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): August 8, 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.

Second Quarter Financial Results

On August 8, 2018, Novavax, Inc. (the "Company") issued a press release announcing the Company's financial results for the quarter ended June 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 August 8, 2018, regarding the Company's financial results for the quarter ended June 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: August 9, 2018

EXHIBIT INDEX

Exhibit No.	Description
99.1	Press release, dated August 8, 2018, regarding the Company's financial results for the quarter ended June 30, 2018.

Exhibit 99.1

Novavax Reports Second Quarter 2018 Financial Results

Novavax Delivers on Key Milestones Supporting its 2018 Objectives

Company to Host Conference Call Today at 4:30 pm ET

Gaithersburg, MD, August 8, 2018 – Novavax, Inc. (Nasdaq: NVAX) today announced its financial results and operational highlights for the second quarter and six months ended June 30, 2018.

"In keeping with our stated 2018 objectives, Novavax reached two important milestones in the second quarter for our lead ResVax™ and NanoFlu™ programs," said Stanley C. Erck, Novavax President and CEO. "With ResVax, we achieved a critical enrollment goal in the Prepare™ trial, enabling us to reach agreement with the FDA to initiate a final efficacy analysis in the first quarter of 2019. This analysis will be used to support the future BLA and MAA in the U.S. and Europe, respectively."

"On the NanoFlu front," Mr. Erck continued, "the data published in *The New England Journal of Medicine* demonstrated that NanoFlu induced significantly improved immune respones compared to the current leading high-dose influenza vaccine. We are on track to initiate a Phase 2 clinical trial of quadrivalent formulations of NanoFlu in the third quarter of this year. Pending successful Phase 2 data, based on discussions with the FDA, we anticipate initiating a Phase 3 immunogenicity clinical trial that may provide the basis of licensure via the FDA's accelerated approval pathway."

Operational Highlights:

ResVax™ Program

- In May 2018, Novavax' Prepare trial reached enrollment of 4,636 pregnant women, at least 3,000 of whom received ResVax.

- Novavax recently reached agreement with the FDA that the efficacy analysis to be conducted in the first quarter of 2019 will be the final analysis used to support the future biologics license application (BLA). This agreement was based on meeting the FDA's minimum standards for evaluation of both the safety and efficacy of ResVax. We anticipate using the same data for filing a marketing authorization application (MAA) submission in Europe. The current and projected numbers of blinded primary endpoint cases provide Novavax with confidence that the trial is powered to make a statistically sound efficacy conclusion. Novavax expects to report on these data in the first quarter of 2019 and, assuming successful results, expects to submit the BLA and the MAA by the first quarter of 2020.

NanoFlu™ Program

- In June 2018, *The New England Journal of Medicine* published a peer-reviewed letter to the editor detailing the positive results from Novavax' Phase 1/2 clinical trial in older adults of NanoFlu compared to the leading licensed egg-based, high-dose influenza vaccine. Novavax had previously presented top-line results from this clinical trial at the World Vaccine Congress in April 2018.

- In June 2018, the FDA acknowledged and agreed that the accelerated approval pathway for seasonal influenza vaccines could be available for NanoFlu.

Corporate

- In April 2018, Novavax conducted a public offering of approximately 34.8 million shares of its common stock, resulting in net proceeds of $54 million.

Anticipated Events:

- Final efficacy results of the Prepare trial are expected in the first quarter of 2019.

- The Phase 2 clinical trial of quadrivalent formulations of NanoFlu is expected to begin in the third quarter of 2018.

- Top-line data from the Phase 2 clinical trial of NanoFlu and End of Phase 2 meeting with the FDA are expected in the first quarter of 2019.

Financial Results for the Three and Six Months Ended June 30, 2018

Novavax reported a net loss of $44.5 million, or $0.12 per share, for the second quarter of 2018, compared to a net loss of $44.5 million, or $0.16 per share, for the second quarter of 2017. For the six months ended June 30, 2018, the net loss was $90.8 million, or $0.25 per share, compared to a net loss of $88.3 million, or $0.32 per share, for the same period in 2017.

Novavax revenue in the second quarter of 2018 was $10.8 million, compared to $6.7 million in the same period in 2017. This 60% increase was driven by higher revenue recorded under the Bill & Melinda Gates Foundation (BMGF) grant of $89 million as a result of increased enrollment in the Prepare trial and increased activities of Novavax AB, a wholly owned subsidiary of Novavax.

Research and development expenses increased 13% to $44.5 million in the second quarter of 2018, compared to $39.3 million for the same period in 2017. The increase was primarily due to increased development activities of ResVax.

General and administrative expenses decreased 8% to $8.2 million in the second quarter of 2018, compared to $8.9 million for the same period in 2017. The decrease was primarily due to lower employee-related costs.

Interest income (expense), net for the second quarter of 2018 was ($2.6) million, compared to ($3.0) million for the same period of 2017.

As of June 30, 2018, Novavax had $178.2 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 second quarter of 2018 was $40.0 million, compared to $12.4 million for same period in 2017. The increase in cash usage was primarily due to the receipt of a $25 million payment under the BMGF grant in the six months ended June 30, 2017, whereas no payment was received in the same period of 2018 (however, we expect to receive a $15 million payment in the third quarter of 2018).

Conference Call

Novavax 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 5886748. A replay of the conference call will be available starting at 7:30 p.m. ET on August 8, 2018 until 7:30 pm ET on August 15, 2018. To access the replay by telephone, dial (855) 859-2056 (Domestic) or (404) 537-3406 (International) and use passcode 5886748.

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 November 8, 2018.

About RSV in infants

RSV (respiratory syncytial virus) is the leading viral cause of severe lower respiratory tract disease in infants and young children worldwide. Estimated annual infections of 64 million and an estimated 160,000 deaths make it the second leading cause of death in children under one year of age. 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. 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. 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. It is being developed to protect infants from RSV disease via maternal immunization and is the only RSV vaccine in a Phase 3 clinical trial for this indication. Protecting infants via maternal immunization has been shown to be effective against influenza, another respiratory virus, in prospective clinical studies. In addition, maternal immunization with tetanus and pertussis vaccines has been shown to be effective in preventing these diseases in infants. Maternal immunization 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.[1] 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 2015 to $5.3 billion by 2025.[2]

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. Novavax expects to begin a Phase 2 for its quadrivalent NanoFlu clinical trial in the third quarter of 2018.

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 BLA 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.

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[1] Resolution of the World Health Assembly (2003) WHA56.19.28

[2] Influenza Vaccines Forecasts. Datamonitor (2013)

About Novavax

Novavax, Inc. (Nasdaq:NVAX) is a late-stage biotechnology company that drives improved health globally through the discovery and development of innovative vaccines to prevent serious respiratory diseases. ResVax, its RSV vaccine for infants via maternal immunization, is the only vaccine in a Phase 3 clinical program and is poised to help prevent the second leading cause of death in children under one year of age worldwide. Novavax is also advancing the clinical study of our influenza nanoparticle vaccine, which addresses key factors that lead to poor efficacy by 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 particles 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 June 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 June 30,		Six Months Ended June 30,	
	2018	**2017**	**2018**	**2017**
Revenue	**$ 10,773**	$ 6,732	**$ 20,426**	$ 12,412
Expenses:				
Research and development	**44,542**	39,263	**89,056**	76,916
General and administrative	**8,224**	8,940	**16,876**	17,793
Total expenses	**52,766**	48,203	**105,932**	94,709
Loss from operations	**(41,993)**	(41,471)	**(85,506)**	(82,297)
Interest income (expense), net	**(2,596)**	(2,993)	**(5,468)**	(6,032)
Other income (expense)	**97**	(1)	**130**	10
Net loss	**$ (44,492)**	$ (44,465)	**$ (90,844)**	$ (88,319)
Basic and diluted net loss per share	**$ (0.12)**	$ (0.16)	**$ (0.25)**	$ (0.32)
Basic and diluted weighted average number of common shares outstanding	**375,923**	283,444	**356,555**	278,836

SELECTED CONSOLIDATED BALANCE SHEET DATA
(in thousands)

	June 30, 2018	December 31, 2017
	(unaudited)	
Cash and cash equivalents	$ 88,475	$ 106,307
Marketable securities	78,636	50,996
Total restricted cash	11,084	29,124
Total current assets	194,335	203,311
Working capital	151,316	129,636
Total assets	285,807	302,493
Notes payable	318,475	317,763
Total stockholders' deficit	(87,707)	(101,732)

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