractions, which form separate matrix structures, to develop modern, multi-purpose immune-modulating adjuvant products for a broad range of potential vaccine applications. We acquired the Matrix technology through our acquisition of Novavax AB in the third quarter of 2013 based on our assessment that this saponin-based adjuvant technology could represent a powerful complement to our recombinant vaccine programs. During the first quarter of 2014, under our contract with HHS BARDA, we initiated a clinical trial using our lead adjuvant for human applications, Matrix-M™, in combination with our H7N9 vaccine candidate and reported positive results from this clinical trial in the third quarter of 2014. Matrix-M is also used in clinical trials with our collaborator Genocea Biosciences in its vaccine candidate against herpes simplex virus type 2.

Our joint venture with Cadila Pharmaceuticals Limited (“Cadila”), named CPL Biologicals Private Limited (“CPLB”), is developing and manufacturing vaccines, biological therapeutics and diagnostics in India. CPLB is owned 20% by us and 80% by Cadila. CPLB operates a manufacturing facility in India for the production of vaccines and is actively developing a number of vaccine candidates that were genetically engineered by us.

## Clinical Product Pipeline

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

<b>Program</b>	<b>Development Phase</b>	<b>Collaborator</b>
<b>Respiratory Syncytial Virus (RSV)</b>		
· Maternal Immunization	Phase 2	PATH
· Elderly	Phase 2	
· Pediatric	Pre-clinical	
<b>Influenza</b>		
· Seasonal Quadrivalent	Phase 2	HHS BARDA/LGLS
· Pandemic (H7N9) <sup>1</sup>	Phase 1/2	HHS BARDA/LGLS
· Pandemic (H5N1) <sup>1</sup>	Phase 1	HHS BARDA/LGLS
<b>Combination (Influenza/RSV)</b>	Pre-clinical	
<b>Ebola</b>	Pre-clinical	
<b>CPLB Programs (India)</b>		
· Seasonal Trivalent Influenza	Phase 3	
· Monovalent (H1N1) Influenza	Phase 3	
· Rabies	Phase 1/2	

## Respiratory Syncytial Virus (RSV)

RSV is a widespread disease that causes infections of the lower respiratory tract. While RSV affects individuals of all ages, it acutely impacts infants, the elderly, young children and others with compromised immune systems. RSV is the number one cause of hospitalization in infants ages 0 to 12 months in the U.S. and is a significant cause of infant morbidity and mortality globally.<sup>2</sup> 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 of age.<sup>3</sup> In

the U.S., nearly all children become infected with RSV before they are two years of age; it has been associated with 20% of hospitalizations and 15% of office visits for acute respiratory infection in young children.<sup>4</sup> In addition, it is estimated that between 11,000 to 17,000 elderly and high-risk adults die of RSV infection or its complications annually in the U.S., and up to 180,000 are hospitalized for serious respiratory symptoms.<sup>5</sup> The World Health Organization (WHO) estimates that the annual global disease burden for RSV is 64 million cases. Because there is no approved prophylactic vaccine, an RSV vaccine has the potential to protect millions of patients from this far-reaching unmet medical need.

<sup>1</sup> Although we initiated development of our pandemic influenza vaccine program under our contract with HHS BARDA against the A(H5N1) strain, because of concern over the potential mutation and spread of the A(H7N9) influenza strain in China, we independently initiated a second pandemic vaccine program in the first half of 2013 against A(H7N9). In February 2014, we amended our contract with HHS BARDA to re-prioritize our development efforts on a pandemic influenza vaccine against the A(H7N9) strain with a Phase 1/2 clinical trial using our H7N9 candidate and Matrix-M™ adjuvant, which began in the first quarter of 2014. HHS BARDA has indicated that, while not a current development priority, the H5N1 vaccine program remains a viable potential development opportunity under our contract.

<sup>2</sup> Dawson-Caswell, D, et al., (2011) Am Fam Physician. 83:143 - 146

<sup>3</sup> Nair, H., et al., (2010) Lancet. 375:1545 - 1555

<sup>4</sup> Hall, CB, et al., (2009) N Engl J Med. 360(6):588-98

<sup>5</sup> Falsey, A., et al., (2014) Infectious Disorders. 12(2): 98-102

We are developing a RSV F-protein nanoparticle vaccine candidate (RSV F vaccine candidate) to prevent RSV disease, and are actively pursuing clinical trials in three susceptible target populations: 1) infants via maternal immunization, 2) the elderly and 3) pediatrics.

***Maternal Immunization Development Program — Clinical Experience***

In April 2013, we announced top-line data from a Phase 2 dose-ranging clinical trial in women of childbearing age. The data were similar to, or exceeded, immune responses seen in our first Phase 1 clinical trial. This randomized, blinded, placebo-controlled Phase 2 clinical trial evaluated the safety and immunogenicity of two dose levels of our RSV F vaccine candidate, with and without an aluminum phosphate adjuvant, in 330 women of childbearing age. We further reported that the vaccine candidate was well-tolerated, the two-dose alum-adjuvanted groups showed a 13 to 16-fold rise in anti-F IgG antibodies to the F protein compared to a six to ten-fold rise in the non-alum groups. In addition, titers of palivizumab-competing antibodies (PCAs), which are antibodies that demonstrate protection similar to the monoclonal antibody currently marketed as Synagis® used to prevent RSV in pre-mature infants, rose eight to nine-fold with four-fold rises in 92% of subjects in the two-dose alum-adjuvanted groups. Recently, we announced follow-up data from this clinical trial which demonstrated that our RSV F vaccine candidate reduced the incidence of RSV infection by as much as 50%, suggesting that our RSV F vaccine candidate, which is expected to provide benefits to newborns, pediatrics and the elderly, could also benefit pregnant women receiving the vaccine.

In April 2014, we announced top-line data from a Phase 2 dose-confirmatory trial clinical trial of our RSV F vaccine candidate in 720 women of childbearing age. The randomized, blinded, placebo-controlled Phase 2 study was designed to evaluate the immunogenicity and safety of multiple formulations of the vaccine candidate adjuvanted with aluminum phosphate. We reported that the vaccine candidate was well-tolerated with no vaccine-related serious adverse events. In addition, we reported that the highest immune responses, as measured by RSV F and PCA levels, were achieved in a single dose formulation, which also demonstrated rapid and sustainable increases in those antibody levels. These data, along with the data from our other RSV F vaccine candidate clinical trials are expected to support the advancement of our maternal immunization program in pregnant women; we have initiated discussions with the FDA in support of the planned initiation of a Phase 2 clinical trial of our RSV F vaccine candidate in pregnant women in the fourth quarter of 2014.

In September 2014, we initiated enrollment in a Phase 2 clinical trial of our RSV vaccine candidate in 50 healthy women in the third trimester of pregnancy. The study is a randomized, observer-blinded, placebo-controlled Phase 2 study, which is designed to evaluate the safety and immunogenicity of the RSV F vaccine candidate in this population. The trial is also designed to assess the impact of maternal immunization on infant safety and RSV-specific antibody levels through one year and six months of life, respectively. We expect to announce data from this trial in the third quarter of 2015.

***Elderly Development Program — Clinical Experience***

In July 2013, we announced top-line data from a Phase 1 clinical trial in the elderly that was initiated in October 2012. This clinical trial was a randomized, blinded, placebo-controlled Phase 1 clinical trial that evaluated the safety and immunogenicity in 220 elderly adults, 60 years of age and older, who received a single intramuscular injection of our RSV F vaccine candidate (with and without alum) or placebo plus a single dose of licensed influenza vaccine or placebo at days 0 and 28. The top-line data further corroborated our previous clinical experiences with our RSV F vaccine candidate: we reported that the vaccine candidate was well-tolerated, that the higher dose groups had better overall immune responses than the lower dose groups, and that essentially undetectable Day 0 levels of PCA increased to between 80% and 97% of active vaccine recipients by Day 28. In May 2014, we announced one-year follow-up data from this Phase 1 clinical trial demonstrating that the 90µg dose without adjuvant resulted in anti-F levels and PCA levels that were significantly elevated and maintained over baseline throughout a 118 day period. These data suggest that the vaccine candidate sustained levels that may provide protection during an entire RSV season and support the accelerated development of the RSV F vaccine candidate as an annual seasonal vaccine for the elderly.

In October 2014, we announced the initiation of a Phase 2 clinical trial of our RSV F vaccine candidate in healthy elderly subjects. The trial is a randomized, observer-blinded, placebo-controlled Phase 2 study scheduled to enroll 1,600 elderly subjects (>60 years of age). The trial is designed to evaluate the incidence of all respiratory illnesses due to RSV, including medically-attended respiratory illnesses due to RSV, and hospitalizations for respiratory illness due to RSV in community-living elderly adults who have been treated with placebo. The study is also designed to evaluate the safety and immunogenicity of a 135µg dose of the RSV F vaccine candidate compared with placebo. The trial will also estimate the efficacy of the RSV F vaccine candidate in reducing the incidence of respiratory illnesses due to RSV. We expect to announce data from this trial in the third quarter of 2015.

### ***Pediatric Development Program — Pre-clinical Experience***

While the burden of RSV disease on newborn infants is well understood, RSV is also a prevalent and currently unaddressed problem in pediatric patients. This third market segment for our RSV F vaccine candidate remains an important opportunity. Our pediatric development plan will likely be based on a series of clinical trials that “step-down” from our past clinical trials in healthy adults into younger pediatric subjects. We also expect that our clinical experience in pregnant women will be significantly important to understanding a vaccine for this patient population. We expect to initiate a Phase 1 clinical trial in pediatric subjects in the fourth quarter of 2014.

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

In July 2012, we entered into a clinical development agreement with PATH to develop our RSV F vaccine candidate for the maternal immunization indication in low-resource countries (our “RSV Collaboration Program”). Under our RSV Collaboration Program, we have been awarded approximately \$6 million, including \$3.5 million in funding pursuant to a December 2013 amendment to partially support our Phase 2 dose-confirmation clinical trial in 720 women of childbearing age, as described above. We retain global rights to commercialize the product and plan to support PATH in its goal to make an RSV maternal vaccine product affordable and available in low-resource countries. To the extent PATH elects to continuously 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 technology for our RSV F vaccine candidate for use in pregnant women in such low-resource countries. We are currently discussing further development under the RSV Collaboration Program with PATH.

## **Influenza**

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



Developing and commercializing a Novavax seasonal influenza vaccine remains an important strategic goal and viable opportunity for us. The Advisory Committee for Immunization Practices of the Center for Disease Control and Prevention recommends that all persons aged six months and older should be vaccinated annually against seasonal influenza. In conjunction with this universal recommendation, attention from the 2009 influenza H1N1 pandemic, along with reports of other cases of avian-based influenza strains, 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.

Among the seasonal influenza vaccines licensed in the U.S., only four products are quadrivalent vaccines (meaning four separate influenza strains: two influenza A strains and two influenza B strains) as opposed to trivalent vaccines (meaning three influenza strains: two influenza A strains and one influenza B strain). However, in coming years, additional quadrivalent seasonal influenza vaccines are expected to be produced and licensed within and outside of the U.S. 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 additional protection. Current estimates for seasonal influenza vaccine growth in the top seven markets (U.S., Japan, France, Germany, Italy, Spain and UK), show potential expansion from the current market of approximately \$3.2 billion (2012/13 season) to \$5.3 billion by the 2021/2022 season.<sup>6</sup> We believe that recombinant seasonal influenza vaccines, like the candidate we are developing, have an important advantage: once licensed for commercial sale, large quantities of vaccines can be quickly and cost-effectively manufactured without the use of either the live influenza virus or chicken eggs.

Top-line data from our most recent Phase 2 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 hemagglutination inhibition (HAI) responses at day 21, and was well-tolerated, as evidenced by the absence of any observed vaccine-related serious adverse events along with 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. Following our last Phase 2 clinical trial, we focused our seasonal influenza vaccine candidate activities on locking the manufacturing process that is expected to provide consistent and enhanced immune responses in all strains. With these activities significantly completed, we have completed manufacturing work for the A and B strain influenza VLPs to be used in the next Phase 2 clinical trial with our quadrivalent vaccine candidate, which is expected to begin late in the fourth quarter of 2014.

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

In the aftermath of the 2009 H1N1 influenza pandemic, preventing 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 manufactured quickly against a potentially threatening influenza strain. Until the spring of 2013, industry and health experts focused attention on developing a monovalent H5N1 influenza vaccine as a potential key defense against a future pandemic threat; however, recent attention from a significant number of reported cases in China of an avian-based influenza strain of H7N9 has shifted to the potential development of an H7N9 influenza vaccine.

In collaboration with HHS BARDA, we have now developed and delivered compelling safety and immunogenicity data on two pandemic vaccine candidates, H5N1 and H7N9, which provide the U.S. government with alternatives for dealing with future potential threats. In October 2012, under our collaboration with HHS BARDA, we reported

positive results from two Phase 1 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.

<sup>6</sup> Influenza Vaccines Forecast. Datamonitor (2013)

20

In April 2013, we initiated manufacturing of a new monovalent influenza vaccine candidate against prototype A(H7N9). This strain was first recognized by Chinese health authorities as a potential pandemic influenza threat in late March 2013. In a three month period, we developed a recombinant baculovirus expressing the published A(H7N9) viral HA and NA gene sequences, developed and purified a VLP vaccine antigen, conducted multiple animal studies and initiated a Phase 1 clinical trial in Australia independent of our HHS BARDA contract. In November 2013, we announced the publication of the clinical results from the Phase 1 clinical trial in *The New England Journal of Medicine*. The publication highlighted the fact that 81% of subjects treated with a 5ug dose of vaccine with a saponin-based adjuvant achieved protective HAI levels, and 97% of subjects showed an anti-neuraminidase antibody response. We achieved protective levels from vaccinations within 116 days of the announcement of the H7N9 outbreak from the industry's first clinical trial of a vaccine against an A(H7N9) influenza strain.

In February 2014, we modified our contract with HHS BARDA to focus our development on our H7N9 vaccine candidate. In September 2014, we announced data from a Phase 1/2 clinical trial of our H7N9 vaccine candidate in conjunction with our proprietary saponin-based adjuvant, Matrix-M. The study, initiated in the first quarter of 2014, was a dose-ranging, randomized, observer-blinded, placebo-controlled clinical trial, in 610 healthy subjects, designed to determine the contribution of Matrix-M to potential antigen dose sparing regimens. Subjects were administered two identical doses of either placebo, 15 µg of H7N9 VLP alone, or one of three dose levels of H7N9 VLP in combination with one of two dose levels of Matrix-M. The trial indicated that the H7N9 VLP, with and without Matrix-M, was well tolerated. Matrix-M adjuvanted formulations demonstrated a clear immunogenicity benefit relative to the unadjuvanted formulations. A very clear dose sparing profile was demonstrated with the lower dose adjuvanted formulations providing statistically significantly greater immune responses relative to the unadjuvanted formulations. The results of this study give us confidence to dedicate resources towards additional development of the chemistry, manufacturing and control (CMC) profiles of our influenza products in anticipation of progressing into Phase 3. In October, 2014, we announced that the FDA had granted "Fast Track" designation to our H7N9 vaccine candidate adjuvanted with Matrix-M, which is a special regulatory designation available for treatments that potentially address unmet medical needs against serious or life-threatening diseases or conditions. The Fast Track program is intended to facilitate development and expedite regulatory review of such treatments.

### ***Potential Accelerated Approval Pathway for Influenza***

In the past, we have referenced attainment of accelerated approval immunogenicity endpoints for seroprotection and seroconversion as a potential pathway for licensure of our influenza vaccines. The criteria for granting such accelerated approval of a Biologics License Application (BLA, the biologic equivalent to a New Drug Application or NDA) for new seasonal and pandemic influenza vaccines was published by the FDA's Center for Biologics Evaluation and Research. Under this FDA guidance, developers that can demonstrate results that meet or exceed certain specified immunogenicity endpoint criteria in their clinical trials may, at the FDA's discretion, be granted a license to market a product prior to submission of traditional clinical endpoint efficacy trial data. It should be noted that FDA licensure based on accelerated approval nevertheless requires sponsors to conduct a post-licensure clinical endpoint efficacy study to demonstrate the clinical benefit of the vaccine, which would thereby support traditional approval of the vaccine. Because it is not possible to conduct a clinical endpoint efficacy study for a pandemic vaccine in advance of a declared pandemic, FDA's pandemic guidance allows for submission of seasonal influenza clinical efficacy data for

the purpose of confirming clinical benefit of a pandemic vaccine manufactured by the same process. Thus, the demonstration of efficacy with a seasonal vaccine provides a key link between the seasonal and pandemic programs. Accelerated approval further necessitates a shortage of influenza vaccine relative to the total population recommended to receive such vaccine, a situation that persists with seasonal influenza vaccines.

Although we have not ruled out this accelerated approval approach, particularly for our pandemic program or certain subject populations within the seasonal influenza program, we do not expect to pursue accelerated approval of our quadrivalent seasonal influenza vaccine, largely because of the uncertainty as to whether the accelerated approval pathway will be available to us at the time of our BLA submissions and the unknown ability of current and new influenza strains to meet such accelerated approval criteria. We are planning, therefore, to pursue traditional licensure of our quadrivalent seasonal influenza vaccine by conducting a clinical endpoint efficacy study for the purpose of submitting the data within the original BLA. Positive efficacy data would also support the requirement for clinical efficacy data for our pandemic vaccine program. We plan to discuss with the FDA our licensure pathways (both the traditional pathway for seasonal and possible accelerated pathways for pandemic and certain subject populations within the seasonal program) during future formal meetings. The impact of such an efficacy trial could potentially delay FDA licensure by a year or more of our seasonal influenza vaccine.

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

In February 2011, HHS BARDA awarded us a contract that funds the development of both our seasonal and pandemic influenza vaccine candidates. The contract, valued at \$97 million for the first three-year base-period, was extended in February 2014 by seven months to September 2014; this base-period extension was intended to allow us to continue to access base-period funding. In September 2014, HHS BARDA exercised the option-period under the contract, which extends the contract for an additional two years, until September 2016, and allocated \$70 million (of the original \$79 million option-period funding) to the option-period in addition to any funding remaining from the original \$97 million base-period funding. Our contract with HHS BARDA is a cost-plus-fixed-fee contract in which they reimburse us for allowable direct contract costs, allowable indirect costs and a fixed-fee earned in the ongoing clinical development and product scale-up of our multivalent seasonal and monovalent pandemic influenza vaccine candidates. HHS BARDA originally directed us to develop our monovalent pandemic influenza vaccine against the A(H5N1) strain. With the recent amendment, we are developing our monovalent pandemic influenza vaccine against the A(H7N9) strain; nevertheless, our H5N1 vaccine program, while not a current development priority, remains a viable potential development opportunity under the contract. We recognized revenue of \$20.0 million during the nine months ended September 30, 2014, and have recognized approximately \$72 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, we decided to conduct a Phase 2 clinical trial of our quadrivalent seasonal influenza vaccine candidate in Australia (the 205 Trial) under appropriate local regulatory authorization. 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 205 Trial data in a quadrivalent investigational new drug application (Quadrivalent IND), and those costs are approved by HHS BARDA. FDA acceptance of the Quadrivalent IND is expected shortly before initiation of the next Phase 2 dose-confirmatory clinical trial, which is expected to begin later in the fourth quarter of 2014. The outside clinical trial costs of the 205 Trial conducted in 2012 totaled \$2.9 million. These costs have been recorded as an expense in the period incurred as a cost of government contracts revenue.

### ***LG Life Sciences, Ltd. (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 vaccines 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 in the high single digits from LGLS's future commercial sales of influenza VLP vaccines.

### **Combination Respiratory (Influenza and RSV)**

With the ongoing development of both our RSV F vaccine candidate (as a potential annual seasonal vaccine for the elderly) and our seasonal influenza vaccine candidate, we see an important opportunity to develop a combination respiratory vaccine for the elderly population, although we have not ruled out developing a combination respiratory vaccine for children and infants. Early pre-clinical development efforts and data from animal models have given us confidence that such a combination vaccine is viable and provides acceptable immunogenicity. We intend to explore this development opportunity by conducting a Phase 1 clinical trial in such a combination vaccine in 2015.

## **CPLB Programs (India)**

### ***Influenza***

CPLB initiated Phase 1/2 clinical trials on its seasonal trivalent VLP vaccine candidate and monovalent H1N1 influenza vaccine candidate in 2012. The results of these trials showed safety and immunogenicity data similar to our experiences, particularly when taking into account differences between the Indian subjects' baseline titers and the baseline titers of the subjects in our trials. In October 2013, CPLB initiated the manufacture of Phase 3 material in anticipation of starting Phase 3 clinical trials for both vaccine candidates in 2014, applications for which have been approved by the office of the Drug Controller General of India. CPLB initiated Phase 3 trials of its monovalent H1N1 influenza vaccine candidate in July 2014 and its seasonal trivalent VLP influenza vaccine candidate in October 2014.

### ***Rabies***

CPLB is developing a rabies G protein vaccine candidate that we genetically engineered and has initiated a Phase 1/2 clinical trial in India in January 2014. Our common objective with CPLB is to develop a recombinant vaccine that can be administered both as a pre-exposure prophylaxis for residents of certain higher-risk geographies, as well as travelers to such locations, and also has potential to provide post-exposure prophylaxis with fewer doses. In October 2014, CPLB presented clinical results from the Phase 1/2 clinical trial, demonstrating that all vaccine recipients, at various doses levels and schedules, showed seroprotective antibody levels at day 14 and sustained through day 180. The vaccine candidate, which was found to be safe and well-tolerated, also induced seroprotective levels with two-dose and three-dose regimens.

## **Discovery Programs**

Our vaccine platform technology provides an efficient system to rapidly develop antigens to selected targets, refine manufacturing processes and optimize development across multiple vaccine candidates. We pay close attention to global reports of emerging diseases for which there do not appear to be immediate cures and where a vaccine protocol could offer potential protection. In addition to our response to the A(H7N9) influenza strain (see discussion above), we have been monitoring reports concerning the Middle East Respiratory Syndrome Coronavirus (MERS), a novel coronavirus first identified in September 2012 by an Egyptian virologist, as well as the recent outbreak of the Ebola virus disease (EVD) in West Africa.



MERS became an emerging threat in 2013, with the WHO currently reporting more than 800 confirmed cases of infection and approximately 300 deaths. The MERS virus is a part of the coronavirus family that includes the severe acute respiratory syndrome coronavirus (SARS). Because of the public health priority given to MERS, within weeks of getting the virus' sequence, we successfully produced a vaccine candidate designed to provide protection against MERS. This vaccine candidate, which was made using our recombinant nanoparticle vaccine technology, is based on the major surface spike protein, which we had earlier identified as the antigen of choice in our work with a SARS vaccine candidate. In April 2014, in collaboration with the University of Maryland, School of Medicine, we published results that showed our investigational vaccine candidates against both MERS and SARS blocked infection in laboratory studies. Although the development of a MERS vaccine candidate currently remains a pre-clinical program, we believe that our MERS vaccine candidate offers a viable option to interested global public health authorities.

Recent news reports have centered around EVD, formerly known as Ebola hemorrhagic fever, which is a severe, often fatal illness in humans. There is currently no licensed treatment proven to neutralize EVD, but a range of vaccine and therapeutic candidates are under development. Five strains of EVD have been identified; the strain currently afflicting West Africa is known as the Guinea-EVD strain. Current publicly known vaccine approaches target earlier strains of the virus. Our Ebola glycoprotein (GP) vaccine candidate, which was modeled using the 2014 Guinea-EVD strain, has recently been successfully tested in both rodent and rabbit pre-clinical models. We have also tested the vaccine with our Matrix-M adjuvant in these same pre-clinical models, which appears to significantly contribute to enhanced immunogenicity and induction of neutralizing antibodies. We recently initiated a non-human primate study and expect to initiate a Phase 1 clinical trial in December 2014 to evaluate the safety and immunogenicity of this vaccine candidate in ascending doses, with and without our Matrix-M adjuvant. Clinical studies subsequent to Phase 1 data are under discussion and will be developed based on data from this Phase 1 clinical trial. In order to begin the Phase 1 clinical trial, we have initiated small-scale GMP production of our EVD GP vaccine.

### **Sales of Common Stock**

In October 2012, we entered into an At Market Issuance Sales Agreement (2012 Sales Agreement), under which our Board of Directors (the Board) approved the sale of up to an aggregate of \$50 million in gross proceeds of our common stock. The shares of common stock are potentially available pursuant to a shelf registration statement filed with the SEC in March 2013, which replaced the previous shelf registration statement filed in 2010. The Board's standing Finance Committee (the Finance Committee) assists with the Board's responsibilities to monitor, provide advice to our senior management and approve capital raising activities that are not otherwise approved by the Board. The Finance 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 pursuant to the 2012 Sales Agreement. In doing so, the Finance 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. As of September 30, 2014, we have approximately \$15 million available under the 2012 Sales Agreement. The most recent sales that occurred under the 2012 Sales Agreement were on September 10, 2013.

In June 2014, we completed a public offering of 28,750,000 shares of our common stock, including 3,750,000 shares of common stock that were issued upon the exercise in full of an option to purchase additional shares granted to the underwriters, at a price of \$4.00 per share resulting in net proceeds of approximately \$108 million.

### ***Critical Accounting Policies and Use of Estimates***

There are no material changes to our critical accounting policies as described in Item 7 of our Annual Report on Form 10-K for the fiscal year ended December 31, 2013, 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). In May 2014, the Financial Accounting Standards Board issued ASU 2014-09, *Revenue from Contracts with Customers (Topic 606)* ("ASU 2014-09"), which supersedes nearly all existing revenue recognition guidance under Topic 605, *Revenue Recognition*. The new standard requires a company to recognize revenue when it transfers goods and services to customers in an amount that reflects the consideration that the company expects to receive for those goods or services. ASU 2014-09 defines a five-step process that includes identifying the contract with the customer, identifying the performance obligations in the contract, determining the transaction price, allocating the transaction prices to the performance obligations in the contract and recognizing revenue when (or as) the entity satisfies the performance obligations. ASU 2014-09 will be effective for us on January 1, 2017. We are evaluating the potential impact that ASU 2014-09 will have on our consolidated financial position and results of operations.

**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, 2014 and 2013** (amounts in tables are presented in thousands, except per share information)

**Revenue:**

<b>Three Months Ended</b>			
<b>September 30,</b>			<b>Change</b>
<b>2014</b>	<b>2013</b>		<b>2013</b>
			<b>to 2014</b>
Revenue:			
Total revenue	\$8,214	\$4,802	\$3,412

Revenue for the three months ended September 30, 2014 was \$8.2 million as compared to \$4.8 million for the same period in 2013, an increase of \$3.4 million or 71%. Revenue for the three months ended September 30, 2014 and 2013 is primarily comprised of services performed under the HHS BARDA contract. The increase in revenue is primarily due to the higher level of activity in the three months ended September 30, 2014 associated with our Phase 1/2 pandemic (H7N9) clinical trial and manufacturing work for our Phase 2 seasonal influenza clinical trial under the HHS BARDA contract, as compared to the same period in 2013.

For 2014, we expect a significant increase in revenue associated with our increased clinical trial and product development activities under the HHS BARDA contract to support the initiation of later-stage clinical trials of our seasonal influenza and pandemic (H7N9) influenza vaccine candidates.

**Costs and Expenses:****Three Months Ended**

	<b>September 30,</b>		<b>Change</b>
	2014	2013	<b>2013</b>
			<b>to 2014</b>
Costs and Expenses:			
Cost of government contracts revenue	\$4,027	\$2,276	\$1,751
Research and development	19,219	13,948	5,271
General and administrative	4,757	3,857	900
Total costs and expenses	\$28,003	\$20,081	\$7,922

### ***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 increased to \$4.0 million for the three months ended September 30, 2014 from \$2.3 million for the same period in 2013, an increase of \$1.8 million, or 77%. The increase in cost of government contracts revenue is primarily related to the costs of our Phase 1/2 clinical trial using our H7N9 candidate and Matrix-M adjuvant and manufacturing work for our Phase 2 seasonal influenza clinical trial, as compared to the same period in 2013. For 2014, we expect a significant increase in cost of government contracts revenue associated with our increased clinical trial and product development activities under the HHS BARDA contract to support the initiation of later-stage clinical trials of our seasonal influenza and pandemic (H7N9) influenza vaccine candidates.

***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 \$19.2 million for the three months ended September 30, 2014 from \$13.9 million for the same period in 2013, an increase of \$5.3 million, or 38%. The increase in research and development expenses was primarily due to the milestone payment accrued under the Wyeth agreement and higher employee-related costs, as compared to the same period in 2013. For 2014, we expect a significant increase in research and development expenses primarily due to additional RSV F vaccine candidate clinical trials and employee-related costs to support product development of our RSV F vaccine candidate 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 September 30, 2014, we had 227 employees dedicated to our research and development programs versus 153 employees as of September 30, 2013. 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).

	2014	2013
Manufacturing	\$12.8	\$8.7
Vaccine Discovery	1.7	1.5
Clinical and Regulatory	8.7	6.0
Total cost of government contracts revenue and research and development expenses	\$23.2	\$16.2

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 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; whether 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 increased to \$4.8 million for the three months ended September 30, 2014 from \$3.9 million for the same period in 2013, an increase of \$0.9 million, or 23%. The increase was primarily due to higher employee-related costs, as compared to the same period in 2013. For 2014, we expect general and administrative expenses to increase primarily due to a full year of expenses relating to Novavax AB and pre-commercialization activities.

**Other Income (Expense):**

	<b>Three Months Ended</b>		
	<b>September 30,</b>		
	<b>2014</b>	<b>2013</b>	<b>Change 2013 to 2014</b>
Other Income (Expense):			
Interest income	\$128	\$53	\$ 75
Interest expense	(47)	(64)	17
Other income (expense)	(19)	(10)	(9)
Change in fair value of warrant liability			
Realized gains on investments			
Total other income (expense)	\$62	\$(21)	\$( 83 )

We had total other income of \$0.1 million for the three months ended September 30, 2014 compared to total other expense of less than \$0.1 million for the same period in 2013.

**Net Loss:**

	<b>Three Months Ended September 30,</b>		
	<b>2014</b>	<b>2013</b>	<b>Change 2013 to 2014</b>
Net Loss:			
Net loss	\$(19,727)	\$(15,300)	\$(4,427)



Edgar Filing: NOVAVAX INC - Form 10-Q

Net loss per share	\$(0.08	)	\$(0.09	)	\$0.01
Weighted shares outstanding	238,304		168,537		69,767

Net loss for the three months ended September 30, 2014 was \$19.7 million, or \$0.08 per share, as compared to \$15.3 million, or \$0.09 per share, for the same period in 2013, an increased net loss of \$4.4 million. The increased net loss was primarily due to higher research and development spending, including the milestone payment accrued under the Wyeth agreement and higher employee-related costs, as compared to the same period in 2013.

The increase in weighted average shares outstanding for the three months ended September 30, 2014 as compared to the same period in 2013 is primarily a result of sales of our common stock in 2013 and 2014 and shares issued in connection with the acquisition of Novavax AB.

**Nine Months Ended September 30, 2014 and 2013** (amounts in tables are presented in thousands, except per share information)

**Revenue:**

<b>Nine Months Ended</b>			
<b>September 30,</b>			
2014	2013	<b>Change 2013 to 2014</b>	
Revenue:			
Total revenue	\$23,935	\$12,167	\$11,768

Revenue for the nine months ended September 30, 2014 was \$23.9 million as compared to \$12.2 million for the same period in 2013, an increase of \$11.8 million or 97%. Revenue for the nine months ended September 30, 2014 and 2013 is primarily comprised of services performed under the HHS BARDA contract and the PATH clinical development agreement, and to a lesser extent in 2014, revenue from Novavax AB. The increase in revenue is primarily due to the higher level of activity in the nine months ended September 30, 2014 associated with our Phase 1/2 pandemic (H7N9) clinical trial and manufacturing work for our Phase 2 seasonal influenza clinical trial under the HHS BARDA contract, as compared to the same period in 2013. We also had increased revenue in the nine months ended September 30, 2014 associated with our Phase 2 clinical trial in women of childbearing age under the PATH clinical development agreement and Novavax AB resulting from nine months of activity in 2014 as compared to only two months in 2013.

**Costs and Expenses:**

<b>Nine Months Ended</b>			
<b>September 30,</b>			
	2014	2013	<b>Change 2013 to 2014</b>
<b>Costs and Expenses:</b>			
Cost of government contracts revenue	\$12,150	\$5,619	\$6,531
Research and development	48,940	33,989	14,951
General and administrative	14,871	10,740	4,131
Total costs and expenses	\$75,961	\$50,348	\$25,613

***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 increased to \$12.2 million for the nine months ended September 30, 2014 from \$5.6 million for the same period in 2013, an increase of \$6.5 million, or 116%. The increase in cost of government contracts revenue is primarily related to the costs of our Phase 1/2 clinical trial using our H7N9 candidate and Matrix-M adjuvant and manufacturing work for our Phase 2 seasonal influenza clinical trial, as compared to the same period in 2013.

***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 \$48.9 million for the nine months ended September 30, 2014 from \$34.0 million for the same period in 2013, an increase of \$15.0 million, or 44%. Excluding the increase in research and development expenses of \$3.3 million from Novavax AB resulting from nine months of activity in 2014 as compared to only two months in 2013, the increase in research and development expenses was primarily due to higher employee-related costs, the milestone payment accrued under the Wyeth agreement and, to a lesser degree, facility costs, as compared to the same period in 2013.

***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).

	2014	2013
Manufacturing	\$35.5	\$21.9
Vaccine Discovery	4.4	4.0
Clinical and Regulatory	21.2	13.7
Total cost of government contracts revenue and research and development expenses	\$61.1	\$39.6

***General and Administrative Expenses***

General and administrative expenses increased to \$14.9 million for the nine months ended September 30, 2014 from \$10.7 million for the same period in 2013, an increase of \$4.1 million, or 38%. Excluding the increase in general and administrative expenses of approximately \$0.9 million from Novavax AB resulting from nine months of activity in 2014 as compared to only two months in 2013, the increase was primarily due to higher employee-related costs, as compared to the same period in 2013.

**Other Income (Expense):**

	<b>Nine Months Ended</b>		
	<b>September 30,</b>		<b>Change</b>
	<b>2014</b>	<b>2013</b>	<b>2013</b>
			<b>to 2014</b>
Other Income (Expense):			
Interest income	\$160	\$149	\$ 11
Interest expense	(150)	(132)	(18 )
Other income (expense)		(10 )	10
Change in fair value of warrant liability		267	(267 )
Realized gains on investments	615		615
Total other income (expense)	\$625	\$274	\$ 351

We had total other income of \$0.6 million for the nine months ended September 30, 2014 compared to total other income of \$0.3 million for the same period in 2013. The change in fair value of the warrant liability resulted in a \$0.3 million decrease in total other income for the nine months ended September 30, 2014 as compared to the same period in 2013. The warrants expired unexercised on July 31, 2013. For the nine months ended September 30, 2014, we sold our auction rate security and received proceeds of \$1.8 million resulting in a realized gain of \$0.6 million.

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

	2014	2013	<b>Change 2013 to 2014</b>
Net Loss:			
Net loss	\$(51,401 )	\$(37,929 )	\$(13,472)
Net loss per share	\$(0.23 )	\$(0.24 )	\$0.01
Weighted shares outstanding	221,578	156,555	65,023

Net loss for the nine months ended September 30, 2014 was \$51.4 million, or \$0.23 per share, as compared to \$37.9 million, or \$0.24 per share, for the same period in 2013, an increased net loss of \$13.5 million. The increased net loss was primarily due to higher research and development spending, including higher employee-related costs and the milestone payment accrued under the Wyeth agreement, as compared to the same period in 2013.

The increase in weighted average shares outstanding for the nine months ended September 30, 2014 as compared to the same period in 2013 is primarily a result of sales of our common stock in 2013 and 2014 and shares issued in connection with the acquisition of Novavax AB.

**Liquidity Matters and Capital Resources**

Our future capital requirements depend on numerous factors including, but not limited to, the commitments related to 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, 2014, we had \$190.3 million in cash and cash equivalents and investments as compared to \$133.1 million as of December 31, 2013. These amounts consisted of \$34.5 million in cash and cash equivalents and \$155.8 million in investments as of September 30, 2014 as compared to \$119.5 million in cash and cash equivalents and \$13.6 million in investments at December 31, 2013.

The following table summarizes cash flows for the nine months ended September 30, 2014 and 2013 (in thousands):

	<b>Nine Months Ended</b>		
	<b>September 30,</b>		<b>Change 2013 to 2014</b>
	2014	2013	
Summary of Cash Flows:			
Net cash (used in) provided by:			
Operating activities	\$(47,246 )	\$(33,096 )	\$(14,150 )
Investing activities	(147,180)	7,231	(154,411)
Financing activities	109,449	130,943	(21,494 )
Effect on exchange rate on cash and cash equivalents	(21 )	16	(37 )
Net (decrease) increase in cash and cash equivalents	(84,998 )	105,094	(190,092)
Cash and cash equivalents at beginning of period	119,471	17,399	102,072
Cash and cash equivalents at end of period	\$34,473	\$122,493	\$(88,020 )

Net cash used in operating activities increased to \$47.2 million for the nine months ended September 30, 2014 as compared to \$33.1 million for the same period in 2013. The increase in cash usage was primarily due to increased costs relating to our RSV clinical trials and higher employee-related costs and to a lesser extent, timing of customer and vendor payments.

During the nine months ended September 30, 2014 and 2013, our investing activities primarily consisted of purchases and maturities of investments and capital expenditures. In the nine months ended September 30, 2014, we primarily purchased investments to increase our rate of return on our investments relative to returns available to money market funds. Capital expenditures for the nine months ended September 30, 2014 and 2013 were \$4.9 million and \$4.8 million, respectively. In 2014, we expect our level of capital expenditures to be higher than our 2013 spending based on increased capacity demands for clinical trial material in the second half of 2014.

Our financing activities consisted primarily of sales of our common stock, and to a lesser extent, stock option exercises and purchases under our employee stock purchase plan in the nine months ended September 30, 2014. In the nine months ended September 30, 2014, we received net proceeds of approximately \$108 million through our public offering at \$4.00 per share. In the nine months ended September 30, 2013, we received net proceeds of \$94.7 million through our public offering at a sales price of \$3.14 per share and \$34.0 million through our Sales Agreement at an average sales price of \$2.76 per share.

In July 2007, we entered into an agreement to license certain rights from Wyeth Holding Corporation, a subsidiary of Pfizer Inc. (Wyeth). The Wyeth license, which provides for an upfront payment (previously made), ongoing annual license fees, sublicense payments, payments on certain milestone development activities 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. At present, our influenza VLP vaccine programs, both seasonal and pandemic, are the only programs to which the Wyeth license applies. 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, 2014 totaled \$6.4 million. We are currently in discussion with Wyeth to potentially amend the agreement and reduce the milestone payment owed as a result of CPLB's initiation of a Phase 3 clinical trial for its monovalent H1N1 seasonal influenza VLP vaccine candidate in the third quarter of 2014. Such milestone payment is only owed once and we would not be required to pay again if we or any of our affiliates initiate an additional Phase 3 clinical trial in a seasonal influenza VLP vaccine candidate.

We entered into a master services agreement with Cadila, which we and Cadila amended in each of July 2011, March 2013 and March 2014, 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 2015, 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. The Company and Cadila also agreed to an amendment that allows CPLB, as of the beginning of 2013, to provide services on behalf of Cadila. Through September 30, 2014, we have purchased \$4.9 million in services from Cadila pursuant to this agreement, including amounts in which CPLB provided the services on behalf of Cadila.

Based on our September 30, 2014 cash and cash equivalents, investment balances, the anticipated revenue under the contract with HHS BARDA and other resources, we believe we have adequate capital to fund our operating plans into



2016. Additional capital may be required in the future to develop our vaccine candidates through clinical development, manufacturing and commercialization. Our ability to obtain such additional capital will likely be subject to various factors, including our ability to perform and thus generate revenue under the HHS BARDA contract, our overall business performance and market conditions.

Any capital raised by an equity offering will be 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. We cannot 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 may 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 preservation of capital, with the secondary objective of maximizing income. As of September 30, 2014, we had cash and cash equivalents of \$34.5 million, investments of \$155.8 million, of which \$143.6 million are short-term, and working capital of \$173.3 million.

Our exposure to market risk is primarily confined to our investment portfolio. As of September 30, 2014, our investments were classified as available-for-sale. We do not believe that a change in the market rates of interest would have a 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. We have one foreign consolidated subsidiary, Novavax AB, which is located in Sweden. A 10% decline in the exchange rate between the U.S. dollar and Swedish Krona would result in a reduction of stockholders' equity of approximately \$3.3 million at September 30, 2014.

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, 2014. 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 such control objectives. Based on the evaluation of our disclosure controls and procedures as of September 30, 2014, 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 quarterly period ended September 30, 2014, and has concluded that there was no change that occurred during the quarterly period ended September 30, 2014 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, 2013.

### Item 6. Exhibits

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

Confidential treatment has been requested for portions of exhibits marked with a double asterisk (\*\*).

- 3 .1 Amended and Restated Certificate of Incorporation of Novavax, Inc., as amended by Certificates of Amendment dated December 18, 2000, July 8, 2004, May 13, 2009 and June 13, 2013 (Incorporated by reference to Exhibit 3.1 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2013, filed August 8, 2013)
- 3 .2 Amended and Restated By-Laws of the Company (Incorporated by reference to Exhibit 3.2 to the Company's Annual Report on Form 10-K for the year ended December 31, 2012, filed March 12, 2013)
- 10 .1\* Contract Amendment/Modification No. 6 between the Company and HHS/OS/ASPR/BARDA, dated  
\*\* September 22, 2014
- 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 6, 2014 By: /s/ Stanley C. Erck  
President and Chief Executive Officer  
and Director  
(Principal Executive Officer)

Date: November 6, 2014 By: /s/ Barclay A. Phillips  
Senior Vice President, Chief Financial  
Officer and Treasurer  
(Principal Financial and Accounting  
Officer)