Vaxcyte Reports Third Quarter 2024 Financial Results and Provides Business Update

November 5, 2024

-- Company Reported Positive Topline Safety, Tolerability and Immunogenicity Data from Phase 1/2 Study of VAX-31, its 31-Valent Pneumococcal Conjugate Vaccine (PCV) Candidate, in Adults Aged 50 and Older --

-- PCV Adult Indication: VAX-31 Selected to Advance to Phase 3 Program; Initiation of Phase 3 Pivotal, Non-Inferiority Study Expected by Mid-2025 and Announcement of Topline Safety, Tolerability and Immunogenicity Data in 2026 --

-- PCV Pediatric Indication: VAX-24 Infant Phase 2 Study Topline Data from Primary Immunization Series Expected by End of First Quarter of 2025; Initiation of VAX-31 Infant Phase 2 Study Expected in First Quarter of 2025 Subject to IND Application Clearance by Year-End 2024 --

-- $3.3 Billion in Cash, Cash Equivalents and Investments as of September 30, 2024, Including Net Proceeds of $1.4 Billion from September Public Offering --

SAN CARLOS, Calif., Nov. 05, 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 third quarter ended September 30, 2024, and provided a business update.

“We are exceptionally proud of the significant progress we have made across the adult and infant clinical programs for our broad-spectrum, carrier-sparing pneumococcal conjugate vaccine (PCV) candidates, VAX-31 and VAX-24,” said Grant Pickering, Chief Executive Officer and Co-Founder of Vaxcyte. “We believe the recent topline results for VAX-31 in adults demonstrate its potential as a best-in-class PCV to provide protection against both currently circulating and historically prevalent strains while setting a new standard for immunogenicity. For the adult indication, we look forward to moving VAX-31 into a Phase 3 program and plan to initiate the pivotal non-inferiority study by mid-2025. For the pediatric indication, we anticipate delivering the topline data from the primary immunization series of the VAX-24 Phase 2 study by the end of the first quarter of 2025, followed by topline data from the booster dose by the end of 2025. In addition, we plan to initiate the VAX-31 infant Phase 2 study in the first quarter of 2025, subject to IND application clearance by the end of this year.”

“On the heels of our positive VAX-31 data, we completed a follow-on equity offering, raising $1.4 billion in net proceeds and further bolstering our balance sheet,” said Andrew Guggenhime, President and Chief Financial Officer of Vaxcyte. “We are well-positioned to maintain continued positive momentum across our PCV franchise, including the advancement of multiple adult and infant clinical studies and key steps to ensure global manufacturing readiness for the large, well-established pediatric population and the expanding adult market. We also continue to invest 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 Third Quarter and Recent 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, designed to prevent invasive pneumococcal disease (IPD), 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. At the middle and high doses, VAX-31 met or exceeded the OPA response non-inferiority criteria(1) 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(2) 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. For all 11 incremental serotypes unique to VAX-31, and not in PCV20, all three doses met the superiority criteria(3).

  The public health community continues to call for pneumococcal vaccines with broader serotype and disease coverage. VAX-31 has the potential to provide, in a single vaccine, over 95% coverage of IPD in U.S. adults today, with the potential to offer much greater coverage relative to any of today’s PCVs and maintain pressure on historically circulating strains.

- ***Positive Results from VAX-24 Phase 2 Study in Adults Aged 65 and Older Published in the Journal Vaccine Adds 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. The body of evidence derived from the two VAX-24 adult Phase 2 studies and the VAX-31 adult study validates the potential of the Company's site-specific, carrier-sparing platform to deliver broad-spectrum PCVs that provide protection against both currently circulating and historically prevalent strains.

PCV Franchise Infant Indication:

- ***Completed Successful Pre-Investigational New Drug (IND) Meeting with FDA Regarding VAX-31 Pediatric Development Program:*** In August 2024, the Company successfully completed a pre-IND meeting with the FDA regarding the pediatric clinical program for VAX-31. Vaxcyte received written feedback from the FDA supporting the initiation of a pediatric study that proceeds directly into infants, an approach consistent with the infant clinical program currently underway for VAX-24. This approach provides a streamlined clinical path for the company to deliver VAX-31, a potentially best-in-class PCV, to the pediatric population, which represents the largest portion of the pneumococcal vaccine market in the United States. VAX-31 was designed to cover approximately 94% of IPD and approximately 86% of acute otitis media in children under five years of age, with the goal of providing protection against both currently circulating and historically prevalent strains.

Equity Financing:

- ***Completed Follow-On Financing Totaling $1.5 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 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. This includes the exercise in full by the underwriters of their option to purchase up to 1,893,203 additional shares of common stock at the public offering price per share, less underwriting discounts and commissions. The aggregate gross proceeds to Vaxcyte from this offering were $1.5 billion, 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:

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 remaining Phase 3 studies in 2025 and 2026.

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

- Initiate Phase 2 study in the first quarter of 2025 subject to clearance of the IND application by year-end 2024.
- Announce topline safety, tolerability and immunogenicity data from the 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

During the fourth quarter, Company management will participate in fireside chats and host one-on-one meetings at the following investor conferences, and 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:

- **Guggenheim Healthcare Innovation Conference, November 11-13:** Fireside chat will take place live on Tuesday, November 12, at 1:30 p.m. ET / 10:30 a.m. PT.
- **Jefferies London Healthcare Conference, November 19-21:** Fireside chat will take place live on Wednesday, November

20, at 10:00 a.m. GMT / 5:00 a.m. ET.
- **Evercore ISI HealthCONx Conference, December 3-5:** Fireside chat will take place live on Tuesday, December 3, at 12:30 p.m. ET / 9:30 a.m. PT.

Third Quarter 2024 Financial Results

- ***Cash Position:*** Cash, cash equivalents and investments were $3,273.0 million as of September 30, 2024, compared to $1,242.9 million as of December 31, 2023.
- ***Research & Development (R&D) Expenses:*** R&D expenses were $116.9 million for the three months ended September 30, 2024 as compared to $97.4 million for the same period in 2023. The increase was due primarily to personnel expenses related to the growth in the number of R&D employees.
- ***General & Administrative (G&A) Expenses:*** G&A expenses were $23.0 million for the three months ended September 30, 2024, as compared to $15.6 million for the same period in 2023. The increase was due primarily to higher personnel expenses related to the growth in the number of G&A employees.
- ***Net Loss:*** For the three months ended September 30, 2024, net loss was $103.1 million, compared to $92.7 million for the same period in 2023.
- ***Commercial Manufacturing Suite:*** In the third quarter of 2024, Vaxcyte incurred an additional $41.3 million in capital and facility buildout expenditures 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 September 30, 2024, Vaxcyte had incurred $181.3 million in total capital and facility buildout expenditures that were reflected on the Company's balance sheet as of that date.

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 is a Phase 3-ready 31-valent, carrier-sparing PCV 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, and improve upon the standard-of-care and set a new standard for immunogenicity; the process and timing of anticipated future development of Vaxcyte's vaccine candidates; the initiation of VAX-31 adult Phase 3 studies and an infant Phase 2 study, and the timing of such studies and their data readouts; the timing and availability of data for the VAX-24 infant Phase 2 study; 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 Quarterly Report on Form 10-Q filed with the SEC on November 5, 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.

(1) Lower bound of the 2-sided 95% confidence interval of the OPA geometric mean ratio is greater than 0.5.

(2) Lower bound of the 2-sided 95% confidence interval of the OPA geometric mean ratio is greater than 1.0.

(3) 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.

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Vaxcyte, Inc.
Condensed Consolidated Statements of Operations
(in thousands, except share and per share amounts)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	**2023**	**2024**	**2023**
Operating expenses:				
Research and development (1)	$ 116,936	$ 97,421	$ 343,030	$ 228,191
General and administrative (1)	22,988	15,605	64,347	43,174
Total operating expenses	139,924	113,026	407,377	271,365
Loss from operations	(139,924)	(113,026)	(407,377)	(271,365)
Other income, net:				
Interest income	28,057	18,495	73,536	45,339
Grant income	292	1,640	812	4,759
Realized gains on marketable securities	1	-	50	-
Foreign currency transaction losses	8,450	227	6,132	(198)
Total other income, net	36,800	20,362	80,530	49,900
Net loss	$ (103,124)	$ (92,664)	$ (326,847)	$ (221,465)
Net loss per share, basic and diluted	$ (0.83)	$ (0.91)	$ (2.78)	$ (2.32)
Weighted-average shares outstanding, basic and diluted	123,693,461	101,668,655	117,569,424	95,367,751

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

Research and development	$ 10,860	$ 6,335	$ 30,533	$ 16,773
General and administrative	10,405	6,885	29,919	18,639
Total stock-based compensation expense	$ 21,265	$ 13,220	$ 60,452	$ 35,412

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

	September 30, 2024	December 31, 2023
Cash, cash equivalents and investments	$ 3,273,039	$ 1,242,902
Total assets	3,559,746	1,407,917
Total stockholders' equity	3,417,634	1,240,468