

NOVAVAX INC
Form 10-Q
August 09, 2012

UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-Q

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

For the quarterly period ended June 30, 2012

OR

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

For the transition period from to .

Commission File No. 0-26770

NOVAVAX, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

22-2816046
(I.R.S.
Employer

Edgar Filing: NOVAVAX INC - Form 10-Q

Identification
No.)

9920 Belward Campus Drive, Rockville, MD
(Address of principal executive offices)

20850
(Zip code)

(240) 268-2000

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

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

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

Large accelerated filer " Accelerated filer x Non-accelerated filer " Smaller reporting company
(Do not check if a smaller reporting company) "

Indicate by check mark whether the Registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).
Yes " No x

The number of shares outstanding of the Registrant's Common Stock, \$0.01 par value, was 133,675,921 as of July 31, 2012.

NOVAVAX, INC.

TABLE OF CONTENTS

	Page No.
PART I. FINANCIAL INFORMATION	
Item 1. Financial Statements	
Balance Sheets as of June 30, 2012 (unaudited) and December 31, 2011	1
Statements of Operations and Comprehensive Loss for the three and six months ended June 30, 2012 and 2011 (unaudited)	2
Statements of Cash Flows for the six months ended June 30, 2012 and 2011 (unaudited)	3
Notes to the Financial Statements (unaudited)	4
Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations	12
Item 3. Quantitative and Qualitative Disclosures about Market Risk	25
Item 4. Controls and Procedures	25
PART II. OTHER INFORMATION	
Item 1A. Risk Factors	26
Item 6. Exhibits	26
SIGNATURES	27

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

(in thousands, except share and per share information)

	June 30, 2012 (unaudited)	December 31, 2011
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 15,334	\$ 14,104
Short-term investments available-for-sale	11,202	4,205
Accounts receivables	1,498	1,965
Unbilled receivables	4,231	1,836
Prepaid expenses	2,452	2,441
Other current assets	261	1,558
Total current assets	34,978	26,109
Property and equipment, net	7,753	6,857
Goodwill	33,141	33,141
Restricted cash	755	—
Other non-current assets	350	469
Total assets	\$ 76,977	\$ 66,576
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 3,380	\$ 2,645
Accrued expenses and other current liabilities	5,633	4,528
Current portion of notes payable	—	20
Deferred rent	409	386
Total current liabilities	9,422	7,579
Warrant liability	368	368
Deferred revenue	2,500	2,500
Non-current portion of notes payable	400	300
Deferred rent	3,208	1,980
Total liabilities	15,898	12,727
Commitments and contingences	—	—
Stockholders' equity:		

Edgar Filing: NOVAVAX INC - Form 10-Q

Preferred stock, \$0.01 par value, 2,000,000 shares authorized; no shares issued and outstanding	—	—
Common stock, \$0.01 par value, 200,000,000 shares authorized; and 132,607,651 shares issued and 132,152,221 shares outstanding at June 30, 2012 and 117,480,867 shares issued and 117,025,437 shares outstanding at December 31, 2011	1,326	1,175
Additional paid-in capital	404,175	383,948
Accumulated deficit	(342,912)	(329,656)
Treasury stock, 455,430 shares, cost basis	(2,450)	(2,450)
Accumulated other comprehensive income	940	832
Total stockholders' equity	61,079	53,849
Total liabilities and stockholders' equity	\$ 76,977	\$ 66,576

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

NOVAVAX, INC.

STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

(in thousands, except per share information)

(unaudited)

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	2012	2011	2012	2011
Contract revenue	\$7,103	\$3,001	\$11,745	\$3,835
Costs and expenses:				
Cost of contract revenue	5,118	1,231	8,903	1,574
Research and development	5,176	4,353	10,254	9,424
General and administrative	2,664	3,338	5,910	6,188
Total costs and expenses	12,958	8,922	25,067	17,186
Loss from operations	(5,855)	(5,921)	(13,322)	(13,351)
Other income (expense):				
Interest income	39	38	72	84
Interest expense	(3)	(2)	(6)	(4)
Change in fair value of warrant liability	(101)	1,304	—	1,237
Loss from operations before income tax	(5,920)	(4,581)	(13,256)	(12,034)
Income tax expense		412		412
Net loss	\$(5,920)	\$(4,993)	\$(13,256)	\$(12,446)
Basic and diluted net loss per share	\$(0.05)	\$(0.04)	\$(0.11)	\$(0.11)
Basic and diluted weighted average number of common shares outstanding	126,925	112,821	123,741	112,009

For the Three Months		For the Six Months	
Ended June 30,		Ended June 30,	
2012	2011	2012	2011

Comprehensive loss:

Edgar Filing: NOVAVAX INC - Form 10-Q

Net loss	\$ (5,920)	\$ (4,993)	\$ (13,256)	\$ (12,446)
Unrealized gain (loss) on short-term investments available-for-sale	(36)	11	108	138
Comprehensive loss	\$ (5,956)	\$ (4,982)	\$ (13,148)	\$ (12,308)

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

NOVAVAX, INC.

STATEMENTS OF CASH FLOWS

(in thousands)

(unaudited)

	For the Six Months	
	Ended June 30,	
	2012	2011
Operating Activities:		
Net loss	\$(13,256)	\$(12,446)
Reconciliation of net loss to net cash used in operating activities:		
Change in fair value of warrant liability	—	(1,237)
Depreciation and amortization	810	788
Amortization of net premiums on short-term investments	—	231
Gain on disposal of property and equipment	(19)	—
Deferred rent	251	(168)
Non-cash stock-based compensation	1,176	1,135
Changes in operating assets and liabilities:		
Accounts receivables	467	(1,778)
Unbilled receivables	(2,395)	(2,020)
Prepaid expenses and other assets	58	(636)
Accounts payable and accrued expenses	1,562	(3,808)
Deferred revenue		2,500
Lease incentives received	1,000	—
Net cash used in operating activities	(10,346)	(17,439)
Investing Activities:		
Capital expenditures	(1,076)	(178)
Proceeds from disposal of property and equipment	167	
Proceeds from maturities of short-term investments	2,500	15,375
Purchases of short-term investments	(9,389)	(1,082)
Net cash (used in) provided by investing activities	(7,798)	14,115
Financing Activities:		
Principal payments of notes payable	(20)	(40)
Proceeds from notes payable	100	—
Restricted cash	(755)	—
Net proceeds from sales of common stock, net of offering costs of \$0.3 million and \$0.2 million, respectively	20,023	8,280
Proceeds from the exercise of stock options	26	115
Net cash provided by financing activities	19,374	8,355
Net increase in cash and cash equivalents	1,230	5,031

Edgar Filing: NOVAVAX INC - Form 10-Q

Cash and cash equivalents at beginning of period	14,104	8,061
Cash and cash equivalents at end of period	\$15,334	\$13,092
Supplemental disclosure of non-cash activities:		
Deposit applied towards the purchase of laboratory equipment	\$500	\$—
Equipment purchases included in accounts payable and accrued expenses	\$278	\$34

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

NOVAVAX, INC.

NOTES TO FINANCIAL STATEMENTS

June 30, 2012

(unaudited)

Note 1 – Organization

Novavax, Inc. (the “Company”) is a clinical-stage biopharmaceutical company focused on developing novel recombinant vaccines to address a broad range of infectious diseases. The Company’s goal is to become a profitable vaccine company that is aggressively driving towards development, licensure and commercialization of important vaccines worldwide. The Company’s technology platform is based on proprietary recombinant vaccine technology that includes virus-like particles (“VLPs”) and recombinant nanoparticle vaccines combined with a single-use bioprocessing production system. These vaccine candidates are genetically engineered three-dimensional nanostructures that incorporate immunologically important recombinant proteins. The Company’s product pipeline targets a variety of infectious diseases and its vaccine candidates are currently in or have completed clinical trials that target pandemic influenza (H5N1), seasonal influenza and respiratory syncytial virus (“RSV”).

In 2009, the Company formed a joint venture with Cadila Pharmaceuticals Limited named CPL Biologicals Private Limited to develop and manufacture vaccines, biological therapeutics and diagnostics in India. The joint venture is owned 20% by the Company and 80% by Cadila Pharmaceuticals Limited. The Company accounts for its investment in the joint venture using the equity method.

Note 2 – Liquidity Matters

The Company’s vaccine candidates currently under development will require significant additional research and development efforts that may include extensive pre-clinical and clinical testing, and regulatory approval prior to commercial use. The Company’s research and development efforts may not be successful and any potential vaccine candidates may not prove to be safe and effective in clinical trials. Even if developed, these vaccine candidates may not receive regulatory approval or be successfully introduced and marketed at prices that would permit the Company to operate profitably. The commercial launch of any vaccine is subject to significant risks including, but not limited to, manufacturing scale-up and market acceptance.

Since its inception, the Company has incurred, and continues to incur, significant losses from operations. At June 30, 2012, the Company had cash and cash equivalents of \$15.3 million and short-term investments with a fair value of \$11.2 million.

Based on the Company's cash and cash equivalents and short-term investments as of June 30, 2012, anticipated revenue under the contract with the Department of Health and Human Services, Biomedical Advanced Research and Development Authority ("HHS BARDA") that was awarded in February 2011, possible proceeds from sales of the Company's common stock under its At Market Issuance Sales Agreement and funding under the Improvement Allowance (see Note 8) and its current business operations, the Company believes it has adequate capital resources available to operate at planned levels for at least the next twelve months. Additional capital will be required in the future to develop its vaccine candidates through clinical development, manufacturing and commercialization. The Company's ability to obtain such additional capital is subject to various factors:

- generating revenue under the HHS BARDA contract is subject to the Company's performance under the contract, including its ability to collect on delayed reimbursement situations, such as the 205 Trial costs described in Note 5 below;

- raising funds under its At Market Issuance Sales Agreement is subject to both its business performance and market conditions; and

- receiving funds under the Improvement Allowance is subject to compliance with the lease terms.

Further, the Company may seek additional capital through public or private equity offerings, debt financing, strategic alliance and licensing arrangements, non-dilutive government contracts, collaborative arrangements, or some combination of these financing alternatives. Any capital raised by an equity offering, whether public or private, will likely be substantially dilutive to the existing stockholders and any licensing or development arrangement may require the Company to give up rights to a product or technology at less than its full potential value. Other than the Company's At Market Issuance Sales Agreement and the Improvement Allowance, the Company has not secured any additional commitments for new financing, nor can the Company provide any assurance that financing will be available on commercially acceptable terms, if at all. If the Company is unable to perform under the HHS BARDA contract or obtain additional capital, it will assess its capital resources and will likely be required to delay, reduce the scope of, or eliminate one or more of its research and development programs, and/or downsize the organization, including its general and administrative infrastructure.

Note 3 – Summary of Significant Accounting Policies

Basis of Presentation

The accompanying unaudited financial statements have been prepared in accordance with United States Generally Accepted Accounting Principles ("GAAP") for interim financial information and the instructions to Form 10-Q and Article 10 of Regulation S-X. The balance sheet as of June 30, 2012, statements of operations for the three and six months ended June 30, 2012 and 2011 and the statements of cash flows for the six months ended June 30, 2012 and 2011 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 and cash flows, respectively, for the periods presented. Although the Company believes that the disclosures in these financial statements are adequate to make the information presented not misleading, certain information and footnote information normally included in financial statements prepared in accordance with GAAP have been condensed or omitted pursuant to the rules and regulations of the United States Securities and Exchange Commission ("SEC").

Results for any interim period are not necessarily indicative of results for any future interim period or for the entire year. The accompanying unaudited 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, 2011.

Use of Estimates

The preparation of the financial statements in conformity with 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 financial statements and the reported amounts of revenue and expenses during the reporting period.

Actual results could differ materially from these estimates.

Fair Value Measurements

The Company applies Accounting Standards Codification (“ASC”) Topic 820, *Fair Value Measurements and Disclosures*, for financial and non-financial assets and liabilities.

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

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

Financial assets and liabilities measured at fair market value on a recurring basis as of June 30, 2012 and December 31, 2011 are summarized below (in thousands):

	Fair Value at June 30, 2012			Fair Value at December 31, 2011		
	Level 1	Level 2	Level 3	Level 1	Level 2	Level 3
<u>Assets</u>						
Corporate debt and auction rate securities	\$—	\$11,202	\$—	\$—	\$4,205	\$—
<u>Liabilities</u>						
Warrant liability	\$—	\$—	\$368	\$—	\$—	\$368

The following table summarizes the activity of Level 3 inputs measured on a recurring basis as of June 30, 2012 (in thousands):

Fair Value Measurements of Warrants Using Significant Unobservable Inputs	
(Level 3)	
Balance at December 31, 2011	\$ 368
Change in fair value of Warrant liability	
Balance at June 30, 2012	\$ 368

The amounts in the Company's balance sheet for accounts receivable, unbilled receivables and accounts payable approximate fair value due to their short-term nature. Based on borrowing rates available to the Company, the fair

value of notes payable approximates its carrying value.

Short-Term Investments

Short-term investments at June 30, 2012 consist of investments in commercial paper and three auction rate securities. All marketable securities had original maturities greater than 90 days, but less than one year. The auction rate securities have a par value of \$5.1 million. The Company has classified these securities as available-for-sale since the Company may need to liquidate these securities within the next year. The available-for-sale securities are carried at fair value and unrealized gains and losses, if determined to be temporary, on these securities are included in accumulated other comprehensive income (loss) in stockholders' equity. Investments available for sale are evaluated periodically to determine whether a decline in value is "other-than-temporary." The term "other-than-temporary" is not intended to indicate a permanent decline in value. Rather, it means that the prospects for a near term recovery of value are not necessarily favorable, or that there is a lack of evidence to support fair values equal to, or greater than, the carrying value of the security. Management reviews criteria, such as the magnitude and duration of the decline, as well as the Company's ability to hold the securities until market recovery, to predict whether the loss in value is other-than-temporary. If a decline in value is determined to be other-than-temporary, the value of the security is reduced and the impairment is recorded in the statements of operations. The specific identification method is used in computing realized gains and losses on sale of the Company's securities.

Short-term investments classified as available-for-sale as of June 30, 2012 and December 31, 2011 were comprised of (in thousands):

	June 30, 2012				December 31, 2011			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Auction rate securities	\$3,373	\$ 933	\$ —	\$4,306	\$3,373	\$ 832	\$ —	\$4,205
Corporate debt securities	6,889	7	—	6,896	—	—	—	—
Total	\$10,262	\$ 940	\$ —	\$11,202	\$3,373	\$ 832	\$ —	\$4,205

Restricted Cash

The Company's restricted cash with respect to its new manufacturing, laboratory and office space in Gaithersburg, Maryland functions as collateral for letters of credit, which serve as security deposits for the duration of the leases.

Net Loss per Share

Net loss per share is computed using the weighted average number of shares of common stock outstanding. All outstanding warrants, stock options and unvested restricted stock awards totaling 13,110,708 shares and 11,290,256 shares at June 30, 2012 and 2011, respectively, are excluded from the computation, as their effect is antidilutive.

Recent Accounting Pronouncements

In June 2011, the FASB issued ASU 2011-05, *Comprehensive Income (Topic 220): Presentation of Comprehensive Income* ("ASU 2011-05"). This guidance is intended to increase the prominence of other comprehensive income in financial statements by presenting it in either a single-statement or two-statement approach. This ASU was effective for the Company beginning January 1, 2012. This presentation requirement was adopted January 1, 2012 and is reflected on the accompanying statements of operations and comprehensive loss for the periods ended June 30, 2012 and 2011.

In September 2011, the FASB issued ASU 2011-08, *Intangibles – Goodwill and Other (Topic 350): Testing Goodwill for Impairment* (“ASU 2011-08”), to give both public and nonpublic entities the option to qualitatively determine whether they can bypass the two-step goodwill impairment test. Under the new guidance, if an entity chooses to perform a qualitative assessment and determines that it is more likely than not (a more than 50 percent likelihood) that the fair value of a reporting unit is less than its carrying amount, it would then perform Step 1 of the annual goodwill impairment test in ASC 350-20 and, if necessary, proceed to Step 2. Otherwise, no further evaluation would be necessary. The decision to perform a qualitative assessment is made at the reporting unit level, and an entity with multiple reporting units may utilize a mix of qualitative assessments and quantitative tests among its reporting units. The amended guidance was effective for interim and annual goodwill impairment tests performed for fiscal years beginning after December 15, 2011, although early adoption was permitted. The adoption of ASU 2011-08 on January 1, 2012 did not have a material effect on the Company’s financial statements.

Note 4 – Stock-Based Compensation

The Company has granted equity awards under several plans. Under the 2005 Stock Incentive Plan (the “2005 Plan”), equity awards may be granted to officers, directors, employees, consultants and advisors to the Company and any present or future subsidiary. The 2005 Plan, approved in May 2005 and amended in June 2007, June 2011 and June 2012 by the Company’s stockholders, currently authorizes the grant of equity awards for up to 18,312,192 shares of common stock, which included, at the time of approval of the 2005 Plan, a maximum 5,746,468 shares of common stock subject to stock options outstanding under the Company’s 1995 Stock Option Plan (the “1995 Plan”) that may revert to and become issuable under the 2005 Plan if such options should expire or otherwise terminate unexercised. The term of the Company’s 1995 Plan has expired. Outstanding stock options remain in existence in accordance with their terms and no new awards will be made under the 1995 Plan.

Under the 2005 Plan and the 1995 Plan, incentive stock options, having a maximum term of 10 years, can be or were granted at no less than 100% of the fair value of the Company's common stock at the time of grant and are generally exercisable over periods ranging from six months to four years. There is no minimum exercise price for non-statutory stock options.

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

	Three Months Ended		Six Months Ended	
	June 30,		June 30,	
	2012	2011	2012	2011
Research and development	\$236	\$150	\$419	\$273
General and administrative	353	553	757	862
Total stock-based compensation expense	\$589	\$703	\$1,176	\$1,135

Stock Options Awards

The following is a summary of option activity under the 2005 Plan and the 1995 Plan for the six months ended June 30, 2012:

	2005 Stock Incentive Plan		1995 Stock Option Plan	
	Stock Options	Weighted-Average Exercise Price	Stock Options	Weighted-Average Exercise Price
Outstanding at January 1, 2012	7,412,746	\$ 2.22	474,650	\$ 4.38
Granted	3,428,000	\$ 1.28	—	\$ —
Exercised	(47,034)	\$ 0.56	—	\$ —
Canceled	(1,370,312)	\$ 2.28	(184,000)	\$ 4.00
Outstanding at June 30, 2012	9,423,400	\$ 1.88	290,650	\$ 4.59
Shares exercisable at June 30, 2012	3,148,169	\$ 2.39	290,650	\$ 4.59
Shares available for grant at June 30, 2012	5,437,536			

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

Edgar Filing: NOVAVAX INC - Form 10-Q

	Three Months Ended		Six Months Ended	
	June 30, 2012	2011	June 30, 2012	2011
Weighted-average fair value of stock options granted	\$0.71	\$1.09	\$0.71	\$1.23
Risk-free interest rate	0.59%	0.83%-1.91%	0.59%-1.54%	0.83%-1.91%
Dividend yield	0%	0%	0%	0%
Volatility	75.47%-75.52%	73.28%-80.02%	75.47%-80.48%	73.28%-80.48%
Expected term (in years)	4.24	3.34-4.47	3.34-7.09	3.26-4.47
Expected forfeiture rate	0%-23.15%	0%-23.15%	0%-23.15%	0%-23.15%

The aggregate intrinsic value and weighted-average remaining contractual term of stock options outstanding as of June 30, 2012 was approximately \$1.5 million and 7.9 years, respectively. The aggregate intrinsic value and weighted-average remaining contractual term of stock options exercisable as of June 30, 2012 was approximately \$0.4 million and 5.5 years, respectively. The aggregate intrinsic value represents the total intrinsic value (the difference between the Company's closing stock price on the last trading day of the period and the exercise price, multiplied by the number of in-the-money options) that would have been received by the option holders had all option holders exercised their options on June 30, 2012. This amount is subject to change based on changes to the fair value of the Company's common stock. The aggregate intrinsic value of options exercised for the six months ended June 30, 2012 and 2011 was less than \$0.1 million and \$0.1 million, respectively.

Restricted Stock Awards

Under the 2005 Plan, the Company has granted restricted stock awards subject to certain performance-based and time-based vesting conditions which, if not met, would result in forfeiture of the shares and reversal of any previously recognized related stock-based compensation expense.

The following is a summary of restricted stock awards activity for the six months ended June 30, 2012:

	Number of Shares	Per Share Weighted-Average Grant-Date Fair Value
Outstanding at January 1, 2012	53,333	\$ 1.63
Restricted stock granted	—	\$ —
Restricted stock vested	—	\$ —
Restricted stock forfeited	—	\$ —
Outstanding at June 30, 2012	53,333	\$ 1.63

As of June 30, 2012, there was approximately \$3.9 million of total unrecognized compensation expense (net of estimated forfeitures) related to unvested options and restricted stock awards. This unrecognized compensation expense is expected to be recognized over a weighted-average period of 1.7 years. This estimate does not include the impact of other possible stock-based awards that may be made during future periods.

Note 5 – U.S. Government Agreement and Collaboration

HHS BARDA Contract Award for Recombinant Influenza Vaccines

In February 2011, the Company was awarded a contract from HHS BARDA valued at \$97 million for the 36-month base-period, with an HHS BARDA option for an additional period of 24 months valued at \$82 million, for a total contract value of up to \$179 million. The HHS BARDA contract award provides significant funding for the Company's ongoing clinical development and product scale-up of both its seasonal and pandemic influenza vaccine candidates. This is a cost-plus-fixed-fee contract in which HHS BARDA will reimburse the Company for direct contract costs incurred plus allowable indirect costs and a fee earned in the further development of its multivalent seasonal and monovalent pandemic (H5N1) influenza vaccines. Billings under the contract are based on approved provisional indirect billing rates, which permit recovery of fringe benefits, overhead and general and administrative expenses not exceeding certain limits. These indirect rates are subject to audit by HHS BARDA on an annual basis. When the final determination of the allowable costs for any year has been made, revenue and billings may be adjusted accordingly. Since the inception of the contract and during the six months ended June 30, 2012, the Company has recognized revenue of approximately \$26.1 million and \$11.4 million, respectively.

Under certain circumstances HHS BARDA reimbursements may be delayed or even potentially withheld. In March 2012, the Company decided to conduct its Phase II dose-ranging clinical trial of its trivalent and quadrivalent seasonal influenza vaccine candidates (the "205 Trial") under its existing U.S. investigational new drug application ("IND") for its trivalent seasonal influenza vaccine candidate ("Trivalent IND") as opposed to waiting to conduct the 205 Trial under a new IND for its quadrivalent vaccine candidate ("Quadrivalent IND"). In July 2012, the Company reported that it expected to launch its next quadrivalent Phase II clinical trial in 2013 rather than in the second half of 2012; similarly, the filing of the Quadrivalent IND, which the Company had previously indicated was expected in the second half of 2012 will also be delayed. Based on discussions between HHS BARDA and the Company, because the 205 Trial includes its quadrivalent seasonal influenza vaccine candidate, the outside clinical trial costs for the 205 Trial will only be submitted for reimbursement to HHS BARDA and recorded as revenue by the Company after it submits the 205 Trial data to its Quadrivalent IND. Until then, the outside clinical trial costs of the 205 Trial will be expensed and included in cost of contract revenue. The financial impact of this delay in revenue recognition is based on the outside clinical trial costs of the 205 Trial that are expected to total approximately \$3.1 million, of which \$2.4 million was incurred through June 30, 2012.

License Agreement with LG Life Sciences, Ltd.

In February 2011, the Company entered into a license agreement with LG Life Sciences, Ltd. (“LGLS”) that allows LGLS to use the Company’s VLP technology to develop and commercially sell influenza vaccines exclusively in South Korea and non-exclusively in certain other specified countries. At its own cost, LGLS is responsible for funding its clinical development of the influenza VLP vaccines and completing a manufacturing facility in South Korea. The term of the license agreement is expected to terminate in 2027. Payments to the Company under the license agreement include an upfront payment, reimbursements of certain development and product costs and royalty payments between 10 and 20% from LGLS’s future commercial sales of influenza VLP vaccines. The upfront payment has been deferred and will be recognized as revenue when certain obligations in the agreement are satisfied.

Note 6 – Warrant Liability

In July 2008, the Company completed a registered direct offering of 6,686,650 units, raising approximately \$17.5 million in net proceeds. Each unit consisted of one share of common stock and a warrant to purchase 0.5 shares of common stock (the “Warrants”) at a price of \$2.68 per unit. The Warrants represent the right to acquire an aggregate of 3,343,325 shares of common stock at an exercise price of \$3.62 per share and are exercisable between January 31, 2009 and July 31, 2013.

During the six months ended June 30, 2012 and 2011, the Company recorded as other income (expense) in its statements of operations and comprehensive loss a change in fair value of warrant liability of \$0 million and \$1.2 million, respectively. As of June 30, 2012, the warrant liability recorded on the balance sheet was \$0.4 million and all Warrants remain outstanding as of that date.

Note 7 – Sales of Common Stock

In May 2012, the Company sold 10,000,000 shares of its common stock to two affiliates of RA Capital Management, LLC at a price of \$1.22 per share, resulting in \$12.1 million in net proceeds. The shares were offered under an effective shelf registration statement previously filed with the SEC.

In March 2010, the Company entered into a sales agreement, under which the Company may sell an aggregate of \$50 million in gross proceeds of its common stock. The Company’s Board of Directors has authorized the sale of up to 25 million shares of the Company’s common stock pursuant to this agreement. The shares of common stock are being offered pursuant to a shelf registration statement filed with the SEC. For the six months ended June 30, 2012, the

Edgar Filing: NOVAVAX INC - Form 10-Q

Company sold 5.1 million shares at an average sales price of \$1.42 per share, resulting in \$7.1 million in net proceeds; this amount excludes \$0.8 million received in early 2012 for 0.7 million shares traded in late December 2011. Since June 30, 2012 through July 31, 2012, the Company has sold an additional 1.5 million shares resulting in \$3.2 million in net proceeds. Since entering into the sales agreement through July 31, 2012, the Company has sold 23,094,140 shares of its common stock and received gross proceeds of \$46.1 million.

Note 8 – Manufacturing, Laboratory and Office Facility

In November 2011, the Company entered into lease agreements, under which the Company leases its new manufacturing, laboratory and office space in Gaithersburg, Maryland. The lease agreements provide that, among other things, as of January 1, 2012, the Company sublease from the current facility tenant, and subsequently lease directly from the landlord, approximately 74,000 total square feet, with rent payments for such space to the landlord commencing April 1, 2014. Under the terms of the arrangement, the Landlord will provide the Company with a tenant improvement allowance of \$2.5 million and an additional tenant improvement allowance of \$3 million dollars (collectively, the “Improvement Allowance”). The additional tenant improvement allowance is to be paid back to the Landlord over the remaining term of the lease agreement. During the six months ended June 30, 2012, the Company was funded \$2.1 million under the Improvement Allowance. In addition, the Company purchased laboratory equipment under an agreement with the then current facility tenant. The Company is currently renovating the new facility and has started remarketing the Rockville, Maryland facility, which lease term ends January 31, 2017.

Note 9 – Subsequent Events

In July 2012, the Company entered into a clinical development agreement with PATH Vaccine Solutions (“PATH”) to develop its vaccine candidate to protect against RSV through maternal immunization in low resource countries. The Company was awarded approximately \$2.0 million by PATH for initial funding under the agreement to partially support its Phase II dose-ranging clinical trial in women of childbearing age, which is expected to be launched in the second half of 2012. Thereafter, the Company and PATH can elect to continue to collaborate on additional phases to develop the vaccine for maternal immunization in low-resource countries, with PATH potentially funding 50% of the Company’s external clinical development costs. The Company will retain global rights to commercialize the product and has made a commitment to make the product affordable and available in low-resource countries.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

Certain statements contained or incorporated by reference herein constitute forward-looking statements. In some cases, these statements can be identified by the use of forward-looking terminology such as "expect(s)," "intends," "plans," "seeks," "estimates," "could," "should," "feel(s)," "believe(s)," "will," "would," "may," "can," "anticipate(s)," "potential" and expressions or the negative of these terms. Such forward-looking statements are subject to risks and uncertainties that may cause the actual results, performance or achievements of the Company, or industry results, to be materially different from those expressed or implied by such forward-looking statements.

Forward-looking statements in this Quarterly Report on Form 10-Q include, without limitation, statements regarding:

- potential benefits, regulatory approval and commercialization of our vaccine candidates;

- our expectation that we will have adequate capital resources available to operate at planned levels for at least the next twelve months;

- our expected 2012 capital expenditures;

- our expectations for future revenue under the contract with the Department of Health and Human Services, Biomedical Advanced Research and Development Authority (HHS BARDA) and funding requirements and capital raising activity, including possible proceeds from our At Market Issuance Sales Agreement and funding under the Improvement Allowance;

- our expectations on financial or business performance, conditions or strategies and other financial and business matters, including expectations regarding operating expenses, use of cash, and the fluctuations in expenses and capital requirements associated with pre-clinical studies, clinical trials and other research and development activities;

- our expectations on clinical development and anticipated milestones, including under the contract with HHS BARDA, our planned clinical trials and regulatory filings as necessary for our vaccine candidates;

- our expectations that our product candidates will prove to be safe and effective;

- our expectations that our multivalent seasonal influenza virus-like particle (VLP) vaccine could potentially address an unmet medical need in older adults or children;

- our expectations that our RSV vaccine could potentially address unmet medical needs;

our expectation that we will utilize the amount of services that is required to be provided by Cadila Pharmaceuticals Limited (Cadila) under the master services agreement;

- our expectations regarding payments to Wyeth Holdings Corporation, a subsidiary of Pfizer Inc. (Wyeth);

our expectations for the use of results from our Pandemic H1N1 clinical trial in Mexico to support the development of our influenza vaccines in other countries, including the U.S.;

- our expectations concerning payments under existing license agreements; and

other factors referenced herein.

The Company assumes no obligation to update any such forward-looking statements, except as specifically required by law. We caution readers not to place considerable reliance on the forward-looking statements contained in this Quarterly Report.

Overview

Novavax, Inc., a Delaware corporation (“Novavax,” the “Company,” “we,” or “us”), was incorporated in 1987, and is a clinical-stage biopharmaceutical company focused on developing novel recombinant vaccines to address a broad range of infectious diseases. Our goal is to become a profitable vaccine company that is aggressively driving towards development, licensure and commercialization of important vaccines worldwide.

Our technology platform is based on proprietary recombinant vaccine technology that includes VLPs and recombinant nanoparticle vaccines combined with a single-use bioprocessing production system. Our vaccine candidates are genetically engineered three-dimensional nanostructures that incorporate immunologically important recombinant proteins. Our product pipeline targets a variety of infectious diseases and our vaccine candidates are currently in or have completed clinical trials that target pandemic influenza (H5N1), seasonal influenza and respiratory syncytial virus (RSV).

CPL Biologicals Private Limited (the JV), our joint venture formed in 2009 between us and Cadila, of which 20% is owned by us and 80% is owned by Cadila. The JV will develop and manufacture our pandemic and seasonal influenza vaccine candidates and Cadila’s biogeneric products and other diagnostic products for the territory of India. In June 2010, the JV opened its newly constructed state-of-the-art manufacturing facility, 100% funded by Cadila, to be used to produce pandemic and seasonal influenza vaccines, as well as other vaccine candidates. The JV is actively developing a rabies vaccine candidate that was genetically engineered by Novavax; it recently completed initial pre-clinical immunogenicity studies on this vaccine candidate and is progressing with pre-clinical toxicology studies. Because we do not control the JV, we account for our investment using the equity method. Since the carrying value of our contribution was nominal and there is no guarantee or commitment to provide future funding, we have not recorded nor do we expect to record losses related to this investment in the future.

A current summary of our significant research and development programs and status of development follows:

Program	Development Phase
Pandemic Influenza (H1N1)	Phase II (<i>ended</i>)

Edgar Filing: NOVAVAX INC - Form 10-Q

Pandemic Influenza (H5N1)	Phase II
Seasonal Influenza	Phase II
Respiratory Syncytial Virus (RSV)	Phase I
Rabies (through JV)	Pre-clinical

HHS BARDA Contract Award for Recombinant Influenza Vaccines

In February 2011, we were awarded a contract from HHS BARDA valued at \$97 million for the first 36 month base-period, with an HHS BARDA option for an additional period of 24 months valued at \$82 million, for a total contract value of up to \$179 million. The HHS BARDA contract award provides significant funding for our ongoing clinical development and product scale-up of both our seasonal and pandemic influenza vaccine candidates. This is a cost-plus-fixed-fee contract in which HHS BARDA will reimburse us for direct contract costs incurred plus allowable indirect costs and a fee earned in the further development of our multivalent seasonal and monovalent pandemic (H5N1) influenza vaccines.

Under certain circumstances HHS BARDA reimbursements may be delayed or even potentially withheld. In March 2011, we decided to conduct our Phase II dose-ranging clinical trial of our trivalent and quadrivalent seasonal influenza vaccine candidates (the 205 Trial) under our existing U.S. investigational new drug application (IND) for our trivalent seasonal influenza vaccine candidate (Trivalent IND) as opposed to waiting to conduct the 205 Trial under a new IND for our quadrivalent vaccine candidate (Quadrivalent IND). In July 2012, we reported that we expected to launch our next quadrivalent Phase II clinical trial in 2013 rather than in the second half of 2012; similarly, the filing of the Quadrivalent IND, which we had previously indicated was expected in the second half of 2012 will also be delayed. Based on our discussions with HHS BARDA, because the 205 Trial includes our quadrivalent seasonal influenza vaccine candidate, the outside clinical trial costs for the 205 Trial will only be submitted for reimbursement to HHS BARDA and recorded as revenue by us after we submit the 205 Trial data to our Quadrivalent IND. Until then, the outside clinical trial costs of the 205 Trial will be expensed and included in cost of contract revenue. The financial impact of this delay in revenue recognition is based on the outside clinical trial costs of the 205 Trial that are expected to total approximately \$3.1 million, of which \$2.4 million was incurred through June 30, 2012.

Pandemic Influenza (H1N1)

In 2009 and 2010, we dedicated significant resources to demonstrate our ability to develop a recombinant monovalent VLP vaccine against this latest pandemic influenza strain. We produced a non-cGMP H1N1 VLP vaccine candidate within 3 weeks after the genetic sequence of the novel H1N1 virus was announced and manufactured a cGMP vaccine candidate within 11 weeks of the announcement. We conducted a Phase II clinical trial in Mexico, in collaboration with Laboratorio Avi-Mex S.A. de C.V. and GE Healthcare; and published the final data results in 2011 and presented at the World Health Organization (WHO) Meeting for the Evaluation of Pandemic Influenza Vaccines in Clinical Trials. Our results showed that our H1N1 VLP vaccine exceeded the immunogenicity criteria for seasonal influenza vaccine licensure at all dose levels, including the lowest 5µg dose and that a single administration of the VLP vaccine induced high levels of hemagglutination-inhibition (HAI) titers in subjects without pre-existing detectable immunity to H1N1 influenza. Although H1N1 influenza is no longer considered a pandemic and is being addressed as an active strain in the determination of ongoing seasonal influenza strains, we nevertheless expect that the data from our H1N1 clinical trials will be used to support our pandemic (H5N1) and seasonal influenza VLP vaccine programs in the U.S. and in other countries.

Pandemic Influenza (H5N1)

We have made significant progress in the development of our monovalent vaccine that targets the H5N1 influenza strain. In 2007, we released results from an important pre-clinical study in which ferrets that received our H5N1 vaccine candidate were protected from a lethal challenge of the H5N1 virus. After filing an IND, we initiated a Phase I/IIa clinical trial. We released interim data from the first portion of this clinical trial in December 2007. These interim results demonstrated that our pandemic influenza vaccine can generate a protective immune response. We conducted the second portion of the Phase I/IIa trial in 2008 to gather additional subject immunogenicity and safety data and determine a final dose through the completion of this clinical trial. In August 2008, we reported favorable results from this clinical trial, which demonstrated strong neutralizing antibody titers across all three doses tested. The vaccine was well-tolerated at all dose levels as compared with placebo, and no serious adverse events were reported. The vaccine also induced robust HAI responses, which have been shown to be important for protection against influenza disease. In conjunction with our HHS BARDA contract, in May 2012, we launched two Phase I trials of our H5N1 vaccine candidate in combination with several alternative adjuvant candidates. These trials will evaluate the safety and tolerability of the vaccines in the presence and absence of adjuvants; the ability of VLP vaccine antigens with and without adjuvants to generate antibody levels that fulfill the FDA's criteria for accelerated approval, and the ability of these vaccines to provide an expanded number of doses and possible cross-protection against other virus strains to the U.S. population. In July 2012, we reported that both Phase I trials had been completely enrolled.

Seasonal Influenza

We are actively developing our multivalent VLP vaccine that targets the seasonal influenza virus. In April 2010, we reported the final results of our Phase II trial in older adults (60 years of age or older) in a dose-ranging study comparing our seasonal trivalent (three strain) influenza VLP vaccine with a commercially available inactivated trivalent influenza vaccine (TIV). The results showed that the vaccine was both safe and immunogenic against the 2009-2010 seasonal influenza virus strains in older adults. The CDC has indicated that currently approved seasonal influenza vaccines may be suboptimally effective in preventing hospitalization for pneumonia and influenza in older adults; however, we believe that some features of our seasonal influenza VLP vaccine have the potential to offer improved efficacy.

In March 2012, we initiated the 205 Trial. We developed a quadrivalent formulation of our seasonal influenza vaccine candidate as many influenza vaccine manufacturers move from trivalent to quadrivalent formulations, an industry move that has been acknowledged by WHO and the FDA. In July 2012, topline results for the 205 Trial were reported and demonstrated that the quadrivalent VLP vaccine candidate achieved its primary endpoints of safety and immunogenicity. The VLP vaccine candidate demonstrated immunogenicity against all four viral strains based on HAI responses at day 21, was also well-tolerated with no vaccine-related serious adverse events observed and reactogenicity was considered acceptable. We also announced that a secondary endpoint of the study was to evaluate the potential of the VLP vaccine candidate to fulfill the FDA Center for Biologics Evaluation and Research (CBER) criteria for accelerated approval, specifically by meeting certain seroconversion rates and seroprotection rates. The VLP vaccine candidate met the FDA seroprotection rates for all four viral strains; however, the seroconversion rates were met by three of the four viral strains. The fourth virus, B/Brisbane/60/08, despite fulfilling the seroprotection rates, failed to meet the seroconversion rates. In addition, we also compared the immunogenicity of the VLP vaccine candidate against that of a licensed TIV produced in eggs. In general, the results showed the comparator TIV to reach higher levels of HAI than our VLP vaccine candidate. Finally, we reported that we are evaluating further process development and assay refinements that we believe will further improve the immunogenicity profile of the VLP vaccine candidate and will delay the start of our next Phase II trial until 2013. The timing of the launch of our Phase III registration will be coordinated with the completion of the aforementioned Phase II trial launch in 2013.

Respiratory Syncytial Virus (RSV)

We have developed a recombinant nanoparticle vaccine to prevent RSV. In pre-clinical studies, we have demonstrated positive results in models designed to test the safety and efficacy of our RSV vaccine candidate. In December 2010, we initiated a blinded, placebo-controlled, dose-escalating Phase I trial to assess the safety and tolerability of aluminum phosphate-adjuvanted and unadjuvanted formulations of our RSV vaccine candidate. A secondary objective of the study was to evaluate total and neutralizing anti-RSV antibody responses and assess the impact of the adjuvant. The study enrolled 150 healthy adults 18 to 49 years old who were allocated to six cohorts that included four dose levels of vaccine. The primary safety findings were local pain and tenderness at the site of injection, the majority of which were mild in nature with no dose-related increase observed. There were no observed vaccine-related serious adverse events or trends for related systemic side effects. The antibody response to the RSV F protein was significantly increased compared to placebo ($p < 0.001$) in all groups and increased by 19-fold in the highest-dose adjuvant group at day 60. A significant dose-response pattern was observed. High rates of seroconversion were seen at all doses including a rate of 100% at the highest-dose-adjuvant group. In the second half of 2012, we expect to initiate two separate dose-ranging Phase II trials in older adults and women of child bearing age.

License Agreement with LG Life Sciences, Ltd. (LGLS)

In February 2011, we entered into a license agreement with LGLS that allows LGLS to use our VLP technology to develop and commercially sell our influenza vaccines in South Korea and certain other emerging-market countries. LGLS received an exclusive license to our influenza VLP technology in South Korea and a non-exclusive license in the other specified countries. At its own cost, LGLS is responsible for funding its clinical development of the

influenza VLP vaccines and completing a manufacturing facility in South Korea. We received an upfront payment and may receive reimbursements of certain development and product costs and royalty payments between 10 and 20% from LGLS's future commercial sales of influenza VLP vaccines.

Clinical Development Agreement with PATH Vaccine Solutions (PATH)

In July 2012, the Company entered into a clinical development agreement with PATH to develop our vaccine candidate to protect against RSV through maternal immunization in low resource countries. We were awarded approximately \$2.0 million by PATH for initial funding under the agreement to partially support our Phase II dose-ranging clinical trial in women of childbearing age in the second half of 2012. Thereafter, we and PATH can elect to continue to collaborate on additional phases to develop the vaccine for maternal immunization in low-resource countries, with PATH potentially funding 50% of our external clinical development costs. We will retain global rights to commercialize the product and have made a commitment to make the product affordable and available in low-resource countries.

Sales of Common Stock

In May 2012, we sold 10,000,000 shares of our common stock to two affiliates of RA Capital Management, LLC (RA Capital) at a price of \$1.22 per share, resulting in \$12.1 million in net proceeds. The shares were offered under an effective shelf registration statement previously filed with the SEC.

In March 2010, we entered into an At Market Issuance Sales Agreement, under which we could sell an aggregate of \$50 million in gross proceeds of our common stock. Our Board of Directors has authorized the sale of up to 25 million shares of our common stock pursuant to the At Market Issuance Sales Agreement. For the six months ended June 30, 2012, the Company sold 5.1 million shares at an average sales price of \$1.42 per share, resulting in \$7.1 million in net proceeds; this amount excludes \$0.8 million received in early 2012 for 0.7 million shares traded in late December 2011. Since June 30, 2012 through July 31, 2012, we have sold an additional 1.5 million shares resulting in \$3.2 million in net proceeds. Since entering into the sales agreement through July 31, 2012, we have sold 23,094,140 shares of our common stock and received gross proceeds of \$46.1 million

Critical Accounting Policies and Use of Estimates

There are no material changes to the Company's critical accounting policies as described in Item 7 of the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2011, as filed with the SEC.

Recent Accounting Pronouncements Not Yet Adopted

We have considered the applicability and impact of all Financial Accounting Standards Board's Accounting Standards Updates (ASUs). Recently issued ASUs were evaluated and determined to be not applicable in this Quarterly Report.

Results of Operations

The following is a discussion of the historical financial condition and results of operations of the Company and should be read in conjunction with the financial statements and notes thereto set forth in this Quarterly Report.

Three Months Ended June 30, 2012 and 2011 (amounts in tables are presented in thousands, except per share information)

Revenue:

Three Months Ended		
June 30,		
		Change
2012	2011	2011 to
		2012

Revenue:

Total contract revenue	\$7,103	\$3,001	\$4,102
------------------------	---------	---------	---------

Revenue for the three months ended June 30, 2012 was \$7.1 million as compared to \$3.0 million for the same period in 2011, an increase of \$4.1 million or 137%. Revenue for 2012 and 2011 is primarily comprised of services performed under the HHS BARDA contract that was awarded in February 2011. The increase in revenue relates to increased costs associated with our product development activities and clinical trials performed under the HHS BARDA contract.

Revenue for the three months ended June 30, 2012 was negatively impacted due to the Company electing to conduct the 205 Trial without immediate HHS BARDA reimbursement of its outside clinical trial costs, which are expected to total approximately \$3.1 million, of which \$0.7 million was incurred during the three months ended June 30, 2012 (see discussion of the 205 Trial in *Management's Discussion and Analysis of Financial Condition and Results of Operations—Overview* on page 13). In July 2012, we reported that we expected to launch our next quadrivalent Phase II clinical trial in 2013 rather than in the second half of 2012; similarly, the filing of the Quadrivalent IND, which we had previously indicated was expected in the second half of 2012 will also be delayed. Until then, we will not record revenue associated with the outside clinical trial costs of our 205 Trial and such costs will be expensed and included in cost of contract revenue. For 2012, we expect to generate significant revenue from conducting multiple clinical trials, ongoing process development and the manufacture of clinical materials under the HHS BARDA contract.

Costs and Expenses:

Three Months Ended

June 30,	
2012	2011

	Change 2011 to 2012		
Costs and Expenses:			
Cost of contract revenue	\$5,118	\$1,231	\$3,887
Research and development	5,176	4,353	823
General and administrative	2,664	3,338	(674)
Total costs and expenses	\$12,958	\$8,922	\$4,036

Cost of Contract Revenue

Cost of contract revenue was \$5.1 million for the three months ended June 30, 2012 as compared to \$1.2 million for the same period in 2011, an increase of \$3.9 million, primarily due to increased costs associated with our product development activities and clinical trials performed under the HHS BARDA contract that was awarded in February 2011. These costs include direct costs of salaries, laboratory supplies, consultants and subcontractors and other direct costs associated with our process development, manufacturing, clinical, regulatory and quality assurance activities under research contracts.

Cost of contract revenue for the three months ended June 30, 2012 includes \$0.7 million of direct clinical trial costs of our 205 Trial (see discussion of the 205 Trial in *Management's Discussion and Analysis of Financial Condition and Results of Operations—Overview* on page 13). For 2012, we expect a significant increase in the cost of contract revenue from conducting multiple clinical trials, ongoing process development and the manufacture of clinical materials under the HHS BARDA contract.

Research and Development Expenses

Research and development expenses were \$5.2 million for the three months ended June 30, 2012, as compared to \$4.4 million for the same period in 2011, an increase of \$0.8 million or 19%, primarily due to higher employee-related costs and expenses associated with our new manufacturing facility. Research and development expenses include salaries, laboratory supplies, consultants and subcontractors and other expenses associated with our process development, manufacturing, clinical, regulatory and quality assurance activities for internally funded programs. In addition, indirect costs, such as fringe benefits and overhead expenses, are also included in research and development expenses. For 2012, we expect a modest increase in research and development expenses primarily due to two anticipated clinical trials in RSV (an internally funded program at this time).

Costs and Expenses by Functional Area

We track our cost of contract revenue and research and development expenses by the type of costs incurred in identifying, developing, manufacturing and testing vaccine candidates. We evaluate and prioritize our activities according to functional area and therefore believe that project-by-project information would not form a reasonable basis for disclosure to our investors. At June 30, 2012, we had 92 employees dedicated to our research and development programs versus 78 employees as of June 30, 2011. 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 cost of contract revenue and research and development expenses by functional area for the three months ended June 30 (in millions).

	2012	2011
Manufacturing	\$5.0	\$3.0
Vaccine Discovery	0.8	0.7
Clinical & Regulatory	4.5	1.9
Total cost of contract revenue and research and development expenses	\$10.3	\$5.6

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

- the number of patients who participate in the trials;
- the number of sites included in the trials;
- if trial locations are domestic, international or both;
- the time to enroll patients;
- the duration of treatment and follow-up;
- the safety and efficacy profile of the vaccine candidate; and
- the cost and timing of, and the ability to secure, regulatory approvals.

As a result of these uncertainties, we are unable to determine with any significant degree of certainty the duration and completion costs of our research and development projects or when, and to what extent, we will generate future cash flows from our research projects.

General and Administrative Expenses

General and administrative expenses were \$2.7 million for the three months ended June 30, 2012 as compared to \$3.3 million for the same period in 2011, a decrease of \$0.7 million or 20%. The decrease in expenses was primarily due to lower employee-related costs, including severance expenses, partially offset by non-cash expenses associated with our new office facility. For 2012, we expect a moderate increase in general and administrative expenses primarily due to non-cash expenses associated with our new office facility that we leased along with our new manufacturing facility.

Other Income (Expense):

	Three Months Ended		
	June 30,		Change
	2012	2011	2011 to 2012
Other Income (Expense):			
Interest income	\$39	\$38	\$1
Interest expense	(3)	(2)	(1)
Change in fair value of warrant liability	(101)	1,304	(1,405)
Total other income (expense)	\$(65)	\$1,340	\$(1,405)

We had total other expense of \$0.1 million for the three months ended June 30, 2012 compared to total other income of \$1.3 million for the same period in 2011, a change of \$1.4 million. We are required to calculate the fair value of our warrant liability at each reporting period. For the three months ended June 30, 2012 as compared to the same period in 2011, the change in the fair value of the warrant liability resulted in a \$1.4 million decrease in total other income.

Income Tax:

**Three Months
Ended**

	June 30,	Change
	2012	2011 to
		2012

Income Tax:

Total income tax expense	\$—	\$412	\$ (412)
--------------------------	-----	-------	-----------

Income tax expense for the three months ended June 30, 2011 was \$0.4 million. We incurred a foreign withholding tax related to a payment received in accordance with a license agreement.

Net Loss:**Three Months Ended****June 30,**

	2012	2011	Change 2011 to 2012
Net Loss:			
Net loss	\$(5,920)	\$(4,993)	\$(927)
Net loss per share	\$(0.05)	\$(0.04)	\$(0.01)
Weighted shares outstanding	126,925	112,821	14,104

Net loss for the three months ended June 30, 2012 was \$5.9 million, or \$0.05 per share, as compared to \$5.0 million, or \$0.04 per share, for the same period in 2011, an increased net loss of \$0.9 million, or 19%. The increase in net loss is primarily due to lower other income relating to the change in fair value of our warrant liability.

The increase in weighted shares outstanding for the three months ended June 30, 2012 is primarily a result of sales of our common stock under our At Market Issuance Sales Agreement and to RA Capital.

Six Months Ended June 30, 2012 and 2011 (amounts in tables are presented in thousands, except per share information)

Revenue:**Six Months Ended****June 30,**

	2012	2011	Change 2011 to 2012
Revenue:			
Total contract revenue	\$11,745	\$3,835	\$7,910

Revenue for the six months ended June 30, 2012 was \$11.7 million as compared to \$3.8 million for the same period in 2011, an increase of \$7.9 million or 206%. Revenue for 2012 and 2011 is primarily comprised of services performed

under the HHS BARDA contract that was awarded in February 2011. The increase in revenue relates to increased costs associated with our product development activities and clinical trials performed under the HHS BARDA contract.

Revenue for the six months ended June 30, 2012 was negatively impacted due to the Company electing to conduct the 205 Trial without immediate HHS BARDA reimbursement of its outside clinical trial costs, which are expected to total approximately \$3.1 million, of which \$2.4 million was incurred through June 30, 2012 (see discussion of the 205 Trial in *Management's Discussion and Analysis of Financial Condition and Results of Operations—Overview* on page 13). In July 2012, we reported that we expected to launch our next quadrivalent Phase II clinical trial in 2013 rather than in the second half of 2012; similarly, the filing of the Quadrivalent IND, which we had previously indicated was expected in the second half of 2012 will also be delayed. Until then, we will not record revenue associated with the outside clinical trial costs of our 205 Trial and such costs will be expensed and included in cost of contract revenue.

Costs and Expenses:

	Six Months Ended		
	June 30,		Change
	2012	2011	2011 to 2012
Costs and Expenses:			
Cost of contract revenue	\$8,903	\$1,574	\$7,329
Research and development	10,254	9,424	830
General and administrative	5,910	6,188	(278)
Total costs and expenses	\$25,067	\$17,186	\$7,881

Cost of Contract Revenue

Cost of contract revenue was \$8.9 million for the six months ended June 30, 2012 as compared to \$1.6 million for the same period in 2011, an increase of \$7.3 million, primarily due to increased costs associated with our product development activities and clinical trials performed under the HHS BARDA contract that was awarded in February 2011. These costs include direct costs of salaries, laboratory supplies, consultants and subcontractors and other direct costs associated with our process development, manufacturing, clinical, regulatory and quality assurance activities under research contracts.

Cost of contract revenue for the six months ended June 30, 2012 includes \$2.2 million of direct clinical trial costs of our 205 Trial (see discussion of the 205 Trial in *Management's Discussion and Analysis of Financial Condition and Results of Operations—Overview* on page 13).

Research and Development Expenses

Research and development expenses were \$10.3 million for the six months ended June 30, 2012 as compared to \$9.4 million for the same period in 2011, an increase of \$0.8 million or 9%, primarily due to higher employee-related costs and expenses associated with our new manufacturing facility, partially offset by higher RSV clinical trial costs in 2011. Research and development expenses include salaries, laboratory supplies, consultants and subcontractors and other expenses associated with our process development, manufacturing, clinical, regulatory and quality assurance activities for internally funded programs. In addition, indirect costs, such as fringe benefits and overhead expenses, are also included in research and development expenses.

Costs and Expenses by Functional Area

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

	2012	2011
Manufacturing	\$9.3	\$6.1
Vaccine Discovery	1.6	1.6
Clinical & Regulatory	8.3	3.3
Total cost of contract revenue and research and development expenses	\$19.2	\$11.0

General and Administrative Expenses

General and administrative expenses were \$5.9 million for the six months ended June 30, 2012 as compared to \$6.2 million for the same period in 2011, a decrease of \$0.3 million or 4%. The decrease in expenses was primarily due to lower employee-related costs, including severance expenses, partially offset by non-cash expenses associated with our new office facility.

Other Income (Expense):

	Six Months Ended		
	June 30,		Change
	2012	2011	2011 to 2012
Other Income (Expense):			
Interest income	\$72	\$84	\$(12)
Interest expense	(6)	(4)	(2)
Change in fair value of warrant liability	—	1,237	(1,237)
Total other income (expense)	\$66	\$1,317	\$(1,251)

We had total other income of \$0.1 million for the six months ended June 30, 2012 compared to total other income of \$1.3 million for the same period in 2011, a change of \$1.3 million. We are required to calculate the fair value of our warrant liability at each reporting period. For the six months ended June 30, 2012 as compared to the same period in 2011, the change in fair value of the warrant liability resulted in a \$1.2 million decrease in total other income.

Income Tax:

	Six Months Ended		
	June 30,		Change
	2012	2011	2011 to 2012
Income Tax:			
Total income tax expense	\$—	\$412	\$(412)

Income tax expense for the six months ended June 30, 2011 was \$0.4 million. We incurred a foreign withholding tax related to a payment received in accordance with a license agreement.

Net Loss:

Six Months Ended**June 30,**

	2012	2011	Change 2011 to 2012
Net Loss:			
Net loss	\$(13,256)	\$(12,446)	\$810
Net loss per share	\$(0.11)	\$(0.11)	\$
Weighted shares outstanding	123,741	112,009	11,732

Net loss for the six months ended June 30, 2012 was \$13.3 million, or \$0.11 per share, as compared to \$12.4 million, or \$0.11 per share, for the same period in 2011, an increased net loss of \$0.8 million, or 7%. The increase in net loss is primarily due to lower other income relating to the change in the fair value of our warrant liability.

The increase in weighted shares outstanding for the six months ended June 30, 2012 is primarily a result of sales of our common stock under our At Market Issuance Sales Agreement and to a lesser extent, to RA Capital.

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 pre-clinical and clinical testing, the time and costs involved in obtaining regulatory approvals, the costs of filing, prosecuting, defending and enforcing patent claims and other intellectual property rights and manufacturing costs. We plan to continue to have multiple vaccines and products in various stages of development, and we believe our operating expenses and capital requirements will fluctuate depending upon the timing of certain events, such as the scope, initiation, rate and progress of our pre-clinical studies and clinical trials and other research and development activities.

As of June 30, 2012, we had \$26.5 million in cash and cash equivalents and short-term investments as compared to \$18.3 million as of December 31, 2011, which consists of \$15.3 million in cash and cash equivalents and \$11.2 million in short-term investments as of June 30, 2012 as compared to \$14.1 million and \$4.2 million, respectively, at December 31, 2011. The following table summarizes cash flows for the six months ended June 30, 2012 and 2011 (in thousands):

	Six Months Ended		
	June 30,		Change 2011 to 2012
	2012	2011	
Summary of Cash Flows:			
Net cash (used in) provided by:			
Operating activities	\$(10,346)	\$(17,439)	\$7,093
Investing activities	(7,798)	14,115	(21,913)
Financing activities	19,374	8,355	11,019
Net (decrease) increase in cash and cash equivalents	1,230	5,031	(3,801)
Cash and cash equivalents at beginning of period	14,104	8,061	6,043
Cash and cash equivalents at end of period	\$ 15,334	\$ 13,092	\$ 2,242

Net cash used in operating activities decreased to \$10.3 million for the six months ended June 30, 2012 as compared to \$17.4 million for the same period in 2011, respectively. The decrease in cash usage was primarily due to the timing of our vendor payments and funds received under our Improvement Allowance.

During the six months ended June 30, 2012 and 2011, our investing activities included purchases and maturities of short-term investments and capital expenditures. In the six month ended June 30, 2012, we primarily purchased short-term investments to increase our rate of return on our investments. In the same period in 2011, we primarily utilized our short-term investments to fund operations and increase our cash balances. Capital expenditures for the six

months ended June 30, 2012 and 2011 were \$1.1 million and \$0.2 million, respectively. The increase in capital expenditures was primarily due to the purchase of laboratory equipment relating to our new manufacturing facility. For 2012, we expect our level of capital expenditures to increase in connection with the scale-up of our new manufacturing facility.

The increase in our financing activities consists primarily of increased sales of our common stock. We received net proceeds of \$20.0 million in the six months ended June 30, 2012 as compared to \$8.3 million in the same period of 2011 from the sale of our common stock to RA Capital and through our At Market Issuance Sales Agreement.

In November 2011, we entered into lease agreements, under which we lease our new manufacturing, laboratory and office space in Gaithersburg, Maryland. The lease agreements provide that, among other things, as of January 1, 2012, we sublease from the current facility tenant, and subsequently lease directly from the landlord, approximately 74,000 total square feet, with rent payments for such space to the landlord commencing April 1, 2014. Under the terms of the arrangement, the Landlord will provide us with a tenant improvement allowance of \$2.5 million and an additional tenant improvement allowance of \$3 million dollars (collectively, the Improvement Allowance). The additional tenant improvement allowance is to be paid back to the Landlord over the remaining term of the lease agreement. During the six months ended June 30, 2012, the Company was funded \$2.1 million. In addition, we purchased laboratory equipment under an agreement with the then current facility tenant and are currently renovating the new facility.

We have entered into agreements with outside providers to support our clinical development. As of June 30, 2012, \$7.8 million remains unpaid on certain of these agreements in the event our outside providers complete their services in 2012. However, under the terms of the agreements, we have the option to terminate for convenience pursuant to notification, but we would be obligated to pay the provider for all costs incurred through the effective date of termination.

We have licensed certain rights from Wyeth. The Wyeth license, which provides for an upfront payment, annual license fees, milestone payments and royalties on any product sales, is a non-exclusive, worldwide license to a family of patent applications covering VLP technology for use in human vaccines in certain fields; the license may be terminated by Wyeth only for cause and may be terminated by us only after we have provided ninety (90) days notice that we have absolutely and finally ceased activity, including through any affiliate or sublicense, related to the manufacturing, development, marketing or sale of products covered by the license. Payments under the agreement to Wyeth from 2007 through June 30, 2012 totaled \$5.5 million. We do not expect to make a milestone payment to Wyeth in the next twelve months.

In connection with our JV with Cadila, we entered into a master services agreement, which we and Cadila amended in July 2011 to extend the term by one year for which services can be provided by Cadila under this agreement. Under the revised terms, if by March 2013, the amount of services provided by Cadila under the master services agreement is less than \$7.5 million, the Company will pay Cadila the portion of the shortfall amount that is less than or equal to \$2.0 million and 50% of the portion of the shortfall amount that exceeds \$2.0 million. Through June 30, 2012, we have purchased \$0.3 million in services from Cadila pursuant to this agreement.

Based on our cash and cash equivalents and short-term investments as of June 30, 2012, anticipated revenue under the contract with HHS BARDA that was awarded in February 2011, possible proceeds from the sales of our common stock under our At Market Issuance Sales Agreement and funding under the Improvement Allowance and our current business operations, we believe we have adequate capital resources available to operate at planned levels for at least the next twelve months. Additional capital will be required in the future to develop our vaccine candidates through clinical development, manufacturing and commercialization. Our ability to obtain such additional capital is subject to various factors:

- generating revenue under the HHS BARDA contract is subject to our performance under the contract, including our ability to collect on delayed reimbursement situations, such as the 205 Trial costs;

- raising funds under our At Market Issuance Sales Agreement is subject to both our business performance and market conditions; and

- receiving funds under the Improvement Allowance is subject to compliance with the lease terms.

Further, we may seek additional capital through further public or private equity offerings, debt financing, additional strategic alliance and licensing arrangements, non-dilutive government contracts, collaborative arrangements or some combination of these financing alternatives. Any capital raised by an equity offering will likely be substantially dilutive to the existing stockholders and any licensing or development arrangement may require us to give up rights to a product or technology at less than its full potential value. Other than our At Market Issuance Sales Agreement and the Improvement Allowance, we have not secured any additional commitments for new financing nor can we provide any assurance that new financing will be available on commercially acceptable terms, if at all. If we are unable to perform under the HHS BARDA contract or obtain additional capital, we will assess our capital resources and will likely be required to delay, reduce the scope of, or eliminate one or more of our product research and development programs, and/or downsize our organization, including our general and administrative infrastructure.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

The primary objective of our investment activities is to preserve our capital until it is required to fund operations while at the same time maximizing the income we receive from our investments without significantly increasing risk. As of June 30, 2012, we had cash and cash equivalents of \$15.3 million, short-term investments of \$11.2 million and working capital of \$25.6 million.

Our exposure to market risk is primarily confined to our investment portfolio. As of June 30, 2012, our short-term 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 investments when they mature and the proceeds are reinvested into new investments and, therefore, could impact our cash flows and results of operations.

In 2007, we invested in auction rate securities as part of our cash management program. Short-term investments at June 30, 2012 are comprised of investments in commercial paper and three auction rate securities with a par value of \$5.1 million and a fair value of \$4.3 million. At June 30, 2012, we have recorded \$0.9 million in unrealized gains on the auction rate securities included in accumulated other comprehensive income on the balance sheet. These investments are classified within current assets because we may need to liquidate these securities within the next year to fund our ongoing operations.

Interest and dividend income is recorded when earned and included in interest income. Premiums and discounts, if any, on short-term investments are amortized or accreted to maturity and included in interest 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. Accordingly, we have not had any material exposure to foreign currency rate fluctuations.

We do not have material debt and, as such, do not believe that we are exposed to any material interest rate risk as a result of our borrowing activities.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Our management, with the assistance of our Chief Executive Officer and Chief Financial Officer, has reviewed and evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended) as of June 30, 2012. 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 their control objectives. Based on the evaluation of our disclosure controls and procedures as of June 30, 2012, our Chief Executive Officer and Chief Financial Officer concluded that, as of such date, our disclosure controls and procedures were effective.

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 second quarter of 2012, and has concluded that there was no change that occurred during the second quarter of 2012 that materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

Item 1A. Risk Factors

There are no material changes to the Company's risk factors as described in Item 1A of the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2011, as filed with the SEC.

Item 6. Exhibits

Exhibits marked with a single asterisk (*) are filed herewith.

Exhibits marked with a double plus sign (††) refer to management contracts, compensatory plans or arrangements.

10.1†† Novavax, Inc. Amended and Restated 2005 Stock Incentive Plan (Incorporated by reference to Exhibit 10.1 to the Company's Registration Statement on Form S-8, filed August 7, 2012)

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

26

SIGNATURES

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

NOVAVAX, INC.

Date: August 9, 2012 By: /s/ Stanley C. Erck
President and Chief Executive Officer

and Director

(Principal Executive Officer)

Date: August 9, 2012 By: /s/ Frederick W. Driscoll
Vice President, Chief Financial Officer
and Treasurer
(Principal Financial and Accounting Officer)