Vaxcyte Reports Third Quarter 2026 Financial Results and Provides Business Update

November 4, 2026

VAX-31 Adult Indication: Announced Positive Topline Data from OPUS-1 Pivotal Phase 3 Trial; VAX-31 Met All Prespecified Primary Endpoints, Was Well Tolerated and Demonstrated a Safety Profile Similar to PCV20 and PCV21 Across All Ages Studied

VAX-31 Adult Indication: Company Expects to Report Results from OPUS-2 and OPUS-3 Phase 3 Trials in First Half of 2027, Supporting Planned Biologics License Application Submission in First Half of 2028

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

Phase 1 Study of VAX-A1, the Company's Vaccine Candidate Designed to Provide Broad Protection Against Disease Caused by Group A Streptococcus, Advancing to Stage 2 in Adults

Pro Forma Cash, Cash Equivalents and Investments of Approximately $3.4 Billion as of September 30, 2026, Including Approximately $1.1 Billion in Net Proceeds from October 2026 Equity and Convertible Senior Notes Offerings

SAN CARLOS, Calif., Nov. 04, 2026 (GLOBE NEWSWIRE) -- Vaxcyte, Inc. (Nasdaq: PCVX), a clinical-stage vaccine innovation company, today announced financial results for the third quarter ended September 30, 2026, and provided a business update.

"The positive topline results from OPUS-1 represent a significant milestone for Vaxcyte and our broad-spectrum pneumococcal conjugate vaccine (PCV) franchise," said Grant Pickering, Chief Executive Officer and Co-Founder of Vaxcyte. "VAX-31 met all prespecified primary endpoints in this pivotal Phase 3 trial, which inaugurated a more stringent noninferiority standard, and we believe the results further support its potential best-in-class profile. With OPUS-1 serving as the foundation of our planned Biologics License Application (BLA), we remain on track to announce results from the OPUS-2 and OPUS-3 Phase 3 trials in the first half of next year and, together with a manufacturing consistency study, we expect to submit a BLA in the first half of 2028. For the VAX-31 infant indication, we expect to announce topline data from the primary immunization series and booster dose of the ongoing Phase 2 study, either sequentially or together, by the end of the first half of 2027."

"Following our positive OPUS-1 results, we completed concurrent equity and convertible senior notes offerings, raising approximately $1.1 billion in net proceeds, to further strengthen our balance sheet and extend our cash runway," said Andrew Guggenhime, President and Chief Financial Officer of Vaxcyte. "With approximately $3.4 billion in pro forma cash, cash equivalents and investments as of September 30, 2026, we are well positioned to support the potential U.S. commercial launch of VAX-31 for adults and advance our other key initiatives, including the VAX-31 OPUS-2 and OPUS-3 adult Phase 3 studies, the VAX-31 infant Phase 2 study, scale-up of our manufacturing and supply chain, and our earlier stage pipeline including VAX-A1 and VAX-XL."

Key Third Quarter and Recent Highlights

PCV Franchise Adult Indication:

Reported Positive Topline Data from OPUS-1, the Pivotal Adult Phase 3 Trial of VAX-31: In October 2026, the Company announced positive topline results from OPUS-1, which evaluated the safety, tolerability and immunogenicity of VAX-31, its next-generation 31-valent PCV candidate, for the prevention of invasive pneumococcal disease (IPD) and pneumococcal pneumonia. The randomized, double-blind, active-controlled trial evaluated VAX-31 in 4,047 healthy, pneumococcal-naïve[1] U.S. adults, including 3,572 aged 50 years and older and 475 aged 18-49. The results will serve as the cornerstone of a planned BLA submission, which will be subject to U.S. Food and Drug Administration (FDA) review.

In the OPUS-1 trial, VAX-31 met all prespecified co-primary immunogenicity endpoints in adults 50 and older:

- All 28 VAX-31 serotypes shared with Prevnar 20® (PCV20) and/or Capvaxive® (PCV21) met the prespecified noninferiority criteria based on opsonophagocytic activity (OPA) geometric mean ratios (GMRs), using a lower bound of the 95% confidence interval (LBCI) >0.667.[2]
    - For the 11 serotypes shared by VAX-31, PCV20 and PCV21, VAX-31 met all 11 primary noninferiority assessments based on OPA GMRs. For each serotype, the prespecified analysis required noninferiority against at least one comparator, with prespecified multiplicity adjustment.[2]
    - For the nine serotypes only in VAX-31 and PCV20, all nine met the prespecified OPA GMR noninferiority criterion.[3]
    - For the eight serotypes only in VAX-31 and PCV21, all eight met the prespecified OPA GMR noninferiority criterion.[3]
- The three serotypes unique to VAX-31 along with cross-reactive serotype 20B met the OPA GMR superiority criterion (LBCI >2.0) with prespecified multiplicity adjustment.[2]

For the prespecified primary immunobridging endpoint, VAX-31 met the noninferiority criterion (LBCI >0.667) for all 32[4] serotype OPA GMR comparisons in adults aged 18-49 compared to adults aged 50-64.

In the study, VAX-31 was well tolerated and demonstrated a safety profile similar to PCV20 and PCV21 at all ages studied. No serious adverse events were considered to be related to study vaccines, and there were no study discontinuations due to adverse events.

In the prespecified individual comparator analyses, VAX-31 met the noninferiority criterion (LBCI >0.667)[3] for 20 of 20 serotypes shared with PCV20 and 17 of 19 shared with PCV21. Compared to PCV21, serotypes 3 and 12F did not meet the LBCI >0.667 noninferiority criterion, but did meet the historical LBCI >0.5 threshold; compared to PCV20, VAX-31 met the LBCI >0.667 noninferiority criterion.[5] Given current U.S. epidemiology, with the serotypes unique to PCV21 accounting for a larger share of adult disease than those unique to PCV20, the Company expects the comparison of VAX-31 to PCV21 to be a particular focus of FDA review.

OPUS-2 and OPUS-3 Phase 3 Results Expected in First Half of 2027, Supporting Planned BLA Submission in First Half of 2028: The OPUS-2 and OPUS-3 Phase 3 trials, which are fully enrolled, are designed to generate a broad and robust safety, tolerability and immunogenicity dataset as part of the OPUS Phase 3 program evaluating VAX-31 for the prevention of IPD and pneumococcal pneumonia. In addition, the Company is planning a manufacturing consistency study as the final Phase 3 study to enable the submission of the BLA.

- The OPUS-2 Phase 3 study, in which 1,390 participants were dosed, 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 healthy, pneumococcal-naïve 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 OPUS-3 Phase 3 descriptive study, in which 752 participants were dosed, is evaluating the safety, tolerability and immunogenicity of VAX-31 in healthy U.S. adults aged 50 years and older who have previously received pneumococcal vaccination. Among other objectives, the study will evaluate responses to serotypes included in the lower-valency pneumococcal vaccines and the ability of VAX-31 to expand the breadth of serotype-specific immune responses.

Early-Stage Pipeline:

VAX-A1 Phase 1 Study in Adults Advancing to Stage 2: VAX-A1 is an investigational prophylactic vaccine candidate designed to provide broad protection against disease caused by Group A Streptococcus. The VAX-A1 Phase 1 study initiated in June 2026 is advancing to Stage 2 following the completion of an independent Data Safety Monitoring Board (DSMB) review of Stage 1 safety and tolerability data. The Company is completing plans to initiate Stage 2 including an updated study design that incorporates the DSMB's recommendations for sequential enrollment, beginning with the Low and Mid Dose cohorts. Enrollment of the High Dose cohort will be part of a new Stage 3 and will follow completion of the prespecified safety assessments and further DSMB review and approval. The study design has also been updated to add a third vaccination at the Low and Mid Dose levels, while the High Dose regimen remains two vaccinations. These updates are consistent with the stepwise evaluation of safety, tolerability and dosing regimens in first-in-human vaccine development, which is designed to identify the dose that best balances immune response and tolerability.

The randomized, observer-blind, placebo-controlled, dose-escalation study is designed to enroll approximately 80 healthy adults aged 18 to 40 years in Australia. The primary objective is to assess safety and tolerability, with a secondary objective of evaluating immune responses. Participants will be followed for safety through six months after their last vaccination.

Financing:

Completed Public Offerings Generating $1.15 Billion in Gross Proceeds: In October 2026, the Company completed concurrent underwritten public offerings which generated an aggregate $1.15 billion in gross proceeds, consisting of a $575 million offering of common stock and pre-funded warrants and a $575 million offering of convertible senior notes which bear interest at 1.50% per annum and mature in October 2032. The offerings included the full exercise of the underwriters' options. Aggregate net proceeds were approximately $1.1 billion after underwriting discounts and commissions and estimated offering expenses.

Executive Leadership Team:

Appointed Chief Medical Officer and Chief Legal Officer: In September 2026, the Company announced the appointments of experienced industry leaders Luis Jodar, Ph.D., as Chief Medical Officer and David McAvoy, J.D., as Chief Legal Officer.

- Dr. Jodar has more than 30 years of experience in vaccine development and launch across industry, international health organizations and academia. He spent 17 years at Pfizer Inc., most recently as Senior Vice President and Chief Medical Officer for Vaccines and Infectious Diseases.

- Mr. McAvoy brings more than three decades of legal leadership in the biopharmaceutical industry to Vaxcyte. He joined the Company from Teva Pharmaceutical Industries Ltd., where he served as Executive Vice President and Chief Legal Officer.

Anticipated Program Milestones

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

VAX-31 Adult Indication

- 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

- Announce topline data from the Phase 1 study in adults in the second 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 9-11:** Fireside chat will take place live on Tuesday, November 10, at 1:00 p.m. ET / 10:00 a.m. PT.
- **UBS Global Biopharma Conference**, **November 16-17:** Presentation will take place live on Tuesday, November 17, at 4:00 p.m. GMT / 11:00 a.m. ET / 8:00 a.m. PT.
- **Jefferies London Healthcare Conference**, **November 16-19:** Fireside chat will take place live on Wednesday, November 18, at 9:00 a.m. GMT / 4:00 a.m. ET / 1:00 a.m. PT.
- **Evercore Healthcare Conference**, **November 30 to December 2:** Fireside chat will take place live on Tuesday, December 1, at 9:35 a.m. ET / 6:35 a.m. PT.

Third Quarter 2026 Financial Results

- ***Cash Position:*** Cash, cash equivalents and investments were $2,264.4 million as of September 30, 2026, compared to $2,442.6 million as of December 31, 2025. The approximately $1.1 billion in net proceeds from the October 2026 offerings are not included in the September 30, 2026 balance.
- ***Research & Development (R&D) Expenses:*** R&D expenses were $270.3 million for the three months ended September 30, 2026 as compared to $209.9 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 manufacturing activities to support the potential future commercial launches and clinical trial expenses primarily related to the VAX-31 OPUS Phase 3 trials, 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 $37.9 million for the three months ended September 30, 2026 as compared to $32.4 million for the same period in 2025. The increase was due primarily to higher personnel expenses related to the growth in the number of G&A employees and professional and consulting services.
- ***Net Loss:*** For the three months ended September 30, 2026, net loss was $297.1 million, compared to $212.8 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, has generated positive Phase 2 clinical results in both adults and infants and is designed to cover more serotypes than any 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.

VAX-A1 is a prophylactic vaccine candidate designed to provide broad, strain-independent protection against disease caused by Group A Strep and is

currently being evaluated in a Phase 1 clinical study in adults. Group A Strep remains a significant global cause of morbidity and mortality across both adult and pediatric populations and is a leading driver of antibiotic use, underscoring the substantial public health burden.

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 develop and deliver high-fidelity vaccines with enhanced immunological benefits. Vaxcyte's pipeline also includes 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 vaccines and improve upon the standard-of-care; the design, timing, progress and expected results of Vaxcyte's clinical trials and regulatory plans along with the standards for review and licensure of vaccines and regulators accepting our study as designed; the Company's planned BLA submission for VAX-31; 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," "plan," "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, 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.

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[1] Pneumococcal-naïve means no known history of invasive pneumococcal disease, pneumococcal pneumonia or receipt of a licensed or investigational pneumococcal vaccine.

[2] Under the prespecified Hochberg multiplicity adjustment, each of the 11 shared-serotype noninferiority assessments and each of the four primary superiority assessments succeeds against PCV20 and/or PCV21 if the one-sided adjusted p-value is <0.025 against at least one comparator. The OPA GMR margin for primary endpoints is >0.667 for noninferiority and 2.0 for superiority.

[3] For individual comparator-specific noninferiority assessments and the primary immunobridging assessment, the lower bound of the 95% confidence interval (LBCI) for the OPA GMR must exceed 0.667 to establish noninferiority.

[4] 31 vaccine serotypes plus cross-reactive serotype 20B.

[5] In the prespecified individual comparator-specific noninferiority assessments of VAX-31 vs PCV21, the lower bounds of the 95% confidence intervals for the OPA GMRs for serotypes 3 and 12F exceeded 0.5 but did not meet the prespecified individual noninferiority criterion of LBCI >0.667. The historical LBCI >0.5 noninferiority comparison was a prespecified key secondary endpoint.

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,	
	2026	2025	2026	2025
Operating expenses:				
Research and development [1]	$ 270,326	$ 209,933	$ 850,956	$ 552,246
General and administrative [1]	37,948	32,447	105,943	97,146
Total operating expenses	308,274	242,380	956,899	649,392
Loss from operations	(308,274)	(242,380)	(956,899)	(649,392)

Other income, net:				
Interest income	23,189	29,259	75,554	93,267
Other (expense) income	(11,977)	291	(20,641)	36,004
Total other income, net	11,212	29,550	54,913	129,271
Net loss	$ (297,062)	$ (212,830)	$ (901,986)	$ (520,121)
Net loss per share, basic and diluted	$ (1.99)	$ (1.56)	$ (6.25)	$ (3.83)
Weighted-average shares outstanding, basic and diluted	148,908,274	136,196,512	144,337,459	135,975,586

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

Research and development	$ 24,074	$ 18,383	$ 66,897	$ 54,499
General and administrative	17,026	16,923	53,408	48,349
Total stock-based compensation expense	$ 41,100	$ 35,306	$ 120,305	$ 102,848

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

	September 30, 2026	December 31, 2025
Cash, cash equivalents and investments	$ 2,264,385	$ 2,442,623
Total assets	2,989,136	3,002,717
Total stockholders' equity	2,489,218	2,685,510