# Vaxcyte Reports Third Quarter 2025 Financial Results and Provides Business Update Including Final Data from Positive VAX-24 Infant Phase 2 Dose-Finding Study

November 4, 2025

***Final Data from VAX-24 Infant Phase 2 Dose-Finding Study Consistent with Previously Reported Positive Interim Data; Provide Additional Evidence Supporting Higher VAX-31 Doses Being Evaluated in Ongoing Infant Phase 2 Study***

***Modified VAX-31 Infant Phase 2 Dose-Finding Study Advanced to Third and Final Stage***

***Company Expects to Initiate VAX-31 Adult Pivotal, Non-Inferiority Study in December 2025 with Topline Data in 2026***

***Company Establishing Fill-Finish Manufacturing in North Carolina as Key Element of Long-Term United States Commercial Supply Strategy, Aligned with Administration's Focus on Strengthening Domestic Biomanufacturing and Representing up to $1 Billion in Manufacturing and Services***

***Company Appoints Mike Mullette as Chief Commercial Officer as it Advances VAX-31 to Phase 3 and Potential Commercialization***

***Company Remains Focused on Disciplined Capital Allocation and Prioritizing Resources for PCV Programs with Approximately $2.7 Billion in Cash, Cash Equivalents and Investments as of September 30, 2025, Expected to Fund Current Operating Plan into Mid-2028***

SAN CARLOS, Calif., Nov. 04, 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 third quarter ended September 30, 2025, and provided a business update, including the final data from the VAX-24 infant Phase 2 dose-finding study.

"We remain laser-focused on advancing the development of VAX-31, the broadest-spectrum pneumococcal conjugate vaccine (PCV) in the clinic, given its potential to substantially broaden protection against both currently circulating and historically prevalent serotypes compared to currently available PCVs," said Grant Pickering, Chief Executive Officer and Co-founder of Vaxcyte. "For the adult indication, we expect to initiate the VAX-31 pivotal, non-inferiority study in December, with additional Phase 3 study initiations in 2026. For the infant indication, the final data from our VAX-24 infant Phase 2 dose-finding study are consistent with the previously reported positive interim data and show that VAX-24 elicited robust, dose-dependent immune responses, with little to no evidence of carrier suppression observed. These results further validate our rationale for exploring higher doses in the ongoing VAX-31 infant Phase 2 dose-finding study. Together, the growing body of data from both the adult and infant programs reinforces our conviction that VAX-31 has a potential best-in-class profile."

"We continue to take a disciplined approach to capital allocation, ending the third quarter with $2.7 billion in cash, cash equivalents and investments," said Andrew Guggenhime, President and Chief Financial Officer of Vaxcyte. "With this strong financial position, we are advancing both the VAX-31 adult Phase 3 program and the infant Phase 2 study while investing in activities to help ensure commercial readiness. As part of that effort, our recent agreement to significantly expand our fill-finish manufacturing capacity in North Carolina further strengthens our supply chain and underscores our commitment to American biomanufacturing and innovation — all in service of our mission to deliver vaccines that protect against serious infectious diseases."

**Key Third Quarter and Recent Highlights**

**PCV Program Updates**

***Final VAX-24 Infant Phase 2 Dose-Finding Study Data Consistent with Previously Reported Positive Interim Data:*** In March 2025, the Company announced topline, interim data from the VAX-24 infant Phase 2 study, a randomized, observer-blind, dose-finding two-stage clinical study evaluating the safety, tolerability and immunogenicity of VAX-24 in healthy infants that enrolled 803 participants.

Today, the Company shared the final safety, tolerability, and immunogenicity results from this study that are consistent with the previously reported positive interim data and show that VAX-24 elicited robust, dose-dependent immune responses, with little to no evidence of carrier suppression observed. The totality of data from this study affirms the Company's strategy to include the higher doses that are being evaluated in the ongoing VAX-31 infant Phase 2 dose-finding study.

The final data analysis includes full 6-month safety results and complete post-dose 3 (primary immunization series) and post-dose 4 (booster dose) immunoglobulin G (IgG) and opsonophagocytic assay (OPA) results. The key immunogenicity endpoints include an assessment of immune responses for each of the VAX-24 dose levels (Low, Mid, Mixed) in comparison with Prevnar 20 (PCV20) for the 20 common and 4 unique serotypes in VAX-24. At 1-month post-dose 3 and post-dose 4, immune responses were assessed based on serotype-specific IgG seroconversion rates (IgG threshold value of ≥0.35mcg/mL). IgG Geometric Mean Ratios (GMRs) were also assessed at 1-month post-dose 3 and post-dose 4, along with other key immunogenicity endpoints, including OPA.

In this study, VAX-24 was well-tolerated and demonstrated a safety profile similar to PCV20 across all doses studied. Frequently reported local and systemic reactions were generally mild-to-moderate, resolving within several days of vaccination, with no meaningful differences observed across the cohorts. No serious adverse events were considered to be related to study vaccines. Post-dose 3 and post-dose 4, all VAX-24 doses evaluated

demonstrated robust IgG and OPA immunogenicity responses.

Post-dose 3, all VAX-24 doses met target precedent Phase 2 non-inferiority (NI) criteria on relative seroconversion rates[1] for the highest circulating serotypes[2] contained in VAX-24. The Low and Mid doses met the NI criteria for 20 of 24 serotypes overall and the Mixed dose met such criteria for 19 of 24 serotypes. The Mid and Mixed doses met the target Phase 2 IgG GMR point estimate of >0.6[3] for 21 of 24 serotypes.

Post-dose 4, all VAX-24 doses met the Company's target Phase 2 IgG GMR point estimate of >0.6 for the three highest circulating serotypes contained in VAX-24. The Mixed dose met this target for 19 of 24 serotypes overall and the Mid dose met this target for 18 of 24 serotypes. Post-dose 4, VAX-24 elicited robust memory responses across all doses for all serotypes.

Additionally, the four incremental serotypes unique to VAX-24 that provide expanded serotype coverage relative to PCV20 elicited robust immune responses and met all target criteria across all endpoints at all doses evaluated.

Additional information about the study can be found at www.clinicaltrials.gov under the identifier NCT05844423.

***Company Advanced VAX-31 Infant Phase 2 Dose-Finding Study to Third and Final Stage:*** In September 2025, the Company announced that the modified VAX-31 infant Phase 2 randomized, dose-finding study had progressed to the third and final stage. VAX-31 is designed to substantially expand coverage in the pediatric population relative to today's standard-of-care, PCV20, by adding 11 incremental serotypes with the potential to increase protection against invasive pneumococcal disease (IPD) from approximately 69% to approximately 92% of disease circulating in children under five years of age in the U.S. This study is evaluating the safety, tolerability and immunogenicity of VAX-31 compared to PCV20 in approximately 900 healthy infants. The study advanced to the final stage following protocol modifications to add a new dose arm to evaluate the VAX-31 Optimized Dose (majority of serotypes dosed at 4.4mcg and the balance dosed at 3.3mcg) and to discontinue enrollment in the Low Dose arm. The Middle and High Dose arms are continuing as planned.

Additional information about the study can be found at www.clinicaltrials.gov under the identifier NCT06720038.

**U.S. Commercial Manufacturing Expansion**

***Company Establishing Fill-Finish Manufacturing in North Carolina as Key Element of Long-Term United States Commercial Supply Strategy Representing Up to $1 Billion in Manufacturing and Services:*** In September 2025, the Company announced a new agreement with Thermo Fisher Scientific Inc. to provide custom commercial fill-finish capacity for the Company's broad-spectrum PCVs at Thermo Fisher's Greenville, North Carolina facility. This initiative, which includes both manufacturing and related services, represents a long-term U.S. commercial manufacturing commitment of up to $1 billion. Establishing this capacity strengthens the Company's supply chain, supports future commercial readiness and aligns with the Administration's focus on expanding domestic biomanufacturing infrastructure.

**Executive Leadership Team Appointment**

***Company Appointed Mike Mullette as Chief Commercial Officer to Lead Commercialization Strategy and Execution*****:** In October 2025, Mike Mullette joined Vaxcyte as Chief Commercial Officer, bringing more than 20 years of global experience in vaccines and biopharmaceuticals, including senior leadership roles at Moderna, Sanofi Pasteur and Lykos Therapeutics. As part of the Company's strategy to prepare for future commercialization of its PCV programs, Mr. Mullette will lead the continued development and execution of global commercialization, including pre-launch planning and cross-functional readiness. He brings extensive launch leadership, having led Moderna's first ever commercial organization in North America during the COVID-19 pandemic and launched multiple vaccines at Sanofi Pasteur across the U.S., France, Japan, Australia and Canada.

**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**

- Initiate the VAX-31 Phase 3 pivotal, non-inferiority study in December 2025 and announce topline safety, tolerability and immunogenicity data in 2026.
- Initiate remaining Phase 3 studies in 2026 and announce data from these studies in 2027.

**PCV Franchise Infant Indication**

**VAX-31**

- Announce topline safety, tolerability and immunogenicity data for the VAX-31 infant Phase 2 randomized, dose-finding study from both the primary three-dose immunization series and booster dose either sequentially or together by the end of the first half of 2027.

**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.

- **Guggenheim Healthcare Innovation Conference, November 10-12:** Fireside chat will take place live on Tuesday, November 11, at 2:30 p.m. ET / 11:30 a.m. PT.
- **Jefferies London Healthcare Conference, November 17-20:** Fireside chat will take place live on Wednesday, November 19, at 2:30 p.m. GMT / 9:30 a.m. ET.

- **Evercore ISI HealthCONx Conference, December 2-4:** Fireside chat will take place live on Tuesday, December 2, at 1:20 p.m. ET / 10:20 a.m. PT.

**Third Quarter 2025 Financial Results**

- ***Cash Position:*** Cash, cash equivalents and investments were $2,670.6 million as of September 30, 2025, compared to $3,134.7 million as of December 31, 2024.
- ***Research & Development (R&D) Expenses:*** R&D expenses were $209.9 million for the three months ended September 30, 2025 as compared to $116.9 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 support for 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 $32.4 million for the three months ended September 30, 2025 as compared to $23.0 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 September 30, 2025, net loss was $212.8 million, compared to $103.1 million for the same period in 2024.
- ***Commercial Manufacturing Suite:*** In the third quarter of 2025, Vaxcyte incurred an additional $23.0 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, 2025, Vaxcyte had incurred $313.7 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, with total costs expected to be up to $350 million.

**About Vaxcyte**
Vaxcyte is a vaccine innovation company engineering high-fidelity vaccines to protect humankind from the consequences of bacterial diseases. VAX-31, a 31-valent PCV candidate advancing to a Phase 3 adult clinical program and being evaluated in a Phase 2 infant clinical program, is being developed for the prevention of IPD and is the broadest-spectrum PCV candidate in the clinic today. VAX-24, a 24-valent PCV candidate, is designed to cover more serotypes than any infant PCV on-market. VAX-31 and VAX-24 are designed to improve upon standard-of-care PCVs by covering the serotypes in circulation that cause a significant portion of IPD and are associated with high case-fatality rates, antibiotic resistance and meningitis, while maintaining coverage of previously circulating strains.

Vaxcyte is re-engineering the way highly complex vaccines are made through XpressCF®, its 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 develop 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, and VAX-GI, a vaccine candidate designed to prevent Shigella. 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 Vaxcyte's carrier-sparing platform and PCV candidates, including breadth of coverage, the ability to deliver potentially best-in-class PCVs, improve upon the standard-of-care and substantially broaden protection against both currently circulating and historically prevalent serotypes; the process and timing of anticipated future development of Vaxcyte's vaccine candidates, including the timing and availability of data for the VAX-31 infant Phase 2 study, and the initiation of VAX-31 adult Phase 3 studies and the timing of such studies and their data readouts; the future commercialization of Vaxcyte's PCV programs; Vaxcyte's cash runway; 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 4, 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.

**Contacts:**

Patrick Ryan, Executive Director, Corporate Affairs
Vaxcyte, Inc.
415-606-5135
media@vaxcyte.com

Jeff Macdonald, Executive Director, Investor Relations
Vaxcyte, Inc.

917-371-0940
investors@vaxcyte.com

[1]Lower limit of the 95% confidence interval for the difference in 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 in the proportion of participants achieving the pre-defined seroconversion rate (IgG concentration ≥0.35 mcg/mL) be > -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.

**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, | |
|---|---|---|---|---|
| | **2025** | **2024** | **2025** | **2024** |
| Operating expenses: | | | | |
| Research and development[(1)] | $ 209,933 | $ 116,936 | $ 552,246 | $ 343,030 |
| General and administrative[(1)] | 32,447 | 22,988 | 97,146 | 64,347 |
| Total operating expenses | 242,380 | 139,924 | 649,392 | 407,377 |
| Loss from operations | (242,380) | (139,924) | (649,392) | (407,377) |
| Other income, net: | | | | |
| Interest income | 29,259 | 28,057 | 93,267 | 73,536 |
| Other income (expense) | 291 | 8,743 | 36,004 | 6,994 |
| Total other income, net | 29,550 | 36,800 | 129,271 | 80,530 |
| Net loss | $ (212,830) | $ (103,124) | $ (520,121) | $ (326,847) |
| Net loss per share, basic and diluted | $ (1.56) | $ (0.83) | $ (3.83) | $ (2.78) |
| Weighted-average shares outstanding, basic and diluted | 136,196,512 | 123,693,461 | 135,975,586 | 117,596,424 |

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

| | | | | |
|---|---|---|---|---|
| Research and development | $ 18,383 | $ 10,860 | $ 54,499 | $ 30,533 |
| General and administrative | 16,923 | 10,405 | 48,349 | 29,919 |
| Total stock-based compensation expense | $ 35,306 | $ 21,265 | $ 102,848 | $ 60,452 |

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

| | September 30, 2025 | December 31, 2024 |
|---|---|---|
| Cash, cash equivalents and investments | $ 2,670,576 | $ 3,134,718 |
| Total assets | 3,171,600 | 3,511,318 |
| Total stockholders' equity | 2,892,882 | 3,305,819 |