NOVAVAX INC

FORM 8-K
(Current report filing)

Filed 05/09/17 for the Period Ending 05/08/17

Address 21 FIRSTFIELD ROAD
          GAITHERSBURG, MD, 20878
Telephone 240-268-2000
CIK 0001000694
Symbol NVAX
SIC Code 2836 - Biological Products, (No Diagnostic Substances)
Industry Biotechnology & Medical Research
Sector Healthcare
Fiscal Year 12/31
NOVAVAX, INC.
(Exact name of registrant as specified in charter)

Delaware
(Exact or Other Jurisdiction of Incorporation)

0-26770
(Commission File Number)

22-2816046
(I.R.S. Employer Identification No.)

20 Firstfield Road
Gaithersburg, Maryland 20878
(Address of Principal Executive Offices, including Zip Code)

(240) 268-2000
(Registrant’s telephone number, including area code)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))
Item 2.02. Results of Operations and Financial Condition.

First Quarter Financial Results

On May 8, 2017, Novavax, Inc. (the “Company”) issued a press release announcing the Company’s financial results for the quarter ended March 31, 2017. A copy of this press release is attached as Exhibit 99.1 to this Current Report on Form 8-K.

The information in Items 2.02 and 9.01 of this Form 8-K (including Exhibit 99.1) shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934 (the “Exchange Act”) or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933 or the Exchange Act except as expressly set forth by specific reference in such a filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

<table>
<thead>
<tr>
<th>Exhibit No.</th>
<th>Description</th>
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SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Novavax, Inc.
(Registrant)

Date: May 9, 2017

By: /s/ John A. Herrmann III
Name: John A. Herrmann III
Title: Senior Vice President, General Counsel and Corporate Secretary
<table>
<thead>
<tr>
<th>Exhibit No.</th>
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Novavax Reports First Quarter 2017 Financial Results


First Quarter Achievements:

- Enrollment continued during the second global season in the RSV Phase 3 Prepare™ clinical trial for infants via maternal immunization. Enrollment in the first quarter of 2017 transitioned from the northern hemisphere to southern hemisphere sites in Argentina, Australia, Chile, New Zealand and South Africa. The second season of enrollment has benefitted greatly from the establishment of the operational infrastructure and experience from the first global season, resulting in material increases in enrollment and enhanced momentum as we move towards the third global season of enrollment.
- Initiation of a randomized, observer-blinded, multi-arm, dose-ranging Phase 2 clinical trial, in one and two dose formulations, both with and without adjuvants, of its RSV F Vaccine in older adults (60 years of age and older). The trial will evaluate safety and immunogenicity of these formulations in older adults as measured by serum microneutralization titers against RSV/A and RSV/B, palivizumab competing antibodies (“PCA”) and anti-F IgG.

Anticipated 2017 Events:

- Announce top-line data from the Phase 2 safety and immunogenicity clinical trial of the RSV F vaccine in older adults in the next 90 days.
- File revised study documents and conduct an informational analysis of the Prepare trial that would provide an indication of the RSV F Vaccine’s potential efficacy against the trial’s primary endpoint before the end of the year.
- Initiate a Phase 1 clinical trial of the Company’s recombinant seasonal influenza vaccine candidate before the end of the year.
- Initiate a Phase 1 clinical trial of the Company’s Zika vaccine candidate before the end of the year.

Summary

“We continued to make significant progress in the execution of our two key clinical trials of our RSV F vaccine for both infant via maternal immunization and in older adults. We look forward to reporting important clinical data from our older adult trial in the next 90 days. We’ve also been in discussion with the FDA about conducting an informational analysis of the Prepare trial that would provide an indication of our vaccine’s potential efficacy. From these discussions, we believe we can conduct this analysis in late 2017,” said Stanley C. Erck, President and CEO. “In addition, we are seeing the continued adoption and use of our proprietary adjuvant, Matrix-M, in a number of internal and partnered programs.”
Financial Results for the Three Months Ended March 31, 2017

Novavax reported a net loss of $43.9 million, or $0.16 per share, for the first quarter of 2017, compared to a net loss of $77.3 million, or $0.29 per share, for the first quarter of 2016.

Novavax revenue in the first quarter of 2017 increased 35% to $5.7 million, compared to $4.2 million for the same period in 2016, primarily due to increased revenue recorded under the BMGF grant relating to our ongoing Prepare clinical trial.

Research and development expenses decreased 45% to $37.7 million in the first quarter of 2017, compared to $69.0 million for the same period in 2016. The decrease was primarily due to reduced costs associated with the clinical trials and development activities of our RSV F Vaccine and lower employee-related costs.

General and administrative expenses decreased 16% to $8.9 million in the first quarter of 2017, compared to $10.5 million for the same period in 2016. The decrease was primarily due to lower professional fees for pre-commercialization activities.

Interest income (expense), net for the first quarter of 2017 was ($3.0) million, compared to ($1.9) million for the same period in 2016.

As of March 31, 2017, the company had $211.2 million in cash and cash equivalents and marketable securities compared to $235.5 million as of December 31, 2016. Net cash used in operating activities for the first quarter of 2017 was $38.6 million, compared to $69.8 million for the same period in 2016. The decrease in cash usage was primarily due to decreased costs relating to our RSV F Vaccine and lower employee-related costs.

Conference Call

Novavax management will host its quarterly conference call today at 4:30 p.m. ET. The dial-in number for the conference call is (877) 212-6076 (Domestic) or (707) 287-9331 (International), passcode 15607801. A replay of the conference call will be available starting at 7:30 p.m. ET on May 8, 2017 until 7:30 pm ET on May 15, 2017. To access the replay by telephone, dial (855) 859-2056 (Domestic) or (404) 537-3406 (International) and use passcode 15607801.

A webcast of the conference call can also be accessed via a link on the home page of the Novavax website (novavax.com) or through the "Investor Info"/"Events" tab on the Novavax website. A replay of the webcast will be available through the "Investor Info"/"Events" tab on the Novavax website until July 3, 2017.
About Novavax

Novavax, Inc. (Nasdaq:NVAX) is a clinical-stage biotechnology company committed to delivering novel products to prevent a broad range of infectious diseases. Our recombinant nanoparticles and Matrix-M™ adjuvant technology are the foundation for groundbreaking innovation that improves global health through safe and effective vaccines. Additional information about Novavax is available on the Company's website, novavax.com.

About RSV

Respiratory syncytial virus (RSV) is the most common cause of lower respiratory tract infections and the leading viral cause of severe lower respiratory tract disease in infants and young children worldwide, with estimated annual infection and mortality rates of 64 million and 160,000, respectively. ¹ In the U.S., RSV is the leading cause of hospitalization of infants, and globally, is second only to malaria as a cause of death in children under 1 year of age. ² ³ Despite the induction of post-infection immunity, repeat infection and lifelong susceptibility to RSV is common. Currently, there is no approved RSV vaccine available. ⁴

Forward-Looking Statements

Statements herein relating to the future of Novavax and the ongoing development of its vaccine and adjuvant products are forward-looking statements. Novavax cautions that these forward looking statements are subject to numerous risks and uncertainties, which could cause actual results to differ materially from those expressed or implied by such statements. These risks and uncertainties include those identified under the heading “Risk Factors” in the Novavax Annual Report on Form 10-K for the year ended December 31, 2016 and the Report on Form 10-Q for the period ended March 31, 2017, both as filed with the Securities and Exchange Commission (SEC). We caution investors not to place considerable reliance on the forward-looking statements contained in this press release. You are encouraged to read our filings with the SEC, available at sec.gov, for a discussion of these and other risks and uncertainties. The forward-looking statements in this press release speak only as of the date of this document, and we undertake no obligation to update or revise any of the statements. Our business is subject to substantial risks and uncertainties, including those referenced above. Investors, potential investors, and others should give careful consideration to these risks and uncertainties.

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³ Oxford Vaccine Group: http://www.ovg.ox.ac.uk/rsv
<table>
<thead>
<tr>
<th>Three Months Ended</th>
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<tbody>
<tr>
<td></td>
<td>March 31,</td>
<td></td>
</tr>
<tr>
<td></td>
<td>2017</td>
<td>2016</td>
</tr>
<tr>
<td>Revenue</td>
<td>$5,680</td>
<td>$4,218</td>
</tr>
<tr>
<td>Expenses:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Research and development</td>
<td>37,654</td>
<td>68,952</td>
</tr>
<tr>
<td>General and administrative</td>
<td>8,852</td>
<td>10,528</td>
</tr>
<tr>
<td>Total expenses</td>
<td>46,506</td>
<td>79,480</td>
</tr>
<tr>
<td>Loss from operations</td>
<td>(40,826)</td>
<td>(75,262)</td>
</tr>
<tr>
<td>Interest income (expense), net</td>
<td>(3,039)</td>
<td>(1,957)</td>
</tr>
<tr>
<td>Other income (expense)</td>
<td>11</td>
<td>(33)</td>
</tr>
<tr>
<td>Net loss</td>
<td>$ (43,854)</td>
<td>$ (77,252)</td>
</tr>
<tr>
<td>Basic and diluted net loss per share</td>
<td>$ (0.16)</td>
<td>$ (0.29)</td>
</tr>
<tr>
<td>Basic and diluted weighted average</td>
<td></td>
<td></td>
</tr>
<tr>
<td>number of common shares outstanding</td>
<td>274,178</td>
<td>270,179</td>
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</table>
## SELECTED CONSOLIDATED BALANCE SHEET DATA
(in thousands)

<table>
<thead>
<tr>
<th></th>
<th>March 31, 2017 (unaudited)</th>
<th>December 31, 2016</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cash and cash equivalents</td>
<td>$95,847</td>
<td>$144,353</td>
</tr>
<tr>
<td>Marketable securities</td>
<td>115,331</td>
<td>91,126</td>
</tr>
<tr>
<td>Total current assets</td>
<td>258,449</td>
<td>287,830</td>
</tr>
<tr>
<td>Working capital</td>
<td>201,951</td>
<td>221,424</td>
</tr>
<tr>
<td>Total assets</td>
<td>361,504</td>
<td>394,301</td>
</tr>
<tr>
<td>Total notes payable and capital lease obligation</td>
<td>316,714</td>
<td>316,376</td>
</tr>
<tr>
<td>Total stockholders’ deficit</td>
<td>(29,099)</td>
<td>(5,546)</td>
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Contact:

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