NOVAVAX INC
Form 10-Q
November 07, 2018

UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-Q

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

Delaware	**22-2816046**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
20 Firstfield Road, Gaithersburg, MD	**20878**
(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 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, 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	¨
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

The number of shares outstanding of the Registrant’s Common Stock, $0.01 par value, was 382,850,125 as of October 31, 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)

	September 30, 2018 **(unaudited)**	December 31, 2017
ASSETS		
Current assets:		
Cash and cash equivalents	$56,496	$106,307
Marketable securities	70,612	50,996
Restricted cash	17,586	28,234
Prepaid expenses and other current assets	15,847	17,774
Total current assets	160,541	203,311
Restricted cash	954	890
Property and equipment, net	29,343	35,987
Intangible assets, net	6,754	7,873
Goodwill	52,072	53,563
Other non-current assets	814	869
Total assets	$250,478	$302,493
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Current liabilities:		
Accounts payable	$6,790	$5,613
Accrued expenses	20,963	29,610
Accrued interest	2,031	5,078
Deferred revenue	15,365	25,625
Other current liabilities	1,566	7,749
Total current liabilities	46,715	73,675
Deferred revenue	2,500	2,500
Convertible notes payable	318,830	317,763
Other non-current liabilities	9,112	10,287
Total liabilities	377,157	404,225
Commitments and contingencies	—	—
Stockholders' deficit:		

Preferred stock, $0.01 par value, 2,000,000 shares authorized; no shares issued and outstanding as of September 30, 2018 and December 31, 2017, respectively	—	—
Common stock, $0.01 par value, 600,000,000 shares authorized at September 30, 2018 and December 31, 2017; 383,185,993 shares issued and 382,730,563 shares outstanding at September 30, 2018 and 323,684,820 shares issued and 323,229,390 shares outstanding at December 31, 2017	3,832	3,237
Additional paid-in capital	1,132,738	1,020,457
Accumulated deficit	(1,249,773)	(1,114,359)
Treasury stock, 455,430 shares, cost basis at both September 30, 2018 and December 31, 2017	(2,450)	(2,450)
Accumulated other comprehensive loss	(11,026)	(8,617)
Total stockholders' deficit	(126,679)	(101,732)
Total liabilities and stockholders' deficit	$250,478	$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)

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2018	2017	2018	2017
Revenue:				
Grant and other	$7,735	$8,352	$28,161	$20,764
Total revenue	7,735	8,352	28,161	20,764
Expenses:				
Research and development	41,326	41,862	130,382	118,779
General and administrative	8,309	8,118	25,185	25,911
Total expenses	49,635	49,980	155,567	144,690
Loss from operations	(41,900)	(41,628)	(127,406)	(123,926)
Other income (expense):				
Investment income	752	531	2,090	1,528
Interest expense	(3,403)	(3,520)	(10,209)	(10,549)
Other income (expense)	(19)	10	111	20
Net loss	$(44,570)	$(44,607)	$(135,414)	$(132,927)
Basic and diluted net loss per share	$(0.12)	$(0.15)	$(0.37)	$(0.47)
Basic and diluted weighted average number of common shares outstanding	382,315	296,435	365,236	284,767

CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

(in thousands)

(unaudited)

	For the Three Months	For the Nine Months

	Ended September 30,		Ended September 30,	
	2018	2017	2018	2017
Net loss	$(44,570)	$(44,607)	$(135,414)	$(132,927)
Other comprehensive income (loss):				
Net unrealized gains (losses) on marketable debt securities available-for-sale	(13)		9	(34)
Foreign currency translation adjustment	160	1,299	(2,418)	3,544
Other comprehensive income (loss)	147	1,299	(2,409)	3,510
Comprehensive loss	$(44,423)	$(43,308)	$(137,823)	$(129,417)

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

NOVAVAX, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS

(in thousands)

(unaudited)

	Nine Months Ended September 30,	
	2018	2017
Operating Activities:		
Net loss	$**(135,414)**	$**(132,927)**
Reconciliation of net loss to net cash used in operating activities:		
Depreciation and amortization	6,177	7,696
(Gain) Loss on disposal of property and equipment	(55)	294
Non-cash impact of lease termination	(4,381)	
Amortization of debt issuance costs	1,067	1,067
Lease incentives received		1,485
Non-cash stock-based compensation	13,927	13,057
Other	(1,820)	2,469
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	1,693	427
Accounts payable and accrued expenses	(10,497)	364
Deferred revenue	(10,256)	4,991
Net cash used in operating activities	(139,559)	(101,077)
Investing Activities:		
Capital expenditures	(855)	(3,543)
Proceeds from maturities of marketable securities	98,305	189,817
Purchases of marketable securities	(117,172)	(167,069)
Net cash (used in) provided by investing activities	(19,722)	19,205
Financing Activities:		
Principal payments on capital lease		(37)
Net proceeds from sales of common stock	96,486	46,029
Proceeds from the exercise of stock options and employee stock purchases	2,462	1,133
Net cash provided by financing activities	98,948	47,125
Effect of exchange rate on cash, cash equivalents and restricted cash	(62)	180
Net decrease in cash, cash equivalents and restricted cash	(60,395)	(34,567)
Cash, cash equivalents and restricted cash at beginning of period	135,431	179,257
Cash, cash equivalents and restricted cash at end of period	$75,036	$144,690
Supplemental disclosure of non-cash activities:		
Sale of common stock under the Sales Agreement not settled at quarter-end	$—	$592

Property and equipment purchases included in accounts payable and accrued expenses	$126	$81
Supplemental disclosure of cash flow information:		
Cash payments of interest	$12,188	$12,188

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

NOVAVAX, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
September 30, 2018

(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 that 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.

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 the nine months ended September 30, 2018, the Company incurred a net loss of $135.4 million and had net cash flows used in operating activities of $139.6 million. At September 30, 2018, the Company had $145.6 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 upcoming final efficacy analysis of Prepare™, a global pivotal Phase 3 clinical trial of ResVax (with top-line data expected to be announced in the first quarter of 2019), and its Phase 2 clinical trial of NanoFlu that was initiated in the third quarter of 2018 (also with top-line data expected to be announced in the first 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 September 30, 2018, the consolidated statements of operations and the consolidated statements of comprehensive loss for the three and nine months ended September 30, 2018 and 2017 and the consolidated statements of cash flows for the nine months ended September 30, 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 $11.0 million and $8.6 million at September 30, 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 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):

	September 30, 2018	December 31, 2017
Cash	$ 5,216	$ 10,482
Money market funds	36,280	36,762
Asset-backed securities	15,000	16,007
Corporate debt securities		43,056
Cash and cash equivalents	$ 56,496	$ 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 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 with the Bill & Melinda Gates Foundation ("BMGF") under which the Company was awarded a grant up to $89.1 million (see Note 10) and cash collateral accounts under letters of credit that serve as security deposits for certain facility leases. The Company will utilize the Grant Agreement funds as it incurs expenses for services performed under the agreement. At September 30, 2018 and December 31, 2017, the restricted cash balances (both current and non-current) consist of payments received under the Grant Agreement of $17.6 million and $27.4 million, respectively, and security deposits of $1.0 million and $1.7 million, respectively.

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):

	September 30, 2018	December 31, 2017
Cash and cash equivalents	$ 56,496	$ 106,307
Restricted cash current	17,586	28,234
Restricted cash non-current	954	890
Cash, cash equivalents and restricted cash	$ 75,036	$ 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" or "Topic 606"), 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 timing of revenue recognition as the majority of its revenue continues to be recognized under its Grant Agreement with BMGF (see discussion below). Since the Company did not identify any accounting changes that impact its revenue recognition timing, 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 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 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 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 September 30, 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 September 30, 2018 and 2017, the Company had outstanding stock options and unvested restricted stock awards totaling 44,286,355 and 36,556,293, respectively. At September 30, 2018, the Company's Notes (see Note 7) 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 May 2014, the FASB issued 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 timing of recognition of its revenue as the majority of its revenue continues to be recognized under the Grant Agreement with BMGF. 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. In July 2018, the FASB provided an optional transition method of adoption, permitting entities to recognize a cumulative-effect adjustment to the opening balance of retained earnings in the period of adoption as opposed to the beginning of the earliest period presented in the financial statements. The Company will adopt this standard on January 1, 2019 using the optional transition method 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

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 September 30, 2018			Fair Value at December 31, 2017		
	Level 1	Level 2	Level 3	Level 1	Level 2	Level 3
Assets						
Money market funds(1)	$36,280	$	$	$36,762	$	$
Asset-backed securities(2)		19,989			29,750	
Corporate debt securities(3)		65,623			80,309	

Total assets	$36,280	$85,612	$	$36,762	$110,059	$
Liabilities						
Convertible notes payable	$	$197,022	$	$	$152,396	$

(1) Classified as cash and cash equivalents as of September 30, 2018 and December 31, 2017, respectively, on the consolidated balance sheets.

(2) Includes $15,000 and $16,007 classified as cash and cash equivalents as of September 30, 2018 and December 31, 2017, respectively, on the consolidated balance sheets.

(3) Includes $43,056 classified as cash and cash equivalents as of December 31, 2017 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 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 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 nine months ended September 30, 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 their fair value due to their short-term nature.

Note 5 – Marketable Securities

Marketable securities classified as available-for-sale as of September 30, 2018 and December 31, 2017 were comprised of (in thousands):

	September 30, 2018				December 31, 2017			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Asset-backed securities	$4,990	$ —	$ (1)	$ 4,989	$13,748	$ —	$ (5)	$ 13,743
Corporate debt securities	65,630	1	(8)	65,623	37,265	—	(12)	37,253
Total	$70,620	$ 1	$ (9)	$ 70,612	$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 18 available-for-sale securities as of September 30, 2018. Of these 18 securities, 12 had combined unrealized losses of less than $0.1 million as of September 30, 2018. The Company did not have any investments in a loss position for greater than 12 months as of September 30, 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 material unrealized losses, given the Company's current and anticipated financial position.

Note 6 – Goodwill and Other Intangible Assets

Goodwill

The change in the carrying amounts of goodwill for the nine months ended September 30, 2018 was as follows (in thousands):

	Amount
Balance at December 31, 2017	$53,563
Currency translation adjustments	(1,491)
Balance at September 30, 2018	$52,072

Identifiable Intangible Assets

Purchased intangible assets consisted of the following as of September 30, 2018 and December 31, 2017 (in thousands):

	September 30, 2018			**December 31, 2017**		
	Gross Carrying Amount	**Accumulated Amortization**	**Intangible Assets, Net**	**Gross Carrying Amount**	**Accumulated Amortization**	**Intangible Assets, Net**
Finite-lived intangible assets:						
Proprietary adjuvant technology	$8,404	$ (2,171)	$ 6,233	$9,086	$ (2,006)	$ 7,080
Collaboration agreements	3,795	(3,274)	521	4,103	(3,310)	793
Total identifiable intangible assets	$12,199	$ (5,445)	$ 6,754	$13,189	$ (5,316)	$ 7,873

Amortization expense for the nine months ended September 30, 2018 and 2017 was $0.5 million and $2.1 million, respectively.

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)	$ 176
2019	704
2020	586
2021	420
2022	420
2023	420

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):

	September 30, 2018	December 31, 2017
Principal amount of the Notes	$ 325,000	$ 325,000
Unamortized debt issuance costs	(6,170)	(7,237)
Total convertible notes payable	$ 318,830	$ 317,763

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

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2018	2017	2018	2017
Coupon interest at 3.75%	$3,047	$3,047	$9,142	$9,142
Amortization of debt issuance costs	356	356	1,067	1,067
Total interest expense on the Notes	$3,403	$3,403	$10,209	$10,209

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. 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. No sales were made subsequent to March 31, 2018. As of September 30, 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 per share. 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 56,000,000 shares of common stock under equity awards granted under the plan, including an increase of 20,000,000 shares approved at the Company's 2018 annual meeting of stockholders. All such shares authorized for issuance under the 2015 Plan have been reserved. The 2015 Plan will expire on March 4, 2025.

The Amended and Restated 2005 Stock Incentive Plan ("2005 Plan") expired in February 2015 and no new awards may be made under such plan, although awards will continue to be outstanding in accordance with their terms.

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

Stock Options Awards

The following is a summary of option activity under the 2015 Plan and 2005 Plan for the nine months ended September 30, 2018:

	2015 Plan		**2005 Plan**	
	Stock Options	Weighted-Average Exercise Price	Stock Options	**Weighted-Average Exercise Price**
Outstanding at January 1, 2018	33,675,720	$ 3.61	12,818,929	$ 3.26
Granted	701,700	$ 1.69	—	$ —
Exercised	(244,901)	$ 1.35	(401,020)	$ 1.75
Canceled	(1,736,641)	$ 4.08	(527,432)	$ 4.01
Outstanding at September 30, 2018	32,395,878	$ 3.56	11,890,477	$ 3.28
Shares exercisable at September 30, 2018	11,974,942	$ 5.54	11,840,102	$ 3.27
Shares available for grant at September 30, 2018	23,289,221			

The fair value of stock options granted under the 2015 Plan and 2005 Plan was estimated at the date of grant using the Black-Scholes option-pricing model with the following assumptions:

	Three Months Ended		**Nine Months Ended**	
	September 30,		**September 30,**	
	2018	2017	2018	2017
Weighted-average Black-Scholes fair value of stock options granted	$1.09	$0.83	$1.29	$1.02
Risk-free interest rate	2.68%-2.86%	1.61%-1.75%	2.26%-2.86%	1.61%-2.34%
Dividend yield	0%	0%	0%	0%
Volatility	113.64%-114.90%	111.46%-114.10%	113.64%-114.90%	88.91%-114.10%
Expected term (in years)	4.08-4.10	4.17-4.18	4.08-4.14	4.17-7.46
Expected forfeiture rate	0%	0%	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 September 30, 2018 was $11.3 million and 7.1 years, respectively. The total aggregate intrinsic value and weighted-average remaining contractual term of stock options exercisable under the 2015 Plan and 2005 Plan as of September 30, 2018 was $3.1 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 September 30, 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 nine months ended September 30, 2018 and 2017 was $0.3 million and less than $0.1 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 7,600,000 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 8,000,000 shares. The number of authorized shares and the maximum number of shares both include an increase of 4,000,000 shares approved at the Company's 2018 annual meeting of stockholders. The ESPP allows employees to purchase shares of common stock of the Company at each purchase date through payroll deductions of up to a maximum of 15% of their compensation, at 85% of the lesser of the market price of the shares at the time of purchase or the market price on the beginning date of an option period (or, if later, the date during the option period when the employee was first eligible to participate). At September 30, 2018, there were 3,363,066 shares available for issuance under the ESPP.

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

	Three Months Ended		**Nine Months Ended**	
	September 30, 2018	**2017**	**September 30, 2018**	**2017**
Range of Black-Scholes fair value of ESPP shares granted	$0.36-$3.53	$0.45-$5.47	$0.36-$3.53	$0.45-$5.47
Risk-free interest rate	0.74%-2.24%	0.57%-1.13%	0.66%-2.24%	0.45%-1.13%
Dividend yield	0%	0%	0%	0%
Volatility	52.19%-203.83%	54.67%-267.85%	52.19%-203.83%	45.98%-267.85%
Expected term (in years)	0.5-2.0	0.5-2.0	0.5-2.0	0.5-2.0
Expected forfeiture rate	0%	0%	0%	0%

Restricted Stock Awards

The following is a summary of restricted stock awards activity for the nine months ended September 30, 2018:

	Number of	**Per Share Weighted-Average Grant-Date**

	Shares	Fair Value
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 September 30, 2018		$

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

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2018	2017	2018	2017
Research and development	$2,611	$2,395	$8,198	$7,143
General and administrative	1,820	1,936	5,729	5,914
Total stock-based compensation expense	$4,431	$4,331	$13,927	$13,057

As of September 30, 2018, there was approximately $23 million of total unrecognized compensation expense related to unvested stock options and the ESPP. This unrecognized non-cash compensation expense is expected to be recognized over a weighted-average period of 1.2 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 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 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. In the three and nine months ended September 30, 2018, the Company recognized revenue from the Grant of $7.4 million and $25.4 million, respectively, and has recognized approximately $68 million in revenue since the inception of the agreement. At September 30, 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 July 2018, the Company terminated 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 CPL Biologicals Private Limited's ("CPLB") recombinant trivalent seasonal VLP influenza vaccine ("CadiFlu") is only licensed in India. In September 2015, due to CPLB's initiation of a Phase 3 clinical trial of CadiFlu in 2014, the Company entered into an amendment to the Wyeth license that, among other things, increased the milestone payment ("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 September 30, 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 ResVax and other professional services. The agreement has been extended to terminate in July 2019. For the nine months ended September 30, 2018, the Company incurred $0.2 million in consulting expenses under the agreement. The amount due and unpaid for services performed under the agreement at September 30, 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; payments by the Bill & Melinda Gates Foundation ("BMGF"); reimbursement by the Department of Health and Human Services, Biomedical Advanced Research and Development Authority ("HHS BARDA"); our available cash resources and the availability of financing generally, plans regarding partnering activities, business development initiatives and the adoption of stock incentive plans and amendments thereto; the effectiveness, and expected costs and savings, and the timing of such costs and savings, 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," "consider," "anticipate," "intend," "seek," "plan," "project," "expect," "should," "would," or "assume" or the negative of these 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" 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 ResVax™ and NanoFlu™, are genetically engineered, three-dimensional nanostructures of recombinant proteins critical to disease pathogenesis and that may elicit differentiated immune responses, which may be more efficacious than naturally occurring immunity or traditional vaccines. Our product pipeline (see below) 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 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.

Program	Current Development Stage
Respiratory Syncytial Virus ("RSV")	
· **ResVax* (Infants via Maternal Immunization)**	Phase 3
· **Older Adults**	Phase 2
· **Pediatrics**	Phase 1
Seasonal Influenza	
· **NanoFlu (Older Adults and COPD)**	Phase 2
Combination Influenza/RSV	Preclinical
Ebola Virus ("EBOV")	Phase 1

* Supported by $89.1 million grant from BMGF

A summary of our significant research and development programs and status of the related product candidates in development follows:

Respiratory Syncytial Virus (RSV)

Three susceptible target populations could benefit from the development of a 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"). There is no currently approved RSV vaccine available to combat the 64 million RSV infections that occur globally each year.[1,2] With our current estimates of the annual global cost burden of RSV in excess of $88 billion,[3] we believe our RSV F Vaccine represents a multi-billion dollar revenue opportunity, worldwide.

[1] NIH/NIAID. RSV webpage. Accessed July 13, 2018.
https://www.niaid.nih.gov/diseases-conditions/respiratory-syncytial-virus-rsv

[2] WHO Acute Respiratory Infections September 2009 Update:
http://apps.who.int/vaccine_research/diseases/ari/en/index2.html

[3] Estimated value of life lost, future health implications and lost earnings; preliminary data based on Novavax research of available epidemiology and health outcomes data

ResVax Program (Infants via Maternal Immunization)

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.[4] In the U.S., RSV is the leading cause of hospitalization of infants[5] and, globally, is second only to malaria as a cause of death in children under one year of age.[6]

Clinical Trial Update and Analyses

In December 2015, we initiated Prepare™, a global pivotal Phase 3 clinical trial of ResVax, our RSV F Vaccine using aluminum phosphate as an adjuvant for infants via maternal immunization, and by May 2018, we completed enrollment of the Prepare trial with 4,636 pregnant women enrollees, at least 3,000 of which received ResVax. The primary objective of the Prepare trial is 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. We expect to report top-line results from our final efficacy analysis in the first quarter of 2019 and assuming successful results, we expect to 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, both by the first quarter of 2020.

In December 2017, we announced an informational analysis of the Prepare trial data related to the efficacy of ResVax in the initial 1,307 infants from the trial. This analysis allowed us to calculate an observed vaccine efficacy point estimate in the range between 45% and 100% at that time.[7]

The Prepare trial is supported by a grant of up to $89.1 million from BMGF (the "Grant") which supports development activities, product licensing efforts and World Health Organization ("WHO") prequalification of ResVax. The FDA has granted ResVax "Fast Track" designation. In addition, priority review (6-month review versus standard 10-month review) is a potential benefit that may be available to ResVax 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 in part to immunosenescence, the age-related decline in the human immune system.[8] 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.[9] Additionally, RSV infection can lead to exacerbation of underlying co-morbidities such as chronic obstructive pulmonary disease ("COPD"), asthma and congestive heart failure.[10] In the U.S., the reported incidence rate of 5.5% RSV in older adults is approximately 2.5 million infections per year.[11] We estimate that approximately 900,000 medical interventions are directly caused by RSV disease in this population each year.

[4] Nair, H., et al. (2010) Lancet. 375:1545-1555

[5] Leader S., et al. (2003) J Pediatr. 143: S127

[6] Losano R., et al. (2012/Dec15) Lancet. 380: 2095

[7] Assumes 2:1 randomization

[8] Weinberger B. (2017) Clin Exp Immuol. 187:1-3

[9] Falsey, A.R., et al. (1995) JID.172:389-94

[10] Walsh E.E., et al. (2004) JID. 189:233-38

[11] Falsey, A.R., et al. (2005) NEJM. 352: 1749-59

Clinical Trial Update and Analyses

In July 2017, we announced positive top-line data from our Phase 2 clinical trial of our RSV F Vaccine in older adults. The objective of that trial was to assess 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 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. While no additional clinical trials in either the older adult or COPD patient populations are currently planned, we believe these data support future testing of adjuvanted formulations of our RSV F Vaccine in older adults.

RSV Pediatrics Program

Burden of Disease

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.

Clinical Trial Update and Analyses

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 trial evaluated safety and immunogenicity of our RSV F Vaccine, with one or two doses, with or without aluminum phosphate adjuvant. We expect to continue development of our RSV F Vaccine for pediatrics following receipt of regulatory approval for ResVax.

Influenza

NanoFlu Program (Older Adults)

Burden of Disease

Influenza is a world-wide infectious disease that causes illness in humans; serious illness generally occurs in susceptible populations such as pediatrics and older adults, but also occurs in the general population. 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.[12] The Advisory Committee for Immunization Practices of the Center for Disease Control and Prevention ("CDC") estimates that in the U.S. influenza 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 annually since 2010.[13] Although the CDC recommends that all persons aged six months and older be vaccinated annually against seasonal influenza, current flu vaccine effectiveness is low, particularly in the older population (65 years of age and older) where it was 20% effective overall and only 17% for the dominant A(H3N2) strain for the recent 2017-18 influenza season.[14]

[12] Influenza Vaccines Forecasts. Datamonitor (2013)

[13] CDC. Influenza Fact Sheet. (January 31, 2018).
http://www.who.int/news-room/fact-sheets/detail/influenza-(seasonal)

[14] CDC. ACIP Meeting, June 20, 2018. https://www.youtube.com/watch?v=Tj7U2IVR4Jg

Our recombinant seasonal influenza vaccine is produced to display the exact sequence of hemagglutinin antigen found on circulating influenza viruses, a key advantage compared to egg-based influenza vaccines, which have been shown to have sequence mutations arising during production. Our recombinant influenza nanoparticles also 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. Additionally, nanoparticles offer improved purity and manufacturability and advantages for co-formulation with other nanoparticle-based vaccines.

Clinical Trial Update and Analyses

In September 2018, we initiated a Phase 2 clinical trial in older adults with a quadrivalent formulations of our nanoparticle seasonal influenza vaccine candidate, including our proprietary Matrix-M adjuvant ("NanoFlu"). This randomized, observer-blinded, active-controlled trial will assess the safety and tolerability of different doses and formulations of NanoFlu, both adjuvanted with Matrix-M and unadjuvanted, as compared to two U.S.-licensed comparators; the trial is designed to select a dose/formulation of NanoFlu that we will bring forward into our future pivotal Phase 3 immunogenicity clinical trial. In October 2018, we completed enrollment of approximately 1,375 healthy older adults across clinical sites in the U.S. and we expect to report top-line data in the first quarter of 2019. During a pre-IND meeting in 2018, the FDA acknowledged and agreed that the accelerated approval pathway for seasonal influenza vaccines could be available for NanoFlu. We plan to discuss the Phase 2 clinical trial data and the proposed Phase 3 study design, and reach agreement on the use of accelerated approval, with the FDA during an End-of-Phase 2 meeting in the first half of 2019. If Nanoflu is granted accelerated approval, our NanoFlu BLA would include results from a well-controlled Phase 3 trial designed to meet immunogenicity endpoints, with a commitment to conduct confirmatory post-marketing trials to demonstrate clinical effectiveness.

Combination Influenza/RSV F Vaccine

Given the ongoing development of NanoFlu and our RSV F Vaccine, there is a strong rationale for a combination respiratory vaccine with the potential to protect susceptible populations against both diseases. Although testing is at an early stage, we remain confident that a combination vaccine against both influenza and RSV is achievable.

Ebola Virus

EBOV is a severe, often fatal illness in humans. There are currently no licensed treatments proven to neutralize EBOV, although a range of blood, immunological and drug therapies are under development. Our 2015 Phase 1 clinical trial demonstrated that our EBOV glycoprotein vaccine candidate ("Ebola GP Vaccine") is highly immunogenic, well-tolerated and, in conjunction with our proprietary Matrix-M adjuvant, resulted in significant antigen

dose-sparing. We have no current plan to advance our Ebola GP Vaccine without funding or a partner.

CPLB Joint Venture (India)

CPL Biologicals Private Limited ("CPLB") is our joint venture company with Cadila Pharmaceuticals Limited ("Cadila") in India and is actively developing a number of vaccine candidates that were genetically engineered by us. In July 2018, we executed a revised and restated joint venture agreement with Cadila and CPLB, along with a revised and restated license agreement with CPLB, both of which were intended to conform these agreements to our current and planned interactions with CPLB. CPLB continues to be owned 20% by Novavax and 80% by Cadila.

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. During the first quarter of 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. No sales were made subsequent to March 31, 2018. As of September 30, 2018, we have approximately $42.2 million available under the December 2017 Sales Agreement.

Critical Accounting Policies and Use of Estimates

There are no material changes to our critical accounting policies as described in Item 7 of our Annual Report on Form 10-K for the fiscal year ended December 31, 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 consolidated financial statements and notes thereto set forth in this Quarterly Report.

Three Months Ended September 30, 2018 and 2017 (amounts in tables are presented in thousands, except per share information or as otherwise indicated)

Revenue:

	Three Months Ended September 30,		
	2018	2017	**Change 2017 to 2018**
Revenue:			
Total revenue	$7,735	$8,352	$ (617)

Revenue for the three months ended September 30, 2018 was $7.7 million as compared to $8.4 million for the same period in 2017, a decrease of $0.6 million, or 7%. Revenue for the three months ended September 30, 2018 and 2017 was primarily comprised of services performed under the Grant Agreement with BMGF and to a much 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 2018 under the Grant Agreement to be slightly higher than in 2017 due to increased enrollment of participants in Prepare, who we continue to monitor through scheduled follow-up visits.

Expenses:

	Three Months Ended September 30,		
	2018	2017	**Change 2017 to 2018**
Expenses:			
Research and development	$41,326	$41,862	$ (536)
General and administrative	8,309	8,118	191
Total expenses	$49,635	$49,980	$ (345)

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 $41.3 million for the three months ended September 30, 2018 from $41.9 million for the same period in 2017, a decrease of $0.5 million, or 1%. At September 30, 2018, we had 313 employees dedicated to our research and development programs versus 298 employees as of September 30, 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 ResVax and NanoFlu.

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 September 30 (in millions):

	2018	2017
Manufacturing	$19.7	$20.1
Vaccine Discovery	1.4	1.1
Clinical and Regulatory	20.2	20.7
Total research and development expenses	$41.3	$41.9

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 increased to $8.3 million for the three months ended September 30, 2018 from $8.1 million for the same period in 2017, an increase of $0.2 million, or 2%. At September 30, 2018, we had 49 employees dedicated to general and administrative functions versus 50 employees as of September 30, 2017. For 2018, we expect general and administrative expenses to be consistent with 2017.

Other Income (Expense):

	Three Months Ended September 30,		
	2018	2017	**Change 2017 to 2018**
Other Income (Expense):			
Investment income	$752	$531	$ 221
Interest expense	(3,403)	(3,520)	117
Other income (expense)	(19)	10	(29)
Total other income (expense)	$(2,670)	$(2,979)	$ 309

We had total other expense, net of $2.7 million for the three months ended September 30, 2018 compared to total other expense, net of $3.0 million for the same period in 2017, a decrease of $0.3 million.

Net Loss:

	Three Months Ended September 30,		
	2018	2017	Change 2017 to 2018
Net Loss:			
Net loss	$(44,570)	$(44,607)	$37
Net loss per share	$(0.12)	$(0.15)	$0.03
Weighted shares outstanding	382,315	296,435	85,880

Net loss for the three months ended September 30, 2018 was $44.6 million, or $0.12 per share, as compared to $44.6 million, or $0.15 per share, for the same period in 2017.

The increase in weighted average shares outstanding for the three months ended September 30, 2018 is primarily a result of sales of our common stock in 2018 and 2017.

Nine Months Ended September 30, 2018 and 2017 (amounts in tables are presented in thousands, except per share information or as otherwise indicated)

Revenue:

	Nine Months Ended September 30,		
	2018	2017	**Change 2017 to 2018**
Revenue:			
Total revenue	$28,161	$20,764	$7,397

Revenue for the nine months ended September 30, 2018 was $28.2 million as compared to $20.8 million for the same period in 2017, an increase of $7.4 million, or 36%. Revenue for the nine months ended September 30, 2018 and 2017 was primarily comprised of services performed under the Grant Agreement with BMGF and to a lesser extent, revenue from Novavax AB. Revenue increased $5.2 million under the Grant Agreement, as a result of increased enrollment of participants in the Prepare trial, and by an additional $2.1 million as a result of increased Novavax AB activities.

Expenses:

	Nine Months Ended September 30,		
	2018	2017	Change 2017 to 2018
Expenses:			
Research and development	$130,382	$118,779	$11,603
General and administrative	25,185	25,911	(726)
Total expenses	$155,567	$144,690	$10,877

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 $130.4 million for the nine months ended September 30, 2018 from $118.8 million for the same period in 2017, an increase of $11.6 million, or 10%. The increase in research and development expenses was primarily due to increased development activities of ResVax. At September 30, 2018, we had 313 employees dedicated to our research and development programs versus 298 employees as of September 30, 2017.

Expenses by Functional Area

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

	2018	2017
Manufacturing	$60.5	$59.1
Vaccine Discovery	4.7	4.1
Clinical and Regulatory	65.2	55.6
Total research and development expenses	$130.4	$118.8

General and Administrative Expenses

General and administrative expenses decreased to $25.2 million for the nine months ended September 30, 2018 from $25.9 million for the same period in 2017, a decrease of $0.7 million, or 3%. The decrease was primarily due to lower employee-related costs. At September 30, 2018, we had 49 employees dedicated to general and administrative functions versus 50 employees as of September 30, 2017.

Other Income (Expense):

	Nine Months Ended September 30,		
	2018	2017	**Change 2017 to 2018**
Other Income (Expense):			
Investment income	$2,090	$1,528	$ 562
Interest expense	(10,209)	(10,549)	340
Other income (expense)	111	20	91
Total other income (expense)	$(8,008)	$(9,001)	$ 993

We had total other expense, net of $8.0 million for the nine months ended September 30, 2018 compared to total other expense, net of $9.0 million for the same period in 2017, a decrease of $1.0 million. Investment income increased $0.6 million in the nine months ended September 30, 2018 as compared to the same period in 2017 due to higher rates of return on our marketable securities.

Net Loss:

	Nine Months Ended September 30,		
	2018	2017	**Change 2017 to 2018**
Net Loss:			
Net loss	$(135,414)	$(132,927)	$(2,487)
Net loss per share	$(0.37)	$(0.47)	$0.10
Weighted shares outstanding	365,236	284,767	80,469

Net loss for the nine months ended September 30, 2018 was $135.4 million, or $0.37 per share, as compared to $132.9 million, or $0.47 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 ResVax, partially offset by increased revenue under the Grant Agreement with BMGF.

The increase in weighted average shares outstanding for the nine months ended September 30, 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 September 30, 2018, we had $145.6 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 $56.5 million in cash and cash equivalents, $70.6 million in marketable securities and $18.5 million in restricted cash as of September 30, 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 nine months ended September 30, 2018 and 2017 (in thousands):

	Nine Months Ended September 30,		
	2018	2017	Change 2017 to 2018
Summary of Cash Flows:			
Net cash (used in) provided by:			
Operating activities	$(139,559)	$(101,077)	$(38,482)
Investing activities	(19,722)	19,205	(38,927)
Financing activities	98,948	47,125	51,823
Effect on exchange rate on cash, cash equivalents and restricted cash	(62)	180	(242)
Net (decrease) increase in cash, cash equivalents and restricted cash	(60,395)	(34,567)	(25,828)
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.	$75,036	$144,690	$(69,654)

Net cash used in operating activities increased to $139.6 million for the nine months ended September 30, 2018, as compared to $101.1 million for the same period in 2017. The increase in cash usage is primarily due to the receipt of a $15 million payment under the Grant Agreement with BMGF in the nine months ended September 30, 2018, as compared to receipt of a $25 million payment in the same period in 2017, along with increased reimbursements from restricted cash of $5.4 million in the nine months ended September 30, 2018, as compared to the same period in 2017 as a result of higher development costs of ResVax. This increase also includes $13.5 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 (partially offset by the Company’s retention bonus paid in the nine months ended September 30, 2017). We adopted a new accounting standard in 2018 that requires restricted cash to be included in the beginning and ending cash balances on the statements of cash flows for all periods presented.

During the nine months ended September 30, 2018 and 2017, our investing activities consisted of purchases and maturities of marketable securities and capital expenditures. Capital expenditures for the nine months ended September 30, 2018 and 2017 were $0.9 million and $3.5 million, respectively. The decrease in capital expenditures was primarily due to reduced capital requirements based on our current operating plans. In 2018, we expect our level of capital expenditures to be lower than 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 nine months ended September 30, 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 and 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 nine months ended September 30, 2017, we received net proceeds of $46.0 million from selling shares of common stock through our January 2017 Sales Agreement at a weighted average sales price of $1.25 per share.

In May 2016, we entered into a 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 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 July 2018, we terminated 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 licensed in India. In September 2015, due to CPLB's initiation of a Phase 3 clinical trial of CadiFlu in 2014, we entered into an amendment to the Wyeth license that, among other things, increased the milestone payment ("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 September 30, 2018 aggregated to $11.6 million.

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 the nine months ended September 30, 2018, we incurred a net loss of $135.4 million and had net cash flows used in operating activities of $139.6 million. At September 30, 2018, we had $145.6 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 upcoming final efficacy analysis of Prepare, a global pivotal Phase 3 clinical trial of ResVax (with top-line data expected to be announced in the first quarter of 2019), and our Phase 2 clinical trial of NanoFlu that was initiated in the third quarter of 2018 (also with top-line data expected to be announced in the first 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 September 30, 2018.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

The primary objective of our investment activities is preservation of capital, with the secondary objective of maximizing income. As of September 30, 2018, we had cash and cash equivalents of $56.5 million, marketable securities of $70.6 million, all of which are short-term in nature, $18.5 million in restricted cash and working capital of $113.8 million.

Our exposure to market risk is primarily confined to our investment portfolio. As of September 30, 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 $2.7 million at September 30, 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 September 30, 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 September 30, 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 September 30, 2018, and has concluded that there was no change that occurred during the quarterly period ended September 30, 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

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

Given our current cash position, there is substantial doubt about our ability to continue as a going concern through one year from the date of the financial statements included in this Quarterly Report.

We adopted ASU 2014-15, *Presentation of Financial Statements-Going Concern (Subtopic 205-40): Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern,* in 2016, under which standard our management must evaluate whether there are conditions or events, considered in the aggregate, that raise substantial doubt about our ability to continue as a going concern within one year after the date that financial statements are issued. During the nine months ended September 30, 2018, we have incurred a net loss of $135.4 million and had net cash flows used in operating activities of $139.6 million. At September 30, 2018, we had $145.6 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. Our management believes that, given the Company's current cash position, there is substantial doubt about our ability to continue as a going concern through one year from the date that the financial statements included in this Quarterly Report were issued.

Our capital requirements and cash needs are significant and continuing. Over the next twelve months, we anticipate incurring additional net losses and negative cash flows from operating activities as we continue our product development activities, including our upcoming final efficacy analysis of Prepare, our global pivotal Phase 3 clinical trial of ResVax, and our Phase 2 clinical trial of NanoFlu (the results of both trials are expected to be announced in the first quarter of 2019). Our ability to fund our 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. There can be no assurances that new financings or other transactions will 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 adequate capital resources to fund our operations, we may be required to delay, reduce the scope of or eliminate some or all of our operations, which may have a material adverse effect on our business, financial condition, results of operations and ability to operate as a going concern.

Security breaches and other disruptions could compromise our information and expose us to liability, and our failure to comply with data protection laws and regulations could lead to government enforcement actions, which would cause our business and reputation to suffer.

In the ordinary course of our business, we collect and store sensitive data, including intellectual property, our proprietary business information and data about our clinical participants, suppliers and business partners and personally identifiable information. The secure maintenance of this information is critical to our operations and business strategy. Some of this information could be an attractive target of criminal attack by malicious third parties with a wide range of motives and expertise, including organized criminal groups, "hacktivists," patient groups, disgruntled current or former employees and others. Hacker attacks are of ever-increasing levels of sophistication, and despite our security measures, our information technology and infrastructure may be vulnerable to such attacks or may be breached due to employee error or malfeasance. Any such breach could compromise our networks and the information stored there could be accessed, publicly disclosed, lost or stolen. Furthermore, if our systems become compromised, we may not promptly discover the intrusion. Like other companies in our industry, we have experienced attacks to our data and systems, including malware and computer viruses. Attacks could have a material impact on our business, operations or financial results. Any access, disclosure or other loss of information could result in legal claims or proceedings, liability under laws that protect the privacy of personal information, disrupt our operations, and damage our reputation, which could adversely affect our business. In addition, privacy and data protection laws may be interpreted and applied differently from country to country and may create inconsistent or conflicting requirements, which can increase the costs incurred by us in complying with such laws. The European Union's General Data Protection Regulation ("GDPR"), which greatly increases the jurisdictional reach of European Union law and became effective in May 2018, adds a broad array of requirements for handling personal data including the public disclosure of significant data breaches, and imposes substantial penalties for non-compliance of up to the greater of €20 million or 4% of global annual revenue for the preceding financial year. Our efforts to comply with GDPR and other privacy and data protection laws may impose significant costs and challenges that are likely to increase over time, and we could incur substantial penalties or litigation related to violation of existing or future data privacy laws and regulations.

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The recently passed comprehensive tax reform bill could adversely affect our business and financial condition.

On December 22, 2017, President Trump signed into law new legislation that significantly revises the Internal Revenue Code of 1986, as amended. The newly enacted federal income tax law, among other things, contains significant changes to corporate taxation, including reduction of the corporate tax rate from a top marginal rate of 35 percent to a flat rate of 21 percent, limitation of the tax deduction for interest expense to 30 percent of adjusted earnings (except for certain small businesses), limitation of the deduction for net operating losses to 80 percent of current-year taxable income and elimination of net operating loss carrybacks, one time taxation of offshore earnings at reduced rates regardless of whether they are repatriated, immediate deductions for certain new investments instead of deductions for depreciation expense over time, modifying or repealing many business deductions and credits, and puts into effect the migration from a "worldwide" system of taxation to a territorial system. Notwithstanding the reduction in the corporate income tax rate, the overall impact of the new federal tax law is uncertain and our business and financial condition could be adversely affected. In addition, it is uncertain if and to what extent various states will conform to the newly enacted federal tax law.

Item 6. Exhibits

3.1	Second Amended and Restated Certificate of Incorporation of the Company (Incorporated by reference to Exhibit 3.1 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2015, filed August 10, 2015)
3.2	Amended and Restated By-Laws of the Company (Incorporated by reference to Exhibit 3.2 to the Company's Annual Report on Form 10-K for the year ended December 31, 2012, filed March 12, 2013)
10.1* **	Second Amended and Restated Joint Venture Agreement between Novavax, Inc. and Cadila Pharmaceuticals Limited, dated as of July 17, 2018
10.2* **	Second Amended and Restated Novavax Product License Agreement between Novavax, Inc. and CPL Biologicals Private Limited, dated as of July 17, 2018
31.1*	Certification of Chief Executive Officer pursuant to Rule 13a-14(a) or 15d-14(e) of the Securities Exchange Act
31.2*	Certification of Chief Financial Officer pursuant to Rule 13a-14(a) or 15d-14(e) of the Securities Exchange Act
32.1*	Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2*	Certification of Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101	The following financial information from our Quarterly Report on Form 10-Q for the quarter ended September 30, 2018, formatted in Extensible Business Reporting Language (XBRL): (i) the Consolidated Balance Sheets

as of September 30, 2018 and December 31, 2017, (ii) the Consolidated Statements of Operations for the three- and nine-month periods ended September 30, 2018 and 2017, (iii) the Consolidated Statements of Comprehensive Loss for the three- and nine-month periods ended September 30, 2018 and 2017, (iv) the Consolidated Statements of Cash Flows for the nine-month periods ended September 30, 2018 and 2017, and (v) the Notes to Consolidated Financial Statements.

* Filed herewith.
** Confidential treatment has been requested for portions of exhibit.

SIGNATURES

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

NOVAVAX, INC.

Date: November 7, 2018 By: /s/ Stanley C. Erck
President and Chief Executive Officer and Director
(Principal Executive Officer)

Date: November 7, 2018 By: /s/ John J. Trizzino
Senior Vice President, Chief Business Officer, Chief Financial Officer and Treasurer
(Principal Financial and Accounting Officer)