



Edgar Filing: NOVAVAX INC - Form 10-Q

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

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

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

Large accelerated filer  Accelerated filer  Non-accelerated filer  Smaller reporting company   
(Do not check if a smaller reporting company)

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

The number of shares outstanding of the Registrant’s Common Stock, \$0.01 par value, was 269,858,393 as of October 31, 2015.

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, 2015 (unaudited) and December 31, 2014</u>	1
	<u>Unaudited Consolidated Statements of Operations and Unaudited Consolidated Statements of Comprehensive Loss for the three and nine months ended September 30, 2015 and 2014</u>	2
	<u>Unaudited Consolidated Statements of Cash Flows for the nine months ended September 30, 2015 and 2014</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>	17
Item 3.	<u>Quantitative and Qualitative Disclosures about Market Risk</u>	33
Item 4.	<u>Controls and Procedures</u>	34
<b><u>PART II. OTHER INFORMATION</u></b>		
Item 1A.	<u>Risk Factors</u>	34
Item 6.	<u>Exhibits</u>	35
	<b><u>SIGNATURES</u></b>	36

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

(in thousands, except share and per share information)

	September 30, 2015 (unaudited)	December 31, 2014
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 138,144	\$ 32,335
Marketable securities	152,042	135,721
Restricted cash	—	297
Accounts receivable – billed	2,197	7,510
Account receivable – unbilled	2,137	3,100
Prepaid expenses and other current assets	15,582	9,195
Total current assets	310,102	188,158
Property and equipment, net	29,421	19,737
Intangible assets, net	11,005	12,577
Goodwill	53,062	54,612
Other non-current assets	1,044	918
Total assets	\$ 404,634	\$ 276,002
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 8,201	\$ 12,908
Accrued expenses	13,270	19,397
Current portion of notes payable	493	603
Deferred rent	1,212	1,138
Other current liabilities	1,697	70
Total current liabilities	24,873	34,116
Deferred revenue	2,500	2,500
Non-current portion of notes payable	45	395
Deferred rent	7,106	7,734
Other non-current liabilities	3,094	1,639
Total liabilities	37,618	46,384
Commitments and contingences	—	—

Edgar Filing: NOVAVAX INC - Form 10-Q

Stockholders' equity:

Preferred stock, \$0.01 par value, 2,000,000 shares authorized; no shares issued and outstanding as of September 30, 2015 and December 31, 2014, respectively	—	—
Common stock, \$0.01 par value, 600,000,000 shares authorized at September 30, 2015 and 300,000,000 shares authorized at December 31, 2014; 270,274,501 shares issued and 269,819,071 shares outstanding at September 30, 2015 and 239,287,294 shares issued and 238,831,864 shares outstanding at December 31, 2014	2,703	2,393
Additional paid-in capital	947,055	729,373
Accumulated deficit	(571,224)	(493,093)
Treasury stock, 455,430 shares, cost basis at both September 30, 2015 and December 31, 2014	(2,450)	(2,450)
Accumulated other comprehensive loss	(9,068)	(6,605)
Total stockholders' equity	367,016	229,618
Total liabilities and stockholders' equity	\$ 404,634	\$ 276,002

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

NOVAVAX, INC.

**CONSOLIDATED STATEMENTS OF OPERATIONS**

(in thousands, except per share information)

(unaudited)

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2015	2014	2015	2014
Revenue:				
Government contracts	\$6,307	\$7,504	\$29,273	\$20,217
Research and development collaborations	218	710	1,124	3,718
Total revenue	6,525	8,214	30,397	23,935
Costs and expenses:				
Cost of government contracts revenue	2,747	4,027	8,054	12,150
Research and development	27,917	19,219	78,686	48,940
General and administrative	9,060	4,757	21,991	14,871
Total costs and expenses	39,724	28,003	108,731	75,961
Loss from operations	(33,199 )	(19,789 )	(78,334 )	(52,026 )
Other income (expense):				
Investment income	194	128	450	160
Interest expense	(64 )	(47 )	(126 )	(150 )
Other expense	(51 )	(19 )	(121 )	
Realized gains on marketable securities				615
Net loss	\$(33,120 )	\$(19,727 )	\$(78,131 )	\$(51,401 )
Basic and diluted net loss per share	\$(0.12 )	\$(0.08 )	\$(0.30 )	\$(0.23 )
Basic and diluted weighted average number of common shares outstanding	269,554	238,304	259,703	221,578

**CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS**

(in thousands)

(unaudited)

Edgar Filing: NOVAVAX INC - Form 10-Q

	For the Three Months		For the Nine Months	
	Ended September 30,		Ended September 30,	
	2015	2014	2015	2014

Net loss	\$ (33,120 )	\$ (19,727 )	\$ (78,131 )	\$ (51,401 )
Other comprehensive income (loss):				
Net unrealized gains (losses) on investments available-for-sale	48	(54 )	95	(28 )
Reclassification adjustment for gains included in net loss				(615 )
Foreign currency translation adjustment	(406 )	(2,764 )	(2,558 )	(4,307 )
Other comprehensive loss	(358 )	(2,818 )	(2,463 )	(4,950 )
Comprehensive loss	\$ (33,478 )	\$ (22,545 )	\$ (80,594 )	\$ (56,351 )

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

NOVAVAX, INC.

## CONSOLIDATED STATEMENTS OF CASH FLOWS

(in thousands)

(unaudited)

	For the Nine Months Ended September 30,	
	2015	2014
Operating Activities:		
Net loss	\$(78,131 )	\$(51,401 )
Reconciliation of net loss to net cash used in operating activities:		
Depreciation and amortization	4,347	2,995
Amortization of net premiums on marketable securities	955	106
Deferred rent	(554 )	(302 )
Non-cash stock-based compensation	9,278	4,583
Realized gains on marketable securities		(615 )
Other	140	(13 )
Changes in operating assets and liabilities:		
Restricted cash	297	1,417
Accounts receivable – billed	5,503	(999 )
Accounts receivable – unbilled	963	755
Prepaid expenses and other assets	(6,536 )	(3,348 )
Accounts payable and accrued expenses	(7,706 )	(164 )
Deferred revenue	105	(260 )
Net cash used in operating activities	(71,339 )	(47,246 )
Investing Activities:		
Capital expenditures	(13,648 )	(4,877 )
Proceeds from disposal of property and equipment		39
Proceeds from maturities of marketable securities	137,107	18,440
Purchases of marketable securities	(154,288)	(160,782)
Net cash used in investing activities	(30,829 )	(147,180)
Financing Activities:		
Principal payments on capital leases	(49 )	(58 )
Principal payments on notes payable	(458 )	(505 )
Changes in restricted cash	(126 )	(1 )
Cash paid with the Novavax AB acquisition		(171 )
Net proceeds from sales of common stock	204,275	107,896
Proceeds from the exercise of stock options and employee stock purchases	4,440	2,288
Net cash provided by financing activities	208,082	109,449
Effect of exchange rate on cash and cash equivalents	(105 )	(21 )



Edgar Filing: NOVAVAX INC - Form 10-Q

Net increase (decrease) in cash and cash equivalents	105,809	(84,998 )
Cash and cash equivalents at beginning of period	32,335	119,471
Cash and cash equivalents at end of period	\$138,144	\$34,473
Supplemental disclosure of non-cash activities:		
Property and equipment purchases included in accounts payable and accrued expenses	\$2,390	\$999
Supplemental disclosure of cash flow information:		
Cash payments of interest	\$79	\$143

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

NOVAVAX, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

September 30, 2015

(unaudited)

Note 1 – Organization

Novavax, Inc. (“Novavax,” and together with its wholly owned subsidiary “Novavax AB,” the “Company”) is a clinical-stage vaccine 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, pandemic influenza and Ebola virus (“EBOV”). The Company has additional preclinical stage programs in a variety of infectious diseases, including Middle East Respiratory Syndrome (“MERS”).

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 preclinical studies and clinical testing, and regulatory approval prior to commercial use.

As a clinical-stage vaccine 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 prior contract with PATH Vaccine Solutions (“PATH”). Management regularly reviews the Company’s cash and cash equivalents and marketable securities relative to 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 support 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, 2015, the consolidated statements of operations and the consolidated statements of comprehensive loss for the three and nine months ended September 30, 2015 and 2014 and the consolidated statements of cash flows for the nine months ended September 30, 2015 and 2014 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 consolidated financial statements are presented in U.S. dollars. The functional currency of Novavax AB, which is located in Sweden, is the local currency (Swedish Krona). The translation of assets and liabilities of Novavax AB 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 the 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 accumulated other comprehensive loss in the accompanying consolidated balance sheets. The foreign currency translation adjustment balance included in accumulated other comprehensive loss was \$9.1 million and \$6.5 million at September 30, 2015 and December 31, 2014, respectively.

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, 2014. 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 the consolidated financial statements in conformity with accounting principles generally accepted in the United States, 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 those 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, 2015	December 31, 2014
Cash	\$ 5,682	\$ 4,481
Money market funds	71,205	20,354
Government-backed security	28,000	7,500
Asset-backed securities	4,061	

Corporate debt securities	29,196	
Cash and cash equivalents	\$ 138,144	\$ 32,335

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.

#### Marketable Securities

Marketable securities consist of commercial paper, asset-backed securities and corporate notes. Classification of marketable securities between current and non-current is dependent upon the maturity date at the balance sheet date taking into consideration the Company's ability and intent to hold the investment to maturity.

Interest and dividend income is recorded when earned and included in investment income in the consolidated statements of operations. Premiums and discounts, if any, on marketable securities are amortized or accreted to maturity and included in investment income in the consolidated statements of operations. The specific identification method is used in computing realized gains and losses on the sale of the Company's securities.

The Company classifies its marketable securities with readily determinable fair values as "available-for-sale." Investments in securities that are classified as available-for-sale are measured at fair market value in the consolidated balance sheets, and unrealized holding gains and losses on marketable securities are reported as a separate component of stockholders' equity until realized. Marketable securities 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 as other income, net in the consolidated statements of operations.

#### Restricted Cash

The Company's current restricted cash at December 31, 2014 includes payments received under the prior PATH agreement (See Note 9) until such time as the Company has paid for the outside services performed under the agreement, which occurred during the nine months ended September 30, 2015. In addition, the Company's non-current restricted cash with respect to its manufacturing, laboratory and office spaces in Gaithersburg, Maryland functions as collateral for letters of credit, which serve as security deposits for the duration of the leases. At September 30, 2015 and December 31, 2014, non-current restricted cash is \$0.9 million and \$0.8 million, respectively, and is recorded as other non-current assets on the consolidated balance sheets.

## 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 HHS BARDA contract provides the U.S. government 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 the HHS BARDA contract for convenience, 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, such as the HHS BARDA contract, are provisional payments subject to adjustment upon annual audit by the government. 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 and collection is probable.

The Company's collaborative research and development agreements may include an upfront payment, payments for research and development services, milestone payments and royalties. Agreements with multiple deliverables are evaluated to determine if the deliverables can be divided into more than one unit of accounting. A deliverable can generally be considered a separate unit of accounting if both of the following criteria are met: (1) the delivered item(s) has value to the customer on a stand-alone basis; and (2) if the arrangement includes a general right of return relative to the delivered item(s), delivery or performance of the undelivered item(s) is considered probable and substantially in control of the Company. Deliverables that cannot be divided into separate units are combined 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 principal under the arrangement, and whether the arrangement is significant to, and part of, the Company's core operations. Historically, payments received under its contracts and collaborative agreements have been recognized as revenue since the Company acts as a principal in the arrangement and the activities are core to its operations.

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

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

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





***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 23,159,206 and 17,018,180 at September 30, 2015 and 2014, respectively, are excluded from the computation, as their effect is antidilutive.

***Recent Accounting Pronouncements***

In May 2014, the Financial Accounting Standards Board (“FASB”) 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 price to the performance obligations in the contract and recognizing revenue when (or as) the entity satisfies the performance obligations. In July 2015, the FASB approved a one-year deferral of the effective date of the new standard to 2018 for public companies, with an option that would permit companies to adopt the new standard as early as the original effective date of 2017. Early adoption prior to the original effective date is not permitted. The Company is evaluating the potential impact that ASU 2014-09 will have on its consolidated financial position and results of operations.

**Note 4 – Fair Value Measurements**

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

	Fair Value at September 30, 2015			Fair Value at December 31, 2014		
	Level 1	Level 2	Level 3	Level 1	Level 2	Level 3
Assets						
Money market funds	\$ 71,205	\$	\$	\$ 20,354	\$	\$
Government-backed security		28,000			7,500	
Asset-backed securities		17,501			46,624	
Corporate debt securities		167,798			89,097	
Total cash equivalents and marketable securities	\$ 71,205	\$ 213,299	\$	\$ 20,354	\$ 143,221	\$

During the nine months ended September 30, 2015, 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 lease and notes payable approximates their carrying value. The Company's milestone payment due to Wyeth (See Note 11) approximates its fair value at September 30, 2015, as the liability has been calculated based on an anticipated future payment date discounted at borrowing rates available to the Company.

**Note 5 – Marketable Securities**

Marketable securities classified as available-for-sale as of September 30, 2015 and December 31, 2014 were comprised of (in thousands):

	September 30, 2015				December 31, 2014			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Asset-backed securities	\$13,441	\$	\$ (1 )	\$13,440	\$46,660	\$ —	\$ (36 )	\$46,624
Corporate debt securities	138,569	47	(14 )	138,602	89,126	8	(37 )	89,097
Total	\$152,010	\$ 47	\$ (15 )	\$152,042	\$135,786	\$ 8	\$ (73 )	\$135,721

***Marketable Securities – Unrealized Losses***

The Company owned 51 available-for-sale securities as of September 30, 2015. Of these 51 securities, 27 had combined unrealized losses of less than \$0.1 million as of September 30, 2015. The Company did not have any investments in a loss position for greater than 12 months as of September 30, 2015. The Company has evaluated its marketable securities and has determined that none of these investments has an other-than-temporary impairment, as it has no intent to sell securities with unrealized losses and it is not more likely than not that the Company will be required to sell any securities with unrealized losses, given the Company's current and anticipated financial position.

**Note 6 – Goodwill and Other Intangible Assets*****Goodwill***

The change in the carrying amounts of goodwill for the nine months ended September 30, 2015 was as follows (in thousands):

Amount

Balance at December 31, 2014	\$54,612
Currency translation adjustments	(1,550)
Balance at September 30, 2015	\$53,062

***Identifiable Intangible Assets***

Purchased intangible assets consisted of the following as of September 30, 2015 and December 31, 2014 (in thousands):

	September 30, 2015			December 31, 2014		
	Gross Carrying Amount	Accumulated Amortization	Intangible Assets, Net	Gross Carrying Amount	Accumulated Amortization	Intangible Assets, Net
Finite-lived intangible assets:						
Proprietary adjuvant technology	\$8,857	\$ (959)	) \$ 7,898	\$9,565	\$ (678)	) \$ 8,887
Collaboration agreements	3,999	(892)	) 3,107	4,319	(629)	) 3,690
Total identifiable intangible assets	\$12,856	\$ (1,851)	) \$ 11,005	\$13,884	\$ (1,307)	) \$ 12,577

Amortization expense for the nine months ended September 30, 2015 and 2014 was \$0.6 million and \$0.8 million, respectively.

Estimated amortization expense for existing intangible assets for the remainder of 2015 and for each of the five succeeding years ending December 31 will be as follows (in thousands):

Year	Amount
2015 (remainder)	\$ 214
2016	854
2017	854
2018	854
2019	854
2020	729

#### **Note 7 – Stockholders’ Equity**

On June 18, 2015, the Company’s stockholders of record as of April 20, 2015 approved the amendment to the Company’s Amended and Restated Certificate of Incorporation (the “Charter Amendment”) to increase the total number of shares of common stock that the Company is authorized to issue from 300,000,000 shares to 600,000,000 shares.

In March 2015, the Company completed a public offering of 27,758,620 shares of its common stock, including 3,620,689 shares of common stock that were issued upon the exercise in full of the option to purchase additional shares granted to the underwriters, at a price of \$7.25 per share resulting in proceeds, net of offering costs of \$11.6 million, of approximately \$190 million.

In 2012, the Company entered into an At Market Issuance Sales Agreement (“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. These shares of common stock were offered 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 “Committee”) assisted with its responsibilities to monitor, provide advice to the Company’s senior management and approve all capital raising activities. In doing so, the Committee set the amount of shares to be sold, the period of time during which such sales may occur and the minimum sales price per share. During the nine months ended September 30, 2015, the Company sold 1.4 million shares at an average sales price of \$10.63 per share, resulting in \$14.6 million in net proceeds. The Sales Agreement has now been fully utilized.

## **Note 8 – Stock-Based Compensation**

### *Stock Options*

The Amended and Restated 2005 Stock Incentive Plan (“2005 Plan”) expired in February 2015 and no new awards may be made under such plan, although outstanding awards will continue in accordance with their terms. The Board adopted the 2015 Stock Incentive Plan (“2015 Plan”) in March 2015 and, consistent with historical practice, granted annual and new equity awards prior to the Company’s annual meeting of stockholders in June 2015 under the 2015 Plan; however, these awards were contingent upon stockholder approval of both the 2015 Plan and the Company’s Charter Amendment (See Note 7), both of which were approved at the Company’s annual meeting of stockholders in June 2015. Under the 2015 Plan, equity awards may be granted to officers, directors, employees and consultants of and advisors to the Company and any present or future subsidiary. The 2015 Plan authorizes the issuance of up to 25,000,000 shares of common stock under equity awards granted under the plan. All such shares authorized for issuance under the 2015 Plan have been reserved. The 2015 Plan will expire on March 4, 2025.

The 2015 Plan permits and the 2005 Plan permitted the grant of stock options (including incentive stock options), restricted stock, stock appreciation rights, and restricted stock units. In addition, under the 2015 Plan, unrestricted stock, stock units and performance awards may be granted. Stock options and stock appreciation rights generally have a maximum term of 10 years and may be or were granted with an exercise price that is no less than 100% of the fair market value of the Company’s common stock at the time of grant. Grants of stock options are generally subject to vesting over periods ranging from six months to four years.

*Stock Options Awards*

The following is a summary of option activity under the 2015 Plan, 2005 Plan and the 1995 Stock Option Plan (“1995 Plan”) for the nine months ended September 30, 2015:

	2015 Plan	Weighted-	2005 Plan	Weighted-	1995 Plan	Weighted-
	Stock	Average	Stock	Average	Stock	Average
	Options	Exercise	Options	Exercise	Options	Exercise
		Price		Price		Price
Outstanding at January 1, 2015	—	\$ —	16,928,098	\$ 3.24	35,000	\$ 2.21
Granted	7,661,441	\$ 9.02	22,500	\$ 6.70	—	\$ —
Exercised	—	\$ —	(1,159,395 )	\$ 2.30	(35,000)	\$ 2.21
Canceled	(102,188 )	\$ 9.00	(191,250 )	\$ 3.71	—	\$ —
Outstanding at September 30, 2015	7,559,253	\$ 9.02	15,599,953	\$ 3.30	—	\$ —
Shares exercisable at September 30, 2015	240,000	\$ 8.94	8,275,828	\$ 2.53	—	\$ —
Shares available for grant at September 30, 2015	17,440,747					

As discussed in the “*Stock Options*” section above, prior to the Company’s annual meeting of stockholders in June 2015, the Company granted 7,014,441 stock options with a weighted-average exercise price of \$8.94 under the 2015 Plan. Since the 2015 Plan and the Charter Amendment were approved at the Company’s annual meeting of stockholders in June 2015, the Company began to record stock-based compensation expense for these awards at that time.

The fair value of stock options granted under the 2015 Plan and 2005 Plan was estimated at the date of grant or the date upon which the 2015 Plan was approved by the Company’s stockholders for stock options granted prior to that time using the Black-Scholes option-pricing model with the following assumptions:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
Weighted-average Black-Scholes fair value of stock options granted	\$4.70	\$1.92	\$4.43	\$2.41
Risk-free interest rate	1.32%-1.39%	1.43%-1.51%	1.19%-2.13%	1.24%-2.22%
Dividend yield	0%	0%	0%	0%
Volatility	54.93%-57.17%	52.75%-54.25%	53.58%-68.39%	52.47%-67.93%
Expected term (in years)	4.27-4.60	4.10-4.27	3.98-7.34	4.04-6.96
Expected forfeiture rate	14.18%-16.33%	14.18%-16.33%	0%-16.33%	0%-23.15%



The total aggregate intrinsic value and weighted-average remaining contractual term of stock options outstanding under the 2015 Plan and 2005 Plan as of September 30, 2015 was approximately \$58.8 million and 7.9 years, respectively. The total aggregate intrinsic value and weighted-average remaining contractual term of stock options exercisable under the 2015 Plan and 2005 Plan as of September 30, 2015 was approximately \$37.5 million and 6.5 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, 2015. 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 and vesting of restricted stock awards for the nine months ended September 30, 2015 and 2014 was \$9.0 million and \$1.8 million, respectively.

**Employee Stock Purchase Plan**

In April 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, 2015, there were 1,090,010 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		Nine Months Ended	
	September 30, 2015	2014	September 30, 2015	2014
Range of Black-Scholes fair values of ESPP shares granted	\$1.20-\$3.38	\$0.97-\$2.08	\$1.06-\$3.38	\$0.78-\$2.08
Risk-free interest rate	0.07%-0.35%	0.05%-0.24%	0.05%-0.35%	0.04%-0.24%
Dividend yield	0%	0%	0%	0%
Volatility	40.79%-64.24%	51.10%-67.57%	40.79%-64.24%	50.80%-67.57%
Expected term (in years)	0.5-2.0	0.5-1.5	0.5-2.0	0.5-1.5
Expected forfeiture rate	5%	5%	5%	5%

**Restricted Stock Awards**

The following is a summary of restricted stock awards activity for the nine months ended September 30, 2015:

	Number of Shares	Per Share Weighted- Average Grant-Date Fair Value
Outstanding and Unvested at January 1, 2015	15,000	\$ 4.48
Restricted stock granted	—	\$ —
Restricted stock vested	(15,000 )	\$ 4.48

Edgar Filing: NOVAVAX INC - Form 10-Q

Restricted stock forfeited	—	\$ —
Outstanding and Unvested at September 30, 2015		\$

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

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2015	2014	2015	2014
Research and development	\$ 2,240	\$ 780	\$ 4,361	\$ 1,955
General and administrative	2,525	911	4,917	2,628
Total stock-based compensation expense	\$ 4,765	\$ 1,691	\$ 9,278	\$ 4,583

As of September 30, 2015, there was approximately \$33.7 million of total unrecognized compensation expense (net of estimated forfeitures) related to unvested stock options and ESPP. This unrecognized non-cash compensation expense is expected to be recognized over a weighted-average period of 1.5 years, and will be allocated between research and development and general and administrative expenses accordingly. This estimate does not include the impact of other possible stock-based awards that may be made during future periods.

#### Note 9 – U.S. Government Agreement, Joint Venture and Collaborations

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

HHS BARDA initially awarded the Company a contract in 2011, which funds the development of both the Company's seasonal and pandemic influenza virus-like particle ("VLP") vaccine candidates. The contract with HHS BARDA is a cost-plus-fixed-fee contract, which reimburses the Company for allowable direct contract costs incurred plus allowable indirect costs and a fixed-fee earned in the ongoing clinical development and product scale-up of its multivalent seasonal and monovalent pandemic H7N9 influenza VLP vaccine candidates. In September 2014, HHS BARDA exercised and initiated a two-year option to the contract, which included scope to support development activities leading up to planned Phase 3 clinical studies, added \$70 million of funding on top of the remainder of the \$97 million base period funding, and extended the contract until September 2016. In June 2015, the contract was amended to increase the funding by \$7.7 million to allow for the recovery of additional costs under the contract relating to the settlement of indirect rates for fiscal years 2011 and 2012. This additional amount was received and recorded as revenue in the three months ended June 30, 2015. During the three and nine months ended September 30, 2015, the Company recognized revenue of \$6.3 million and \$29.3 million, respectively, and has recognized approximately \$107 million in revenue since the inception of 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. These indirect rates are subject to audit by HHS BARDA on an annual basis. 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 and collection is probable.

In 2012, HHS BARDA withheld payment on the outside costs of the Company's Phase 2 clinical trial of its seasonal quadrivalent influenza VLP vaccine candidate in Australia ("205 Trial"). Such outside costs were recorded as expenses in the period incurred as a cost of government contracts revenue and the Company did not record revenue relating to such outside costs prior to the first quarter of 2015 because collection of the amount was not reasonably assured. In late 2014, the U.S. Food and Drug Administration, Center for Biologics Evaluation and Research ("FDA") accepted the data from the 205 Trial as part of the Company's investigational new drug ("IND") application for its seasonal quadrivalent influenza VLP vaccine candidate. In the first quarter of 2015, HHS BARDA approved the reimbursement of the 205 Trial costs, and the Company recorded revenue of \$3.1 million as collection of the amount became reasonably assured during the period. The Company also collected this amount in 2015.

***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. Because CPLB’s activities and operations are controlled and funded by Cadila, the Company accounts for its investment using the equity method. Since the carrying value of the Company’s initial investment was nominal and there is no guarantee or commitment to provide future funding, the Company has not recorded nor expects to record losses related to this investment in the foreseeable future.

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

In 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 term of the license agreement is expected to terminate in 2027. Payments to the Company under the license agreement include an upfront payment of \$2.5 million, reimbursements of certain development and product costs, payments related to the achievement of certain milestones and royalty payments in the high single digits from LGLS’s future commercial sales of influenza VLP vaccines. The upfront payment has been deferred and recorded in deferred revenue in the consolidated balance sheets and will be recognized when the previously mentioned obligations in the agreement are satisfied, which may not occur until the end of the term of the agreement. Payments for milestones under the agreement will be recognized on a straight-line basis over the remaining term of the research and development period upon achievement of such milestone. Any royalties under the agreement will be recognized as earned.

***Bill & Melinda Gates Foundation (“BMGF”) Grant Agreement***

In support of the Company’s development of its respiratory syncytial virus fusion (F) protein nanoparticle vaccine candidate (“RSV F Vaccine”) for infants via maternal immunization, in September 2015, the Company entered into an agreement (“Grant Agreement”) with BMGF, under which it was awarded a grant totaling up to \$89.1 million (the “Grant”). The Grant will support development activities, including the Company’s global Phase 3 clinical trial in pregnant women in their third trimester, product licensing efforts and WHO prequalification of the RSV F Vaccine. The Company concurrently entered into a Global Access Commitments Agreement (“GACA”) with BMGF as a part of the Grant Agreement. Under the terms of the GACA, among other things, the Company agreed to make the RSV F Vaccine available and accessible at affordable pricing to people in certain low and middle income countries. Unless earlier terminated by BMGF, the GACA will continue in effect until the latter of 15 years from its effective date, or 10 years after the first sale of a product under defined circumstances. The term of the GACA may be extended in certain circumstances, by a period of up to five additional years. Payments received under the Grant Agreement are anticipated to be recognized in the period in which the research activities are performed. Payments received in advance that are related to future performance are deferred and recognized as revenue when the research activities are performed. Cash payments received under the Grant are restricted as to their use until expenditures contemplated in the Grant are incurred. The Company didn’t recognize any revenue under the Grant Agreement in the three months ended September 30, 2015.

***PATH Vaccine Solutions (“PATH”) Clinical Development Agreement***

In 2012, the Company entered into a clinical development agreement with PATH to develop its RSV F Vaccine for infants via maternal immunization in certain low-resource countries. Under the terms of the PATH agreement, which expired in April 2015, the Company was awarded \$6.8 million by PATH to partially support Phase 2 clinical trials in women of childbearing age, reproductive toxicology studies and the development of a Phase 3 clinical trial strategy. The Company recognized revenue of \$0.5 million in the nine months ended September 30, 2015 and has recognized \$6.8 million in revenue since the inception of the agreement. Revenue under this arrangement was 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 10 – 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, preclinical development, clinical development, process development, manufacturing scale-up and general manufacturing related services in India. In July 2011, and subsequently in March 2013, March 2014 and February 2015, the master services agreement was amended 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, 2016, 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. Through September 30, 2015, the Company has purchased \$7.2 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, 2015, the Company purchased \$1.5 million in services from Cadila pursuant to this agreement, all of which were provided by CPLB on behalf of Cadila. As of September 30, 2015, the Company's remaining obligation to Cadila under the master services agreement is \$0.3 million. The Company has recognized as an expense the entire amount of purchases to date related to CPLB as the Company has not recorded any equity income (loss) of CPLB (see Note 9).

**Note 11 – License agreement with Wyeth Holding Corporation**

In 2007, the Company entered into an agreement to license certain rights from Wyeth Holding Corporation, a subsidiary of Pfizer Inc. ("Wyeth"). The Wyeth license is a non-exclusive, worldwide license to a family of patents and patent applications covering VLP technology for use in human vaccines in certain fields, with expected patent expiration in early 2022. The Wyeth license provides for the Company to make an upfront payment (previously made), ongoing annual license fees, sublicense payments, milestone payments on certain development and commercialization activities and royalties on any product sales. Except in certain circumstances in which the Company continuously markets multiple products in a country within the same vaccine program, the milestone payments are one-time only payments applicable to each related vaccine program. At present, the Company's seasonal influenza VLP vaccine program (including CPLB's seasonal influenza program) and its pandemic influenza VLP vaccine program are the only two 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. In September 2015, the Company entered into an amendment to the license agreement with Wyeth. Among other things, the amendment restructures the \$3 million milestone payment ("Milestone") owed as a result of CPLB's initiation of a Phase 3 clinical trial for its recombinant trivalent seasonal VLP influenza vaccine candidate in 2014. Under the amendment, the milestone payment, which may increase slightly over time, shall be due in connection with the initiation of a Phase 3 clinical trial for the initial seasonal influenza VLP vaccine candidate being developed outside India, but in any case no later than December 31, 2017. The amendment also restructures the final milestone payment to apply to the initial seasonal influenza VLP vaccine candidate being developed outside India. Thus, the aggregate milestone payments for a seasonal influenza VLP vaccine candidate developed and commercialized is increased from \$14 million to up to \$15 million. In connection with the execution of the amendment, the Company agreed to pay a one-time only, upfront



payment to Wyeth. The amendment also increases annual license maintenance fees associated with VLP vaccine candidates from \$0.2 million to \$0.3 million per year. Payments under the agreement to Wyeth as of September 30, 2015 aggregated \$7.3 million. The Milestone was accrued for on the consolidated balance sheet in other current liabilities at December 31, 2014. As a result of the September 2015 amendment discussed above, the Milestone payment is not expected to occur within the next 12 months. Therefore, the Milestone has been accrued for, on a discounted basis calculated based on its anticipated future payment date, in other non-current liabilities at September 30, 2015. The milestone was recorded as a research and development expense in the third quarter of 2014.

**Note 12 – Facility Lease**

In August 2015, the Company amended the lease for its new facility located in Gaithersburg, Maryland to increase the amount of space leased by the Company to now include the entire facility. The lease has a term expiring in 2026, unless terminated early by the Company in 2023. The lease contains provisions for future rent increases and periods in which rent payments are reduced (abated). Also, the lease obligates the Company to pay building operating costs. Under the terms of the amended lease, the landlord shall provide the Company with a tenant improvement allowance of approximately \$3.9 million.

Future minimum rental commitments under non-cancelable leases are as follows (in thousands) as of September 30, 2015:

Year	Amount
2015 (remainder)	\$ 1,351
2016	5,656
2017	4,458
2018	4,291
2019	4,309
Thereafter	18,457
Total minimum lease payments	\$38,522

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

Any statements in the discussion below and elsewhere in this Quarterly 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, 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 capabilities, goals, 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 development of our preclinical product candidates; the conduct, timing and potential results from clinical trials and other preclinical studies; plans for and potential timing of regulatory filings; the expected timing and content of regulatory actions; reimbursement by Department of Health and Human Services, Biomedical Advanced Research and Development Authority ("HHS BARDA"); payments under our license with Wyeth Holding Corporation, a subsidiary of Pfizer Inc. ("Wyeth"); payments by the Bill & Melinda Gates Foundation ("BMGF"); 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," "should," "would," or the negative of these terms, or other comparable terminology, although not all forward-looking statements contain these words.

Accordingly, these statements involve estimates, assumptions and uncertainties that could cause actual results to differ materially from those expressed or implied in them. Any or all of our forward-looking statements in this Quarterly Report may turn out to be inaccurate or materially different than actual results.

Because the risk factors discussed in this Quarterly Report and identified in our Annual Report on Form 10-K for the fiscal year ended December 31, 2014, and other risk factors of which we are not aware, could cause actual results or outcomes to differ materially from those expressed in any forward-looking statements made by or on behalf of us, you should not place undue reliance on any such forward-looking statements. These statements are subject to risks and uncertainties, known and unknown, which could cause actual results and developments to differ materially from those expressed or implied in such statements. We have included important factors in the cautionary statements included in this Quarterly Report, particularly those identified in Part II, Item 1A "Risk Factors," and in Part I, Item 1A "Risk Factors" of our Annual Report on Form 10-K, that we believe could cause actual results or events to differ materially from the forward-looking statements that we make. These and other risks may also be detailed and modified or updated in our reports and other documents filed with the Securities and Exchange Commission ("SEC") from time to time. You are encouraged to read these filings as they are made.

Although we believe that the expectations reflected in our forward-looking statements are reasonable, we cannot guarantee future results, events, levels of activity, performance or achievement. Further, any forward-looking

statements speak only as of the date on which it is made, and 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. New factors emerge from time to time, and it is not possible for us to predict which factors will arise. In addition, we cannot assess the impact of each factor on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements.

## Overview

We are a clinical-stage vaccine company focused on the discovery, development and commercialization of recombinant nanoparticle vaccines and adjuvants. Using innovative proprietary recombinant nanoparticle vaccine technology, we produce vaccine candidates to efficiently and effectively respond to both known and newly emerging diseases. Our vaccine candidates are genetically engineered three-dimensional nanostructures that incorporate immunologically important proteins. Our product pipeline targets a variety of infectious diseases with vaccine candidates currently in clinical development for respiratory syncytial virus (“RSV”), seasonal influenza, pandemic influenza and Ebola virus (“EBOV”). We have additional preclinical stage programs in a variety of infectious diseases, including Middle East Respiratory Syndrome (“MERS”). Further, CPL Biologics Private Limited (“CPLB”), our joint venture company with Cadila Pharmaceuticals Limited (“Cadila”) in India, is actively developing a number of vaccine candidates that were genetically engineered by us, including its trivalent seasonal virus-like particle (“VLP”) influenza vaccine candidate that successfully completed a Phase 3 clinical trial in India in 2014, and its rabies vaccine that successfully completed a Phase 1/2 clinical trial in India in 2014. CPLB is owned 20% by us and 80% by Cadila. CPLB operates a manufacturing facility in India for the production of vaccines.

We are also developing proprietary technology for the production of immune stimulating saponin-based adjuvants, through our Swedish wholly owned subsidiary, Novavax AB. Our Matrix™ adjuvant technology utilizes selected quillaja fractions, which form separate matrix structures, to develop multi-purpose immune-modulating adjuvant products for a broad range of potential vaccine applications. Our lead adjuvant for human applications, Matrix-M™, has been successfully tested in a Phase 1/2 clinical trial for our pandemic H7N9 influenza VLP vaccine candidate, conducted under our contract with HHS BARDA, and in a Phase 1 clinical trial for our EBOV vaccine candidate. Genocea Biosciences, Inc. (“Genocea”) has licensed rights to our Matrix technology and is developing its herpes simplex 2 vaccine candidate using Matrix-M.

### Clinical Product Pipeline

A current summary of our significant research and development programs, along with the programs of our joint venture, CPLB, and status of the related products in development follows:

Program	Development Stage	Funding Collaborator
<b>Respiratory Syncytial Virus (RSV)</b>		
·Older Adults	Phase 3	
·Maternal Immunization	Phase 2	BMGF*
·Pediatrics	Phase 1	
<b>Influenza</b>		
·Seasonal Quadrivalent	Phase 2	HHS BARDA
·Pandemic H7N9	Phase 2	HHS BARDA
<b>Other</b>		
·Ebola Virus (EBOV)	Phase 1	
·Combination (Influenza/RSV)	Preclinical	
<b>CPLB Programs (India)</b>		
·Seasonal Influenza	Phase 3	
·Rabies	Phase 1/2	

\*As detailed herein, our funding and development arrangement with PATH expired in April 2015; we entered into a grant agreement with BMGF in September 2015.

### Respiratory Syncytial Virus (RSV)

RSV is a major respiratory pathogen with a significant burden of disease in the very young and in older adults. In healthy adults, RSV infections are generally mild to moderate in severity, but are typically more severe in infants and young children, as well as adults over the age of 60.<sup>1</sup> Globally, RSV is a common cause of childhood respiratory infection, with a disease burden of 64 million cases and approximately 160,000 deaths annually.<sup>2</sup> Severe RSV disease results in 3.4 million hospital admissions per year globally<sup>3</sup> and disproportionately affects infants below six months of age. In infants, toddlers and young pre-school and school-age children, RSV infections result in the need for frequent medical care, including emergency room and office visits and are associated with increased recurrent wheezing that can persist for years. In the U.S., RSV is the leading cause of hospitalization of infants.<sup>4</sup> Despite the induction of post-infection immunity, repeat infection and lifelong susceptibility of RSV is common.<sup>5</sup> It is also estimated that approximately 14,000 older and high risk adults die of RSV infection or its complications annually in the U.S., and as many as 177,000 are hospitalized for serious respiratory symptoms.<sup>6</sup> Currently, there is no approved RSV vaccine available for any of these populations, so an RSV vaccine has the potential to protect millions of people from this far-reaching unmet medical need.

<sup>1</sup> Dawson-Caswell, D, et al., (2011) *Am Fam Physician*. 83:143 - 146

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

<sup>3</sup> WHO, (2014) "RSV Vaccine Status;"  
[www.who.int/immunization/research/meetings\\_workshops/WHO\\_PDVCAC\\_RSV.pdf](http://www.who.int/immunization/research/meetings_workshops/WHO_PDVCAC_RSV.pdf)

<sup>4</sup> Hall, CB, *et al.*, Respiratory Syncytial Virus-Associated hospitalizations Among Children Less Than 24 Months of Age. *Pediatrics*, 2013; 132(2): E341-348

<sup>5</sup> Glezen, W.P. *et al.* Risk of primary infection and reinfection with respiratory syncytial virus. *Am J Dis Child*, 1986; 140:543-546

<sup>6</sup> Falsey, A., et al., (2014) *Infectious Disorders*. 12(2): 98-102

We are developing our respiratory syncytial virus fusion (F) protein nanoparticle vaccine candidate (“RSV F Vaccine”) for the benefit of three susceptible target populations: older adults 60 years of age and older, infants via maternal immunization (receiving protection through antibodies transferred from their mothers who would be immunized during the last trimester of pregnancy) and children between six months and five years of age (“pediatrics”).

### ***RSV Older Adults Program***

In August 2015, we announced positive top-line data from a Phase 2 clinical trial of our RSV F Vaccine in 1,600 older adults ( $\geq 60$  years of age). The clinical trial was designed to prospectively examine the incidence of all symptomatic respiratory illnesses associated with RSV infection, in community-living older adults who were treated with placebo. The trial also evaluated safety and immunogenicity of our RSV F Vaccine compared to placebo. Finally, the trial estimated the efficacy of the RSV F Vaccine in reducing the incidence of respiratory illness due to RSV. The trial was the first to demonstrate efficacy of an active RSV immunization in any clinical trial population. In the per the protocol population, the clinical trial showed statistically significant vaccine efficacy in prevention of all symptomatic RSV disease (44%) and, by ad hoc analysis, showed a decrease in RSV disease with symptoms of lower respiratory tract infection (45%)<sup>7</sup> in older adults. The trial established an attack rate for symptomatic RSV disease of 4.9% in older adults, 95% of which included lower respiratory tract symptoms. Efficacy against more severe RSV illness, defined by the presence of multiple lower respiratory tract symptoms associated with difficulty breathing, was 64% in ad hoc analyses.

In November 2015, we announced that we had initiated a pivotal Phase 3 clinical trial of our RSV F Vaccine for which we plan to enroll up to 11,850 older adults at 60 sites in the U.S. The primary objective of the clinical trial is the prevention of moderate-severe RSV-associated lower respiratory tract disease, as defined by the presence of multiple lower respiratory tract symptoms. We expect to provide top-line data from this clinical trial in approximately one year.

In addition, in October 2015, we announced that we had initiated a Phase 2 rollover clinical trial of our RSV F Vaccine designed to enroll the same 1,600 older adults who participated in the recently concluded prior Phase 2 clinical trial. The clinical trial is designed to evaluate safety and immunogenicity in response to immunization with the RSV F Vaccine during a second RSV season and we expect to provide top-line data in approximately one year.

<sup>7</sup> Interim analysis initially reported 46%; 4 subjects subsequently re-categorized as RSV + URI only, resulting in adjusted number of 45%.





***RSV Infants via Maternal Immunization Program***

In September 2015, we announced positive top-line data from a Phase 2 clinical trial of our RSV F Vaccine in 50 healthy pregnant women in their third trimester. This clinical trial evaluated the safety and immunogenicity of the RSV F Vaccine in healthy pregnant women; it also assessed the transplacental transfer of maternal antibodies induced by the vaccine, the impact of maternal immunization on infant safety during the first year of life and RSV-specific antibody levels through the infants' first six months of life. Immunized women demonstrated geometric mean 14-fold rises in anti-F IgG, 29-fold rise in palivizumab competing antibodies, and 2-fold rise in microneutralization titers, versus women who received placebo who demonstrated no significant change in antibody levels. The infants' antibody levels at delivery, on average, equaled 90-100% of the mothers' levels. The estimated half-lives of infant PCA, anti-F IgG, RSV/A and RSV/B microneutralizing antibodies, based on data through day 60, were 41, 30, 36 and 34 days, respectively. We anticipate that the next steps in the development of the RSV F Vaccine for the protection of infants via maternal immunization will include the initiation of a pivotal Phase 3 global clinical trial, with sites located in the U.S. and other countries. Although initiation of this Phase 3 clinical trial may be contingent on discussions with regulatory authorities, it is our current expectation that we will begin to enroll participants in the first quarter of 2016. The group-sequential adaptive design of this Phase 3 trial is expected to take between two to four years to complete.

In November 2014, we announced that the U.S. Food and Drug Administration, Center for Biologics Evaluation and Research ("FDA") had granted Fast Track Designation to our RSV F Vaccine for protection of infants via maternal immunization. The Fast Track designation, established by the FDA Modernization Act of 1997, is intended for products that treat serious or life-threatening diseases or conditions, and that demonstrate the potential to address unmet medical needs for such diseases or conditions. The program is intended to facilitate development and expedite review of drugs to treat serious and life-threatening conditions so that an approved product can reach the market expeditiously. Fast Track designation specifically facilitates meetings to discuss all aspects of development to support licensure and it provides the opportunity to submit sections of a Biologics License Application ("BLA") on a rolling basis as data become available, which permits the FDA to review modules of the BLA as they are received instead of waiting for the entire BLA submission.

***Bill & Melinda Gates Foundation Grant Agreement***

In support of our development of our RSV F Vaccine for infants via maternal immunization, in September 2015, we entered into an agreement ("Grant Agreement") with BMGF, under which we were awarded a grant totaling up to \$89.1 million (the "Grant"). The Grant will support development activities, including our global Phase 3 clinical trial in pregnant women in their third trimester, product licensing efforts and WHO prequalification of our RSV F Vaccine. We concurrently entered into a Global Access Commitments Agreement ("GACA") with BMGF as a part of the Grant Agreement. Under the terms of the GACA, among other things, we agreed to make the RSV F Vaccine available and accessible at affordable pricing to people in certain low and middle income countries. Unless earlier terminated by BMGF, the GACA will continue in effect until the latter of 15 years from its effective date, or 10 years after the first sale of a product under defined circumstances. The term of the GACA may be extended in certain circumstances, by a

period of up to five additional years.

***PATH Vaccine Solutions (“PATH”) Clinical Development Agreement for RSV Maternal Program***

In 2012, we entered into a clinical development agreement with PATH to develop our RSV F Vaccine for infants via maternal immunization in certain low-resource countries. Under the term of the PATH agreement, which expired in April 2015, we were awarded \$6.8 million by PATH to partially support our Phase 2 clinical trials in women of childbearing age, reproductive toxicology studies and the development of a Phase 3 clinical trial strategy.

### ***RSV Pediatrics Program***

In September 2015, we announced positive top-line data from our Phase 1 clinical trial of our RSV F Vaccine in healthy children between two and six years of age. This clinical trial evaluated the safety and immunogenicity of our RSV F Vaccine, with one or two doses, with or without aluminum phosphate adjuvant. We concluded this trial's enrollment with a smaller than planned cohort so that dosing could be completed ahead of the 2014-15 RSV season. We announced that serum samples, collected from 18 immunized children, demonstrated that the RSV F Vaccine was well-tolerated and highly immunogenic at all formulations and regimens and there were greater than 10-fold increases in both anti-F IgG and PCA antibody titers in the adjuvanted group and greater than 6-fold increases in anti-F IgG and PCA antibody titers in the unadjuvanted group. We are assessing the data from this clinical trial and evaluating the next steps in the development of our RSV F Vaccine for pediatrics.

### **Influenza**

Influenza is a world-wide infectious disease that causes illness in humans with symptoms ranging from mild to life-threatening; serious illness occurs not only in susceptible populations such as pediatrics and older adults, but also in the general population because of unique strains of influenza for which most humans have not developed protective antibodies. Influenza is a major burden on public health worldwide: estimates of one million deaths each year are attributed to influenza.<sup>8</sup> It is further estimated that, each year, influenza attacks between 5% and 10% of adults and 20% to 30% of children, causing significant levels of illness, hospitalization and death.<sup>9</sup>

Although a number of licensed seasonal influenza vaccines are currently commercially available in most geographies, and these manufacturers have capabilities to develop influenza vaccines that are responsive to unique and emerging influenza strains, we believe our influenza VLP vaccine candidates have immunological advantages over currently available vaccines. These immunological advantages stem from the fact that our influenza VLPs contain three of the major structural virus proteins that are important for fighting influenza: hemagglutinin ("HA") and neuraminidase ("NA"), both of which stimulate the body to produce antibodies that neutralize the influenza virus and prevent its spread through the cells in the respiratory tract, and matrix 1 ("M1"), which stimulates cytotoxic T lymphocytes to kill cells that may already be infected. Our VLPs are not made from live viruses and have no genetic nucleic material in their inner core, which render them incapable of replicating and causing disease. We also believe there are inherent advantages to our vaccine platform technology for more rapid and efficient development of new influenza vaccine candidates.

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

Developing and commercializing a seasonal influenza vaccine is an important business opportunity and strategic goal for us. The Advisory Committee for Immunization Practices of the Center for Disease Control and Prevention (“CDC”) recommends that all persons aged six months and older should be vaccinated annually against seasonal influenza. In conjunction with these universal recommendations, attention from the 2009 influenza H1N1 pandemic, 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.

In recent years, public health authorities have advocated for the development and licensure of quadrivalent (*i.e.*, four influenza strains: two influenza A strains and two influenza B strains) influenza vaccines. It is expected that quadrivalent seasonal influenza vaccines will ultimately replace trivalent seasonal influenza vaccines in the global market. There are currently four quadrivalent influenza vaccines licensed in the U.S., although additional quadrivalent seasonal influenza vaccines are expected to be licensed over the next several years. Current estimates for seasonal influenza vaccine growth in the top seven markets (U.S., Japan, France, Germany, Italy, Spain and UK), show potential growth from approximately \$3.2 billion in the 2012/13 season to \$5.3 billion by the 2021/2022 season.<sup>10</sup> 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 eggs.

<sup>8</sup> Resolution of the World Health Assembly. Prevention and control of influenza pandemics and annual epidemics. WHA56.19. 28 May 2003

<sup>9</sup> WHO. Vaccines against influenza. WHO position paper – November 2012 Weekly Epidemiol Record 2012;87(47):461–76.

<sup>10</sup> Influenza Vaccines Forecasts. Datamonitor (2013)

In July 2015, we reported positive data from our Phase 2 clinical trial of our quadrivalent seasonal influenza VLP vaccine candidate in 400 healthy adults that we initiated in November 2014 under our contract with HHS BARDA. These data show that our quadrivalent seasonal influenza VLP vaccine candidate is both safe and well-tolerated, with results that met the immunogenicity targets. These results demonstrate the potential for our seasonal quadrivalent influenza VLP vaccine candidate to meet the FDA criteria for accelerated approval. We are assessing these data from this trial, and in conjunction with HHS BARDA, we are evaluating the next steps in the development of our quadrivalent seasonal influenza VLP vaccine candidate.

### ***Pandemic H7N9 Influenza Vaccine***

In the aftermath of the 2009 pandemic of the A(H1N1) influenza strain, prevention of the potential devastation of a human influenza pandemic remains a key priority with both governmental health authorities and influenza vaccine manufacturers. In the U.S. alone, the 2009 H1N1 influenza 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, a significant number of reported cases in China of an avian-based influenza strain, known as A(H7N9), has shifted attention to the potential development of a monovalent 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 September 2014, we announced positive results from a Phase 1/2 clinical trial of our H7N9 influenza VLP vaccine candidate adjuvanted with Matrix-M in 610 healthy adults. Under our contract with HHS BARDA, the Phase 1/2 clinical trial was designed as a dose-ranging, randomized, observer-blinded, placebo-controlled clinical trial, to determine the contribution of Matrix-M to potential antigen dose sparing regimens. Our H7N9 influenza VLP vaccine candidate, with and without Matrix-M, was well tolerated and demonstrated a safety profile similar to our prior experience with another saponin-based adjuvant. Matrix-M adjuvanted formulations demonstrated immunogenicity and dose-sparing benefits relative to unadjuvanted antigen. Hemagglutination-inhibiting antibody titers were generally comparable to those reported in prior studies with another saponin adjuvant and the vaccine also elicited significant anti-neuraminidase antibodies. In October 2014, we announced that the FDA had granted fast track designation to our H7N9 influenza VLP vaccine candidate with Matrix-M. Along with our quadrivalent seasonal influenza vaccine program and in conjunction with HHS BARDA, we are currently evaluating the next steps in the development our pandemic influenza VLP vaccine candidate.

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

According to FDA guidance, influenza vaccine developers that can demonstrate results that meet or exceed certain specified immunogenicity endpoint criteria for seroprotection and seroconversion 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. This is referred to as "accelerated approval" of a BLA (the biologic equivalent to a New Drug Application). It should be noted that FDA licensure based on accelerated approval requires sponsors to conduct a post-licensure 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 influenza program or certain populations within our seasonal influenza program, we do not expect to pursue accelerated approval of our quadrivalent seasonal influenza VLP vaccine candidate, largely because of the uncertainty as to whether the accelerated approval pathway will be available to us at the time of our BLA submission 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 VLP vaccine candidate by conducting a clinical endpoint efficacy study for the purpose of submitting the data within the original BLA. These efficacy data will 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 populations within the seasonal program) during future formal meetings. The likely impact of such an efficacy trial would be an additional year or more before the FDA grants licensure to our quadrivalent seasonal influenza VLP vaccine candidate.

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

HHS BARDA awarded us a contract in 2011, which funds the development of both our multivalent seasonal influenza and pandemic influenza VLP vaccine candidates. Our contract with HHS BARDA is a cost-plus-fixed-fee contract, which reimburses us for allowable direct contract costs incurred plus allowable indirect costs and a fixed-fee earned in the ongoing clinical development and product scale-up of our multivalent seasonal and monovalent pandemic influenza vaccines. In September 2014, we announced that HHS BARDA had exercised and initiated a two-year option to our contract, which not only extended the contract until September 2016, but also added scope to support our development activities leading up to planned Phase 3 clinical studies and \$70 million of funding on top of the remainder of the \$97 million base period funding. In June 2015, the contract was amended to increase the funding by \$7.7 million to allow for the recovery of additional costs under the contract relating to the settlement of indirect rates for fiscal years 2011 and 2012. This additional amount was received and recorded as revenue in the second quarter of 2015. During the nine months ended September 30, 2015, we recognized revenue of \$29.3 million and have recognized approximately \$107 million in revenue since the inception of the contract. In recent meetings with HHS BARDA, we have been discussing the next steps in both our seasonal influenza VLP vaccine program and our pandemic influenza VLP vaccine program, as well as some of the delays associated with our development of both vaccine candidates. We expect to continue discussions with HHS BARDA into 2016 and to present plans for continued clinical and product development, although there can be no guarantee that the HHS BARDA contract will not be terminated or will be extended beyond September 2016.

#### **Other**

#### ***Ebola Virus (EBOV)***

Beginning in 2014, a number of news reports have centered around EBOV, formerly known as Ebola hemorrhagic fever, which is a severe, often fatal illness in humans. Five strains of EBOV have been identified, the most recent of which, the Makona EBOV strain (formerly referred to as the 2014 Guinea-based EBOV strain), is associated with a case fatality rate of 50% to 90%. There are currently no licensed treatments proven to neutralize the virus, but a range of blood, immunological and drug therapies are under development. Despite the development of such therapies, current vaccine approaches target either a previous strain of the virus or were initially developed to be delivered by genetic vectors. Our EBOV glycoprotein vaccine candidate (“Ebola GP Vaccine”) was developed using the Makona EBOV strain.



In July 2015, we announced data from our Phase 1 clinical trial of our Ebola GP Vaccine in ascending doses, with and without our Matrix-M adjuvant, in 150 healthy adults that we initiated in February 2015. Participants received either one or two intramuscular injections ranging from 6.5µg to 50µg of antigen. Immunogenicity was assessed at multiple time points, including days 28 and 35. These Phase 1 data show that our Ebola GP Vaccine is highly immunogenic, well-tolerated and, in conjunction with our proprietary Matrix-M adjuvant, resulted in significant antigen dose-sparing. Although the adjuvanted Ebola GP Vaccine was highly immunogenic at all dose levels, the adjuvanted two-dose regimens induced Ebola anti-GP antibody geometric mean responses between 45,000 and 70,000 ELISA units, representing a 500 to 750-fold rise over baseline at day 35. In addition, in the first quarter of 2015, we announced successful data from two separate non-human primate challenge studies of our Ebola GP Vaccine in which, in both cases, the challenge was lethal for the control animal, whereas 100% of the immunized animals were protected. Large-scale global clinical trials towards licensure of our Ebola GP Vaccine will be developed based on the published results of our Phase 1 clinical trial and in collaboration with global regulatory authorities and world health agencies.

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

Given the ongoing development of our quadrivalent seasonal influenza VLP vaccine candidate and our RSV F Vaccine, we see an important opportunity to develop a combination respiratory vaccine candidate. This opportunity presents itself most evidently in older adults, although we have not ruled out developing a combination respiratory vaccine for other populations. Early preclinical development efforts have given us confidence that such a combination vaccine is viable, and in animal models, provides acceptable immunogenicity. We intend to explore this development opportunity by conducting a Phase 1 clinical trial in such a combination vaccine in the second half of 2016.

### **CPLB Programs (India)**

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

CPLB successfully completed its Phase 3 clinical trial of its recombinant trivalent seasonal VLP influenza vaccine candidate in 2014 and filed for regulatory market authorization, the Indian equivalent of a BLA, in the second quarter of 2015. As part of its strategy to establish a regulatory pathway for the recombinant trivalent seasonal VLP influenza vaccine, CPLB had previously completed a Phase 3 clinical trial of its monovalent H1N1 seasonal influenza vaccine in 2014, and subsequently filed for and received regulatory approval in the first quarter of 2015. While this marks the first approval of a Novavax VLP vaccine, the market for seasonal influenza vaccines is dominated by multivalent vaccines and there are no current expectations for sales from CPLB's monovalent H1N1 seasonal product.

***Rabies***

CPLB successfully completed Stage II of its Phase 1/2 clinical trial in India of a rabies G protein vaccine candidate that we genetically engineered. The objective was to develop a recombinant vaccine that can be administered both as a pre-exposure prophylaxis for residents of certain higher-risk geographies and travelers to such locations, and as a post-exposure prophylaxis using fewer doses than the current standard of care. In October 2014, CPLB presented clinical results from Stage I of the Phase 1/2 clinical trial, demonstrating that all vaccine recipients, at various doses levels and schedules, showed seroprotective antibody levels at day 14 that were 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. CPLB filed an application to initiate a Phase 3 clinical trial in the third quarter of 2015, which would likely initiate in 2016.

## 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 (as previously discussed), we have been monitoring reports concerning MERS, a novel coronavirus first identified in 2012. MERS became a potential emerging threat in 2013 and is currently being monitored by global health agencies, with the WHO reporting significant confirmed cases of infection and 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 preclinical program, we believe that our MERS vaccine candidate offers a viable option to interested global public health authorities.

## Sales of Common Stock

In March 2015, we completed a public offering of 27,758,620 shares of our common stock, including 3,620,689 shares of common stock that were issued upon the exercise in full of the option to purchase additional shares granted to the underwriters, at a price of \$7.25 per share resulting in net proceeds of approximately \$190 million.

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 the 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.

In 2012, we entered into an At Market Issuance Sales Agreement (“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 have been offered 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 “Committee”) assisted with its responsibilities to monitor, provide advice to our senior management and approve all capital raising activities. In doing so, the Committee set the amount of shares to be sold, the period of time during which such sales may occur and the minimum sales price per share. During the nine months ended September 30, 2015, we sold 1.4 million shares at an average sales price of \$10.63 per share, resulting in approximately \$15 million

in net proceeds. The Sales Agreement has now been fully utilized.

### ***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, 2014, 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 ("FASB") Accounting Standards Updates (ASUs). In May 2014, the FASB 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 price to the performance obligations in the contract and recognizing revenue when (or as) the entity satisfies the performance obligations. In July 2015, the FASB approved a one-year deferral of the effective date of the new standard to 2018 for public companies, with an option that would permit companies to adopt the new standard as early as the original effective date of 2017. Early adoption prior to the original effective date is not permitted. 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, 2015 and 2014** (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>2015</b>	<b>2014</b>	<b>2014 to 2015</b>	
Revenue:			
Total revenue	\$6,525	\$8,214	\$(1,689)

Revenue for the three months ended September 30, 2015 was \$6.5 million as compared to \$8.2 million for the same period in 2014, a decrease of \$1.7 million or 21%. Revenue for the three months ended September 30, 2015 and 2014 is primarily comprised of services performed under the HHS BARDA contract, and to a much lesser extent, the prior PATH clinical development agreement. The decrease in revenue is due to a lower level of activity in the three months ended September 30, 2015 associated with our Phase 2 seasonal influenza clinical trial as compared to our Phase 1/2 clinical trial of our H7N9 pandemic VLP candidate in the same period in 2014 under the HHS BARDA contract.

For 2015, we expect an increase in revenue primarily due to the recovery of additional costs under the HHS BARDA contract for the settlement of indirect rates for fiscal years 2011 and 2012, which occurred in the second quarter of 2015, and development activities under the BMGF grant agreement.

**Costs and Expenses:**

**Three Months Ended****September 30,****Change**

2015      2014

**2014 to  
2015**

## Costs and Expenses:

Cost of government contracts revenue	\$2,747	\$4,027	\$(1,280 )
Research and development	27,917	19,219	8,698
General and administrative	9,060	4,757	4,303
Total costs and expenses	\$39,724	\$28,003	\$11,721

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

Cost of government contracts revenue includes direct costs of salaries, laboratory supplies, consultants and subcontractors and other direct costs associated with our process development, manufacturing, clinical, regulatory and quality assurance activities under research contracts. Cost of government contracts revenue decreased to \$2.7 million for the three months ended September 30, 2015 from \$4.0 million for the same period in 2014, a decrease of \$1.3 million, or 32%. The decrease in cost of government contracts revenue is primarily related to a lower level of activity in the three months ended September 30, 2015 associated with our Phase 2 seasonal influenza clinical trial as compared to our Phase 1/2 clinical trial of our H7N9 pandemic VLP candidate in the same period in 2014. For 2015, we expect a decrease in cost of government contracts revenue primarily due to lower level of project development activities under our HHS BARDA contract in 2015 as compared to 2014.

### ***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 \$27.9 million for the three months ended September 30, 2015 from \$19.2 million for the same period in 2014, an increase of \$8.7 million, or 45%. The increase in research and development expenses was primarily due to increased costs associated with our ongoing and planned RSV F Vaccine clinical trials and higher employee-related costs, including non-cash stock-based compensation, as compared to the same period in 2014. These increases were partially offset by the milestone payment accrued under the Wyeth agreement in the three months ended September 30, 2014. For 2015, we expect a significant increase in research and development expenses primarily due to additional RSV F Vaccine clinical trials, the EBOV GP vaccine clinical trial and employee-related and facility costs to support product development of our RSV F Vaccine 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, 2015, we had 332 employees dedicated to our research and development programs versus 230 employees as of September 30, 2014. 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).

	2015	2014
Manufacturing	\$22.1	\$12.8
Vaccine Discovery	1.5	1.7
Clinical and Regulatory	7.1	8.7
Total cost of government contracts revenue and research and development expenses	\$30.7	\$23.2

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 preclinical 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 \$9.1 million for the three months ended September 30, 2015 from \$4.8 million for the same period in 2014, an increase of \$4.3 million, or 90%. The increase was primarily due to higher employee-related costs, including non-cash stock-based compensation, and professional fees for pre-commercialization activities, as compared to the same period in 2014. At September 30, 2015, we had 46 employees dedicated to general and administrative functions versus 33 employees as of September 30, 2014. For 2015, we expect general and administrative expenses to continue to increase primarily due to increased employee costs and pre-commercialization activities.

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

	<b>Three Months Ended</b>		
	<b>September 30,</b>		
	<b>2015</b>	<b>2014</b>	<b>Change 2014 to 2015</b>
Other Income (Expense):			
Investment income	\$194	\$128	\$ 66
Interest expense	(64 )	(47 )	(17 )
Other expense	(51 )	(19 )	(32 )
Total other income (expense)	\$79	\$62	\$ 17

We had total other income of \$0.1 million for the three months ended September 30, 2015 and 2014.

### **Net Loss:**

### **Three Months Ended**

	<b>September 30,</b>		<b>Change</b>
	2015	2014	<b>2014 to</b>
			<b>2015</b>
Net Loss:			
Net loss	\$(33,120 )	\$(19,727 )	\$(13,393)
Net loss per share	\$(0.12 )	\$(0.08 )	\$(0.04 )
Weighted shares outstanding	269,554	238,304	31,250

Net loss for the three months ended September 30, 2015 was \$33.1 million, or \$0.12 per share, as compared to \$19.7 million, or \$0.08 per share, for the same period in 2014, an increased net loss of \$13.4 million. The increased net loss was primarily due to higher research and development spending, including increased costs relating to clinical trials of our RSV F Vaccine and higher employee-related costs, as compared to the same period in 2014.

The increase in weighted average shares outstanding for the three months ended September 30, 2015 as compared to the same period in 2014 is primarily a result of sales of our common stock in 2015 and 2014.

**Nine Months Ended September 30, 2015 and 2014** (amounts in tables are presented in thousands, except per share information)

**Revenue:**

<b>Nine Months Ended</b>		
<b>September 30,</b>		
		<b>Change</b>
2015	2014	<b>2014 to</b>
		<b>2015</b>

Revenue:

Total revenue	\$30,397	\$23,935	\$6,462
---------------	----------	----------	---------

Revenue for the nine months ended September 30, 2015 was \$30.4 million as compared to \$23.9 million for the same period in 2014, an increase of \$6.5 million or 27%. Revenue for the nine months ended September 30, 2015 and 2014 is primarily comprised of services performed under the HHS BARDA contract, and to a much lesser extent, the prior PATH clinical development agreement. The increase in revenue is primarily due to revenue of \$7.7 million relating to the recovery of additional costs for the settlement of indirect rates for fiscal years 2011 and 2012 under the HHS BARDA contract in the second quarter of 2015 and revenue of \$3.1 million relating to our Phase 2 clinical trial of our quadrivalent seasonal influenza VLP vaccine candidate in Australia (“205 Trial”) as collection of the amount became reasonably assured in the first quarter of 2015. These increases in revenue were partially offset by a lower level of activity in the nine months ended September 30, 2015 associated with our Phase 2 seasonal influenza clinical trial as compared to our Phase 1/2 clinical trial of our H7N9 pandemic VLP candidate in the same period in 2014 under the HHS BARDA contract and a decrease in revenue under the prior PATH clinical development agreement.

In 2012, HHS BARDA withheld payment on the outside costs of the 205 Trial. Such outside costs were recorded as expenses in the period incurred as a cost of government contracts revenue and the Company did not record revenue relating to such outside costs prior to the first quarter of 2015 because collection of the amount was not reasonably assured. In late 2014, the FDA accepted the data from the 205 Trial as part of the Company’s investigational new drug (“IND”) application for its seasonal quadrivalent influenza VLP vaccine candidate. In the first quarter of 2015, HHS BARDA approved the reimbursement of the 205 Trial costs. We also collected this amount in 2015.

**Costs and Expenses:**

	<b>Nine Months Ended</b>		
	<b>September 30,</b>		<b>Change</b>
	2015	2014	<b>2014 to 2015</b>
Costs and Expenses:			
Cost of government contracts revenue	\$8,054	\$12,150	\$(4,096 )
Research and development	78,686	48,940	29,746
General and administrative	21,991	14,871	7,120
Total costs and expenses	\$108,731	\$75,961	\$32,770

***Cost of Government Contracts Revenue***

Cost of government contracts revenue includes direct costs of salaries, laboratory supplies, consultants and subcontractors and other direct costs associated with our process development, manufacturing, clinical, regulatory and quality assurance activities under research contracts. Cost of government contracts revenue decreased to \$8.1 million for the nine months ended September 30, 2015 from \$12.2 million for the same period in 2014, a decrease of \$4.1 million, or 34%. The decrease in cost of government contracts revenue is primarily related to a lower level of activity in the nine months ended September 30, 2015 associated with our Phase 2 seasonal influenza clinical trial as compared to our Phase 1/2 clinical trial of our H7N9 pandemic VLP candidate in the same period in 2014.

***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 \$78.7 million for the nine months ended September 30, 2015 from \$48.9 million for the same period in 2014, an increase of \$29.7 million, or 61%. The increase in research and development expenses was primarily due to increased costs associated with our ongoing and anticipated RSV F Vaccine clinical trials and our EBOV GP vaccine clinical trial and higher employee-related costs, including non-cash stock-based compensation, as compared to the same period in 2014. These increases were partially offset by the milestone payment accrued under the Wyeth agreement in the nine months ended September 30, 2014. At September 30, 2015, we had 332 employees dedicated to our research and development programs versus 230 employees as of September 30, 2014.

***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).

	2015	2014
Manufacturing	\$57.6	\$35.5
Vaccine Discovery	4.7	4.4
Clinical and Regulatory	24.4	21.2
Total cost of government contracts revenue and research and development expenses	\$86.7	\$61.1

***General and Administrative Expenses***

General and administrative expenses increased to 22.0 million for the nine months ended September 30, 2015 from \$14.9 million for the same period in 2014, an increase of \$7.1 million, or 48%. The increase was primarily due to higher employee-related costs, including non-cash stock-based compensation, and professional fees for pre-commercialization activities, as compared to the same period in 2014. At September 30, 2015, we had 46 employees dedicated to general and administrative functions versus 33 employees as of September 30, 2014.

**Other Income (Expense):**

**Nine Months Ended**

**September 30,**  
**Change**  
**2015 2014 2014 to**  
**2015**

Other Income (Expense):			
Investment income	\$450	\$160	\$ 290
Interest expense	(126)	(150)	24
Other expense	(121)		(121 )
Realized gains on marketable securities	—	615	(615 )
Total other income (expense)	\$203	\$625	\$ (422 )

We had total other income of \$0.2 million for the nine months ended September 30, 2015 as compared to total other income of \$0.6 million for the same period in 2014. For the nine months ended September 30, 2014, we sold our remaining auction rate security and received proceeds of \$1.8 million resulting in a realized gain of \$0.6 million.

Net Loss:

	<b>Nine Months Ended</b>		
	<b>September 30,</b>		<b>Change</b>
	<b>2015</b>	<b>2014</b>	<b>2014 to 2015</b>
Net Loss:			
Net loss	\$(78,131 )	\$(51,401 )	\$(26,730)
Net loss per share	\$(0.30 )	\$(0.23 )	\$(0.07 )
Weighted shares outstanding	259,703	221,578	38,125

Net loss for the nine months ended September 30, 2015 was \$78.1 million, or \$0.30 per share, as compared to \$51.4 million, or \$0.23 per share, for the same period in 2014, an increased net loss of \$26.7 million. The increased net loss was primarily due to higher research and development spending, including increased costs relating to clinical trials of our RSV F Vaccine and a clinical trial of our EBOV GP vaccine candidate and higher employee-related costs, as compared to the same period in 2014.

The increase in weighted average shares outstanding for the nine months ended September 30, 2015 as compared to the same period in 2014 is primarily a result of sales of our common stock in 2015 and 2014.

### **Liquidity Matters and Capital Resources**

Our future capital requirements depend on numerous factors including, but not limited to, the commitments and progress of our research and development programs, the progress of preclinical 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 preclinical studies and clinical trials and other research and development activities.

As of September 30, 2015, we had \$290.2 million in cash and cash equivalents and marketable securities as compared to \$168.1 million as of December 31, 2014. These amounts consisted of \$138.1 million in cash and cash equivalents and \$152.0 million in marketable securities as of September 30, 2015 as compared to \$32.3 million in cash and cash equivalents and \$135.7 million in marketable securities, as described in Note 3 under section “*Marketable Securities*,” as of December 31, 2014.



The following table summarizes cash flows for the nine months ended September 30, 2015 and 2014 (in thousands):

	<b>Nine Months Ended</b>		
	<b>September 30,</b>		<b>Change 2014 to 2015</b>
	2015	2014	
Summary of Cash Flows:			
Net cash (used in) provided by:			
Operating activities	\$(71,339 )	\$(47,246 )	\$(24,093 )
Investing activities	(30,829 )	(147,180)	116,351
Financing activities	208,082	109,449	98,633
Effect on exchange rate on cash and cash equivalents	(105 )	(21 )	(84 )
Net increase (decrease) in cash and cash equivalents	105,809	(84,998 )	190,807
Cash and cash equivalents at beginning of period	32,335	119,471	(87,136 )
Cash and cash equivalents at end of period	\$138,144	\$34,473	\$103,671

Net cash used in operating activities increased to \$71.3 million for the nine months ended September 30, 2015 as compared to \$47.2 million for the same period in 2014. The increase in cash usage was primarily due to increased costs relating to our RSV F Vaccine and EBOV GP vaccine candidate, higher employee-related costs and timing of customer and vendor payments.

During the nine months ended September 30, 2015 and 2014, our investing activities consisted primarily of purchases and maturities of marketable securities and capital expenditures. Capital expenditures for the nine months ended September 30, 2015 and 2014 were \$13.6 million and \$4.9 million, respectively. The increase in capital expenditures was primarily due to the purchase of laboratory equipment for process development, analytical development and manufacturing scale-up required to support our maturing product portfolio. In 2015, we expect our level of capital expenditures to be significantly higher than our 2014 spending as we continue to scale up our capacity in anticipation of Phase 3 clinical trials and related regulatory obligations in the upcoming years.

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, 2015, we received net proceeds of approximately \$190 million through our public offering at \$7.25 per share and approximately \$15 million through our Sales Agreement at an average sales price of \$10.63 per share. 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. We sold the remaining common stock under the Sales Agreement in July 2015. The Sales Agreement has now been fully utilized.

In August 2015, we amended the lease for our new facility located in Gaithersburg, Maryland to increase the amount of space leased by us to now include the entire facility. Under the terms of the amended lease, the landlord shall provide us with a tenant improvement allowance of approximately \$3.9 million. We have not utilized the tenant improvement allowance as of September 30, 2015.

In 2007, we entered into an agreement to license certain rights from Wyeth. The Wyeth license is a non-exclusive, worldwide license to a family of patents and patent applications covering VLP technology for use in human vaccines in certain fields, with expected patent expiration in early 2022. The Wyeth license provides for us to make an upfront payment (previously made), ongoing annual license fees, sublicense payments, milestone payments on certain development and commercialization activities and royalties on any product sales. Except in certain circumstances in which we continuously market multiple products in a country within the same vaccine program, the milestone payments are one-time only payments applicable to each related vaccine program. At present, our seasonal influenza VLP vaccine program (including CPLB's seasonal influenza program) and our pandemic influenza VLP vaccine program are the only two 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. In September 2015, we amended the license agreement with Wyeth. Among other things, the amendment restructures the \$3 million milestone payment ("Milestone") owed as a result of CPLB's initiation of a Phase 3 clinical trial for its recombinant trivalent seasonal VLP influenza vaccine candidate in 2014. Under the amendment, the milestone payment, which may increase slightly over time, shall be due in connection with the initiation of a Phase 3 clinical trial for the initial seasonal influenza VLP vaccine candidate being developed outside India, but in any case no later than December 31, 2017. The amendment also restructures the final milestone payment to apply to the initial seasonal influenza VLP vaccine candidate being developed outside India. Thus, the aggregate milestone payments for a seasonal influenza VLP vaccine candidate developed and commercialized is increased from \$14 million to up to \$15 million. In connection with the execution of the amendment, we agreed to pay a one-time only, upfront payment to Wyeth. The amendment also increases annual license maintenance fees associated with VLP vaccine candidates from \$0.2 million to \$0.3 million per year. Payments under the agreement to Wyeth as of September 30, 2015 aggregated \$7.3 million. The Milestone was accrued for on the consolidated balance sheet in other current liabilities at December 31, 2014. As a result of the September 2015 amendment discussed above, the Milestone payment is not expected to occur within the next 12 months. Therefore, the Milestone has been accrued for, on a discounted basis calculated based on the anticipated future payment date, in other non-current liabilities at September 30, 2015. The milestone was recorded as a research and development expense in the third quarter of 2014.

In connection with CPLB, we entered into a master services agreement with Cadila, which we and Cadila amended in July 2011, March 2013, March 2014 and February 2015, in each case to extend the term by one year for which services can be provided by Cadila under this agreement. Under the revised terms, if, by March 2016, 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. The Company and Cadila have also agreed to an amendment that allows CPLB, as of the beginning of 2013, to provide services on behalf of Cadila. Through September 30, 2015, we have purchased \$7.2 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, 2015 cash and cash equivalents and marketable securities balances, along with anticipated revenue under the contract with HHS BARDA and grant agreement with BMGF and other resources, we believe we have adequate capital to fund our operating plans for a minimum of twelve months. 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 and BMGF grant agreement, our overall business performance and market conditions.

Any capital raised by an equity offering will likely be substantially dilutive to the existing stockholders and any licensing or development arrangement may require us to give up rights to a product or technology at less than its full potential value. 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 and BMGF grant agreement 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, 2015, we had cash and cash equivalents of \$138.1 million, marketable securities of \$152.0 million, all of which are short-term, and working capital of \$285.2 million.

Our exposure to market risk is primarily confined to our investment portfolio. As of September 30, 2015, our investments were classified as available-for-sale. We do not believe that a change in the market rates of interest would have any significant impact on the realizable value of our investment portfolio. Changes in interest rates may affect the investment income we earn on our marketable securities when they mature and the proceeds are reinvested into new marketable securities and, therefore, could impact our cash flows and results of operations.



Interest and dividend income is recorded when earned and included in investment income. Premiums and discounts, if any, on marketable securities are amortized or accreted to maturity and included in investment 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 \$2.8 million at September 30, 2015.

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, 2015. 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, 2015, 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, 2015, and has concluded that there was no change that occurred during the quarterly period ended September 30, 2015 that materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

## **PART II. OTHER INFORMATION**

### **Item 1A. Risk Factors**

Other than the additional risk factors disclosed below, 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, 2014.

*Security breaches and other disruptions could compromise our information and expose us to liability, which would cause our business and reputation to suffer.*

In the ordinary course of our business, we collect and store sensitive data, including intellectual property, our proprietary business information and data about our clinical subjects, suppliers, and business partners, and personally identifiable information. The secure maintenance of this information is critical to our operations and business strategy. Some of this information could be an attractive target of criminal attack by malicious third parties with a wide range of motives and expertise, including organized criminal groups, "hactivists," patient groups, disgruntled current or former employees, and others. Hacker attacks are of ever-increasing levels of sophistication, and despite our security measures, our information technology and infrastructure may be vulnerable to such attacks or may be breached due to employee error or malfeasance. Any such breach could compromise our networks and the information stored there could be accessed, publicly disclosed, lost or stolen. Furthermore, if our systems become compromised, we may not promptly discover the intrusion. Like other companies in our industry, we have experienced attacks to our data and systems, including malware and computer viruses. Attacks could have a material impact on our business, operations or financial results. Any access, disclosure or other loss of information could result in legal claims or proceedings, liability under laws that protect the privacy of personal information, disrupt our operations, and damage our reputation, which could adversely affect our business.

**Item 6. Exhibits**

- 3.1 Second Amended and Restated Certificate of Incorporation of the Company (Incorporated by reference to Exhibit 3.1 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2015, filed August 10, 2015)
- 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\*\*\* Grant Agreement between Bill and Melinda Gates Foundation and Novavax, Inc., dated as of September 25, 2015
- 10.2\*\*\* Global Access Commitments Agreement between Bill and Melinda Gates Foundation and Novavax, Inc., dated as of September 25, 2015
- 10.3\*\*\* Second Amendment to License Agreement between Wyeth Holdings LLC and Novavax, Inc., dated as of September 1, 2015 (Incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K, filed September 8, 2015)
- 10.4 Lease Agreement for space at 21 Firstfield Road between Firstfield Holdco, LLC and Novavax, Inc., dated as of February 4, 2015 (Incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K, filed August 21, 2015)
- 10.5 First Amendment to Lease Agreement for space at 21 Firstfield Road between Firstfield Holdco, LLC and Novavax, Inc., dated as of August 17, 2015 (Incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K, filed August 21, 2015)
- 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
- 101 The following financial information from our Quarterly Report on Form 10-Q for the quarter ended September 30, 2015, formatted in Extensible Business Reporting Language (XBRL): (i) the Consolidated Balance Sheets as of September 30, 2015 and December 31, 2014, (ii) the Consolidated Statements of Operations for the three and nine-month periods ended September 30, 2015 and 2014, (iii) the Consolidated Statements of Comprehensive Loss for the three and nine-month periods ended September 30, 2015 and 2014, (iv) the Consolidated Statements of Cash Flows for the nine-month periods ended September 30, 2015 and

2014, and (v) the Notes to Consolidated Financial Statements.

\* Filed herewith.

\*\* Confidential treatment has been requested for portions of exhibit.

\*\*\* Confidential treatment has been granted for portions of exhibit.



SIGNATURES

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

**NOVAVAX, INC.**

Date: November 9, 2015 By: /s/ Stanley C. Erck  
President and Chief Executive Officer and Director  
(Principal Executive Officer)

Date: November 9, 2015 By: /s/ Barclay A. Phillips  
Senior Vice President, Chief Financial Officer and Treasurer  
(Principal Financial and Accounting Officer)