Vaxcyte Reports First Quarter 2022 Financial Results and Provides Business Update

May 9, 2022

-- Company Continues to Advance Phase 2 Portion of the Ongoing Phase 1/2 Clinical Proof-of-Concept Study Evaluating VAX-24 in Adults Aged 18 to 64 for the Prevention of Invasive Pneumococcal Disease and Pneumonia --

-- Announcement of Topline Safety, Tolerability and Immunogenicity Results from Both the Phase 1 and 2 Portions of the VAX-24 Phase 1/2 Study Expected by the End of 2022 --

-- Initiation of Separate VAX-24 Phase 2 Study in Adults Aged 65 and Older Expected in mid-2022 --

-- $352.3 Million in Cash, Cash Equivalents and Investments as of March 31, 2022, Including Net Proceeds of Approximately $107.6 Million from Recent Public Offering --

SAN CARLOS, Calif., May 09, 2022 (GLOBE NEWSWIRE) -- Vaxcyte, Inc. (Nasdaq: PCVX), a clinical-stage vaccine innovation company engineering high-fidelity vaccines to protect humankind from the consequences of bacterial diseases, today announced financial results for the first quarter ended March 31, 2022 and provided a business update.

"We are pleased with the progress of our ongoing Phase 1/2 proof-of-concept study, which is now dosing participants in the Phase 2 portion designed to evaluate the safety, tolerability and immunogenicity of VAX-24, our 24-valent pneumococcal conjugate vaccine (PCV), for the prevention of invasive pneumococcal disease and pneumonia in adults," said Grant Pickering, Chief Executive Officer and Co-founder of Vaxcyte. "We anticipate announcing the topline results of both the Phase 1 and Phase 2 portions of this study by year-end. If successful, this will be an important milestone for the Company that we expect will put us in a position to trigger additional development activities with our PCV franchise."

Mr. Pickering continued, "Over the coming months, we anticipate continued momentum across our pipeline, including VAX-XP, our PCV candidate with an expanded breadth of coverage of greater than 30 strains. We are actively advancing our PCV franchise, VAX-24 and VAX-XP, as we believe these vaccine candidates have the potential to offer the broadest protection from this very serious disease."

Recent Highlights

- ***Dosed First Participants in Both the Phase 1 and Phase 2 Portions of Ongoing VAX-24 Phase 1/2 Clinical Proof-of-Concept Study in Adults:*** In February 2022, Vaxcyte announced that the first participants were dosed in the Phase 1 portion of the VAX-24 Phase 1/2 clinical study. This was followed by an announcement in April 2022 that the first participants had been dosed in the Phase 2 portion of this study. The initiation of the Phase 2 portion, which includes healthy adults 50 to 64 years of age, occurred after the independent Data Monitoring Committee completed a prespecified review of initial Phase 1 safety and tolerability data and recommended that the study progress as planned.
    - The VAX-24 Phase 1/2 clinical proof-of-concept study is a randomized, observer-blind, dose-finding, controlled study designed to evaluate the safety, tolerability and immunogenicity of VAX-24 in healthy adults (NCT05266456).
    - The Phase 1 portion of the study is evaluating safety and tolerability of a single injection of VAX-24 at three dose levels and compared to Prevnar 20™ in 64 healthy adults 18 to 49 years of age.
    - The Phase 2 portion is evaluating the safety, tolerability and immunogenicity of a single injection of VAX-24 at three dose levels and compared to Prevnar 20™ in approximately 800 healthy adults 50 to 64 years of age. The prespecified immunogenicity endpoints of the Phase 2 portion of the study include an assessment of the induction of antibody responses, using immunoglobulin G (IgG) and opsonophagocytic activity (OPA), at each of the three VAX-24 doses and compared to Prevnar 20™ and, for the additional four serotypes contained in VAX-24 and Pneumovax® 23, but not in Prevnar 20™, the four-fold rise in antibody titers. The study is currently being conducted at 13 sites in the United States.

- ***Completed Successful $115 Million Follow-On Financing:*** In the first quarter of 2022, Vaxcyte completed an underwritten public offering of 3,250,000 shares of its common stock, which included the full exercise of the underwriters' option to purchase additional shares, and pre-funded warrants to purchase 2,500,000 shares of common stock. The aggregate gross proceeds to Vaxcyte from the offering were $115.0 million, before deducting underwriting discounts and commissions and other estimated offering expenses payable by Vaxcyte, and excluding the exercise of any pre-funded warrants.

- ***Appointed Mikhail Eydelman as Senior Vice President, General Counsel & Corporate Secretary*****:** In April 2022, Mikhail Eydelman joined as Senior Vice President, General Counsel and Corporate Secretary and a member of the

executive committee. Mr. Eydelman is an accomplished legal executive who brings significant experience in multiple areas, including commercial agreements and partnerships, securities matters, business development, litigation, healthcare compliance and product launches. Most recently, Mr. Eydelman served as General Counsel at Sagent Pharmaceuticals, a publicly traded commercial-stage pharmaceutical company. Previously, he was Assistant General Counsel for Integrated DNA Technologies, a supplier of nucleic acids acquired by Danaher Corporation. Mr. Eydelman also held legal roles of increasing responsibility at Akorn, a publicly traded commercial-stage pharmaceutical company. Prior to that, he practiced law at the premier international law firms of Latham & Watkins, Allen & Overy and Bryan Cave.

"I would also like to acknowledge the key role that Kurt von Emster, Managing Partner at Abingworth, who will be stepping down from our board at the end of his term in June, has played in Vaxcyte's progress. Having led our first institutional financing and previously serving as our interim board chair, we are grateful for Kurt's quality stewardship as a director, his consistent support of the company as an investor and, in particular, his early recognition of the potential of our platform to develop high-fidelity vaccines to address bacterial infectious diseases," said Mr. Pickering.

Anticipated Key Milestones

- ***VAX-24:***
  - ***Phase 1/2 Study in Adults Aged 18-64:*** Vaxcyte expects to announce topline safety, tolerability and immunogenicity results from both the Phase 1 and Phase 2 portions of the Phase 1/2 clinical study evaluating VAX-24 for the prevention of invasive pneumococcal disease (IPD) and pneumonia in adults by the end of 2022. The Phase 1 portion is evaluating safety and tolerability of the enrolled 64 healthy adults 18 to 49 years of age. The Phase 2 portion is evaluating safety, tolerability and immunogenicity of approximately 800 healthy adults 50 to 64 years of age.

  - ***Phase 2 Study in Adults Aged 65 and Older:*** With the successful completion of the initial safety and tolerability assessment of the Phase 1 portion of the ongoing Phase 1/2 study in adults aged 18 to 64, the Company expects to begin enrollment in a separate Phase 2 study of approximately 200 healthy adults aged 65 and older in mid-2022. This Phase 2 study will also evaluate the safety, tolerability and immunogenicity of a single injection of VAX-24 at three dose levels and compared to Prevnar 20™. The topline results from this study, which will further add to the body of data in the adult population, are expected to be announced in the first half of 2023.

  - ***Pediatric IND Application:*** Vaxcyte also anticipates submitting its first VAX-24 pediatric Investigational New Drug (IND) application to the U.S. Food and Drug Administration (FDA) in the first half of 2023, subject to a pre-IND meeting with the FDA and successful topline results from the ongoing VAX-24 Phase 1/2 study in adults 18 to 64 years of age.

- ***VAX-XP:*** Vaxcyte continues to progress VAX-XP, the Company's PCV candidate with an expanded breadth of coverage of greater than 30 strains, and expects to provide guidance for the anticipated submission of its IND application in adults to the FDA following the announcement of the topline results from the ongoing VAX-24 Phase 1/2 study in adults aged 18 to 64.

- ***VAX-A1:*** Vaxcyte continues to advance development of VAX-A1, a novel conjugate vaccine designed to prevent infections caused by Group A Streptococcus (Strep) bacteria, and expects to provide guidance for its anticipated IND application submission to the FDA in the second half of 2022.

- ***VAX-PG:*** Vaxcyte expects to nominate a final vaccine candidate for VAX-PG, its novel therapeutic vaccine designed to treat periodontal disease, by the end of 2022.

First Quarter 2022 Financial Results

- ***Cash Position:*** Cash, cash equivalents and investments were $352.3 million as of March 31, 2022, compared to $273.1 million as of December 31, 2021. The March 31, 2022 balance includes the approximately $107.6 million in net proceeds from the Company's underwritten public offering completed in the first quarter of 2022, yet excludes $43.6 million in net proceeds from sales of common stock under the Company's ATM Sales Agreement generated from April 1 through May 6, 2022.

- ***Research & Development (R&D) Expenses:*** R&D expenses were $31.7 million for the three months ended March 31, 2022 as compared to $17.3 million for the same period in 2021. The increase was due primarily to higher manufacturing expenses related to Vaxcyte's VAX-XP program and VAX-24 Phase 3 readiness activities, the initiation of the VAX-24 Phase 1/2 clinical study, lease expense related to the Company's new corporate headquarters allocated to research and development and personnel-related expenses. These increases were partially offset by a decrease in manufacturing expenses related to Vaxcyte's VAX-24 IND-enabling activities.

- ***General & Administrative (G&A) Expenses:*** G&A expenses were $7.5 million for the three months ended March 31, 2022 as compared to $5.9 million for the same period in 2021. The increase was due primarily to an increase in personnel-related expenses.

- ***Net Loss:*** For the three months ended March 31, 2022, net loss was $39.0 million, compared to $21.2 million for the same period in 2021.

About Vaxcyte
Vaxcyte is a vaccine innovation company engineering high-fidelity vaccines to protect humankind from the consequences of bacterial diseases. The Company is developing broad-spectrum conjugate and novel protein vaccines to prevent or treat bacterial infectious diseases. Vaxcyte's lead candidate, VAX-24, is a 24-valent, broad-spectrum pneumococcal conjugate vaccine being developed for the prevention of IPD and pneumonia. Vaxcyte is re-engineering the way highly complex vaccines are made through modern synthetic techniques, including advanced chemistry and the XpressCF™ cell-free protein synthesis platform, exclusively licensed from Sutro Biopharma, Inc. Unlike conventional cell-based approaches, the Company's system for producing difficult-to-make proteins and antigens is intended to accelerate its ability to efficiently create and deliver high-fidelity vaccines with enhanced immunological benefits. Vaxcyte's pipeline also includes VAX-XP, a PCV with an expanded breadth of coverage of greater than 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. Vaxcyte is driven to eradicate or treat invasive bacterial infections, which have serious and costly health consequences when left unchecked. 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, including breadth of coverage; the process and timing of anticipated future development and manufacture of Vaxcyte's vaccine candidates; the timing and availability of topline data for the VAX-24 Phase 1/2 clinical proof-of-concept study in adults aged 18 to 64; the initiation and timing of the separate Phase 2 study in adults aged 65 and older; the submission of a VAX-24 pediatric IND application; the announcement of guidance for the VAX-XP IND application submission; the announcement of guidance for the VAX-A1 IND application submission; the nomination of a product candidate for VAX-PG; and the demand for Vaxcyte's vaccine candidates; 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; impacts of COVID-19; 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 May 9, 2022 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,	
	2022	**2021**
Operating expenses:		
Research and development[(1)]	$ 31,678	$ 17,258
General and administrative[(1)]	7,543	5,885
Total operating expenses	39,221	23,143
Loss from operations	(39,221)	(23,143)
Other income (expense), net		
Interest income	134	61
Grant income	160	—
Realized loss on marketable securities	(65)	—

Foreign currency transaction gains	6	1,862
Total other income (expense), net	235	1,923
Net loss	$ (38,986)	$ (21,220)
Net loss per share, basic and diluted	$ (0.68)	$ (0.41)
Weighted-average shares outstanding, basic and diluted	57,547,808	51,174,978

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

Research and development	$ 1,775	$ 683
General and administrative	2,324	1,182
Total stock-based compensation expense	$ 4,099	$ 1,865

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

	March 31, 2022	December 31, 2021
Cash, cash equivalents and investments	$ 352,338	$ 273,087
Total assets	402,717	324,337
Total stockholders' equity	359,543	284,018