Vaxcyte Reports Fourth Quarter and Full Year 2021 Financial Results and Provides Business Update

February 28, 2022

-- First Participants Dosed in Phase 1/2 Clinical Study Evaluating VAX-24 for the Prevention of Invasive Pneumococcal Disease and Pneumonia in Adults --

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

-- $273.1 Million in Cash, Cash Equivalents and Investments as of December 31, 2021, Excluding Net Proceeds of Approximately $107.6 Million from Recent Public Offering --

-- Company to Host Webcast/Conference Call Today at 4:30 p.m. ET / 1:30 p.m. PT --

SAN CARLOS, Calif., Feb. 28, 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 fourth quarter and full year ended December 31, 2021 and provided a business update.

“In 2021, we achieved significant milestones for VAX-24, our lead, 24-valent pneumococcal conjugate vaccine candidate, having completed both the manufacture of the GMP drug product and submission of our IND application,” said Grant Pickering, Chief Executive Officer and Co-founder of Vaxcyte. “This strong momentum continues in 2022 with the initiation of the VAX-24 Phase 1/2 clinical study in adults, bringing us closer to clinical proof-of-concept, and the recent $115 million follow-on equity offering to further strengthen our balance sheet.”

Mr. Pickering continued, “As we advance VAX-24, along with our entire pipeline of vaccines to prevent or treat bacterial infectious diseases, we anticipate several important milestones, including the announcement of topline safety, tolerability and immunogenicity results from the VAX-24 Phase 1/2 clinical study by the end of this year.”

Key 2021 and 2022 Highlights to Date

- ***Completed the Manufacture of VAX-24 Drug Product:*** In the fourth quarter of 2021, Vaxcyte completed all steps in the manufacturing process, including formulation, fill and finish, along with the testing and release, for the VAX-24 drug product. This achievement led to the submission of the VAX-24 Investigational New Drug (IND) application to the U.S. Food and Drug Administration (FDA) before the end of 2021.

- ***Dosed First Participants in VAX-24 Phase 1/2 Clinical Study:*** Following the early January 2022 clearance of the VAX-24 IND application, Vaxcyte initiated the Phase 1/2 clinical study of VAX-24, a 24-valent pneumococcal conjugate vaccine (PCV) candidate designed to prevent invasive pneumococcal disease (IPD) and pneumonia in adults. The VAX-24 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. The Phase 1 portion of the study will evaluate the safety and tolerability of a single injection of VAX-24 at three dose levels and compared to Prevnar 20™ in approximately 64 healthy adults 18 to 49 years of age. The Phase 2 portion will evaluate 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 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.

- ***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 shares of common stock were sold at a public offering price of $20.00 per share, and the pre-funded warrants were sold at a public offering price of $19.999 per underlying share. 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.

- ***Advanced and Presented Preclinical Data for VAX-XP Program:*** The Company has continued to advance VAX-XP, its PCV candidate with an expanded breadth of coverage of greater than 30 strains. During IDWeek 2021, the Company

presented findings from a preclinical study that evaluated the immunogenicity of VAX-XP, which showed VAX-XP exhibited conjugate-like immune responses for all 31 serotypes, as demonstrated by IgG immune responses 14 days after both an initial and booster dose that were superior to polysaccharide-based vaccines and comparable to Prevnar 13®. Additionally, all serotypes in VAX-XP elicited a T-cell dependent immune response as demonstrated by the increase in IgG titers post-boost.

- ***Initiated VAX-A1 IND-Enabling Activities:*** Vaxcyte continues to advance development of VAX-A1, a novel conjugate vaccine designed to prevent infections caused by Group A Streptococcus (Strep) bacteria. Following the nomination of its final VAX-A1 vaccine candidate in the first quarter of 2021, the Company initiated IND-enabling studies in the second half of 2021.

- ***Strengthened Leadership Team and Board of Directors with Key Appointments:*** During 2021, Vaxcyte added several key leaders to its executive team and Board of Directors. In October, Harp Dhaliwal joined as Senior Vice President of Commercial Manufacturing and Supply Chain, and the Company appointed Dr. Carlos Paya, who serves as the Board Chair, and Dr. Michael Kamarck to its board of directors. This followed the September 2021 board appointments of Annie Drapeau and Teri Loxam. These accomplished industry leaders have deep experience across the biopharmaceutical and vaccine industries and will provide additional skills and expertise as the Company advances and scales its business.

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 IPD and pneumonia in adults by the end of 2022. The Phase 1 portion includes approximately 64 healthy adults 18 to 49 years of age and the Phase 2 portion includes approximately 800 healthy adults 50 to 64 years of age.
  - ***Phase 2 Study in Adults Aged 65 and Older:*** Upon successful completion of the Phase 1 portion of the recently initiated Phase 1/2 study in adults aged 18 to 64, the Company expects to begin enrollment in a separate Phase 2 study in healthy adults aged 65 and older. The topline safety, tolerability and immunogenicity 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 IND application to the FDA in the first half of 2023, subject to a pre-IND meeting with the FDA and successful topline results from the VAX-24 Phase 1/2 study in adults 18 to 64 years of age.

- ***VAX-XP:*** Vaxcyte continues to advance VAX-XP 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 VAX-24 Phase 1/2 study in adults aged 18 to 64.

- ***VAX-A1:*** Vaxcyte continues to advance development of VAX-A1 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.

Fourth Quarter and Full Year 2021 Financial Results

- ***Cash Position:*** Cash, cash equivalents and investments were $273.1 million as of December 31, 2021, compared to $386.2 million as of December 31, 2020. The December 31, 2021 balance excludes the approximately $107.6 million in net proceeds from the Company's underwritten public offering completed in the first quarter of 2022.
- ***Research & Development (R&D) Expenses:*** R&D expenses were $23.1 million for the three months ended December 31, 2021 and $78.4 million for the full year 2021 as compared to $14.6 million and $73.6 million, respectively, for the same periods in 2020. The increase for the year ended December 31, 2021 was due primarily to higher manufacturing expenses related to Vaxcyte's VAX-XP program and personnel-related expenses, which were partially offset by a decrease in manufacturing expenses related to Vaxcyte's VAX-24 program.

- ***General & Administrative (G&A) Expenses:*** G&A expenses were $6.8 million for the three months ended December 31, 2021 and $25.3 million for the full year 2021 as compared to $4.8 million and $16.0 million, respectively, for the same periods in 2020. The increase for the year ended December 31, 2021 was due primarily to an increase in personnel-related and other expenses related to Vaxcyte's first full year of operations as a public company, including directors and officers insurance and consulting services.

- ***Net Loss:*** For the three months and year ended December 31, 2021, net loss was $28.6 million and $100.1 million, respectively, compared to $20.7 million and $89.2 million for the same periods in 2020.

Conference Call and Webcast
Vaxcyte will host a conference call and webcast to discuss this announcement today, February 28, 2022 at 4:30 p.m. ET / 1:30 p.m. PT. To participate in the conference call, please dial (833) 519-1403 (domestic) or (270) 215-9736 (international) and refer to conference ID 6886437. A live audio webcast will be available in the Investors & Media section of the Company's website at www.vaxcyte.com. A replay of the webcast will be available for 30 days following the call.

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 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 VAX-A1; the nomination of a product candidate for VAX-PG; 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 Annual Report on Form 10-K filed with the SEC on February 28, 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)

	Year Ended December 31,		
	2021	**2020**	**2019**
Operating expenses:			
Research and development [1]	$ 78,411	$ 73,564	$ 45,607
General and administrative [1]	25,259	16,017	8,546
Total operating expenses	103,670	89,581	54,153
Loss from operations	(103,670)	(89,581)	(54,153)
Other income (expense), net			
Interest expense	(7)	(7)	(40)
Interest income	344	244	632

Grant income	1,585	2,478	237
Realized gains on marketable securities	2	—	—
Foreign currency transaction gains (losses)	1,669	(2,351)	(135)
Change in fair value of the redeemable convertible preferred stock tranche liability	—	—	3,185
Total other income (expense), net	3,593	364	3,879
Net loss and comprehensive loss	(100,077)	$ (89,217)	$ (50,274)
Net loss per share, basic and diluted	$ (1.93)	$ (3.02)	$ (13.25)
Weighted-average shares outstanding, basic and diluted	51,922,108	29,545,810	3,795,090

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

Research and development	$ 3,954	$ 1,861	$ 368
General and administrative	6,775	3,573	817
Total stock-based compensation expense	$ 10,729	$ 5,434	$ 1,185

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

	December 31,	
	2021	**2020**
Cash, cash equivalents and investments	$ 273,087	$ 386,200
Total assets	324,337	392,826
Total stockholders' equity	284,018	345,843