Vaxcyte Reports Second Quarter 2024 Financial Results and Provides Business Update

August 6, 2024

-- VAX-31 Adult Phase 1/2 Study Topline Safety, Tolerability and Immunogenicity Data Expected in September 2024 --

-- Following VAX-31 Adult Phase 1/2 Study Results, Vaxcyte to Advance VAX-24 or VAX-31 to Adult Phase 3 Program --

-- VAX-24 Infant Phase 2 Study Topline Data from Primary Immunization Series Expected by End of First Quarter of 2025, Followed by Topline Data from Booster Dose by End of 2025 --

-- $1.9 Billion in Cash, Cash Equivalents and Investments as of June 30, 2024 --

SAN CARLOS, Calif., Aug. 06, 2024 (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, 2024, and provided a business update.

“We continue to make significant strides toward building the potentially best-in-class pneumococcal conjugate vaccine (PCV) franchise and expect to announce the VAX-31 adult Phase 1/2 study topline safety, tolerability and immunogenicity data in September,” said Grant Pickering, Chief Executive Officer and Co-founder of Vaxcyte. “Our clinical program assessing VAX-31, the broadest-spectrum PCV in the clinic today, will provide significant insights into the full potential of this vaccine candidate across the adult population. Following the VAX-31 adult data readout, we plan to advance either VAX-24 or VAX-31 into Phase 3 clinical development in adults.”

Mr. Pickering continued, “Additionally, we look forward to delivering the topline data from the primary immunization series of the VAX-24 infant Phase 2 study by the end of the first quarter of 2025, followed by topline data from the booster dose by the end of 2025. We believe VAX-24 has a potential best-in-class profile for this vital population and is designed to cover more serotypes than any infant pneumococcal vaccine on-market today.”

Key Second Quarter and Recent Highlights

- ***VAX-24 Phase 2 Data in Adults Aged 65 and Older Published in Vaccine:*** In July 2024, the results from the VAX-24 Phase 2 study in adults aged 65 and older were published in the journal *Vaccine*. The study evaluated the safety, tolerability and immunogenicity of Vaxcyte’s investigational 24-valent, carrier-sparing PCV compared to Prevnar 20® (PCV20), for the prevention of invasive pneumococcal disease (IPD) in healthy adults. The results showed VAX-24 demonstrated a safety and tolerability profile comparable to PCV20 across all ages and doses studied. The VAX-24 2.2mcg dose showed an overall improvement in immune responses compared to PCV20 relative to the results from the prior Phase 2 study in adults aged 50-64.

- ***National Institute of Allergy and Infectious Diseases (NIAID) Grant Awarded for Preclinical Chlamydia Vaccine Development Program:*** In July 2024, the NIAID awarded a five-year, $9.5 million grant to the University of North Carolina at Chapel Hill, Vaxcyte and the University of Chicago to develop a vaccine candidate for the prevention of Chlamydia. There is a significant need for a vaccine to protect against Chlamydia. It is the most common bacterial sexually transmitted infection worldwide, with nearly 130 million new cases per year. While it is treatable when detected early, it can cause permanent damage to the female reproductive system, potentially leading to complications such as infertility and ectopic pregnancy.

- ***Appointed Seasoned Industry Expert to its Board of Directors:*** In July 2024, Vaxcyte appointed John Furey to its Board of Directors. Mr. Furey is a seasoned biopharmaceutical executive with over 30 years of experience developing and implementing operational strategies and leading commercial and technical teams, including senior leadership roles in the U.S., Europe and Asia. He has extensive vaccine experience from his time at Baxter and Pfizer, including having served as the General Manager of Pfizer’s vaccine business unit in China and a leadership role overseeing Pfizer Vaccines’ global pricing and reimbursement. Earlier in his career, Mr. Furey held both commercial and operations positions at Wyeth Pharmaceuticals (prior to Pfizer’s acquisition of Wyeth), including serving as Project Director of the Grange Castle Biopharmaceutical Campus where Prevnar is manufactured. He currently serves as Chief Executive Officer of Imvax, a clinical-stage biotechnology company developing novel immunotherapies for cancer. Mr. Furey earned an executive Master of Business Administration from Saint Joseph’s University, a Bachelor of Science degree from Trinity College, Dublin, and a Diploma in Environmental Health from the Technological University, Dublin. Mr. Furey also serves on the Board of Directors of Adaptimmune and Sensorion.

Anticipated Key Milestones
Vaxcyte is advancing the clinical development of its PCV programs with several anticipated key upcoming milestones:

PCV Franchise Adult Indication:

- Announce topline safety, tolerability and immunogenicity data from VAX-31 adult Phase 1/2 study in September 2024.
- Following VAX-31 data, advance either VAX-24 or VAX-31 to an adult Phase 3 program.

If VAX-24:

- Following the initiation of Phase 3 pivotal, non-inferiority study in adults aged 50 and older, announce topline safety, tolerability and immunogenicity data in the second half of 2025.
- Initiate balance of expected Phase 3 studies in 2025 and 2026.

If VAX-31:

- Initiate full complement of expected Phase 3 studies in 2025 and 2026.

PCV Franchise Infant Indication:

VAX-24:

- Announce topline safety, tolerability and immunogenicity data from VAX-24 infant Phase 2 study primary three-dose immunization series by the end of the first quarter of 2025, followed by topline data from the booster dose by the end of 2025.

Second Quarter 2024 Financial Results

- ***Cash Position:*** Cash, cash equivalents and investments were $1,851.9 million as of June 30, 2024, compared to $1,242.9 million as of December 31, 2023.
- ***Research & Development (R&D) Expenses:*** R&D expenses were $131.5 million for the three months ended June 30, 2024 as compared to $72.7 million for the same period in 2023. The increase was due primarily to higher manufacturing expenses related to the Company's PCV programs, including for potential future commercial launch and Phase 3 clinical trials; expenses related to the ongoing VAX-31 adult and VAX-24 infant clinical studies; and an increase in personnel expenses related to the growth in the number of R&D employees.
- ***General & Administrative (G&A) Expenses:*** G&A expenses were $21.5 million for the three months ended June 30, 2024, as compared to $14.5 million for the same period in 2023. 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, 2024, net loss was $128.7 million, compared to $68.3 million for the same period in 2023.
- ***Commercial Manufacturing Suite:*** In the second quarter of 2024, Vaxcyte incurred an additional $38.2 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, 2024, Vaxcyte had incurred $140.0 million in total capital and facility buildout expenditures that were reflected on the Company's balance sheet as of that date.

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. Vaxcyte's lead candidate, VAX-24, is a Phase 3-ready 24-valent, broad-spectrum, carrier-sparing PCV being developed for the prevention of IPD. VAX-31, the Company's next-generation 31-valent PCV, is the broadest-spectrum PCV candidate in the clinic today. Both VAX-24 and VAX-31 are designed to improve upon the standard-of-care PCVs for both children and adults by covering the serotypes that are responsible for a significant portion of IPD in circulation 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 the potentially best-in-class PCV franchise and improvement upon the standard-of-care; the process and timing of anticipated future development of Vaxcyte's vaccine candidates; the timing and availability of data for the VAX-24 infant Phase 2 study and VAX-31 adult Phase 1/2 study; the advancement of either VAX-24 or VAX-31 into a Phase 3 adult clinical program, and the timing of such studies and their data readouts; the demand for Vaxcyte's vaccine candidates; Vaxcyte's ability to establish global commercial manufacturing capacity for its PCV candidates; Vaxcyte's plans to utilize Lonza infrastructure to support the potential global commercialization of Vaxcyte's PCV programs; 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, 2024 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,	
	2024	**2023**	**2024**	**2023**
Operating expenses:				
Research and development (1)	$ 131,507	$ 72,691	$ 226,094	$ 130,771
General and administrative (1)	21,474	14,456	41,359	27,567
Total operating expenses	152,981	87,147	267,453	158,338
Loss from operations	(152,981)	(87,147)	(267,453)	(158,338)
Other income, net:				
Interest income	23,813	16,451	45,479	26,844
Grant income	394	2,464	520	3,119
Realized gains on marketable securities	27	-	49	-
Foreign currency transaction losses	44	(107)	(2,318)	(426)
Total other income, net	24,278	18,808	43,730	29,537
Net loss	$ (128,703)	$ (68,339)	$ (223,723)	$ (128,801)
Net loss per share, basic and diluted	$ (1.10)	$ (0.70)	$ (1.95)	$ (1.40)
Weighted-average shares outstanding, basic and diluted	117,256,561	98,057,870	114,473,758	92,165,076

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

Research and development	$ 10,855	$ 5,911	$ 19,673	$ 10,438
General and administrative	10,703	6,633	19,514	11,754
Total stock-based compensation expense	$ 21,558	$ 12,544	$ 39,187	$ 22,192

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

	June 30, 2024	December 31, 2023
Cash, cash equivalents and investments	$ 1,851,940	$ 1,242,902
Total assets	2,087,267	1,407,917
Total stockholders' equity	1,986,132	1,240,468