Vaxcyte Reports Fourth Quarter and Full Year 2023 Financial Results and Provides Business Update

February 27, 2024

-- VAX-31 Adult Program Phase 1/2 Study Enrollment Complete; Topline Safety, Tolerability and Immunogenicity Data Expected in Third Quarter of 2024 --

-- Completed Successful VAX-24 Phase 2 Adult Program and End-of-Phase 2 Meeting; VAX-24 is Phase 3-Ready in Adults --

-- Following VAX-31 Adult Phase 1/2 Study Readout, Vaxcyte to Advance VAX-24 or VAX-31 to Adult Phase 3 Program --

-- Enrollment in VAX-24 Infant Phase 2 Study Nearing Completion; Topline Data from Primary Immunization Series Expected by End of First Quarter of 2025, Followed by Topline Data from Booster Dose by End of 2025 --

-- Significant Progress in Establishing Global Commercial Manufacturing Capacity for Vaxcyte's PCV Candidates, Including Expanded Collaboration with Lonza --

-- $1.2 Billion in Cash, Cash Equivalents and Investments as of December 31, 2023, Excluding Net Proceeds of $816.5 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. 27, 2024 (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, 2023, and provided a business update.

“Over the past year, we made significant progress across clinical, regulatory and manufacturing with our broad-spectrum, carrier-sparing pneumococcal conjugate vaccine (PCV) franchise, comprising VAX-24 and VAX-31, which are designed to prevent invasive pneumococcal disease (IPD) in adults and children. These notable achievements, coupled with two follow-on equity financings totaling approximately $1.4 billion in gross proceeds, fortified our efforts to build what we believe is a best-in-class PCV franchise,” said Grant Pickering, Chief Executive Officer and Co-founder of Vaxcyte. “This year promises an important anticipated milestone with the VAX-31 adult Phase 1/2 topline data expected in the third quarter, following which we intend to advance either VAX-24 or VAX-31 into a Phase 3 adult clinical program. Additionally, enrollment in the VAX-24 infant Phase 2 study is nearing completion, and we remain on track to announce Phase 2 topline data from the primary immunization series by the end of the first quarter of 2025.”

“The follow-on equity offering completed earlier this month generated approximately $816.5 million in net proceeds, further strengthening our balance sheet to advance our PCV franchise, including Phase 3 studies and manufacturing scale-up, along with our early-stage vaccine candidates while also growing the organization in support of these initiatives,” said Andrew Guggenhime, President and Chief Financial Officer of Vaxcyte. “We look forward to delivering multiple anticipated Phase 3 data readouts over the next few years as we progress toward a Biologics License Application (BLA) submission for either the VAX-24 or VAX-31 adult program.”

Key 2023 and 2024 to Date Highlights

PCV Franchise Adult Indication:

- ***Completed Enrollment of Phase 1/2 Study Evaluating VAX-31 for the Prevention of IPD in Adults Aged 50 and Older:*** In January 2024, Vaxcyte announced the completion of enrollment in its Phase 1/2 clinical study evaluating VAX-31, a 31-valent PCV candidate designed to prevent IPD, in healthy adults. This is a randomized, observer-blind, active-controlled, dose-finding study designed to evaluate the safety, tolerability and immunogenicity of VAX-31 at three dose levels (low, middle and high) compared to Prevnar 20® (PCV20) in 1,015 healthy adults aged 50 and older. Additional information about the study can be found at www.clinicaltrials.gov under the identifier NCT06151288.

- ***Completed End-of-Phase 2 Meeting with FDA and Held CMC Regulatory Discussions; VAX-24 Adult Clinical Program is Phase 3-Ready:*** In October 2023, Vaxcyte completed a successful End-of-Phase 2 meeting with the U.S. Food and Drug Administration (FDA). The meeting focused on the VAX-24 adult Phase 3 clinical program, including the design of the pivotal, non-inferiority study and other Phase 3 studies needed to support a BLA submission. Based on the End-of-Phase 2 meeting, the Company believes there is agreement with the FDA on the clinical design of the adult Phase 3 program, including the approximate overall number of subjects, the primary and secondary endpoints for the pivotal, non-inferiority study as well as confirmation that the planned immunogenicity analyses are sufficient to support licensure and an efficacy study is therefore not required. Additionally, as part of ongoing Chemistry, Manufacturing and Controls (CMC)-focused discussions, Vaxcyte received encouraging input from the FDA regarding the VAX-24 adult licensure

requirements. The Company was granted these discussions under the VAX-24 adult Breakthrough Therapy designation and expects to seek additional CMC-focused input from the FDA as it continues to prepare for and potentially conduct the VAX-24 adult Phase 3 program.

- ***Reported Positive Data from Phase 2 Study of VAX-24 in Adults Aged 65 and Older and Full Six-Month Safety Data from Adult Phase 1/2 and Phase 2 Studies***: In April 2023, Vaxcyte announced positive results from the VAX-24 Phase 2 study in adults aged 65 and older, as well as data from the full six-month safety assessment and prespecified pooled immunogenicity analyses from both the Phase 2 study in adults aged 65 and older and the prior Phase 1/2 proof-of-concept (POC) study in adults aged 18-64 (Phase 1 portion included adults aged 18-49, Phase 2 portion included adults aged 50-64). In the Phase 2 study in adults aged 65 and older, VAX-24 demonstrated robust opsonophagocytic activity (OPA) immune responses for all 24 serotypes at all doses studied, confirming the prior adult Phase 1/2 POC study results. The six-month safety data from both studies showed safety and tolerability results for VAX-24 similar to PCV20 at all doses studied.

- ***VAX-24 Adult Phase 1/2 POC Data Published in The Lancet Infectious Diseases Highlighting Best-in-Class Potential of VAX-24:*** In December 2023, the results from the VAX-24 Phase 1/2 clinical POC study were published in the journal *The Lancet Infectious Diseases*.

- ***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 has 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 Breakthrough Therapy designation process is designed to expedite the development and review of drugs and biologics that are intended to treat a serious or life-threatening condition, where preliminary clinical evidence indicates that the drug or biologic may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints.

PCV Franchise Infant Indication:

- ***Enrollment in VAX-24 Infant Phase 2 Study Nearing Completion:*** The VAX-24 infant Phase 2 study is nearing enrollment completion. This is a randomized, observer-blind, dose-finding two-stage clinical study evaluating the safety, tolerability and immunogenicity of VAX-24 in healthy infants. The Stage 1 portion of the study evaluated the safety and tolerability of a single injection of VAX-24 at three dose levels (low dose/1.1mcg, middle dose/2.2mcg, mixed dose/2.2mcg or 4.4mcg) and compared to VAXNEUVANCE™ (PCV15) in 48 infants. The Stage 2 portion, which commenced in July 2023, is evaluating the safety, tolerability and immunogenicity of VAX-24 for the prevention of IPD at the same three dose levels and compared to PCV20, currently the broadest-spectrum PCV recommended by the Advisory Committee on Immunization Practices, in approximately 750 infants. Additional information about the study can be found at www.clinicaltrials.gov under the identifier NCT05844423.

Global Manufacturing:

- ***Exercised Option and Entered into Manufacturing Rights Agreement with Sutro Biopharma, Inc. (Sutro) to Obtain Control Over Manufacturing and Development of Cell-Free Extract for Vaxcyte's Vaccine Candidates:*** In November 2023, Vaxcyte exercised its option and entered into a manufacturing rights agreement with Sutro to obtain control over the development and manufacture of cell-free extract, a key component of Vaxcyte's PCV candidates. Pursuant to the manufacturing rights agreement, Vaxcyte obtained exclusive rights to independently, or through certain third parties, develop, improve and manufacture cell-free extract for use in connection with the Company's vaccine candidates.

- ***Expanded Collaboration with Lonza for Global Commercial Manufacturing of Vaxcyte's PCV Candidates:*** In October 2023, Vaxcyte and Lonza entered into a new commercial manufacturing agreement, expanding the existing collaboration. This agreement supports the potential global commercialization of Vaxcyte's PCV candidates in both the adult and pediatric populations and complements Vaxcyte's plans to utilize existing Lonza infrastructure to advance clinical development and support the anticipated initial U.S. launch of VAX-24 or VAX-31 for the adult population.

Equity Financings:

- ***Completed Two Successful Follow-On Financings Totaling Approximately $1.4 Billion in Gross Proceeds, Further Strengthening Vaxcyte's Balance Sheet:***
    - In February 2024, Vaxcyte completed an underwritten public offering of 12,695,312 shares of its common stock, which included the full exercise of the underwriters' option to purchase additional shares, at a public offering price of $64.00 per share and pre-funded warrants to purchase 781,250 shares of common stock at a public offering price of $63.999 per underlying share. The aggregate gross proceeds to Vaxcyte from this offering were

approximately $862.5 million, before deducting underwriting discounts and commissions and other offering expenses payable by Vaxcyte.

- In April 2023, Vaxcyte completed an underwritten public offering of 13,030,000 shares of its common stock, which included the full exercise of the underwriters' option to purchase additional shares, at a public offering price of $41.00 per share and pre-funded warrants to purchase 1,000,000 shares of common stock at a public offering price of $40.999 per underlying share. The aggregate gross proceeds to Vaxcyte from the offering were approximately $575.2 million, before deducting underwriting discounts and commissions and other offering expenses payable by Vaxcyte.

Anticipated Key Milestones

Vaxcyte is advancing the clinical development of its PCV programs with several anticipated key upcoming milestones:

PCV Franchise Adult Indication

- Announce topline safety, tolerability and immunogenicity data from VAX-31 adult Phase 1/2 study in the third quarter of 2024.
- Following VAX-31 data in the third quarter, advance either VAX-24 or VAX-31 to an adult Phase 3 program:

If VAX-24:

- Initiate Phase 3 pivotal, non-inferiority study in adults aged 50 and older in the second half of 2024 and announce topline safety, tolerability and immunogenicity data in the second half of 2025.
- Initiate balance of expected Phase 3 studies in 2025 and 2026.

If VAX-31:

- Initiate full complement of expected Phase 3 studies in 2025 and 2026.

PCV Franchise Infant Indication

- Announce topline safety, tolerability and immunogenicity data from VAX-24 infant Phase 2 study primary three-dose immunization series by the end of the first quarter of 2025, followed by topline data from the booster dose by the end of 2025.

Upcoming March Investor Conferences

Company management will participate in fireside chats and host one-on-one meetings at the following investor conferences. A live webcast of the fireside chats will be accessible through the Investors & Media section of the Company's website at http://investors.vaxcyte.com for approximately 30 days following each conference.

- **Cowen 44th Annual Health Care Conference, March 4-6, 2024*:*** Fireside Chat will take place live on Tuesday, March 5 at 2:10 p.m. ET.

- **Leerink Global Biopharma Conference, March 11-13, 2024:** Fireside Chat will take place live on Tuesday, March 12 at 8:40 a.m. ET.

- **Jefferies Biotech on the Bay Summit, March 11-13, 2024:** One-on-one investor meetings will be held on Wednesday, March 13.

Fourth Quarter and Full Year 2023 Financial Results

- ***Cash Position:*** Cash, cash equivalents and investments were $1,242.9 million as of December 31, 2023, compared to $957.9 million as of December 31, 2022. The December 31, 2023 balance excludes approximately $816.5 million in net proceeds from the Company's underwritten public offering completed in February 2024.

- ***Research & Development (R&D) Expenses:*** R&D expenses were $104.1 million for the three months ended December 31, 2023 and $332.3 million for the full year 2023 as compared to $51.6 million and $169.5 million, respectively, for the same periods in 2022. The increase for the year ended December 31, 2023 was due primarily to higher manufacturing expenses related to the planned adult Phase 3 clinical trials and the potential commercial launches of the Company's PCV programs, as well as an increase in personnel expenses related to the growth in R&D employees.

- ***Acquired Manufacturing Rights:*** Acquired manufacturing rights expenses of $75.0 million for the three months and full year ended December 31, 2023 related to the exercise of the option with Sutro Biopharma, of which $50.0 million was paid in cash in the fourth quarter of 2023. Acquired manufacturing rights expenses of $23.0 million for the three months and full year ended December 31, 2022 related to the upfront consideration incurred in connection with the original option

agreement entered into with Sutro Biopharma.

- ***General & Administrative (G&A) Expenses:*** G&A expenses were $17.5 million for the three months ended December 31, 2023 and $60.7 million for the full year 2023 as compared to $12.0 million and $39.8 million, respectively, for the same periods in 2022. The increase for the year ended December 31, 2023 was due primarily to higher personnel expenses related to the growth in G&A employees.

- ***Net Loss:*** For the three months and year ended December 31, 2023, net loss was $180.8 million and $402.3 million, respectively, compared to $78.1 million and $223.5 million for the same periods in 2022.

- ***Commercial Manufacturing Suite:*** In the fourth quarter of 2023, construction and buildout commenced on the manufacturing suite to support the potential global commercialization of Vaxcyte's PCV programs in connection with the commercial manufacturing agreement Vaxcyte entered into with Lonza in October 2023. As of December 31, 2023, Vaxcyte had incurred $86.5 million of capital and facility buildout expenditures that were reflected on the Company's consolidated balance sheet as of that date.

Conference Call and Webcast
Vaxcyte will host a conference call and webcast to discuss this announcement today, February 27, 2024, at 4:30 p.m. ET / 1:30 p.m. PT. To participate in the conference call, please dial 800-225-9448 (domestic) or 203-518-9708 (international) and refer to conference ID PCVXQ423. A live webcast of the conference call will be available in the Investors & Media section of the Company's website at www.vaxcyte.com. After the live webcast, the event will remain archived on Vaxcyte's website for 30 days.

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 Phase 3-ready 24-valent, broad-spectrum, carrier-sparing PCV being developed for the prevention of IPD. VAX-31, the Company's next-generation 31-valent PCV, is the broadest-spectrum PCV candidate in the clinic today. Both VAX-24 and VAX-31 are designed to improve upon the standard-of-care PCVs for both children and adults by covering the serotypes that are responsible for a significant portion of IPD in circulation and are associated with high case-fatality rates, antibiotic resistance and meningitis, while maintaining coverage of previously circulating strains that are currently contained through continued vaccination practice.

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-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 candidate 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 and VAX-31, including breadth of coverage, the ability to deliver a potentially best-in-class PCV franchise and the improvement upon the standard-of-care; the process and timing of anticipated future development of Vaxcyte's vaccine candidates; the advancement of either VAX-24 or VAX-31 into a Phase 3 adult clinical program, and the timing of such studies and their data readouts; the design, timing and availability of data for the VAX-24 infant Phase 2 study; the design, timing and availability of data for the VAX-31 adult Phase 1/2 study;; the timing of a potential BLA submission for VAX-24 or VAX-31; the demand for Vaxcyte's vaccine candidates; the potential global commercialization of Vaxcyte's PCV candidates in both the adult and pediatric populations; Vaxcyte's ability to establish global commercial manufacturing capacity for its PCV candidates; Vaxcyte's plans to utilize existing Lonza infrastructure to advance clinical development and support the anticipated initial U.S. launch of VAX-24 or VAX-31 for the adult population; 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; 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, 2024 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,		
	2023	**2022**	**2021**
Operating expenses:			
Research and development (1)	$ 332,341	$ 169,451	$ 78,411
Acquired manufacturing rights	75,000	22,995	-
General and administrative (1)	60,700	39,810	25,259
Total operating expenses	468,041	232,256	103,670
Loss from operations	(468,041)	(232,256)	(103,670)
Other income (expense), net			
Interest expense	-	(2)	(7)
Interest income	62,907	8,356	344
Grant income	4,765	1,931	1,585
Realized gains on marketable securities	-	-	2
Loss on disposal of fixed assets	-	(44)	-
Foreign currency transaction (losses) gains	(1,897)	(1,470)	1,669
Total other income (expense), net	65,775	8,771	3,593
Net loss	$ (402,266)	$ (223,485)	$ (100,077)
Net loss per share, basic and diluted	$ (4.14)	$ (3.44)	$ (1.93)
Weighted-average shares outstanding, basic and diluted	97,157,690	64,877,988	51,922,108

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

Research and development	$ 23,275	$ 9,899	$ 3,954
General and administrative	25,485	13,751	6,775
Total stock-based compensation expense	$ 48,760	$ 23,650	$ 10,729

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

	December 31,	
	2023	**2022**
Cash, cash equivalents and investments	$ 1,242,902	$ 957,925
Total assets	1,407,917	1,006,178
Total stockholders' equity	1,240,468	953,613