Vaxcyte Reports First Quarter 2021 Financial Results and Provides Business Update

May 11, 2021

FOSTER CITY, Calif., May 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 first quarter ended March 31, 2021 and provided a business update.

“Over the past few months, we have made good progress as we advance VAX-24, our 24-valent pneumococcal conjugate vaccine (PCV), toward the anticipated submission of the Investigational New Drug (IND) application in order to generate clinical proof-of-concept data,” said Grant Pickering, Chief Executive Officer and Co-founder of Vaxcyte. “While we remain laser-focused on delivering on our VAX-24 milestones, I am also very excited by the progress made to advance our pipeline vaccines, including VAX-XP, our PCV candidate with an expanded breadth of coverage, and VAX-A1, our novel conjugate vaccine designed to provide universal protection from Group A Strep infections.”

Recent Highlights

- ***Advanced VAX-24 IND-Enabling Activities:*** Vaxcyte continues to progress several initiatives for VAX-24 in connection with its anticipated IND application submission to the U.S. Food and Drug Administration (FDA) and ensuing Phase 1/2 clinical proof-of-concept study initiation. Among other activities, the Company made substantive progress toward completion of the final stage of production of the 24 good manufacturing practice (GMP) conjugated drug substances.

- ***Published New Research Supporting VAX-24 and Vaxcyte’s Technology Platform:*** Since the beginning of 2021, Vaxcyte published preclinical VAX-24 data as well as research supporting its technology platform. The papers can be accessed here: https://vaxcyte.com/posters-publications/.

    - The paper, *“Non-clinical Immunological Comparison of a Next-Generation 24-Valent Pneumococcal Conjugate Vaccine (VAX-24) Using Site-Specific Carrier Protein Conjugation to the Current Standard of Care (PCV13 and PPV23),”* published in the journal *Vaccine*, uses a rabbit model to evaluate the immune response of Vaxcyte’s 24-valent PCV candidate compared to Prevnar13® (PCV13) and Pneumovax®23 (PPV23). In this study, all serotype conjugates (pneumococcal strains) in VAX-24 met the primary objective to elicit immune responses that were more robust compared to PPV23 and at least comparable to PCV13.
    - The paper, *“Site -specific antigen-adjuvant conjugation using cell-free protein synthesis enhances antigen presentation and CD8+ T-cell response,”* was published in the journal *Scientific Reports*, and demonstrated an enhanced CD8 positive T-cell response by directly conjugating an adjuvant to a candidate antigen. This expansion of Vaxcyte’s site-specific technology platform has potential application in viral vaccines where an enhanced CD8 T-cell response is required.

- ***Appointed Janet Graesser, Vice President, Corporate Communications and Investor Relations:*** In April 2021, Vaxcyte appointed Janet Graesser as Vice President of Corporate Communications and Investor Relations. Mrs. Graesser brings to Vaxcyte over 20 years of healthcare communications experience and expertise across a variety of areas, including corporate communications and strategy, public relations and organizational communications. She dedicated 13 years of her career working at leading healthcare communications firms, ultimately serving as an Executive Vice President, delivering communications strategy and implementation to biotech, pharmaceutical and consumer health companies, including Amgen, GlaxoSmithKline (GSK), Johnson & Johnson (J&J), Pfizer and Merck. She went on to hold an operating role at J&J with responsibility for internal and external communications across seven J&J medical device companies, including Cordis. Mrs. Graesser remained in a senior leadership role with Cordis when it was acquired by Cardinal Health, ultimately serving as the Vice President of Global Communications and Strategy Implementation. Mrs. Graesser went on to establish her own consulting practice that successfully supported both large and small biotech companies.

“I would also like to acknowledge the key role that Bill Newell, the Chief Executive Officer of Sutro Biopharma who will be stepping down from the board at the end of his term in June, has played in the creation of Vaxcyte,” said Mr. Pickering. “We are grateful for Bill’s quality stewardship as a director and his recognition that the cell-free protein synthesis platform could be more broadly applied, which was an instrumental catalyst in starting Vaxcyte.”

Anticipated Key Milestones

Vaxcyte reaffirmed its previously issued guidance for its pipeline programs.

- ***VAX-24:*** Vaxcyte expects to submit an IND application for VAX-24 to the FDA between January and June 2022. Vaxcyte expects to announce topline data from the ensuing Phase 1/2 clinical proof-of-concept study between late 2022 and early 2023.

- ***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 second half of 2021.

First Quarter 2021 Financial Results

- ***Cash Position:*** Cash, cash equivalents and investments were $370.9 million as of March 31, 2021, compared to $386.2 million as of December 31, 2020.

- ***Research & Development (R&D) Expenses:*** R&D expenses were $17.3 million for the three months ended March 31, 2021 as compared to $24.3 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 and drug product activities and VAX-XP activities.

- ***General & Administrative (G&A) Expenses:*** G&A expenses were $5.9 million for the three months ended March 31, 2021 as compared to $3.3 million for the same period in 2020. The increase was due primarily to an increase in personnel-related and directors and officers liability insurance expenses.

- ***Net Loss:*** Net loss was $21.2 million for the three months ended March 31, 2021 as compared to $27.1 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 are based on Vaxcyte's current beliefs and expectations. Such statements include, but are not limited to, statements related to: the preventative 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 initiation of IND-enabling activities for VAX-A1; the nomination of a final vaccine candidate for VAX-PG; and other statements that are not historical fact. The words "anticipate," "believe," "continue," "could," "estimate," "expect," "intend," "may," "plan," "potential," "predict," "project," "should," "target," "will," "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; Vaxcyte's reliance on third-party manufacturers; 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; sufficiency of cash and other funding to support Vaxcyte's development programs and other operating expenses; and the ongoing COVID-19 pandemic, which could materially and adversely affect Vaxcyte's business and operations. 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 May 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.

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

	Three Months Ended March 31,	
	2021	**2020**
Operating expenses:		
Research and development [1]	$ 17,258	$ 24,315
General and administrative [1]	5,885	3,281
Total operating expenses	23,143	27,596
Loss from operations	(23,143)	(27,596)
Other income (expense), net		
Interest expense	—	(7)
Interest income	61	135
Grant income	—	329
Foreign currency transaction gains (losses)	1,862	(3)
Total other income (expense), net	1,923	454
Net loss	$ (21,220)	$ (27,142)
Net loss per share, basic and diluted	$ (0.41)	$ (6.70)
Weighted-average shares outstanding, basic and diluted	51,174,978	4,049,848

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

Research and development	$ 683	$ 149
General and administrative	1,182	223
Total stock-based compensation expense	$ 1,865	$ 372

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

	March 31, 2021	December 31, 2020
Cash, cash equivalents and investments	$ 370,873	$ 386,200
Total assets	382,351	392,826
Total stockholders' equity	326,937	345,843