Vaxcyte Reports First Quarter 2024 Financial Results and Provides Business Update

May 8, 2024

-- VAX-31 Adult Phase 1/2 Study Enrollment Completed; Topline Safety, Tolerability and Immunogenicity Data Expected in Third Quarter of 2024 --

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

-- VAX-24 Infant Phase 2 Study Enrollment Completed; 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 March 31, 2024, Including Net Proceeds of $816.5 Million from February Public Offering --

SAN CARLOS, Calif., May 08, 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 first quarter ended March 31, 2024, and provided a business update.

“We continue to make meaningful progress across our business, including for our pneumococcal conjugate vaccine (PCV) candidates, VAX-24 and VAX-31, which are intended to deliver the broadest spectrum of coverage against invasive pneumococcal disease (IPD),” said Grant Pickering, Chief Executive Officer and Co-founder of Vaxcyte. “We remain on track to announce the VAX-31 adult Phase 1/2 study topline safety, tolerability and immunogenicity data in the third quarter of this year, following which we plan to advance either VAX-24 or VAX-31 into Phase 3 clinical development in adults. Additionally, with enrollment completed in the VAX-24 infant Phase 2 study, we expect to deliver topline data from the primary immunization series by the end of the first quarter of 2025. Together, these two milestones will provide significant insight into our PCV franchise’s ability to achieve its full potential across the adult and pediatric populations.”

“We closed the first quarter with a strong balance sheet bolstered by $816.5 million in net proceeds from the follow-on equity offering in February, propelling advancement of our PCV franchise and the scale-up of our manufacturing infrastructure,” said Andrew Guggenhime, President and Chief Financial Officer of Vaxcyte. “We also continue to progress our early-stage pipeline led by VAX-A1, a vaccine candidate designed to prevent Group A Strep infections. We believe our cell-free platform has the potential to enable the development of first-in-class vaccines to prevent or treat bacterial infections, which have serious and costly health consequences when left unchecked.”

Key First Quarter Highlights

PCV Franchise Adult Indication:

- ***Completed Enrollment of Phase 1/2 Study Evaluating VAX-31 for the Prevention of IPD in Adults Aged 50 and Older:*** In January 2024, Vaxcyte announced the completion of enrollment in its Phase 1/2 clinical study evaluating VAX-31, a 31-valent PCV candidate designed to prevent IPD, in healthy adults. This is a randomized, observer-blind, active-controlled, dose-finding study designed to evaluate the safety, tolerability and immunogenicity of VAX-31 at three dose levels (low, middle and high) compared to Prevnar 20® (PCV20) in 1,015 healthy adults aged 50 and older. VAX-31, the broadest-spectrum PCV in the clinic, has the potential to address a significant public health need by covering approximately 95% of IPD circulating in the U.S. adult population while maintaining coverage of previously circulating strains that are currently contained via ongoing vaccination. Additional information about the study can be found at www.clinicaltrials.gov under the identifier NCT06151288.

PCV Franchise Infant Indication:

- ***Completed Enrollment of Phase 2 Study Evaluating VAX-24 for the Prevention of IPD in Infants:*** In March 2024, Vaxcyte announced the completion of enrollment in its Phase 2 clinical study evaluating VAX-24, a broad-spectrum, carrier-sparing 24-valent PCV candidate designed to prevent IPD, in healthy infants. The Phase 2 clinical study, which enrolled 802 healthy infants, is a randomized, observer-blind, dose-finding two-stage clinical study evaluating the safety, tolerability and immunogenicity of VAX-24 in infants. The Stage 1 portion of the study evaluated the safety and tolerability of a single injection of VAX-24 at three dose levels (low dose/1.1mcg, middle dose/2.2mcg, mixed dose/2.2mcg or 4.4mcg) and compared to VAXNEUVANCE™ (PCV15), which was the broadest-spectrum PCV at the time of study initiation, in 48 infants. The Stage 2 portion, which commenced in July 2023, is evaluating the safety, tolerability and immunogenicity of VAX-24 for the prevention of IPD at the same three dose levels and compared to PCV20, currently the broadest-spectrum

PCV recommended by the Advisory Committee on Immunization Practices (ACIP). Participants who received VAX-24 in Stage 1 will continue the standard dosing regimen as part of Stage 2 and will be included in the safety, tolerability and immunogenicity analysis of the study. Additional information about the study can be found at www.clinicaltrials.gov under the identifier NCT05844423.

Equity Financing:

- ***Completed Successful $862.5 Million Follow-On Financing, Further Strengthening Vaxcyte's Balance Sheet:*** In February 2024, Vaxcyte completed an underwritten public offering of 12,695,312 shares of its common stock, which included the full exercise of the underwriters' option to purchase additional shares, at a public offering price of $64.00 per share and pre-funded warrants to purchase 781,250 shares of common stock at a public offering price of $63.999 per underlying share. The aggregate gross proceeds to Vaxcyte from this offering were $862.5 million, before deducting underwriting discounts and commissions and other offering expenses payable by Vaxcyte.

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 the third quarter of 2024.
- Following VAX-31 data, advance either VAX-24 or VAX-31 to an adult Phase 3 program.

If VAX-24:

- Initiate Phase 3 pivotal, non-inferiority study in adults aged 50 and older in the second half of 2024 and 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:

- 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.

Upcoming May and June Investor Conferences

Company management will participate in fireside chats and host one-on-one meetings at the following investor conferences, and 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:

- **Bank of America Securities Health Care Conference, May 14-16, 2024:** Fireside chat will take place live on Tuesday, May 14 at 9:20 a.m. PT / 12:20 p.m. ET.

- **Jefferies Global Healthcare Conference, June 5-6, 2024:** Fireside chat will take place live on Wednesday, June 5 at 8:30 a.m. PT / 11:30 a.m. ET.

First Quarter 2024 Financial Results

- ***Cash Position:*** Cash, cash equivalents and investments were $1,899.8 million as of March 31, 2024, compared to $1,242.9 million as of December 31, 2023. The March 31, 2024 amount includes the $816.5 million in net proceeds from the follow-on offering completed in February 2024.
- ***Research & Development (R&D) Expenses:*** R&D expenses were $94.6 million for the three months ended March 31, 2024 as compared to $58.1 million for the same period in 2023. The increase was due primarily to higher expenses related to the ongoing VAX-31 adult and VAX-24 infant clinical studies, higher manufacturing expenses related to the planned VAX-24 or VAX-31 adult Phase 3 clinical trials and the potential commercial launches of the Company's PCV programs, initially in the adult population, as well as 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 $19.9 million for the three months ended March 31, 2024 as compared to $13.1 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 March 31, 2024, net loss was $95.0 million, compared to $60.5 million for the same period in 2023.

- ***Commercial Manufacturing Suite:*** In the first quarter of 2024, Vaxcyte incurred an additional $15.3 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 March 31, 2024, Vaxcyte had incurred $101.8 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 pneumococcal conjugate vaccine (PCV) being developed for the prevention of invasive pneumococcal disease (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 a potentially first-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 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 design, timing and availability of data for the VAX-24 infant Phase 2 study; the design, timing and availability of data for the VAX-31 adult Phase 1/2 study; the demand for Vaxcyte's vaccine candidates; the potential global commercialization of Vaxcyte's PCV candidates in both the adult and pediatric populations; 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; the ability of Vaxcyte's cell-free platform to potentially enable the development of first-in-class vaccines to prevent or treat bacterial infections; 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 8, 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 March 31,	
	2024	**2023**
Operating expenses:		
Research and development (1)	$ 94,587	$ 58,080
General and administrative (1)	19,885	13,112
Total operating expenses	114,472	71,192
Loss from operations	(114,472)	(71,192)
Other income (expense), net:		
Interest income	21,666	10,393
Grant income	126	654
Realized gains on marketable securities	22	-
Foreign currency transaction losses	(2,362)	(317)
Total other income (expense), net	19,452	10,730
Net loss	$ (95,020)	$ (60,462)
Net loss per share, basic and diluted	$ (0.85)	$ (0.70)
Weighted-average shares outstanding, basic and diluted	111,690,951	86,206,817

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

Research and development	$ 8,818	$ 4,527
General and administrative	8,811	5,121
Total stock-based compensation expense	$ 17,629	$ 9,648

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

	March 31, 2024	**December 31, 2023**
Cash, cash equivalents and investments	$ 1,899,765	$ 1,242,902
Total assets	2,091,305	1,407,917
Total stockholders' equity	1,983,983	1,240,468