

NanoFlu top-line data from Phase 3 clinical trial expected by the end of this month

Novavax awarded CEPI funding to support COVID-19 vaccine program

COVID-19 Phase 1 clinical trial expected to initiate in late spring of 2020

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

GAITHERSBURG, Md., March 11, 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 fourth quarter and twelve months ended December 31, 2019.

“We remain on track to announce top-line results from our pivotal Phase 3 clinical trial for NanoFlu by the end of this month. Positive clinical data from this trial would support a subsequent U.S. BLA using the FDA’s accelerated approval pathway,” said Stanley C. Erck, President and Chief Executive Officer of Novavax. “We continue to make progress towards partnering our ResVax program and recently announced progress in our efforts to develop a vaccine against COVID-19, with the goal of moving one or more optimized COVID-19 candidates into the clinic by the end of this spring.”

Fourth Quarter 2019 and Subsequent Operational Highlights

NanoFlu™ Program

- Results of the pivotal Phase 3 clinical trial for NanoFlu, Novavax’ recombinant quadrivalent seasonal influenza vaccine candidate, are expected later this month. The trial includes 2,652 healthy older adults across 19 U.S. clinical sites. The primary objective of the randomized, observer-blinded, active-controlled trial is to demonstrate non-inferior immunogenicity as measured by hemagglutination inhibition (HAI) titers of vaccine homologous influenza strains and safety compared against a licensed vaccine, Fluzone® Quadrivalent.
- Positive top-line results from this Phase 3 clinical trial would support a subsequent U.S. biologics license application (BLA) and licensure of NanoFlu using the U.S. Food and Drug Administration’s (FDA) accelerated approval pathway. In addition, in January 2020, the FDA granted Fast Track designation for NanoFlu.

COVID-19 Program

- Novavax recently announced that the Coalition for Epidemic Preparedness Innovations (CEPI) awarded an initial funding of \$4 million to support its effort to develop a COVID-19 vaccine. CEPI and Novavax are having ongoing discussions on additional funding from CEPI to address Novavax’ costs through Phase 1.
- Novavax began efforts to develop a novel vaccine to protect against COVID-19 in January. Novavax has produced and is currently assessing multiple nanoparticle vaccine candidates in animal models prior to advancing to clinical trials. Initiation of Phase I clinical testing is expected in May or June 2020. Novavax expects to utilize its proprietary Matrix-M™ adjuvant with its COVID-19 vaccine candidate to enhance immune responses.

ResVax™ Program

- Novavax is continuing its discussions with both global regulatory authorities and potential partners to explore the opportunity to bring ResVax to market.

Matrix-M Partnership

- Earlier today, Novavax announced a commercial license agreement related to its Matrix-M vaccine adjuvant. Matrix-M is a key component of Serum Institute of India’s malaria vaccine candidate, which it licensed from Jenner Institute at Oxford University. The vaccine candidate is currently in a Phase 2b clinical trial being conducted in Burkina Faso with top-line data expected in the second quarter of 2020.

Corporate

- Through utilization of At-the-market (ATM) offerings during the fourth quarter of 2019, Novavax raised net proceeds of \$30 million. For the twelve months of 2019, Novavax raised net proceeds of \$97 million. Subsequent to year-end, through March 6, 2020, Novavax raised additional net proceeds of \$156 million.

Financial Results for the Three and Twelve Months Ended December 31, 2019

Share and per share data have been restated to reflect the reverse stock split that was completed in May 2019.

Novavax reported a net loss of \$31.8 million, or \$1.13 per share, for the fourth quarter of 2019, compared to a net loss of \$49.3 million, or \$2.57 per share, for the fourth quarter of 2018. For the twelve months ended December 31, 2019, the net loss was \$132.7 million, or \$5.51 per share, compared to a net loss of \$184.7 million, or \$9.99 per share, for the same period in 2018.

Novavax revenue in the fourth quarter of 2019 was \$8.8 million, compared to \$6.1 million in the same period in 2018. This 44% increase was driven by \$7.5 million in revenue for the recovery of additional costs under the closeout of the HHS BARDA contract, partially offset by lower revenue from the completion of enrollment of participants in the Prepare™ trial in second quarter of 2018.

Research and development expenses decreased 32% to \$29.3 million in the fourth quarter of 2019, compared to \$43.4 million in the same period in 2018. This decrease was primarily due to decreased development activities of ResVax, lower employee-related costs and other cost savings due to the Catalent transaction, partially offset by NanoFlu’s Phase 3 clinical trial and development activities.

General and administrative expenses decreased to \$8.2 million in the fourth quarter of 2019, compared to \$9.2 million for the same period in 2018.

Interest income (expense), net for the fourth quarter of 2019 was (\$3.1) million, compared to (\$2.8) million for the same period of 2018.

As of December 31, 2019, Novavax had \$82.2 million in cash, cash equivalents, marketable securities and restricted cash, compared to \$103.9 million as of December 31, 2018. Net cash used in operating activities for the twelve months of 2019 was \$136.6 million, compared to \$184.8 million for same period in 2018.

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 (877) 212-6076 (Domestic) or (707) 287-9331 (International), passcode 5695528. A replay of the conference call will be available starting at 7:30 p.m. ET on March 11, 2020 until 7:30 p.m. ET on March 18, 2020. To access the replay by telephone, dial (855) 859-2056 (Domestic) or (404) 537-3406 (International) and use passcode 5695528.

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 June 11, 2020.

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. Top-line data from Novavax' ongoing Phase 3 clinical trial of NanoFlu is expected late in the first quarter of 2020.

About COVID-19

A new strain of coronavirus first appeared in late 2019 in China before beginning its rapid spread across the globe. The disease, named COVID-19, continues to cause severe pneumonia-like symptoms in many of those infected. Coronaviruses, so named for their "crown-like" appearance, are a large family of viruses that spread from animals to humans and include diseases such as Middle East Respiratory Syndrome (MERS) and Severe Acute Respiratory Syndrome (SARS) in addition to COVID-19. While much remains unknown about the new coronavirus, it is known that the virus can spread via human-to-human transmission before any symptoms appear.

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. NanoFlu™, its quadrivalent influenza nanoparticle vaccine, is currently in a pivotal Phase 3 clinical trial to address key factors that can lead to the poor effectiveness of currently approved flu vaccines. ResVax™, its RSV vaccine for infants via maternal immunization, is the only vaccine in a Phase 3 clinical program and is designed to prevent severe lower respiratory tract infection, which is the second leading cause of death in children under one year of age worldwide. 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, 2019, 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)

	Three Months Ended		Twelve Months Ended	
	December 31, 2019	2018	December 31 2019	2018
	(unaudited)			
Revenue	\$ 8,816	\$ 6,127	\$ 18,662	\$ 34,415
Expenses:				
Research and development	29,341	43,415	113,842	173,415
Gain on Catalent transaction	--	--	(9,016)	--
General and administrative	8,180	9,224	34,417	34,415
Total expenses	37,521	52,639	139,243	208,230
Loss from operations	(28,705)	(46,512)	(120,581)	(173,815)
Interest income (expense), net	(3,127)	(2,819)	(12,100)	(10,938)
Other income (expense)	2	(3)	(13)	108
Net loss	\$ (31,830)	\$ (49,334)	\$ (132,694)	\$ (183,645)
Basic and diluted net loss per share	\$ (1.13)	\$ (2.57)	\$ (5.51)	\$ (9.55)
Basic and diluted weighted average number of common shares outstanding	28,063	19,159	24,100	18,450

SELECTED CONSOLIDATED BALANCE SHEET DATA (in thousands)

	December 31, 2019	December 2018
Cash and cash equivalents	\$ 78,823	\$ 70,154
Marketable securities	--	21,980
Total restricted cash	3,357	11,805
Total current assets	97,247	119,276

Working capital	71,452	73,737
Total assets	172,957	207,978
Notes payable	320,611	319,187
Total stockholders' deficit	(186,017)	(167,935)

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<https://ir.novavax.com/2020-03-11-Novavax-Reports-Fourth-Quarter-and-Full-Year-2019-Financial-Results>