NOVAVAX INC
Form 10-Q
November 12, 2013

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, 2013**
OR

.. **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
**For the transition period from _____to_____ .**

**Commission File No. 0-26770**

**NOVAVAX, INC.**

(Exact name of registrant as specified in its charter)

| | |
|---|---|
| **Delaware** | **22-2816046** |
| (State or other jurisdiction of incorporation or organization) | (I.R.S. Employer Identification No.) |
| **9920 Belward Campus Drive, Rockville, MD** | **20850** |
| (Address of principal executive offices) | (Zip code) |

**(240) 268-2000**

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

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, 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 ¨ (Do not check if a smaller reporting company) | 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 208,510,739 as of October 31, 2013.

**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, 2013 (unaudited) | December 31, 2012 |
|---|---|---|
| ASSETS | | |
| Current assets: | | |
| Cash and cash equivalents | $122,493 | $17,399 |
| Short-term investments available-for-sale | 23,917 | 26,712 |
| Restricted cash | 124 | 986 |
| Accounts receivables | 1,911 | 1,011 |
| Unbilled receivables | 3,194 | 1,570 |
| Prepaid expenses | 3,016 | 2,559 |
| Other current assets | 365 | 171 |
| Total current assets | 155,020 | 50,408 |
| Investments available-for-sale | — | 6,233 |
| Property and equipment, net | 13,969 | 11,456 |
| Intangibles, net | 16,405 | — |
| Goodwill | 58,759 | 33,141 |
| Restricted cash | 757 | 756 |
| Other non-current assets | 164 | 351 |
| Total assets | $245,074 | $102,345 |
| | | |
| LIABILITIES AND STOCKHOLDERS' EQUITY | | |
| Current liabilities: | | |
| Accounts payable | $3,339 | $3,228 |
| Accrued expenses and other current liabilities | 9,553 | 7,275 |
| Deferred revenue | 190 | 258 |
| Current portion of capital leases | 115 | 58 |
| Current portion of notes payable | 597 | 157 |
| Warrant liability | — | 267 |
| Deferred rent | 466 | 432 |
| Total current liabilities | 14,260 | 11,675 |
| Deferred revenue | 2,500 | 2,500 |
| Non-current portion of capital leases | 222 | 237 |

| | | |
|---|---|---|
| Non-current portion of notes payable | 1,653 | 753 |
| Deferred rent | 8,287 | 6,940 |
| Other non-current liabilities | 1,578 | |
| Total liabilities | 28,500 | 22,105 |
| Commitments and contingences | — | — |
| Stockholders' equity: | | |
| Preferred stock, $0.01 par value, 2,000,000 shares authorized; no shares issued and outstanding | — | — |
| Common stock, $0.01 par value, 300,000,000 shares authorized at September 30, 2013 and 200,000,000 shares authorized at December 31, 2012; and 208,965,169 shares issued and 208,509,739 shares outstanding at September 30, 2013 and 148,398,747 shares issued and 147,943,317 shares outstanding at December 31, 2012 | 2,090 | 1,484 |
| Additional paid-in capital | 611,913 | 438,939 |
| Accumulated deficit | (396,092) | (358,163) |
| Treasury stock, 455,430 shares, cost basis | (2,450) | (2,450) |
| Accumulated other comprehensive income | 1,113 | 430 |
| Total stockholders' equity | 216,574 | 80,240 |
| Total liabilities and stockholders' equity | $245,074 | $102,345 |

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,** | |
|---|---|---|---|---|
| | 2013 | 2012 | 2013 | 2012 |
| Revenue: | | | | |
| Government contracts | $4,268 | $5,583 | $10,985 | $17,328 |
| Research and development collaborations | 534 | 182 | 1,182 | 182 |
| Total revenue | 4,802 | 5,765 | 12,167 | 17,510 |
| Costs and expenses: | | | | |
| Cost of government contracts revenue | 2,276 | 3,838 | 5,619 | 12,740 |
| Research and development | 13,948 | 6,642 | 33,989 | 17,270 |
| General and administrative | 3,857 | 2,134 | 10,740 | 7,670 |
| Total costs and expenses | 20,081 | 12,614 | 50,348 | 37,680 |
| Loss from operations | (15,279) | (6,849) | (38,181) | (20,170) |
| Other income (expense): | | | | |
| Interest income | 53 | 39 | 149 | 111 |
| Interest expense | (64) | (6) | (132) | (12) |
| Other expense | (10) | | (10) | |
| Change in fair value of warrant liability | | (401) | 267 | (401) |
| Loss from operations before income tax | (15,300) | (7,217) | (37,907) | (20,472) |
| Income tax expense | | | 22 | |
| Net loss | $(15,300) | $(7,217) | $(37,929) | $(20,472) |
| Basic and diluted net loss per share | $(0.09) | $(0.05) | $(0.24) | $(0.16) |
| Basic and diluted weighted average number of common shares outstanding | 168,537 | 134,178 | 156,555 | 127,246 |

**CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS**

**(in thousands)**

**(unaudited)**

| | For the Three Months Ended September 30, | | For the Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2013 | 2012 | 2013 | 2012 |
| Net loss | $(15,300) | $(7,217) | $(37,929) | $(20,472) |
| Other comprehensive income (loss): | | | | |
| Net unrealized gains (losses) on investments available-for-sale | (33) | 96 | 174 | 204 |
| Foreign currency adjustment | 509 | | 509 | |
| Other comprehensive income (loss) | 476 | 96 | 683 | 204 |
| Comprehensive loss | $(14,824) | $(7,121) | $(37,246) | $(20,268) |

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

NOVAVAX, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS

(in thousands)

(unaudited)

| | For the Nine Months Ended September 30, | |
|---|---|---|
| | 2013 | 2012 |
| Operating Activities: | | |
| Net loss | $(37,929) | $(20,472) |
| Reconciliation of net loss to net cash used in operating activities: | | |
| Change in fair value of warrant liability | (267) | 401 |
| Depreciation and amortization | 1,636 | 1,216 |
| Amortization of net premiums on investments | 326 | — |
| Gain on disposal of property and equipment | (37) | (26) |
| Deferred rent | 678 | 436 |
| Non-cash stock-based compensation | 1,784 | 1,668 |
| Changes in operating assets and liabilities: | | |
| Restricted cash | 862 | (838) |
| Accounts receivables | (291) | (504) |
| Unbilled receivables | (1,624) | 111 |
| Prepaid expenses and other assets | 639 | (271) |
| Accounts payable and accrued expenses | 623 | (304) |
| Deferred revenue | (199) | 803 |
| Lease incentives received | 703 | 2,803 |
| Net cash used in operating activities | (33,096) | (14,977) |
| | | |
| Investing Activities: | | |
| Capital expenditures | (4,762) | (2,202) |
| Proceeds from disposal of property and equipment | 83 | 318 |
| Net cash received from the Isconova AB acquisition | 3,034 | — |
| Proceeds from maturities of investments | 23,630 | 2,500 |
| Purchases of investments | (14,754) | (15,763) |
| Net cash provided by (used in) investing activities | 7,231 | (15,147) |
| | | |
| Financing Activities: | | |
| Principal payments of capital leases | (54) | (90) |
| Principal payments of notes payable | (305) | (20) |
| Proceeds from notes payable | 1,450 | 650 |
| Restricted cash | (1) | (756) |

| | | |
|---|---|---|
| Net proceeds from sales of common stock, net of offering costs of $6.1 million and $0.4 million, respectively | 128,659 | 26,925 |
| Proceeds from the exercise of stock options | 1,194 | 49 |
| Net cash provided by financing activities | 130,943 | 26,758 |
| Effect of exchange rate on cash and cash equivalents | 16 | — |
| Net increase (decrease) in cash and cash equivalents | 105,094 | (3,366) |
| Cash and cash equivalents at beginning of period | 17,399 | 14,104 |
| Cash and cash equivalents at end of period | $122,493 | $10,738 |
| | | |
| Supplemental disclosure of non-cash activities: | | |
| Common stock issued in connection with the Isconova AB acquisition | $41,942 | $— |
| Property and equipment purchases included in accounts payable and accrued expenses | $407 | $1,365 |
| Deposit applied towards the purchase of laboratory equipment | $— | $500 |
| Equipment acquired under a capital lease | $— | $399 |
| | | |
| Supplemental disclosure of cash flow information: | | |
| Cash payments of interest | $120 | $— |

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

NOVAVAX, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
September 30, 2013

(unaudited)

Note 1 – Organization

Novavax, Inc. (“Novavax,” and together with its subsidiary, “Novavax AB,” the “Company”) is a clinical-stage biopharmaceutical company focused on the discovery, development and commercialization of recombinant protein nanoparticle vaccines and adjuvants. The Company’s product pipeline targets a variety of infectious diseases with vaccine candidates currently in clinical development for seasonal influenza, pandemic influenza and respiratory syncytial virus (“RSV”).

Note 2 – Operations

The Company’s vaccine candidates, some of which may include an adjuvant, currently under development will require significant additional research and development efforts that include extensive pre-clinical and clinical testing, and regulatory approval prior to commercial use.

As a clinical-stage biopharmaceutical company, the Company has primarily funded its operations from proceeds through the sale of its common stock in equity offerings and revenue under its contract with the Department of Health and Human Services, Biomedical Advanced Research and Development Authority (“HHS BARDA”). Management regularly reviews the Company’s cash and cash equivalents and investments against its operating budget to ensure the Company will have sufficient working capital, and will continue to draw upon such available sources of capital to meet its product development activities.

Note 3 – Summary of Significant Accounting Policies

***Basis of Presentation***

The accompanying unaudited consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP") for interim financial information and the instructions to Form 10-Q and Article 10 of Regulation S-X. The consolidated balance sheet as of September 30, 2013, consolidated statements of operations and consolidated statements of comprehensive loss for the three and nine months ended September 30, 2013 and 2012 and the consolidated statements of cash flows for the nine months ended September 30, 2013 and 2012 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 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").

As discussed in more detail in Note 4, the Company acquired Swedish-based Isconova AB ("Isconova") on July 31, 2013. Isconova was subsequently renamed Novavax AB. The consolidated financial statements include the accounts of Novavax, Inc. and its subsidiary, Novavax AB. All intercompany accounts and transactions have been eliminated in consolidation.

The accompanying consolidated financial statements are presented in U.S. dollars. The translation of assets and liabilities 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 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 income in the accompanying consolidated balance sheets. The foreign currency translation adjustment balance included in accumulated other comprehensive income was $0.5 million at September 30, 2013.

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, 2012. 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: developing recombinant vaccines.

***Use of Estimates***

The preparation of 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 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.

***Investments***

Investments consist of commercial paper, corporate notes and an investment in one auction rate security. Classification of marketable securities between current and non-current is dependent upon the original maturity date at purchase. Those securities purchased with original maturities greater than 90 days, but less than one year are classified as current and those with greater than one year are classified as non-current.

Interest and dividend income is recorded when earned and included in interest income. Premiums and discounts, if any, on 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 the Company's securities.

The Company has classified its investments 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 on these securities, if determined to be temporary, are included in accumulated other comprehensive income (loss) in stockholders' equity. Investments 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 statement of operations.

Restricted Cash

The Company's restricted cash includes payments received under the PATH agreement (See Note 10) until such time as the Company has paid for the work performed under the agreement. In addition, the Company's non-current restricted cash with respect to its 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 12,157,634 shares and 12,951,625 shares at September 30, 2013 and 2012, respectively, are excluded from the computation, as their effect is antidilutive.

***Reclassifications***

Overhead expenses relating to supply chain management of $0.2 million and $0.6 million for the three and nine months ended September 30, 2012, respectively, have been reclassified from general and administrative expenses to research and development expenses. Also, within the September 30, 2012 statement of cash flows, restricted cash received of $0.8 million recorded in financing activities has been reclassified and is included in operating activities. These reclassifications have been made to conform to current year presentation.

**Note 4 – Acquisition of Isconova AB**

On July 31, 2013 (the "acquisition date"), Novavax announced the acquisition of Isconova (the "Acquisition") pursuant to its public tender offer to acquire all outstanding shares and warrants of the company directly from such holders and its private offer for all of Isconova's outstanding stock options. As a result of the public offer for shares and warrants and private offer for stock options, Novavax issued approximately 15.6 million shares of its Common Stock valued at $41.9 million and paid cash of approximately $22,000 to acquire 99.5% of the outstanding shares and all of the outstanding stock options and warrants of Isconova. On September 6, 2013, Isconova AB was renamed "Novavax AB" and was delisted as a publicly traded company in Sweden. This transaction has been accounted for using the purchase method of accounting, with Novavax as the acquirer. The results of Novavax AB's operations have been included in the consolidated financial statements since the acquisition date. For the three months ended September 30, 2013, the minority interest in Novavax AB's net loss and stockholders' equity is immaterial.

Novavax AB has focused its recent efforts on the development of saponin-based, immune-modulating adjuvants that work with different types of vaccine antigens to enhance the immunogenic effect of the antigen. Novavax AB has collaborated with several vaccine companies to allow its lead adjuvant, Matrix-M™, to be tested with a number of antigens in development; the Company has recently begun development work pairing the Novavax AB adjuvant with its own pandemic influenza VLP antigen. The Company believes that the Novavax AB adjuvants can be powerful complements to certain of its recombinant vaccine programs and will enable future discovery efforts and potentially reduce vaccine development timeframes and costs both by eliminating the need to in-license third-party adjuvants and related costs and by harmonizing operating and regulatory processes. The total purchase price is summarized as follows (in thousands):

| | |
|---|---|
| Value of shares of Novavax Common Stock issued | $41,942 |
| Cash paid to Isconova warrant holders | 22 |
| Total purchase price | $41,964 |

The value of Novavax Common Stock issued is based on the closing price of Novavax' Common Stock on the acquisition date.

The table below summarizes the preliminary allocation of the purchase price based upon the fair values of assets acquired and liabilities assumed at the acquisition date. The preliminary allocation is based upon information that was available to management at the time the consolidated financial statements were prepared. Accordingly, the allocation may change.

| | (in thousands) |
|---|---|
| Cash and cash equivalents | $ 3,056 |
| Accounts receivable | 603 |
| Prepaid expenses and other assets | 1,092 |
| Property and equipment | 165 |
| Intangible assets | 16,380 |
| Goodwill | 25,298 |
| Accounts payable and other current liabilities | (2,784) |
| Capital leases | (94) |
| Notes payable | (193) |
| Other non-current liabilities | (1,559) |
| Total purchase price | $ 41,964 |

A substantial portion of the assets acquired from Isconova consisted of intangible assets relating to its proprietary adjuvant technology and collaboration agreements. The preliminary fair values of the proprietary technology and agreements were determined based on estimates of expected future net cash flows. The present value of future net cash flows was then determined utilizing an estimate of the appropriate discount rate, which is consistent with the uncertainties of the cash flows utilized. The fair value measurements are based on significant unobservable inputs that were developed by the Company using publicly available information, market participant assumptions, cost and development assumptions, expected synergies and other cost savings that a market participant would be expected to realize as a result of the combination and certain other high-level assumptions. The proprietary technology is amortized over its estimated remaining useful life based on the Company's expected future net cash flows. The agreements are amortized over the estimated periods of expected future net cash flows. Amortization expense for intangible assets will be recorded on a straight-line basis over the expected useful lives of the assets, ranging from seven to 20 years. The carrying value and expected lives of the intangible assets may change based upon finalizing the purchase price allocation, and such intangibles will be periodically reviewed to determine if the facts and circumstances suggest that a potential impairment may have occurred. Impairment charges, if any, will be recorded in the period in which the impairment occurs.

The Company recorded $25.3 million in goodwill related to the Acquisition representing the purchase price paid in the Acquisition that was in excess of the fair value of the assets acquired and liabilities assumed, which is included in the Company's vaccine operations because of the anticipated complementary use of Novavax AB adjuvants with its vaccine candidates discussed above. The goodwill generated from the Acquisition is expected to be deductible for U.S. federal income tax purposes.

The Company incurred approximately $1.3 million in transaction costs related to the Acquisition, which is included in general and administrative expenses in the Company's consolidated statement of operations.

From the acquisition date to September 30, 2013, the Company has recognized revenue of $0.4 million and recorded a net loss of $1.5 million from the operations of Novavax AB.

The following unaudited consolidated pro forma financial information is presented as if the Acquisition occurred on January 1, 2012. The unaudited pro forma financial information has been presented for comparative purposes only and is not necessarily indicative of results of operations that would have been achieved had the Company completed the Acquisition during the periods presented, or the future consolidated results of operations of the combined company. The unaudited pro forma financial information combines the historical results of operations of Novavax and Isconova for the periods presented below and reflects the application of the following adjustments:

- Elimination of the historical intangible assets and amortization expense unrelated to the Acquisition;
- Amortization expense related to the fair value of intangible assets acquired; and
- The exclusion of acquisition-related costs incurred for the Acquisition.

| | **Three Months Ended** | | **Nine Months Ended** | |
|---|---|---|---|---|
| | **September 30,** | | **September 30,** | |
| | 2013 | 2012 | 2013 | 2012 |
| | (in thousands) | | | |
| Revenue | $4,869 | $6,272 | $14,195 | $19,530 |
| Net loss | $(15,687) | $(8,490) | $(40,565) | $(25,033) |
| Basic and diluted net loss per share | $(0.09) | $(0.06) | $(0.24) | $(0.18) |

Novavax AB has an operating lease for its facility that expires in 2017. As of September 30, 2013, the aggregate remaining rental payments due under this operating lease commitment was approximately $1.9 million.

**Note 5 – Fair Value Measurements**

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

| | Fair Value at September 30, 2013 | | | Fair Value at December 31, 2012 | | |
|---|---|---|---|---|---|---|
| Assets | **Level 1** | **Level 2** | **Level 3** | **Level 1** | **Level 2** | **Level 3** |
| | $— | $23,917 | $— | $— | $32,945 | $— |

| | | | | | | |
|---|---|---|---|---|---|---|
| Corporate debt securities and auction rate securities | | | | | | |
| Total investments | $— | $23,917 | $— | $— | $32,945 | $— |
| Liabilities | | | | | | |
| Warrant liabilities | $— | $— | $— | $— | $— | $267 |

During the nine months ended September 30, 2013, the Company did not have any transfers between levels.

The following table provides a reconciliation of the beginning and ending balance of Level 3 assets and liabilities measured on a recurring basis for the nine months ended September 30, 2013 (in thousands):

| | **Fair Value Measurements of Warrants Using Significant Unobservable Inputs (Level 3)** |
|---|---|
| Balance at December 31, 2012 | $ 267 |
| Change in fair value of Warrant liability | (267) |
| Balance at September 30, 2013 | $ — |

The amounts in the Company’s consolidated balance sheet for accounts receivables, 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 capital leases and notes payable approximates their carrying value.

**Note 6 – Investments**

Investments classified as available-for-sale as of September 30, 2013 and December 31, 2012 were comprised of (in thousands):

| | September 30, 2013 | | | | December 31, 2012 | | | |
|---|---|---|---|---|---|---|---|---|
| | Amortized Cost | Gross Unrealized Gains | Gross Unrealized Losses | Fair Value | Amortized Cost | Gross Unrealized Gains | Gross Unrealized Losses | Fair Value |
| Auction rate securities | $1,175 | $ 601 | $ — | $1,776 | $1,175 | $ 409 | $ — | $1,584 |
| Corporate debt securities | 22,137 | 4 | — | 22,141 | 31,340 | 21 | — | 31,361 |
| Total | $23,312 | $ 605 | $ — | $23,917 | $32,515 | $ 430 | $ — | $32,945 |

**Note 7 – Goodwill and Other Intangible Assets**

***Goodwill***

The changes in the carrying amounts of goodwill for the nine months ended September 30, 2013 and 2012 were as following (in thousands):

| | Nine Months Ended September 30, | |
|---|---|---|
| | 2013 | 2012 |
| Beginning balance | $33,141 | $33,141 |
| Goodwill resulting from acquisition of business | 25,298 | — |
| Currency translation | 320 | — |
| Ending balance | $58,759 | $33,141 |

***Identifiable Intangible Assets***

Identifiable intangible assets consisted of the following as of September 30, 2013 (in thousands):

| | Gross Carrying Amount | Accumulated Amortization | Intangible Assets, Net |
|---|---|---|---|
| Finite-lived intangible assets: | | | |
| Proprietary adjuvant technology | $ 11,594 | $ (97) | $ 11,497 |
| Collaboration agreements | 4,992 | (84) | 4,908 |
| Total identifiable intangible assets | $ 16,586 | $ (181) | $ 16,405 |

Amortization expense for the nine months ended September 30, 2013 was $0.2 million. Estimated amortization expense for existing intangible assets for the remainder of 2013 and for each of the five succeeding years ending December 31,will be as follows (in thousands):

| Year | Amount |
|---|---|
| 2013 (remainder) | $ 271 |
| 2014 | 1,084 |
| 2015 | 1,084 |
| 2016 | 1,084 |
| 2017 | 1,084 |
| 2018 | 1,084 |

**Note 8 – Stockholders' Equity**

On June 13, 2013, the Company's stockholders of record as of April 16, 2013 approved the amendment of the Company's certificate of incorporation to increase the total number of shares of Common Stock that the Company is authorized to issue from 200,000,000 shares to 300,000,000 shares.

In October 2012, the Company entered into an At Market Issuance Sales Agreement ("2012 Sales Agreement"), under which the Board of Directors of the Company (the "Board") approved the Company's sale of up to an aggregate of $50 million in gross proceeds of its common stock. The shares of common stock are being offered pursuant to a shelf registration statement filed with the SEC in March 2013, which replaced the previous shelf registration statement filed in 2010. The Board's standing Finance Committee (the "Committee") assists with its responsibilities to monitor, provide advice to senior management of the Company and approve all capital raising activities. The Committee has been authorized by the Board, absent any action by the Board to the contrary, to take any additional actions necessary to carry out the Board's authorization of the issuance and sale of the common stock sold pursuant to the 2012 Sales Agreement. In doing so, the Committee is authorized to set the amount of shares to be sold, the period of time during which such sales may occur and the minimum sales price per share. During the nine months ended September 30, 2013, the Company sold 12.6 million shares at sales prices ranging from $2.06 to $3.38 per share, resulting in $34.0 million in net proceeds. The most recent sales to occur under the 2012 Sales Agreement were on September 10, 2013.

In September 2013, the Company completed a public offering of 31,846,950 shares of its common stock, including 4,153,950 shares of common stock that were issued upon the exercise in full of the over-allotment granted to the underwriters, at a price of $3.14 per share resulting in net proceeds of approximately $94.7 million.

**Note 9 – Stock-Based Compensation**

***Stock Options***

The Company has granted equity awards under several plans, two of which remain active. 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, June 2012 and June 2013 by the Company's stockholders, currently authorizes the grant of equity awards for up to 22,312,192 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 expire or otherwise terminate unexercised. The Company received approval at its 2013 annual meeting of stockholders to increase the number of shares of common stock available for issuance under the 2005 Plan by 4,000,000 shares. The term of the Company's 1995 Plan has expired and no new awards will be made under the 1995 Plan; however, outstanding stock options remain in existence in accordance with their terms.

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.

***Stock Options Awards***

The following is a summary of option activity under the 2005 Plan and the 1995 Plan for the nine months ended September 30, 2013:

| | 2005 Stock Incentive Plan | | 1995 Stock Option Plan | |
|---|---|---|---|---|
| | **Stock Options** | **Weighted-Average Exercise Price** | **Stock Options** | **Weighted-Average Exercise Price** |
| Outstanding at January 1, 2013 | 9,143,825 | $ 1.87 | 211,900 | $ 4.94 |
| Granted | 4,117,500 | $ 1.92 | — | $ — |
| Exercised | (522,292 ) | $ 2.29 | — | $ — |
| Canceled | (802,883 ) | $ 1.74 | (23,750 ) | $ 4.05 |
| Outstanding at September 30, 2013 | 11,936,150 | $ 1.88 | 188,150 | $ 5.04 |
| Shares exercisable at September 30, 2013 | 4,647,873 | $ 2.12 | 188,150 | $ 5.04 |

Shares available for grant at September 30, 2013 6,461,494

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:

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2013 | 2012 | 2013 | 2012 |
| Weighted-average fair value of stock options granted | $1.41 | $1.09 | $1.02 | $0.71 |
| Risk-free interest rate | 1.12%-1.36% | 0.55% | 0.54%-1.36% | 0.55%-1.54% |
| Dividend yield | 0% | 0% | 0% | 0% |
| Volatility | 56.75%-62.51 | 76.60%-76.71% | 55.81%-73.72% | 75.47%-80.48% |
| Expected term (in years) | 4.25 | 4.24 | 3.98-7.05 | 3.34-7.09 |
| Expected forfeiture rate | 23.15% | 23.15% | 0%-23.15% | 0%-23.15% |

The aggregate intrinsic value and weighted-average remaining contractual term of stock options outstanding as of September 30, 2013 was approximately $15.9 million and 7.6 years, respectively. The aggregate intrinsic value and weighted-average remaining contractual term of stock options exercisable as of September 30, 2013 was approximately $5.5 million and 5.9 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, 2013. 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 nine months ended September 30, 2013 and 2012 was $0.3 million and less than $0.1 million, respectively.

***Employee Stock Purchase Plan***

The Company received approval at its 2013 annual meeting of stockholders to adopt an Employee Stock Purchase Plan (the "ESPP"), which currently authorizes an aggregate of 2,000,000 shares of Common Stock to be purchased. 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). The first option period under the ESPP commenced on August 1, 2013.

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 September 30, 2013 |
|---|---|
| Weighted-average fair value of ESPP shares granted | $0.78 |
| Risk-free interest rate | 0.04% |
| Dividend yield | 0% |
| Volatility | 50.80% |
| Expected term (in years) | 0.5 |
| Expected forfeiture rate | 5% |

***Restricted Stock Awards***

Under the 2005 Plan, the Company has granted restricted stock awards subject to certain performance-based and/or 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 nine months ended September 30, 2013:

| | **Number of Shares** | **Per Share Weighted-Average Grant-Date Fair Value** |
|---|---|---|
| Outstanding and Unvested at January 1, 2013 | 33,334 | $ 1.39 |
| Restricted stock granted | — | $ — |
| Restricted stock vested | — | $ — |
| Restricted stock forfeited | — | $ — |
| Outstanding and Unvested at September 30, 2013 | 33,334 | $ 1.39 |

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

| | Three Months Ended | | Nine Months Ended | |
|---|---|---|---|---|
| | September 30, | | September 30, | |
| | 2013 | 2012 | 2013 | 2012 |
| Research and development | $316 | $219 | $829 | $638 |
| General and administrative | 347 | 274 | 955 | 1,030 |
| Total stock-based compensation expense | $663 | $493 | $1,784 | $1,668 |

As of September 30, 2013, there was approximately $4.7 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 1.5 years. This estimate does not include the impact of other possible stock-based awards that may be made during future periods.

Note 10 – U.S. Government Agreement, Joint Venture and Collaborations

***HHS BARDA Contract for Recombinant Influenza Vaccines***

In February 2011, the Company was awarded a contract from HHS BARDA valued at $97 million for the first three-year base-period, with an HHS BARDA option for an additional two-year period 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 allowable direct contract costs incurred plus allowable indirect costs and a fixed-fee earned in the further development of its multivalent seasonal and monovalent pandemic influenza vaccines. HHS BARDA originally directed the Company to develop its monovalent pandemic influenza vaccines against the A(H5N1) strain. Recently, however, HHS BARDA has directed the Company to develop its monovalent pandemic influenza vaccines against the A(H7N9) strain and is working with the Company to modify the contract in this respect; nevertheless, the Company's H5N1 vaccine program remains a viable development opportunity under the contract. 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. An audit by the U.S. government of fiscal years 2011 and 2012 has been initiated, but has not been completed as of the date of this filing. When the final determination of the allowable costs for any year has been made, revenue and billings may be adjusted accordingly; however, management believes that revenue for periods subject to audit has been recorded in amounts that are expected to be realized upon final audit and settlement. The Company recognized revenue of approximately $10.7 million in the nine months ended September 30, 2013, and has recognized approximately $45 million in revenue since the inception of the contract.

Under certain circumstances, HHS BARDA reimbursements may be delayed or even potentially withheld. In March 2012, the Company decided to conduct a Phase 2 clinical trial of its quadrivalent seasonal influenza vaccine candidate ("205 Trial") under its existing U.S. investigational new drug application ("IND") for its trivalent seasonal influenza vaccine candidate as opposed to waiting to conduct this clinical trial under a new IND for its quadrivalent vaccine candidate ("Quadrivalent IND"). Based on the Company's discussions with HHS BARDA in 2012, the outside clinical trial costs for the 205 Trial may only be submitted for reimbursement to HHS BARDA and recorded as revenue by the Company after it submits the clinical trial data in a future Quadrivalent IND. The submission of the Quadrivalent IND is expected shortly before the Company initiates the next Phase 2 dose-confirmatory clinical trial, which is currently expected in the first quarter of 2014. The outside clinical trial costs of the 205 Trial conducted last year total $2.9 million, which was incurred from the inception of the clinical trial through September 30, 2013. These costs have been recorded as an expense and are included in cost of government contracts revenue.

***CPL Biologicals Private Limited ("CPLB") Joint Venture***

In 2009, the Company formed a joint venture with Cadila Pharmaceuticals Limited ("Cadila") named CPL Biologicals Private Limited ("CPLB") to develop and manufacture vaccines, biological therapeutics and diagnostics in India. CPLB is owned 20% by the Company and 80% by Cadila. The Company accounts for its investment in CPLB using the equity method. Since the carrying value of the Company's initial investment was nominal and there is no guarantee or commitment to provide future funding, the Company has not recorded any losses related to this investment.

***LG Life Sciences, Ltd. ("LGLS") License Agreement***

In February 2011, the Company entered into a license agreement with LGLS that allows LGLS to use the Company's 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 both its clinical development of the influenza VLP vaccines and a manufacturing facility to produce such vaccine in South Korea. Under the license agreement, the Company is obligated to provide LGLS with information and materials related to the manufacture of the licensed products, provide on-going project management and regulatory support and conduct clinical trials of its influenza vaccines in order to obtain FDA approval in the U.S. The term of the license agreement is expected to terminate in 2027. Payments to the Company under the license agreement include an upfront payment of $2.5 million, reimbursements of certain development and product costs, payments related to the achievement of certain milestones and royalty payments in the high single digits from LGLS's future commercial sales of influenza VLP vaccines. The upfront payment has been deferred and will be recognized when the previously mentioned obligations in the agreement are satisfied, which may not occur until the end of the term of the agreement. Payments for milestones under the agreement will be recognized on a straight-line basis over the remaining term of the research and development period upon achievement of such milestone. Any royalties under the agreement will be recognized as earned.

***PATH Vaccine Solutions ("PATH") Clinical Development Agreement***

In July 2012, the Company entered into a clinical development agreement with PATH to develop its vaccine candidate to protect against RSV through maternal immunization in low-resource countries (the "RSV Collaboration Program"). The Company was awarded approximately $2.0 million by PATH for initial funding under the agreement to partially support its initial Phase 2 dose-ranging clinical trial in women of childbearing age, which was launched in October 2012. The funding under the agreement was increased by $0.4 million and the term extended to April 2014 to support the Company's reproductive toxicology studies, which are necessary before it conducts clinical trials in pregnant women. The Company retains global rights to commercialize the product and has made a commitment to make the vaccine affordable and available in low-resource countries. To the extent PATH elects to continue to fund 50% of the Company's external clinical development costs for the RSV Collaboration Program, but the Company does not continue development, the Company would then grant PATH a fully-paid license to its RSV vaccine technology for use in pregnant women in such low-resource countries. The Company recognized revenue of approximately $0.7 million in the nine months ended September 30, 2013, and has recognized approximately $2.0 million in revenue since the inception of the agreement. Revenue under this arrangement is being recognized under the proportional performance method and earned in proportion to the contract costs incurred in performance of the work as compared to total estimated contract costs. Costs incurred under this agreement represent a reasonable measurement of proportional performance of the services being performed.

Note 11 – Notes Payable

In September 2012, the Company entered into a master security agreement with General Electric Capital Corporation ("GE"), whereby the Company could borrow up to $2.0 million to finance the purchases of equipment through June 2013 (each, an "Equipment Loan"). Each Equipment Loan bears interest at the three-year U.S. Government treasury rate plus 11.68%, provided that the rate shall not be less than 12.1%, and is to be repaid over forty-two (42) months. GE will maintain a security interest in all equipment financed under the Equipment Loan. During the nine months ended September 30, 2013, the Company financed $1.5 million at interest rates of 12.1% with monthly principal payments totaling $34,529 ("2013 Funding"). Interest accrues on the outstanding balance until paid in full. As of September 30, 2013, the Company has financed $2.0 million in total under the Equipment Loan.

Aggregate future minimum principal payments on the GE notes payable, including the 2013 Funding, at September 30, 2013 are as follows (in thousands):

| Year | Amount |
|---|---|
| 2013 (remainder) | $ 143 |
| 2014 | 571 |
| 2015 | 571 |
| 2016 | 396 |

$ 1,681

14

Note 12 – 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 were exercisable between January 31, 2009 and July 31, 2013.

During the nine months ended September 30, 2013 and 2012, the Company recorded as other income (expense) in its consolidated statements of operations a change in fair value of warrant liability of $0.3 million and ($0.4) million, respectively. All Warrants expired unexercised on July 31, 2013.

Note 13 – Manufacturing, Laboratory and Office Facility

The Company leases its new manufacturing, laboratory and office space in Gaithersburg, Maryland with rent payments for such space to the landlord commencing April 1, 2014. Under the terms of one lease agreement, the landlord provided the Company with a tenant improvement allowance of $2.5 million and an additional tenant improvement allowance of $3 million, such additional tenant improvement allowance is to be paid back to the landlord during the remainder of the term of such lease agreement through additional rent payments (collectively, the "Improvement Allowance"). The Company has been funded $0.7 million in the nine months ended September 30, 2013, and has been funded $5.0 million in total under the Improvement Allowance. The Improvement Allowance is being amortized on a straight-line basis over the remaining term of the lease.

Note 14 – Master Services Agreement with Cadila

In connection with the JV with Cadila, the Company entered into a master services agreement, which the Company and Cadila amended in July 2011, and subsequently in March 2013, in each case 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 2014, 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 September 30, 2013, the Company has purchased $2.4 million in services from Cadila pursuant to this agreement, which includes $0.8 million of services provided, since the beginning of 2013, by CPLB to the Company on behalf of Cadila pursuant to an October 2013 amendment authorizing such CPLB services. The Company plans to explore with Cadila ways to potentially address its remaining financial obligation and/or extend the time period during which the Company could utilize such services. The Company can provide no assurance, however, that these efforts will be successful. If the Company fails to negotiate a change in this

arrangement, the Company expects that it will be obligated to spend a portion of its available cash and cash equivalents to pay Cadila for its shortfall in services purchased.

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

Any statements in the discussion below and elsewhere in this report, about our expectations, beliefs, plans, objectives, assumptions or future events or performance are not historical facts and are forward-looking statements. Such forward-looking statements include, without limitation, statements regarding our expectations regarding future revenue and expense levels, 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 future development of our product candidates by us, the conduct, timing and results of future clinical trials, plans regarding regulatory filings, our available cash resources and the availability of financing generally, our plans regarding partnering activities and business development initiatives, and other factors referenced herein. You can identify these forward-looking statements by the use of words or phrases such as "believe," "may," "could," "will," "possible," "can," "estim "continue," "ongoing," "consider," "anticipate," "intend," "seek," "plan," "project," "expect," "should," "would," or "assume" these terms, or other comparable terminology, although not all forward-looking statements contain these words.

Any or all of our forward-looking statements in the Quarterly Report may turn out to be inaccurate. Among the factors that could cause actual results to differ materially from those indicated in the forward-looking statements are risks and uncertainties inherent in our business including, without limitation, the progress, timing or success of our clinical trials; difficulties or delays in development, testing, obtaining regulatory approval for producing and marketing our product candidates; regulatory developments in the United States or in foreign countries; the risks associated with our reliance on collaborations for the development and commercialization of our product candidates; unexpected adverse side effects or inadequate efficacy of our product candidates that could delay or prevent product development or commercialization, or that could result in recalls or product liability claims; our ability to attract and retain key scientific, management or operational personnel; the size and growth potential of the markets for our product candidates and our ability to serve those markets; the scope and validity of patent protection for our product candidates; competition from other pharmaceutical or biotechnology companies; our ability to establish and maintain strategic collaborations or to otherwise obtain additional financing to support our operations on commercially reasonable terms; successful administration of our business and financial reporting capabilities; and other risks detailed in this report, including those identified in Part II, Item 1A, "Risk Factors" of our Annual Report on Form 10-K for year ended December 31, 2012. In light of these risks and uncertainties, the forward-looking events and circumstances discussed in this Quarterly Report may not occur as we contemplate, and actual results could differ materially from those anticipated or implied by the forward-looking statements and we therefore caution readers not to place undue reliance on such forward-looking statements.

Although we believe that the expectations reflected in our forward-looking statements are reasonable, we cannot guarantee future results, events, levels of activity, performance or achievement. We undertake no obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, unless required by law.

**Overview**

Novavax, Inc. (Novavax, and together with its subsidiary, Novavax AB, the Company, we or us) is a clinical-stage biopharmaceutical company focused on the discovery, development and commercialization of recombinant protein nanoparticle vaccines and adjuvants. Our vaccine technology platform is based on proprietary recombinant nanoparticle vaccine technology that includes virus-like particles ("VLPs") vaccines and recombinant protein micelle vaccines. These vaccine candidates are genetically engineered three-dimensional nanostructures that incorporate immunologically important recombinant proteins. Our vaccine product pipeline targets a variety of infectious diseases with candidates currently in clinical development for seasonal influenza, pandemic influenza and respiratory syncytial virus ("RSV"). We operate in one business segment: developing recombinant vaccines.

Through our Sweden-based subsidiary, Novavax AB (formerly Isconova AB), we are also developing patented technology for the production of immune stimulating saponin-based adjuvants that we expect to utilize in conjunction with our pandemic influenza vaccine candidates and potentially with other vaccine candidates that may benefit from such an adjuvant. The Matrix™ technology utilizes selected Quillaja saponaria fractions, which form separate matrix structures, to develop modern, multi-purpose immune-modulating adjuvant products for a broad range of vaccine applications. We acquired the Matrix™ technology through our acquisition of Isconova AB in the third quarter of 2013 because we believe this saponin-based adjuvant technology is a powerful complement to our recombinant vaccine programs. Our lead adjuvant for human applications, Matrix-M™, is in clinical trials with our partner Genocea Biosciences and is planned for a clinical trial in combination with our H7N9 vaccine candidate in the first quarter of 2014 under our contract with the Department of Health and Human Services, Biomedical Advanced Research and Development Authority (HHS BARDA).

In 2009, we formed a joint venture with Cadila Pharmaceuticals Limited ("Cadila") named CPL Biologicals Private Limited ("CPLB") to develop and manufacture vaccines, biological therapeutics and diagnostics in India. CPLB is owned 20% by us and 80% by Cadila. CPLB operates a state-of-the-art manufacturing facility for the production of influenza vaccine and other vaccine candidates. CPLB is actively developing a number of vaccine candidates that were genetically engineered by Novavax. CPLB's rabies vaccine candidate is expected to begin a Phase 1 clinical trial in India in late 2013 or in early 2014. We continue to account for our investment in CPLB using the equity method. Since the carrying value of our initial investment 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.

**Clinical Product Pipeline**

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

| Program | Development Phase | Collaborator |
|---|---|---|
| RSV | Phase 2 | PATH |
| Seasonal Quadrivalent Influenza | Phase 2 | HHS BARDA/LGLS |
| Pandemic (H5N1) Influenza | Phase 1 | HHS BARDA/LGLS[1] |
| Pandemic (H7N9) Influenza | Phase 1 | HHS BARDA/LGLS[1] |
| Seasonal Trivalent Influenza (India) | Phase 1 | CPLB |
| Pandemic (H1N1) Influenza (India) | Phase 1 | CPLB |
| Rabies | Phase 1-ready | CPLB |

**Respiratory Syncytial Virus (RSV)**

RSV is a widespread disease that causes infections of the lower respiratory tract. While RSV affects persons of all ages, it acutely impacts infants, the elderly, young children and others with compromised immune systems. Current estimates indicate that RSV is responsible for over 30 million new acute lower respiratory infection episodes and between 150,000 and 200,000 deaths in children under five years old[2]. In the U.S., nearly all children become infected with RSV before they are two years old; it has been associated with 20% of hospitalizations and 15% of office visits for acute respiratory infection in young children. The World Health Organization (WHO) estimates that the global disease burden for RSV is 64 million cases. Because there is no approved prophylactic vaccine, the unmet medical need of an RSV vaccine has the potential to protect millions of patients from this far-reaching disease.

[1] Although we initiated development of our pandemic influenza vaccine program under our contract with HHS BARDA against the A(H5N1) strain, because of concern over the potential mutation and spread of the A(H7N9) influenza strain in China, we independently initiated a second pandemic vaccine program in the first half of 2013 against A(H7N9). Recently, HHS BARDA has directed us to shift our contracted development activities to our H7N9 program; however, the H5N1 vaccine program remains a validated clinical asset and a viable potential development opportunity under the HHS BARDA contract.

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

We are developing a vaccine candidate to prevent RSV disease and are looking at susceptible target populations, including infants who may receive protection through antibodies transferred from their mothers who would be immunized during the last trimester of pregnancy, the elderly and young children.

*Maternal Immunization Development Program - Clinical Experience*

In April 2013, we announced top-line data from a Phase 2 dose-ranging clinical trial in women of childbearing age that were similar to, or exceeded, immune responses seen in our first Phase 1 clinical trial. This randomized, blinded, placebo-controlled Phase 2 clinical trial evaluated the safety and immunogenicity of two dose levels of our RSV vaccine candidate, with and without an aluminum phosphate adjuvant, in 330 women of childbearing age. We further reported that the vaccine candidate was well-tolerated, the two-dose alum-adjuvanted groups showed a 13 to 16-fold rise in anti-F IgG antibodies to the F protein compared to a 6 to 10-fold rise in the non-alum groups, and Palivizumab-like antibody titers rose 8 to 9-fold with four-fold rises in ≥92% of subjects in the two-dose alum-adjuvanted groups.

In August, 2013, in advance of initiating a Phase 2 clinical trial in a small group of pregnant women expected in 2014 and in consultation with the FDA, we initiated a reproductive toxicology study in rabbits to confirm the safety of our proposed formulation, which we expect to complete in the first quarter of 2014.

In October 2013, we initiated and completed enrollment in a Phase 2 dose-confirmation clinical trial in 720 women of childbearing age, which further supports our maternal immunization program.

*Elderly Development Program - Clinical Experience*

In October 2012, we initiated a Phase 1 dose-ranging clinical trial in the elderly, which supports our goals of developing a vaccine in elderly adults. This clinical trial was a randomized, blinded, placebo-controlled Phase 1 clinical trial that evaluated the safety and immunogenicity in 220 enrolled elderly adults, 60 years of age and older, who received a single intramuscular injection of our RSV vaccine candidate (with and without alum) or placebo plus a single dose of licensed influenza vaccine or placebo at days 0 and 28. In July 2013, we announced top-line data from the Phase 1 clinical trial in the elderly that further corroborated our previous clinical experiences with our RSV vaccine candidate. We further reported that the vaccine candidate was well-tolerated, that the higher dose groups had better overall immune responses than the lower dose groups and that essentially undetectable Day 0 levels of antibodies that compete with palivizumab increased to between 80% and 97% of active vaccine recipients by Day 28.

Our expected path forward in the elderly would include a dose-confirmation clinical trial, as we continue to assess the potential for a combination RSV and influenza vaccine for the elderly.

***PATH Vaccine Solutions (PATH) Clinical Development Agreement***

In July 2012, we entered into a clinical development agreement with PATH to develop our vaccine candidate to protect against RSV through maternal immunization in low-resource countries (RSV Collaboration Program). We were awarded approximately $2.0 million by PATH for initial funding under the agreement to partially support our Phase 2 dose-ranging clinical trial in women of childbearing age as described above. Funding under the agreement was increased by $0.4 million and the term extended to April 2014 to support our reproductive toxicology studies, which are necessary before we conduct clinical trials in pregnant women. We retain global rights to commercialize the product and have made a commitment to make the vaccine affordable and available in low-resource countries. To the extent PATH elects to continue to fund 50% of our external clinical development costs for the RSV Collaboration Program, but we do not continue development, we would then grant PATH a fully-paid license to our RSV vaccine technology for use in pregnant women in such low-resource countries.

**Influenza**

***Seasonal Influenza Vaccine***

Developing and commercializing a Novavax seasonal influenza vaccine remains an important strategic goal and viable opportunity for us. The Advisory Committee for Immunization Practices of the Center for Disease Control and Prevention (CDC) recommends that all persons aged six months and older should be vaccinated annually against seasonal influenza. In conjunction with these universal recommendations, attention from the 2009 influenza H1N1 pandemic has increased public health awareness of the importance of seasonal influenza vaccination, the market for which is expected to continue to grow worldwide in both developed and developing global markets.

There are currently four quadrivalent influenza vaccines licensed in the U.S., but in the coming years, additional seasonal influenza vaccines are expected to be produced and licensed within and outside of the U.S. in a quadrivalent formulation (four influenza strains: two influenza A strains and two influenza B strains), as opposed to the current trivalent formulation (three influenza strains: two influenza A strains and one influenza B strain). With two distinct lineages of influenza B viruses circulating, governmental health authorities have advocated for the addition of a second influenza B strain to provide additional protection. Current estimates for seasonal influenza vaccines growth in the top seven markets (U.S., Japan, France, Germany, Italy, Spain and UK), show potential growth from the current market of approximately $3.6 billion to $4.7 billion over the next ten years[3]. Recombinant seasonal influenza vaccines, like the candidate we are developing, have an important advantage; once licensed for commercial sale, large quantities of vaccines can be quickly and cost-effectively manufactured without the use of either the live influenza virus or eggs.

Top-line data from our most recent Phase 2 clinical trial for our quadrivalent influenza vaccine candidate were announced in July 2012. In that clinical trial, our quadrivalent VLP vaccine candidate demonstrated immunogenicity against all four viral strains based on HAI responses at day 21, and was also well-tolerated, as evidenced by the absence of any observed vaccine-related serious adverse events (SAEs) and an acceptable reactogenicity profile. Our vaccine candidate met the FDA accelerated approval seroprotection rates criterion for all four viral strains. The potential to fulfill the seroconversion rates criterion was demonstrated for three of the four viral strains. The fourth strain, B/Brisbane/60/08, despite fulfilling the seroprotection criterion, failed to demonstrate a satisfactory seroconversion rate. Following our last Phase 2 clinical trial, our seasonal influenza vaccine candidate activities focused on locking the manufacturing process that will ensure consistent and enhanced immune responses in all strains. We completed these activities in September 2013. In October 2013, we began manufacturing A and B strain influenza VLPs for the next Phase 2 clinical trial with our quadrivalent vaccine candidate.

***Pandemic Influenza Vaccine***

In the aftermath of the 2009 H1N1 influenza pandemic, recognition of the potential devastation of a human influenza pandemic remains a key priority with both governmental health authorities and influenza vaccine manufacturers. In the U.S. alone, the 2009 H1N1 pandemic led to the production of approximately 126 million doses of monovalent (single strain) vaccine. Public health awareness and government preparedness for the next potential influenza pandemic are driving development of vaccines that can be manufactured quickly against a potentially threatening influenza strain. Until the spring of 2013, industry and health experts focused attention on developing a monovalent H5N1 influenza vaccine as a potential key defense against a future pandemic threat; however, recent attention has shifted to the potential development of an H7N9 influenza vaccine.

[3] Market Forecasts: Seasonal Influenza Vaccines. Datamonitor (2012)

In October 2012, we reported positive results from two Phase 1 clinical trials of our pandemic (H5N1) vaccine candidate in combination with two different adjuvants, both of which are designed to improve the immunogenicity of vaccines at lower doses and thus provide antigen dose-sparing. The top-line data demonstrated safety and immunogenicity of varying dose-levels of the vaccine, with and without adjuvant, and further demonstrated statistically significant robust adjuvant effects on immune response.

In April 2013, we initiated manufacturing of a new monovalent influenza vaccine candidate against the A/Anhui/1/13-like H7N9 strain of avian influenza (A(H7N9)). This strain was first recognized by Chinese health authorities as a potential pandemic influenza threat in late March 2013. In a three month period, we took the A(H7N9) viral gene sequence provided to vaccine manufacturers by the WHO, developed and purified a VLP antigen, conducted multiple animal studies, and initiated a Phase 1 clinical trial in Australia on our own, independent from our HHS BARDA contract. In September 2013, HHS BARDA directed us to focus our development of a monovalent pandemic influenza vaccine on the A(H7N9) strain and notified us that they intend to fund a Phase 1 U.S. clinical trial with our H7N9 candidate and Matrix-M adjuvant in the first half of 2014; however, HHS BARDA has also indicated that our H5N1 vaccine program remains a viable development opportunity under our contract. The initiation and funding of any such study is contingent on the completion of a contract modification with HHS BARDA that is currently underway.

***Potential Accelerated Approval Pathway for Influenza***

In the past, we have referenced attainment of accelerated approval immunogenicity endpoints for seroprotection and seroconversion as a potential pathway for licensure of our influenza vaccines. The criteria for granting such accelerated approval of a Biologics License Application (BLA, the biologic equivalent to a New Drug Application or NDA) for new seasonal and pandemic influenza vaccines was published by the U.S. Food and Drug Administration, Center for Biologics Evaluation and Research (FDA). Under FDA guidance, developers that can demonstrate results that meet or exceed certain specified immunogenicity endpoint criteria in their clinical trials may, at the FDA's discretion, be granted a license to market a product prior to submission of traditional clinical endpoint efficacy trial data. It should be noted that FDA licensure based on accelerated approval nevertheless requires sponsors to conduct a post-licensure efficacy study to demonstrate the clinical benefit of the vaccine, which would thereby support traditional approval of the vaccine. Because it is not possible to conduct a clinical endpoint efficacy study for a pandemic vaccine in advance of a declared pandemic, FDA's pandemic guidance allows for submission of seasonal influenza clinical efficacy data for the purpose of confirming clinical benefit of a pandemic vaccine manufactured by the same process. Thus, the demonstration of efficacy with a seasonal vaccine provides a key link between the seasonal and pandemic programs. Accelerated approval further necessitates a shortage of influenza vaccine relative to the total population recommended to receive such vaccine, a situation that persists with seasonal influenza vaccine.

Although we have not ruled out this accelerated approval approach, particularly for our pandemic program or certain subject populations within the seasonal influenza program, we do not expect to pursue accelerated approval of our

quadrivalent seasonal influenza vaccine, largely because of the uncertainty as to whether the accelerated approval pathway will be available to us at the time of our BLA submissions and the unknown ability of current and new influenza strains to meet such accelerated approval criteria. We are planning, therefore, to pursue traditional licensure of our quadrivalent seasonal influenza vaccine by conducting a clinical endpoint efficacy study for the purpose of submitting the data within the original BLA. These efficacy data will also support the requirement for clinical efficacy data for our pandemic vaccine program. Novavax plans to discuss with the FDA our licensure pathways (both the traditional pathway for seasonal and possible accelerated pathways for pandemic and certain subject populations within the seasonal program) during future formal meetings. The likely impact of such an efficacy trial would be an additional year or more before the FDA grants licensure to our seasonal influenza vaccine.

***HHS BARDA Contract for Recombinant Influenza Vaccines***

HHS BARDA awarded us a contract in February 2011, which funds the development of both our seasonal and pandemic influenza vaccine candidates. The contract, valued at $97 million for the first three-year base-period and $82 million for an HHS BARDA optional two-year period, is a cost-plus-fixed-fee contract in which HHS BARDA reimburses us for allowable direct contract costs incurred plus allowable indirect costs and a fixed-fee earned in the ongoing clinical development and product scale-up of our multivalent seasonal and monovalent pandemic influenza vaccines. HHS BARDA originally directed us to develop our monovalent pandemic influenza vaccine against the A(H5N1) strain. Recently, however, HHS BARDA has directed us to develop our monovalent pandemic influenza vaccine against the A(H7N9) strain and is working with us to modify the HHS BARDA contract in this respect; nevertheless, our H5N1 vaccine program remains a viable development opportunity under the contract. We recognized revenue of approximately $10.7 million in the nine months ended September 30, 2013, and have recognized approximately $45 million in revenue since the inception of the contract.

Under certain circumstances, HHS BARDA reimbursements may be delayed or even potentially withheld. In March 2012, we decided to conduct a Phase 2 clinical trial of our quadrivalent seasonal influenza vaccine candidate (the 205 Trial) under our existing U.S. investigational new drug application (IND) for our trivalent seasonal influenza vaccine candidate as opposed to waiting to conduct this clinical trial under a new IND for our quadrivalent vaccine candidate (Quadrivalent IND). Based on our discussions with HHS BARDA in 2012, the outside clinical trial costs for the 205 Trial may only be submitted for reimbursement to HHS BARDA and recorded as revenue by us after we submit the clinical trial data in a future Quadrivalent IND. The submission of the Quadrivalent IND is expected shortly before we initiate the next Phase 2 dose-confirmatory clinical trial, which is currently expected in the first quarter of 2014. The outside clinical trial costs of the 205 Trial conducted last year total $2.9 million, which was incurred from the inception of the clinical trial through June 30, 2013. These costs have been recorded as an expense and are included in cost of government contracts revenue.

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

In February 2011, we entered into a license agreement with LGLS that allows LGLS to use our 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 both its clinical development of the influenza VLP vaccines and a manufacturing facility to produce such vaccine in South Korea. We received an upfront payment and may receive reimbursements of certain development and product costs, payments related to the achievement of certain milestones and royalty payments in the high single digits from LGLS’s future commercial sales of influenza VLP vaccines.

**Rabies**

CPLB is currently developing a rabies vaccine candidate that we genetically engineered and expects to initiate its Phase 1 clinical trial in India in late 2013 or early 2014. Our common objective is to develop a recombinant vaccine that can be administered as a pre-exposure prophylaxis for residents of certain higher-risk geographies, as well as travelers to such locations, and with the potential to provide post-exposure prophylaxis with fewer doses. Preliminary pre-clinical results have demonstrated that this vaccine candidate has the potential to successfully prevent the rabies virus from entering the central nervous system, thus preventing death.

**Other Emerging Diseases**

We pay close attention to global reports of emerging diseases for which there do not appear to be immediate cures and where a vaccine protocol could offer potential protection. In addition to our response to the A(H7N9) influenza strain (see discussion above), we have been monitoring reports around the Middle East Respiratory Syndrome Coronavirus (MERS), a novel coronavirus first identified in September 2012 by an Egyptian virologist. MERS has become an emerging threat in 2013 with more than 50 confirmed cases of infection and 30 deaths. The MERS virus is a part of the coronavirus family that includes the severe acute respiratory syndrome coronavirus (SARS). Because of the public health priority given to MERS, within weeks of getting the virus' sequence, Novavax successfully produced a vaccine candidate designed to provide protection against MERS. This vaccine candidate, which was made using our recombinant nanoparticle vaccine technology, is based on the major surface spike protein, which we had earlier identified as the antigen of choice in our work with a SARS vaccine candidate. Although this currently remains a pre-clinical program, we believe that our MERS vaccine candidate offers a viable option to interested global public health authorities.

**Sales of Common Stock**

In October 2012, we entered into an At Market Issuance Sales Agreement (2012 Sales Agreement), under which our Board of Directors (the Board) approved the sale of up to an aggregate of $50 million in gross proceeds of our common stock. The shares of common stock are being offered pursuant to a shelf registration statement filed with the SEC in March 2013, which replaced the previous shelf registration statement filed in 2010. The Board's standing Finance Committee (the Committee) assists with its responsibilities to monitor, provide advice to our senior management and approve all capital raising activities. The Committee has been authorized by the Board, absent any action by the Board to the contrary, to take any additional actions necessary to carry out the Board's authorization of the issuance and sale of the common stock sold pursuant to the 2012 Sales Agreement. In doing so, the Committee is authorized to set the amount of shares to be sold, the period of time during which such sales may occur and the minimum sales price per share. During the nine months ended September 30, 2013, we sold 12.6 million shares at sales prices ranging from $2.06 to $3.38 per share, resulting in approximately $34.0 million in net proceeds. The most recent sales to occur under the 2012 Sales Agreement were on September 10, 2013.

In September 2013, we completed a public offering of 31,846,950 shares of our common stock, including 4,153,950 shares of common stock that were issued upon the exercise in full of the over-allotment granted to the underwriters, at a price of $3.14 per share resulting in net proceeds of approximately $94.7 million.

***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, 2012, 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 our historical financial condition and results of operations, which includes Novavax AB's operations since the acquisition date of July 31, 2013, and should be read in conjunction with the consolidated financial statements and notes thereto set forth in this Quarterly Report.

**Three Months Ended September 30, 2013 and 2012** (amounts in tables are presented in thousands, except per share information)

**Revenue:**

| | Three Months Ended September 30, | | |
|---|---|---|---|
| | 2013 | 2012 | Change 2012 to 2013 |
| Revenue: | | | |
| Total revenue | $4,802 | $5,765 | $ (963 ) |

Revenue for the three months ended September 30, 2013 was $4.8 million as compared to $5.8 million for the same period in 2012, a decrease of $1.0 million or 17%. Revenue for the three months ended September 30, 2013 and 2012 is primarily comprised of services performed under the HHS BARDA contract and, to a much lesser extent in 2013, revenue of recently acquired Novavax AB. The decrease in revenue is primarily due to the higher level of activity in the three months ended September 30, 2012 associated with our influenza clinical trials under the HHS BARDA contract as compared to the same period in 2013 when no similar clinical trials were initiated.

For 2013, we expect a decrease in revenue due to fewer externally funded clinical trials in 2013 as compared to 2012, offset by increased product development activities under the HHS BARDA contract to support the ultimate initiation of later-stage clinical trials of our seasonal influenza and pandemic (H7N9) influenza vaccine candidates.

**Costs and Expenses:**

| | Three Months Ended September 30, | | |
|---|---|---|---|
| | 2013 | 2012 | Change 2012 to 2013 |
| Costs and Expenses: | | | |
| Cost of government contracts revenue | $2,276 | $3,838 | $(1,562 ) |
| Research and development | 13,948 | 6,642 | 7,306 |
| General and administrative | 3,857 | 2,134 | 1,723 |
| Total costs and expenses | $20,081 | $12,614 | $7,467 |

***Cost of Government Contracts Revenue***

Cost of government contracts revenue includes 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 government contracts revenue decreased to $2.3 million for the three months ended September 30, 2013 from $3.8 million for the same period in 2012, a decrease of $1.6 million, or 41%. The decrease in cost of government contracts revenue is primarily related to the levels of activity associated with our influenza clinical trials previously mentioned, including the 205 Trial (see discussion of the 205 Trial in *HHS BARDA Contract for Recombinant Influenza Vaccines* above).

For 2013, we expect the cost of government contracts revenue to decrease due to fewer externally funded clinical trials in 2013 as compared to 2012, offset by increased product development activities under the HHS BARDA contract.

***Research and Development Expenses***

Research and development expenses include salaries, laboratory supplies, consultants and subcontractors and other expenses associated with our process development, manufacturing, clinical, regulatory and quality assurance activities for internally funded programs. In addition, indirect costs such as fringe benefits and overhead expenses are also included in research and development expenses. Research and development expenses increased to $13.9 million for the three months ended September 30, 2013 from $6.6 million for the same period in 2012, an increase of $7.3 million, or 110%. Excluding the increase in research and development expenses of approximately $1.4 million of recently acquired Novavax AB, the remaining increase in research and development expenses was primarily due to increased costs relating to our RSV and pandemic (H7N9) influenza clinical trials (internally funded programs at this time) and higher employee-related costs. For 2013, we expect a significant increase in research and development expenses primarily due to additional clinical trials of our RSV and pandemic (H7N9) influenza vaccine candidates and employee-related costs to support product development of RSV and other potential vaccine candidates.

***Costs and Expenses by Functional Area***

We track our cost of government contracts 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 September 30, 2013, we had 153 employees dedicated to our research and development programs versus 103 employees as of September 30, 2012. 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 government contracts revenue and research and development expenses by functional area for the three months ended September 30 (in millions).

| | 2013 | 2012 |
|---|---|---|
| Manufacturing | $8.7 | $5.3 |
| Vaccine Discovery | 1.5 | 0.9 |
| Clinical and Regulatory | 6.0 | 4.3 |
| Total cost of government contracts revenue and research and development expenses | $16.2 | $10.5 |

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 clinical trials in order to focus our resources on more promising vaccine candidates. Completion of clinical trials may take several years or more, but the length of time can vary substantially depending

upon the phase, size of clinical trial, primary and secondary endpoints and the intended use of the vaccine candidate. The cost of clinical trials may vary significantly over the life of a project as a result of a variety of factors, including:

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

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

***General and Administrative Expenses***

General and administrative expenses increased to $3.9 million for the three months ended September 30, 2013 from $2.1 million for the same period in 2012, an increase of $1.7 million, or 81%. Excluding the increase in general and administrative expenses of approximately $0.6 million of recently acquired Novavax AB, the remaining increase was primarily due to higher professional fees, including those associated with our acquisition of Novavax AB. For 2013, we expect general and administrative expenses to increase as a result of increased professional fees, including those associated with our acquisition of Novavax AB.

**Other Income (Expense):**

| | Three Months Ended September 30, | | |
|---|---|---|---|
| | 2013 | 2012 | Change 2012 to 2013 |
| Other Income (Expense): | | | |
| Interest income | $53 | $39 | $ 14 |
| Interest expense | (64) | (6) | (58) |
| Other expense | (10) | | (10) |
| Change in fair value of warrant liability | | (401) | 401 |
| Total other income (expense) | $(21) | $(368) | $ 347 |

We had total other expense of less than $0.1 million for the three months ended September 30, 2013 compared to total other expense of $0.4 million for the same period in 2012. For the three months ended September 30, 2013, the change in fair value of the warrant liability resulted in a $0.4 million decrease in total other expense as compared to the same period in 2012. The warrants expired unexercised on July 31, 2013.

Net Loss:

| | Three Months Ended September 30, | | |
|---|---|---|---|
| | 2013 | 2012 | Change 2012 to 2013 |
| Net Loss: | | | |
| Net loss | $(15,300) | $(7,217) | $(8,083) |
| Net loss per share | $(0.09) | $(0.05) | $(0.04) |
| Weighted shares outstanding | 168,537 | 134,178 | 34,359 |

Net loss for the three months ended September 30, 2013 was $15.3 million, or $0.09 per share, as compared to $7.2 million, or $0.05 per share, for the same period in 2012, an increased net loss of $8.1 million. The increased net loss was primarily due to higher research and development spending, including increased costs relating to our RSV and pandemic (H7N9) influenza clinical trials and higher employee-related costs.

The increase in weighted average shares outstanding for the three months ended September 30, 2013 is primarily a result of sales of our common stock in 2012 and 2013.

**Nine Months Ended September 30, 2013 and 2012** (amounts in tables are presented in thousands, except per share information)

**Revenue:**

| | Nine Months Ended September 30, | | |
|---|---|---|---|
| | 2013 | 2012 | **Change 2012 to 2013** |
| Revenue: | | | |
| Total revenue | $12,167 | $17,510 | $(5,343) |

Revenue for the nine months ended September 30, 2013 was $12.2 million as compared to $17.5 million for the same period in 2012, a decrease of $5.3 million or 31%. Revenue for the nine months ended September 30, 2013 and 2012 is primarily comprised of services performed under the HHS BARDA contract and, to a much lesser extent in 2013, the PATH clinical development agreement. The decrease in revenue is primarily due to the higher level of activity in the nine months ended September 30, 2012 associated with our influenza clinical trials under the HHS BARDA contract as compared to the same period in 2013 when no similar clinical trials were initiated, partially offset by revenue under the PATH clinical development agreement in 2013.

**Costs and Expenses:**

| | Nine Months Ended September 30, | | |
|---|---|---|---|
| | 2013 | 2012 | **Change 2012 to 2013** |
| Costs and Expenses: | | | |
| Cost of government contracts revenue | $5,619 | $12,740 | $(7,121 ) |
| Research and development | 33,989 | 17,270 | 16,719 |
| General and administrative | 10,740 | 7,670 | 3,070 |
| Total costs and expenses | $50,348 | $37,680 | $12,668 |

***Cost of Government Contracts Revenue***

Cost of government contracts revenue includes 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 government contracts revenue decreased to $5.6 million for the nine months ended September 30, 2013 from $12.7 million for the same period in 2012, a decrease of $7.1 million, or 56%. The decrease in cost of government contracts revenue is primarily related to the levels of activity associated with our influenza clinical trials previously mentioned, including the 205 Trial (see discussion of the 205 Trial in HHS BARDA Contract for Recombinant Influenza Vaccines above).

***Research and Development Expenses***

Research and development expenses include salaries, laboratory supplies, consultants and subcontractors and other expenses associated with our process development, manufacturing, clinical, regulatory and quality assurance activities for internally funded programs. In addition, indirect costs such as fringe benefits and overhead expenses are also included in research and development expenses. Research and development expenses increased to $34.0 million for the nine months ended September 30, 2013 from $17.3 million for the same period in 2012, an increase of $16.7 million, or 97%. Excluding the increase in research and development expenses of approximately $1.4 million of recently acquired Novavax AB, the remaining increase in research and development expenses was primarily due to increased costs relating to our RSV and pandemic (H7N9) influenza clinical trials (internally funded programs at this time) and higher employee-related costs.

***Costs and Expenses by Functional Area***

The following summarizes our cost of government contracts revenue and research and development expenses by functional area for the nine months ended September 30 (in millions).

| | 2013 | 2012 |
|---|---|---|
| Manufacturing | $21.9 | $14.8 |
| Vaccine Discovery | 4.0 | 2.5 |
| Clinical and Regulatory | 13.7 | 12.7 |
| Total cost of government contracts revenue and research and development expenses | $39.6 | $30.0 |

***General and Administrative Expenses***

General and administrative expenses increased to $10.7 million for the nine months ended September 30, 2013 from $7.7 million for the same period in 2012, an increase of $3.1 million, or 40%. Excluding the increase in general and administrative expenses of approximately $0.6 million of recently acquired Novavax AB, the remaining increase was primarily due to higher professional fees, including those associated with our acquisition of Novavax AB.

**Other Income (Expense):**

| | **Nine Months Ended September 30,** | | **Change 2012 to 2013** |
|---|---|---|---|
| | 2013 | 2012 | |
| Other Income (Expense): | | | |
| Interest income | $149 | $111 | $ 38 |
| Interest expense | (132) | (12) | (120) |
| Other expense | (10) | | (10) |
| Change in fair value of warrant liability | 267 | (401) | 668 |
| Total other income (expense) | $274 | $(302) | $ 576 |

We had total other income of $0.3 million for the nine months ended September 30, 2013 compared to total other expense of $0.3 million for the same period in 2012. For the nine months ended September 30, 2013, the change in fair value of the warrant liability resulted in a $0.7 million increase in total other income as compared to the same

period in 2012. The warrants expired unexercised on July 31, 2013.

Net Loss:

| | Nine Months Ended September 30, | | |
|---|---|---|---|
| | 2013 | 2012 | Change 2012 to 2013 |
| Net Loss: | | | |
| Net loss | $(37,929) | $(20,472) | $(17,457) |
| Net loss per share | $(0.24) | $(0.16) | $(0.08) |
| Weighted shares outstanding | 156,555 | 127,246 | 29,309 |

Net loss for the nine months ended September 30, 2013 was $37.9 million, or $0.24 per share, as compared to $20.5 million, or $0.16 per share, for the same period in 2012, an increased net loss of $17.5 million. The increased net loss was primarily due to higher research and development spending, including increased costs relating to our RSV and pandemic (H7N9) influenza clinical trials and higher employee-related costs.

The increase in weighted average shares outstanding for the nine months ended September 30, 2013 is primarily a result of sales of our common stock in 2012 and 2013.

**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 September 30, 2013, we had $146.4 million in cash and cash equivalents and investments as compared to $50.3 million as of December 31, 2012. These amounts consisted of $122.5 million in cash and cash equivalents and $23.9 million in investments as of September 30, 2013 as compared to $17.4 million in cash and cash equivalents and $32.9 million in investments at December 31, 2012.

The following table summarizes cash flows for the nine months ended September 30, 2013 and 2012 (in thousands):

| | **Nine Months Ended September 30,** | | |
|---|---|---|---|
| | **2013** | **2012** | **Change 2012 to 2013** |
| **Summary of Cash Flows:** | | | |
| Net cash (used in) provided by: | | | |
| Operating activities | $(33,096) | $(14,977) | $(18,119) |
| Investing activities | 7,231 | (15,147) | 22,378 |
| Financing activities | 130,943 | 26,758 | 104,185 |
| Effect of exchange rate on cash and cash equivalents | 16 | | 16 |
| Net increase (decrease) in cash and cash equivalents | 105,094 | (3,366) | 108,460 |
| Cash and cash equivalents at beginning of period | 17,399 | 14,104 | 3,295 |
| Cash and cash equivalents at end of period | $122,493 | $10,738 | $111,755 |

Net cash used in operating activities increased to $33.1 million for the nine months ended September 30, 2013 as compared to $15.0 million for the same period in 2012, respectively. The increase in cash usage was primarily due to increased costs relating to our RSV and pandemic (H7N9) influenza clinical trials and higher employee-related costs.

During the nine months ended September 30, 2013 and 2012, our investing activities consisted of purchases and maturities of investments and capital expenditures. In the nine months ended September 30, 2013, we primarily utilized our short-term investments to fund operations and increase our cash balances. In the same period in 2012, we primarily purchased short-term investments to increase our rate of return on our investments. Capital expenditures for the nine months ended September 30, 2013 and 2012 were $4.8 million and $2.2 million, respectively. The increase in capital expenditures was primarily due to purchase of laboratory equipment and tenant improvements relating to our new manufacturing facility. In late 2013, we expect our level of capital expenditures to decrease due to the expected completion of the scale-up work on our new manufacturing facility.

Our financing activities consist primarily of sales of our common stock. In the nine months ended September 30, 2013, we received net proceeds of $94.7 million through our public offering at a sales price of $3.14 per share and $34.0 million through our At Market Issuance Sales Agreements at an average sales price of $2.76 per share. In the same period in 2012, we received net proceeds of $14.8 million through our At Market Issuance Sales Agreements at an average sales price of $1.70 per share and $12.1 million to two affiliates of RA Capital Management, LLC at a sales price of $1.22.

In November 2011, we entered into lease agreements under which we lease our new manufacturing, laboratory and office space in Gaithersburg, Maryland with rent payments for such space to the landlord commencing April 1, 2014. Under the terms of the arrangement, the landlord provided us with a tenant improvement allowance of $2.5 million and an additional tenant improvement allowance of $3 million (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 through additional rent payments. We were funded $0.7 million in the nine months ended September 30, 2013, and have been funded $5.0 million in total under the Improvement Allowance.

In September 2012, we entered into a master security agreement, whereby we could borrow up to $2.0 million to finance the purchases of equipment through June 2013 (Equipment Loan). We financed $1.5 million in the nine months ended September 30, 2013, and have financed $2.0 million in total under the Equipment Loan.

We have entered into agreements with outside providers to support our clinical development. As of September 30, 2013, $8.0 million remains unpaid on certain of these agreements in the event our outside providers complete their services in 2013. 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 (previously made), ongoing 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, with expected patent expiration in early 2022. 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 September 30, 2013 totaled $5.9 million, of which $0.2 million was paid in the nine months ended September 30, 2013. We do not expect to make a milestone payment to Wyeth in the next 12 months.

In connection with CPLB, we entered into a master services agreement with Cadila, which we and Cadila amended in July 2011, and subsequently in March 2013, in each case 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 2014, the amount of services provided by Cadila under the master services agreement is less than $7.5 million, we 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. Recently, the Company and Cadila agreed to an amendment that allows CPLB, as of the beginning of 2013, to provide services on behalf of Cadila. Through September 30, 2013, we have purchased $2.4 million in services from Cadila pursuant to this agreement, including amounts in which CPLB provided the services on behalf of Cadila.

Based on our September 30, 2013 cash and cash equivalents and investment balances and the anticipated revenue under the contract with HHS BARDA, we believe we have adequate capital to fund our operating plans into 2016. Additional capital may be required in the future to develop our vaccine candidates through clinical development, manufacturing and commercialization. Our ability to obtain such additional capital will likely be subject to various factors, including our ability to perform and thus generate revenue under the HHS BARDA contract, our overall business performance and market conditions.

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. We cannot 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 may be required to delay, reduce the scope of, or eliminate one or more of our product research and development programs, and/or downsize our organization, including our general and administrative infrastructure.

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

The primary objective of our investment activities is preservation of capital, with the secondary objective of maximizing income. As of September 30, 2013, we had cash and cash equivalents of $122.5 million, investments of $23.9 million, all of which are short-term, and working capital of $140.8 million.

Our exposure to market risk is primarily confined to our investment portfolio. As of September 30, 2013, 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 investments when they mature and the proceeds are reinvested into new investments and, therefore, could impact our cash flows and results of operations.

Interest and dividend income is recorded when earned and included in interest income. Premiums and discounts, if any, on 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, even with the acquisition of Novavax AB, 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 September 30, 2013. 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 September 30, 2013, 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 third quarter of 2013, and has concluded that there was no change that occurred during the third quarter of 2013 that materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

During the third quarter of 2013, the Company acquired Novavax AB. The Company is currently in the process of integrating Novavax AB pursuant to the Sarbanes-Oxley Act of 2002. The Company is evaluating changes to processes, information technology systems and other components of internal controls over financial reporting as part of its ongoing integration activities, and as a result, controls will be changed as needed.

**PART II. OTHER INFORMATION**

**Item 1A. Risk Factors**

The following risk factors reflect material changes to the Company's risk factors as described in Part II, Item 1A, "Risk Factors" of the Company's Annual Report on Form 10-K for the year ended December 31, 2012:

**RISKS RELATED TO OUR BUSINESS**

***Even with the HHS BARDA contract award, we may not be able to fully fund our influenza programs.***

The HHS BARDA contract is a cost-plus-fixed-fee contract that only reimburses certain specified activities that have been previously authorized by HHS BARDA. There is no guarantee that additional activities will not be needed and, if so, that HHS BARDA will reimburse us for these activities. Additionally, we have limited experience meeting the significant requirements of a federal government contractor, which includes having appropriate accounting, project tracking and earned-value management systems implemented and operational, and our existing operations may not meet these requirements in a timely way or at all. Performance under the HHS BARDA contract requires that we comply with appropriate regulations and operational mandates, with which we have minimal operational experience. Our ability to be regularly and fully reimbursed for our activities will depend on our ability to comply and demonstrate compliance with such requirements.

***We may not meet the milestones of our contract with HHS BARDA during the contract period and HHS BARDA may elect not to extend the contract period for us to meet these milestones.***

The HHS BARDA contract anticipates that we file Biologics License Applications (BLA, the biologic equivalent to a New Drug Application or NDA) for licensure of both a seasonal influenza vaccine and a pandemic influenza vaccine; however, the contract is for a base-period of three years plus an option-period of two additional years, and there is no guarantee that we will successfully complete all of the tasks required to file these BLAs during the anticipated contract period. For example, while we have made significant progress during the last year in addressing our goal of consistent and enhanced immune responses in all strains of our influenza vaccine candidates, there is no guarantee that we will ever be successful in having all the strains meet the immunogenicity criteria for accelerated approval by the FDA. The inability to meet such goals could cause delays in our influenza vaccine candidate programs.

***HHS BARDA directed activities under the contract may require us to change our plans such that other activities anticipated under the contract may not occur during the contract period, which may necessitate that we fund such activities ourselves or not conduct them at all.***

HHS BARDA has directed us to focus on developing our pandemic influenza vaccine against the A(H7N9) strain; while we expect to be able to initiate a Phase 2 clinical trial for our pandemic (H7N9) influenza vaccine candidate, certain work that had been conducted on our pandemic (H5N1) influenza vaccine candidate may need to be duplicated or re-conducted on our pandemic (H7N9) influenza vaccine candidate. To the extent that such work is reimbursed by HHS BARDA under our contract, such funds may not be available for other development activities that we had anticipated would be performed under the contract. In such cases, we will need to decide whether to conduct the activities at our own expense or to determine that such activities are unnecessary.

***Our expectation that our pandemic influenza vaccine candidate will be granted accelerated approval by the FDA is not guaranteed and if we don't get accelerated approval, development of this vaccine will take longer and cost significantly more prior to BLA approval.***

As is the case with seasonal influenza, FDA has articulated the immunogenicity criteria for accelerated approval of vaccines that address potential pandemic influenza strains. Because a controlled efficacy clinical trial of a pandemic vaccine candidate is not logistically or ethically possible, accelerated approval will require evidence that a seasonal vaccine made by the same manufacturing process as the pandemic vaccine is efficacious. There is no guarantee the FDA will grant accelerated approval of our pandemic vaccine before we provide seasonal influenza efficacy data. If our seasonal influenza vaccine does not get accelerated approval from the FDA, it is likely that we will need to conduct larger and more expensive efficacy clinical trials and that licensure of our seasonal vaccine will be materially delayed for a year or more, assuming such licensure occurs at all, which may, in turn, delay the FDA approval of our pandemic vaccine.

***Because of changes to the influenza vaccine industry and regulatory environment, accelerated approval by the FDA of our seasonal influenza vaccine candidate may not be available in which case development of this vaccine will take longer and cost significantly more prior to BLA approval.***

While FDA regulations allow for the accelerated approval of a seasonal influenza vaccine based on surrogate endpoint criteria for products that treat serious diseases and fill an unmet medical need, which can allow developers to obtain licensure well ahead of the timeline for demonstrating clinical results in a traditional efficacy trial, the seasonal influenza vaccine industry has made significant steps to provide sufficient supply to the recommended population in the U.S. Thus, the FDA may no longer view the development of our seasonal influenza vaccine as meeting an unmet medical need. If our seasonal influenza vaccine does not receive accelerated approval from the FDA, we will need to conduct larger and more expensive efficacy clinical trials and that licensure of our seasonal vaccine will be materially delayed for a year or more, assuming such licensure occurs at all.

***Our recent acquisition of Novavax AB, collaborations with regional partners, such as Cadila, LGLS, and PATH, as well as contracts with international providers, expose us to additional risks associated with doing business outside the U.S., and any adverse event could have a material negative impact on our operations.***

We acquired Novavax AB on July 31, 2013. We have also formed a joint venture with Cadila in India, entered into a license agreement with LGLS in South Korea, a clinical development agreement with PATH and have entered into other agreements and arrangements with companies in other countries. We plan to continue to enter into collaborations or partnerships with companies, non-profit organizations and local governments in other parts of the world. Risks of conducting business outside the U.S. include:

- multiple regulatory requirements could affect our ability to develop, manufacture and sell products in such local markets;

- compliance with anti-bribery laws such as the United States Foreign Corrupt Practices Act and similar anti-bribery laws in other jurisdictions;

- trade protections measures and import and export licensing requirements;

- different labor regulations;

- changes in environmental, health and safety laws;

- exchange rates;

- potentially negative consequences from changes in or interpretations of tax laws;

- political instability and actual or anticipated military or potential conflicts;

- economic instability, inflation, recession and interest rate fluctuations;

- minimal or diminished protection of intellectual property in some countries; and

- possible nationalization and expropriation.

These risks, individually or in the aggregate, could have a material adverse effect on our business, financial conditions, results of operations and cash flows.

***Our business may be adversely affected if we do not successfully execute our business development initiatives.***

We anticipate growing through both internal development projects, as well as external opportunities, which include the acquisition, partnering and in-licensing of products, technologies and companies or the entry into strategic alliances and collaborations. The availability of high quality opportunities is limited, and we may fail to identify candidates that we and our stockholders consider suitable or complete transactions on terms that prove advantageous. In order to pursue such opportunities, we may require significant additional financing, which may not be available to us on favorable terms, if at all. Even if we are able to successfully identify and complete acquisitions, like our business combination with Novavax AB, we may not be able to integrate the assets or take full advantage of the opportunities and, consequently, may not realize the benefits that we expect.

To effectively manage our current and future potential growth, we will need to continue to enhance our operational, financial and management processes and to effectively expand, train and manage our employee base. Supporting our growth initiatives will require significant expenditures and management resources, including investments in research and development, manufacturing and other areas of our business. If we do not successfully manage our growth and do not successfully execute our growth initiatives, then our business and financial results may be adversely impacted, and we may incur asset impairment or restructuring charges.

**RISKS RELATED TO OUR ACQUISITION OF NOVAVAX AB**

***We may not be able to successfully integrate our business with the business of Novavax AB.***

The acquisition of Novavax AB involves the integration of two companies based in different countries that had been operating independently. This integration will be a complex, costly and time-consuming process. We may encounter difficulties in integrating our operations, technology and personnel with those of Novavax AB and this may continue for some time. Our management has limited experience integrating operations as substantial and geographically diverse as those of Novavax AB. We may not successfully integrate our operations and Novavax AB's operations in a timely manner, or at all. The failure to successfully integrate the businesses' operations could adversely affect our business, financial condition and results of operations. The anticipated benefits relate to utilizing Novavax AB's proprietary adjuvants, including Matrix-M, with one or more of Novavax' product candidates and retaining the full economics and developmental control of these adjuvanted vaccines, as well as other opportunities resulting from Novavax' and Novavax AB's complementary product candidates, industry specialties and technology platforms. However, these anticipated benefits are based on projections and assumptions, not actual experience, and assume a

successful integration.

***As a result of the combination with Novavax AB, we may face risks upon entering into certain specific areas of vaccine development for which we have limited or no experience.***

Novavax AB develops adjuvants in veterinary vaccines. The development and improvement of vaccines for the global veterinary market is an area of vaccine development for which we have limited or no experience. Although comprising a small part of our business, this lack of experience may have a negative impact to operations.

***Novavax AB adjuvants, including Matrix-M, may prove to have limited or no benefit to our vaccine development programs.***

We cannot guarantee that Matrix-M, or any other of Novavax AB's saponin-based adjuvants, will offer immunogenic benefits to any of our vaccine programs until such adjuvants are tested in clinical trials.

***We may not be able to achieve the anticipated strategic benefits of our recent combination with Novavax AB.***

We are not able to guarantee that anticipated strategic benefits from the completed acquisition of Novavax AB, including cost savings from operational activities, will be realized within the time periods contemplated or that they will be realized at all. We are not able to guarantee that the combination of Novavax and Novavax AB will result in the realization of the full benefits.

***Adjuvants, including saponin-based adjuvants such as Matrix-M, are likely to face increased regulatory scrutiny and may prove to be unpopular with vaccine-using consumers and advocacy groups.***

Regulatory agencies, including the FDA, have been cautious in approving adjuvants for use in commercial vaccines. Recent reports on adjuvants that contain squalene, a commercially extracted adjuvant derived from shark liver oil, as an active ingredient, and links to neurological disorders like narcolepsy may cause regulatory agencies to increase their scrutiny of all adjuvants, whether they contain squalene or not. Although none of the adjuvants made by Novavax AB contain squalene, the impact of such regulatory scrutiny may be detrimental to vaccine products containing non-squalene adjuvants. In addition, adjuvant usage has been unpopular with a small group of vaccine advocacy and consumer groups who oppose the addition of further active ingredients in vaccines; their opposition may gain support and have a detrimental impact on commercialization efforts and opportunities.

***As a result of the acquisition of Novavax AB, we will have revenue and expenses outside of the U.S., so we will be subject to fluctuations in foreign currency rates, and if our management is unable to manage our exposure to foreign currencies successfully, our operating results will suffer.***

With the acquisition of Novavax AB, we will be exposed to risks associated with the translation of Novavax AB's Swedish Krona (SEK)-denominated financial results and balance sheet into U.S. dollars. Our reporting currency will remain as the U.S. dollar. Any inability to successfully manage fluctuations in foreign currency rates could have a material adverse effect on our results of operations and, as a result, on the market price of our common stock.

***The uncertainties associated with our combination with Novavax AB may cause key personnel to leave.***

Our employees, including the employees of Novavax AB, may perceive uncertainty about their future role with the combined business until strategies with regard to the combined business are fully executed. Any uncertainty may affect either our ability to retain key scientific, management or operational personnel. Novavax AB's technology is based, in part, on trade secret and know-how, so if we are not able to retain key technical employees, we might have difficulties in continuing to develop and maintain Novavax AB's proprietary adjuvants, which may impede the achievement of our objectives with this acquisition.

**PRODUCT DEVELOPMENT RISKS**

***We have not completed the development of vaccine products and we may not succeed in obtaining the FDA approval necessary to sell such vaccine products.***

The development, manufacture and marketing of our pharmaceutical and biological products are subject to government regulation in the U.S. and other countries, including the European Medicines Agency and the Swedish Medical Products Agency with respect to our adjuvant product being developed in Sweden. In the U.S. and most foreign countries, we must complete rigorous pre-clinical testing and extensive clinical trials that demonstrate the safety and efficacy of a product in order to apply for regulatory approval to market the product. None of our vaccine candidates have yet gained regulatory approval in the U.S. or elsewhere. We also have vaccine candidates in clinical trials and pre-clinical laboratory or animal studies.

The steps required by the FDA before our proposed investigational products may be marketed in the U.S. include:

- performance of pre-clinical (animal and laboratory) tests;
- submissions to the FDA of an IND, which must become effective before clinical trials may commence;
- performance of adequate and well-controlled clinical trials to establish the safety and efficacy of the investigational product in the intended target population;
- performance of a consistent and reproducible manufacturing process intended for commercial use, including appropriate manufacturing data and regulatory inspections;
- submission to the FDA of a BLA or a NDA; and
- FDA approval of the BLA or NDA before any commercial sale or shipment of the product.

The processes are expensive and can take many years to complete, and we may not be able to demonstrate the safety and efficacy of our vaccine candidates to the satisfaction of regulatory authorities. The start of clinical trials can be delayed or take longer than anticipated for many and varied reasons, many of which are out of our control. Safety concerns may emerge that could lengthen the ongoing clinical trials or require additional clinical trials to be conducted. Promising results in early clinical trials may not be replicated in subsequent clinical trials. Regulatory authorities may also require additional testing, and we may be required to demonstrate that our proposed products represent an improved form of treatment over existing therapies, which we may be unable to do without conducting further clinical trials. Moreover, if the FDA or a foreign regulatory body grants regulatory approval of a product, the approval may be limited to specific indications or limited with respect to its distribution. Expanded or additional indications for approved products may not be approved, which could limit our revenue. Foreign regulatory authorities may apply similar limitations or may refuse to grant any approval. Consequently, even if we believe that pre-clinical and clinical data are sufficient to support regulatory approval for our vaccine candidates, the FDA and foreign regulatory authorities may not ultimately grant approval for commercial sale in any jurisdiction. If our vaccine candidates are not approved, our ability to generate revenue will be limited and our business will be adversely affected.

***We may not be able to secure sufficient supplies of a key component of our adjuvant technology.***

Because an important component of our recently acquired adjuvant technology is extracted from trees (Quillaja saponins) grown in Chile, we need to establish long term access to Quillaja extract with a consistent and sufficiently

high quality. We will need to find partners and make investments to secure the supply of raw material or the introduction of products may be delayed.

***We expect to continue to use all of our current manufacturing facility; however, if we choose not to do so, we may not be able to defray the lease payments and operating expenses of that facility.***

With our new late-stage and commercial launch manufacturing facility in Gaithersburg, Maryland, we have the opportunity to continue to fully utilize our current facility in Rockville, Maryland to develop early-stage clinical material and perform other pilot manufacturing activities. Although we expect to utilize the entire Rockville facility, depending on our needs, we may decide to sublease a portion or all of the Rockville facility prior to the end of our lease on January 31, 2017. Further, while we have structured our new facility arrangement to limit our financial exposure over the next five months, the expenses of leasing two manufacturing facilities are significant. If we decide to sublease a portion or all of the Rockville facility, such a sublease may prove difficult to obtain and even if we are able to do so, the sublease payments may not cover our lease payments and operating expenses for the space that we would sublet.

**Item 6. Exhibits**

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

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|---|---|
| 3.1 | Amended and Restated Certificate of Incorporation of Novavax, Inc., as amended by Certificates of Amendment dated December 18, 2000, July 8, 2004, May 13, 2009 and June 13, 2013 (Incorporated by reference to Exhibit 3.1 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2013) |
| 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) |
| 10.1 | Amendment No. 3 to Master Services Agreement between Novavax, Inc. and Cadila Pharmaceuticals Ltd. Dated October 29, 2013 (Incorporated by reference to Exhibit 1.1 to the Company's Report on Form 8-K dated October 30, 2013) |
| 31.1* | Certification of Chief Executive Officer pursuant to Rule 13a-14(a) or 15d-14(e) of the Securities Exchange Act |
| 31.2* | Certification of Chief Financial Officer pursuant to Rule 13a-14(a) or 15d-14(e) of the Securities Exchange Act |
| 32.1* | Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 |
| 32.2* | Certification of Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 |

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 12, 2013 By: /s/ Stanley C. Erck
President and Chief Executive Officer
and Director
(Principal Executive Officer)

Date: November 12, 2013 By: /s/ Barclay A. Phillips
Senior Vice President, Chief Financial Officer and Treasurer
(Principal Financial and Accounting Officer)