Vaxcyte Reports Third Quarter 2023 Financial Results and Provides Business Update

November 6, 2023

-- Completed Successful End-of-Phase 2 Meeting with FDA for VAX-24; Topline Phase 3 Data in Adults Expected in 2025 --

-- Received FDA Clearance of VAX-31 Adult IND Application; Phase 1/2 Study Initiation Expected This Quarter and Topline Data Expected in the Second Half of 2024 --

-- Advanced Ongoing VAX-24 Infant Phase 2 Study; Topline Data from Primary Immunization Series Expected by 2025 --

-- Expanded Collaboration with Lonza for Global Commercial Manufacturing of Broad-Spectrum Pneumococcal Conjugate Vaccine Candidates,
VAX-24 and VAX-31, in Adult and Pediatric Populations --

-- $1.4 Billion in Cash, Cash Equivalents and Investments as of September 30, 2023 --

SAN CARLOS, Calif., Nov. 06, 2023 (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 third quarter ended September 30, 2023 and provided a business update.

"Vaxcyte has continued to make significant strides toward our goal of building a best-in-class PCV franchise, including VAX-24 and VAX-31, with the intent of delivering the broadest-spectrum of coverage against invasive pneumococcal disease," said Grant Pickering, Chief Executive Officer and Co-founder of Vaxcyte. "Following the positive results from the VAX-24 adult Phase 2 clinical studies, we are pleased to have completed a successful End-of-Phase 2 meeting with the FDA focused on the clinical design of our Phase 3 program. We look forward to continued interactions with regulators through the first quarter of next year to finalize the CMC-related licensure requirements as we prepare to initiate the VAX-24 adult Phase 3 program, with topline data from the pivotal, non-inferiority study expected in 2025."

Mr. Pickering continued, "Additionally, we are excited to advance VAX-31, which will be the broadest-spectrum PCV to enter the clinic, into a Phase 1/2 study this quarter following the recent FDA clearance of the IND application. We expect to announce topline safety, tolerability and immunogenicity data from this study in the second half of 2024."

Key Third Quarter and Recent Highlights

- ***Completed Successful End-of-Phase 2 Meeting with FDA to Inform VAX-24 Adult Phase 3 Clinical Program:*** At the end of October 2023, Vaxcyte completed a successful End-of-Phase 2 meeting with the U.S. Food and Drug Administration (FDA). The meeting focused on the VAX-24 adult Phase 3 clinical program, including the design of the pivotal, non-inferiority study and other Phase 3 studies needed to support a Biologics License Application (BLA) submission. Based on the End-of-Phase 2 meeting, the Company believes there is agreement with the FDA on the clinical design of the adult Phase 3 program, including the approximate overall number of subjects, the primary and secondary endpoints for the pivotal, non-inferiority study as well as confirmation that the planned immunogenicity analyses are sufficient to support licensure and an efficacy study is therefore not required. Vaxcyte plans to provide additional details about the VAX-24 adult Phase 3 program following additional regulatory discussions focused on the Company's chemistry, manufacturing and controls (CMC) strategy that are expected to occur through the first quarter of 2024.

- ***Received FDA Clearance for VAX-31 Adult IND Application for the Prevention of IPD:*** In October 2023, Vaxcyte announced FDA clearance of the VAX-31 Investigational New Drug (IND) application for the prevention of invasive pneumococcal disease (IPD) in adults. The VAX-31 Phase 1/2 study, which will enroll approximately 1,000 adults aged 50 and older, is designed to enable Vaxcyte to understand the clinical potential of VAX-31 to improve upon the standard-of-care for adults by providing a broader-spectrum of protection against IPD. VAX-31 is a 31-valent pneumococcal conjugate vaccine (PCV) designed to provide coverage for approximately 95% of IPD currently circulating in the U.S. adult population.

- ***Expanded Collaboration with Lonza for Global Commercial Manufacturing of VAX-24 and VAX-31:*** In October 2023, Vaxcyte and Lonza announced a new commercial manufacturing agreement, which expands the existing collaboration, to support the potential global commercialization of VAX-24 and VAX-31 in both the adult and pediatric populations. This agreement builds upon the long-standing relationship between the companies and complements Vaxcyte's plans to utilize existing Lonza infrastructure to advance clinical development and support the anticipated initial U.S. launch of VAX-24 for

the adult population. Under the terms of the new agreement, Lonza will provide Vaxcyte with a custom-built manufacturing suite as part of Lonza's Ibex ® facility in Visp, Switzerland to support the manufacture of key components, including the drug substances, for Vaxcyte's PCV franchise.

- ***Advanced to Second and Final Stage of Phase 2 Study Evaluating VAX-24 for the Prevention of IPD in Infants and Dosed First New Participants:*** In July 2023, Vaxcyte announced that the ongoing Phase 2 study of VAX-24 in healthy infants advanced to the second and final stage of the study. The independent Data Safety Monitoring Board approved advancing to the second stage of the study following the review of the safety and tolerability results from the first stage. New participants began enrolling and dosing in Stage 2 of the study in July 2023. Additionally, in agreement with the FDA, Vaxcyte amended the study protocol for Stage 2, changing the study comparator to Prevnar 20®, which is currently the broadest-spectrum PCV recommended by the Advisory Committee on Immunization Practices for infants.

Anticipated Key Milestones

Vaxcyte is advancing the clinical development of its PCV programs with several anticipated key upcoming milestones, including:

- ***VAX-24 Adult Program:***
  - Meetings with the FDA regarding the Company's CMC strategy to finalize the Company's Phase 3 program and BLA requirements expected to occur through the first quarter of 2024.
  - Topline safety, tolerability and immunogenicity data from the Phase 3 pivotal non-inferiority study in adults in 2025.
- ***VAX-24 Infant Program:***
  - Topline safety, tolerability and immunogenicity data from the primary three-dose immunization series of the infant Phase 2 study by 2025, followed by topline data from the booster dose approximately nine months later.
- ***VAX-31 Adult Program:***
  - Initiation of the Phase 1/2 study in the fourth quarter of 2023.
  - Topline safety, tolerability and immunogenicity data from the Phase 1/2 study in adults in second half of 2024.

Third Quarter 2023 Financial Results

- ***Cash Position:*** Cash, cash equivalents and investments were $1,434.2 million as of September 30, 2023, compared to $957.9 million as of December 31, 2022.
- ***Research & Development (R&D) Expenses:*** R&D expenses were $97.4 million for the three months ended September 30, 2023 as compared to $47.7 million for the same period in 2022. The increase was due primarily to higher manufacturing expenses related to the planned VAX-24 Phase 3 clinical trials and the potential commercial launches of VAX-24 and VAX-31, as well as an increase in personnel-related expenses related to R&D growth.
- ***General & Administrative (G&A) Expenses:*** G&A expenses were $15.6 million for the three months ended September 30, 2023 as compared to $10.9 million for the same period in 2022. The increase was due primarily to higher personnel-related expenses related to the growth in G&A employees as the Company continues to scale.
- ***Net Loss:*** For the three months ended September 30, 2023, net loss was $92.7 million, compared to $57.9 million for the same period in 2022.

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 24-valent, broad-spectrum, carrier-sparing PCV being developed for the prevention of IPD and is poised to move into late-stage development. VAX-31, the only 31-valent PCV in development, is a follow-on candidate to VAX-24 and part of the Company's PCV franchise.

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 program 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 and clinical potential, the ability to deliver a potentially best-in-class profile and the improvement upon the standard-of-care; the design, process and timing of anticipated

future development of Vaxcyte's vaccine candidates, including the timing and availability of data for the VAX-24 adult and infant studies and related regulatory interactions and the timing of the initiation of the VAX-31 adult Phase 1/2 study and availability of the corresponding topline data; the potential of VAX-31 to serve as a follow-on candidate to VAX-24; the ability of Vaxcyte to commercialize VAX-24 and VAX-31; the timing and strategy regarding the initial commercial launch of VAX-24; the ability of Vaxcyte's dedicated manufacturing suite as part of Lonza's Ibex ® facility to support the manufacture of key components, including the drug substances; 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 November 6, 2023 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 Statements of Operations
(in thousands, except share and per share amounts)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	**2022**	**2023**	**2022**
Operating expenses:				
Research and development (1)	$ 97,421	$ 47,679	$ 228,191	$ 117,825
General and administrative (1)	15,605	10,898	43,174	27,858
Total operating expenses	113,026	58,577	271,365	145,683
Loss from operations	(113,026)	$ (58,577)	(271,365)	(145,683)
Other income (expense), net:				
Interest expense	-	-	-	(2)
Interest income	18,495	1,190	45,339	1,723
Grant income	1,640	157	4,759	1,006
Foreign currency transaction (losses) gains	227	(687)	(198)	(2,479)
Total other income (expense), net	20,362	660	49,900	248
Net loss	$ (92,664)	$ (57,917)	$ (221,465)	$ (145,435)
Net loss per share, basic and diluted	$ (0.91)	$ (0.93)	$ (2.32)	$ (2.42)
Weighted-average shares outstanding, basic and diluted	101,668,655	61,989,347	95,367,751	60,166,583

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

Research and development	$ 6,335	$ 2,682	$ 16,774	$ 6,804
General and administrative	6,885	3,966	18,639	9,837
Total stock-based compensation expense	$ 13,220	$ 6,648	$ 35,413	$ 16,641

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

	September 30, 2023	December 31, 2022
Cash, cash equivalents and investments	$ 1,434,248	$ 957,925
Total assets	1,496,057	1,006,178
Total stockholders' equity	1,402,716	953,613