

Announced Positive Phase 1 data of Phase 1/2 clinical trial of NVX-CoV2373

Secured \$2 billion in funding for global coronavirus vaccine program through CEPI, DoD, and OWS

Expanded large scale global manufacturing capacity through acquisition and partnering

Company to host conference call today at 4:30 p.m. ET

GAITHERSBURG, Md., Aug. 10, 2020 (GLOBE NEWSWIRE) -- Novavax, Inc. (NASDAQ: NVAX), a late-stage biotechnology company developing next-generation vaccines for serious infectious diseases, today announced its financial results and operational highlights for the second quarter ended June 30, 2020.

"Novavax' unprecedented development activities for NVX-CoV2373 and progress continued through the second quarter," said Stanley C. Erck, President and Chief Executive Officer of Novavax. "Since identifying a candidate vaccine to address the COVID-19 pandemic in March, we've secured significant funding, implemented global manufacturing capacity and completed and reported our successful Phase 1 trial. We've also expanded our senior leadership team to advance our efforts to bring NVX-CoV2373 to market as rapidly as possible and grow our infrastructure to support commercial stage operations."

Second Quarter 2020 and Recent Highlights

COVID-19 Program

- Announced Phase 1 data from its Phase 1/2 randomized, observer-blinded, placebo-controlled clinical trial of NVX-CoV2373 in healthy adults 18-59 years of age
 - Neutralization levels numerically superior to convalescent serum
 - Significantly higher immune response with 2-dose, Matrix-MTM adjuvanted vaccine
 - Strong T cell responses
 - Reassuringly safe and tolerable vaccine profile
 - Presentation included on Novavax website [here](#)
 - Data submitted for peer-review publication and posted to online preprint server at [medRxiv.org](#)
- Demonstrated protection and high immunogenicity in animal models
 - Presented data from non-human primate models that demonstrate protection in challenge studies, enhancement of multifunctional T cells, and production of anti-S IgG and neutralizing antibodies
 - Data submitted for peer-review publication and posted to online preprint server at [medRxiv.org](#)
- Secured \$2 billion in funding for development and commercialization of NVX-CoV2373
 - Coalition for Epidemic Preparedness Innovations (CEPI) funding up to \$388 million
 - U.S. Department of Defense (DoD) funding up to \$60 million
 - U.S. Government funding through Operation Warp Speed (OWS) up to \$1.6 billion
- Completed collaborations for global development and commercialization of NVX-CoV2373
 - Partnered with Takeda Pharmaceutical Company Limited for development, manufacture and commercialization in Japan
 - Novavax to receive payments based on achievement of certain development and commercial milestones
 - Novavax shares in proceeds from vaccine sales
 - Partnered with Serum Institute of India for development and commercialization in India and low- and middle-income countries (LMIC)
 - Novavax and Serum Institute will split revenue from sale of product, net of agreed costs
- Secured global manufacturing capacity for NVX-CoV2373
 - Acquired Praha Vaccines in a cash transaction of approximately \$167 million
 - Includes biologics manufacturing facility and related assets in Czech Republic
 - Facility expected to provide annual capacity approaching 1 billion antigen doses starting in 2021
 - Entered into agreements with FUJIFILM Diosynth Biotechnologies' (FDB) to manufacture bulk drug substance at facilities in North Carolina and Texas
 - Large scale manufacturing initiated at FDB North Carolina site
 - Entered into manufacturing arrangements with AGC Biologics and PolyPeptide Group for large-scale production of Novavax' Matrix-M adjuvant in both U.S. and Europe

NanoFlu™ Program

- Successful pivotal NanoFlu Phase 3 clinical trial announced in March 2020
 - Added important immunogenicity data regarding development of robust T cell mediated responses
 - All results expected to support future BLA submission using U.S. FDA accelerated approval pathway
 - Company exploring pathways to manufacture for required lot consistency clinical trial
- Phase 2 and Phase 3 data submitted for peer-review publications and posted to online preprint server at [medRxiv.org](#)

Corporate

- Strengthened leadership with numerous executive management promotions and hiring
- Appointed David M. Mott to Novavax' Board of Directors
 - Brings more than three decades of global management, board and investment experience across multiple private and public biopharmaceutical companies

Financial Results for the Three and Six Months Ended June 30, 2020

Novavax reported a net loss of \$17.5 million, or \$0.30 per share, for the second quarter of 2020, compared to a net loss of \$39.6 million, or \$1.69 per share, for the second quarter of 2019. For the six months ended June 30, 2020, the net loss was \$43.4 million, or \$0.84 per share, compared to a net loss of \$82.8 million, or \$3.77 per share, for the same period in 2019.

Novavax revenue in the second quarter of 2020 was \$35.5 million, compared to \$3.4 million in the same period in 2019. This significant increase was due to increased development activities relating to NVX-CoV2373 under the CEPI agreement.

Research and development expenses increased 15% to \$34.8 million in the second quarter of 2020, compared to \$30.4 million in the same period in 2019. The increase was primarily due to increased development activities relating to NVX-CoV2373 under the CEPI agreement, partially offset by decreased employee-related and other costs and development activities of ResVax as compared to the same period in 2019.

General and administrative expenses increased 84% to \$17.7 million in the second quarter of 2020, compared to \$9.6 million for the same period in 2019. This increase was primarily due to increased professional fees relating to the Novavax CZ acquisition and supporting our NVX-CoV2373 program and increased employee-related expenses.

As of June 30, 2020, Novavax had \$609.5 million in cash, cash equivalents, marketable securities and restricted cash, compared to \$82.2 million as of December 31, 2019. Net cash provided by operating activities for the first six months of 2020 was \$92.5 million, compared to net cash used in operating activities was \$80.6 million for same period in 2019.

Novavax has continued to strengthen its balance sheet. Recent activities include:

- In June, Novavax entered into an agreement to sell Series A Convertible preferred stock, convertible into 4,388,850 shares of common stock, to an investment fund affiliated with RA Capital Management (RA Capital) in a private placement. Novavax received gross proceeds of \$200 million.
- Through utilization of at-the-market (ATM) offerings during the second quarter of 2020, Novavax raised net proceeds of \$206.3 million and a total of \$392.3 million since the beginning of the year.

Conference Call

Novavax will host its quarterly conference call today at 4:30 p.m. ET. The dial-in numbers for the conference call are (866) 923-9367 (Domestic) or (707) 287-9331 (International), passcode 3048947. A replay of the conference call will be available starting at 7:30 p.m. ET on August 10, 2020 until 7:30 p.m. ET on August 17, 2020. To access the replay by telephone, dial (855) 859-2056 (Domestic) or (404) 537-3406 (International) and use passcode 3048947.

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 "For Investors"/"Events" tab on the Novavax website. A replay of the webcast will be available on the Novavax website until November 10, 2020.

About NVX-CoV2373

NVX-CoV2373 is a vaccine candidate engineered from the genetic sequence of SARS-CoV-2, the virus that causes COVID-19 disease. NVX-CoV2373 was created using Novavax' recombinant nanoparticle technology to generate antigen derived from the coronavirus spike (S) protein and contains Novavax' patented saponin-based Matrix-M™ adjuvant to enhance the immune response and stimulate high levels of neutralizing antibodies. In preclinical trials, NVX-CoV2373 demonstrated indication of antibodies that block binding of spike protein to receptors targeted by the virus, a critical aspect for effective vaccine protection. In its Phase 1 portion of the Phase 1/2 clinical trial, NVX-CoV2373 was generally well-tolerated and elicited robust antibody responses numerically superior to that seen in human convalescent sera. Novavax was awarded \$1.6 billion by the federal government as part of Operation Warp Speed (OWS), a U.S. government program to deliver millions of doses of a safe, effective vaccine for COVID-19 to the U.S. population. The OWS funding is being used by Novavax to complete late-stage clinical development, including a pivotal Phase 3 clinical trial; establish large-scale manufacturing; and deliver 100 million doses of NVX-CoV2373 beginning as early as late 2020. The Coalition for Epidemic Preparedness Innovations (CEPI) is also investing up to \$388 million, and Department of Defense (DoD) is investing up to \$60 million of funding to advance clinical development of NVX-CoV2373.

About NanoFlu™

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.

About Matrix-M™

Novavax' patented saponin-based Matrix-M adjuvant 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, boosting immune response.

About Novavax

Novavax, Inc. (Nasdaq:NVAX) is a late-stage biotechnology company that promotes improved health globally through the discovery, development, and commercialization of innovative vaccines to prevent serious infectious diseases. Novavax is undergoing clinical trials for NVX-CoV2373, its vaccine candidate against SARS-CoV-2, the virus that causes COVID-19. NVX-CoV2373 was generally well-tolerated and elicited robust antibody responses numerically superior to that seen in human convalescent sera in its Phase 1 portion of the Phase 1/2 clinical trial. NanoFlu™, its quadrivalent influenza nanoparticle vaccine, met all primary objectives in its pivotal Phase 3 clinical trial in older adults. Both vaccine candidates incorporate Novavax' proprietary saponin-based Matrix-M™ adjuvant in order to enhance the immune response and stimulate high levels of neutralizing antibodies. Novavax is a leading innovator of recombinant vaccines; its proprietary recombinant technology platform combines the power and speed of genetic engineering to efficiently produce highly immunogenic nanoparticles in order to address 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, 2019, and Quarterly Report on Form 8-K for the period ended June 30, 2020, as filed with the Securities and Exchange Commission (SEC). We caution investors not to place considerable reliance on 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		Six Months Ended	
June 30,		June 30,	
2020	2019	2020	2019

Revenue	\$ 35,538	\$ 3,357	\$ 38,915	\$ 7,339
Expenses:				
Research and development	34,846	30,417	51,741	65,890
General and administrative	17,719	9,606	27,098	18,338
Total expenses	52,565	40,023	78,839	84,228
Loss from operations	(17,027)	(36,666)	(39,924)	(76,889)
Interest income (expense), net	(3,106)	(2,929)	(6,074)	(5,912)
Other income (expense)	2,612	(8)	2,613	(20)
Net loss	\$ (17,521)	\$ (39,603)	\$ (43,385)	\$ (82,821)
Basic and diluted net loss per share	\$ (0.30)	\$ (1.69)	\$ (0.84)	\$ (3.77)
Basic and diluted weighted average number of common shares outstanding	58,618	23,473	51,401	21,966

SELECTED CONSOLIDATED BALANCE SHEET DATA
(in thousands)

	June 30, 2020 (unaudited)	December 31, 2019
Cash and cash equivalents	\$ 424,395	\$ 78,823
Marketable securities	77,902	--
Total restricted cash	107,179	3,357
Total current assets	636,381	97,247
Working capital	423,050	71,452
Total assets	932,227	172,957
Notes payable	321,323	320,611
Total stockholders' equity (deficit)	184,526	(186,017)

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<https://ir.novavax.com/2020-08-10-Novavax-Reports-Second-Quarter-2020-Financial-and-Operational-Results>