Vaxcyte Reports Fourth Quarter and Full Year 2022 Financial Results and Provides Business Update

February 27, 2023

-- Company Received U.S. Food and Drug Administration (FDA) Clearance of VAX-24 Infant Investigational New Drug (IND) Application and Expects to Initiate Phase 2 Study in Second Quarter 2023 --

-- Topline Safety, Tolerability and Immunogenicity Results from VAX-24 Phase 2 Study in Adults 65 and Older on Track for Second Quarter 2023 --

-- Positive Topline Results from VAX-24 Phase 1/2 Proof-of-Concept Study in Adults Aged 18-64 Indicate Potential Best-in-Class Profile and Validate Company's Carrier-Sparing Approach --

-- VAX-31 Progressing with Adult IND Application Expected in Second Half 2023 and Topline Phase 1/2 Data in 2024 --

-- Successfully Raised Approximately $805 Million in Gross Proceeds in Two Follow-On Equity Offerings in 2022; $957.9 Million in Cash, Cash Equivalents and Investments as of December 31, 2022 --

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

SAN CARLOS, Calif., Feb. 27, 2023 (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, 2022 and provided a business update.

"Last year was transformational for Vaxcyte, with the positive VAX-24 clinical proof-of-concept data validating the potential of our pneumococcal conjugate vaccine (PCV) franchise and carrier-sparing approach to enable the development of broader-spectrum PCVs for the prevention of invasive pneumococcal disease (IPD). These results also support the utility of our cell-free platform that is being deployed across our full pipeline of novel vaccine candidates," said Grant Pickering, Chief Executive Officer and Co-founder of Vaxcyte. "We also added to our strong foundation by bolstering our balance sheet, raising approximately $805 million in gross proceeds from two follow-on equity offerings that provide additional funding for the continued development of VAX-24 and our earlier-stage pipeline, including VAX-31, our 31-valent PCV candidate, through important incremental milestones."

Mr. Pickering continued, "Progressing our VAX-24 adult and infant clinical programs is a critical focus for 2023 and we remain on track to announce the topline Phase 2 data from the study in adults 65 and older and initiate the Phase 2 infant study in the second quarter of this year. We anticipate additional milestones across our broader portfolio, including the submission of the VAX-31 adult IND application to the FDA in the second half of the year, with topline data expected in 2024."

Key 2022 and 2023 Highlights to Date

- ***VAX-24 Infant IND Application for the Prevention of IPD Cleared by the FDA:*** In late February 2023, the Company announced that the FDA cleared the VAX-24 IND application for the prevention of IPD in infants. Vaxcyte plans to initiate the infant Phase 2 study in the second quarter of 2023, with topline safety, tolerability and immunogenicity data following the primary three-dose immunization series expected by 2025. The study design will include a primary immunization series consisting of three doses followed by a subsequent booster dose.

- ***VAX-24 Granted Breakthrough Therapy Designation from the FDA for the Prevention of IPD in Adults Aged 18 and Older:*** In January 2023, Vaxcyte announced that the FDA granted Breakthrough Therapy designation for VAX-24 for the prevention of IPD in adults. With Breakthrough Therapy designation, Vaxcyte will have access to all of the elements of the FDA's Fast Track program, as well as the ability to receive guidance and support from the FDA on an efficient drug development program and an organizational commitment from senior managers within the FDA. The FDA's decision was based on positive topline results from the Phase 1/2 proof-of-concept study of VAX-24 in adults 18-64 years of age.

- ***Reported Positive Topline Data from Phase 1/2 Proof-of-Concept Study of VAX-24 in Adults Aged 18-64:*** In the fourth quarter of 2022, Vaxcyte reported positive topline results from the Phase 1/2 clinical proof-of-concept study evaluating the safety, tolerability and immunogenicity of VAX-24 in healthy adults aged 18-64. In this study, VAX-24 met the primary safety and tolerability objectives, demonstrating a safety profile similar to Prevnar 20™ (PCV20) for all doses studied. The study also showed VAX-24 met or exceeded the established regulatory immunogenicity standards for all 24 serotypes at the conventional 2.2mcg dose, which Vaxcyte intends to move forward into a pivotal Phase 3 clinical program. At this dose, VAX-24 met the standard non-inferiority criteria for opsonophagocytic activity (OPA) response for all 20

serotypes common with PCV20, of which 16 achieved higher immune responses. Additionally, at all three doses, VAX-24 met the standard superiority criteria for all four serotypes unique to VAX-24. VAX-24 has the potential to cover an additional 10-28 percent of strains causing IPD in adults over the current standard-of-care PCVs. The 24 serotypes that comprise VAX-24 eclipse the coverage of all currently available conjugate and polysaccharide-only vaccines to prevent IPD.

- ***Completed Enrollment of Phase 2 Study Evaluating Safety, Tolerability and Immunogenicity of VAX-24 in Adults Aged 65 Years and Older:*** In the third quarter 2022, Vaxcyte completed enrollment in the Phase 2 study evaluating VAX-24 in healthy adults 65 years of age and older. This Phase 2 clinical study is a randomized, observer-blind, dose-finding study designed to evaluate the safety, tolerability and immunogenicity of VAX-24 at three dose levels and compared to PCV20 in approximately 200 healthy adults 65 years of age and older, or approximately 50 adults per cohort. The study was designed to further inform the powering of the pivotal Phase 3 study, while adding to the existing body of research supporting the potential clinical utility of VAX-24 in adults and was not powered to demonstrate non-inferiority. Given the size of the study, the focal point will be the point estimates for the OPA geometric mean ratios for each serotype, rather than the lower limit of the 95^{th} confidence intervals.

- ***Revealed Serotypes Included in VAX-31 (Formerly VAX-XP), the Broadest-Spectrum PCV in Development:*** The Company announced the seven additional serotypes (7C, 15A, 16F, 23A, 23B, 31, 35B) included in VAX-31 beyond the 24 serotypes in VAX-24. VAX-31 is the broadest-spectrum PCV the Company believes to be currently in development and has the potential to cover approximately 95% of the IPD circulating in the U.S. adult population.

- ***Progressed and Bolstered Early-Stage Pipeline, Leveraging Unique Capabilities of Cell-Free Technology Platform:***
  - VAX-A1: Vaxcyte continues to advance the development of VAX-A1, a novel conjugate vaccine designed to prevent infections caused by Group A Strep bacteria in adults and children, and further information about the anticipated timing of an IND application will be provided as the program progresses.
  - VAX-PG: Vaxcyte nominated a final vaccine candidate for VAX-PG, its novel therapeutic vaccine designed to treat periodontal disease, in the fourth quarter of 2022 and continues to progress the program.
  - VAX-GI: Vaxcyte has added a new vaccine program, VAX-GI, designed to prevent Shigella, a bacterial illness that affects an estimated 188 million people worldwide each year and results in approximately 164,000 deaths annually, mostly among children under five years of age in low- and middle-income settings.

- ***Entered into an Agreement with Sutro Biopharma, Inc. for Expanded Rights to Develop and Manufacture Cell-Free Extract:*** In December 2022, Vaxcyte and Sutro entered into an agreement through which Vaxcyte acquired expanded rights related to the supply of cell-free extract and an option to acquire additional rights to develop and manufacture cell-free extract. This agreement is an expansion of a nearly decade-long relationship between Sutro and Vaxcyte, during which Sutro has been responsible for supplying Vaxcyte with extract, a key material used to develop Vaxcyte's cell-free vaccine candidates. This new agreement enables Vaxcyte to obtain direct oversight and control of the manufacturing of the cell-free extract for its products and provides additional flexibility as it continues to advance VAX-24 and its pipeline.

- ***Completed Two Successful Follow-On Financings Totaling Approximately $805 Million in Gross Proceeds:***
  - In the fourth quarter of 2022, Vaxcyte completed an underwritten public offering of 17,812,500 shares of its common stock, which included the full exercise of the underwriters' option to purchase additional shares, and pre-funded warrants to purchase 3,750,000 shares of common stock. The shares of common stock were sold at a public offering price of $32.00 per share, and the pre-funded warrants were sold at a public offering price of $31.999 per underlying share. The aggregate gross proceeds to Vaxcyte from the offering were approximately $690.0 million, before deducting underwriting discounts and commissions and other estimated offering expenses payable by Vaxcyte and excluding the exercise of any pre-funded warrants.
  - Additionally, 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 approximately $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.

- ***Strengthened Leadership Team with Addition of Key Talent in 2022:***
  - Vaxcyte added several key leaders to its executive team. In October, Mark Wiggins joined as Chief Business Officer and Jakub Simon joined as Chief Medical Officer. In April, Mikhail Eydelman joined as Senior Vice President, General Counsel and Corporate Secretary. 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.
- The Company also continues to add key senior leaders to its bench across the finance, regulatory, clinical and CMC teams, among others, to further broaden crucial capabilities.

Anticipated Key Milestones
Vaxcyte is advancing the clinical development of its PCV programs with several anticipated key upcoming milestones, including:

- ***VAX-24 Adult Program:***
  - Topline safety, tolerability and immunogenicity data from the Phase 2 study in adults 65 and older in the second quarter of 2023.
  - Final results with the six-month safety data from the two Phase 2 adult studies in the first half of 2023.
  - Following the receipt of the final safety reports from the two adult Phase 2 studies, an end-of-Phase 2 meeting with the FDA in the second half of 2023 to inform the Phase 3 program.
  - Topline safety, tolerability and immunogenicity data from the Phase 3 pivotal non-inferiority study in adults in 2025.

- ***VAX-24 Infant Program:***
  - Initiation of the infant Phase 2 study in the second quarter of 2023.
  - Topline safety, tolerability and immunogenicity data from the infant Phase 2 study following the primary three-dose immunization series by 2025. The study design will include a primary immunization series consisting of three doses followed by a subsequent booster dose.

- ***VAX-31 (Formerly VAX-XP) Adult Program:***
  - Submission of adult IND application in the second half of 2023.
  - Topline safety, tolerability and immunogenicity data from the Phase 1/2 study in adults in 2024.

Fourth Quarter and Full Year 2022 Financial Results

- ***Cash Position:*** Cash, cash equivalents and investments were $957.9 million as of December 31, 2022, compared to $273.1 million as of December 31, 2021. The December 31, 2022, balance includes $651.6 million in net proceeds from the Company's underwritten public offering completed in the fourth quarter of 2022.

- ***Research & Development (R&D) Expenses:*** R&D expenses were $51.6 million for the three months ended December 31, 2022 and $169.5 million for the full year 2022 as compared to $23.1 million and $78.4 million, respectively, for the same periods in 2021. The increase for the year ended December 31, 2022 was due primarily to higher product and clinical development expenses for Vaxcyte's VAX-24 and VAX-31 programs and, to a lesser extent, the growth in the number of R&D employees and the related laboratory expenses to support their activities.

- ***Acquired Manufacturing Rights:*** Acquired manufacturing rights of $23.0 million for the three months and full year ended December 31, 2022 were related to the upfront consideration incurred by Vaxcyte in connection with the December 2022 agreement entered into with Sutro Biopharma.

- ***General & Administrative (G&A) Expenses:*** G&A expenses were $12.0 million for the three months ended December 31, 2022 and $39.8 million for the full year 2022 as compared to $6.8 million and $25.3 million, respectively, for the same periods in 2021. The increase for the year ended December 31, 2022 was due primarily to higher personnel-related expenses related to an increase in G&A employees to support the overall growth and scaling of the Company.

- ***Net Loss:*** For the three months and year ended December 31, 2022, net loss was $78.1 million and $223.5 million, respectively, compared to $28.6 million and $100.1 million for the same periods in 2021.

Conference Call and Webcast
Vaxcyte will host a conference call and webcast to discuss this announcement today, February 27, 2023, at 4:30 p.m. ET / 1:30 p.m. PT. Those who would like to participate may access the live webcast here, or register in advance for the teleconference here. 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, carrier-sparing PCV being developed for the prevention of IPD. 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-31, a 31-valent PCV candidate; VAX-A1, a prophylactic vaccine candidate designed to prevent Group A Strep infections; VAX-PG, a therapeutic vaccine candidate designed to slow or stop the progression of periodontal disease; and VAX-GI, a vaccine program designed to prevent Shigella. 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 potential benefits of VAX-24, including breadth of coverage, the ability to deliver a potentially best-in-class PCV and the improvement upon the standard-of-care; the process and timing of anticipated future development of Vaxcyte's vaccine candidates; the timing and availability of data for the VAX-24 Phase 2 and Phase 3 studies and related regulatory interactions; the timing of the initiation of the VAX-24 Phase 2 infant study and the availability of Phase 2 topline results; the timing and submission of an IND application for the VAX-31 adult program and the timing and availability of the Phase 1/2 topline data for such program; the demand for Vaxcyte's vaccine candidates; the potential benefits and opportunities available as a result of the Breakthrough Therapy designation for VAX-24 in adults; and other statements that are not historical fact. The words "anticipate," "believe," "could," "expect," "intend," "may," "on track," "potential," "should," "would" and similar expressions (as well as other words or expressions referencing future events, conditions or circumstances) convey uncertainty of future events or outcomes and 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 27, 2023 or in other documents Vaxcyte subsequently files with or furnishes to the SEC. All forward-looking statements contained in this press release speak only as of the date on which they were made and are based on management's assumptions and estimates as of such date, and readers should not rely upon the information in this press release as current or accurate after its publication date. 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,		
	2022	**2021**	**2020**
Operating expenses:			
Research and development (1)	$ 169,451	$ 78,411	$ 73,564
Acquired manufacturing rights	22,995	-	-
General and administrative (1)	39,810	25,259	16,017
Total operating expenses	232,256	103,670	89,581
Loss from operations	(232,256)	(103,670)	(89,581)
Other income (expense), net:			
Interest expense	(2)	(7)	(7)
Interest income	8,356	344	244
Grant income	1,931	1,585	2,478
Realized gains on marketable securities	-	2	-
Loss on disposal of fixed assets	(44)	-	-
Foreign currency transaction gains (losses)	(1,470)	1,669	(2,351)
Total other income (expense), net	8,771	3,593	364
Net loss	$ (223,485)	$ (100,077)	$ (89,217)
Net loss per share, basic and diluted	$ (3.44)	$ (1.93)	$ (3.02)
Weighted-average shares outstanding, basic and diluted	64,877,988	51,922,108	29,545,810

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

Research and development	$ 9,899	$ 3,954	$ 1,861
General and administrative	13,751	6,775	3,573
Total stock-based compensation expense	$ 23,650	$ 10,729	$ 5,434

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

	December 31,	
	2022	**2021**
Cash, cash equivalents and investments	$ 957,925	$ 273,087
Total assets	1,006,178	324,337
Total stockholders' equity	953,613	284,018