

NOVAVAX INC  
Form 10-Q  
May 02, 2019

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, 2019**

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> (State or other jurisdiction of incorporation or organization)	<b>22-2816046</b> (I.R.S. Employer Identification No.)
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<b>20 Firstfield Road, Gaithersburg, MD</b> (Address of principal executive offices)	<b>20878</b> (Zip code)
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**(240) 268-2000**

(Registrant's telephone number, including area code)

**Securities registered pursuant to Section 12(b) of the Act:**

Title of each class	Trading	Name of each exchange on which registered
	Symbol(s)	
Common Stock, Par Value \$0.01 per share	NVAX	The Nasdaq Global Select Market

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 every Interactive Data File required to be submitted 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 such files). Yes x No

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

Large accelerated filer      " Accelerated filer                      x

Non-accelerated filer      " Smaller reporting company x

Emerging growth company "

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided 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

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The number of shares outstanding of the Registrant's Common Stock, \$0.01 par value, was 469,453,883 as of April 25, 2019.

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, 2019 (unaudited)	December 31, 2018
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$97,711	\$ 70,154
Marketable securities	2,484	21,980
Restricted cash	6,628	10,847
Prepaid expenses and other current assets	16,571	16,295
Total current assets	123,394	119,276
Restricted cash	1,860	958
Property and equipment, net	26,972	28,426
Intangible assets, net	6,114	6,541
Goodwill	51,245	51,967
Other non-current assets	11,734	810
Total assets	\$221,319	\$ 207,978
<b>LIABILITIES AND STOCKHOLDERS' DEFICIT</b>		
Current liabilities:		
Accounts payable	\$6,150	\$ 9,301
Accrued expenses	13,881	19,550
Accrued interest	2,031	5,078
Deferred revenue	5,943	10,010
Other current liabilities	3,491	1,600
Total current liabilities	31,496	45,539
Deferred revenue	3,399	2,500
Convertible notes payable	319,543	319,187
Other non-current liabilities	17,464	8,687
Total liabilities	371,902	375,913
Commitments and contingencies		

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Stockholders' deficit:

Preferred stock, \$0.01 par value, 2,000,000 shares authorized; no shares issued and outstanding as of March 31, 2019 and December 31, 2018, respectively	—	—
Common stock, \$0.01 par value, 600,000,000 shares authorized at March 31, 2019 and December 31, 2018; 469,909,313 shares issued and 469,453,883 shares outstanding at March 31, 2019 and 384,906,037 shares issued and 384,450,607 shares outstanding at December 31, 2018	4,699	3,849
Additional paid-in capital	1,201,853	1,140,964
Accumulated deficit	(1,342,325)	(1,299,107 )
Treasury stock, 455,430 shares, cost basis at both March 31, 2019 and December 31, 2018	(2,450 )	(2,450 )
Accumulated other comprehensive loss	(12,360 )	(11,191 )
Total stockholders' deficit	(150,583 )	(167,935 )
Total liabilities and stockholders' deficit	\$221,319	\$ 207,978

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

NOVAVAX, INC.

## CONSOLIDATED STATEMENTS OF OPERATIONS

(in thousands, except per share information)

(unaudited)

	<b>For the Three Months</b>	
	<b>Ended March 31,</b>	
	2019	2018
Revenue:		
Grant and other	\$ 3,982	\$ 9,653
Total revenue	3,982	9,653
Expenses:		
Research and development	35,473	44,514
General and administrative	8,732	8,652
Total expenses	44,205	53,166
Loss from operations	(40,223 )	(43,513 )
Other income (expense):		
Investment income	420	531
Interest expense	(3,403 )	(3,403 )
Other income (expense)	(12 )	33
Net loss	\$(43,218 )	\$(46,352 )
Basic and diluted net loss per share	\$(0.11 )	\$(0.14 )
Basic and diluted weighted average number of common shares outstanding	408,843	336,972

## CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

(in thousands)

(unaudited)

**For the Three Months****Ended March 31,**

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	2019	2018
Net loss	\$ (43,218 )	\$ (46,352 )
Other comprehensive income (loss):		
Net unrealized gains on marketable debt securities available-for-sale	5	8
Foreign currency translation adjustment	(1,174 )	(462 )
Other comprehensive loss	(1,169 )	(454 )
Comprehensive loss	\$ (44,387 )	\$ (46,806 )

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



NOVAVAX, INC.

## CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' DEFICIT

Three Months Ended March 31, 2019 and 2018

(unaudited)

	Common Stock Shares	Common Stock Amount	Additional Paid-in Capital	Accumulated Deficit	Treasury Stock	Other Comprehensive Income(Loss)	Stockholders' Equity (Deficit)
(in thousands, except share information)							
Balance at December 31, 2018	384,906,037	\$ 3,849	\$ 1,140,964	\$(1,299,107 )	\$(2,450 )	\$( 11,191 )	\$(167,935 )
Non-cash compensation cost for stock options, RSUs and ESPP	—	—	5,558	—	—	—	5,558
Exercise of stock options/Purchases under ESPP	1,027,753	10	932	—	—	—	942
Issuance of common stock, net of issuance costs of \$1,115	83,975,523	840	54,399	—	—	—	55,239
Unrealized gain on marketable securities	—	—	—	—	—	5	5
Foreign currency translation adjustment	—	—	—	—	—	(1,174 )	(1,174 )
Net loss	—	—	—	(43,218 )	—	—	(43,218 )
Balance at March 31, 2019	469,909,313	\$ 4,699	\$ 1,201,853	\$(1,342,325 )	\$(2,450 )	\$( 12,360 )	\$(150,583 )
Balance at December 31, 2017	323,684,820	\$ 3,237	\$ 1,020,457	\$(1,114,359 )	\$(2,450 )	\$( 8,617 )	\$(101,732 )
Non-cash compensation cost for stock options, ESPP and restricted stock	—	—	5,245	—	—	—	5,245
Exercise of stock options/Purchases under ESPP	1,108,210	11	1,314	—	—	—	1,325
Restricted stock cancelled	(18,750 )	—	—	—	—	—	—
Issuance of common stock, net of issuance costs of \$607	22,430,136	224	42,375	—	—	—	42,599
	—	—	—	—	—	8	8

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Unrealized gain on marketable securities								
Foreign currency translation adjustment	—	—	—	—	—	(462	)	(462 )
Net loss	—	—	—	(46,352	)	—	—	(46,352 )
Balance at March 31, 2018	347,204,416	\$3,472	\$1,069,391	\$(1,160,711)	\$(2,450)	\$(9,071	)	\$(99,369 )

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>March 31,</b>	
	2019	2018
Operating Activities:		
Net loss	\$ (43,218 )	\$ (46,352 )
Reconciliation of net loss to net cash used in operating activities:		
Depreciation and amortization	1,939	2,079
Loss (Gain) on disposal of property and equipment	88	(47 )
Non-cash impact of lease termination	—	(4,381 )
Amortization of debt issuance costs	356	356
Non-cash stock-based compensation	5,558	5,245
Other	(14 )	(435 )
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	(296 )	—
Accounts payable and accrued expenses	(11,853 )	(13,293 )
Deferred revenue	(3,167 )	(9,247 )
Net cash used in operating activities	(50,607 )	(66,075 )
Investing Activities:		
Capital expenditures	(805 )	(150 )
Proceeds from maturities of marketable securities	22,000	22,721
	(2,484 )	(1,984 )

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Purchases of marketable securities				
Net cash provided by investing activities		18,711		20,587
Financing Activities:				
Net proceeds from sales of common stock		55,239		42,599
Proceeds from the exercise of stock options and employee stock purchases		942		1,325
Net cash provided by financing activities		56,181		43,924
Effect of exchange rate on cash, cash equivalents and restricted cash		(45 )		(26 )
Net increase (decrease) in cash, cash equivalents and restricted cash		24,240		(1,590 )
Cash, cash equivalents and restricted cash at beginning of period		81,959		135,431
Cash, cash equivalents and restricted cash at end of period	\$	106,199	\$	133,841
Supplemental disclosure of non-cash activities:				
Property and equipment purchases included in accounts payable and accrued expenses	\$	194	\$	62
Supplemental disclosure of cash flow information:				
Cash payments of interest	\$	6,094	\$	6,094

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

NOVAVAX, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

March 31, 2019

(unaudited)

Note 1 – Organization

Novavax, Inc. (“Novavax,” and together with its wholly owned subsidiary, Novavax AB, the “Company”) is a late-stage biotechnology company focused on the discovery, development and commercialization of innovative vaccines to prevent serious infectious diseases. The Company’s vaccine candidates, including ResVax™ and NanoFlu™, are genetically engineered, three-dimensional nanostructures of 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 technology targets a variety of infectious diseases.

Note 2 – Going Concern

The accompanying unaudited consolidated financial statements have been prepared assuming that the Company will continue as a going concern within one year after the date that the financial statements are issued. During 2018, the Company incurred a net loss of \$184.7 million and had net cash flows used in operating activities of \$184.8 million. At March 31, 2019, the Company had \$108.7 million in cash and cash equivalents, marketable securities and restricted cash and had no committed source of additional funding from either debt or equity financings. Management believes that given the Company’s current cash position and forecasted negative cash flows from operating activities over the next twelve months as it continues its product development activities, including its potential ResVax submission of a Biologics License Application (“BLA”) with the U.S. Food and Drug Administration (“FDA”) and/or a Marketing Authorization Application (“MAA”) with the European Medicines Agency in 2020, and its planned Phase 3 clinical trial of NanoFlu following discussions with the FDA in the third quarter of 2019, there is substantial doubt about its ability to continue as a going concern through one year from the date that these financial statements are issued, without obtaining additional financing or entering into another form of non-equity or debt arrangement.

The Company’s ability to fund its operations is dependent upon management’s plans, which include raising additional capital in the near term primarily through 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. New financings may not be available to the Company on commercially acceptable terms, or at all. Also, any collaborations, strategic

alliances and marketing, distribution or licensing arrangements may require the Company to give up some or all of its rights to a product or technology, which in some cases may be at less than the full potential value of such rights. If the Company is unable to 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 research and development programs, and/or downsize its organization.

The unaudited consolidated financial statements do not include any adjustments that might be necessary if the Company is not able to continue as a going concern.

Note 3 – Summary of Significant Accounting Policies

***Basis of Presentation***

The accompanying unaudited consolidated financial statements have been prepared in accordance with generally accepted accounting principles 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, 2019, the consolidated statements of operations and the consolidated statements of comprehensive loss for the three months ended March 31, 2019 and 2018, the consolidated statements of changes in stockholders’ deficit for the three months ended March 31, 2019 and 2018 and the consolidated statements of cash flows for the three months ended March 31, 2019 and 2018 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, changes in stockholders’ deficit and cash flows, respectively, for the periods presented. Although the Company believes that the disclosures in these unaudited consolidated financial statements are adequate to make the information presented not misleading, certain information and footnote information normally included in consolidated financial statements prepared in accordance with U.S. GAAP have been condensed or omitted as permitted under the rules and regulations of the United States Securities and Exchange Commission (“SEC”).

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

The accompanying unaudited consolidated financial statements are presented in U.S. dollars. The functional currency of Novavax AB, which is located in Sweden, is the local currency (Swedish Krona). The translation of assets and liabilities of Novavax AB to U.S. dollars is made at the exchange rate in effect at the consolidated balance sheet date, while equity accounts are translated at historical rates. The translation of the statement of operations data is made at the average exchange rate in effect for the period. The translation of operating cash flow data is made at the average exchange rate in effect for the period, and investing and financing cash flow data is translated at the exchange rate in effect at the date of the underlying transaction. Translation gains and losses are recognized as a component of accumulated other comprehensive loss in the accompanying unaudited consolidated balance sheets. The foreign currency translation adjustment balance included in accumulated other comprehensive loss was \$12.4 million and \$11.2 million at March 31, 2019 and December 31, 2018, 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, 2018. 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 U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the consolidated financial statements and the reported amounts of revenue and expenses during the reporting period. Actual results could differ materially from 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>December 31,</b>
	<b>2019</b>	<b>2018</b>
Cash	\$ 9,370	\$ 6,750
Money market funds	49,113	39,168
Asset-backed securities	15,000	15,000
Corporate debt securities	24,228	9,236
Cash and cash equivalents	\$ 97,711	\$ 70,154

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



## Marketable Securities

Marketable securities consist of debt securities with maturities greater than three months from the date of purchase 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 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 (as defined in Note 11) with the Bill & Melinda Gates Foundation ("BMGF") under which the Company was awarded a grant up to \$89.1 million 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, 2019 and December 31, 2018, the restricted cash balances (both current and non-current) consist of payments received under the Grant Agreement of \$7.5 million and \$10.8 million, respectively, and security deposits of \$1.0 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>December 31,</b>
	<b>2019</b>	<b>2018</b>
Cash and cash equivalents	\$ 97,711	\$ 70,154
Restricted cash current	6,628	10,847
Restricted cash non-current	1,860	958
Cash, cash equivalents and restricted cash	\$ 106,199	\$ 81,959

#### Revenue Recognition

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 11). 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 for infants via maternal immunization ("ResVax"). 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 ResVax 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 Accounting Standards Update ("ASU") 2014-09, *Revenue from Contracts with Customers (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 with BMGF to determine whether the payments received should be recorded as revenue or as a reduction to research and development expenses. In reaching the determination that such payments should be recorded as revenue, 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.

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

Net loss per share is computed using the weighted average number of shares of common stock outstanding. At March 31, 2019 and 2018, the Company had outstanding stock options and unvested restricted stock units ("RSUs") totaling 61,260,970 and 45,126,499, respectively. At March 31, 2019, the Company's Notes (see Note 8) would have been convertible into approximately 47,716,900 shares of the Company's common stock assuming a common stock price of \$6.81 or higher. 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 February 2016, the Financial Accounting Standards Board ("FASB") issued ASU 2016-02, *Leases (Topic 842)*, subsequently amended in 2018 by ASU 2018-01, ASU 2018-10, ASU 2018-11 and ASU 2018-20 (collectively, "Topic 842"), that increases transparency and comparability among organizations by requiring the recognition of right-of-use

assets and lease liabilities on the balance sheet and disclosure of key information about leasing arrangements for both lessees and lessors. Leases will be classified as either finance or operating, with classification affecting the pattern of expense recognition in the income statement. In connection with the adoption of Topic 842, the Company conducted reviews of its facility and equipment operating leases and assessed contracts that may contain a right-of-use asset or embedded leasing arrangement.

The Company adopted Topic 842 on January 1, 2019 under the optional transition method, which does not require restatement of prior periods. The Company elected the package of practical expedients permitted under the transition guidance, which allowed the Company to carryforward its historical lease classification, its assessment of whether a contract is or contains a lease and its initial direct costs for any leases that existed prior to adoption of the standard. The Company also elected to combine lease and non-lease components for its facility leases and to exclude leases with an initial term of 12 months or less from its consolidated balance sheet and recognize the associated lease payments in its consolidated statements of operations on a straight-line basis over the lease term. The Company's equipment leases had a remaining term of 12 months or less at the adoption date.

The Company recorded approximately \$12 million in total right-of-use assets, net of the deferred rent liability, and approximately \$22 million in total lease liabilities on its consolidated balance sheet as of January 1, 2019. Adoption of the standard did not materially impact its consolidated statements of cash flows or results of operations.

Not Yet Adopted

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

**Note 4 – Fair Value Measurements**

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

	Fair Value at March 31, 2019			Fair Value at December 31, 2018		
	Level 1	Level 2	Level 3	Level 1	Level 2	Level 3
<u>Assets</u>						
Money market funds(1)	\$ 49,113	\$	\$	\$ 39,168	\$	\$
Asset-backed securities(2)		15,000			19,997	
Corporate debt securities(3)		26,712			26,219	
Total assets	\$ 49,113	\$ 41,712	\$	\$ 39,168	\$ 46,216	\$
<u>Liabilities</u>						
Convertible notes payable	\$	\$ 117,267	\$	\$	\$ 197,935	\$

(1) Classified as cash and cash equivalents as of March 31, 2019 and December 31, 2018, respectively, on the consolidated balance sheets.

(2) Includes \$15,000 classified as cash and cash equivalents as of both March 31, 2019 and December 31, 2018 on the consolidated balance sheets.

(3)

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Includes \$24,228 and \$9,236 classified as cash and cash equivalents as of March 31, 2019 and December 31, 2018, respectively, on the consolidated balance sheet.

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 8) 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 when there is sufficient volume of trading. 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, 2019 and 2018, the Company did not have any transfers between levels.

The amount recorded in the Company's unaudited consolidated balance sheets for accounts payable and accrued expenses 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, 2019 and December 31, 2018 were comprised of (in thousands):

	March 31, 2019				December 31, 2018			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Asset-backed securities	\$—	\$	— \$	— \$	\$4,999	\$	— \$	(2 ) \$ 4,997
Corporate debt securities	2,484	—	—	2,484	16,986	—	(3 )	16,983
Total	\$2,484	\$	— \$	— \$ 2,484	\$21,985	\$	— \$	(5 ) \$ 21,980

**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.

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

The change in the carrying amounts of goodwill for the three months ended March 31, 2019 was as follows (in thousands):

	Amount
Balance at December 31, 2018	\$51,967
Currency translation adjustments	(722 )
Balance at March 31, 2019	\$51,245

**Identifiable Intangible Assets**

Purchased intangible assets consisted of the following as of March 31, 2019 and December 31, 2018 (in thousands):

	March 31, 2019			December 31, 2018		
	<b>Gross Carrying Amount</b>	<b>Accumulated Amortization</b>	<b>Intangible Assets, Net</b>	<b>Gross Carrying Amount</b>	<b>Accumulated Amortization</b>	<b>Intangible Assets, Net</b>
Finite-lived intangible assets:						
Proprietary adjuvant technology	\$8,026	\$ (2,274 )	\$ 5,752	\$8,357	\$ (2,263 )	\$ 6,094
Collaboration agreements	3,624	(3,262 )	362	3,773	(3,326 )	447
Total identifiable intangible assets	\$11,650	\$ (5,536 )	\$ 6,114	\$12,130	\$ (5,589 )	\$ 6,541

Amortization expense for the three months ended March 31, 2019 and 2018 was \$0.2 million.



Estimated amortization expense for existing intangible assets for the remainder of 2019 and for each of the five succeeding years ending December 31 will be as follows (in thousands):

Year	Amount
2019 (remainder)	\$ 505
2020	560
2021	401
2022	401
2023	401
2024	401

#### Note 7 – Leases

The Company has operating leases for its research and development and manufacturing facilities, corporate headquarters and offices and certain equipment. The operating leases have expirations that range from 1 year to 8 years, some of which include options to extend the leases or terminate the leases early. Options to extend the leases or terminate the leases early are only included in the lease term when it is reasonably certain that the option will be exercised. The facility leases contain provisions for future rent increases, and obligate the Company to pay building operating costs.

The operating leases represent the right to obtain substantially all of the economic benefits from use of the identified asset and the right to direct the use of the asset and are capitalized as right of use (“ROU”) assets for the expected lease term (net of the deferred rent liability) with corresponding lease liabilities representing the obligation to make lease payments arising from the lease.

Supplemental balance sheet information related to leases as of March 31, 2019 was as follows (in thousands, except weighted-average remaining lease term and discount rate):

Lease Assets and Liabilities	Classification	Amount
Assets:		
Operating lease ROU assets	Other non-current assets	\$11,049
Liabilities:		
Current operating lease liabilities	Other current liabilities	\$3,491
Non-current operating lease liabilities	Other non-current liabilities	17,396
Total operating lease liabilities		\$20,887

Weighted-average remaining lease term (years)	5.58
Weighted-average discount rate	15.25 %

Lease expense for the operating and short-term leases for the three months ended March 31, 2019 was as follows (in thousands):

	Amount
Operating lease expense	\$ 1,265
Short-term lease expense	170
Total lease expense	\$ 1,435

Supplemental cash flow information related to leases for the three months ended March 31, 2019 was as follows (in thousands):

	Amount
Cash paid for amounts included in the measurement of operating lease liabilities	\$1,646
ROU assets obtained in exchange for operating lease obligations	11,893

As of March 31, 2019, maturities of lease liabilities were as follows (in thousands):

Year	Amount
2019 (remainder)	\$ 5,008
2020	5,311
2021	5,292
2022	5,409
2023	4,919
Thereafter	5,754
Total operating lease payments	31,693
Less: imputed interest	(10,806)
Total operating lease liabilities	\$ 20,887

During the three months ended March 31, 2019, the Company did not enter into any additional operating or finance leases. In April 2019, the Company extended the lease at its Rockville, MD facility to expire in January 2024. Under the amended lease, the Company will pay approximately \$1.7 million per year in base rent, which was not included in the Company's operating lease liabilities as of March 31, 2019 as the Company was not reasonably certain that the option would be exercised.

## Note 8 – 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):

**March 31,    December 31,**

	<b>2019</b>	<b>2018</b>
Principal amount of the Notes	\$ 325,000	\$ 325,000
Unamortized debt issuance costs	(5,457 )	(5,813 )
Total convertible notes payable	\$ 319,543	\$ 319,187

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

	<b>Three Months Ended</b>	
	<b>March 31,</b>	
	2019	2018
Coupon interest at 3.75%	\$ 3,047	\$ 3,047
Amortization of debt issuance costs	356	356
Total interest expense on the Notes	\$ 3,403	\$ 3,403

#### **Note 9 – Stockholders’ Deficit**

The Company will seek approval to effect a reverse stock split of its issued and outstanding common stock at a ratio of 1-for-20 at its May 8, 2019 special meeting of its stockholders.

In December 2018, the Company entered into an At Market Sales Agreement (“December 2018 Sales Agreement”), which allows it to issue and sell up to \$100 million in gross proceeds of its common stock. During the first quarter of 2019, the Company sold 33.6 million shares of common stock under the December 2018 Sales Agreement resulting in \$17.4 million in net proceeds at a weighted average sales price of \$0.53 per share, leaving \$82.2 million remaining available to be sold.

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. During the first quarter of 2019, the Company sold 50.3 million shares of common stock under the December 2017 Sales Agreement resulting in \$37.9 million in net proceeds at a weighted average sales price of \$0.77 per share. The December 2017 Sales Agreement was fully utilized at that time. During the first quarter of 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.

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. During the first quarter of 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 per share. The January 2017 Sales Agreement was fully utilized at that time.

## **Note 10 – 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 56,000,000 shares of common stock under equity awards granted under the plan. All such shares authorized for issuance under the 2015 Plan have been reserved. The 2015 Plan will expire on March 4, 2025.

The 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 one 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, 2019:

	2015 Plan		2005 Plan	
	Stock Options	Weighted-Average Exercise Price	Stock Options	Weighted-Average Exercise Price
Outstanding at January 1, 2019	47,856,238	\$ 3.12	11,653,372	\$ 3.29
Granted	196,060	\$ 1.78	—	\$ —
Exercised	(30,267 )	\$ 1.37	(30,000 )	\$ 0.56
Canceled	(915,624 )	\$ 4.81	(433,400 )	\$ 4.63
Outstanding at March 31, 2019	47,106,407	\$ 3.08	11,189,972	\$ 3.24
Shares exercisable at March 31, 2019	17,762,576	\$ 4.70	11,189,972	\$ 3.24
Shares available for grant at March 31, 2019	5,576,007			

The fair value of stock options granted under the 2015 Plan was estimated at the date of grant using the Black-Scholes option-pricing model with the following assumptions:

	Three Months Ended	
	March 31, 2019	2018
Weighted-average Black-Scholes fair value of stock options granted	\$1.38	\$1.50
Risk-free interest rate	2.43%-2.55%	2.26%-2.54%
Dividend yield	0%	0%
Volatility	111.65%-126.76%	113.98%-114.12%
Expected term (in years)	4.06-4.50	4.12-4.14
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, 2019 was \$0 million and 7.4 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, 2019 was \$0 million and 5.8 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, 2019. This amount is subject to change based on changes to the closing price of the Company's common stock. The aggregate intrinsic value of options exercised for the three months ended March 31, 2019 and 2018 was \$0.1 million and \$0.3 million, respectively.

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

The Employee Stock Purchase Plan, as amended (the "ESPP"), was approved at the Company's annual meeting of stockholders in June 2013. The ESPP currently authorizes an aggregate of 7,950,000 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 8,000,000 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, 2019, there were 2,745,580 shares available for issuance under the ESPP.



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

	<b>Three Months Ended</b>	
	<b>March 31,</b> 2019	2018
Range of Black-Scholes fair value of ESPP shares granted	\$0.36-\$1.74	\$0.45-\$3.53
Risk-free interest rate	1.20%-2.50%	0.66%-1.79%
Dividend yield	0%	0%
Volatility	52.19%-171.60%	59.84%-203.83%
Expected term (in years)	0.5-2.0	0.5-2.0
Expected forfeiture rate	0%	0%

### ***Restricted Stock Units***

The following is a summary of restricted stock units activity for the three months ended March 31, 2019:

	<b>Number of Shares</b>	<b>Per Share Weighted- Average Grant-Date Fair Value</b>
Outstanding and Unvested at January 1, 2019		\$
Restricted stock units granted	2,964,591	\$ 0.52
Restricted stock units vested		\$
Restricted stock units forfeited		\$
Outstanding and Unvested at March 31, 2019	2,964,591	\$ 0.52

During the three months ended March 31, 2019, the Company granted 3.0 million restricted stock units, of which 1.3 million contain performance-based vesting requirements associated with the development of its vaccine candidates.

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

**Three Months Ended**

	<b>March 31,</b>	
	2019	2018
Research and development	\$ 3,179	\$ 3,098
General and administrative	2,379	2,147
Total stock-based compensation expense	\$ 5,558	\$ 5,245

As of March 31, 2019, there was approximately \$41 million of total unrecognized compensation expense related to unvested stock options, restricted stock units and the ESPP. This unrecognized non-cash compensation expense is expected to be recognized over a weighted-average period of 1.5 years, and will be allocated between research and development and general and administrative expenses accordingly. This estimate does not include the impact of other possible stock-based awards that may be made during future periods.

## **Note 11 – Grant Agreement**

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

In support of the Company's development of ResVax, in September 2015, the Company entered into the grant agreement with BMGF (the "Grant Agreement"), 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 WHO prequalification of ResVax. 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 ResVax 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 Agreement are restricted as to their use until expenditures contemplated in the Grant Agreement are incurred. During the three months ended March 31, 2019, the Company recognized revenue from the Grant of \$3.2 million, and has recognized approximately \$76 million in revenue since the inception of the agreement. At March 31, 2019, 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 12 – 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 ResVax and other professional services. The agreement has been extended to terminate in July 2019. For the three months ended March 31, 2019 and 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, 2019 was \$0.1 million and at December 31, 2018 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 2018 Sales Agreement (defined below); 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; our expectations with respect to the anticipated ongoing development and potential commercialization or licensure of ResVax; the expected timing and content of regulatory actions; payments by the Bill & Melinda Gates Foundation ("BMGF"); our available cash resources and usage and the availability of financing generally, plans regarding partnering activities, business development initiatives; the adoption of stock incentive plans and amendments thereto; our proposed reverse stock split of our common stock at a ratio of 1-for-20 and its expected impact on the trading price of our common stock 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," "would," or "assume" or the negative of these terms, or other comparable terminology, although not all forward-looking statements contain these words.

Forward-looking statements involve estimates, assumptions and uncertainties that could cause actual results to differ materially from those expressed or implied in the statements. Any or all of our forward-looking statements in this Quarterly Report may turn out to be inaccurate or materially different from 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, 2018, 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" of this Quarterly Report and in Part I, Item 1A "Risk Factors" of our Annual Report on Form 10-K. 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 late-stage biotechnology company focused on the discovery, development and commercialization of innovative vaccines to prevent serious infectious diseases. Our vaccine candidates, including our lead candidates, ResVax™ and NanoFlu™, are genetically engineered, three-dimensional nanostructures of 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 technology targets a variety of infectious diseases. 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 has been well-tolerated in multiple clinical trials.

## Product Pipeline

<b>Program</b>	<b>Current Development Stage</b>
<b>Respiratory Syncytial Virus (“RSV”)</b>	
·ResVax* (Infants via Maternal Immunization)	Phase 3
·Older Adults	Phase 2
·Pediatrics	Phase 1
<b>Seasonal Influenza</b>	
·NanoFlu (Older Adults)	Phase 2
<b>Combination Seasonal Influenza/RSV</b>	Preclinical

\*Supported by a grant of up to \$89.1 million from BMGF

A summary and status of these vaccine programs follows:

### Respiratory Syncytial Virus (RSV)

Currently, there is no approved RSV vaccine available to combat the estimated 64 million RSV infections that occur globally each year. We have identified three susceptible target populations that we believe could benefit from the

development of our respiratory syncytial virus fusion (F) protein nanoparticle vaccine candidate (“RSV F Vaccine”) in different formulations: (1) infants via maternal immunization, (2) older adults (60 years and older) and (3) children six months to five years old (“pediatrics”). With our current estimates of the annual global cost burden of RSV in excess of \$88 billion, we believe our RSV F Vaccine represents a multi-billion dollar worldwide opportunity.

***ResVax Program (Infants via Maternal Immunization)***

ResVax is our adjuvanted RSV F Vaccine for infants via maternal immunization. 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. 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.

In February 2019, we announced top-line data from the Prepare trial, which we initiated in December 2015 to determine the efficacy of ResVax against medically significant RSV-positive lower respiratory tract infection (“LRTI”) in infants through a minimum of the first 90 days of life and up through the first six months of life. While the Prepare trial did not meet its pre-specified primary efficacy endpoint, it did demonstrate efficacy against one of the secondary objectives (RSV LRTI hospitalizations), the first RSV vaccine to show efficacy in a Phase 3 clinical trial. In addition, in the Prepare trial, other pre-specified exploratory endpoints and post-hoc analyses highlight ResVax’ potential to improve global health against RSV disease in this vulnerable population. Like previous clinical trials, ResVax showed a favorable safety and tolerability profile from the Prepare trial. With these results, we plan to meet with the U.S. Food and Drug Administration (“FDA”) and certain European regulatory agencies, including the European Medicines Agency (“EMA”) later in 2019, to discuss and assess opportunities for submitting a Biologics License Application (“BLA”) with the FDA and/or a Marketing Authorization Application (“MAA”) with the EMA, in 2020. We are also considering seeking licensure strategically in a number of geographic regions, other than the U.S. and Europe, where the Prepare results support such efforts. The development of ResVax and the conduct of the Prepare trial are supported by a grant of up to \$89.1 million from BMGF for development activities, product licensing efforts and WHO prequalification of ResVax.



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

Older adults (60 years and older) are at increased risk for RSV disease due in part to immunosenescence, the age-related decline in the human immune system. RSV infection can also lead to exacerbation of underlying co-morbidities such as chronic obstructive pulmonary disease, asthma and congestive heart failure. In the U.S. alone, a reported RSV incidence rate of 5.5% in older adults would account for approximately 2.5 million infections per year. We estimate that approximately 900,000 medical interventions are caused by RSV disease in this U.S. population each year. In our 2017 Phase 2 clinical trial of our RSV F Vaccine in older adults, we assessed safety and immunogenicity of one and two dose regimens of our RSV F Vaccine, with and without aluminum phosphate or our proprietary Matrix-M adjuvant. Immunogenicity results indicate that both adjuvants increase the magnitude, duration and quality of the immune response versus the non-adjuvanted RSV F Vaccine. The 2016 Phase 3 clinical trial of our RSV F Vaccine failed to meet its pre-specified primary or secondary efficacy objectives and did not demonstrate vaccine efficacy. We are currently assessing the development opportunities for our RSV F Vaccine in older adults in the United States.

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

By the age of five, essentially all children will have been exposed to RSV and will likely develop natural immunity against the virus; however, children under five remain vulnerable to RSV disease, offering a strong rationale for a pediatric vaccine that could offer enhanced protection. In 2015, we announced positive results in our Phase 1 clinical trial evaluating the safety and immunogenicity of our RSV F Vaccine in healthy children between two and six years of age. To the extent we receive regulatory approval for ResVax, we expect to continue development of our RSV F Vaccine for pediatrics.

### **Seasonal Influenza**

#### ***NanoFlu Program (Older Adults)***

Influenza is a world-wide infectious disease with serious illness generally occurring in more susceptible populations such as pediatrics and older adults, but also occurring in the general population. According to influenza vaccines forecasts by Datamonitor in 2013, the market for seasonal influenza vaccines is expected to grow from approximately \$3.2 billion in the 2015-16 flu season to approximately \$5.3 billion in the 2021-22 flu season (in the countries comprising the top seven markets). The Center for Disease Control and Prevention estimates that each year since 2010, influenza in the U.S. has resulted in between 9.2 million and 35.6 million illnesses, between 140,000 and 710,000 hospitalizations and between 12,000 and 56,000 deaths.

In January 2019, we announced positive top-line data from our Phase 2 clinical trial of NanoFlu in older adults. Top-line results showed that all formulations of NanoFlu were well-tolerated and elicited vigorous immune responses to all four strains included in the vaccine; importantly, use of our Matrix-M adjuvant resulted in significantly enhanced immune responses when compared to a non-adjuvanted formulation. NanoFlu also showed superior hemagglutination inhibition antibody responses against wild-type A(H3N2) viruses, including drifted strains, when compared to Fluzone High-Dose<sup>®</sup>, the leading flu vaccine in older adults. During a pre-investigational new drug application meeting in 2018, the FDA indicated that an accelerated approval pathway for seasonal influenza vaccines could be available for NanoFlu. We expect to reach agreement on a protocol that utilizes an accelerated approval pathway with the FDA in the third quarter of 2019. We are currently planning a pivotal Phase 3 clinical trial of NanoFlu that could begin as early as the second half of 2019.

### **Combination Seasonal Influenza/RSV F Vaccine**

With the ongoing development of our NanoFlu and RSV F Vaccine, a strong rationale exists for developing a combination respiratory vaccine that is designed to protect susceptible populations against both diseases. Although testing is at an early stage, we believe that a combination vaccine against both influenza and RSV may be achievable.

### **Early-Stage Vaccine Candidates**

Because our nanoparticle technology targets antigens with conserved epitopes essential for viral function, our vaccine candidates have the potential to be applied broadly to a wide variety of human infectious diseases. Our nanoparticle vaccine technology has already demonstrated the ability to produce vaccine candidates against a wide variety of infectious diseases: in addition to our ResVax and NanoFlu vaccine candidates, we have also developed nanoparticle vaccine candidates for clinic testing against ebola virus (positive Phase 1 clinical trial results) and MERS coronavirus (positive animal studies). While we have focused most of our corporate efforts towards our RSV and seasonal influenza vaccine candidates, we stand ready to continue development of emerging infectious disease vaccine candidates as circumstances warrant.

### **CPLB Joint Venture**

CPL Biologicals Private Limited (“CPLB”), our joint venture between Novavax and Cadila Pharmaceuticals Limited (“Cadila”), is actively developing a number of vaccine candidates in India. CPLB is owned 20% by Novavax and 80% by Cadila.

### **Sales of Common Stock**

In December 2018, we entered into an At Market Sales Agreement (“December 2018 Sales Agreement”), which allows us to issue and sell up to \$100 million in gross proceeds of our common stock. During the first quarter of 2019, we sold 33.6 million shares of common stock under the December 2018 Sales Agreement resulting in \$17.4 million in net proceeds at a weighted average sales price of \$0.53 per share, leaving \$82.2 million remaining available to be sold.

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. During the first quarter of 2019, we sold 50.3 million shares of common stock under the December 2017 Sales Agreement resulting in \$37.9 million in net proceeds at a weighted average sales price of \$0.77 per share. The December 2017 Sales Agreement was fully utilized at that time.

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

There are no material changes to our critical accounting policies as described in Item 7 of our Annual Report on Form 10-K for the fiscal year ended December 31, 2018, as filed with the SEC.

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

**Three Months Ended March 31, 2019 and 2018** (amounts in tables are presented in thousands, except per share information or as otherwise indicated)

**Revenue:**

<b>Three Months Ended</b>			
<b>March 31,</b>			
			<b>Change</b>
<b>2019</b>	<b>2018</b>		<b>2018 to</b>
			<b>2019</b>
Revenue:			
Total revenue	\$3,982	\$9,653	\$(5,671)

Revenue for the three months ended March 31, 2019 was \$4.0 million as compared to \$9.7 million for the same period in 2018, a decrease of \$5.7 million, or 59%. Revenue for the three months ended March 31, 2019 and 2018 was primarily comprised of services performed under the Grant Agreement with BMGF and to a lesser extent, revenue from Novavax AB. Revenue decreased as a result of completing enrollment of the Prepare trial in the second quarter of 2018.

We expect revenue in 2019 under the Grant Agreement to be significantly lower than in 2018 as the Prepare trial is expected to conclude in 2019.

**Expenses:****Three Months Ended**

	<b>March 31,</b>		<b>Change</b>
	<b>2019</b>	<b>2018</b>	<b>2018 to</b>
			<b>2019</b>
Expenses:			
Research and development	\$35,473	\$44,514	\$(9,041)
General and administrative	8,732	8,652	80
Total expenses	\$44,205	\$53,166	\$(8,961)

### ***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 decreased to \$35.5 million for the three months ended March 31, 2019 from \$44.5 million for the same period in 2018, a decrease of \$9.0 million, or 20%. This decrease was primarily due to decreased development activities, including lower clinical trial costs, of ResVax. At March 31, 2019, we had 324 employees dedicated to our research and development programs versus 301 employees as of March 31, 2018. For 2019, we expect research and development expenses overall to decrease primarily due to the completion of activities related to the conclusion of the Prepare trial and partially offset by our planned Phase 3 clinical trial of NanoFlu following discussions with the FDA in the third quarter of 2019.

*Expenses by Functional Area*

We track our research and development expenses by the type of costs incurred in identifying, developing, manufacturing and testing vaccine candidates. We evaluate and prioritize our activities according to functional area and therefore believe that project-by-project information would not form a reasonable basis for disclosure to our investors. Historically, we did not account for internal research and development expenses by project, since our employees' work time is spread across multiple programs and our internal manufacturing clean-room facility produces multiple vaccine candidates.

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

	2019	2018
Manufacturing	\$21.6	\$19.8
Vaccine Discovery	1.8	1.6
Clinical and Regulatory	12.1	23.1
Total research and development expenses	\$35.5	\$44.5

We do not provide forward-looking estimates of costs and time to complete our research projects 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 were flat at \$8.7 million for the three months ended March 31, 2019 and 2018. At March 31, 2019, we had 49 employees dedicated to general and administrative functions versus 50 employees as of March 31, 2018. For 2019, we expect general and administrative expenses to decrease due to reduced activities related to the development and potential commercialization of ResVax.

**Other Income (Expense):**

	<b>Three Months Ended</b>		
	<b>March 31,</b>		<b>Change</b>
	<b>2019</b>	<b>2018</b>	<b>2018 to 2019</b>
Other Income (Expense):			
Investment income	\$420	\$531	\$ (111 )
Interest expense	(3,403)	(3,403)	—
Other income (expense)	(12 )	33	(45 )
Total other income (expense)	\$(2,995)	\$(2,839)	\$ (156 )



We had total other expense, net of \$3.0 million for the three months ended March 31, 2019 as compared to total other expense, net of \$2.8 million for the same period in 2018, an increase of \$0.2 million.

**Net Loss:**

	<b>Three Months Ended</b>		
	<b>March 31,</b>		<b>Change</b>
	<b>2019</b>	<b>2018</b>	<b>2018 to 2019</b>
Net Loss:			
Net loss	\$(43,218 )	\$(46,352 )	\$3,134
Net loss per share	\$(0.11 )	\$(0.14 )	\$0.03
Weighted shares outstanding	408,843	336,972	71,871

Net loss for the three months ended March 31, 2019 was \$43.2 million, or \$0.11 per share, as compared to \$46.4 million, or \$0.14 per share, for the same period in 2018. The decrease in net loss was primarily due to decreased development activities, including lower clinical trial costs, of ResVax, partially offset by decreased revenue under the Grant Agreement.

The increase in weighted average shares outstanding for the three months ended March 31, 2019 is primarily a result of sales of our common stock in 2019 and 2018.

**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, 2019, we had \$108.7 million in cash and cash equivalents, marketable securities and restricted cash as compared to \$103.9 million as of December 31, 2018. These amounts consisted of \$97.7 million in cash and cash equivalents, \$2.5 million in marketable securities and \$8.5 million in restricted cash as of March 31, 2019 as compared to \$70.2 million in cash and cash equivalents, \$22.0 million in marketable securities and \$11.8 million in restricted cash as of December 31, 2018.

The following table summarizes cash flows for the three months ended March 31, 2019 and 2018 (in thousands):

	<b>Three Months Ended</b>		
	<b>March 31,</b>		<b>Change</b>
	2019	2018	<b>2018 to 2019</b>
<b>Summary of Cash Flows:</b>			
Net cash (used in) provided by:			
Operating activities	\$(50,607 )	\$(66,075 )	\$15,468
Investing activities	18,711	20,587	(1,876 )
Financing activities	56,181	43,924	12,257
Effect on exchange rate on cash, cash equivalents and restricted cash	(45 )	(26 )	(19 )
Net increase (decrease) in cash, cash equivalents and restricted cash	24,240	(1,590 )	25,830
Cash, cash equivalents and restricted cash at beginning of period	81,959	135,431	(53,472)
Cash, cash equivalents and restricted cash at end of period	\$106,199	\$133,841	\$(27,642)

Net cash used in operating activities decreased to \$50.6 million for the three months ended March 31, 2019, as compared to \$66.1 million for the same period in 2018. The decrease in cash usage is primarily due to approximately \$9.3 million of one-time payments made in the first quarter of 2018 that included our lease termination fee and the milestone payment to Wyeth Holdings LLC along with the Company's reduced bonus payout in the first quarter of 2019 as compared to the same period in 2018. We expect our cash used in operating activities to decrease for the subsequent quarters of 2019 as compared to the first quarter of 2019 due to the timing of payments in the first quarter of 2019 and as the Prepare trial is expected to conclude in 2019.

During the three months ended March 31, 2019 and 2018, our investing activities consisted of purchases and maturities of marketable securities and capital expenditures. Capital expenditures for the three months ended March 31, 2019 and 2018 were \$0.8 million and \$0.2 million, respectively. In 2019, we expect our capital expenditures to decrease due to reduced activities related to the development and potential commercialization of ResVax.

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, 2019, we received net proceeds of \$55.2 million from selling shares of common stock through our December 2017 and December 2018 Sales Agreements at a weighted average sales price of \$0.67 per share. 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 2018 Sales Agreements at a weighted average sales price of \$1.93 per share.

The accompanying unaudited consolidated financial statements have been prepared assuming that the Company will continue as a going concern within one year after the date that the financial statements are issued. During 2018, we incurred a net loss of \$184.7 million and had net cash flows used in operating activities of \$184.8 million. At March 31, 2019, we had \$108.7 million in cash and cash equivalents, marketable securities and restricted cash and had no committed source of additional funding from either debt or equity financings. Management believes that given the Company's current cash position and forecasted negative cash flows from operating activities over the next twelve months as we continue our product development activities, including our potential ResVax submission of a BLA with the FDA and/or a MAA with the EMA in 2020, and our planned Phase 3 clinical trial of NanoFlu following discussions with the FDA in the third quarter of 2019, there is substantial doubt about our ability to continue as a going concern through one year from the date that these financial statements are issued, without obtaining additional financing or entering into another form of non-equity or debt arrangement.

Our ability to fund Company operations is dependent upon management's plans, which include raising additional capital in the near term primarily through 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. New financings may not be available to us on commercially acceptable terms, or at all. Also, any collaborations, strategic alliances and marketing, distribution or licensing arrangements may require us to give up some or all of our rights to a product or technology, which in some cases may be at less than the full potential value of such rights. If we are unable to 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 research and development programs, and/or downsize our organization.

### **Off-Balance Sheet Arrangements**

We did not have any material off-balance sheet arrangements as of March 31, 2019.

### **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, 2019, we had cash and cash equivalents of \$97.7 million, marketable securities of \$2.5 million, all of which are short-term in nature, \$8.5 million in restricted cash and working capital of \$91.9 million.

Our exposure to market risk is primarily confined to our investment portfolio. As of March 31, 2019, 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 \$2.5 million at March 31, 2019.

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, 2019. 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, 2019, 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, 2019, and has concluded that there was no change that occurred during the quarterly period ended March 31, 2019 that materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

## **PART II. OTHER INFORMATION**

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

Other than the additional risk factor disclosed below, there are no material changes to the Company's risk factors as described in Item 1A of the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2018.

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

The Nasdaq Global Select Market ("Nasdaq"), on which our common stock is listed and traded, has listing requirements that include a \$1 minimum closing bid price requirement. On April 11, 2019, we received a notification letter from Nasdaq (the "Notice") advising us that for 30 consecutive business days preceding the date of the Notice, the bid price of our common stock had closed below this \$1.00 per share minimum closing bid price. In accordance with Nasdaq Listing Rule 5810(c)(3)(A), the Company has been provided a compliance period of 180 calendar days, or until October 8, 2019, to regain compliance with this requirement. The Company can regain compliance with the minimum closing bid price rule if the bid price of its common stock closes at \$1.00 or higher for a minimum of ten consecutive business days during this initial 180-day compliance period. If compliance is not achieved by October 8, 2019, Nasdaq will provide written notification to the Company that its securities are subject to delisting.

We continue to monitor the bid price for our common stock. We have scheduled a special meeting of our stockholders on May 8, 2019 to consider a proposal to effect a reverse split of our issued and outstanding common stock at a ratio of 1-for-20. If approved at the special meeting, the proposed reverse stock split would be expected to have the effect of increasing the bid price for a share of our common stock. However, if the proposed reverse stock split is not approved at the special meeting, or if our common stock otherwise does not trade at a level sufficient to satisfy the minimum bid price requirement within the 180-day initial compliance period, Nasdaq may elect, subject to any potential cure periods, to initiate a process to delist our common stock. Should such a delisting occur, it may adversely impact the liquidity and price of our common stock, impede our ability to raise capital and would constitute a fundamental change under our Notes.

### **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 (File No. 000-26770))

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 (File No. 000-26770))

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, 2019, formatted in Extensible Business Reporting Language (XBRL): (i) the Consolidated Balance Sheets as of March 31, 2019 and December 31, 2018, (ii) the Consolidated Statements of Operations for the three-month period ended March 31, 2019 and 2018, (iii) the Consolidated Statements of Comprehensive Loss for the three-month period ended March 31, 2019 and 2018, (iv) the Consolidated Statements of Changes in Stockholders' Deficit for the three-month period ended March 31, 2019 and 2018, (v) the Consolidated Statements of Cash Flows for the three-month periods ended March 31, 2019 and 2018, and (vi) the Notes to Consolidated Financial Statements.

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\* 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 2, 2019 By: /s/ Stanley C. Erck  
President and Chief Executive Officer  
(Principal Executive Officer)

Date: May 2, 2019 By: /s/ John J. Trizzino  
Senior Vice President, Chief Business Officer, Chief Financial Officer and Treasurer  
(Principal Financial and Accounting Officer)