

NOVAVAX INC  
Form 10-Q  
May 09, 2018

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 March 31, 2018**

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. 000-26770**

**NOVAVAX, INC.**

(Exact name of registrant as specified in its charter)

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

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

(240) 268-2000

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

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, 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 x

The number of shares outstanding of the Registrant’s Common Stock, \$0.01 par value, was 381,674,924 as of April 30, 2018.

NOVAVAX, INC.

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

(in thousands, except share and per share information)

	March 31, 2018 (unaudited)	December 31, 2017
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 113,402	\$ 106,307
Marketable securities	30,358	50,996
Restricted cash	19,548	28,234
Prepaid expenses and other current assets	17,726	17,774
Total current assets	181,034	203,311
Restricted cash	891	890
Property and equipment, net	32,422	35,987
Intangible assets, net	7,575	7,873
Goodwill	53,286	53,563
Other non-current assets	859	869
Total assets	\$ 276,067	\$ 302,493
<b>LIABILITIES AND STOCKHOLDERS' DEFICIT</b>		
Current liabilities:		
Accounts payable	\$ 5,770	\$ 5,613
Accrued expenses	19,225	29,610
Accrued interest	2,031	5,078
Deferred revenue	16,377	25,625
Other current liabilities	1,501	7,749
Total current liabilities	44,904	73,675
Deferred revenue	2,500	2,500
Convertible notes payable	318,119	317,763
Other non-current liabilities	9,913	10,287
Total liabilities	375,436	404,225
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 March 31, 2018 and December 31, 2017, respectively	—	—
Common stock, \$0.01 par value, 600,000,000 shares authorized at March 31, 2018 and December 31, 2017; 347,204,416 shares issued and 346,748,986 shares outstanding at March 31, 2018 and 323,684,820 shares issued and 323,229,390 shares outstanding at December 31, 2017	3,472	3,237
Additional paid-in capital	1,069,391	1,020,457
Accumulated deficit	(1,160,711)	(1,114,359 )
Treasury stock, 455,430 shares, cost basis at both March 31, 2018 and December 31, 2017	(2,450 )	(2,450 )
Accumulated other comprehensive loss	(9,071 )	(8,617 )
Total stockholders' deficit	(99,369 )	(101,732 )
Total liabilities and stockholders' deficit	\$276,067	\$ 302,493

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>Three Months Ended March 31,</b>	
	2018	2017
Revenue:		
Grant and other	\$ 9,653	\$ 5,680
Total revenue	9,653	5,680
Expenses:		
Research and development	44,514	37,654
General and administrative	8,652	8,852
Total expenses	53,166	46,506
Loss from operations	(43,513 )	(40,826 )
Other income (expense):		
Investment income	531	474
Interest expense	(3,403 )	(3,513 )
Other income (expense)	33	11
Net loss	\$(46,352 )	\$(43,854 )
Basic and diluted net loss per share	\$(0.14 )	\$(0.16 )
Basic and diluted weighted average number of common shares outstanding	336,972	274,178

CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

(in thousands)

(unaudited)

	<b>Three Months Ended March 31,</b>	
	2018	2017
Net loss	\$(46,352 )	\$(43,854 )

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Other comprehensive (loss) income:

Net unrealized gains (losses) on marketable securities available-for-sale	8	(1	)
Foreign currency translation adjustment	(462	)	480
Other comprehensive (loss) income	(454	)	479
Comprehensive loss	\$(46,806	)	\$(43,375)

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

NOVAVAX, INC.

## CONSOLIDATED STATEMENTS OF CASH FLOWS

(in thousands)

(unaudited)

	<b>Three Months Ended</b>	
	<b><u>March 31,</u></b>	
	2018	2017
Operating Activities:		
Net loss	\$(46,352 )	\$(43,854 )
Reconciliation of net loss to net cash used in operating activities:		
Depreciation and amortization	2,079	2,111
(Gain) Loss on disposal of property and equipment	(47 )	65
Non-cash impact of lease termination	(4,381 )	
Amortization of debt issuance costs	356	356
Lease incentives received		1,248
Non-cash stock-based compensation	5,245	4,213
Other	(435 )	(6 )
Changes in operating assets and liabilities:		
Prepaid expenses and other assets		1,093
Accounts payable and accrued expenses	(13,293 )	(4,867 )
Deferred revenue	(9,247 )	(5,399 )
Other liabilities		543
Net cash used in operating activities	(66,075 )	(44,497 )
Investing Activities:		
Capital expenditures	(150 )	(1,084 )
Proceeds from maturities of marketable securities	22,721	86,130
Purchases of marketable securities	(1,984 )	(110,330 )
Net cash provided by (used in) investing activities	20,587	(25,284 )
Financing Activities:		
Principal payments on capital lease		(18 )
Net proceeds from sales of common stock	42,599	14,585
Proceeds from the exercise of stock options and employee stock purchases	1,325	797
Net cash provided by financing activities	43,924	15,364
Effect of exchange rate on cash, cash equivalents and restricted cash	(26 )	31
Net decrease in cash, cash equivalents and restricted cash	(1,590 )	(54,386 )
Cash, cash equivalents and restricted cash at beginning of period	135,431	179,257
Cash, cash equivalents and restricted cash at end of period	\$ 133,841	\$ 124,871



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Supplemental disclosure of non-cash activities:

Sale of common stock under the Sales Agreement not settled at quarter-end	\$—	\$225
Property and equipment purchases included in accounts payable and accrued expenses	\$62	\$823

Supplemental disclosure of cash flow information:

Cash payments of interest	\$6,094	\$6,094
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The accompanying notes are an integral part of these financial statements.

NOVAVAX, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

March 31, 2018

(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, and its proprietary saponin-based adjuvant 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 and may elicit differentiated immune responses, which may be more efficacious than naturally occurring immunity or traditional vaccines. The Company’s product pipeline targets a variety of infectious diseases, with lead clinical vaccine candidates against respiratory syncytial virus (“RSV”) and influenza, along with other clinical and preclinical infectious disease vaccine candidates.

Note 2 – Liquidity

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

As a clinical-stage biotechnology company, the Company has primarily funded its operations with proceeds from the sale of its common stock in equity offerings, the issuance of convertible debt, revenue under its grant agreement (“Grant Agreement”) with the Bill & Melinda Gates Foundation (“BMGF”), and in past years, under its former contract with the Department of Health and Human Services, Biomedical Advanced Research and Development Authority (“HHS BARDA”). Management regularly reviews the Company’s cash and cash equivalents and 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 the Company’s most recent cash flow forecast, the Company believes its current capital, along with anticipated revenue under the Grant Agreement (see Note 10) and the proceeds from the public offering of the Company’s common stock in April 2018 (see Note 8), is sufficient 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 March 31, 2018, the consolidated statements of operations and the consolidated statements of comprehensive loss for the three months ended March 31, 2018 and 2017 and the consolidated statements of cash flows for the three months ended March 31, 2018 and 2017 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 consolidated balance sheets. The foreign currency translation adjustment balance included in accumulated other comprehensive loss was \$9.1 million and \$8.6 million at March 31, 2018 and December 31, 2017, 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, 2017. 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>March 31,</b> <b><u>2018</u></b>	<b>December 31,</b> <b><u>2017</u></b>
Cash	\$ 13,448	\$ 10,482
Money market funds	31,056	36,762
Asset-backed securities	18,750	16,007
Corporate debt securities	50,148	43,056
Cash and cash equivalents	\$ 113,402	\$ 106,307

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 debt securities that include 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 non-current 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 March 31, 2018 and December 31, 2017, the restricted cash balances (both current and non-current) consist of payments received under the Grant Agreement of \$18.7 million and \$27.4 million, respectively, and security deposits of \$1.7 million at both dates.

The following table provides a reconciliation of cash, cash equivalents and restricted cash reported within the consolidated balance sheets that sum to the total of the same such amounts shown in the statement of cash flows (in thousands):

	<b>March 31,</b> <b><u>2018</u></b>	<b>December 31,</b> <b><u>2017</u></b>
Cash and cash equivalents	\$ 113,402	\$ 106,307
Restricted cash current	19,548	28,234
Restricted cash non-current	891	890
Cash, cash equivalents and restricted cash	\$ 133,841	\$ 135,431

## Revenue Recognition

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"), and subsequently issued amendments to ASU 2014-09, to supersede nearly all existing revenue recognition guidance under U.S. GAAP. The new revenue standard became effective for the Company on January 1, 2018, and was adopted using the modified retrospective method. The adoption of the new revenue standard as of January 1, 2018 did not materially change the Company's revenue recognition policies as the majority of its revenue continues to be recognized under the Grant Agreement (see discussion below). Since the Company did not identify any accounting changes that impacts its revenue recognition policies, no adjustment to accumulated deficit was required upon adoption.

Under the new revenue standard for arrangements that are determined within the scope of Topic 606, the Company recognizes revenue following the five-step model: (i) identify the contract(s) with a customer; (ii) identify the performance obligation(s) in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the entity satisfies a performance obligation. The Company only applies the five-step model to contracts when it is probable that the entity will collect



the consideration it is entitled to in exchange for the goods or services it transfers to the customer. At contract inception, once the contract is determined to be within the scope of Topic 606, the Company assesses the goods or services promised within each contract and determines the performance obligations, and assesses whether each promised good or service is distinct. The Company then recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied.

The Company performs research and development under grant, license and clinical development agreements. Payments received in advance of work performed are recorded as deferred revenue.

The Company's current revenue primarily consists of revenue 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. The Company's Grant Agreement does not provide a direct economic benefit to BMGF. Rather, the Company entered into an agreement with BMGF to make a certain amount of the RSV F Vaccine available and accessible at affordable pricing to people in certain low and middle income countries. Based on these circumstances, the Company does not consider BMGF to be a customer and concluded the Grant Agreement is outside the scope of Topic 606. Payments received under the Grant Agreement are considered conditional contributions under the scope of ASC 958-605, *Not-for-Profit Entities – Revenue Recognition*, and are recorded as deferred revenue until the period in which such research and development activities are performed and revenue can be recognized.

The Company analyzed the Grant Agreement 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 considered 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. Further, management has consistently applied its policy of presenting such amounts as revenue.

### ***Income Taxes***

In December 2017, the SEC issued Staff Accounting Bulletin No. 118, *Income Tax Accounting Implications of the Tax Cuts and Jobs Act* ("SAB 118"), which provides guidance on accounting for the tax effects of the Tax Cuts and Jobs Act of 2017 (the "Act") and allows the Company to record provisional amounts during the measurement period not to extend beyond one year of the enactment date. The Company was able to reasonably estimate certain effects of the Act as of December 31, 2017 and has not changed the preliminary estimates as of March 31, 2018. The Company expects to complete its analysis within the measurement period in accordance with SAB 118, although it does not expect there to be any adjustment to the income tax expense on the Company's consolidated statement of operations during the re-measurement period.

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

Net loss per share is computed using the weighted average number of shares of common stock outstanding. At March 31, 2018 and 2017, the Company had outstanding stock options and unvested restricted stock awards totaling 45,126,499 and 38,202,248 respectively. At March 31, 2018, the Company's Notes (see Note 7) were 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 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. The Company completed its 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 assessment, there were no material changes to the recognition of its revenue. The Company applied ASU 2014-09 on a modified retrospective basis as of January 1, 2018.

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 was adopted on its effective date of January 1, 2018, and was applied using a retrospective transition method to each period presented. Although the Company’s restricted cash is now included with cash and cash equivalents when reconciling the beginning-of-period and end-of-period total amounts shown on the statements of cash flows, the adoption did not 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.

*Not Yet Adopted*

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 expecting to adopt this standard on January 1, 2019 and is currently evaluating the potential impact to its consolidated financial statements and 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**

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

	Fair Value at March 31, 2018			Fair Value at December 31, 2017		
	Level 1	Level 2	Level 3	Level 1	Level 2	Level 3
<u>Assets</u>						
Money market funds(1)	\$ 31,056	\$	\$	\$ 36,762	\$	\$
Asset-backed securities(2)		28,496			29,750	
Corporate debt securities(3)		70,760			80,309	
Total assets	\$ 31,056	\$ 99,256	\$	\$ 36,762	\$ 110,059	\$
<u>Liabilities</u>						
Convertible notes payable	\$	\$ 228,621	\$	\$	\$ 152,396	\$

(1) Classified as cash and cash equivalents as of March 31, 2018 and December 31, 2017, respectively (see Note 3).

(2) Includes \$18,750 and \$16,007 classified as cash and cash equivalents as of March 31, 2018 and December 31, 2017, respectively (see Note 3).

(3) Includes \$50,148 and \$43,056 classified as cash and cash equivalents as of March 31, 2018 and December 31, 2017, respectively (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 March 31, 2018, 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.

#### Note 5 – Marketable Securities

Marketable securities classified as available-for-sale as of March 31, 2018 and December 31, 2017 were comprised of (in thousands):

	March 31, 2018				December 31, 2017			
	<b>Amortized Cost</b>	<b>Gross Unrealized Gains</b>	<b>Gross Unrealized Losses</b>	<b>Fair Value</b>	<b>Amortized Cost</b>	<b>Gross Unrealized Gains</b>	<b>Gross Unrealized Losses</b>	<b>Fair Value</b>
Asset-backed securities	\$9,749	\$ —	\$ (3)	\$ 9,746	\$13,748	\$ —	\$ (5)	\$ 13,743
Corporate debt securities	20,618	—	(6)	20,612	37,265	—	(12)	37,253
Total	\$30,367	\$ —	\$ (9)	\$ 30,358	\$51,013	\$ —	\$ (17)	\$ 50,996

#### 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 11 available-for-sale securities as of March 31, 2018. Of these 11 securities, 10 had combined unrealized losses of less than \$0.1 million as of March 31, 2018. The Company did not have any investments in a loss position for greater than 12 months as of March 31, 2018. The Company has evaluated its marketable securities and has determined that none of these investments had an other-than-temporary impairment, as it has no intent to sell securities with unrealized losses and it is not likely 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 three months ended March 31, 2018 was as follows (in thousands):

	Amount
Balance at December 31, 2017	\$53,563
Currency translation adjustments	(277 )
Balance at March 31, 2018	\$53,286

**Identifiable Intangible Assets**

Purchased intangible assets consisted of the following as of March 31, 2018 and December 31, 2017 (in thousands):

	March 31, 2018		Intangible Assets, Net	December 31, 2017		Intangible Assets, Net
	<u>Gross Carrying Amount</u>	<u>Accumulated Amortization</u>		<u>Gross Carrying Amount</u>	<u>Accumulated Amortization</u>	
Finite-lived intangible assets:						
Proprietary adjuvant technology	\$8,959	\$ (2,090)	) \$ 6,869	\$9,086	\$ (2,006)	) \$ 7,080
Collaboration agreements	4,045	(3,339)	) 706	4,103	(3,310)	) 793
Total identifiable intangible assets	\$13,004	\$ (5,429)	) \$ 7,575	\$13,189	\$ (5,316)	) \$ 7,873

Amortization expense for the three months ended March 31, 2018 and 2017 was \$0.2 million.

Estimated amortization expense for existing intangible assets for the remainder of 2018 and for each of the five succeeding years ending December 31 will be as follows (in thousands):

Year	Amount
2018 (remainder)	\$ 563
2019	751
2020	625
2021	448
2022	448
2023	448

**Note 7 – Long-Term Debt****Convertible Notes**

The Company incurred approximately \$10.0 million of debt issuance costs during the first quarter of 2016 relating to the issuance of \$325 million aggregate principal amount of convertible senior unsecured notes that will mature on February 1, 2023 (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 on a straight-line basis, which approximates the effective interest rate method.

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

	<b>March 31,</b>	December 31,
	<b>2018</b>	2017
Principal amount of Notes	\$ 325,000	\$ 325,000
Unamortized debt issuance costs	(6,881 )	(7,237 )
Total convertible notes payable	\$ 318,119	\$ 317,763

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

	<b>Three Months Ended</b>	
	<b><u>March 31,</u></b>	
	2018	2017
Coupon interest at 3.75%	\$ 3,047	\$ 3,047
Amortization of debt issuance costs	356	356
Total interest expense on Notes	\$ 3,403	\$ 3,403

#### **Note 8 – Stockholders’ Deficit**

In April 2018, the Company completed a public offering of 34,848,507 shares of its common stock, including 4,545,457 shares of common stock that were issued upon the exercise in full of the option to purchase additional shares granted to the underwriters, at a price of \$1.65 per share resulting in net proceeds of approximately \$54 million.

In December 2017, the Company entered into an At Market Issuance Sales Agreement (“December 2017 Sales Agreement”), which allows it to issue and sell up to \$75 million in gross proceeds of its common stock. From January 17, 2018 through March 31, 2018, the Company sold 15.7 million shares of common stock under the December 2017 Sales Agreement resulting in \$32.3 million in net proceeds at a weighted average sales price of \$ 2.09 per share. As of March 31, 2018, the Company has approximately \$42.2 million available under the December 2017 Sales Agreement.

In January 2017, the Company entered into an At Market Issuance Sales Agreement (“January 2017 Sales Agreement”), which allowed it to issue and sell up to \$75 million in gross proceeds of its common stock. From January 1 through January 17, 2018, the Company sold 6.8 million shares of common stock resulting in \$10.3 million in net proceeds at a weighted average sales price of \$1.54. The January 2017 Sales Agreement was fully utilized at that time.

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

##### ***Stock Options***

The 2015 Stock Incentive Plan, as amended, (“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. All such shares authorized for issuance under the 2015 Plan have been reserved. The Company will seek approval to increase the number of shares of common stock available for issuance under the 2015 Plan by 20,000,000 shares at its June 2018 annual meeting of stockholders. 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 three months ended March 31, 2018:

	2015 Plan		2005 Plan	
	Stock Options	<b>Weighted- Average Exercise Price</b>	Stock Options	<b>Weighted- Average Exercise Price</b>
Outstanding at January 1, 2018	33,675,720	\$ 3.61	12,818,929	\$ 3.26
Granted	140,500	\$ 1.95	—	\$ —
Exercised	(139,645 )	\$ 1.35	(281,020 )	\$ 1.89
Canceled	(744,928 )	\$ 4.47	(343,057 )	\$ 4.08
Outstanding at March 31, 2018	32,931,647	\$ 3.59	12,194,852	\$ 3.27
Shares exercisable at March 31, 2018	10,614,915	\$ 5.86	11,789,727	\$ 3.22
Shares available for grant at March 31, 2018	2,883,708			

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 March 31,</b>	
	2018	2017
Weighted-average Black-Scholes fair value of stock options granted	\$1.50	\$1.13
Risk-free interest rate	2.26%-2.54%	1.73%-2.34%
Dividend yield	0%	0%
Volatility	113.98%-114.12%	88.91%-109.50%
Expected term (in years)	4.12-4.14	4.19-7.46
Expected forfeiture rate	0%	0%

The total aggregate intrinsic value and weighted-average remaining contractual term of stock options outstanding under the 2015 Plan and 2005 Plan as of March 31, 2018 was \$16.9 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 March 31, 2018 was \$4.4 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 March 31, 2018. 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 March 31, 2018 and 2017 was

\$0.3 million and less than \$0.1 million, respectively.

***Employee Stock Purchase Plan***

In 2013, the Company adopted an Employee Stock Purchase Plan (the “ESPP”), which currently authorizes an aggregate of 3,600,000 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 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 March 31, 2018, there were 270,880 shares available for issuance under the ESPP. The Company will seek approval to increase the maximum number of shares of common stock available for issuance under the ESPP by 4,000,000 shares at its June 2018 annual meeting of stockholders.

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><u>March 31,</u></b>	
	2018	2017
Range of Black-Scholes fair value of ESPP shares granted	\$0.45-\$3.53	\$1.05-\$5.47
Risk-free interest rate	0.66%-1.79%	0.45%-0.70%
Dividend yield	0%	0%
Volatility	59.84%-203.83%	45.98%-267.85%
Expected term (in years)	0.5-2.0	0.5-2.0
Expected forfeiture rate	0%	0%

***Restricted Stock Awards***

The following is a summary of restricted stock awards activity for the three months ended March 31, 2018:

	<b><u>Number of</u></b>	<b><u>Per Share</u></b>
	<b><u>Shares</u></b>	<b><u>Weighted-</u></b>
		<b><u>Average</u></b>
		<b><u>Grant-Date</u></b>
		<b><u>Fair Value</u></b>
Outstanding and Unvested at January 1, 2018	18,750	\$ 4.99
Restricted stock granted		\$

Restricted stock vested		\$
Restricted stock forfeited	(18,750 )	\$ 4.99
Outstanding and Unvested at March 31, 2018		\$

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

	<b>Three Months Ended</b>	
	<b><u>March 31,</u></b>	
	2018	2017
Research and development	\$ 3,098	\$ 2,215
General and administrative	2,147	1,998
Total stock-based compensation expense	\$ 5,245	\$ 4,213

As of March 31, 2018, there was approximately \$31 million of total unrecognized compensation expense related to unvested stock options and ESPP. This unrecognized non-cash compensation expense is expected to be recognized over a weighted-average period of 1.6 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 – Grant Agreement**

### ***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 the 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 a certain amount of 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 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. In the three months ended March 31, 2018, the Company recognized revenue from the Grant of \$9.3 million, and has recognized approximately \$51 million in revenue since the inception of the agreement. At March 31, 2018, 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.

## **Note 11 – License Agreement with Wyeth Holdings LLC**

In April 2018, the Company provided written notice of its intent to terminate (90 days after such notice) a 2007 agreement to license certain rights from Wyeth Holdings LLC (formerly Wyeth Holdings Corporation), a subsidiary of Pfizer Inc. (“Wyeth”). The Wyeth license offered a non-exclusive, worldwide license to a family of patents and patent applications covering virus-like particles (“VLP”) technology for use in human vaccines in certain fields, with expected patent expiration in early 2022. At present, the Company has no programs to which the Wyeth license applies and CPLB’s recombinant trivalent seasonal VLP influenza vaccine (“CadiFlu”) is only being marketed in India. In September 2015, the Company entered into an amendment to the Wyeth license that, among other things, increased the milestone payment owed as a result of CPLB’s initiation of a Phase 3 clinical trial for CadiFlu in 2014 (“Milestone”) from \$3 million to as much as \$4 million if not paid before December 31, 2017. The Milestone was paid in the first quarter of 2018. The Milestone was recorded as a research and development expense in 2014. Payments under the Wyeth license



as of March 31, 2018 aggregated to \$11.6 million.

#### **Note 12 – Facility Leases**

In January 2018, the Company's 1201 Clopper Road lease was terminated and the Company paid a termination fee to the landlord of \$5.3 million, which the Company believes is less than the potential total lease and operating expense cash obligations that could have been incurred over one year. The Company recorded total expense, which includes the termination fee and write-down of the related leasehold improvements, and is partially offset by deferred rent expense previously recorded, of \$0.9 million in the first quarter of 2018 in connection with the termination of the 1201 Clopper Road lease.

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

In July 2017, the Company entered into a consulting agreement with Dr. Sarah Frech, the spouse of Mr. Stanley C. Erck, the Company's President and Chief Executive Officer. Dr. Frech is a seasoned biotechnology executive with significant experience managing multiple clinical programs. Under the agreement, Dr. Frech provides clinical development and operations services related to the Company's Phase 3 clinical trial of its RSV F Vaccine for infants via maternal immunization and other professional services. The agreement is scheduled to terminate in July 2018. For the three months ended March 31, 2018, the Company incurred \$0.1 million in consulting expenses under the agreement. The amount due and unpaid for services performed under the agreement at March 31, 2018 and December 31, 2017 was less than \$0.1 million.

**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, including possible proceeds from our December 2017 Sales Agreement; 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 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; 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,” “intend,” “seek,” “plan,” “project,” “expect,” “assume” or the negative of these terms, or other comparable terminology, although not all forward-looking statements contain these words.

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, 2017, and other risk factors of which we are not aware, could cause actual results or outcomes to differ materially from those expressed or implied 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 could cause actual results or events to differ materially from forward-looking statements. 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, level 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 and may elicit differentiated immune responses, which may be more efficacious than naturally occurring immunity or traditional vaccines. Our product pipeline targets a variety of infectious diseases, with lead clinical vaccine candidates against respiratory syncytial virus (“RSV”) and influenza, along with other clinical and preclinical 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 and others have conducted.

## 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. 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>	
· <b>Infants via Maternal Immunization*</b>	Phase 3
· <b>Older Adults</b>	Phase 2
· <b>Pediatrics</b>	Phase 1
<b>Nanoparticle Influenza (“NanoFlu”)</b>	Phase 1/2
<b>Combination Influenza/RSV</b>	Preclinical
<b>Ebola Virus (“EBOV”)</b>	Phase 1

\*Supported by the \$89.1 million grant from BMGF

A current summary of our significant research and development programs and status of the related product candidates 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 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> 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. We genetically engineered a novel F-protein antigen resulting in enhanced immunogenicity by exposing a number of 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>

<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)

## *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, using aluminum phosphate as an adjuvant, in December 2015. In May 2018, we announced that we had enrolled approximately 4,600 pregnant women, of which at least 3,000 were actively vaccinated. 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 and up to the first six months of life.

The Prepare trial utilizes a group sequential design. We will initiate a prespecified interim efficacy analysis following the trial’s six months of follow-up for the last infant born from these enrolled women. We expect to report on the interim data in the first quarter of 2019. Assuming successful interim analysis results, the trial would be concluded without further enrollment and we would file a biologics license application (“BLA”) with the U.S. Food and Drug Administration (“FDA”) and a marketing authorization application (“MAA”) with the European Medicines Agency (“EMA”) by the first quarter of 2020. In December 2017, we conducted an informational analysis related to the prevention of medically significant RSV-positive LRTI in a subset of 1,300 infants from the Prepare trial. This analysis allows us to conclude that the vaccine’s potential observed efficacy in this subset group is in the range of 45% and 100%<sup>10</sup> and further allows us to make go-forward decisions relating to various program-related activities.

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 a certain amount of the RSV F Vaccine available and accessible at affordable pricing to people in certain low and middle income countries.

<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

<sup>10</sup> Assumes 2:1 randomization

*Phase 2 Safety and Immunogenicity Trial (Completed)*

In September 2015, we announced positive top-line data from our 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, a 29-fold rise in palivizumab-competing antibodies and 2.7 and 2.1-fold rises 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, and 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 approved products can reach the market expeditiously. Specifically, Fast Track designation facilitates meetings to discuss all aspects of development to support licensure and it provides the opportunity to submit sections of a BLA on a rolling basis as data become available, which permits the FDA to review modules of the BLA as they are received instead of waiting for the entire BLA submission. In addition, priority review (6-month review versus standard 10-month review) is a potential benefit that may be available to our RSV F vaccine in the future.

***RSV Older Adults Program***

*Burden of Disease*

Older 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 ("COPD"), asthma and congestive heart failure. In the U.S., the incidence rate



of RSV in older adults 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>11,12</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>13,14</sup> Annually, we estimate that there are approximately 900,000 medical interventions directly caused by RSV disease across all populations.<sup>15,16</sup>

<sup>11</sup> Falsey, A.R. *et al.* (2005) NEJM. 352:1749–59 extrapolated to 2015 census population

<sup>12</sup> Falsey, A.R. *et al.* (1995) JID.172:389-94

<sup>13</sup> Falsey, A.R. *et al.* (2005) NEJM. 352:1749–59 extrapolated to 2015 census population

<sup>14</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>15</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>16</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 our 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 indicated both aluminum phosphate and Matrix-M adjuvants 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, although we do not currently expect to initiate such trials in 2018 without additional funding.

*Further Analyses of Prior Clinical Trials*

Following the September 2016 announcement of 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 conducted multiple analyses on the clinical data from the Resolve trial, as well as the other completed Phase 2 clinical trials conducted in older adults. 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 under “Clinical Trial Updates and Analyses” below; the trials are named and briefly described in the following table:

Clinical Trial Name	Phase	Description	Conducted	Participants(#)
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 doses, with or without adjuvant	2017	300

We have found that seasonal variation in attack rate, meaning the incidence of infectious disease in an at-risk population, may have a large impact on demonstrating vaccine efficacy in a particular year. Lower attack rates may mean that either the virus is less common in a given season, or alternatively, that the population being studied has increased intrinsic resistance in that season due to a variety of potential factors such as recent prior exposure. 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 a primary endpoint attack rate of only one-fourth that of the previous season. This scenario represents 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 COPD exacerbations, and the same analysis of the E-201 trial showed a similar signal, supporting this finding. We believe that such higher-risk patients represent an unmet medical need with a significant healthcare cost burden that could potentially be addressed by such a vaccine.

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

In September 2016, we announced top-line data from our Resolve trial. 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 its 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 (“RSV ARD”). The trial also evaluated the safety of an unadjuvanted, 135 microgram dose of the RSV F Vaccine compared to placebo. 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 our 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 were to evaluate 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 to receive either 135 microgram RSV F Vaccine or placebo. This trial design resulted in 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 our 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 tract 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>17</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>18,19,20,21,22</sup>

<sup>17</sup> U.S. Census. [www.census.gov/population/international/data/idb/informationGateway.php](http://www.census.gov/population/international/data/idb/informationGateway.php)

<sup>18</sup> Stockman, L.J. *et al* (2012) *Pediatr Infect Dis J*. 31: 5-9

<sup>19</sup> CDC update May 5, 2015. <http://www.cdc.gov/rsv/research/us-surveillance.html>

<sup>20</sup> Boyce, T.G. *et al* (2000) *Pediatrics*; 137: 865-870

<sup>21</sup> Hall, C.B. *et al* (2009) *NEJM*; 360(6): 588-98

<sup>22</sup> Hall, C.B. *et al* (2013) *Pediatrics*; 132(2): E341-8

### *Clinical Trial Update*

In September 2015, we announced positive top-line data from our Phase 1 clinical trial of our RSV F Vaccine in healthy children between two and six years of age. This clinical trial evaluated the safety and immunogenicity of our RSV F Vaccine, with one or two doses, with or without aluminum phosphate adjuvant. Trial enrollment was concluded with a smaller than planned cohort so that dosing could be completed ahead of the 2014-15 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. Development of our RSV F Vaccine for pediatrics would likely follow successful development of our RSV F Vaccine for maternal immunization.

## **Influenza**

### *Burden of Disease*

Influenza is a world-wide infectious disease that causes illness in humans ranging from mild to life-threatening symptoms 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 2012-13 season to \$5.3 billion by the 2021-22 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> One important advantage of recombinant seasonal influenza vaccines, like the candidate we are developing, is that once licensed for commercial sale, large quantities of such vaccine could potentially be manufactured quickly and in a cost-effective manner, without the use of either live influenza virus or eggs. Our recombinant influenza nanoparticles also can display conserved antigenic regions, which have the potential to elicit broadly neutralizing antibodies that appear to protect against a range of “drifted” strains, or influenza strains in which, over time, the hemagglutinin antigen undergoes an accumulation of genetic mutations at the hemagglutinin antigen sites that bind with neutralizing antibodies, potentially resulting in reduced protection of those antibodies. Additionally, nanoparticles offer improved purity and manufacturability and advantages for co-formulation with other nanoparticle-based vaccines.

<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

### *Clinical Trial Update*

In February 2018, we reported positive top-line results from our Phase 1/2 clinical trial of our nanoparticle seasonal trivalent influenza vaccine candidate, including our proprietary Matrix-M adjuvant (“NanoFlu™”), in older adults that was initiated in September 2017. The trial was a randomized, observer-blinded, active comparator-controlled trial in approximately 330 healthy older adults. The primary objective of the trial was to assess the safety and immunogenicity of two dose levels (15 micrograms or 60 micrograms of hemagglutinin per strain) of NanoFlu compared to Fluzone® High Dose, the market-leading licensed egg-based, high-dose influenza vaccine for older adults (“IIV3-HD”). NanoFlu was well tolerated and had an acceptable safety profile; short-term reactogenicity was comparable to IIV3-HD.<sup>26</sup> With regard to immunogenicity, NanoFlu induced:

· Significantly higher hemagglutination inhibition (“HAI”) immune responses as compared to IIV3-HD against the homologous and four generations of drifted wild-type A(H3N2) influenza strains:

· 28-38% increase in HAI against distant historic drifted A(H3N2) viruses A/Texas (the 2014-15 vaccine strain) and A/Victoria (the 2012-13 vaccine strain), respectively (p=0.0366; p=0.0058);

· 54% increase in HAI against recent historic drifted A(H3N2) virus A/Switzerland (the 2015-16 vaccine strain)(p=0.0065);

· 47% increase in HAI against the vaccine homologous A(H3N2) virus A/Hong Kong (the 2016-17 and 2017-18 vaccine strain)(p=0.0056); and

· 64% increase in HAI against forward drifted virus A(H3N2) virus A/Singapore (the future 2018-19 vaccine strain)(p=0.0009).

· Higher HAI antibody responses against the homologous A(H1N1) influenza strain and comparable HAI responses against the homologous B/Brisbane strain, as compared to IIV3-HD; and

· Strong neutralizing antibody responses that correlate with HAI results.

Overall, NanoFlu was well-tolerated over the three-week trial period. Given the strength of these trial results, we have submitted for publication in a peer-reviewed medical journal. Based on these results, we expect to begin a Phase 2 quadrivalent NanoFlu clinical trial in the third quarter of 2018.

### *Preclinical Analyses*



Preclinical data in which NanoFlu was compared in a head-to-head challenge study against IIV3-HD, as well as IIV3-SD (standard dose) seasonal influenza vaccine, was announced in August 2017 and provided a strong rationale for the initiation of the Phase 1/2 trial. Our NanoFlu demonstrated significantly stronger and broader immune responses (microneutralizing antibodies) against homologous and heterologous influenza strains, including a series of drifted H3N2 strains evolved across over more than a decade of influenza seasons, compared to IIV3-HD. In this preclinical challenge study, we showed that our NanoFlu was more protective than the licensed comparator vaccines against both a homologous H3N2 virus and a ten-year old drifted H3N2 strain. In parallel, we announced the achievement of significant improvements in manufacturing yields and product purity.

### **Combination Influenza/RSV 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. We remain confident that a combination nanoparticle vaccine against both RSV and influenza is feasible.

<sup>26</sup> Fluzone® High-Dose Prescribing Information, 02 March 2017 v0.1. Sanofi Pasteur, Swiftwater, PA

### ***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>27</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 positive 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 6.5 micrograms to 50 micrograms 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.

### **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***

Since 2016, CPLB has been marketing CadiFlu, its trivalent VLP influenza vaccine in India, with limited sales in 2017 and expected in 2018.

***Rabies***

In October 2016, CPLB initiated its Phase 3 clinical trial in India of a recombinant rabies G protein vaccine candidate 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). Data from the trial are expected in the second half of 2018.

**Sales of Common Stock**

In April 2018, we completed a public offering of 34,848,507 shares of our common stock, including 4,545,457 shares of common stock that were issued upon the exercise in full of the option to purchase additional shares granted to the underwriters, at a price of \$1.65 per share resulting in net proceeds of approximately \$54 million.

In December 2017, we entered into an At Market Issuance Sales Agreement (“December 2017 Sales Agreement”), which allows us to issue and sell up to \$75 million in gross proceeds of our common stock. From January 17, 2018 through March 31, 2018, we sold 15.7 million shares of common stock under the December 2017 Sales Agreement resulting in \$32.3 million in net proceeds at a weighted average sales price of \$2.09 per share. As of March 31, 2018, we have approximately \$42.2 million available under the December 2017 Sales Agreement.

<sup>27</sup> WHO: <http://www.who.int/mediacentre/factsheets/fs103/en/>

After giving effect to our public offering above, our pro forma cash, cash equivalents, marketable securities and restricted cash as of March 31, 2018 would have been \$218.1 million as shown below.

	Amount
Cash and cash equivalents	\$ 113,402
Marketable securities	30,358
Restricted cash current	19,548
Restricted cash non-current	891
Cash, cash equivalents, marketable securities and restricted cash at March 31, 2018	164,199
Public offering net proceeds in April 2018	53,907
Pro forma cash, cash equivalents, marketable securities and restricted cash	\$218,106

### ***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, 2017, as filed with the SEC, other than the adoption of the new revenue standard as described in Note 3.

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

See “Note 3 Summary of Significant Accounting Policies” included in our Notes to Consolidated Financial Statements (under the caption “*Recent Accounting Pronouncements*”).

### **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 unaudited financial statements and notes thereto set forth in this Quarterly Report.

**Three Months Ended March 31, 2018 and 2017** (amounts in tables are presented in thousands, except per share information)

**Revenue:****Three Months Ended****March 31,**

			<b>Change</b>
2018	2017		<b><u>2017 to</u></b>
			<b><u>2018</u></b>

Revenue:

Total revenue	\$9,653	\$5,680	\$ 3,973
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Revenue for the three months ended March 31, 2018 was \$9.7 million as compared to \$5.7 million for the same period in 2017, an increase of \$4.0 million, or 70%. Revenue for the three months ended March 31, 2018 and 2017 was primarily comprised of services performed under the Grant Agreement and to a much lesser extent, revenue from Novavax AB. Revenue increased under the Grant Agreement in the amount of \$3.8 million as a result of increased enrollment of participants in the Prepare trial.

We expect revenue in 2018 under the Grant Agreement to be higher than in 2017 due to increased enrollment of participants in Prepare, who we continue to monitor through scheduled follow-up visits.

**Expenses:**

	<b>Three Months Ended</b>		
	<b><u>March 31,</u></b>		
	2018	2017	<b>Change</b>
			<b><u>2017 to</u></b>
			<b><u>2018</u></b>
Expenses:			
Research and development	\$44,514	\$37,654	\$ 6,860
General and administrative	8,652	8,852	(200 )
Total expenses	\$53,166	\$46,506	\$ 6,660

***Research and Development Expenses***

Research and development expenses include salaries, stock-based compensation, laboratory supplies, consultants and subcontractors, including external contract research organizations, 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 related to research and development activities, are also included in research and development expenses. Research and development expenses increased to \$44.5 million for the three months ended March 31, 2018 from \$37.7 million for the same period in 2017, an increase of \$6.9 million, or 18%. The increase in research and development expenses was primarily due to increased development activities of our RSV F Vaccine for infants via maternal immunization. At March 31, 2018, we had 301 employees dedicated to our research and development programs versus 302 employees as of March 31, 2017. For 2018, we expect an increase in research and development expenses from 2017 primarily due to higher anticipated costs to support product development of our RSV F Vaccine 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.

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The following summarizes our research and development expenses by functional area for the three months ended March 31 (in millions):

	2018	2017
Manufacturing	\$19.8	\$18.9
Vaccine Discovery	1.6	1.5
Clinical and Regulatory	23.1	17.3
Total research and development expenses	\$44.5	\$37.7

We do not provide forward-looking estimates of costs and time to complete our research programs due to the many uncertainties associated with vaccine development. As we obtain data from preclinical studies and clinical trials, we may elect to discontinue or delay clinical trials in order to focus our resources on more promising vaccine candidates. Completion of clinical trials may take several years or more, but the length of time can vary substantially depending upon the phase, size of clinical trial, primary and secondary endpoints and the intended use of the vaccine candidate. The cost of clinical trials may vary significantly over the life of a project as a result of a variety of factors, including:

· the number of participants who participate in the clinical trials;  
· the number of sites included in the clinical trials;

if clinical trial locations are domestic, international or both;  
the time to enroll participants;  
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 slightly to \$8.7 million for the three months ended March 31, 2018 from \$8.9 million for the same period in 2017. At March 31, 2018, we had 50 employees dedicated to general and administrative functions versus 53 employees as of March 31, 2017. For 2018, we expect general and administrative expenses to slightly increase from 2017 primarily due to higher anticipated professional fees.

**Other Income (Expense):**

	<b>Three Months Ended</b>		
	<b><u>March 31,</u></b>		
	2018	2017	<b>Change</b>
			<b><u>2017 to</u></b>
			<b><u>2018</u></b>
Other Income (Expense):			
Investment income	\$531	\$474	\$ 57
Interest expense	(3,403)	(3,513)	110
Other income (expense)	33	11	22
Total other income (expense)	\$(2,839)	\$(3,028)	\$ 189

We had total other expense, net of \$2.8 million for the three months ended March 31, 2018 compared to total other expense, net of \$3.0 million for the same period in 2017, a decrease of \$0.2 million.

**Net Loss:**



**Three Months Ended  
March 31,**

	2018	2017	<b>Change 2017 to 2018</b>
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Net Loss:			
Net loss	\$(46,352 )	\$(43,854 )	\$(2,498 )
Net loss per share	\$(0.14 )	\$(0.16 )	\$0.02
Weighted shares outstanding	336,972	274,178	62,794

Net loss for three months ended March 31, 2018 was \$46.4 million, or \$0.14 per share, as compared to \$43.9 million, or \$0.16 per share, for the same period in 2017, an increased net loss of \$2.5 million. The increased net loss was primarily due to higher research and development spending, including increased development activities of our RSV F Vaccine for infants via maternal immunization, partially offset by increased revenue under the Grant Agreement.

The increase in weighted average shares outstanding for the three months ended March 31, 2018 is primarily a result of sales of our common stock in 2018 and 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 product candidates in various stages of development, and we believe our operating expenses and capital requirements will fluctuate depending upon the timing of events, such as the scope, initiation, rate and progress of our preclinical studies and clinical trials and other research and development activities. We have primarily funded our operations with proceeds from the sale of common stock in equity offerings, the issuance of convertible debt and revenue under our current Grant Agreement with BMGF and our former contract with HHS BARDA.

As of March 31, 2018, we had \$164.2 million in cash and cash equivalents, marketable securities and restricted cash as compared to \$186.4 million as of December 31, 2017. These amounts consisted of \$113.4 million in cash and cash equivalents, \$30.4 million in marketable securities and \$20.4 million in restricted cash as of March 31, 2018 as compared to \$106.3 million in cash and cash equivalents, \$51.0 million in marketable securities and \$29.1 million in restricted cash as of December 31, 2017.

The following table summarizes cash flows for the three months ended March 31, 2018 and 2017 (in thousands):

	<b>Three Months Ended</b>		<b>Change</b>
	<b><u>March 31,</u></b>		
	<b>2018</b>	<b>2017</b>	<b>2017 to</b>
			<b><u>2018</u></b>
Summary of Cash Flows:			
Net cash (used in) provided by:			
Operating activities	\$(66,075 )	\$(44,497 )	\$(21,578 )
Investing activities	20,587	(25,284 )	45,871
Financing activities	43,924	15,364	28,560
Effect on exchange rate on cash, cash equivalents and restricted cash	(26 )	31	(57 )
Net (decrease) increase in cash, cash equivalents and restricted cash	(1,590 )	(54,386 )	52,796
Cash, cash equivalents and restricted cash at beginning of period	135,431	179,257	(43,826)
Cash, cash equivalents and restricted cash at end of period	\$133,841	\$124,871	\$8,970

Net cash used in operating activities increased to \$66.1 million for the three months ended March 31, 2018, as compared to \$44.5 million for the same period in 2017. The increase in cash usage was primarily due to approximately \$16 million of one-time payments that included our lease termination fee and the Milestone to Wyeth along with the Company's annual bonus that was paid in the first quarter of 2018 whereas no such bonus was paid in the same period in 2017. As a result, we expect our cash used in operating activities to significantly decrease for the subsequent quarters of 2018 as compared to the first quarter of 2018. In addition, the adoption of ASU 2016-18, which requires restricted cash to be included in the beginning and ending balances above, has increased our cash used in operating activities by approximately \$9 million and \$6 million in the three months ended March 31, 2018 and 2017, respectively.

During the three months ended March 31, 2018 and 2017, our investing activities consisted primarily of purchases and maturities of marketable securities and capital expenditures. Capital expenditures for the three months ended March 31, 2018 and 2017 were \$0.2 million and \$1.1 million, respectively. The decrease in capital expenditures was primarily due to the timing of purchases of laboratory equipment and systems based on our current operating plans. In 2018, we expect our level of capital expenditures to be consistent with our 2017 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, and to a much lesser extent, stock option exercises and purchases under our employee stock purchase plan. In the three months ended March 31, 2018, we received net proceeds of \$42.6 million from selling shares of common stock through our January 2017 and December 2017 Sales Agreements at a weighted average sales price of \$1.93 per share. In the three months ended March 31, 2017, we received net proceeds of \$14.6 million from selling shares of common stock through our January 2017 Sales Agreements at a weighted average sales price of \$1.43 per share. In April 2018, we completed a public offering of 34,848,507 shares of our common stock at a price of \$1.65 per share resulting in net proceeds of approximately \$54 million.

In May 2016, we entered into a new lease for a facility located in Gaithersburg, Maryland and under the terms of the lease the landlord provided us with a tenant improvement allowance of up to \$9.6 million, and \$1.2 million was funded through the lease termination. In January 2018, this new lease was terminated and we paid a termination fee to the landlord of \$5.3 million in the first quarter of 2018, which we believe is less than the potential total lease and operating expense cash obligations that could have been incurred over one year.

In April 2018, we provided written notice of our intent to terminate (90 days after such notice) a 2007 agreement to license certain rights from Wyeth Holdings LLC (formerly Wyeth Holdings Corporation), a subsidiary of Pfizer Inc. (“Wyeth”). The Wyeth license offered 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. At present, we have no programs to which the Wyeth license applies and CPLB’s recombinant trivalent seasonal VLP influenza vaccine (“CadiFlu”) is only being marketed in India. In September 2015, we entered into an amendment to the Wyeth license that, among other things, increased the milestone payment owed as a result of CPLB’s initiation of a Phase 3 clinical trial for CadiFlu in 2014 (“Milestone”) from \$3 million to as much as \$4 million if not paid before December 31, 2017. The Milestone was paid in the first quarter of 2018. The Milestone was recorded as a research and development expense in 2014. Payments under the Wyeth license as of March 31, 2018 aggregated to \$11.6 million.

Based on our most recent cash flow forecast, we believe our current capital, along with anticipated revenue under the Grant Agreement and the proceeds from the public offering of our common stock in April 2018, is sufficient 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 March 31, 2018, we had cash and cash equivalents of \$113.4 million, marketable securities of \$30.4 million, all of which are short-term in nature, and working capital of \$136.1 million.

Our exposure to market risk is primarily confined to our investment portfolio. As of March 31, 2018, 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 decline of stockholders' deficit of approximately \$2.9 million at March 31, 2018.

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 March 31, 2018. 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 March 31, 2018, 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 March 31, 2018, and has concluded that there was no change that occurred during the quarterly period ended March 31, 2018 that materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

**PART II. OTHER INFORMATION**

**Item 1A. Risk Factors**

There are no material changes to the Company's risk factors as described in Item 1A of the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2017.

**Item 5. Other Information**

None

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**Item 6. Exhibits**

- 3.1 Second Amended and Restated Certificate of Incorporation of the Company (Incorporated by reference to Exhibit 3.1 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2015, filed August 10, 2015)
- 3.2 Amended and Restated By-Laws of the Company (Incorporated by reference to Exhibit 3.2 to the Company's Annual Report on Form 10-K for the year ended December 31, 2012, filed March 12, 2013)
- 31.1\* Certification of Chief Executive Officer pursuant to Rule 13a-14(a) or 15d-14(e) of the Securities Exchange Act
- 31.2\* Certification of Chief Financial Officer pursuant to Rule 13a-14(a) or 15d-14(e) of the Securities Exchange Act
- 32.1\* Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
- 32.2\* Certification of Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

101 The following financial information from our Quarterly Report on Form 10-Q for the quarter ended March 31, 2018, formatted in Extensible Business Reporting Language (XBRL): (i) the Consolidated Balance Sheets as of March 31, 2018 and December 31, 2017, (ii) the Consolidated Statements of Operations for the three-month periods ended March 31, 2018 and 2017, (iii) the Consolidated Statements of Comprehensive Loss for the three-month periods ended March 31, 2018 and 2017, (iv) the Consolidated Statements of Cash Flows for the three-month periods ended March 31, 2018 and 2017, 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: May 9, 2018 By: /s/ Stanley C. Erck  
President and Chief Executive Officer  
and Director  
(Principal Executive Officer)

Date: May 9, 2018 By: /s/ John J. Trizzino  
Senior Vice President, Chief Business Officer, Chief Financial Officer and Treasurer  
(Principal Financial and Accounting Officer)