

NOVAVAX INC  
Form 10-Q  
November 09, 2016

UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-Q

**QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE  
ACT OF 1934**  
**For the quarterly period ended September 30, 2016**

OR

**TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT  
OF 1934**  
**For the transition period from        to        .**

**Commission File No. 0-26770**

**NOVAVAX, INC.**

(Exact name of registrant as specified in its charter)

<b>Delaware</b>	<b>22-2816046</b>
(State or other jurisdiction of	(I.R.S. Employer
incorporation or organization)	Identification No.)

<b>20 Firstfield Road, Gaithersburg, MD 20878</b>	<b>20878</b>
(Address of principal executive offices)	(Zip code)

**(240) 268-2000**

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

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

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

Large accelerated filer  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 271,245,967 as of October 31, 2016.

**NOVAVAX, INC.**

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

(in thousands, except share and per share information)

	September 30, 2016 (unaudited)	December 31, 2015
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 119,948	\$93,108
Marketable securities	180,335	137,548
Restricted cash	31,521	34,964
Accounts receivable	591	2,320
Prepaid expenses and other current assets	21,510	19,317
Total current assets	353,905	287,257
Restricted cash	1,704	2,422
Property and equipment, net	40,955	32,342
Intangible assets, net	9,958	10,793
Goodwill	52,694	53,065
Other non-current assets	410	159
Total assets	\$459,626	\$386,038
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 16,231	\$11,889
Accrued expenses	26,098	26,734
Accrued interest	2,031	—
Deferred revenue	30,157	34,469
Notes payable	45	395
Deferred rent	1,067	1,409
Other current liabilities	55	1,598
Total current liabilities	75,684	76,494
Deferred revenue	2,500	4,171

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Convertible notes payable	315,983	—
Deferred rent	12,241	9,534
Other non-current liabilities	3,434	3,170
Total liabilities	409,842	93,369
Commitments and contingencies	—	—
Stockholders' equity:		
Preferred stock, \$0.01 par value, 2,000,000 shares authorized; no shares issued and outstanding as of September 30, 2016 and December 31, 2015, respectively	—	—
Common stock, \$0.01 par value, 600,000,000 shares authorized at September 30, 2016 and December 31, 2015; 271,693,897 shares issued and 271,238,467 shares outstanding at September 30, 2016 and 270,426,662 shares issued and 269,971,232 shares outstanding at December 31, 2015	2,717	2,704
Additional paid-in capital	932,208	951,569
Accumulated deficit	(872,887 )	(650,030)
Treasury stock, 455,430 shares, cost basis at both September 30, 2016 and December 31, 2015	(2,450 )	(2,450 )
Accumulated other comprehensive loss	(9,804 )	(9,124 )
Total stockholders' equity	49,784	292,669
Total liabilities and stockholders' equity	\$ 459,626	\$ 386,038

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		For the Nine Months	
	Ended September 30,		Ended September 30,	
	2016	2015	2016	2015
Revenue:				
Government contracts	\$102	\$6,307	\$2,182	\$29,273
Research and development collaborations	3,129	218	7,772	1,124
Total revenue	3,231	6,525	9,954	30,397
Expenses:				
Research and development	52,983	30,664	186,839	86,740
General and administrative	13,556	9,060	38,183	21,991
Total expenses	66,539	39,724	225,022	108,731
Loss from operations	(63,308 )	(33,199 )	(215,068 )	(78,334 )
Other income (expense):				
Investment income	554	194	1,701	450
Interest expense	(3,511 )	(64 )	(9,457 )	(126 )
Other income (expense)	11	(51 )	(33 )	(121 )
Net loss	\$(66,254 )	\$(33,120 )	\$(222,857 )	\$(78,131 )
Basic and diluted net loss per share	\$(0.24 )	\$(0.12 )	\$(0.82 )	\$(0.30 )
Basic and diluted weighted average number of common shares outstanding	271,064	269,554	270,669	259,703

## CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

(in thousands)

(unaudited)

	<b>For the Three Months</b>		<b>For the Nine Months</b>	
	<b>Ended September 30,</b>		<b>Ended September 30,</b>	
	2016	2015	2016	2015
Net loss	\$ (66,254)	\$ (33,120)	\$ (222,857)	\$ (78,131)
Other comprehensive income (loss):				
Net unrealized gains (losses) on marketable securities available-for-sale	(121 )	48	172	95
Foreign currency translation adjustment	(540 )	(406 )	(852 )	(2,558 )
Other comprehensive loss	(661 )	(358 )	(680 )	(2,463 )
Comprehensive loss	\$ (66,915)	\$ (33,478)	\$ (223,537)	\$ (80,594)

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

NOVAVAX, INC.

## CONSOLIDATED STATEMENTS OF CASH FLOWS

(in thousands)

(unaudited)

	<b>For the Nine Months</b>	
	<b>Ended September</b>	
	<b>30,</b>	
	2016	2015
Operating Activities:		
Net loss	\$(222,857)	\$(78,131 )
Reconciliation of net loss to net cash used in operating activities:		
Depreciation and amortization	6,287	4,347
Amortization of net premiums on marketable securities	263	955
Amortization of debt issuance costs	949	
Deferred rent	402	(554 )
Lease incentives received	1,963	
Non-cash stock-based compensation	15,380	9,278
Other	301	140
Changes in operating assets and liabilities:		
Restricted cash	4,980	297
Accounts receivable	1,716	6,466
Prepaid expenses and other assets	(2,478 )	(6,536 )
Accounts payable and accrued expenses	6,396	(7,706 )
Deferred revenue	(5,980 )	105
Other liabilities	(1,541 )	
Net cash used in operating activities	(194,219)	(71,339 )
Investing Activities:		
Capital expenditures	(15,009 )	(13,648 )
Proceeds from maturities of marketable securities	284,871	137,107
Purchases of marketable securities	(327,750)	(154,288)
Net cash used in investing activities	(57,888 )	(30,829 )
Financing Activities:		
Principal payments on capital leases	(53 )	(49 )
Principal payments on notes payable	(350 )	(458 )
Changes in restricted cash	(819 )	(126 )
Proceeds from issuance of convertible notes	325,000	
Payments of costs related to issuance of convertible notes	(9,966 )	
Payments for capped call transactions and costs	(38,521 )	



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Net proceeds from sales of common stock		204,275
Proceeds from the exercise of stock options and employee stock purchases	3,793	4,440
Net cash provided by financing activities	279,084	208,082
Effect of exchange rate on cash and cash equivalents	(137 )	(105 )
Net increase in cash and cash equivalents	26,840	105,809
Cash and cash equivalents at beginning of period	93,108	32,335
Cash and cash equivalents at end of period	\$119,948	\$138,144
Supplemental disclosure of non-cash activities:		
Property and equipment purchases included in accounts payable and accrued expenses	\$2,060	\$2,390
<b>Supplemental disclosure of cash flow information:</b>		
Cash payments of interest	\$6,186	\$79

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

NOVAVAX, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

September 30, 2016

(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. Using innovative proprietary recombinant nanoparticle vaccine platform technology, the Company produces vaccine candidates to efficiently and effectively respond to both known and emerging disease threats. The Company’s vaccine candidates are genetically engineered three-dimensional nanostructures that incorporate recombinant protein antigens critical to disease pathogenesis. The Company’s product pipeline targets a variety of infectious diseases with clinical vaccine candidates for respiratory syncytial virus (“RSV”) and Ebola virus (“EBOV”), and preclinical programs for Zika virus, seasonal influenza and a combination respiratory vaccine candidate, as well as other disease vaccine candidates.

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, the issuance of convertible debt and revenue under its prior contract with the Department of Health and Human Services, Biomedical Advanced Research and Development Authority (“HHS BARDA”) and, to a lesser degree, revenue under the grant agreement with the Bill & Melinda Gates Foundation (“BMGF”) and 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.

Following the results of the top-line data from the Phase 3 clinical trial of its RSV F Vaccine in older adults, on November 9, 2016, the Company announced a restructuring plan (the “Restructuring Plan”) designed to meet the following key objectives:

- Prioritize development activities to achieve clinical data events during 2017;
- Reduce cash burn, extend financial horizon and minimize near-term dilution; and
- Maintain operational core competencies to execute development plans.

The Restructuring Plan includes an immediate reduction in workforce of approximately 30%. The Company expects to incur one-time restructuring costs of approximately \$3 million to \$4 million, including cash severance expenses, in the fourth quarter of 2016.

The Restructuring Plan was engineered to support the following high-level operating priorities (each of which is more fully articulated in the program descriptions in Management’s Discussion and Analysis of Financial Condition and Results of Operations):

· Continued execution of the global pivotal Phase 3 clinical trial, known as Prepare™, of its RSV F Vaccine for infants via maternal immunization;

- Initiation of a multi-arm, dose-ranging Phase 2 clinical trial of its RSV F Vaccine in older adults; and
- Initiation of a Phase 1 clinical trial of its Zika vaccine candidate in 2017.

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, 2016, the consolidated statements of operations and the consolidated statements of comprehensive loss for the three and nine months ended September 30, 2016 and 2015 and the consolidated statements of cash flows for the nine months ended September 30, 2016 and 2015 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 \$10.0 million and \$9.1 million at September 30, 2016 and December 31, 2015, 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, 2015. 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):

	<b>September 30, 2016</b>	<b>December 31, 2015</b>
Cash	\$ 8,325	\$ 29,569
Money market funds	89,623	14,950
Government-backed security	22,000	20,000
Asset-backed securities		8,185
Corporate debt securities		20,404
Cash and cash equivalents	\$ 119,948	\$ 93,108

Cash equivalents are recorded at cost, 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, U.S. Treasury 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 in other income (expense) in the consolidated statements of operations.

## Restricted Cash

The Company's current and noncurrent restricted cash includes payments received under the Grant Agreement (see Note 10) and cash collateral accounts under letters of credit that serve as security deposits for certain facility leases. The Company will utilize the Grant Agreement funds as it incurs expenses for services performed under the agreement. At September 30, 2016 and December 31, 2015, the restricted cash balances consist of payments received under the Grant Agreement of \$31.5 million and \$36.5 million and security deposits of \$1.7 million and \$0.9 million, respectively.

## 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, grant 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 with U.S. Government agencies, 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 (see Note 10), certain activities were 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 research and development expenses. 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 years 2013 and 2014 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.

Under its grant agreement with BMGF (see Note 10), the Company is reimbursed for certain costs that support development activities, including the Company's global Phase 3 clinical trial in pregnant women in their third trimester, product licensing efforts and World Health Organization ("WHO") prequalification of the RSV F Vaccine. Payments received under the grant agreement are recognized as revenue in the period in which such research and development activities are performed.



The Company's collaborative research and development agreements may include upfront payments, payments for research and development services, milestone payments and royalties. Agreements with multiple deliverables are evaluated to determine if the deliverables can be divided into more than one unit of accounting. A deliverable can generally be considered a separate unit of accounting if both of the following criteria are met: (1) the delivered item(s) has value to the customer on a stand-alone basis; and (2) if the arrangement includes a general right of return relative to the delivered item(s), delivery or performance of the undelivered item(s) is considered probable and substantially in control of the Company. Deliverables that cannot be divided into separate units are combined and treated as one unit of accounting. Consideration received is allocated among the separate units of accounting based on the relative selling price method. Deliverables under these arrangements typically include rights to intellectual property, research and development services and involvement by the parties in steering committees. Historically, deliverables under the Company's collaborative research and development agreements have been deemed to have no stand-alone value and as a result have been treated as a single unit of accounting. In addition, the Company analyzes its contracts and collaborative agreements to determine whether the payments received should be recorded as revenue or as a reduction to research and development expenses. In reaching this determination, management considers a number of factors, including whether the Company is 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. At September 30, 2016 and 2015, the Company had outstanding stock options and unvested restricted stock awards totaling 32,696,757 and 23,159,206, respectively. As of September 30, 2016, the Company's Notes were initially convertible into approximately 47,716,900 shares of the Company's common stock. These and any shares due to the Company upon settlement of its capped call transactions are excluded from the computation, as their effect is antidilutive.

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

#### ***Recently Adopted***

In April 2015, the Financial Accounting Standards Board (“FASB”) issued ASU No. 2015-03, *Interest - Imputation of Interest (Subtopic 835-30): Simplifying the Presentation of Debt Issuance Costs* (“ASU 2015-03”). The new standard requires that debt issuance costs related to a recognized debt liability be presented in the balance sheet as a direct deduction from the carrying amount of that debt liability, consistent with debt discounts. This ASU became effective for the Company beginning January 1, 2016. The adoption of ASU 2015-03 did not have a material effect on the Company’s financial statements.

*Not Yet Adopted*

In February 2016, the FASB issued ASU 2016-02, *Leases (Topic 842)* (“ASU 2016-02”) that increases transparency and comparability among organizations by requiring the recognition of lease assets and lease liabilities on the balance sheet and disclosure of key information about leasing arrangements for both lessees and lessors. The standard will be effective January 1, 2019 for the Company, with early adoption permitted. The standard will be applied using a modified retrospective approach to the beginning of the earliest period presented in the financial statements. The Company is currently evaluating when it will adopt the standard and the expected impact to its consolidated financial statements and related disclosures.

In March 2016, the FASB issued ASU 2016-09, *Compensation - Stock Compensation (Topic 718)* (“ASU 2016-09”) that simplifies the accounting for share-based payment transactions, including the income tax consequences, classification of awards as either equity or liabilities, and classification on the statement of cash flows. The Company plans to adopt this standard on the effective date, January 1, 2017, and does not expect the adoption will have a material impact on its consolidated financial statements and related disclosure.

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. ASU 2014-09 allows for either full retrospective or modified retrospective adoption. The Company is evaluating the potential impact that ASU 2014-09 will have on its consolidated financial position and results of operations.

### ***Reclassifications***

For the three and nine months ended September 30, 2015, cost of government contracts revenue of \$2.7 million and \$8.1 million, respectively, have been reclassified to research and development expenses. At December 31, 2015, accounts receivable - unbilled of \$0.9 million has been reclassified to accounts receivable and restricted cash of \$0.9 million has been reclassified from other non-current assets to restricted cash (non-current). These reclassifications have been made to conform to the current year presentation.

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

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

	<b>Fair Value at September 30, 2016</b>		<b>Fair Value at December 31, 2015</b>	
<u>Assets</u>	Level 1	Level 2	Level 1	Level 2

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			<b>Level</b>			<b>Level</b>
			<b>3</b>			<b>3</b>
Money market funds	\$89,623	\$	\$	\$14,950	\$	\$
U.S. Treasury securities		15,078				
Government-backed security		22,000			20,000	
Asset-backed securities		43,151			28,924	
Corporate debt securities		122,106			137,213	
Total assets	\$89,623	\$202,335	\$	\$14,950	\$186,137	\$
<b>Liabilities</b>						
Convertible notes payable	\$	\$176,774	\$	\$	\$	\$

Fixed-income investments categorized as Level 2 are valued at the custodian bank by a third-party pricing vendor's valuation models that use verifiable observable market data, e.g., interest rates and yield curves observable at commonly quoted intervals and credit spreads, bids provided by brokers or dealers or quoted prices of securities with similar characteristics. Pricing of the Company's Notes (see Note 7) has been estimated using other observable inputs, including the price of the Company's common stock, implied volatility, interest rates and credit spreads among others. Over time, the Company expects a market for the Notes to develop. At that time, the Company intends to use trade data as the principal basis for measuring fair value.

During the nine months ended September 30, 2016, the Company did not have any transfers between levels.

The amounts in the Company's consolidated balance sheet for accounts receivable 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, 2016.

### Note 5 – Marketable Securities

Marketable securities classified as available-for-sale as of September 30, 2016 and December 31, 2015 were comprised of (in thousands):

	September 30, 2016				December 31, 2015			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
U.S. Treasury securities	\$15,066	\$ 12	\$ —	\$15,078	\$—	\$ —	\$ —	\$—
Asset-backed securities	43,152	1	(2 )	43,151	20,748	—	(9 )	20,739
Corporate debt securities	121,966	156	(16 )	122,106	116,821	29	(41 )	116,809
Total	\$180,184	\$ 169	\$ (18 )	\$180,335	\$137,569	\$ 29	\$ (50 )	\$137,548

#### Marketable Securities – Unrealized Losses

The primary objective of the Company's investment policy is the preservation of capital; limiting investments to certain types of instruments with high-grade credit ratings, restricting maturities and concentrations in certain industries and requiring the Company to maintain a certain level of liquidity.

The Company owned 42 available-for-sale securities as of September 30, 2016. Of these 42 securities, 14 had combined unrealized losses of less than \$0.1 million as of September 30, 2016. The Company did not have any investments in a loss position for greater than 12 months as of September 30, 2016. The Company has evaluated its marketable securities and has determined that none of these investments have 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, 2016 was as follows (in thousands):

	<b>Amount</b>
Balance at December 31, 2015	\$ 53,065
Currency translation adjustments	(371 )
Balance at September 30, 2016	\$ 52,694

***Identifiable Intangible Assets***

Purchased intangible assets consisted of the following as of September 30, 2016 and December 31, 2015 (in thousands):

	September 30, 2016			December 31, 2015		
	Gross Carrying Amount	Accumulated Amortization	Intangible Assets, Net	Gross Carrying Amount	Accumulated Amortization	Intangible Assets, Net
Finite-lived intangible assets:						
Proprietary adjuvant technology	\$ 8,689	\$ (1,375 )	\$ 7,314	\$ 8,858	\$ (1,070 )	\$ 7,788
Collaboration agreements	3,923	(1,279 )	2,644	3,999	(994 )	3,005
Total identifiable intangible assets	\$ 12,612	\$ (2,654 )	\$ 9,958	\$ 12,857	\$ (2,064 )	\$ 10,793

Amortization expense for the nine months ended September 30, 2016 and 2015 was \$0.6 million.

Estimated amortization expense for existing intangible assets for the remainder of 2016 and for each of the five succeeding years ending December 31 will be as follows (in thousands):



Year	Amount
2016 (remainder)	\$ 210
2017	838
2018	838
2019	838
2020	716
2021	569

## Note 7 – Long-Term Debt

### *Convertible Notes*

In the first quarter of 2016, the Company issued \$325 million aggregate principal amount of convertible senior unsecured notes that will mature on February 1, 2023 (the “Notes”). The Notes are senior unsecured debt obligations and were issued at par. The Notes were issued pursuant to an indenture dated January 29, 2016 (the “Indenture”), between the Company and the trustee. The Company received \$315.0 million in net proceeds from the offering after deducting underwriting fees and offering expenses. The Notes bear cash interest at a rate of 3.75%, payable on February 1 and August 1 of each year, beginning on August 1, 2016. The Notes are not redeemable prior to maturity and are convertible into shares of the Company’s common stock. The Notes are initially convertible into approximately 47,716,900 shares of the Company’s stock based on the initial conversion rate of 146.8213 shares of the Company’s common stock per \$1,000 principal amount of the Notes. This represents an initial conversion price of approximately \$6.81 per share of the Company’s common stock, representing an approximate 22.5% conversion premium based on the last reported sale price of the Company’s common stock of \$5.56 per share on January 25, 2016. In addition, the holders of the Notes may require the Company to repurchase the Notes at par value plus accrued and unpaid interest following the occurrence of a Fundamental Change (as described in the Indenture). If a holder of the Notes converts upon a Make-Whole Adjustment Event (as described in the Indenture), they may be eligible to receive a make-whole premium through an increase to the conversion rate up to a maximum of 179.8561 shares per \$1,000 principal amount of Notes (subject to other adjustments as described in the Indenture).

The Notes are accounted for in accordance with ASC 470-20, *Debt with Conversion and Other Options* and ASC 815-40, *Contracts in Entity's Own Equity*. Under ASC 815-40, to qualify for equity classification (or nonbifurcation, if embedded) the instrument (or embedded feature) must be both (1) indexed to the issuer's stock and (2) meet the requirements of the equity classification guidance. Based upon the Company's analysis, it was determined the Notes do contain embedded features indexed to its own stock, but do not meet the requirements for bifurcation, and therefore do not need to be separately accounted for as an equity component. Since the embedded conversion feature meets the equity scope exception from derivative accounting, and also since the embedded conversion option does not need to be separately accounted for as an equity component under ASC 470-20, the proceeds received from the issuance of the convertible debt was recorded as a liability on the consolidated balance sheet.

In connection with the issuance of the Notes, the Company also paid \$38.5 million, including expenses, to enter into privately negotiated capped call transactions with certain financial institutions (the "capped call transactions"). The capped call transactions are generally expected to reduce the potential dilution upon conversion of the Notes in the event that the market price per share of the Company's common stock, as measured under the terms of the capped call transactions, is greater than the strike price of the capped call transactions, which initially corresponds to the conversion price of the Notes, and is subject to anti-dilution adjustments generally similar to those applicable to the conversion rate of the Notes. The cap price of the capped call transactions will initially be \$9.73 per share, which represented a premium of approximately 75% based on the last reported sale price of the Company's common stock of \$5.56 per share on January 25, 2016, and is subject to certain adjustments under the terms of the capped call transactions. If, however, the market price per share of the Company's common stock, as measured under the terms of the capped call transactions, exceeds the cap price, there would nevertheless be dilution upon conversion of the Notes to the extent that such market price exceeds the cap price. The Company evaluated the capped call transactions under ASC 815-10 and determined that it should be accounted for as a separate transaction and that the capped call transactions will be classified as an equity instrument.

The Company incurred approximately \$10.0 million of debt issuance costs during the first quarter of 2016 relating to the issuance of the Notes, which were recorded as a reduction to the Notes on the consolidated balance sheet. The \$10.0 million of debt issuance costs is being amortized and recognized as additional interest expense over the 7 year contractual term of the Notes using the effective interest rate method. The Company also incurred \$0.9 million of expenses related to the capped call transactions, which were recorded as a reduction to additional paid-in-capital.

Total convertible notes payable consisted of the following at (in thousands):

	<b>September 30, 2016</b>	<b>December 31, 2015</b>
Principal amount of Notes	\$ 325,000	\$
Unamortized debt issuance costs	(9,017 )	
Total convertible notes payable	\$ 315,983	\$



Interest expense incurred in connection with the Notes consisted of the following (in thousands):

	<b>Three Months Ended</b>		<b>Nine Months Ended</b>	
	<b>September 30,</b>		<b>September 30,</b>	
	2016	2015	2016	2015
Coupon interest	\$3,047	\$	\$8,193	\$
Amortization of debt issuance costs	356		949	
Total interest expense on Notes	\$3,403	\$	\$9,142	\$

#### **Note 8 – Stockholders’ Equity**

During the first quarter of 2016, in connection with the Company’s issuance of the Notes, the Company also entered into privately negotiated capped call transactions as discussed in Note 7. The cost of the capped call transactions and associated expenses totaling \$38.5 million were recorded as a reduction to additional paid-in-capital.

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 Company sold an aggregate of \$50 million in gross proceeds of its common stock. 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 was fully utilized at that time.

#### **Note 9 – 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 awards will continue to be outstanding in accordance with their terms. Under the Company’s 2015 Stock Incentive Plan, as amended (“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 31,000,000 shares of common stock under equity awards granted under the plan, including an increase of 6,000,000 shares approved at the Company’s 2016 annual meeting of stockholders. 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 and 2005 Plan for the nine months ended September 30, 2016:

	2015 Plan		2005 Plan	
	Stock Options	Weighted-Average Exercise Price	Stock Options	Weighted-Average Exercise Price
Outstanding at January 1, 2016	8,357,003	\$ 8.97	15,450,542	\$ 3.31
Granted	10,384,437	\$ 5.10	—	\$ —
Exercised	—	\$ —	(694,163 )	\$ 2.15
Canceled	(598,687 )	\$ 7.29	(247,375 )	\$ 4.75
Outstanding at September 30, 2016	18,142,753	\$ 6.81	14,509,004	\$ 3.34
Shares exercisable at September 30, 2016	2,297,355	\$ 8.56	10,559,379	\$ 2.83
Shares available for grant at September 30, 2016	12,812,247			

The fair value of stock options granted under the 2015 Plan and 2005 Plan 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, 2016	2015	September 30, 2016	2015
Weighted-average Black-Scholes fair value of stock options granted	\$3.34	\$4.70	\$2.50	\$4.43
Risk-free interest rate	0.97%-1.09%	1.32%-1.39%	0.97%-1.70%	1.19%-2.13%
Dividend yield	0%	0%	0%	0%
Volatility	58.58%-59.02%	54.93%-57.17%	57.86%-68.28%	53.58%-68.39%
Expected term (in years)	4.24	4.27-4.60	4.24-7.28	3.98-7.34
Expected forfeiture rate	10.31%	14.18%-16.33%	0%-16.33%	0%-16.33%

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, 2016 was approximately \$2.8 million and 7.8 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, 2016 was approximately \$2.7 million and 6.3 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, 2016. 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, 2016 and 2015 was \$2.4 million and \$9.0 million, respectively.

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

The Company's Employee Stock Purchase Plan, as amended (the "ESPP") currently authorizes an aggregate of 3,300,000 shares of common stock to be purchased, such aggregate will continue to increase 5% on each anniversary of its adoption up to a maximum of 4,000,000 shares. The number of authorized shares and the maximum number of shares both include an increase of 1,000,000 shares approved at the Company's 2016 annual meeting of stockholders. 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 eligible 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, 2016, there were 1,636,938 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:

	<b>Three Months Ended</b>		<b>Nine Months Ended</b>	
	<b>September 30, 2016</b>	<b>2015</b>	<b>September 30, 2016</b>	<b>2015</b>
Range of Black-Scholes fair value of ESPP shares granted	\$1.97-\$4.76	\$1.20-\$3.38	\$1.86-\$4.76	\$1.06-\$3.38
Risk-free interest rate	0.32%-0.61%	0.07%-0.35%	0.22%-0.61%	0.05%-0.35%
Dividend yield	0%	0%	0%	0%
Volatility	43.03%-86.75%	40.79%-64.24%	43.03%-86.75%	40.79%-64.24%
Expected term (in years)	0.5-2.0	0.5-2.0	0.5-2.0	0.5-2.0
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, 2016:

	<b>Number of  Shares</b>	<b>Per Share Weighted-Average Grant-Date Fair Value</b>
		<b>Fair Value</b>
Outstanding and Unvested at January 1, 2016	25,000	\$ 8.72
Restricted stock granted	45,000	\$ 4.99
Restricted stock vested		\$
Restricted stock forfeited	(25,000)	\$ 8.72
Outstanding and Unvested at September 30, 2016	45,000	\$ 4.99

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



	<b>Three Months Ended</b>		<b>Nine Months Ended</b>	
	<b>September 30,</b>		<b>September 30,</b>	
	2016	2015	2016	2015
Research and development	\$2,917	\$2,240	\$9,108	\$4,361
General and administrative	2,239	2,525	6,272	4,917
Total stock-based compensation expense	\$5,156	\$4,765	\$15,380	\$9,278

As of September 30, 2016, there was approximately \$45.7 million of total unrecognized compensation expense (net of estimated forfeitures) related to unvested stock options, ESPP and restricted stock awards. This unrecognized non-cash compensation expense is expected to be recognized over a weighted-average period of 1.4 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 10 – Collaboration, U.S. Government Agreement and Joint Venture

***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 being recognized as revenue in the period in which the research and development activities are performed. Payments received in advance that are related to future performance are deferred and recognized as revenue when the research and development activities are performed. Cash payments received under the Grant are restricted as to their use until expenditures contemplated in the Grant are incurred. During the three and nine months ended September 30, 2016, the Company recognized revenue of \$2.6 million and \$5.9 million, respectively, and has recognized approximately \$7.5 million in revenue since the inception of the contract. At September 30, 2016, the Company’s current restricted cash and deferred revenue balances on the consolidated balance sheet represent its estimate of costs to be reimbursed and revenue to be recognized, respectively, in the next twelve months under the Grant Agreement.

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

HHS BARDA initially awarded the Company a contract in 2011, which has funded the development of both the Company’s quadrivalent seasonal and pandemic influenza virus-like particle (“VLP”) vaccine candidates. The contract with HHS BARDA was a cost-plus-fixed-fee contract, which reimbursed 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 second quarter of 2015. Advances in the Company’s seasonal influenza nanoparticle program have resulted in a natural conclusion of its activities under the HHS BARDA contract, which expired in accordance with its terms in September 2016. During the three and nine months ended September 30, 2016, the

Company recognized revenue of \$0.1 million and \$2.2 million, respectively, and has recognized approximately \$113.7 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 years 2013 and 2014 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.

### *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. 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.

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

In 2007, the Company entered into an agreement to license certain rights from Wyeth Holdings Corporation (now Wyeth Holdings LLC), 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 restructured 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, would 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 restructured 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 was 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 payment to Wyeth. The amendment also increased 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, 2016 aggregated to \$7.6 million. The Milestone has been accrued for, on a discounted basis calculated based on the probable future payment date, in other non-current liabilities at September 30, 2016. The Milestone was recorded as a research and development expense in 2014.

Note 12 – Facility Leases

In May 2016, the Company signed a new lease for a facility of approximately 150,000 square feet located in Gaithersburg, Maryland with a term expiring in 2030, unless terminated early by the Company in 2026. 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 lease, the landlord shall provide the Company with a tenant improvement allowance of up to \$9.6 million. In addition, the Company extended its Rockville, Maryland lease with a term expiring in 2020, unless terminated early by the Company in 2019. Novavax AB also extended its lease in Uppsala, Sweden with a term expiring in 2026, unless terminated early by the Company in 2023.

Future minimum rental commitments under non-cancelable leases are as follows (in thousands and including the new lease):

Year	Amount
2016 (remainder)	\$ 1,596
2017	7,053
2018	10,314
2019	9,144
2020	8,711
Thereafter	46,312
Total minimum lease payments	\$83,130

### **Note 13 – Related Party Transactions**

Dr. Rajiv Modi, a director of the Company, is also the managing director of Cadila. The Company and Cadila have formed a joint venture, CPLB (see Note 10). A subsidiary of Cadila owns 2.5 million shares of the Company's outstanding common stock as of September 30, 2016. The Company and Cadila have also entered into a master services agreement, pursuant to which Cadila or CPLB may perform certain research, development and manufacturing services for the Company. For the nine months ended September 30, 2016 and 2015, the Company incurred \$0.3 million and \$1.5 million, respectively, in expenses under the master services agreement. No amount was owed to CPLB under the master services agreement at September 30, 2016; however, the Company owed \$0.7 million at December 31, 2015.

## 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 the Department of Health and Human Services, Biomedical Advanced Research and Development Authority ("HHS BARDA"); payments under our license with Wyeth Holdings LLC (formerly known as Wyeth Holdings 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 amendments thereto; the effectiveness, and expected costs and savings, and the timing of such costs and savings, associated with the implementation, of our recently announced plan to restructure our operations, 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," "we" 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, 2015, 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 statement speaks 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 platform technology, we produce vaccine candidates to efficiently and effectively respond to both known and emerging disease threats. Our vaccine candidates are genetically engineered three-dimensional nanostructures that incorporate recombinant proteins critical to disease pathogenesis. Our product pipeline targets a variety of infectious diseases with clinical vaccine candidates for respiratory syncytial virus (“RSV”) and Ebola virus (“EBOV”), and preclinical programs for Zika virus, seasonal influenza and a combination respiratory vaccine candidate, as well as other infectious disease vaccine candidates.

We are also developing proprietary technology for the production of immune stimulating saponin-based adjuvants through our wholly owned Swedish subsidiary, Novavax AB. Our lead adjuvant, Matrix-M™, has been successfully tested in a Phase 1/2 clinical trial for our pandemic H7N9 influenza virus-like particle (“VLP”) vaccine candidate, and in a Phase 1 clinical trial for our EBOV vaccine candidate. Genocea Biosciences, Inc. (“Genocea”) has licensed rights to our Matrix technology and has conducted Phase 2 clinical trials with its herpes simplex 2 vaccine candidate using Matrix-M.

Following the results of the top-line data from the Phase 3 clinical trial of our RSV F Vaccine in older adults, on November 9, 2016, we announced a restructuring plan (the “Restructuring Plan”) designed to meet the following key objectives:

- Prioritize our development activities to achieve clinical data events during 2017;
- Reduce our cash burn, extend our financial horizon and minimize our near-term dilution; and
- Maintain our operational core competencies to execute against our development plans.

The Restructuring Plan includes an immediate reduction in our workforce of approximately 30%. We expect to incur one-time restructuring costs of approximately \$3 million to \$4 million, including cash severance expenses, in the fourth quarter of 2016. In addition, we have initiated expense reduction measures relating to pre-commercialization activities, capital equipment investments, project specific and general research and development, and general and administrative expenses. As a result of the Restructuring Plan, we estimate a reduction in cash burn of \$70 million to \$100 million in 2017 relative to 2016.

The Restructuring Plan was engineered to support the following high-level operating priorities (each of which is more fully articulated in our program descriptions in this Management’s Discussion and Analysis of Financial Condition and Results of Operations below):

Continued execution of the global pivotal Phase 3 clinical trial, known as Prepare™, of our RSV F Vaccine for infants via maternal immunization;

- Initiation of a multi-arm, dose-ranging Phase 2 clinical trial of our RSV F Vaccine in older adults; and
- Initiation of a Phase 1 clinical trial of our Zika vaccine candidate in 2017.

## Product Pipeline

Our product pipeline includes vaccine candidates engineered to elicit differentiated immune responses with potential to provide increased protection. Our nanoparticle technology platform targets antigens with conserved epitopes essential for viral function. Unlike traditional vaccines that ‘mimic’ viruses and elicit naturally occurring immune responses to them, our nanoparticles are engineered to elicit differentiated immune responses, which may be more efficacious than naturally-occurring immunity. Our vaccine technology has the potential to be applied broadly to a wide variety of human infectious diseases.

<b>Program</b>	<b>Development Stage</b>
<b>Respiratory Syncytial Virus (RSV)</b>	
· <b>Infants via Maternal Immunization</b>	Phase 3*
· <b>Older Adults</b>	Phase 2
· <b>Pediatrics</b>	Phase 1
<b>Emerging Disease</b>	
· <b>Ebola Virus (EBOV)</b>	Phase 1
· <b>Zika Virus (ZIKV)</b>	Preclinical
<b>Seasonal Influenza Nanoparticle</b>	Preclinical
<b>Combination Respiratory Vaccine</b>	Preclinical

\*Supported by \$89 million grant from BMGF

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

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

We are developing our respiratory syncytial virus fusion (F) protein nanoparticle vaccine candidate (“RSV F Vaccine”) for three susceptible target populations: infants via maternal immunization, older adults (60 years of age and older) and children six months to five years of age (“pediatrics”). We believe our RSV F Vaccine represents a multi-billion dollar revenue opportunity, worldwide. Currently there is no approved RSV vaccine available.

Repeat infection and lifelong susceptibility to RSV are common and we currently estimate the global cost burden of RSV in excess of \$88 billion. Despite decades of effort to develop an RSV vaccine, there are currently no licensed vaccines. Although the monoclonal antibody palivizumab (Synagis®) is effective in pre-term infants, it is not indicated for use in other populations. We made a breakthrough in developing a vaccine that targets the fusion protein, or F-protein, of the virus. The F-protein has a highly conserved amino acid sequence called antigenic site II, which we believe is an ideal vaccine target. Palivizumab, which also targets antigenic site II, has demonstrated protection in five randomized clinical trials. We genetically engineered a novel F-protein antigen and enhanced its immunogenicity by exposing antigenic site II. Novavax' RSV F Vaccine assembles into a recombinant protein nanoparticle optimized for F-protein antigen presentation. The Novavax RSV F Vaccine has demonstrated efficacy in a Phase 2 clinical trial, and we are seeking to bring the first RSV vaccine to market to combat the 64 million RSV infections that occur globally each year.<sup>1,2</sup>

<sup>1</sup>Nair, H., et al., (2010) Lancet. 375:1545 - 1555

<sup>2</sup>WHO Acute Respiratory Infections September 2009 Update:

[http://apps.who.int/vaccine\\_research/diseases/ari/en/index2.html](http://apps.who.int/vaccine_research/diseases/ari/en/index2.html)

## *RSV Infants via Maternal Immunization Program*

### *Burden of Disease*

RSV is the most common cause of lower respiratory tract infections and the leading viral cause of severe lower respiratory tract disease in infants and young children worldwide.<sup>3</sup> In the U.S., RSV is the leading cause of hospitalization of infants, and globally, is second only to malaria as a cause of death in children under one year of age.<sup>4,5</sup> Despite the induction of post-infection immunity, repeat infection and lifelong susceptibility to RSV is common.<sup>6,7</sup>

### *Clinical Trial Update*

We announced the initiation of a global pivotal Phase 3 clinical trial, known as Prepare, of the RSV F Vaccine in 5,000 to 8,255 healthy pregnant women in December 2015. The primary objective of the Prepare trial is to determine the efficacy of maternal immunization with the RSV F Vaccine against symptomatic RSV lower respiratory tract infection with hypoxemia in infants through a minimum of the first 90 days of life. This Phase 3 trial utilizes a group sequential design and is expected to take between three and four years to complete. We are currently in discussion with the U.S. Food and Drug Administration, Center for Biologics Evaluation and Research (“FDA”) about conducting an interim analysis of the Prepare trial as early as late 2017, although a decision has not yet been made.

The Phase 3 trial is supported by a grant (the “Grant”) of up to \$89.1 million from BMGF. The Grant will support development activities, product licensing efforts and World Health Organization (“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 (the “Grant Agreement”). Under the terms of the GACA, we agreed to make the RSV F Vaccine available and accessible at affordable pricing to people in certain low and middle income countries.

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 and their infants. This clinical trial evaluated the safety and immunogenicity of our RSV F Vaccine in pregnant women in their third trimester, and assessed the transplacental transfer of maternal antibodies induced by the vaccine. The trial also examined 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 a geometric mean 14-fold rise in anti-F IgG, 29-fold rise in palivizumab-competing antibodies and a 2.7 and 2.1-fold rise in microneutralization titers against RSV/A and RSV/B, respectively. In contrast, women who received placebo demonstrated no significant change in antibody levels. The infants' antibody levels at delivery averaged 90-100% of the mothers' levels, indicating efficient transplacental transfer of antibodies from mother to

infant. 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.

In November 2014, the FDA granted Fast Track designation to our RSV F Vaccine for protection of infants via maternal immunization. Fast Track designation 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 designed 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.

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

<sup>4</sup>Hall, C.B. *et al.* (2013) *Pediatrics*; 132(2):E341-348

<sup>5</sup>Oxford Vaccine Group: <http://www.ovg.ox.ac.uk/rsv>

<sup>6</sup>Glezen, W.P. *et al.* (1986) *Am J Dis Child*; 140:543-546

<sup>7</sup>Glenn, G.M. *et al.* (2016) *JID*; 213(3):411-12

## *RSV Older Adults Program*

### *Burden of Disease*

Adults 60 years of age and older are at increased risk for RSV disease due to age related declines in their immune systems. In this population, RSV is an important respiratory virus, distinct from influenza viruses, that is responsible for serious lower respiratory tract disease and may lead to hospitalization or even death. Additionally, RSV infection can lead to exacerbation of underlying co-morbidities such as chronic obstructive pulmonary disease, asthma and congestive heart failure. In the U.S., the incidence rate is approximately 2.5 million infections per year, and RSV is increasingly recognized as a significant cause of morbidity and mortality in the population of 64 million older adults.<sup>8,9</sup> Based on our analysis of published literature applied to 2014 population estimates, the disease causes 207,000 hospitalizations and 16,000 deaths among adults older than 65. Annually, we estimate that there are approximately 900,000 medical interventions directly caused by RSV disease across all populations.

### *Clinical Trial Update*

#### *Resolve Phase 3 Trial*

We announced top-line data from the Phase 3 clinical trial of our RSV F Vaccine in older adults, known as Resolve™, in the third quarter of 2016. Resolve, a randomized, observer-blinded, placebo-controlled trial, began in November 2015 and was fully enrolled with 11,856 older adult subjects at 60 sites in the U.S. by December 2015. Historically, annual seasonal attack rates for all symptomatic respiratory disease due to RSV (RSV ARD) of between 3% and 7% have been observed in older adults.<sup>10</sup> In our Phase 2 trial conducted during the 2014-2015 RSV season, we observed an RSV ARD attack rate of 4.9%, with an attack rate of 1.8% for moderate-severe RSV-associated lower respiratory tract disease (RSV msLRTD). In the Resolve trial, in contrast, we observed an RSV ARD attack rate of 2.0% and an RSV msLRTD attack rate of 0.4%. These unexpectedly low attack rates indicate a mild RSV season in older adults. The trial did not meet the pre-specified primary or secondary efficacy objectives and did not demonstrate vaccine efficacy. The primary objective of the Resolve trial was to demonstrate efficacy in the prevention of moderate-severe RSV-associated lower respiratory tract disease (RSV msLRTD), as defined by the presence of multiple lower respiratory tract symptoms. The secondary objective of the trial was to demonstrate efficacy of the RSV F Vaccine in reducing the incidence of all symptomatic respiratory disease due to RSV (RSV ARD). The trial also evaluated the safety of the unadjuvanted, 135 microgram dose of the RSV F Vaccine compared to placebo and consistent with our previous clinical experience, the vaccine was well-tolerated. We are continuing to investigate potential root causes that may have contributed to the outcome of this trial, including the impact of the unexpectedly low RSV attack rates.

*Phase 2 Rollover Trial*

In September 2016, we announced positive top-line data from the Phase 2 rollover clinical trial of our RSV F Vaccine in older adults in the third quarter of 2016. The trial was a randomized, observer-blinded, placebo-controlled rollover trial which enrolled 1,329 older adults from the prior Phase 2 trial, conducted at the same 10 sites in the U.S. as our completed Phase 2 clinical trial in older adults. The primary objectives of the trial evaluated safety and serum anti-F IgG antibody concentrations in response to immunization with the RSV F Vaccine. The exploratory objectives of the trial evaluated the efficacy of a second annual dose of the RSV F Vaccine in the prevention of RSV ARD and RSV msLRTD. Participants previously randomized to receive 135 microgram RSV F Vaccine or placebo were re-enrolled and re-randomized in the current trial to receive either 135 microgram RSV F Vaccine or placebo. This resulted in analysis of four separate trial arms: a) participants receiving a placebo in both the first trial and second trial (Placebo-Placebo); b) participants receiving RSV F Vaccine in the first trial and placebo in the second trial (Vaccine-Placebo); c) participants receiving placebo in the first trial and RSV F Vaccine in the second trial (Placebo-Vaccine); and d) participants receiving RSV F Vaccine in both the first trial and second trial (Vaccine-Vaccine).

<sup>8</sup>Falsey, A.R. *et al.* (2005) NEJM. 352:1749–59 extrapolated to 2015 census population

<sup>9</sup>Falsey, A.R. *et al.* (1995) JID.172:389-94

<sup>10</sup>Falsey, A.R. *et al.* (2005) NEJM. 352:1749–59



The rollover trial demonstrated immunogenicity in all active vaccine recipients, with a 6-fold increase in anti-F IgG in the Placebo-Vaccine arm, consistent with the Phase 2 efficacy trial. There was higher anti-F IgG at baseline in the Vaccine-Vaccine arm compared to the Placebo-Vaccine arm and the Vaccine-Vaccine arm showed a greater than 2-fold increase in anti-F IgG from the higher baseline. The rollover trial confirmed the low attack rates witnessed during the Resolve trial. While there was an absence of efficacy in the Placebo-Vaccine trial arm, the Vaccine-Vaccine trial arm did suggest efficacy, although this result was not statistically significant.

### *Phase 2 Trial in Older Adults (Completed)*

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. 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 our 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 protocol population, the clinical trial showed statistically significant vaccine efficacy in prevention of all symptomatic RSV disease (41%) and, in an *ad hoc* analysis, showed a decrease in RSV disease with any symptoms of lower respiratory tract infection (45%) in older adults. The clinical trial established an attack rate for symptomatic RSV disease of 4.9% in older adults, 95% of which included lower respiratory track symptoms. Efficacy against more severe RSV illness, defined by the presence of multiple lower respiratory tract symptoms or signs associated with difficulty breathing, was 64% in *ad hoc* analyses.

### *Older Adults Next Steps*

Based on our ongoing observations from the Resolve trial and additional analyses, in the first quarter of 2017 we expect to initiate a randomized, observer-blinded, multi-arm, dose-ranging Phase 2 clinical trial in healthy older adults, in one and two dose formulations, and both with and without adjuvants. The trial will evaluate safety and immunogenicity of these formulations in older adults as measured by serum microneutralization titers against RSV/A and RSV/B, palivizumab competing antibodies (“PCA”) and anti-F IgG.

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

#### *Burden of Disease*

There are currently approximately 18 million children in the U.S. between six months and five years of age.<sup>11</sup> In the U.S., RSV is responsible for approximately 57,000 hospitalizations of children under five years of age annually, the vast majority of which occur in infants less than one year old, and especially those under six months of age.<sup>12,13,14,15,16</sup>

<sup>11</sup> U.S. Census. [www.census.gov/population/international/data/idb/informationGateway.php](http://www.census.gov/population/international/data/idb/informationGateway.php)

<sup>12</sup> Stockman, L.J. et al (2012) *Pediatr Infect Dis J*. 31: 5-9

<sup>13</sup> CDC update May 5, 2015. <http://www.cdc.gov/rsv/research/us-surveillance.html>

<sup>14</sup> Boyce, T.G. et al (2000) *Pediatrics*; 137: 865-870

<sup>15</sup> Hall, C.B. et al (2009) *NEJM*; 360(6): 588-98

<sup>16</sup> Hall, C.B. et al (2013) *Pediatrics*; 132(2): E341-8

### *Clinical Trial Update*

In September 2015, we announced positive top-line data from a 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. Trial enrollment was concluded with a smaller than planned cohort so that dosing could be completed ahead of the 2014-2015 RSV season. The vaccine was well-tolerated and serum samples collected from a subset of 18 immunized children in the per-protocol population, demonstrated that the RSV F Vaccine was highly immunogenic at all formulations and regimens. 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 next steps in the development of our RSV F Vaccine for pediatrics.

### **Emerging Disease**

#### *Ebola Virus (EBOV)*

EBOV, formerly known as Ebola hemorrhagic fever, is a severe, often fatal illness in humans. Multiple strains of EBOV have been identified, the most recent of which, the Makona EBOV strain, is associated with a case fatality rate of 50% to 90%.<sup>17</sup> 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. In contrast, 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 230 healthy adults. Participants received either one or two intramuscular injections ranging from 6.5µg to 50µg of antigen, with or without adjuvant, or placebo. Immunogenicity was assessed at multiple time points, including days 28 and 35. These Phase 1 data demonstrated 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 2015, we also 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.

***ZIKV EnvD Vaccine***

We initiated development of a Zika virus (ZIKV) vaccine in response to the unmet global medical need for this serious disease. Over the last 18 months, ZIKV has demonstrated epidemic spread in South, Central and North America, with both mosquito-borne and sexual transmission. Although acute ZIKV infections in adults are generally either asymptomatic or associated with mild symptoms (fever, joint pains and skin rash), more serious outcomes can occur, including Guillain-Barré syndrome in adults and, microcephaly in infants of women infected during pregnancy. There is no approved vaccine against ZIKV, although a number of companies have announced vaccine development efforts. In October 2016, we initiated a preclinical study of our ZIKV envelope dimer nanoparticle vaccine candidate (“ZIKV EnvD Vaccine”) in non-human primates. We have also requested a pre-IND meeting with the FDA about a Phase 1 clinical trial of our Zika EnvD Vaccine. Pending the outcome of this preclinical study and the FDA meeting, we expect to initiate a Phase 1 clinical trial in healthy adults in the first half of 2017.

17 WHO. <http://www.who.int/mediacentre/factsheets/fs103/en/>

## **Influenza**

### ***Seasonal Influenza***

Influenza is a world-wide infectious disease that causes illness in humans with symptoms ranging from mild to life-threatening or even death. 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. Current estimates for seasonal influenza vaccine growth in the top seven markets (U.S., Japan, France, Germany, Italy, Spain and UK), show a potential increase from approximately \$3.2 billion in the 2012-2013 season to \$5.3 billion by the 2021-2022 season.<sup>18</sup>

The Advisory Committee for Immunization Practices of the Center for Disease Control and Prevention (“CDC”) recommends that all persons aged six months and older be vaccinated annually against seasonal influenza. Influenza is a major burden on public health worldwide: an estimated one million deaths each year are attributed to influenza.<sup>19</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>20</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 potentially be manufactured quickly and in a cost-effective manner, without the use of either the live influenza virus or eggs.

After many years of developing seasonal influenza vaccine candidates as VLPs, we have identified advantages of developing a nanoparticle-based seasonal influenza vaccine. In particular, influenza nanoparticles can display conserved antigenic regions, which have the potential to elicit broadly neutralizing antibodies that may offer protection against a range of drifted strains. Additionally, nanoparticles offer improved purity and manufacturability and advantages for co-formulation with other nanoparticle-based vaccines. We expect to continue to develop our nanoparticle influenza vaccine program into 2017 with an ongoing goal of generating additional proof-of-concept data.

### ***Combination Respiratory Vaccine***

Given the ongoing development of our RSV F Vaccine and our desire to develop a combination respiratory vaccine with the potential to protect against both RSV and seasonal influenza, we made the decision to shift our seasonal influenza vaccine development focus from VLP-based seasonal influenza vaccines to nanoparticle-based seasonal influenza vaccines. Early preclinical development efforts give us confidence that such a combination vaccine is feasible.

***CPLB Joint Venture (India)***

CPL Biologicals 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. CPLB is owned 20% by us and 80% by Cadila. CPLB operates a manufacturing facility in India for the production of vaccines.

***Seasonal Influenza***

CPLB received marketing authorization, the Indian equivalent of approval of a Biologics License Application, for its seasonal VLP influenza vaccine and is currently manufacturing with limited sales in 2016.

<sup>18</sup> Influenza Vaccines Forecasts.  
Datamonitor (2013)

<sup>19</sup>Resolution of the World Health Assembly. (2003) WHA56.19. 28

<sup>20</sup>WHO position paper (2012) Weekly Epidemiol Record;87(47):461–76

### ***Rabies***

CPLB successfully completed Stage II of its 2-stage Phase 1/2 clinical trial in India of a rabies G protein vaccine candidate that we genetically engineered, and that can be administered both as a pre-exposure and a post-exposure prophylactic regimen. The post-exposure regimen has the potential to use fewer doses than the current standard of care. CPLB initiated its Phase 3 clinical trial in October 2016.

### **Convertible Senior Notes**

In the first quarter of 2016, we issued \$325 million aggregate principal amount of convertible senior unsecured notes that will mature on February 1, 2023 (the “Notes”). The Notes bear cash interest at a rate of 3.75%, payable on February 1 and August 1 of each year, beginning on August 1, 2016. The Notes are not redeemable prior to maturity and are convertible into shares of the Company’s common stock. The initial conversion rate for the Notes is 146.8213 shares of the Company’s common stock per \$1,000 principal amount of the Notes, which is equivalent to an initial conversion price of approximately \$6.81 per share of the Company’s common stock, representing an approximate 22.5% conversion premium based on the last reported sale price of the Company’s common stock of \$5.56 per share on January 25, 2016.

In connection with the issuance of the Notes, we paid \$38.5 million, including expenses, to enter into privately negotiated capped call transactions with certain financial institutions (the “capped call transactions”). The capped call transactions are generally expected to reduce the potential dilution upon conversion of the Notes in the event that the market price per share of our common stock, as measured under the terms of the capped call transactions, is greater than the strike price of the capped call transactions, which initially corresponds to the conversion price of the Notes, and is subject to anti-dilution adjustments generally similar to those applicable to the conversion rate of the Notes. The cap price of the capped call transactions will initially be \$9.73 per share, which represented a premium of approximately 75% based on the last reported sale price of our common stock of \$5.56 per share on January 25, 2016, and is subject to certain adjustments under the terms of the capped call transactions. If, however, the market price per share of the Company’s common stock, as measured under the terms of the capped call transactions, exceeds the cap price, there would nevertheless be dilution upon conversion of the Notes to the extent that such market price exceeds the cap price.

### **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 2012, we entered into an At Market Issuance Sales Agreement (“Sales Agreement”), under which we sold an aggregate of \$50 million in gross proceeds of our common stock. During 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 was fully utilized at that time.

*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, 2015, as filed with the SEC.



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

In February 2016, the Financial Accounting Standards Board (“FASB”) issued ASU 2016-02, *Leases (Topic 842)* (“ASU 2016-02”) that increases transparency and comparability among organizations by requiring the recognition of lease assets and lease liabilities on the balance sheet and disclosure of key information about leasing arrangements for both lessees and lessors. The standard will be effective January 1, 2019 for us, with early adoption permitted. The standard will be applied using a modified retrospective approach to the beginning of the earliest period presented in the financial statements. We are currently evaluating when we will adopt the standard and the expected impact to our consolidated financial statements and related disclosures.

In March 2016, the FASB issued ASU 2016-09, *Compensation - Stock Compensation (Topic 718)* (“ASU 2016-09”) that simplifies the accounting for share-based payment transactions, including the income tax consequences, classification of awards as either equity or liabilities, and classification on the statement of cash flows. We plan to adopt this standard on the effective date, January 1, 2017, and do not expect the adoption will have a material impact on our consolidated financial statements and related disclosure.

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. ASU 2014-09 allows for either full retrospective or modified retrospective adoption. 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, 2016 and 2015** (amounts in tables are presented in thousands, except per share information)

**Revenue:**

<b>Three Months Ended</b>			
<b>September 30</b>			
		<b>Change</b>	
2016	2015	<b>2015 to</b>	
		<b>2016</b>	
Revenue:			
Total revenue	\$3,231	\$6,525	\$(3,294)

Revenue for the three months ended September 30, 2016 was \$3.2 million as compared to \$6.5 million for the same period in 2015, a decrease of \$3.3 million, or 50%. Revenue for the three months ended September 30, 2016 and 2015 is primarily comprised of services performed under the HHS BARDA contract and the Grant Agreement. The decrease in revenue under the HHS BARDA contract of \$6.2 million was due to a lower level of activity in the three months ended September 30, 2016 as compared to the same period in 2015. This decrease in revenue was partially offset by \$2.6 million in revenue recorded under the Grant Agreement relating to our ongoing RSV F Vaccine Phase 3 clinical trial for the protection of infants via maternal immunization.

We expect our 2016 revenue to be lower than 2015 revenue, due to the wind-down and the expiration of the HHS BARDA contract, which expired in September 2016. In addition, we expect revenue in 2016 under the Grant Agreement to be significantly higher than in 2015 as we continue to enroll participants in the global pivotal Phase 3 clinical trial, known as Prepare, of the RSV F Vaccine in 5,000 to 8,255 healthy pregnant women.

**Expenses:**

	<b>Three Months Ended</b>		
	<b>September 30,</b>		<b>Change</b>
	<b>2016</b>	<b>2015</b>	<b>2015 to 2016</b>
Expenses:			
Research and development	\$52,983	\$30,664	\$22,319
General and administrative	13,556	9,060	4,496
Total expenses	\$66,539	\$39,724	\$26,815

***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 our 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 \$53.0 million for the three months ended September 30, 2016 from \$30.7 million for the same period in 2015, an increase of \$22.3 million, or 73%. The increase in research and development expenses was primarily due to increased costs associated with the clinical trials and development activities of our RSV F Vaccine and higher employee-related costs, including increased non-cash stock-based compensation of \$0.7 million. For 2016, we expect a significant increase in research and development expenses primarily due to our ongoing RSV F Vaccine candidate clinical trials and employee-related and facility costs to support product development of our RSV F Vaccine candidate and other potential vaccine candidates.

***Expenses by Functional Area***

We track our research and development expenses by the type of costs incurred in identifying, developing, manufacturing and testing vaccine candidates. We evaluate and prioritize our activities according to functional area

and therefore believe that project-by-project information would not form a reasonable basis for disclosure to our investors. At September 30, 2016, we had 468 employees dedicated to our research and development programs versus 332 employees as of September 30, 2015. 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 research and development expenses by functional area for the three months ended September 30 (in millions).

	2016	2015
Manufacturing	\$32.8	\$22.1
Vaccine Discovery	1.6	1.5
Clinical and Regulatory	18.6	7.1
Total research and development expenses	\$53.0	\$30.7

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 \$13.6 million for the three months ended September 30, 2016 from \$9.1 million for the same period in 2015, an increase of \$4.5 million, or 50%. The increase was primarily due to higher employee-related costs and professional fees for pre-commercialization activities, as compared to the same period in 2015. At September 30, 2016, we had 71 employees dedicated to general and administrative functions versus 46 employees as of September 30, 2015. For 2016, we expect an increase in general and administrative expenses primarily due to increased employee costs and pre-commercialization activities of our RSV F Vaccine.

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

	<b>Three Months Ended</b>		
	<b>September 30,</b>		<b>Change</b>
	<b>2016</b>	<b>2015</b>	<b>2015 to 2016</b>
Other Income (Expense):			
Investment income	\$554	\$194	\$360
Interest expense	(3,511)	(64)	(3,447)
Other income (expense)	11	(51)	62
Total other income (expense)	\$(2,946)	\$79	\$(3,025)

We had total other expense of \$2.9 million for the three months ended September 30, 2016 as compared to total other income of \$0.1 million for the same period in 2015. Our investment income increased in the three months ended September 30, 2016 as compared to the same period in 2015 due to higher cash, cash equivalents and marketable securities balances. Our interest expense increased due to the issuance of the Notes in the first quarter of 2016.

Net Loss:

	<b>Three Months Ended</b>		
	<b>September 30,</b>		<b>Change</b>
	<b>2016</b>	<b>2015</b>	<b>2015 to 2016</b>
Net Loss:			
Net loss	\$(66,254 )	\$(33,120 )	\$(33,134)
Net loss per share	\$(0.24 )	\$(0.12 )	\$(0.12 )
Weighted shares outstanding	271,064	269,554	1,510

Net loss for the three months ended September 30, 2016 was \$66.3 million, or \$0.24 per share, as compared to \$33.1 million, or \$0.12 per share, for the same period in 2015, an increased net loss of \$33.1 million. The increased net loss was primarily due to higher research and development spending, including increased costs relating to the clinical trials and development activities of our RSV F Vaccine and higher employee-related costs, as compared to the same period in 2015.

Weighted average shares outstanding for the three months ended September 30, 2016 increased by 0.6% as compared to the same period in 2015, as a result of stock option exercises and purchases under our employee stock purchase plan.

**Nine Months Ended September 30, 2016 and 2015** (amounts in tables are presented in thousands, except per share information)

**Revenue:**

**Nine Months Ended**

**September 30**

			<b>Change 2015 to 2016</b>
2016	2015		

Revenue:

Total revenue	\$9,954	\$30,397	\$(20,443)
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Revenue for the nine months ended September 30, 2016 was \$10.0 million as compared to \$30.4 million for the same period in 2015, a decrease of \$20.4 million, or 67%. Revenue for the nine months ended September 30, 2016 and 2015 is primarily comprised of services performed under the HHS BARDA contract, and to a lesser extent, the Grant Agreement. The decrease in revenue under the HHS BARDA contract of \$27.1 million was primarily due to \$7.7 million relating to the recovery of additional costs under the HHS BARDA contract for the settlement of indirect rates for fiscal years 2011 and 2012 that was recorded in the second quarter of 2015, a lower level of activity in the nine months ended September 30, 2016 as compared to the same period in 2015 and revenue of \$3.1 million relating to our Phase 2 clinical trial of our quadrivalent seasonal influenza VLP vaccine candidate in Australia that was recorded in the first quarter of 2015 when collection of the amount became reasonably assured. These decreases in revenue were partially offset by \$5.9 million in revenue recorded under the Grant Agreement relating to our ongoing RSV F Vaccine Phase 3 clinical trial for the protection of infants via maternal immunization.

**Expenses:****Nine Months Ended****September 30,**

	2016	2015	<b>Change 2015 to 2016</b>
Expenses:			
Research and development	\$ 186,839	\$ 86,740	\$ 100,099
General and administrative	38,183	21,991	16,192
Total expenses	\$ 225,022	\$ 108,731	\$ 116,291

***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 our 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 \$186.8 million for the nine months ended September 30, 2016 from \$86.7 million for the same period in 2015, an increase of \$100.1 million, or 115%. The increase in research and development expenses was primarily due to increased costs associated with the clinical trials and development activities of our RSV F Vaccine and higher employee-related costs, including increased non-cash stock-based compensation of \$4.7 million. At September 30, 2016, we had 468 employees dedicated to our research and development programs versus 332 employees as of September 30, 2015.



**Expenses by Functional Area**

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

	2016	2015
Manufacturing	\$93.4	\$57.6
Vaccine Discovery	4.8	4.7
Clinical and Regulatory	88.6	24.4
Total research and development expenses	\$186.8	\$86.7

**General and Administrative Expenses**

General and administrative expenses increased to \$38.2 million for the nine months ended September 30, 2016 from \$22.0 million for the same period in 2015, an increase of \$16.2 million, or 74%. The increase was primarily due to higher employee-related costs, including increased non-cash stock-based compensation of \$1.4 million, and professional fees for pre-commercialization activities, as compared to the same period in 2015. At September 30, 2016, we had 71 employees dedicated to general and administrative functions versus 46 employees as of September 30, 2015.

**Other Income (Expense):**

	Nine Months Ended		
	September 30,		Change 2015 to 2016
	2016	2015	
Other Income (Expense):			
Investment income	\$1,701	\$450	\$1,251
Interest expense	(9,457)	(126)	(9,331)
Other expense	(33 )	(121)	88
Total other income (expense)	\$(7,789)	\$203	\$(7,992)

We had total other expense of \$7.8 million for the nine months ended September 30, 2016 as compared to total other income of \$0.2 million for the same period in 2015. Our investment income increased in the nine months ended September 30, 2016 as compared to the same period in 2015 due to higher cash, cash equivalents and marketable securities balances. Our interest expense increased due to the issuance of the Notes in the first quarter of 2016.

Net Loss:

	<b>Nine Months Ended</b>		
	<b>September 30,</b>		<b>Change</b>
	2016	2015	<b>2015 to 2016</b>
Net Loss:			
Net loss	\$(222,857)	\$(78,131 )	\$(144,726)
Net loss per share	\$(0.82 )	\$(0.30 )	\$(0.52 )
Weighted shares outstanding	270,669	259,703	10,966

Net loss for the nine months ended September 30, 2016 was \$222.9 million, or \$0.82 per share, as compared to \$78.1 million, or \$0.30 per share, for the same period in 2015, an increased net loss of \$144.7 million. The increased net loss was primarily due to higher research and development spending, including increased costs relating to the clinical trials and development activities of our RSV F Vaccine and higher employee-related costs, as compared to the same period in 2015.

Weighted average shares outstanding for the nine months ended September 30, 2016 increased by 4.2% as compared to the same period in 2015, primarily as a result of sales of our common stock in 2015.

### 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. Following our Restructuring Plan, 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, 2016, we had \$300.3 million in cash and cash equivalents and marketable securities as compared to \$230.7 million as of December 31, 2015. These amounts consisted of \$119.9 million in cash and cash equivalents and \$180.3 million in marketable securities as of September 30, 2016 as compared to \$93.1 million in cash and cash equivalents and \$137.5 million in marketable securities as of December 31, 2015.

The following table summarizes cash flows for the nine months ended September 30, 2016 and 2015 (in thousands):

	<b>Nine Months Ended</b>		
	<b>September 30,</b>		
	2016	2015	Change 2015 to 2016
Summary of Cash Flows:			
Net cash (used in) provided by:			
Operating activities	\$(194,219)	\$(71,339)	\$(122,880)

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Investing activities.	(57,888 )	(30,829 )	(27,059 )
Financing activities	279,084	208,082	71,002
Effect on exchange rate on cash and cash equivalents	(137 )	(105 )	(32 )
Net increase (decrease) in cash and cash equivalents	26,840	105,809	(78,969 )
Cash and cash equivalents at beginning of period	93,108	32,335	60,773
Cash and cash equivalents at end of period	\$119,948	\$138,144	\$(18,196 )

Net cash used in operating activities increased to \$194.2 million for the nine months ended September 30, 2016 as compared to \$71.3 million for the same period in 2015. The increase in cash usage was primarily due to increased costs relating to our RSV F Vaccine, higher employee-related costs and timing of vendor payments.

During the nine months ended September 30, 2016 and 2015, our investing activities consisted of purchases and maturities of marketable securities and capital expenditures. During the nine months ended September 30, 2016, we primarily purchased marketable securities to increase our rate of return on our marketable securities relative to returns available to money market funds. Capital expenditures for the nine months ended September 30, 2016 and 2015 were \$15.0 million and \$13.6 million, respectively. The increase in capital expenditures was primarily due to facility improvements and the purchase of laboratory equipment to support our maturing product portfolio. In 2016, we expect our level of capital expenditures to be higher than our 2015 spending as we invest in our core operational infrastructure.

Our financing activities consisted primarily of sales of our common stock, issuance of Notes and to a lesser extent, stock option exercises and purchases under our employee stock purchase plan. In the nine months ended September 30, 2016, we received net proceeds of \$276.5 million through the issuance of our Notes and payments of capped call transactions (see Note 7 to the quarterly financial statements in Item 1). 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 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 \$3.9 million. Through September 30, 2016, we were funded \$3.4 million under this tenant improvement allowance. In May 2016, we entered into a new lease for a facility located in Gaithersburg, Maryland and under the terms of the lease the landlord shall provide us with a tenant improvement allowance of up to \$9.6 million.

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 restructured 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 restructured 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 was 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 payment to Wyeth. The amendment also increased 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, 2016 aggregated \$7.6 million. The Milestone has been accrued for, on a discounted basis calculated based on the probable future payment date, in other non-current liabilities at September 30, 2016.

Based on our September 30, 2016 cash and cash equivalents and marketable securities balances, along with anticipated revenue under the Grant Agreement 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 overall business performance and market conditions.

Any capital raised by an equity offering will likely be dilutive to the existing stockholders and any licensing or development arrangement may require us to give up rights to a product or technology at less than its full potential value. We cannot provide any assurance that new financing will be available on commercially acceptable terms, if at all. We will continue to assess our capital resources, including our ability to obtain additional capital, to support our research and development programs, and as a result of such assessment, we 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, 2016, we had cash and cash equivalents of \$119.9 million, marketable securities of \$180.3 million, all of which are short-term, and working capital of \$278.2 million.

Our exposure to market risk is primarily confined to our investment portfolio. As of September 30, 2016, 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 \$3.2 million at September 30, 2016.

Our Notes have a fixed interest rate and we have no additional material debt. As such, we 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, 2016. 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, 2016, our chief executive officer and chief financial officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

### **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, 2016, and has concluded that there was no change that occurred during the quarterly period ended September 30, 2016 that materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.



## **PART II. OTHER INFORMATION**

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

There are no material changes to the Company's risk factors as described in Item 1A of the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2015, other than as described below.

*If we are unable to attract or retain key management or other personnel, our business, operating results and financial condition could be materially adversely affected.*

We depend on our senior executive officers, as well as key scientific and other personnel. The loss of these individuals could harm our business and significantly delay or prevent the achievement of research, development or business objectives. We may have turnover situations in key executive positions and the lack of management continuity and resulting lack of long-term history with our Company along with the learning curve that executives experience when they join our management team could result in operational and administrative inefficiencies and added costs. If we were to experience turnover at the executive level, these risks could be exacerbated.

We may not be able to attract qualified individuals for other key management or other personnel positions on terms acceptable to us. Competition for qualified employees is intense among pharmaceutical and biotechnology companies, and the loss of qualified employees, or an inability, given the announcement of our plans to reduce our workforce, to attract, retain and/or motivate additional highly skilled employees required for the continuation and/or expansion of our activities, could hinder our ability to complete clinical trials successfully and develop marketable products. The workforce reduction we announced in November 2016 may yield unintended consequences, such as attrition beyond our planned reduction in workforce and reduced employee morale, which may cause our remaining employees to seek alternative employment. Although we intend to implement a retention plan, our retention plan may not be successful in incentivizing our employees to continue their employment with us.

We also rely from time to time on outside advisors who assist us in formulating our research and development and clinical strategy. We may not be able to attract and retain these individuals on acceptable terms, which could have a material adverse effect on our business, financial condition and results of operations.

### **Item 5. Other Information**

Please see the disclosure under Part 1, Item 2 “Management’s Discussion and Analysis of Financial Condition and Results of Operations – Overview” of this Quarterly Report on Form 10-Q for the information required by Item 2.05 of Form 8-K regarding our November 9, 2016 announcement of our Restructuring Plan.

## 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)
- 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, 2016, formatted in Extensible Business Reporting Language (XBRL): (i) the Consolidated Balance Sheets as of September 30, 2016 and December 31, 2015, (ii) the Consolidated Statements of Operations for the three and nine-month periods ended September 30, 2016 and 2015, (iii) the Consolidated Statements of Comprehensive Loss for the three and nine-month periods ended September 30, 2016 and 2015, (iv) the Consolidated Statements of Cash Flows for the nine-month periods ended September 30, 2016 and 2015, and (v) the Notes to Consolidated Financial Statements.

\*Filed herewith.

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, 2016 By: /s/ Stanley C. Erck  
President and Chief Executive Officer  
and Director  
(Principal Executive Officer)

Date: November 9, 2016 By: /s/ Barclay A. Phillips  
Senior Vice President, Chief Financial Officer and Treasurer  
(Principal Financial and Accounting Officer)