Vaxcyte Reports Fourth Quarter and Full Year 2024 Financial Results and Provides Business Update

February 25, 2025

-- Completed Successful VAX-31 Phase 2 Adult Program; Company Remains on Track to Initiate VAX-31 Adult Phase 3 Pivotal, Non-Inferiority Study by Mid-2025 and Announce Topline Safety, Tolerability and Immunogenicity Data in 2026 --

-- Company Expects to Announce Topline Safety, Tolerability and Immunogenicity Data from Primary Immunization Series of VAX-24 Infant Phase 2 Study by the End of First Quarter, Followed by Topline Data from Booster Dose by the End of 2025 --

-- Initiated Second and Final Stage of VAX-31 Infant Phase 2 Study; Topline Safety, Tolerability and Immunogenicity Data from Primary Immunization Series Expected in Mid-2026, Followed by Topline Data from Booster Dose Approximately Nine Months Later --

-- Raised Approximately $2.2 Billion in Net Proceeds in Two Follow-On Equity Offerings in 2024; $3.1 Billion in Cash, Cash Equivalents and Investments as of December 31, 2024 --

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

SAN CARLOS, Calif., Feb. 25, 2025 (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, 2024, and provided a business update.

"We continue to make meaningful progress across the adult and infant clinical programs for our broad-spectrum pneumococcal conjugate vaccine (PCV) candidates, and based on the positive results from the VAX-31 and VAX-24 adult studies, we believe that our carrier-sparing platform has the potential to set a new standard in disease coverage," said Grant Pickering, Chief Executive Officer and Co-Founder of Vaxcyte. "For the adult indication, we remain on track to initiate the VAX-31 adult Phase 3 pivotal, non-inferiority study by mid-2025, with topline data expected in 2026. For the pediatric indication, we expect to announce the topline safety, tolerability and immunogenicity data from the VAX-24 infant Phase 2 study primary immunization series by the end of the first quarter, followed by topline data from the booster dose by the end of 2025. We also recently advanced the VAX-31 infant Phase 2 study to the second and final stage and expect topline data for the primary immunization series in mid-2026."

"Vaxcyte's financial position has been further strengthened with the completion of two follow-on equity offerings last year that generated $2.2 billion in net proceeds," said Andrew Guggenhime, President and Chief Financial Officer of Vaxcyte. "The strength of our balance sheet enables continued momentum in several areas, including advancing our PCV franchise with multiple adult and infant clinical studies, establishing global manufacturing readiness for our current PCVs and growing our organization to support these initiatives. We are also investing in our early-stage pipeline, including candidates targeting Group A Strep and Shigella, which, along with Streptococcus pneumoniae, are among the World Health Organization's top antibiotic-resistant pathogens requiring urgent solutions."

Key 2024 and 2025 to Date Highlights

PCV Franchise Adult Indication:

- ***Reported Positive Topline Data from Phase 1/2 Study of VAX-31, Company's 31-Valent PCV Candidate, in Adults Aged 50 and Older:*** In September 2024, Vaxcyte announced positive topline results from the Phase 1/2 study evaluating the safety, tolerability and immunogenicity of VAX-31 in 1,015 healthy adults aged 50 and older. Based on the strength of the results from this study, the Company selected VAX-31 to exclusively advance to an adult Phase 3 program.
  In the Phase 1/2 study, VAX-31 was observed to be well tolerated and demonstrated a safety profile at all doses studied through the full six-month evaluation period similar to Prevnar 20® (PCV20). VAX-31 showed robust opsonophagocytic activity (OPA) immune responses for all 31 serotypes at all doses studied. For all 11 incremental serotypes unique to VAX-31, and not in PCV20, all three doses met the superiority criteria(1). At the middle and high doses, VAX-31 met or exceeded the OPA response non-inferiority criteria(2) for all 20 serotypes common with PCV20. At the VAX-31 high dose, average OPA immune responses were greater for 18 of 20 serotypes compared to PCV20 (geometric mean ratio (GMR) greater than 1.0), with seven of these serotypes achieving statistically higher immune responses(3) compared to PCV20. At the middle dose, 13 of 20 serotypes had a GMR greater than 1.0 and five serotypes achieved statistically higher immune responses compared to PCV20.
- ***VAX-31 Granted Breakthrough Therapy Designation from the FDA for the Prevention of IPD in Adults:*** In November 2024, Vaxcyte announced that the U.S. Food and Drug Administration (FDA) granted Breakthrough Therapy designation (BTD) for VAX-31 for the prevention of IPD in adults. The FDA's decision was informed by the positive topline results from the VAX-31 Phase 1/2 study in adults. With BTD, Vaxcyte has access to all 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.

- ***Positive Results from VAX-24 Phase 2 Study in Adults Aged 65 and Older Published in the Journal Vaccine Add to Body of Evidence Validating the Potential of the Company's Carrier-Sparing Platform:*** In July 2024, the safety, tolerability and immunogenicity results from the VAX-24 Phase 2 study in adults aged 65 and older were published in the journal *Vaccine*. In the study, VAX-24, the Company's 24-valent PCV candidate, demonstrated a safety and tolerability profile similar to PCV20 across all doses studied. VAX-24 also demonstrated robust OPA immune responses for all 24 serotypes at all doses studied, confirming the prior VAX-24 study results in adults 50 to 64 years of age.

PCV Franchise Infant Indication:

- ***Completed Enrollment of Phase 2 Study Evaluating VAX-24 for the Prevention of IPD in Infants:*** In March 2024, Vaxcyte announced the completion of enrollment in its Phase 2 clinical study evaluating VAX-24 in 802 healthy infants. The ongoing Phase 2 clinical study is evaluating the safety, tolerability and immunogenicity of VAX-24 compared to PCV20 in Stage 2 of the study, following the evaluation of VAX-24 compared to VAXNEUVANCE™ (PCV15) in Stage 1, which was the broadest-spectrum PCV at the time of study initiation. Additional information about the study can be found at www.clinicaltrials.gov under the identifier NCT05844423.
- ***Initiated Phase 2 Study Evaluating VAX-31 for the Prevention of IPD in Infants and Advanced to Second and Final Stage:***
  - In November 2024, Vaxcyte announced FDA clearance of the VAX-31 Investigational New Drug application for the prevention of IPD in infants. The FDA's decision was supported by the positive topline safety, tolerability and immunogenicity results from the VAX-31 adult Phase 1/2 study.
  - In December 2024, Vaxcyte announced the initiation of the first stage of the VAX-31 Phase 2 study in healthy infants. This study is evaluating the safety, tolerability and immunogenicity of VAX-31 compared to PCV20.
  - In February 2025, Vaxcyte announced that the VAX-31 infant study had progressed to the second and final stage. Advancement to Stage 2 followed a blinded assessment of the Stage 1 safety and tolerability data per the study protocol. Additional information about the study can be found at www.clinicaltrials.gov under the identifier NCT06720038.

Equity Financings:

- ***Completed Two Successful Follow-On Financings Totaling Approximately $2.4 Billion in Gross Proceeds, Further Strengthening Vaxcyte's Balance Sheet:***
  - In September 2024, Vaxcyte completed an underwritten public offering of 12,087,378 shares of common stock, which included the full exercise of the underwriters' option to purchase an additional 1,893,203 shares, at a public offering price of $103.00 per share and pre-funded warrants to purchase 2,427,184 shares of common stock at a public offering price of $102.999 per pre-funded warrant. The aggregate gross proceeds to Vaxcyte from this offering were approximately $1.5 billion, before deducting underwriting discounts and commissions and other offering expenses payable by Vaxcyte.
  - 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 an additional 1,757,812 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.

Executive Leadership Team and Board of Directors Appointments:

- ***Strengthened Leadership Team and Board of Directors:***
  - In January 2025, Vaxcyte appointed two leaders.
    - Harp Dhaliwal was named the Company's Chief Technical Operations Officer. Mr. Dhaliwal has more than 25 years of experience in engineering, operations strategy, manufacturing and supply chain to establish launch and global supply capacity for multiple major biopharmaceutical products. During his tenure with Vaxcyte, Mr. Dhaliwal's leadership and expertise have been instrumental in scaling the organization to prepare for the potential global commercialization of the Company's PCVs.
    - Roger Nosal was appointed as Vaxcyte's Head of Global Regulatory and Quality Assurance. Mr. Nosal brings over 40 years of expertise focused on chemistry, manufacturing and controls product development and global regulatory product approvals across many therapeutics and vaccines, including PCVs. He will provide vital insights to optimize the Company's late-stage, global clinical trial development and execution.
  - In January 2024, Vaxcyte announced the appointment of Whitney Jones as Chief People Officer. Ms. Jones is a seasoned executive with over 20 years of experience spanning biotech, healthcare diagnostics, financial technology and retail with extensive expertise in human resources strategy and operations.
  - In July 2024, Vaxcyte appointed John Furey to its Board of Directors. Mr. Furey is an accomplished executive with

over 30 years of experience in operational strategy, commercial and technical leadership and vaccine development. He brings a wealth of biopharmaceutical expertise, including the manufacture, supply and commercialization of PCVs. Mr. Furey currently serves as Chief Executive Officer of Imvax, a clinical-stage biotechnology company developing novel immunotherapies for cancer.

Anticipated Key Milestones

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

PCV Franchise Adult Indication

VAX-31

- Following an FDA End-of-Phase 2 meeting, initiate a Phase 3 pivotal, non-inferiority study by mid-2025 and announce topline safety, tolerability and immunogenicity data in 2026.
- Initiate the remaining Phase 3 studies in 2025 and 2026 and announce data from these studies in 2026 and 2027.

PCV Franchise Infant Indication

VAX-24

- Announce topline safety, tolerability and immunogenicity data from the primary three-dose immunization series of the Phase 2 study, which is fully enrolled with 802 healthy infants, by the end of the first quarter of 2025, followed by topline data from the booster dose by the end of 2025.

VAX-31

- Announce topline safety, tolerability and immunogenicity data from the ongoing VAX-31 infant Phase 2 study primary three-dose immunization series in mid-2026, followed by topline data from the booster dose approximately nine months later.

Upcoming 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 45th Annual Health Care Conference, March 3-5, 2025*:*** Fireside Chat will take place live on Tuesday, March 4 at 1:50 p.m. ET.
- **Leerink Global Healthcare Conference, March 10-12, 2025:** Fireside Chat will take place live on Tuesday, March 11 at 2:20 p.m. ET.
- **Jefferies Biotech on the Beach Summit, March 11-12, 2025:** One-on-one investor meetings will be held on Wednesday, March 12.
- **Needham 24th Annual Virtual Healthcare Conference, April 7-10, 2025:** Fireside Chat will take place live on Monday, April 7 at 1:30 p.m. ET.

Fourth Quarter and Full Year 2024 Financial Results

- ***Cash Position:*** Cash, cash equivalents and investments were $3,134.7 million as of December 31, 2024, compared to $1,242.9 million as of December 31, 2023. The increase was primarily due to the $2.2 billion in net proceeds from two follow-on financings in 2024.
- ***Research & Development (R&D) Expenses:*** R&D expenses were $133.6 million for the three months ended December 31, 2024 and $476.6 million for the full year 2024 as compared to $104.1 million and $332.3 million, respectively, for the same periods in 2023. The increase for the year ended December 31, 2024 was due primarily to increased development and manufacturing activities in connection with the adult and infant PCV programs, including to support the potential future commercial launches, as well as an increase in personnel expenses related to the growth in R&D employees.
- ***General & Administrative (G&A) Expenses:*** G&A expenses were $28.5 million for the three months ended December 31, 2024 and $92.9 million for the full year 2024 as compared to $17.5 million and $60.7 million, respectively, for the same periods in 2023. The increase for the year ended December 31, 2024 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, 2024, net loss was $137.1 million and $463.9 million, respectively, compared to $180.8 million and $402.3 million for the same periods in 2023.
- ***Commercial Manufacturing Suite:*** For the three months and year ended December 31, 2024, Vaxcyte incurred an additional $33.0 million and $127.8 million in capital and facility buildout expenditures, respectively, related to the ongoing construction of the dedicated manufacturing suite at Lonza intended to support the potential global commercialization of the

Company's PCV programs. As of December 31, 2024, Vaxcyte had incurred $214.3 million in total capital and facility buildout expenditures that were reflected on the Company's balance sheet as of that date.

Conference Call and Webcast
Vaxcyte will host a conference call and webcast to discuss this announcement today, February 25, 2025, 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 PCVXQ424. 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. VAX-31, a 31-valent PCV candidate advancing to a Phase 3 adult clinical program and currently being evaluated in a Phase 2 infant clinical program, is being developed for the prevention of IPD in adults and infants and is the broadest-spectrum PCV candidate in the clinic today. VAX-24, the Company's 24-valent PCV candidate, is designed to cover more serotypes than any infant PCV on-market and is currently being evaluated in a Phase 2 infant study. Both VAX-31 and VAX-24 are designed to improve upon the standard-of-care PCVs by covering the serotypes in circulation that are responsible for a significant portion of IPD 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 potentially best-in-class PCVs, improve upon the standard-of-care and set a new standard for immunogenicity and disease coverage; the process and timing of anticipated future development of Vaxcyte's vaccine candidates; the initiation of VAX-31 adult Phase 3 studies and the timing of such studies and their data readouts; the timing and availability of data for the VAX-24 and VAX-31 infant Phase 2 studies; the ability to maintain continued positive momentum across the PCV franchise; the potential of the Company's site-specific, carrier-sparing platform; the demand for Vaxcyte's vaccine candidates; Vaxcyte's ability to establish global commercial manufacturing capacity for its PCV candidates; 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 25, 2025 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.

(1) Lower bound of the 2-sided 95% confidence interval of the difference in the proportions of participants with a ≥4-fold increase from Day 1 to Month 1 is greater than 10%, and lower bound of the 2-sided 95% confidence interval of the OPA geometric mean ratio is greater than 2.0.
(2) Lower bound of the 2-sided 95% confidence interval of the OPA geometric mean ratio is greater than 0.5.
(3) Lower bound of the 2-sided 95% confidence interval of the OPA geometric mean ratio is greater than 1.0.

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Vaxcyte, Inc.
Condensed Statements of Operations

(in thousands, except share and per share amounts)

	Year Ended December 31,		
	2024	**2023**	**2022**
Operating expenses:			
Research and development (1)	$ 476,644	$ 332,341	$ 169,451
Acquired manufacturing rights	-	75,000	22,995
General and administrative (1)	92,902	60,700	39,810
Total operating expenses	569,546	468,041	232,256
Loss from operations	$ (569,546)	$ (468,041)	$ (232,256)
Other income (expense), net			
Interest expense	-	-	(2)
Interest income	109,994	62,907	8,356
Other income (expense)	(4,375)	2,868	417
Total other income (expense), net	105,619	65,775	8,771
Net loss	$ (463,927)	$ (402,266)	$ (223,485)
Net loss per share, basic and diluted	$ (3.80)	$ (4.14)	$ (3.44)
Weighted-average shares outstanding, basic and diluted	121,997,348	97,157,690	64,877,988

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

Research and development	$ 42,819	$ 23,275	$ 9,899
General and administrative	42,003	25,485	13,751
Total stock-based compensation expense	$ 84,822	$ 48,760	$ 23,650

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

	December 31,	
	2024	**2023**
Cash, cash equivalents and investments	$ 3,134,718	$ 1,242,902
Total assets	3,511,318	1,407,917
Total stockholders' equity	3,305,819	1,240,468