

NOVAVAX INC  
Form 10-Q  
August 08, 2017

UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-Q

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

**For the quarterly period ended June 30, 2017**

OR

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

**For the transition period from to .**

**Commission File No. 0-26770**

**NOVAVAX, INC.**

(Exact name of registrant as specified in its charter)

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

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

**(240) 268-2000**

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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, smaller reporting company, or an emerging growth company. See the definitions of “large accelerated filer,” “accelerated filer,” “smaller reporting company,” and “emerging growth company” in Rule 12b-2 of the Exchange Act. (Check one):

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

If an emerging growth company, indicate by check mark if the registrant had elected not to use the extended transition period for complying with any new or revised financial accounting standards provide pursuant to Section 13(a) of the Exchange Act.

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 294,183,270 as of July 31, 2017.

NOVAVAX, INC.

**TABLE OF CONTENTS**

	<b>Page No.</b>
<b><u>PART I. FINANCIAL INFORMATION</u></b>	
Item 1. <u>Consolidated Financial Statements</u>	
<u>Consolidated Balance Sheets as of June 30, 2017 (unaudited) and December 31, 2016</u>	1
<u>Unaudited Consolidated Statements of Operations and Unaudited Consolidated Statements of Comprehensive Loss for the three and six months ended June 30, 2017 and 2016</u>	2
<u>Unaudited Consolidated Statements of Cash Flows for the six months ended June 30, 2017 and 2016</u>	3
<u>Notes to the Consolidated Financial Statements (unaudited)</u>	4
Item 2. <u>Management’s Discussion and Analysis of Financial Condition and Results of Operations</u>	18
Item 3. <u>Quantitative and Qualitative Disclosures about Market Risk</u>	34
Item 4. <u>Controls and Procedures</u>	34
<b><u>PART II. OTHER INFORMATION</u></b>	
Item 1A. <u>Risk Factors</u>	35
Item 5. <u>Other Information</u>	35
Item 6. <u>Exhibits</u>	35
<b><u>SIGNATURES</u></b>	37

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

(in thousands, except share and per share information)

	June 30, 2017 (unaudited)	December 31, 2016
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$75,793	\$ 144,353
Marketable securities	111,515	91,126
Restricted cash	30,188	30,314
Prepaid expenses and other current assets	19,187	22,037
Total current assets	236,683	287,830
Restricted cash	17,179	4,590
Property and equipment, net	38,531	40,184
Intangible assets, net	9,475	9,225
Goodwill	52,991	51,673
Other non-current assets	847	799
Total assets	\$355,706	\$ 394,301
<b>LIABILITIES AND STOCKHOLDERS' DEFICIT</b>		
Current liabilities:		
Accounts payable	\$8,021	\$ 5,685
Accrued expenses	22,305	24,508
Accrued interest	5,078	5,078
Deferred revenue	30,028	30,079
Other current liabilities	1,359	1,056
Total current liabilities	66,791	66,406
Deferred revenue	15,477	2,500
Convertible notes payable	317,051	316,339
Other non-current liabilities	15,449	14,602
Total liabilities	414,768	399,847
Commitments and contingencies	—	—
Stockholders' deficit:		

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Preferred stock, \$0.01 par value, 2,000,000 shares authorized; no shares issued and outstanding as of June 30, 2017 and December 31, 2016, respectively	—	—
Common stock, \$0.01 par value, 600,000,000 shares authorized at June 30, 2017 and December 31, 2016; 290,374,408 shares issued and 289,918,978 shares outstanding at June 30, 2017 and 271,701,397 shares issued and 271,245,967 shares outstanding at December 31, 2016	2,904	2,717
Additional paid-in capital	968,996	935,997
Accumulated deficit	(1,018,909)	(929,996 )
Treasury stock, 455,430 shares, cost basis at both June 30, 2017 and December 31, 2016	(2,450 )	(2,450 )
Accumulated other comprehensive loss	(9,603 )	(11,814 )
Total stockholders' deficit	(59,062 )	(5,546 )
Total liabilities and stockholders' deficit	\$355,706	\$ 394,301

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

NOVAVAX, INC.

## CONSOLIDATED STATEMENTS OF OPERATIONS

(in thousands, except per share information)

(unaudited)

	<b>For the Three Months</b>		<b>For the Six Months</b>	
	<b><u>Ended June 30,</u></b>		<b><u>Ended June 30,</u></b>	
	2017	2016	2017	2016
Revenue:				
Government contracts	\$	\$ 134	\$	\$2,080
Research and development collaborations	6,732	2,371	12,412	4,643
Total revenue	6,732	2,505	12,412	6,723
Expenses:				
Research and development	39,263	64,904	76,916	133,856
General and administrative	8,940	14,099	17,793	24,627
Total expenses	48,203	79,003	94,709	158,483
Loss from operations	(41,471 )	(76,498 )	(82,297 )	(151,760 )
Other income (expense):				
Investment income	523	670	997	1,147
Interest expense	(3,516 )	(3,512 )	(7,029 )	(5,946 )
Other income (expense)	(1 )	(11 )	10	(44 )
Net loss	\$(44,465 )	\$(79,351 )	\$(88,319 )	\$(156,603 )
Basic and diluted net loss per share	\$(0.16 )	\$(0.29 )	\$(0.32 )	\$(0.58 )
Basic and diluted weighted average number of common shares outstanding	283,444	270,760	278,836	270,469

## CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

(in thousands)

(unaudited)

	<b>For the Three</b>	<b>For the Six Months</b>
	<b>Months</b>	<b>Ended June 30,</b>
	<b><u>Ended June 30,</u></b>	<b><u>Ended June 30,</u></b>

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	2017	2016	2017	2016
Net loss	\$(44,465)	\$(79,351)	\$(88,319)	\$(156,603)
Other comprehensive income (loss):				
Net unrealized gains (losses) on marketable securities available-for-sale	(33 )	(25 )	(34 )	292
Foreign currency translation adjustment	1,765	(1,571 )	2,245	(312 )
Other comprehensive income (loss)	1,732	(1,596 )	2,211	(20 )
Comprehensive loss	\$(42,733)	\$(80,947)	\$(86,108)	\$(156,623)

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

NOVAVAX, INC.

## CONSOLIDATED STATEMENTS OF CASH FLOWS

(in thousands)

(unaudited)

	<b>For the Six Months Ended June 30,</b>	
	2017	2016
Operating Activities:		
Net loss	\$(88,319 )	\$(156,603)
Reconciliation of net loss to net cash used in operating activities:		
Depreciation and amortization	4,167	4,066
Loss on disposal of property and equipment	296	
Amortization of debt issuance costs	712	593
Lease incentives received	1,485	1,963
Non-cash stock-based compensation	8,726	10,218
Other	1,347	319
Changes in operating assets and liabilities:		
Restricted cash	(12,463 )	2,370
Prepaid expenses and other assets	1,869	1,064
Accounts payable and accrued expenses	(105 )	9,028
Deferred revenue	12,922	(3,331 )
Other liabilities		(1,550 )
Net cash used in operating activities	(69,363 )	(131,863)
Investing Activities:		
Capital expenditures	(2,318 )	(11,046 )
Proceeds from maturities of marketable securities	130,609	151,217
Purchases of marketable securities	(151,044)	(290,630)
Net cash used in investing activities	(22,753 )	(150,459)
Financing Activities:		
Principal payments on capital lease	(37 )	(37 )
Principal payments on notes payable		(246 )
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 )
Net proceeds from sales of common stock	22,735	
Proceeds from the exercise of stock options and employee stock purchases	797	2,374
Net cash provided by financing activities	23,495	278,604
Effect of exchange rate on cash and cash equivalents	61	5
Net decrease in cash and cash equivalents	(68,560 )	(3,713 )



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Cash and cash equivalents at beginning of period	144,353	93,108
Cash and cash equivalents at end of period	\$75,793	\$89,395
Supplemental disclosure of non-cash activities:		
Sale of common stock under the Sales Agreement not settled at quarter-end	\$334	\$—
Property and equipment purchases included in accounts payable and accrued expenses	\$686	\$2,712
Supplemental disclosure of cash flow information:		
Cash payments of interest	\$6,094	\$21

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

NOVAVAX, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

June 30, 2017

(unaudited)

Note 1 – Organization

Novavax, Inc. (“Novavax,” and together with its wholly owned subsidiary, “Novavax AB,” the “Company”) is a clinical-stage biotechnology company focused on the discovery, development and commercialization of recombinant nanoparticle vaccines and adjuvants. Using innovative proprietary recombinant nanoparticle vaccine 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 proteins 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 (“ZIKV”), influenza and a combination respiratory vaccine candidate, as well as other infectious 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 biotechnology 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 current grant agreement with the Bill & Melinda Gates Foundation (“BMGF”). 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. Based on its June 30, 2017 cash and cash equivalents and marketable securities balances of \$187.3 million, along with anticipated revenue under the Grant Agreement (see Note 10), the Company believes it has adequate capital to fund its operating plans for a minimum of twelve months from the date that this Quarterly Report was filed. The Company plans to meet its near term capital requirements primarily through cash and investments on hand, and a combination of equity and debt financings, collaborations, strategic alliances and marketing distribution or licensing arrangements and

in the longer term, from revenue related to product sales, to the extent its product candidates receive marketing approval and can be commercialized. There can be no assurances that new financings will be available to the Company on commercially acceptable terms, if at all. Also, any collaborations, strategic alliances and marketing distribution or licensing arrangements may require the Company to give up some or all rights to a product or technology at less than its full potential value. If the Company is unable to perform under the Grant Agreement or obtain additional capital, the Company will assess its capital resources and may be required to delay, reduce the scope of, or eliminate one or more of its product research and development programs, and/or downsize its organization, including its general and administrative infrastructure.

### 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 June 30, 2017, the consolidated statements of operations and the consolidated statements of comprehensive loss for the three and six months ended June 30, 2017 and 2016 and the consolidated statements of cash flows for the six months ended June 30, 2017 and 2016 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 unaudited consolidated financial statements are adequate to make the information presented not misleading, certain information and footnote information normally included in consolidated financial statements prepared in accordance with U.S. GAAP have been condensed or omitted as permitted under the rules and regulations of the United States Securities and Exchange Commission (“SEC”).

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

The accompanying unaudited consolidated financial statements are presented in U.S. dollars. The 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 unaudited consolidated balance sheets. The foreign currency translation adjustment balance included in accumulated other comprehensive loss was \$9.6 million and \$11.8 million at June 30, 2017 and December 31, 2016, 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, 2016. 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>June 30,</b>	<b>December 31,</b>
	<b>J017</b>	<b>J016</b>
Cash	\$17,266	\$ 17,481
Money market funds	41,527	95,896
Government-backed securities	17,000	19,000
Corporate debt securities	—	11,976
Cash and cash equivalents	\$75,793	\$ 144,353

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* (“ASC 820”), for financial and non-financial assets and liabilities.

ASC 820 discusses valuation techniques, such as the market approach (comparable market prices), the income approach (present value of future income or cash flow) and the cost approach (cost to replace the service capacity of an asset or replacement cost). The statement utilizes a fair value hierarchy that prioritizes the inputs to valuation techniques used to measure fair value into three broad levels. The following is a brief description of those three levels:

- Level 1: Observable inputs such as quoted prices (unadjusted) in active markets for identical assets or liabilities.
- Level 2: Inputs other than quoted prices that are observable for the asset or liability, either directly or indirectly. These include quoted prices for similar assets or liabilities in active markets and quoted prices for identical or similar assets or liabilities in markets that are not active.
- Level 3: Unobservable inputs that reflect the reporting entity’s own assumptions.

### Marketable Securities

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

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

The Company classifies its marketable securities with readily determinable fair values as “available-for-sale.” Investments in securities that are classified as available-for-sale are measured at fair market value in the consolidated balance sheets, and unrealized holding gains and losses on marketable securities are reported as a separate component of stockholders’ deficit until realized. Marketable securities are evaluated periodically to determine whether a decline in value is “other-than-temporary.” The term “other-than-temporary” is not intended to indicate a permanent decline in value. Rather, it means that the prospects for a near term recovery of value are not necessarily favorable, or that there is a lack of evidence to support fair values equal to, or greater than, the carrying value of the security. Management

reviews criteria, such as the magnitude and duration of the decline, as well as the Company's ability to hold the securities until market recovery, to predict whether the loss in value is other-than-temporary. If a decline in value is determined to be other-than-temporary, the value of the security is reduced and the impairment is recorded as other income (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 June 30, 2017 and December 31, 2016, the restricted cash balances (both current and non-current) consist of payments received under the Grant Agreement of \$45.7 million and \$33.2 million, respectively, and security deposits of \$1.7 million at both dates.

## 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 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 efforts to obtain World Health Organization ("WHO") prequalification of its 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.

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 audit by the government. An audit of indirect rates of fiscal years 2013 and 2014 was completed in the first quarter of 2017. When the final determination of the additional reimbursable costs for fiscal years 2013 and 2014 has been made, and such amount is known and collection of the amount is reasonably assured, revenue and billings will be adjusted accordingly.

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.

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 milestones 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 June 30, 2017 and 2016, the Company had outstanding stock options and unvested restricted stock awards totaling 37,361,469 and 32,819,830, respectively. At June 30, 2017, the Company's Notes (see Note 7) are 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 March 2016, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2016-09, *Compensation - Stock Compensation (Topic 718)* 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 adopted this standard on the effective date, January 1, 2017, and, as part of the adoption, elected to account for forfeitures when they occur. The adoption did not have a material impact on its consolidated financial statements and related disclosures.

#### **Not Yet Adopted**

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 has completed an initial assessment of the potential changes from adopting ASU 2014-09, primarily by reviewing its current revenue streams and deferred revenue balances. Based on the Company’s initial assessment, it does not expect any material changes to the recognition of its revenue. The Company has not yet completed its final review of the impact of this guidance, and will continue to evaluate the impacts of adoption over the coming quarters. The Company currently expects to apply ASU 2014-09 on a modified retrospective basis as of January 1, 2018. The Company will continue to monitor additional changes, modifications, clarifications or interpretations being undertaken by the FASB, which may impact its current evaluation.

In February 2016, the FASB issued ASU 2016-02, *Leases (Topic 842)* 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 November 2016, the FASB issued ASU 2016-18, *Statement of Cash Flows - Restricted Cash* (“ASU 2016-18”), which requires that the change in total cash and cash equivalents at the beginning of period and end of period on the statement of cash flows include restricted cash and restricted cash equivalents. ASU 2016-18 also requires companies who report cash and cash equivalents and restricted cash separately on the balance sheet to reconcile those amounts to the statement of cash flows. The standard will be effective January 1, 2018 for the Company, with early adoption permitted, and should be applied using a retrospective transition method to each period presented. The Company currently expects to adopt ASU 2016-18 as of January 1, 2018. Although the Company’s cash and cash equivalents balance on the cash flow statement will increase for the restricted cash balance on its balance sheets, the adoption is not expected to have a material impact on the other aspects of the Company’s cash flow statements, or its consolidated financial statements as a whole, including related disclosures.

In January 2017, the FASB issued ASU No. 2017-04, *Intangibles-Goodwill and Other (Topic 350)* (“ASU 2017-04”), which will simplify the goodwill impairment calculation, by eliminating Step 2 from the current goodwill impairment test. The new standard does not change how a goodwill impairment is identified. The Company will continue to perform its quantitative goodwill impairment test by comparing the fair value of its reporting unit to its carrying amount, but if the Company is required to recognize a goodwill impairment charge, under the new standard, the amount of the charge will be calculated by subtracting the reporting unit’s fair value from its carrying amount. Under the current standard, if the Company is required to recognize a goodwill impairment charge, Step 2 requires it to calculate the implied value of goodwill by assigning the fair value of a reporting unit to all of its assets and liabilities as if that reporting unit had been acquired in a business combination and the amount of the charge is calculated by subtracting the reporting unit’s implied fair value of goodwill from the goodwill carrying amount. The standard will be effective January 1, 2020 for the Company, with early adoption permitted, and should be applied prospectively from the date of adoption. The Company is currently evaluating when it will adopt ASU 2017-04 and its expected impact to related disclosures.

#### **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):

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	Fair Value at June 30, 2017			Fair Value at December 31, 2016		
	Level 1	Level 2	Level 3	Level 1	Level 2	Level 3
Assets						
Money market funds(1)	\$41,527	\$	\$	\$95,896	\$	\$
Government-backed securities(1)		17,000			19,000	
Asset-backed securities		33,860			23,632	
Corporate debt securities(2)		77,655			79,470	
Total assets	\$41,527	\$128,515	\$	\$95,896	\$122,102	\$
Liabilities						
Convertible notes payable	\$	\$139,880	\$	\$	\$141,989	\$

(1)Classified as cash and cash equivalents as of June 30, 2017 and December 31, 2016, respectively (see Note 3).

(2)Includes \$11,976 classified as cash and cash equivalents as of December 31, 2016 (see Note 3).

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 three months ended June 30, 2017, the Company did not have any transfers between levels.

The amount in the Company's unaudited consolidated balance sheets for accounts payable approximates its fair value due to its short-term nature. The Company's milestone payment due to Wyeth (see Note 11) approximates its fair value at June 30, 2017.

## Note 5 – Marketable Securities

Marketable securities classified as available-for-sale as of June 30, 2017 and December 31, 2016 were comprised of (in thousands):

	June 30, 2017				December 31, 2016			
	<b>Amortized Cost</b>	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value	<b>Amortized Cost</b>	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Asset-backed securities	\$33,872	\$ —	\$ (12 )	\$33,860	\$23,636	\$ —	\$ (4 )	\$23,632
Corporate debt securities	77,643	22	(10 )	77,655	67,457	43	(6 )	67,494
Total	\$111,515	\$ 22	\$ (22 )	\$111,515	\$91,093	\$ 43	\$ (10 )	\$91,126

### Marketable Securities – Unrealized Losses

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

The Company owned 36 available-for-sale securities as of June 30, 2017. Of these 36 securities, 21 had combined unrealized losses of less than \$0.1 million as of June 30, 2017. The Company did not have any investments in a loss position for greater than 12 months as of June 30, 2017. The Company has evaluated its marketable securities and has determined that none of these investments has an other-than-temporary impairment, as it has no intent to sell securities with unrealized losses and it is not more likely than not that the Company will be required to sell any securities with unrealized losses, given the Company's current and anticipated financial position.

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

*Goodwill*

The change in the carrying amounts of goodwill for the six months ended June 30, 2017 was as follows (in thousands):

	<b>Amount</b>
Balance at December 31, 2016	\$51,673
Currency translation adjustments	1,318
Balance at June 30, 2017	\$52,991

**Identifiable Intangible Assets**

Purchased intangible assets consisted of the following as of June 30, 2017 and December 31, 2016 (in thousands):

	June 30, 2017			December 31, 2016		
	Gross Carrying Amount	Accumulated Amortization	Intangible Assets, Net	Gross Carrying Amount	Accumulated Amortization	Intangible Assets, Net
Finite-lived intangible assets:						
Proprietary adjuvant technology	\$8,824	\$ (1,727)	) \$ 7,097	\$8,222	\$ (1,404)	) \$ 6,818
Collaboration agreements	3,984	(1,606)	) 2,378	3,713	(1,306)	) 2,407
Total identifiable intangible assets	\$12,808	\$ (3,333)	) \$ 9,475	\$11,935	\$ (2,710)	) \$ 9,225

Amortization expense for the six months ended June 30, 2017 and 2016 was \$0.4 million.

Estimated amortization expense for existing intangible assets for the remainder of 2017 and for each of the five succeeding years ending December 31 will be as follows (in thousands):

Year	Amount
2017 (remainder)	\$ 426
2018	851
2019	851
2020	727
2021	578
2022	553

**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 common 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* (“ASC 470-20”) and ASC 815-40, *Contracts in Entity’s Own Equity* (“ASC 815-40”). 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, *Derivatives and Hedging - Overall* 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 seven 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):

	June 30, 2017	December 31, 2016
Principal amount of Notes	\$325,000	\$325,000
Unamortized debt issuance costs	(7,949 )	(8,661 )
Total convertible notes payable	\$317,051	\$316,339

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

	<b>Three Months Ended</b>		<b>Six Months Ended</b>	
	<b>June 30, 2017</b>	<b>2016</b>	<b>June 30, 2017</b>	<b>2016</b>

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Coupon interest	\$3,047	\$3,047	\$6,094	\$5,146
Amortization of debt issuance costs	356	356	712	593
Total interest expense on Notes	\$3,403	\$3,403	\$6,806	\$5,739

12

## **Note 8 – Stockholders’ Deficit**

In December 2016, the Company filed a \$200 million universal shelf registration statement that allows the Company to issue and sell common stock, preferred stock, warrants and/or units in one or more offerings up to an aggregate maximum offering amount of \$125 million and up to \$75 million in gross proceeds of its common stock pursuant to an At Market Issuance Sales Agreement (“Sales Agreement”), which the Company entered into in January 2017.

During the six months ended June 30, 2017, the Company sold 18.0 million shares of common stock between February 28, 2017 and June 27, 2017 (the “Trading Period”) resulting in \$22.7 million in net proceeds (this amount excludes \$0.3 million received in the third quarter of 2017 for shares traded in late June 2017). The weighted average sales price achieved during the Trading Period was \$1.31 per share. From July 1, 2017 through August 4, 2017, the Company sold an additional 3.9 million shares of common stock resulting in \$5.7 million in net proceeds. Through August 4, 2017, the Company sold aggregate gross proceeds of \$29.4 million of common stock of the \$75 million total amount available under the Sales Agreement.

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.

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

### ***Stock Options***

The 2015 Stock Incentive Plan (“2015 Plan”) was approved at the Company’s annual meeting of stockholders in June 2015. Under the 2015 Plan, equity awards may be granted to officers, directors, employees and consultants of and advisors to the Company and any present or future subsidiary.

The 2015 Plan authorizes the issuance of up to 36,000,000 shares of common stock under equity awards granted under the plan, including an increase of 5,000,000 shares approved at the Company’s 2017 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 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.

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 six months ended June 30, 2017:

	<b>2015 Plan</b>		<b>2005 Plan</b>	
	<b>Stock Options</b>	<b>Weighted-Average Exercise Price</b>	<b>Stock Options</b>	<b>Weighted-Average Exercise Price</b>
Outstanding at January 1, 2017	25,104,603	\$ 4.87	14,128,129	\$ 3.30
Granted	1,138,350	\$ 1.34	—	\$ —
Exercised	—	\$ —	(100,000 )	\$ 1.24
Canceled	(2,015,288 )	\$ 4.91	(913,075 )	\$ 3.73
Outstanding at June 30, 2017	24,227,665	\$ 4.70	13,115,054	\$ 3.28
Shares exercisable at June 30, 2017	6,177,198	\$ 7.16	11,687,679	\$ 3.02
Shares available for grant at June 30, 2017	11,727,335			

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:

	<b>Three Months Ended</b>		<b>Six Months Ended</b>	
	<b>June 30, 2017</b>	<b>2016</b>	<b>June 30, 2017</b>	<b>2016</b>
Weighted-average Black-Scholes fair value of stock options granted	\$0.81	\$2.99	\$1.03	\$2.47
Risk-free interest rate	1.63%-1.71%	1.07%-1.09%	1.63%-2.34%	1.07%-1.70%
Dividend yield	0%	0%	0%	0%
Volatility	106.92-111.46%	58.10%-58.97%	88.91%-111.46%	57.86%-68.28%
Expected term (in years)	4.18-4.60	4.24-4.26	4.18-7.46	4.24-7.28
Expected forfeiture rate	0%	10.31%	0%	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 June 30, 2017 was less than \$0.1 million and 7.5 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 June 30, 2017 was less than \$0.1 million and 6.1 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 June 30, 2017. 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 three months ended June 30, 2017 and 2016 was less than \$0.1 million and \$2.1 million, respectively.

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

In 2013, the Company adopted an Employee Stock Purchase Plan (the "ESPP"), which currently authorizes an aggregate of 3,450,000 shares of common stock to be purchased, and the aggregate amount of shares 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 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 June 30, 2017, there were 1,185,869 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>Six Months Ended</b>	
	<b>June 30,</b> 2017	2016	<b>June 30,</b> 2017	2016
Range of Black-Scholes fair value of ESPP shares granted	\$1.05-\$5.47	\$1.97-\$3.88	\$1.05-\$5.47	\$1.86-\$3.88
Risk-free interest rate	0.57%-0.70%	0.32%-0.47%	0.45%-0.70%	0.22%-0.47%
Dividend yield	0%	0%	0%	0%
Volatility	54.67%-267.85%	43.03%-86.75%	45.98%-267.85%	43.03%-86.75%
Expected term (in years)	0.5-2.0	0.5-2.0	0.5-2.0	0.5-2.0
Expected forfeiture rate	0%	5%	0%	5%

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

The following is a summary of restricted stock awards activity for the six months ended June 30, 2017:

	<b>Number of  Shares</b>	<b>Per Share</b>
		<b>Weighted-Average Grant-Date  Fair Value</b>
Outstanding and Unvested at January 1, 2017	45,000	\$ 4.99
Restricted stock granted		\$
Restricted stock vested	(26,250)	\$ 4.99
Restricted stock forfeited		\$
Outstanding and Unvested at June 30, 2017	18,750	\$ 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>Six Months Ended</b>
<b>June 30,</b>	<b>June 30,</b>



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	2017	2016	2017	2016
Research and development	\$2,534	\$2,952	\$4,748	\$6,185
General and administrative	1,980	2,305	3,978	4,033
Total stock-based compensation expense	\$4,514	\$5,257	\$8,726	\$10,218

As of June 30, 2017, there was approximately \$34 million of total unrecognized compensation expense 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 1.5 years, and will be allocated between research and development and general and administrative expenses accordingly. This estimate does not include the impact of other possible stock-based awards that may be made during future periods.

Note 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 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 supports development activities, including the Company’s global Phase 3 clinical trial in pregnant women in their third trimester, product licensing efforts, and efforts to obtain World Health Organization (“WHO”) prequalification of its RSV F Vaccine. Unless terminated earlier by BMGF, the Grant Agreement will continue in effect until the end of 2021. 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 terminated earlier 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 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 six months ended June 30, 2017, the Company recognized revenue from the Grant of \$6.7 million and \$12.2 million, respectively, and has recognized approximately \$25 million in revenue since the inception of the agreement. At June 30, 2017, 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 awarded the Company a contract in 2011, which 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. The HHS BARDA contract expired in accordance with its terms in September 2016. Billings under the contract were provisional billings, subject to adjustment upon audit by the government, and were 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 indirect rates of fiscal years 2013 and 2014 was completed in the first quarter of 2017. When the final determination of the additional reimbursable costs for fiscal years 2013 and 2014 has been made, and such amount is known and collection of the amount is reasonably assured, revenue and billings will be adjusted accordingly. The Company recognized approximately \$114 million in revenue under the HHS BARDA contract since the inception of the contract.

### *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 the Company has provided 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. The Company has recognized as an expense the entire amount of purchases to date under the master services agreements related to CPLB as the Company has not recorded any equity income (loss) of CPLB (see Note 12).

### **Note 11 – License agreement with Wyeth Holding LLC**

In 2007, the Company entered into an agreement to license certain rights from 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. The Company’s former seasonal and pandemic influenza VLP vaccine programs 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, which has increased 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 June 30, 2017 aggregated to \$7.6 million. The Milestone has been accrued for, on a discounted basis calculated based on the probable future payment date, and at June 30, 2017, the Milestone is recorded in accrued expenses. The Milestone was recorded as a research and development expense in 2014.

### **Note 12 – 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 June 30, 2017. The Company and Cadila have also entered into master services agreements, pursuant to which Cadila or CPLB may perform certain research, development and manufacturing services for the Company. For the six months ended June 30, 2017 and 2016, the Company incurred \$0.1 million and \$0.3 million, respectively, in expenses under the master services agreements. The amount due and unpaid for services performed under the master services agreements at June 30, 2017 and December 31, 2016 was less than \$0.1 million and \$0.1 million, respectively.



## **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 and capital raising activities; 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, 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 restructuring efforts, and other matters 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,” “in project,” “expect,” “should,” “would,” or “assume” or the negative of these terms, or other comparable terminology, although not all forward-looking statements contain these words.

Forward-looking statements involve estimates, assumptions and uncertainties that could cause actual results to differ materially from those expressed or implied in the statements. 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, 2016, 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 that could cause results to differ 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.

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 biotechnology company focused on the discovery, development and commercialization of recombinant nanoparticle vaccines and adjuvants. Using innovative proprietary recombinant nanoparticle vaccine technology, we produce vaccine candidates to efficiently and effectively respond to both known and 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 (“ZIKV”), influenza and a combination respiratory vaccine candidate, as well as other infectious disease vaccine candidates.

We are also developing immune stimulating saponin-based adjuvants through our wholly owned Swedish subsidiary, Novavax AB. Our lead adjuvant, Matrix-M™, has been shown to enhance immune responses and was well-tolerated in multiple clinical trials that we have conducted. In addition, Genocea Biosciences, Inc. has licensed rights to our Matrix technology and has conducted Phase 2 clinical trials with its herpes simplex 2 vaccine candidate using Matrix-M.

## Product Pipeline

Our product pipeline includes vaccine candidates engineered to elicit differentiated immune responses with the potential to provide increased protection. Our nanoparticle technology 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>Current Development Stage</b>
<b>Respiratory Syncytial Virus (“RSV”)</b>	
·Infants via Maternal Immunization	Phase 3*
·Older Adults	Phase 2
·Pediatrics	Phase 1
<b>Emerging Viruses</b>	
·Ebola Virus (“EBOV”)	Phase 1
·Zika Virus (“ZIKV”)	Preclinical



**Nanoparticle Influenza (“NanoFlu”)** Preclinical

**Combination Respiratory** Preclinical

\*Supported by the \$89.1 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**

We have identified three susceptible target populations that could benefit from the development of our respiratory syncytial virus fusion (F) protein nanoparticle vaccine candidate (“RSV F Vaccine”) in potentially different formulations: 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 to be in excess of \$88 billion.<sup>1</sup> Despite decades of effort to develop an RSV vaccine, there are currently no licensed vaccines. Although the monoclonal antibody palivizumab (Synagis®) is indicated for the prevention of serious lower respiratory tract disease caused by RSV in children at high risk of RSV disease, 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 highly conserved amino acid sequences, called antigenic sites, which we believe are ideal vaccine targets. Palivizumab, which targets one such site, antigenic site II, has demonstrated protection in five randomized clinical trials. We genetically engineered a novel F-protein antigen resulting in enhanced immunogenicity by exposing these antigenic sites. The Novavax RSV F Vaccine assembles into a recombinant protein nanoparticle optimized for F-protein antigen presentation. We are seeking to bring the first RSV vaccine to market to combat the 64 million RSV infections that occur globally each year.<sup>2,3</sup>

### ***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>4,5</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>6,7</sup> Despite the induction of post-infection immunity, repeat infection and lifelong susceptibility to RSV is common.<sup>8,9</sup>

#### *Clinical Trial Update*

##### *Prepare Phase 3 Trial (Ongoing)*

We initiated Prepare™, a global pivotal Phase 3 clinical trial of our 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 (“LRTI”) with objective measures of medical significance in infants through a minimum of the first 90 days of life.

The Prepare trial utilizes a group sequential design and is expected to take between three and four years for enrollment to complete. After discussion with the U.S. Food and Drug Administration, Center for Biologics Evaluation and

Research (“FDA”), we now have an opportunity to conduct an informational analysis of the Prepare trial that would provide an indication of our vaccine’s potential efficacy against the primary endpoint. While the results of this informational analysis will not be public information, it would allow us to make decisions relating to future program-related activities and investments.

The Prepare trial is supported by a grant (the “Grant”) of up to \$89.1 million from BMGF. The Grant supports development activities, product licensing efforts and World Health Organization (“WHO”) prequalification of our RSV F Vaccine. In 2015, along with the Grant agreement (the “Grant Agreement”), we concurrently entered into a Global Access Commitments Agreement with BMGF, under which we agreed to make the RSV F Vaccine available and accessible at affordable pricing to people in certain low and middle income countries.

<sup>1</sup> Estimated value of life lost, future health implications and lost earnings; Preliminary data based on Novavax research of available epidemiology and health outcomes data

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

<sup>3</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)

<sup>4</sup> Nair, H., *et al.*, (2010) *Lancet*. 375:1545 - 1555

<sup>5</sup> CDC: <https://www.cdc.gov/rsv/research/us-surveillance.html>

<sup>6</sup> Hall, C.B. *et al.* (2013) *Pediatrics*; 132(2):E341-348

<sup>7</sup> Oxford Vaccine Group: <http://www.ovg.ox.ac.uk/rsv>

<sup>8</sup> Glezen, W.P. *et al.* (1986) *Am J Dis Child*; 140:543-546

<sup>9</sup> Glenn, G.M. *et al.* (2016) *JID*; 213(3):411-12

*Phase 2 Safety and Immunogenicity Trial (Completed)*

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.

*Fast Track Designation*

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.

*RSV Older Adults Program*

*Burden of Disease*

Adults 60 years of age and older are at increased risk for RSV disease due to immunosenescence, the age-related decline in the human immune system. In this population, RSV is an important respiratory virus, distinct from influenza, which is frequently 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>10,11</sup> Based on our analysis of published literature applied to 2014 U.S. population estimates, the disease causes 207,000 hospitalizations and 16,000 deaths among adults older than 65.<sup>12,13</sup> Annually, we estimate that there are approximately 900,000 medical interventions directly caused by RSV disease

across all populations.<sup>14,15</sup>

<sup>10</sup> Falsey, A.R. *et al.* (2005) NEJM. 352:1749–59 extrapolated to 2015 census population

<sup>11</sup> Falsey, A.R. *et al.* (1995) JID.172:389-94

<sup>12</sup> Falsey, A.R. *et al.* (2005) NEJM. 352:1749–59 extrapolated to 2015 census population

<sup>13</sup> W.W. Thompson et al. Mortality associated with influenza and respiratory syncytial virus in the United States. JAMA 2003; 289(2): 179-186

<sup>14</sup> K. Widmer *et al.* Rates of hospitalizations for respiratory syncytial virus, human metapneumovirus, and influenza virus in older adults. J Infect Dis. 2012; 206: 56-62

<sup>15</sup> K. Widmer *et al.* Respiratory syncytial virus & human metapneumovirus-associated emergency department and hospital burden in adults. Influenza and Other Respiratory Viruses. 2014; 8(3): 347-352.

*Clinical Trial Updates and Analyses**Phase 2 (E-205) Safety and Immunogenicity Clinical Trial (Completed)*

In July 2017, we announced positive top-line data from the Phase 2 clinical trial of our RSV F Vaccine in older adults known as E-205. The objective of the E-205 trial was to assess safety and immunogenicity to one and two dose regimens of the RSV F Vaccine, with and without aluminum phosphate or our proprietary Matrix-M adjuvant, in older adults. The trial was a randomized, observer-blinded, placebo-controlled trial which enrolled 300 older adults in the Southern Hemisphere. Participants were enrolled and vaccinated outside of the RSV season to best assess immunogenicity. Immunogenicity results indicate both aluminum phosphate and Matrix-M adjuvants significantly increased the magnitude, duration and quality of the immune response relative to RSV F antigen alone. All formulations and regimens were safe and well-tolerated. The data support the inclusion of adjuvanted formulations of our RSV F Vaccine in future older adult trials; those specific trial designs are currently being assessed.

*Further Analyses of Prior Clinical Trials*

Following the September 2016 announcement of the top-line results of Resolve™, our Phase 3 clinical trial of our RSV F Vaccine in older adults conducted during the 2015-16 RSV season in the U.S., we have conducted multiple analyses on the clinical data from the Resolve trial, the two other completed Phase 2 clinical trials conducted in older adults, and top-line data from the most recent Phase 2 trial conducted in 2017. Our analyses of these clinical trials sought to better understand their results. More detailed descriptions of each of these RSV older adult clinical trials are found in this “Clinical Trial Updates and Analyses” below; the trials are named and briefly described in the following table:

<b>Clinical Trial Name</b>	<b>Phase</b>	<b>Description</b>	<b>Conducted</b>	<b>Participants(#)</b>
E-201	Phase 2	Efficacy in prevention of all symptomatic RSV disease	2014-15 RSV season	1,600
Resolve (or E-301)	Phase 3	Efficacy in prevention of msLRTD	2015-16 RSV season	11,856
E-202 Rollover	Phase 2	Immunogenicity in response to serial immunization after E-201	2015-16 RSV season	1,329
E-205	Phase 2	Immunogenicity in one or two dose, with or without adjuvant	2017	300

We have found that seasonal variation in attack rate, due to varying susceptibility in the older adult population, may have a large impact on demonstrating vaccine efficacy in a particular year. In our E-201 trial, we witnessed a high

attack rate and showed a clear demonstration of efficacy. In our Resolve trial the following year, we observed an attack rate of only one-fourth that of the previous season. This scenario is a conundrum that influenza vaccine developers have experienced for decades: “low attack rate” influenza seasons make it very difficult to demonstrate vaccine efficacy.

Additional further analyses of the Resolve trial data indicate that our RSV F Vaccine was associated with a 61% reduction in hospitalizations due to chronic obstructive pulmonary disease (“COPD”) exacerbations, and the same analysis of the E-201 trial showed a similar signal, supporting this finding. COPD exacerbations represent an unmet medical need and a significant healthcare cost burden. We plan to initiate a Phase 2 efficacy trial in older adults in 2018 that will evaluate COPD exacerbations as a prospective endpoint. We believe such a clinical pathway could lead to a pivotal study in a more susceptible, higher-risk population that could demonstrate vaccine efficacy regardless of RSV acute respiratory disease (“RSV ARD”) attack rates in older adults.

*Resolve (E-301) Phase 3 Trial (Completed)*

In September 2016, we announced top-line data from the Phase 3 clinical trial of our RSV F Vaccine in older adults, known as Resolve. Resolve was a randomized, observer-blinded, placebo-controlled trial that began in November 2015, and was fully enrolled with 11,856 older adults at 60 sites in the U.S. by December 2015. 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 (“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 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.

*Phase 2 (E-202) Rollover Trial (Completed)*

In September 2016, we announced positive top-line data from the E-202 Rollover trial of our RSV F Vaccine in older adults. The trial was a randomized, observer-blinded, placebo-controlled rollover trial, which enrolled 1,329 older adults from our prior E-201 trial, conducted at the same 10 sites in the U.S. as the E-201 trial. 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”).

The E-202 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 E-201 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.

*Phase 2 (E-201) Trial in Older Adults (Completed)*



In August 2015, we announced positive top-line data from the E-201 trial of our RSV F Vaccine in 1,600 older adults. The E-201 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.

## ***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>16</sup> By the age of five, essentially all children will have been exposed to RSV and will likely have developed natural immunity against the virus, thus decreasing the rate of severe disease in these children. 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>17,18,19,20,21</sup>

### ***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, 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>22</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 top-line 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. 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.

<sup>16</sup> U.S. Census. [www.census.gov/population/international/data/idb/informationGateway.php](http://www.census.gov/population/international/data/idb/informationGateway.php)

<sup>17</sup> Stockman, L.J. *et al* (2012) *Pediatr Infect Dis J*. 31: 5-9

<sup>18</sup> CDC update May 5, 2015. <http://www.cdc.gov/rsv/research/us-surveillance.html>

<sup>19</sup> Boyce, T.G. *et al* (2000) *Pediatrics*; 137: 865-870

<sup>20</sup> Hall, C.B. *et al* (2009) *NEJM*; 360(6): 588-98

<sup>21</sup> Hall, C.B. *et al* (2013) *Pediatrics*; 132(2): E341-8

<sup>22</sup> WHO: <http://www.who.int/mediacentre/factsheets/fs103/en/>

### ***ZIKV EnvD Vaccine***

We initiated development of a vaccine against the Zika virus (“ZIKV”) in response to the unmet global medical need for a response to this serious disease. Beginning in 2015, ZIKV spread in South, Central and North America via 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. Our ZIKV vaccine candidate is based on highly purified ZIKV envelope protein dimers (“EnvD”) stabilized with a proprietary formulation; in early animal studies, it appears to induce neutralizing antibody responses against multiple strains of ZIKV and other flaviviruses. We are currently conducting IND-enabling preclinical studies, including studies in non-human primates and other animal models, with the goal of initiating a Phase 1 clinical trial of our ZIKV envelope dimer nanoparticle vaccine candidate (“ZIKV EnvD Vaccine”) in 2017.

### **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 largely because of infection by 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>23</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>24</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>25</sup> Recombinant seasonal influenza vaccines, like the candidate we are developing, have an important advantage: once licensed for commercial sale, large quantities of such vaccine 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 virus-like particle (“VLP”)-based seasonal influenza vaccine candidates, we have identified advantages of developing nanoparticle-based seasonal influenza vaccines. 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.

In August 2017, we announced preclinical data from a ferret study in which our seasonal nanoparticle influenza vaccine (“NanoFlu”) was compared in a head-to-head challenge study against Sanofi’s high dose seasonal influenza vaccine, currently the leading licensed influenza vaccine for the older adult market, as well as Sanofi’s regular dose seasonal influenza vaccine. Our NanoFlu demonstrated significantly stronger and broader immune responses against homologous and heterologous influenza strains, including a series of “drift” strains evolved across over more than a decade of influenza seasons. In a preclinical challenge study, we showed that our NanoFlu was protective against both a homologous virus and a ten-year old drifted strain. In parallel, we announced the achievement of significant improvements in manufacturing yields and product purity. We expect to continue to develop our NanoFlu with the goal of initiating a Phase 1/2 clinical trial in the second half of 2017.

<sup>23</sup> Influenza Vaccines Forecasts. Datamonitor (2013)

<sup>24</sup> Resolution of the World Health Assembly. (2003) WHA56.19. 28

<sup>25</sup> WHO position paper (2012) Weekly Epidemiol Record;87(47):461–76

### **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 a combination nanoparticle vaccine against both RSV and influenza 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 vaccines (both trivalent and monovalent formulations) and is currently manufacturing with limited expected sales in 2017.

### ***Rabies***

In October 2016, CPLB initiated its Phase 3 clinical trial in India of a rabies G protein vaccine candidate that we genetically engineered that can be administered in prophylactic regimens, both pre and post-exposure. The post-exposure regimen has the potential to use fewer doses (three doses) than the current standard of care (five doses).

### **Sales of Common Stock**

In January 2017, we entered into an At Market Issuance Sales Agreement (“Sales Agreement”), which allows us to issue and sell up to \$75 million in gross proceeds of our common stock. During the six months ended June 30, 2017, we sold 18.0 million shares of common stock between February 28, 2017 and June 27, 2017 (the “Trading Period”) resulting in \$22.7 million in net proceeds (this amount excludes \$0.3 million received in the third quarter of 2017 for shares traded in late June 2017). The weighted average sales price achieved during the Trading Period was \$1.31 per share. From July 1, 2017 through August 4, 2017, we sold an additional 3.9 million shares of common stock resulting in \$5.7 million in net proceeds. Through August 4, 2017, we sold aggregate gross proceeds of \$29.4 million of common stock of the \$75 million total amount available under the Sales Agreement.

***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, 2016, as filed with the SEC.

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

In May 2014, the Financial Accounting Standards Board (“FASB”) issued Accounting Standards Update (“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 have completed an initial assessment of the potential changes from adopting ASU 2014-09, primarily by reviewing our current revenue streams and deferred revenue balances. Based on our initial assessment, we do not expect any material changes to the recognition of our revenue. We have not yet completed our final review of the impact of this guidance, and in 2017, we will continue to evaluate the impacts of adoption over the coming quarters. We currently expect to apply ASU 2014-09 on a modified retrospective basis as of January 1, 2018. We will continue to monitor additional changes, modifications, clarifications or interpretations being undertaken by the FASB, which may impact our current evaluation.

In February 2016, the FASB issued ASU 2016-02, *Leases (Topic 842)* 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 November 2016, the FASB issued ASU 2016-18, *Statement of Cash Flows - Restricted Cash* (“ASU 2016-18”), which requires that the change in total cash and cash equivalents at the beginning of period and end of period on the statement of cash flows include restricted cash and restricted cash equivalents. ASU 2016-18 also requires companies who report cash and cash equivalents and restricted cash separately on the balance sheet to reconcile those amounts to the statement of cash flows. The standard will be effective January 1, 2018 for us, with early adoption permitted, and should be applied using a retrospective transition method to each period presented. We currently expect to adopt ASU 2016-18 as of January 1, 2018. Although our cash and cash equivalents balance on the cash flow statement will increase for the restricted cash balance on our balance sheets, the adoption is not expected to have a material impact on the other aspects of our cash flow statements, or our consolidated financial statements as a whole, including related disclosures.



In January 2017, the FASB issued ASU No. 2017-04, *Intangibles-Goodwill and Other (Topic 350)* (“ASU 2017-04”), which will simplify the goodwill impairment calculation, by eliminating Step 2 from the current goodwill impairment test. The new standard does not change how a goodwill impairment is identified. We will continue to perform our quantitative goodwill impairment test by comparing the fair value of our reporting unit to its carrying amount, but if we are required to recognize a goodwill impairment charge, under the new standard, the amount of the charge will be calculated by subtracting the reporting unit’s fair value from its carrying amount. Under the current standard, if we are required to recognize a goodwill impairment charge, Step 2 requires us to calculate the implied value of goodwill by assigning the fair value of a reporting unit to all of its assets and liabilities as if that reporting unit had been acquired in a business combination and the amount of the charge is calculated by subtracting the reporting unit’s implied fair value of goodwill from the goodwill carrying amount. The standard will be effective January 1, 2020 for us, with early adoption permitted, and should be applied prospectively from the date of adoption. We are currently evaluating when we will adopt ASU 2017-04 and its expected impact to related disclosures.

## **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 June 30, 2017 and 2016** (amounts in tables are presented in thousands, except per share information)

**Revenue:**

<b>Three Months Ended</b>			<b>Change</b>
<b><u>June 30,</u></b>			
2017	2016		<b><u>2016 to</u></b>
			<b><u>2017</u></b>
Revenue:			
Total revenue	\$6,732	\$2,505	\$ 4,227

Revenue for the three months ended June 30, 2017 was \$6.7 million as compared to \$2.5 million for the same period in 2016, an increase of \$4.2 million or 169%. Revenue for the three months ended June 30, 2017 and 2016 is primarily comprised of services performed under the Grant Agreement. Revenue increased under the Grant Agreement as a result of increased enrollment of participants in Prepare.

We expect revenue in 2017 under the Grant Agreement to be significantly higher than in 2016 as we increase enrollment of participants in Prepare.

**Expenses:**

<b>Three Months Ended</b>			<b>Change</b>
<b><u>June 30,</u></b>			
2017	2016		<b><u>2016 to</u></b>
			<b><u>2017</u></b>
Expenses:			
Research and development	\$39,263	\$64,904	\$(25,641)
General and administrative	8,940	14,099	(5,159 )
Total expenses	\$48,203	\$79,003	\$(30,800)

***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 decreased to \$39.3 million for the three months ended June 30, 2017 from \$64.9 million for the same period in 2016, a decrease of \$25.6 million, or 40%. The decrease in research and development expenses was primarily due to lower costs associated with the clinical trials and development activities of our RSV F Vaccine and lower employee-related costs. At June 30, 2017, we had 294 employees dedicated to our research and development programs versus 445 employees as of June 30, 2016. For 2017, we expect a significant decrease in research and development expenses from 2016 primarily due to lower anticipated RSV F Vaccine candidate clinical trials and employee-related costs to support product development of our RSV F Vaccine candidate and other potential vaccine candidates.

### *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. 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 June 30 (in millions).

	2017	2016
Manufacturing	\$20.3	\$32.0
Vaccine Discovery	1.4	1.8
Clinical and Regulatory	17.6	31.1
Total research and development expenses	\$39.3	\$64.9

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 decreased to \$8.9 million for the three months ended June 30, 2017 from \$14.1 million for the same period in 2016, a decrease of \$5.2 million, or 37%. The decrease was primarily due to lower professional fees for pre-commercialization activities and lower employee-related costs, as compared to the same period in 2016. At June 30, 2017, we had 52 employees dedicated to general and administrative functions versus 62 employees as of June 30, 2016. For 2017, we expect general and administrative expenses to decrease from 2016 primarily due to employee headcount reductions announced in November 2016, which we anticipate will result in lower anticipated employee costs, and reduced activities related to the anticipated commercialization of our RSV F Vaccine.

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

**Three Months Ended****June 30,**

	2017	2016	<b>Change 2016 to <u>2017</u></b>
Other Income (Expense):			
Investment income	\$523	\$670	\$ (147 )
Interest expense	(3,516)	(3,512)	(4 )
Other income (expense)	(1 )	(11 )	10
Total other income (expense)	\$(2,994)	\$(2,853)	\$ (141 )

We had total other expense of \$3.0 million for the three months ended June 30, 2017 as compared to \$2.9 million for the same period in 2016.

Net Loss:

	<b>Three Months Ended</b>		
	<b><u>June 30,</u></b>		
	2017	2016	<b>Change</b>
			<b><u>2016 to</u></b>
			<b><u>2017</u></b>
Net Loss:			
Net loss	\$(44,465 )	\$(79,351 )	\$ 34,886
Net loss per share	\$(0.16 )	\$(0.29 )	\$ 0.13
Weighted shares outstanding	283,444	270,760	12,684

Net loss for the three months ended June 30, 2017 was \$44.5 million, or \$0.16 per share, as compared to \$79.4 million, or \$0.29 per share, for the same period in 2016, a decreased net loss of \$34.9 million. The decreased net loss was primarily due to lower research and development spending, including decreased costs relating to the clinical trials and development activities of our RSV F Vaccine, and lower overall employee-related costs, as compared to the same period in 2016.

Weighted average shares outstanding for the three months ended June 30, 2017 increased by 5% as compared to the same period in 2016, primarily as a result of sales of our common stock in 2017.

**Six Months Ended June 30, 2017 and 2016** (amounts in tables are presented in thousands, except per share information)

Revenue:

	<b>Six Months Ended</b>		
	<b><u>June 30,</u></b>		
	2017	2016	<b>Change</b>
			<b><u>2016 to</u></b>
			<b><u>2017</u></b>
Revenue:			
Total revenue	\$ 12,412	\$ 6,723	\$ 5,689

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Revenue for the six months ended June 30, 2017 was \$12.4 million as compared to \$6.7 million for the same period in 2016, an increase of \$5.7 million or 85%. Revenue for the six months ended June 30, 2017 and 2016 is primarily comprised of services performed under the Grant Agreement and the HHS BARDA contract. Revenue increased under the Grant Agreement as a result of increased enrollment of participants in Prepare. This increase in revenue was partially offset by \$2.1 million in decreased revenue from the HHS BARDA contract, which expired in accordance with its terms in September 2016.

**Expenses:**

	<b>Six Months Ended</b>		
	<b><u>June 30,</u></b>		
	2017	2016	<b>Change</b>
			<b><u>2016 to</u></b>
			<b><u>2017</u></b>
Expenses:			
Research and development	\$76,916	\$133,856	\$(56,940)
General and administrative	17,793	24,627	(6,834 )
Total expenses	\$94,709	\$158,483	\$(63,774)

***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 decreased to \$76.9 million for the six months ended June 30, 2017 from \$133.9 million for the same period in 2016, a decrease of \$56.9 million, or 43%. The decrease in research and development expenses was primarily due to lower costs associated with the clinical trials and development activities of our RSV F Vaccine and lower employee-related costs. At June 30, 2017, we had 294 employees dedicated to our research and development programs versus 445 employees as of June 30, 2016.

***Expenses by Functional Area***

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

	2017	2016
Manufacturing	\$39.1	\$60.6
Vaccine Discovery	2.9	3.3
Clinical and Regulatory	34.9	70.0
Total research and development expenses	\$76.9	\$133.9

***General and Administrative Expenses***

General and administrative expenses decreased to \$17.8 million for the six months ended June 30, 2017 from \$24.6 million for the same period in 2016, a decrease of \$6.8 million, or 28%. The decrease was primarily due to lower professional fees for pre-commercialization activities and lower employee-related costs, as compared to the same period in 2016. At June 30, 2017, we had 52 employees dedicated to general and administrative functions versus 62 employees as of June 30, 2016.

**Other Income (Expense):**



**Six Months Ended****June 30,****Change**

	2017	2016	<b>2016 to <u>2017</u></b>
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## Other Income (Expense):

Investment income	\$997	\$1,147	\$(150 )
Interest expense	(7,029)	(5,946)	(1,083 )
Other income (expense)	10	(44 )	54
Total other income (expense)	\$(6,022)	\$(4,843)	\$(1,179)

We had total other expense of \$6.0 million for the six months ended June 30, 2017 as compared to \$4.8 million for the same period in 2016. Our interest expense increased due to the issuance of \$325 million aggregate principal amount of convertible senior unsecured notes (the “Notes”) in the first quarter of 2016, which will mature on February 1, 2023.

Net Loss:

	<b>Six Months Ended</b>		<b>Change</b>
	<b><u>June 30,</u></b>		
	2017	2016	<b><u>2016 to</u></b>
			<b><u>2017</u></b>
Net Loss:			
Net loss	\$(88,319 )	\$(156,603)	\$68,284
Net loss per share	\$(0.32 )	\$(0.58 )	\$0.26
Weighted shares outstanding	278,836	270,469	8,367

Net loss for the six months ended June 30, 2017 was \$88.3 million, or \$0.32 per share, as compared to \$156.6 million, or \$0.58 per share, for the same period in 2016, a decreased net loss of \$68.3 million. The decreased net loss was primarily due to lower research and development spending, including decreased costs relating to the clinical trials and development activities of our RSV F Vaccine, and lower overall employee-related costs, as compared to the same period in 2016.

Weighted average shares outstanding for the six months ended June 30, 2017 increased by 3% as compared to the same period in 2016, primarily as a result of sales of our common stock in 2017.

**Liquidity Matters and Capital Resources**

Our future capital requirements depend on numerous factors including, but not limited to, the commitments and progress of our research and development programs, the progress of preclinical and clinical testing, the time and costs involved in obtaining regulatory approvals, the costs of filing, prosecuting, defending and enforcing patent claims and other intellectual property rights and manufacturing costs. We plan to continue to have multiple vaccines and products in various stages of development, and we believe our operating expenses and capital requirements will fluctuate depending upon the timing of certain events, such as the scope, initiation, rate and progress of our preclinical studies and clinical trials and other research and development activities.

As of June 30, 2017, we had \$187.3 million in cash and cash equivalents and marketable securities as compared to \$235.5 million as of December 31, 2016. These amounts consisted of \$75.8 million in cash and cash equivalents and \$111.5 million in marketable securities as of June 30, 2017 as compared to \$144.4 million in cash and cash equivalents and \$91.1 million in marketable securities as of December 31, 2016.

The following table summarizes cash flows for the six months ended June 30, 2017 and 2016 (in thousands):

	<b>Six Months Ended</b>		<b>Change</b>
	<b><u>June 30,</u></b>		
	2017	2016	<b><u>2016 to</u></b>
			<b><u>2017</u></b>
Summary of Cash Flows:			
Net cash (used in) provided by:			
Operating activities	\$(69,363 )	\$(131,863)	\$62,500
Investing activities	(22,753 )	(150,459)	127,706
Financing activities	23,495	278,604	(255,109)
Effect on exchange rate on cash and cash equivalents	61	5	56
Net decrease in cash and cash equivalents	(68,560 )	(3,713 )	(64,847 )
Cash and cash equivalents at beginning of period	144,353	93,108	51,245
Cash and cash equivalents at end of period	\$75,793	\$89,395	\$(13,602 )

Net cash used in operating activities decreased to \$69.4 million for the six months ended June 30, 2017 as compared to \$131.9 million for the same period in 2016. The decrease in cash usage was primarily due to decreased costs relating to our RSV F Vaccine and lower overall employee-related costs.

During the six months ended June 30, 2017 and 2016, our investing activities consisted of purchases and maturities of marketable securities and capital expenditures. During the first half of 2017 and 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 six months ended June 30, 2017 and 2016 were \$2.3 million and \$11.0 million, respectively. The decrease in capital expenditures was primarily due to reduced capital requirements based on our current operating plans. In 2017, we expect our level of capital expenditures to be significantly lower than our 2016 spending primarily due to the timelines being extended for the commercialization of our RSV F Vaccine.

Our financing activities consisted primarily of sales of our common stock, issuance of Notes and to a much lesser extent, stock option exercises and purchases under our employee stock purchase plan. In the six months ended June 30, 2017, we received net proceeds of \$22.7 million from selling shares of common stock through our Sales Agreement during the Trading Period. The weighted average sales price achieved during the Trading Period was \$1.31 per share. From July 1, 2017 through August 4, 2017, we sold an additional 3.9 million shares of common stock resulting in \$5.7 million in net proceeds. In the six months ended June 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 consolidated financial statements in Item 1).

In August 2015, we amended the lease for our 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 provides us with a tenant improvement allowance of \$3.9 million. Through June 30, 2017, we were funded \$3.4 million under this tenant improvement allowance. In May 2016, we entered into a lease for a facility located in Gaithersburg, Maryland and under the terms of the lease the landlord provides us with a tenant improvement allowance of up to \$9.6 million, and \$1.2 million has been funded as of June 30, 2017.

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. Our former seasonal and pandemic influenza VLP vaccine programs 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 has increased 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 June 30, 2017 aggregated \$7.6 million. The Milestone was accrued for on the consolidated balance sheet in other current liabilities at December 31, 2014. The Milestone has been accrued for, on a discounted basis calculated based on the probable future payment date, and at June 30, 2017, the Milestone is recorded in accrued expenses. The Milestone was recorded as a research and development expense in 2014.

Based on our June 30, 2017 cash and cash equivalents and marketable securities balances, along with anticipated revenue under the Grant Agreement, we believe we have adequate capital to fund our operating plans for a minimum of twelve months from the date that this Quarterly Report was filed. Additional capital may be required in the future to develop our vaccine candidates through clinical development, manufacturing and commercialization. We plan to meet such near term capital requirements primarily through cash and investments on hand, and a combination of equity and debt financings, collaborations, strategic alliances and marketing distribution or licensing arrangements and in the longer term, from revenue related to product sales, to the extent our product candidates receive marketing approval and can be commercialized. Our ability to obtain additional capital in the near term will likely be subject to various factors, including our ability to perform and thus generate revenue under the Grant Agreement, our overall business performance and market conditions.

Any capital raised by an equity offering or convertible securities has the potential to be substantially dilutive to the existing stockholders and any collaborations, strategic alliances and marketing distribution or licensing arrangements may require us to give up some or all rights to a product or technology at less than its full potential value. There can be no assurances that new financing will be available to us on commercially acceptable terms, if at all. If we are unable to perform under the Grant Agreement or obtain additional capital, we will assess our capital resources and may be required to delay, reduce the scope of, or eliminate one or more of our product research and development programs, and/or downsize our organization, including our general and administrative infrastructure.

### **Item 3. Quantitative and Qualitative Disclosures About Market Risk**

The primary objective of our investment activities is preservation of capital, with the secondary objective of maximizing income. As of June 30, 2017, we had cash and cash equivalents of \$75.8 million, marketable securities of \$111.5 million, all of which are short-term, and working capital of \$169.9 million.

Our exposure to market risk is primarily confined to our investment portfolio. As of June 30, 2017, 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' deficit of approximately \$3.0 million at June 30, 2017.

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 June 30, 2017. 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 June 30, 2017, 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 June 30, 2017, and has concluded that there was no change that occurred during the quarterly period ended June 30, 2017 that materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

## **PART II. OTHER INFORMATION**

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

Other than the additional risk factor disclosed below, there are no material changes to the Company's risk factors as described in Item 1A of the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2016.

*The NASDAQ Global Select Market has a listing requirement; if a participating company no longer meets such requirements and fails to correct the listing deficiency, its stock may be delisted.*

The NASDAQ Global Select Market ("NASDAQ"), on which our common stock is listed and traded, has listing requirements that include a \$1 minimum closing bid price requirement. If we fail to satisfy this or other listing requirements, NASDAQ may elect to initiate a process that may delist our common stock. Such a delisting may adversely impact the liquidity and price of our common stock or impede our ability to raise capital.

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

None

### **Item 6. Exhibits**



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3.1 Second Amended and Restated Certificate of Incorporation of the Company (Incorporated by reference to Exhibit 3.1 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2015, filed August 10, 2015)

3.2 Amended and Restated By-Laws of the Company (Incorporated by reference to Exhibit 3.2 to the Company's Annual Report on Form 10-K for the year ended December 31, 2012, filed March 12, 2013)

10.1 Novavax, Inc. Amended and Restated 2015 Stock Incentive Plan (Incorporated by reference to Appendix A of the Company's Definitive Proxy Statement filed April 28, 2017 in connection with the Annual Meeting held on June 15, 2017)

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 June 30, 2017, formatted in Extensible Business Reporting Language (XBRL): (i) the Consolidated Balance Sheets as of June 30, 2017 and December 31, 2016, (ii) the Consolidated Statements of Operations for the three and six-month periods ended June 30, 2017 and 2016, (iii) the Consolidated Statements of Comprehensive Loss for the three and six-month periods ended June 30, 2017 and 2016, (iv) the Consolidated Statements of Cash Flows for the six-month periods ended June 30, 2017 and 2016, 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: August 8, 2017 By: /s/ Stanley C. Erck  
President and Chief Executive Officer  
and Director  
(Principal Executive Officer)

Date: August 8, 2017 By: /s/ Barclay A. Phillips  
Senior Vice President, Chief Financial Officer and Treasurer  
(Principal Financial and Accounting Officer)