Novavax Investor Relations

CEPI increases investment up to $388 million for NVX-CoV2373 vaccine development & manufacturing

NVX-CoV2373 Phase I trial initiating in May with preliminary results in July

NanoFlu recently achieved all primary endpoints in pivotal Phase 3 clinical trial

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

GAITHERSBURG, Md., May 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 first quarter ended March 31, 2020.

“Our accomplishments to-date in 2020, including significant progress in our influenza and COVID-19 vaccine programs, are the most impressive in the company’s history,” said Stanley C. Erck, President and Chief Executive Officer of Novavax. “We shared successful pivotal Phase 3 results for NanoFlu that demonstrated both efficacy and safety in a pivotal trial, a significant milestone towards bringing this innovative product to an influenza market in need of new options. We also reacted quickly to the coronavirus pandemic by developing and quickly advancing NVX-CoV2373, our COVID-19 vaccine candidate, which shows strong potential to have a positive impact on this global health crisis. Looking ahead, with a strengthened balance sheet and CEPI’s substantial funding, we will focus on scaling up manufacturing and delivering clinical data for NVX-CoV2373, while simultaneously completing the necessary actions needed to prepare our BLA filing for NanoFlu.”

First Quarter 2020 and Subsequent Operational Highlights

NanoFlu™ Program

- Novavax announced in March that NanoFlu, its recombinant quadrivalent seasonal influenza vaccine candidate with Matrix-M™ adjuvant, achieved all primary objectives in its pivotal Phase 3 clinical trial in older adults. As required by the FDA’s accelerated approval pathway, the trial’s primary objectives were to demonstrate non-inferior immunogenicity of NanoFlu compared to a licensed vaccine (Fluzone® Quadrivalent), using the day 28 ratio of geometric mean titers (GMT) and the difference in seroconversion rates (SCR), as well as the overall safety of NanoFlu. These endpoints were met for all four strains included in NanoFlu. Immunogenicity was measured by hemagglutination inhibition (HAI) assays using egg-derived reagents. NanoFlu was well-tolerated, with a safety profile comparable to Fluzone Quadrivalent with a modest increase in local adverse events (AEs).

- NanoFlu also achieved statistical significance for key secondary endpoints. These key endpoints assessed GMT and SCR, but with an HAI assay based on wild-type reagents. NanoFlu demonstrated significantly higher GMT and SCR than Fluzone Quadrivalent across all four strains included in the vaccine and, importantly, for four tested drifted H3N2 strains not included in the vaccine but circulating this year.

- Results from this Phase 3 clinical trial will support a U.S. biologics license application (BLA) and licensure of NanoFlu using the U.S. Food and Drug Administration’s (FDA) accelerated approval pathway.

COVID-19 Program

- As announced today, the Coalition for Epidemic Preparedness Innovations (CEPI) will invest up to an additional $384 million to advance clinical development of NVX-CoV2373. Novavax will use the CEPI funds to advance NVX-CoV2373 into clinical testing. With its earlier $4 million commitment in March, the extended collaboration brings CEPI’s total investment in NVX-CoV2373 to $388 million.

- In January, Novavax identified its coronavirus vaccine candidate, NVX-CoV2373, a stable, prefusion protein made using its proprietary nanoparticle technology. Novavax’ proprietary Matrix-M adjuvant is included in NVX-CoV2373, to enhance immune responses and stimulate high levels of neutralizing antibodies.

- NVX-CoV2373 was highly immunogenic in animal models measuring spike protein-specific antibodies, with ACE-2 human receptor binding domain blocking activity and SARS-CoV-2 wild-type virus neutralizing antibodies observed. Blocking of the binding of the spike protein to the receptor as well as wild-type virus neutralizing antibodies was also observed, with high levels of spike protein-specific antibodies after a single immunization. The already high microneutralization titers seen after one dose increased eight fold with a second dose. High titer microneutralizing antibodies are generally accepted evidence that a vaccine is likely to be protective in humans.

- The NVX-CoV2373 clinical development plan combines a Phase 1/Phase 2 approach to allow rapid advancement during the current coronavirus pandemic. The Phase 1 portion of this trial will be placebo-controlled and observer blinded in ~130 healthy adults and will include assessment of dosage and vaccination. Recruiting for the trial began this month with preliminary immunogenicity and safety results expected in July.

- Novavax entered into an agreement with Emergent BioSolutions to provide contract development and manufacturing services, supplying Novavax with GMP vaccine product for use in its clinical trials. This agreement offers the potential to leverage Emergent’s rapid deployment capabilities and expertise that provide Novavax scalability and capacity to produce vaccine product.

ResVax™ Program

- Novavax is currently discussing the opportunity to bring ResVax to market globally with multiple potential commercial partners. In addition, Novavax continues to define regulatory licensure requirements and pathways in the U.S., the European Union and other geographies.

Matrix-M Partnership

- In March, 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 first quarter of 2020, Novavax raised net proceeds of $186 million. Subsequent to quarter-end, through May 8, 2020, Novavax raised additional net proceeds of $74 million, for a total of $260 million since the beginning of the year.

Financial Results for the Three Months Ended March 31, 2020

Novavax reported a net loss of $25.9 million, or $0.58 per share, for the first quarter of 2020, compared to a net loss of $43.2 million, or $2.11 per share, for the first quarter of 2019.

Novavax revenue in the first quarter of 2020 was $3.4 million, compared to $4.0 million in the same period in 2019. This 15% decrease was primarily due to the conclusion of the

Prepare™ trial in 2019, partially offset by revenue from CEPI's funding.

Research and development expenses decreased 52% to $16.9 million in the first quarter of 2020, compared to $35.5 million in the same period in 2019. This decrease was primarily due to decreased development activities of ResVax, lower employee-related costs and other cost savings due to the Catalent transaction in 2019.

General and administrative expenses increased to $9.4 million in the first quarter of 2020, compared to $8.7 million for the same period in 2019.

Interest income (expense), net for the first quarter of 2020 and 2019 was ($3.0) million.

As of March 31, 2020, Novavax had $244.7 million in cash, cash equivalents, marketable securities and restricted cash, compared to $82.2 million as of December 31, 2019. Net cash used in operating activities for the first quarter of 2020 was $23.1 million, compared to $50.6 million for same period in 2019.

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

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 1274143. A replay of the conference call will be available starting at 7:30 p.m. ET on May 11, 2020 until 7:30 p.m. ET on May 18, 2020. To access the replay by telephone, dial (855) 859-2056 (Domestic) or (404) 537-3406 (International) and use passcode 1274143.

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 August 11, 2020.

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. Top-line data from Novavax' ongoing Phase 3 clinical trial of NanoFlu is expected late in the first quarter of 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 efficient binding with receptors targeted by the virus, a critical aspect for effective vaccine protection. A Phase 1 clinical trial of NVX-CoV2373 will initiate in May 2020 with preliminary immunogenicity and safety results expected in July 2020. The Coalition for Epidemic Preparedness Innovations (CEPI) is investing up to $388 million of funding to advance clinical development of NVX-CoV2373.

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 and address urgent, global health needs. Novavax recently initiated development of NVX-CoV2373, its vaccine candidate against SARS-CoV-2, the virus that causes COVID-19, with Phase 1 clinical trial results expected in July of 2020. 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, 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 March 31	
	2020	2019
Revenue	$ 3,377	$ 3,982
Expenses:		
Research and development	16,895	35,473
General and administrative	9,379	8,732

Total expenses	26,274	44,205
Loss from operations	(22,897)	(40,22
Interest income (expense), net	(2,967)	(2,983
Other income (expense)	--	(12
Net loss	$ (25,864)	$ (43,21
Basic and diluted net loss per share	$ (0.58)	$ (2.11
Basic and diluted weighted average number of common shares outstanding	44,421	20,442

SELECTED CONSOLIDATED BALANCE SHEET DATA
(in thousands)

	March 31, 2020 (unaudited)	Decembe 2019
Cash and cash equivalents	$ 179,881	$ 78,823
Marketable securities	57,474	--
Total restricted cash	7,311	3,357
Total current assets	255,232	97,247
Working capital	236,250	71,452
Total assets	328,068	172,95
Notes payable	320,967	320,61
Total stockholders' deficit	(23,971)	(186,0

Contacts:

Investors
Novavax, Inc.
Erika Trahan
ir@novavax.com
240-268-2022

Westwicke
John Woolford
john.woolford@westwicke.com
443-213-0506

Media
Brandzone/COGS Communication
Edna Kaplan
kaplan@kogspr.com
617-974-8659
