Vaxcyte Reports First Quarter 2025 Financial Results and Provides Business Update

May 7, 2025

-- Company Reported Positive Topline Safety, Tolerability and Immunogenicity Data from Phase b2 Dose-Finding Study of VAX-24 in Healthy Infants; Balance of Data Expected by End of 2025 --

-- Initiated Second and Final Stage of VAX-31 Infant Phase 2 Dose-Finding Study; Topline Safety, Tolerability and Immunogenicity Data from Primary Three-Dose Immunization Series Expected in Mid-2026, With Complete Booster Data Up to Nine Months Later --

-- Company Expects to Initiate VAX-31 Adult Phase 3 Pivotal, Non-Inferiority Study by Mid-2025 and Announce Topline Safety, Tolerability and Immunogenicity Data in 2026 --

-- Announced VAX-XL, Third-Generation Pneumococcal Conjugate Vaccine Candidate Designed to Further Expand Spectrum of Coverage --

-- Approximately $3.0 Billion in Cash, Cash Equivalents and Investments as of March 31, 2025 --

SAN CARLOS, Calif., May 07, 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 first quarter ended March 31, 2025, and provided a business update.

"We continue to make meaningful progress across our pneumococcal conjugate vaccine (PCV) candidates, with each milestone bringing us closer to potentially delivering the broadest-spectrum PCVs to address the substantial invasive pneumococcal disease burden in both adults and infants," said Grant Pickering, Chief Executive Officer and Co-founder of Vaxcyte. "For the adult indication, we expect to initiate the VAX-31 adult Phase 3 pivotal, non-inferiority study by the middle of this year with topline data expected next year. For the pediatric indication, we expect to announce the balance of the VAX-24 infant Phase 2 dose-finding study data by the end of 2025 and share topline data from the VAX-31 infant Phase 2 dose-finding study primary immunization series in mid-2026, followed by complete booster data up to nine months later. Pending the VAX-31 infant study readout, we plan to initiate a Phase 3 program with an optimized dose formulation of VAX-24 or VAX-31."

"With a strong balance sheet totaling approximately $3.0 billion in cash, cash equivalents and investments, we are well-positioned to continue advancing our PCV pipeline, which we believe has the potential to redefine the standard of protection against devastating diseases caused by *Streptococcus pneumoniae*," said Andrew Guggenhime, President and Chief Financial Officer of Vaxcyte. "As we enter this next chapter of growth within a dynamic macro environment, we are evaluating our investment priorities and allocation of capital to ensure the continued strength of our balance sheet and to deliver on the promise of our PCV franchise."

Key First Quarter Highlights

PCV Franchise

- ***Reported Positive Topline Results from VAX-24 Infant Phase 2 Dose-Finding Study:*** *In March 2025, Vaxcyte announced positive topline results from the Phase 2 dose-finding study evaluating the safety, tolerability and immunogenicity of VAX-24, the Company's 24-valent PCV candidate, in healthy infants. In this study, VAX-24 was well-tolerated and demonstrated a safety profile similar to Prevnar 20® (PCV20) across all doses studied.*
  - All VAX-24 doses evaluated (Low: 1.1 mcg, Mid: 2.2mcg and Mixed: 2.2mcg/4.4mcg) elicited substantial immunoglobulin G (IgG) and opsonophagocytic assay (OPA) immune responses at 1-month post-dose 3 (primary immunization series):
    - Post-dose 3, the VAX-24 Mid dose met target precedent Phase 2 non-inferiority (NI) criteria on relative seroconversion rates[(1)], particularly for the highest circulating serotypes[(2)] contained in VAX-24 and for 20 of 24 serotypes overall. The Mid dose also met the Company's historical target Phase 2 IgG Geometric Mean Ratio (GMR) point estimate of >0.6[(3)] on all currently circulating serotypes contained in VAX-24 and for 22 of 24 serotypes overall.
    - Interim post-dose 3 data demonstrated that VAX-24 generated robust OPA responses, which are correlated with effectiveness against IPD, across all serotypes and doses.
    - The four serotypes unique to VAX-24 elicited robust immune responses and met all target criteria across all endpoints at all doses evaluated post-dose 3.
    - Dose-dependent immune responses were consistently demonstrated at 1.1mcg, 2.2mcg and 4.4mcg doses and little to no carrier suppression was observed.
  - Full post-dose 4 booster data is expected by the end of 2025. An interim assessment of the IgG results was performed with then-available study samples:

    - The Mid dose met the Company's historical target Phase 2 IgG GMR point estimate of >0.6 for the highest circulating serotypes contained in VAX-24 and for 19 of 24 serotypes overall.
    - VAX-24 elicited robust memory responses across all doses for all serotypes, as evidenced by the boost demonstrated post-dose 4 for IgG responses relative to post-dose 3 IgG responses.
- ***Advanced to Second and Final Stage of VAX-31 Infant Phase 2 Dose-Finding Study:*** In February 2025, Vaxcyte announced that the VAX-31 infant Phase 2 dose-finding study had progressed to the second and final stage. This study is evaluating the safety, tolerability and immunogenicity of VAX-31 compared to PCV20 in healthy infants. Advancement to Stage 2 followed a blinded assessment of the Stage 1 safety and tolerability data in infants per the study protocol. Based on the positive safety, tolerability and immunogenicity data demonstrated in adults with the VAX-31 program, this ongoing study is testing higher doses for most serotypes relative to the VAX-24 program. Additional information about the study can be found at www.clinicaltrials.gov under the identifier NCT06720038.
- ***Announced VAX-XL, Third-Generation PCV Candidate Designed to Further Expand Spectrum of Coverage:*** In March 2025, Vaxcyte announced VAX-XL, its third-generation PCV candidate designed to provide the broadest coverage of any PCV currently in development for infants or adults.

Board of Directors Appointment

- ***Appointed Dr. Olivier Brandicourt:*** In May 2025, Vaxcyte appointed Dr. Olivier Brandicourt to its Board of Directors. Dr. Brandicourt is a veteran biopharmaceutical industry executive and the former Chief Executive Officer of Sanofi S.A. and Bayer HealthCare AG. He brings a wealth of expertise, with significant experience in commercial strategy and execution within the global vaccine market. Dr. Brandicourt is currently a Senior Advisor at Blackstone Life Sciences and serves on the boards of Alnylam Pharmaceuticals, Inc., AvenCell Therapeutics, Inc., BeOne Medicines Ltd. and Dewpoint Therapeutics, Inc.

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

The Company plans to initiate an infant Phase 3 program with an optimized dose formulation of VAX-24 or VAX-31, pending the VAX-31 topline Phase 2 dose-finding study readout.

VAX-24

- Announce the balance of the VAX-24 Phase 2 dose-finding study data, including final safety data, full post-dose 3 OPA data, and full post-dose 4 IgG and OPA data, by end of 2025.

VAX-31

- Announce topline safety, tolerability and immunogenicity data for the Phase 2 dose-finding study primary three-dose immunization series in mid-2026, with complete booster data up to nine months later.

Upcoming May and June 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.

- **BofA Securities 2025 Health Care Conference, May 13-15, 2025:** Fireside Chat will take place live on Tuesday, May 13 at 8:40 a.m. PT / 11:40 a.m. ET.
- **Jefferies Global Healthcare Conference, June 3-5, 2025:** Fireside Chat will take place live on Thursday, June 5 at 6:55 a.m. PT / 9:55 a.m. ET.
- **Goldman Sachs 46th Annual Global Healthcare Conference, June 9-11, 2025:** Fireside Chat will take place live on Tuesday, June 10 at 10:20 a.m. PT / 1:20 p.m. ET.

First Quarter 2025 Financial Results

- ***Cash Position:*** Cash, cash equivalents and investments were $2,950.8 million as of March 31, 2025, compared to $3,134.7 million as of December 31, 2024.

- ***Research & Development (R&D) Expenses:*** R&D expenses were $148.1 million for the three months ended March 31, 2025 as compared to $94.6 million for the same period in 2024. The increase was due primarily to development and manufacturing activities in connection with the adult and infant PCV programs, including to support potential future commercial launches, as well as higher personnel expenses related to the growth in the number of R&D employees.
- ***General & Administrative (G&A) Expenses:*** G&A expenses were $32.7 million for the three months ended March 31, 2025 as compared to $19.9 million for the same period in 2024. 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 March 31, 2025, net loss was $140.7 million, compared to $95.0 million for the same period in 2024.
- ***Commercial Manufacturing Suite:*** In the first quarter of 2025, Vaxcyte incurred an additional $31.7 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 March 31, 2025, Vaxcyte had incurred $246.0 million in total capital and facility buildout expenditures that were reflected on the Company's balance sheet as of that date. Vaxcyte continues to expect the buildout to be completed by early 2026 at a total cost of approximately $300-350 million.

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, including the timing and availability of data for the VAX-24 and VAX-31 infant Phase 2 studies, the initiation of VAX-24 or VAX-31 infant Phase 3 studies, and the initiation of VAX-31 adult Phase 3 studies and the timing of such studies and their data readouts; the demand for Vaxcyte's vaccine 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 May 7, 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 limit of the 95% confidence interval for the difference between the proportion of participants achieving the pre-defined seroconversion rate (IgG concentration ≥0.35 mcg/mL) is > -15% for each ST (https://pmc.ncbi.nlm.nih.gov/articles/PMC7360095/). Larger Phase 3 registration studies have required that lower limit of the 95% confidence interval for the difference between the proportion of participants achieving the pre-defined seroconversion rate (IgG concentration ≥0.35 mcg/mL) is > -10% for each ST.

(2) Percentage of IPD caused in individuals <5 yrs of age in the U.S. in 2023 based on ABC surveillance data (https://data.cdc.gov/Public-Health-Surveillance/1998-2023-Serotype-Data-for-Invasive-Pneumococcal-/qvzb-qs6p/about_data).

(3) Target point estimate of 0.6 is based on the Company's statistical analysis of precedent Phase 2 and Phase 3 studies.

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

	Three Months Ended March 31,	
	2025	**2024**
Operating expenses:		
Research and development (1)	$ 148,134	$ 94,587
General and administrative (1)	32,659	19,885
Total operating expenses	180,793	114,472
Loss from operations	(180,793)	(114,472)
Other income, net:		
Interest income	32,935	21,666
Other income (expense)	7,140	(2,214)
Total other income, net	40,075	19,452
Net loss	$ (140,718)	$ (95,020)
Net loss per share, basic and diluted	$ (1.04)	$ (0.85)
Weighted-average shares outstanding, basic and diluted	135,690,949	111,690,951

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

Research and development	$ 15,925	$ 8,818
General and administrative	14,690	8,811
Total stock-based compensation expense	$ 30,615	$ 17,629

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

	March 31, 2025	**December 31, 2024**
Cash, cash equivalents and investments	$ 2,950,762	$ 3,134,718
Total assets	3,378,103	3,511,318
Total stockholders' equity	3,200,026	3,305,819