Vaxcyte Reports First Quarter 2026 Financial Results and Provides Business Update

May 6, 2026

Enrollment Now Completed for OPUS-1, OPUS-2 and OPUS-3 Phase 3 Trials Evaluating VAX-31 for the Prevention of Invasive Pneumococcal Disease and Pneumonia in Adults

Topline Safety, Tolerability and Immunogenicity Data from OPUS-1 Expected in Fourth Quarter of 2026; OPUS-2 and OPUS-3 Results Expected in First Half of 2027

Enrollment Completed for VAX-31 Infant Phase 2 Dose-Finding Study; Topline Safety, Tolerability and Immunogenicity Data from Primary Immunization Series and Booster Dose Expected Either Sequentially or Together by End of First Half of 2027

Company Expects to Initiate Phase 1 Adult Clinical Study for VAX-A1, a Vaccine Candidate to Prevent Disease Caused by Group A Strep, in Mid-2026

Approximately $2.7 Billion in Cash, Cash Equivalents and Investments as of March 31, 2026, Including $601.8 Million in Net Proceeds from February 2026 Equity Offering

SAN CARLOS, Calif., May 06, 2026 (GLOBE NEWSWIRE) -- Vaxcyte, Inc. (Nasdaq: PCVX), a clinical-stage vaccine innovation company, today announced financial results for the first quarter ended March 31, 2026, and provided a business update.

"With the recent completion of OPUS-3 enrollment, our OPUS-1, OPUS-2 and OPUS-3 adult Phase 3 trials are now fully enrolled, and we remain on track to deliver data from these studies beginning with the expected OPUS-1 topline readout in the fourth quarter," said Grant Pickering, Chief Executive Officer and Co-Founder of Vaxcyte. "Our OPUS Phase 3 program was designed to establish not only a best-in-class pneumococcal conjugate vaccine (PCV), but also a new standard by which other pneumococcal vaccines will be judged. Based on the unprecedented results from our VAX-31 Phase 1/2 study in adults and the advantages of our carrier-sparing platform, we designed the OPUS-1 noninferiority trial as a head-to-head comparison against both Prevnar 20® (PCV20) and Capvaxive® (PCV21) with the potential to deliver a 14-34% increase in coverage against invasive pneumococcal disease (IPD) and a 19-31% increase in coverage against pneumococcal pneumonia relative to the current standard-of-care PCVs in U.S. adults. Following the anticipated OPUS-1 data in the fourth quarter, we expect to announce the results of the OPUS-2 and OPUS-3 Phase 3 trials in the first half of 2027, maintaining the timeline for our planned Biologics Application License (BLA) submission and potential U.S. commercial launch."

"In the first quarter of 2026, we completed an equity financing that further strengthened our balance sheet and extended our cash runway," said Andrew Guggenhime, President and Chief Financial Officer of Vaxcyte. "With $2.7 billion in cash, cash equivalents and investments as of March 31, 2026, we are well positioned to execute on our planned clinical, manufacturing and commercial readiness milestones for our PCV development programs and support the Company's next phase of growth. This includes advancing VAX-A1, a prophylactic vaccine candidate designed to prevent disease caused by Group A Strep, into the clinic in mid-2026."

Key First Quarter and Recent Highlights

PCV Franchise Adult Indication:

Advanced Comprehensive VAX-31 Phase 3 Adult Clinical Program to Support Planned BLA Submission, with Enrollment Completed for Three OPUS Trials: All three ongoing VAX-31 Phase 3 clinical trials (OPUS-1, OPUS-2 and OPUS-3) are now fully enrolled with 6,191 adults dosed in total, approximately 3,500 of whom received VAX-31. These studies, which were finalized in consultation and alignment with the U.S. Food and Drug Administration (FDA), are designed to generate a broad and robust safety, tolerability and immunogenicity dataset. In addition, the Company is also planning a manufacturing consistency study (e.g., a lot-to-lot study) as the final Phase 3 study.

- In March 2026, the Company announced the completion of enrollment in the OPUS-1 Phase 3 pivotal, noninferiority trial with 4,049 participants dosed and the OPUS-2 Phase 3 trial evaluating VAX-31 concomitantly administered with a seasonal influenza vaccine with 1,390 participants dosed. OPUS-1 is evaluating the safety, tolerability and immune responses of VAX-31 in healthy, pneumococcal-naïve[1] adults aged 50 and older through direct, head-to-head comparisons with both PCV20 and PCV21, the current standard-of-care PCVs, with the objective of establishing a best-in-class profile for VAX-31. The trial is also evaluating the safety, tolerability and immune responses of VAX-31 in a separate cohort of adults aged 18-49. OPUS-2 is evaluating the safety, tolerability and immunogenicity of VAX-31 when administered either concomitantly with or one month following administration of a licensed seasonal influenza vaccine in pneumococcal-naïve, healthy U.S. adults aged 50 years and older. The results of this descriptive study are intended to inform the design of a potential post-licensure outcomes study that further evaluates VAX-31 in concomitant use with an influenza vaccine and to provide supportive evidence as part of the broader Phase 3 dataset.
- The Company recently completed enrollment in the OPUS-3 trial, a Phase 3 descriptive study evaluating the safety,

tolerability and immunogenicity of VAX-31 in adults who have previously received pneumococcal vaccination, including whether VAX-31 can expand the breadth of protection and boost responses to the serotypes included in the lower-valency pneumococcal vaccines that participants previously received. In the study, 752 adults aged 50 years and older who have previously received lower-valency pneumococcal vaccines were dosed.

Positive VAX-31 Phase 1/2 Adult Data Published in The Lancet Infectious Diseases: In March 2026, the Company announced the publication of results from the positive VAX-31 adult Phase 1/2 clinical study in the journal *The Lancet Infectious Diseases*. The study results showed that VAX-31 at all doses studied was observed to be well tolerated and demonstrated a safety profile similar to PCV20 through the full six-month evaluation period. At all doses studied, VAX-31 demonstrated robust opsonophagocytic activity (OPA) and immunoglobulin G (IgG) immune responses, with high geometric mean concentrations (GMCs) across all 31 serotypes. The VAX-31 High Dose, which is currently being evaluated in the VAX-31 adult OPUS Phase 3 program, met or exceeded the OPA response noninferiority criteria[2] for all 20 serotypes common with PCV20 and met the superiority criteria[3] for the 11 incremental serotypes unique to VAX-31 and not in PCV20. 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[4] compared to PCV20.

PCV Franchise Infant Indication:

Completed Enrollment in VAX-31 Infant Phase 2 Study: In January 2026, the Company announced the completion of enrollment in the VAX-31 infant Phase 2 dose-finding study, with 900 healthy infants dosed. Participants have received at least their second dose in the primary immunization series. VAX-31 is designed to substantially expand coverage in the pediatric population by adding 11 incremental serotypes over and above today's standard-of-care, PCV20. VAX-31 has the potential to increase protection against IPD from approximately 69% to approximately 92% of disease circulating in children under five years of age in the U.S. and increase protection against acute otitis media from approximately 61% to approximately 96% in U.S. children five years of age or under.

Early-Stage Pipeline:

Advancing VAX-A1, a Potential Best-in-Class Vaccine Candidate Designed to Provide Universal Protection Against Disease Caused by Group A Strep, into the Clinic: In mid-2026, the Company plans to initiate a Phase 1 adult study for its most advanced preclinical program, VAX-A1, a prophylactic vaccine candidate designed to prevent disease caused by Group A Strep (*Streptococcus pyogenes*), with the primary objective of assessing safety and tolerability, along with a secondary objective of evaluating initial immunogenicity data, to support potential further advancement. This approach is designed to generate high-quality initial safety data and provide a foundation for evaluating next steps in the program's development. The Company intends to conduct this study in Australia, where Group A Strep has been problematic and there are experienced investigator networks with a high degree of expertise in the field. Group A Strep remains a major global cause of morbidity and mortality in adults and children and is a leading driver of antibiotic use, underscoring the significant public health burden.

Equity Financing:

Completed Underwritten Public Offering, Further Strengthening Balance Sheet: In February 2026, Vaxcyte completed an underwritten public offering of 12,650,000 shares of its common stock, which included the full exercise of the underwriters' option to purchase an additional 1,650,000 shares, at a public offering price of $50.00 per share. The aggregate gross proceeds to Vaxcyte from this offering were $632.5 Million, before deducting underwriting discounts and commissions and other offering expenses payable by Vaxcyte.

Commercial Manufacturing & Supply Chain:

Progressed Manufacturing and Supply Chain Capabilities to Support Commercial Launch: In collaboration with Lonza, Vaxcyte completed construction of a dedicated, large-scale manufacturing facility designed to support potential global commercial manufacturing of its PCV candidates for all indications.

Established North Carolina Presence Including Buildout of Custom PCV Fill-Finish Line: In January 2026, Vaxcyte announced the establishment of a dedicated local North Carolina presence, comprising full-time employees focused on chemistry, manufacturing and controls (CMC) activities as part of its commitment to expand U.S.-based fill-finish manufacturing capacity for its PCVs in North Carolina. As the Company advances its long-term domestic manufacturing strategy, it is recruiting experienced scientific and manufacturing professionals in one of the country's most established vaccine-development hubs. In parallel, the buildout of the custom PCV fill-finish line at the North Carolina facility is well underway.

Anticipated Program Milestones

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

VAX-31 Adult Indication

- Announce topline safety, tolerability and immunogenicity data from the OPUS-1 Phase 3 pivotal, noninferiority trial in the fourth quarter of 2026.
- Announce safety, tolerability and immunogenicity data from the OPUS-2 and OPUS-3 Phase 3 trials in the first half of 2027.

VAX-31 Infant Indication

- Announce topline safety, tolerability and immunogenicity data from 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.

VAX-A1

- Initiate Phase 1 adult clinical study in mid-2026, with the primary objective of assessing safety and tolerability.

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.

- **BofA Securities 2026 Health Care Conference, May 12-14:** Fireside chat will take place live on Tuesday, May 12, at 4:40 p.m. ET / 1:40 p.m. PT.
- **Jefferies Global Healthcare Conference, June 2-4:** Fireside chat will take place live on Wednesday, June 3, at 4:20 p.m. ET / 1:20 p.m. PT.

First Quarter 2026 Financial Results

- ***Cash Position:*** Cash, cash equivalents and investments were $2,741.2 million as of March 31, 2026, compared to $2,442.6 million as of December 31, 2025.
- ***Research & Development (R&D) Expenses:*** R&D expenses were $312.8 million for the three months ended March 31, 2026 as compared to $148.1 million for the same period in 2025. The increase was due primarily to higher development and product manufacturing costs associated with the Company's PCV programs, including an increase in manufacturing activities to support the potential future commercial launches, clinical trial expenses primarily related to the initiation and enrollment of the VAX-31 OPUS Phase 3 trials and higher personnel expenses related to the growth in the number of R&D employees.
- ***General & Administrative (G&A) Expenses:*** G&A expenses were $33.1 million for the three months ended March 31, 2026 as compared to $32.7 million for the same period in 2025.
- ***Net Loss:*** For the three months ended March 31, 2026, net loss was $320.6 million, compared to $140.7 million for the same period in 2025.

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 being evaluated in the OPUS Phase 3 adult clinical program and 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. VAX-XL, in earlier-stage development, also leverages the Company’s carrier-sparing, site-specific conjugation technology with the aim of further expanding coverage to deliver the broadest-spectrum candidate in the Company’s PCV franchise.

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 vaccine candidates, including breadth of coverage, the ability to deliver potentially best-in-class PCVs and improve upon the standard-of-care; the design, timing of initiation, progress and expected results of Vaxcyte's clinical trials and regulatory plans; 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 May 6, 2026 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 March 31,	
	2026	**2025**
Operating expenses:		
Research and development [1]	$ 312,779	$ 148,134
General and administrative [1]	33,071	32,659
Total operating expenses	345,850	180,793
Loss from operations	(345,850)	(180,793)
Other income, net:		
Interest income	26,610	32,935
Other income (expense)	(1,382)	7,140
Total other income, net	25,228	40,075
Net loss	$ (320,622)	$ (140,718)
Net loss per share, basic and diluted	$ (2.30)	$ (1.04)
Weighted-average shares outstanding, basic and diluted	139,506,680	135,690,949

[1] Amounts include stock-based compensation expense as follows:

Research and development	$ 20,678	$ 15,925
General and administrative	17,286	14,690
Total stock-based compensation expense	$ 37,964	$ 30,615

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

	March 31, 2026	**December 31, 2025**
Cash, cash equivalents and investments	$ 2,741,195	$ 2,442,623
Total assets	3,348,308	3,002,717
Total stockholders' equity	2,996,014	2,685,510

[1] Pneumococcal-naïve is defined as having no known prior history of IPD or pneumococcal pneumonia, or receipt of any licensed or investigational pneumococcal vaccine.

[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 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.

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