



Vaxcyte Reports Second Quarter 2021 Financial Results and Provides Business Update

August 11, 2021

FOSTER CITY, Calif., Aug. 11, 2021 (GLOBE NEWSWIRE) -- Vaxcyte, Inc. (Nasdaq: PCVX), a next-generation vaccine company seeking to improve global health by developing superior and novel vaccines designed to prevent or treat some of the most common and deadly infectious diseases worldwide, today announced financial results for the second quarter ended June 30, 2021 and provided a business update.

"The public health community continues to affirm the need for vaccines that can offer broader protection to prevent pneumococcal disease and, importantly, reach an expanded population including adults aged 50 and older as well as those at higher risk due to existing health conditions," said Grant Pickering, Chief Executive Officer and Co-founder of Vaxcyte. "We are focused on making a significant contribution to fulfill this need with VAX-24, our lead, 24-valent pneumococcal conjugate vaccine (PCV) candidate, and VAX-XP, our PCV candidate with an expanded breadth of coverage."

Pickering continued, "We have made meaningful strides with VAX-24 in collaboration with Lonza, including the completion of the manufacturing and testing of the 24 conjugated drug substances (DS). We are well on our way to the final release of the DS and have now entered the final drug product (DP) formulation, fill and finish phase as we advance toward the anticipated submission of the Investigational New Drug (IND) application required to generate clinical proof-of-concept data."

Recent Highlights

- **Advanced VAX-24 IND-Enabling Activities:** Vaxcyte continues to progress several initiatives for VAX-24. The Company has manufactured and tested the 24 good manufacturing practice (GMP) conjugated DS and is now completing the final steps prior to release. Based upon the data collected to date, the Company has initiated the final process steps of GMP DP formulation, fill and finish leading to the anticipated IND filing.
- **Received Additional Award from CARB-X to Advance VAX-A1:** In August 2021, the Company received an additional award from CARB-X (Combating Antibiotic Resistant Bacteria Biopharmaceutical Accelerator) that commits \$3.2 million in funding to advance development of VAX-A1, a novel conjugate vaccine designed to prevent infections caused by Group A *Streptococcus pyogenes* (Strep) bacteria. The award will fund IND-enabling work for VAX-A1. It also builds on the CARB-X award of \$2.7 million for the initial funding period, which was completed in December 2020. Vaxcyte is eligible to receive up to a total of \$29.7 million in CARB-X funding, inclusive of grants to date, upon the achievement of future VAX-A1 development milestones.
- **Published New Research Supporting the Power of Vaxcyte's Technology Platform:** The paper, "A *Porphyromonas gingivalis* Capsule-Conjugate Vaccine Protects From Experimental Oral Bone Loss," published in the July 2021 edition of the journal *Frontiers in Oral Health*, showed that conjugation of a polysaccharide from *Porphyromonas gingivalis* protects against oral bone loss in a mouse model of periodontal disease. This is another demonstration of the power of Vaxcyte's technology to enable site-specific conjugation of polysaccharides to a protein carrier in order to potentially generate robust and protective immune responses. The paper can be accessed here: <https://vaxcyte.com/posters-publications/>.
- **Strengthened Advisory Board with Appointment of Dr. Emmanuel Walter from Duke University School of Medicine:** In May 2021, Vaxcyte added Dr. Emmanuel Walter, MD, MPH, Professor of Pediatrics, of Duke University School of Medicine to its Scientific Advisory Board. In his roles as the Duke Human Vaccine Institute (DHVI) Chief Medical Officer and Director of the Duke Vaccine and Trials Unit, Dr. Walter provides strategic and operational leadership for clinical research conducted at the DHVI. In addition, he provides oversight of regulatory compliance for DHVI clinical research activities. Dr. Walter has dedicated his career to advancing research and clinical practice in vaccinology, infectious diseases and child health. He currently serves as the principal investigator for the Duke Clinical Core of the Collaborative Influenza Vaccine Innovations Centers funded by the National Institute of Allergy and Infectious Diseases (NIAID). Dr. Walter is the Duke Co-Principal Investigator for the NIAID Vaccine and Treatment Evaluation Unit, which conducts clinical trials of vaccines and treatments for infectious diseases. He is also the Duke Principal Investigator for the Centers for Disease Control and Prevention-funded Clinical Immunization Safety Assessment Project, which conducts studies to identify risk factors and preventive strategies for adverse events following immunization, particularly in special populations.

Anticipated Key Milestones

- **VAX-24:** Vaxcyte expects to submit an IND application for VAX-24 to the U.S. Food and Drug Administration (FDA) between January and June 2022. Vaxcyte anticipates announcing topline data between late 2022 and early 2023 from the ensuing Phase 1/2 clinical proof-of-concept study in adults aged 50 and older.
- **VAX-A1:** Following the nomination of its final vaccine candidate for VAX-A1 in the first quarter of 2021, Vaxcyte plans to initiate IND-enabling studies in the second half of 2021.
- **VAX-PG:** Vaxcyte expects to nominate a final vaccine candidate for VAX-PG, its novel therapeutic vaccine designed to treat periodontal disease, in the first half of 2022. The Company has updated its estimate for this milestone based on the extended timelines required to access certain critical components due to the COVID-19 pandemic, as well as the availability of research support to complete preclinical proof-of-concept studies.

Second Quarter 2021 Financial Results

- **Cash Position:** Cash, cash equivalents and investments were \$341.0 million as of June 30, 2021, compared to \$386.2 million as of December 31, 2020.
- **Research & Development (R&D) Expenses:** R&D expenses were \$17.7 million for the three months ended June 30, 2021 as compared to \$18.2 million for the same period in 2020. The decrease was due primarily to a decrease in manufacturing expenses and outsourced research services related to Vaxcyte's VAX-24 program as a result of the completion of the eCRM™ and polysaccharide GMP campaigns in 2020, partially offset by increases in VAX-24 drug substance, drug product and manufacturing scale-up activities and personnel-related expenses.
- **General & Administrative (G&A) Expenses:** G&A expenses were \$6.1 million for the three months ended June 30, 2021 as compared to \$3.0 million for the same period in 2020. The increase was due primarily to an increase in personnel-related and other expenses to support public company operations.
- **Net Loss:** Net loss was \$23.7 million for the three months ended June 30, 2021 as compared to \$20.3 million for the same period in 2020.

About Vaxcyte

Vaxcyte is a next-generation vaccine company seeking to improve global health by developing superior and novel vaccines designed to prevent or treat some of the most common and deadly infectious diseases worldwide. The Company's cell-free protein synthesis platform, comprising the XpressCF™ platform, exclusively licensed from Sutro Biopharma, Inc., together with Vaxcyte's proprietary know-how, enables the design and production of protein carriers and antigens, the critical building blocks of vaccines, in ways that the Company believes conventional vaccine technologies currently cannot. Vaxcyte's lead vaccine candidate, VAX-24, is a preclinical, 24-valent broad-spectrum pneumococcal conjugate vaccine (PCV) being developed for the prevention of invasive pneumococcal disease. Vaxcyte's pipeline also includes VAX-XP, a PCV with an expanded breadth of coverage of at least 30 strains; VAX-A1, a prophylactic vaccine candidate designed to prevent Group A Strep infections; and VAX-PG, a therapeutic vaccine candidate designed to slow or stop the progression of periodontal disease by targeting the keystone pathogen responsible for this chronic, oral inflammatory disease. For more information, visit www.vaxcyte.com.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. These statements include, but are not limited to, statements related to the benefit of Vaxcyte's vaccine candidates; the process and timing of anticipated future development of Vaxcyte's vaccine candidates, including the timing and submission of an IND application for VAX-24 and the initiation of the VAX-24 Phase 1/2 clinical proof-of-concept study thereafter; the timing and availability of topline data for VAX-24; the ability to complete the manufacturing of the GMP drug product; the achievement of future funding milestones; the use and availability of funds from CARB-X; the initiation of IND-enabling activities for VAX-A1; the nomination of a final vaccine candidate for VAX-PG; the achievement of funding milestones; and other statements that are not historical fact. The words "believe," "could," "expect," "may," "potential," "should," "would" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. These forward-looking statements are based on Vaxcyte's current expectations and actual results and timing of events could differ materially from those anticipated in such forward-looking statements as a result of risks and uncertainties, including, without limitation, risks related to Vaxcyte's product development programs, including development timelines, success and timing of chemistry, manufacturing and controls and related manufacturing activities, potential delays or inability to obtain and maintain required regulatory approvals for its vaccine candidates, and the risks and uncertainties inherent with preclinical and clinical development processes; the success, cost and timing of all development activities and clinical trials; and sufficiency of cash and other funding to support Vaxcyte's development programs and other operating expenses. These and other risks are described more fully in Vaxcyte's filings with the Securities and Exchange Commission (SEC), including its Quarterly Report on Form 10-Q filed with the SEC on August 11, 2021 or in other documents Vaxcyte subsequently files with or furnishes to the SEC. Vaxcyte undertakes no duty or obligation to update any forward-looking statements contained in this release as a result of new information, future events or changes in its expectations. Readers should not rely upon the information in this press release as current or accurate after its publication date.

Contacts:

Andrew Guggenheimer, President and Chief Financial Officer
 Vaxcyte, Inc.
 650-837-0111
investors@vaxcyte.com

Vaxcyte, Inc.
Condensed Statements of Operations
(in thousands, except share and per share amounts)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Operating expenses:				
Research and development ⁽¹⁾	\$ 17,651	\$ 18,178	\$ 34,909	\$ 42,493
General and administrative ⁽¹⁾	6,079	3,046	11,964	6,327
Total operating expenses	<u>23,730</u>	<u>21,224</u>	<u>46,873</u>	<u>48,820</u>
Loss from operations	(23,730)	(21,224)	(46,873)	(48,820)
Other income (expense), net				
Interest expense	(7)	—	(7)	(7)
Interest income	93	44	155	179
Grant income	378	1,036	378	1,365
Realized gain on marketable securities	1	—	1	—
Foreign currency transaction gains (losses)	(414)	(176)	1,447	(179)
Total other income (expense), net	<u>51</u>	<u>904</u>	<u>1,974</u>	<u>1,358</u>
Net loss	<u>\$ (23,679)</u>	<u>\$ (20,320)</u>	<u>\$ (44,899)</u>	<u>\$ (47,462)</u>
Net loss per share, basic and diluted	<u>\$ (0.46)</u>	<u>\$ (1.72)</u>	<u>\$ (0.87)</u>	<u>\$ (5.99)</u>
Weighted-average shares outstanding, basic and diluted	<u>51,508,340</u>	<u>11,803,778</u>	<u>51,342,585</u>	<u>7,926,818</u>

(1) Amounts include stock-based compensation expense as follows:

Research and development	\$ 982	\$ 374	\$ 1,665	\$ 523
General and administrative	1,787	915	2,969	1,138
Total stock-based compensation expense	<u>\$ 2,769</u>	<u>\$ 1,289</u>	<u>\$ 4,634</u>	<u>\$ 1,661</u>

Vaxcyte, Inc.
Summary Balance Sheet Data
(in thousands)

	June 30, 2021	December 31, 2020
Cash, cash equivalents and investments	\$ 340,951	\$ 386,200
Total assets	358,054	392,826
Total stockholders' equity	317,025	345,843