Vaxcyte Reports Second Quarter 2025 Financial Results and Provides Business Update, Highlighting Key Clinical and Regulatory Progress for VAX-31, a Potential Best-in-Class Pneumococcal Conjugate Vaccine (PCV)

August 6, 2025

Following Interactions with FDA on VAX-31 Adult Program, Including End-of-Phase 2 Meeting, Company Finalizing Phase 3 Clinical Program to Validate VAX-31 as Potential New Standard-of-Care Adult PCV; Pivotal, Non-Inferiority Study Expected to be Initiated in Fourth Quarter of 2025 with Topline Data in 2026

FDA Provided Input on VAX-31 Adult CMC Licensure Requirements Facilitating Progression to Phase 3; Company Plans to Seek Ongoing Input as Program Advances

Company Expects Multiple VAX-31 Adult Phase 3 Program Data Readouts in 2026 and 2027 to Support Biologics License Application Submission

For VAX-31 Pediatric Program, Company Modifies Ongoing Infant Phase 2 Dose-Finding Study to Add a VAX-31 Optimized Dose Arm (4.4mcg/3.3mcg) and Discontinues Enrollment of Low Dose Arm; Enrollment in Modified Study Expected to Proceed by End of Third Quarter of 2025 with Topline Data from Both Primary Immunization Series and Booster Dose by End of First Half of 2027

Company Remains Focused on Disciplined Capital Allocation; Streamlining Early-Stage Pipeline to Prioritize Resources for PCV Programs and Further Extend Cash Runway

Approximately $2.8 Billion in Cash, Cash Equivalents and Investments as of June 30, 2025

SAN CARLOS, Calif., Aug. 06, 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 second quarter ended June 30, 2025, and provided a business update, highlighting key clinical and regulatory progress for VAX-31, a potential best-in-class pneumococcal conjugate vaccine (PCV).

“We are laser-focused on advancing the development of VAX-31 in both adults and infants, given its potential to meaningfully elevate the standard-of-care by broadening protection against invasive pneumococcal disease,” said Grant Pickering, Chief Executive Officer and Co-founder of Vaxcyte. “For the adult indication, following a series of interactions with the FDA, including an End-of-Phase 2 meeting, we are finalizing the Phase 3 program, the results of which we believe could validate the best-in-class potential of VAX-31. This work includes final-stage planning for the pivotal, non-inferiority study, which we intend to initiate in the fourth quarter of this year with topline data expected in 2026, consistent with prior readout guidance. We look forward to delivering multiple anticipated Phase 3 data readouts in 2026 and 2027 to support our potential BLA submission for the VAX-31 adult indication. For the infant indication, we have leveraged key insights from the robust VAX-24 and VAX-31 data generated to date, as well as our carrier-sparing platform, to support the evaluation of a new, Optimized dose in the ongoing VAX-31 Phase 2 dose-finding study to elicit even stronger immune responses in this population. We expect the modified study to proceed by the end of the third quarter of this year with topline data from both the primary immunogenicity series and the booster dose expected by the end of the first half of 2027. We believe the incorporation of this new, Optimized dose arm, which results in a minor extension to our prior readout timeline, best positions VAX-31 for long-term success.”

“With a strong balance sheet totaling approximately $2.8 billion in cash, cash equivalents and investments as of the end of the second quarter, we remain focused on advancing VAX-31, our lead candidate and the broadest-spectrum PCV in the clinic today,” said Andrew Guggenhime, President and Chief Financial Officer of Vaxcyte. “In this dynamic macro environment, we continue to take a disciplined approach to capital allocation, directing resources to further extend our cash runway and fully support the continued progress of our PCV programs, including preparation for our planned VAX-31 adult Phase 3 program and pursuit of potential U.S. commercialization. As part of this focused strategy, among other initiatives, we are streamlining activities across our early-stage pipeline while preserving the option to advance promising programs in the future.”

Key Second Quarter and Recent Highlights

PCV Program Updates

VAX-31 Adult Program Updates

- ***Following Interactions with U.S. Food and Drug Administration (FDA) on VAX-31 Adult Program, Including End-of-Phase 2 Meeting, Company Finalizing Phase 3 Clinical Program to Validate VAX-31 as Potential New Standard-of-Care Adult PCV to Prevent Invasive Pneumococcal Disease (IPD) and Pneumonia*:** Through a series of interactions with the FDA, including an End-of-Phase 2 meeting, regarding the VAX-31 adult Phase 3 clinical program, the FDA provided input on the adult commercial licensure requirements, including the approximate number of study participants in the Phase 3 program; key immunogenicity and safety endpoints for the pivotal, non-inferiority study; and a continued indication that the scale of the planned immunogenicity and safety assessments are in line with precedent

requirements and will be sufficient to support potential licensure. Additionally, as part of ongoing discussions granted under the VAX-31 adult Breakthrough Therapy designation (BTD), the FDA provided input on the chemistry, manufacturing and controls (CMC) licensure requirements in support of the Company's path to delivering a Biologics License Application (BLA) submission.

The Company is incorporating the FDA's input to finalize the Phase 3 program designed to validate VAX-31 as the potential new standard-of-care adult PCV. This includes conducting final-stage planning for the pivotal, non-inferiority study, which is expected to be initiated in the fourth quarter of this year, with topline data expected in 2026, consistent with prior readout guidance. Initiation of the remaining Phase 3 studies, which are shorter in duration than the non-inferiority study, is planned for 2025 and 2026. The VAX-31 High dose (all serotypes dosed at 3.3mcg or 4.4mcg) has been selected to advance into Phase 3. Subject to the results of the Phase 3 studies, which are expected to read out in 2026 and 2027, the Company plans to submit a BLA shortly following the completion of the last Phase 3 study.

- ***FDA Expanded VAX-31 Adult BTD to Include Prevention of Pneumonia Caused by Streptococcus Pneumoniae in Addition to IPD:*** In May 2025, the FDA expanded the adult BTD for VAX-31 to include the prevention of pneumonia in addition to the prevention of IPD based on the positive topline results from the VAX-31 adult Phase 1/2 study, indicating that VAX-31 may demonstrate substantial improvement over existing therapies. The BTD process is designed to expedite the development and review of drugs and biologics that are intended to treat a serious or life-threatening condition.

VAX-31 Infant Program Updates

- ***Company Modified Ongoing VAX-31 Infant Phase 2 Dose-Finding Study to Add a VAX-31 Optimized Dose Designed to Elicit Even Stronger Immune Responses in Pediatric Population:*** The Company has modified the ongoing VAX-31 infant Phase 2 randomized, dose-finding study to add a new dose arm to evaluate a VAX-31 Optimized dose with the majority of serotypes dosed at 4.4mcg and the balance dosed at 3.3mcg. Both the Middle dose and High dose VAX-31 arms in the study will proceed, while the Company has elected to discontinue enrollment in the Low dose arm. The modified study will evaluate VAX-31 in approximately 900 participants, including the 100 participants previously enrolled in the Low dose arm. Enrollment in the modified study is expected to proceed by the end of the third quarter of this year with topline data from both the primary immunization series and the booster dose by the end of the first half of 2027.

Early-Stage Pipeline Updates

- ***Streamlined Early-Stage Pipeline to Prioritize Resources for PCV Programs:*** As part of its continued focus on strategic capital deployment, the Company is prioritizing resources toward its PCV franchise. To this end, the Company has paused the advancement, beyond preclinical development, of VAX-A1, a prophylactic vaccine candidate designed to prevent Group A Strep infections, and VAX-GI, a vaccine candidate designed to prevent Shigella, while remaining confident in their potential and preserving the option to advance the programs in the future. Additionally, the Company has discontinued further development of VAX-PG, a therapeutic vaccine candidate designed to slow or stop the progression of periodontal disease. VAX-PG preclinical data demonstrated an acceptable safety profile but not sufficient efficacy signals to warrant further investment.

Executive Leadership Team Appointment

- ***Appointed Chief Business and Strategy Officer:*** In July, Chris Griffith joined Vaxcyte as Chief Business and Strategy Officer. With more than 20 years of experience spanning corporate and business development, portfolio strategy and business operations, Mr. Griffith brings deep expertise to this newly expanded role. His leadership will help ensure strong cross-functional alignment and execution as the Company advances its late-stage programs and prepares for the next phase of growth.

Anticipated Key PCV Program 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 Phase 3 pivotal, non-inferiority study in the fourth quarter of 2025 and announce topline safety, tolerability and immunogenicity data in 2026, consistent with prior readout guidance.
- Initiate remaining Phase 3 studies in 2025 and 2026 and announce data from these studies in 2026 and 2027, consistent

with prior guidance.

PCV Franchise Infant Indication

VAX-24

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

VAX-31

- Proceed with the modified Phase 2 randomized, dose-finding study by the end of the third quarter of 2025.
- Announce topline safety, tolerability and immunogenicity data for the Phase 2 randomized, dose-finding study from both the primary three-dose immunization series and booster dose by the end of the first half of 2027, representing a minor extension to prior readout guidance.

Upcoming Investor Conferences

Company management will participate in the following upcoming investor conferences.

- **Cantor Global Healthcare Conference, September 3-5, 2025:** Fireside chat will take place live on Wednesday, September 3 at 11:45 a.m. PT / 2:45 p.m. ET. The fireside chat webcast will be accessible through the Investors & Media section of the Company's website at http://investors.vaxcyte.com for approximately 30 days.

- **Wells Fargo Healthcare Conference, September 3-5, 2025**

Second Quarter 2025 Financial Results

- ***Cash Position:*** Cash, cash equivalents and investments were $2,826.5 million as of June 30, 2025, compared to $3,134.7 million as of December 31, 2024. As a result of the Company's continued focus on disciplined capital allocation and evaluation of investment priorities, including streamlining activities across the early-stage pipeline, the Company has extended its cash runway and now expects its cash, cash equivalents and investments to fund its current operating plan to mid-2028.

- ***Research & Development (R&D) Expenses:*** R&D expenses were $194.2 million for the three months ended June 30, 2025 as compared to $131.5 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 $32.0 million for the three months ended June 30, 2025 as compared to $21.5 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 June 30, 2025, net loss was $166.6 million, compared to $128.7 million for the same period in 2024.

- ***Commercial Manufacturing Suite:*** In the second quarter of 2025, Vaxcyte incurred an additional $44.6 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 June 30, 2025, Vaxcyte had incurred $290.6 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. 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 and is being evaluated in a Phase 2 infant study. 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 set a new standard for immunogenicity and disease coverage while maintaining coverage of previously circulating strains; the process and timing of anticipated future development of Vaxcyte's vaccine candidates, including the continuation of the VAX-31 infant Phase 2 dose-finding study, timing and availability of data for the VAX-24 and VAX-31 infant Phase 2 studies, and the initiation of VAX-31 adult Phase 3 studies and the timing of such studies and their data readouts and the ability of such studies to validate the best-in-class potential of VAX-31 and support a BLA submission, the timing of such BLA submission; 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 August 6, 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.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2025	2024	2025	2024
Operating expenses:				
Research and development (1)	$ 194,179	$ 131,507	$ 342,313	$ 226,094
General and administrative (1)	32,040	21,474	64,699	41,359
Total operating expenses	226,219	152,981	407,012	267,453
Loss from operations	(226,219)	(152,981)	(407,012)	(267,453)
Other income, net:				
Interest income	31,073	23,813	64,008	45,479
Other income (expense)	28,573	465	35,713	(1,749)
Total other income, net	59,646	24,278	99,721	43,730
Net loss	$ (166,573)	$ (128,703)	$ (307,291)	$ (223,723)
Net loss per share, basic and diluted	$ (1.22)	$ (1.10)	$ (2.26)	$ (1.95)
Weighted-average shares outstanding, basic and diluted	136,033,746	117,256,561	135,863,299	114,473,758

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

Research and development	$ 20,191	$ 10,855	$ 36,117	$ 19,673
General and administrative	16,736	10,703	31,425	19,514
Total stock-based compensation expense	$ 36,927	$ 21,558	$ 67,542	$ 39,187

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

	June 30, 2025	December 31, 2024
Cash, cash equivalents and investments	$ 2,826,518	$ 3,134,718
Total assets	3,305,363	3,511,318
Total stockholders' equity	3,071,334	3,305,819