UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 8-K

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

Date of Report (Date of earliest event reported): November 7, 2018

NOVAVAX, INC.

(Exact name of registrant as specified in charter)

Delaware	**000-26770**	**22-2816046**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(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)

(Former name or former address, if changed since last report.)

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))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 2.02. Results of Operations and Financial Condition.

Third Quarter Financial Results

On November 7, 2018, Novavax, Inc. (the "Company") issued a press release announcing the Company's financial results for the quarter ended September 30, 2018. 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, as amended (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, as amended, 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.**

Exhibit No.	Description
99.1	Press release, dated November 7, 2018, regarding the Company's financial results for the quarter ended September 30, 2018.

SIGNATURE

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.

/s/ John A. Herrmann III
Name: John A. Herrmann III
Title: Senior Vice President, General Counsel and Corporate Secretary

Date: November 8, 2018

Exhibit 99.1

Novavax Reports Third Quarter 2018 Financial Results

Company to Host Conference Call Today at 4:30 p.m. ET

Gaithersburg, MD, November 7, 2018 – Novavax, Inc., (Nasdaq: NVAX) today announced its financial results and operational highlights for the third quarter and nine months ended September 30, 2018.

"We remain on track to meet our 2018 objectives, as we continue to execute on our clinical milestones for ResVax and NanoFlu," said Stanley C. Erck, President and Chief Executive Officer of Novavax, Inc. "In Prepare, our Phase 3 trial of ResVax, we will complete monitoring of the efficacy endpoints by year-end, which would allow us to announce top-line efficacy results in the first quarter of 2019. For NanoFlu, we have completed enrollment of our Phase 2 clinical trial and anticipate top-line results in the first quarter of 2019. Based on this progress, we expect to conduct an End-of-Phase 2 meeting with the FDA in the first half of 2019 and to initiate a pivotal Phase 3 clinical trial later in the year."

Third Quarter 2018 Operational Highlights

ResVax™ Program

- Novavax expects to report top-line results from its final efficacy analysis in the first quarter of 2019 and, assuming successful results, expects to submit the Biologics License Application (BLA) and Marketing Authorization Application (MAA) by the first quarter of 2020.

NanoFlu™ Program

- In September 2018, Novavax initiated a Phase 2 clinical trial in older adults of quadrivalent formulations of NanoFlu, its nanoparticle seasonal influenza vaccine candidate, and in October 2018, Novavax completed enrollment of approximately 1,375 healthy older adults across clinical sites in the U.S. This randomized, observer-blinded, active-controlled trial will assess the safety and tolerability of different doses and formulations of NanoFlu, both adjuvanted with Matrix-M™ and unadjuvanted, as compared to two U.S.-licensed comparators. Phase 2 clinical trial top-line results are expected in the first quarter of 2019.

- During a pre-IND meeting in 2018, the FDA acknowledged and agreed that the accelerated approval pathway for seasonal influenza vaccines could be available for NanoFlu. Novavax plans to discuss the Phase 2 data and the proposed Phase 3 study design, and reach agreement on the use of accelerated approval, with the FDA during an End-of-Phase 2 meeting in the first half of 2019. Novavax will bring forward the selected dose/formulation of the Phase 2 clinical trial into its future pivotal Phase 3 immunogenicity clinical trial.

Corporate

- Novavax announced the appointment of Rachel King, Co-Founder and Chief Executive Officer of GlycoMimetics, Inc., to its Board of Directors. In addition to extensive experience as an executive in the biotechnology industry, Mrs. King has also worked in the venture capital side of life sciences, and has held executive positions within a global multinational pharmaceutical company.

Key Upcoming Anticipated Events

- Final efficacy results of the Prepare trial are expected in the first quarter of 2019.
- Top-line data from the Phase 2 clinical trial of NanoFlu are expected in the first quarter of 2019.
- An End-of-Phase 2 meeting for NanoFlu is expected in the first half of 2019.

Financial Results for the Three and Nine Months Ended September 30, 2018

Novavax reported a net loss of $44.6 million, or $0.12 per share, for the third quarter of 2018, compared to a net loss of $44.6 million, or $0.15 per share, for the third quarter of 2017. For the nine months ended September 30, 2018, the net loss was $135.4 million, or $0.37 per share, compared to a net loss of $132.9 million, or $0.47 per share, for the same period in 2017.

Novavax revenue in the third quarter of 2018 was $7.7 million, compared to $8.4 million in the same period in 2017. This 7% decrease was driven by the completion of enrollment of the Prepare trial in the second quarter of 2018.

Research and development expenses decreased 1% to $41.3 million in the third quarter of 2018, compared to $41.9 million for the same period in 2017.

General and administrative expenses increased 2% to $8.3 million in the third quarter of 2018, compared to $8.1 million for the same period in 2017.

Interest income (expense), net for the third quarter of 2018 was ($2.7) million, compared to ($3.0) million for the same period of 2017.

As of September 30, 2018, Novavax had $145.6 million in cash, cash equivalents, marketable securities and restricted cash, compared to $186.4 million as of December 31, 2017. Net cash used in operating activities for the third quarter of 2018 was $33.5 million, compared to $44.2 million for same period in 2017. The decrease in cash usage was primarily due to receiving a $15 million payment under the BMGF grant in the third quarter of 2018, whereas no payment was received in the same period of 2017.

Conference Call

Novavax will host its quarterly conference call today at 4:30 p.m. ET. The dial-in numbers for the conference call is (877) 212-6076 (Domestic) or (707) 287-9331 (International), passcode 3639227. A replay of the conference call will be available starting at 7:30 p.m. ET on November 7, 2018 until 7:30 pm ET on November 14, 2018. To access the replay by telephone, dial (855) 859-2056 (Domestic) or (404) 537-3406 (International) and use passcode 3639227.

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 on the Novavax website until February 7, 2019.

About RSV in Infants

Globally, RSV (respiratory syncytial virus) is the leading viral cause of severe lower respiratory tract disease in infants and young children.[1] It is the second leading cause of death in children under one year of age.[2] Estimated annual hospitalizations of 1.4 million and an estimated 27,300 in-hospital deaths were due to RSV acute lower respiratory infection in children under six months of age.[3] RSV results in a total global economic burden of $6.2 billion annually.

In the U.S., RSV is the leading cause of hospitalization of infants, with estimated annual hospitalizations of up to 76,000.[4,5,6] While RSV can impact all infants, babies under six months of age are among those at highest risk, as approximately 77% of all first-year RSV infections occur before six months.[7] In the U.S., the total economic burden is $2.7 billion annually.

About ResVax™

ResVax is an RSV fusion (F) protein recombinant nanoparticle vaccine with aluminum phosphate as an adjuvant. It is being developed to protect infants from RSV disease via maternal immunization, which may offer the best method of protection from RSV disease in infants through the first months of life. Currently, ResVax is being evaluated in Prepare™, a global Phase 3 clinical trial in 4,636 pregnant women, at least 3,000 of whom have received the vaccine, and their infants. Prepare is supported by an $89.1 million grant from the Bill & Melinda Gates Foundation (BMGF).

About Influenza

Influenza is a world-wide infectious disease that causes illness in humans with symptoms ranging from mild to life-threatening or even death. Serious illness occurs not only in susceptible populations such as infants, young children and older adults, but also in the general population largely because of infection by continuously evolving strains of influenza which can evade the existing protective antibodies in humans. An estimated one million deaths globally each year are attributed to influenza.[8] Current estimates for seasonal influenza vaccine growth in the top seven markets (U.S., Japan, France, Germany, Italy, Spain and UK), show a potential increase from approximately $3.2 billion in 2012-13 season to $5.3 billion by the 2021-22 season.[9]

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1 Nair, H., et al. (2010) Lancet. 375:1545-1555
2 Losano R., et al. (2012/Dec15) Lancet. 380: 2095
3 Ting S/Nair H. Lancet. (2017). Sep2;390:946
4 Leader S., et al. (2003) J Pediatr. 143: S127
5 Hall CB. N Engl J Med (2009). 360:588
6 CDC-Stockman LJ. Pediatr Infect Dis J (2012). 31:5
7 Hall CB. (2013) Pediatrics. 132:e341
8 Resolution of the World Health Assembly. (2003) WHA56.19.28
9 Influenza Vaccines Forecasts. Datamonitor (2013)

About NanoFlu™and Matrix M™

NanoFlu is a recombinant hemagglutinin (HA) protein nanoparticle influenza vaccine produced by Novavax in its SF9 insect cell baculovirus system. NanoFlu uses HA amino acid protein sequences that are the same as the recommended wild-type circulating virus HA sequences. NanoFlu contains Novavax' patented saponin-based Matrix-M adjuvant, which has demonstrated a potent and well-tolerated effect by stimulating the entry of antigen-presenting cells into the injection site and enhancing antigen presentation in local lymph nodes. In October 2018, Novavax completed enrollment in its Phase 2 clinical trial in older adults of quadrivalent formulations of NanoFlu in 1,375 healthy older adults across clinical sites in the U.S.

About Accelerated Approval

Accelerated approval may be granted for certain biological products that have been studied for their safety and effectiveness in treating serious or life-threatening illnesses and that provide meaningful therapeutic benefit over existing treatments. Such an approval will be based on adequate and well-controlled clinical trials establishing that the biological product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit. For seasonal influenza vaccines, the hemagglutination inhibition (HAI) antibody response may be an acceptable surrogate marker of activity that is reasonably likely to predict clinical benefit. To be considered for accelerated approval, a biologics license application for a new seasonal influenza vaccine should include results from one or more well-controlled studies designed to meet immunogenicity endpoints and a commitment to conduct confirmatory post-marketing studies of clinical effectiveness in preventing influenza.

About Novavax

Novavax, Inc. (Nasdaq:NVAX) is a late-stage biotechnology company that drives improved health globally through the discovery, development, and commercialization of innovative vaccines to prevent serious infectious diseases. ResVax™, its RSV vaccine for infants via maternal immunization, is the only vaccine in a Phase 3 clinical program and is designed to prevent the second leading cause of death in children under one year of age worldwide. Novavax is also advancing NanoFlu™, its quadrivalent influenza nanoparticle vaccine, to address key factors that can lead to the poor effectiveness of currently approved flu vaccines. Novavax is a leading innovator of recombinant vaccines; its proprietary recombinant technology platform combines the power and speed of genetic engineering to efficiently produce a new class of highly immunogenic nanoparticles addressing urgent global health needs.

For more information, visit www.novavax.com and connect with us on Twitter and LinkedIn.

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, 2017 and the Quarterly Report on Form 10-Q for the period ended September 30, 2018 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.

NOVAVAX, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(in thousands, except per share information)
(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30	
	2018	**2017**	**2018**	**2017**
Revenue	**$ 7,735**	$ 8,352	**$ 28,161**	$ 20,764
Expenses:				
Research and development	**41,326**	41,862	**130,382**	118,779
General and administrative	**8,309**	8,118	**25,185**	25,911
Total expenses	**49,635**	49,980	**155,567**	144,690
Loss from operations	**(41,900)**	(41,628)	**(127,406)**	(123,926)
Interest income (expense), net	**(2,651)**	(2,989)	**(8,119)**	(9,021)
Other income (expense)	**(19)**	10	**111**	20
Net loss	**$ (44,570)**	$ (44,607)	**$ (135,414)**	$ (132,927)
Basic and diluted net loss per share	**$ (0.12)**	$ (0.15)	**$ (0.37)**	$ (0.47)
Basic and diluted weighted average number of common shares outstanding	**382,315**	296,435	**365,236**	284,767

SELECTED CONSOLIDATED BALANCE SHEET DATA
(in thousands)

	September 30, 2018	December 31, 2017
	(unaudited)	
Cash and cash equivalents	**$ 56,496**	$ 106,307
Marketable securities	**70,612**	50,996
Total restricted cash	**18,540**	29,124
Total current assets	**160,541**	203,311
Working capital	**113,826**	129,636
Total assets	**250,478**	302,493
Notes payable	**318,830**	317,763
Total stockholders' deficit	**(126,679)**	(101,732)

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