Vaxcyte Reports Third Quarter 2022 Financial Results and Provides Business Update

November 7, 2022

-- Vaxcyte Reported Positive Topline Data from Phase 1/2 Proof-of-Concept Study of its 24-Valent Pneumococcal Conjugate Vaccine (PCV) Candidate Being Investigated for the Prevention of Invasive Pneumococcal Disease (IPD) in Adults Aged 18-64 --

-- Phase 1/2 Study Met Safety, Tolerability and Immunogenicity Objectives; Findings Indicate a Potential Best-in-Class Profile for VAX-24 --

-- Company Advancing VAX-24 in Adult and Pediatric Populations with Submission of Infant Investigational New Drug (IND) Application and Study Initiation Expected in First Half of 2023 --

-- $366.2 Million in Cash, Cash Equivalents and Investments as of September 30, 2022, Excluding Net Proceeds of Approximately $650.7 Million from Recent Public Offering --

SAN CARLOS, Calif., Nov. 07, 2022 (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, 2022 and provided a business update.

"We were thrilled to recently announce the positive results from our Phase 1/2 clinical proof-of-concept study, which demonstrated VAX-24 has the potential to provide broader coverage and better immune responses relative to the standard-of-care. These noteworthy findings validate the potential of our cell-free platform and carrier-sparing approach to enable the development of broader-spectrum PCVs," said Grant Pickering, Chief Executive Officer and Co-founder of Vaxcyte. "We believe these results support a best-in-class potential for VAX-24 and present an opportunity to set a new bar for immunogenicity standards for pneumococcal vaccines."

Mr. Pickering continued, "With the recent follow-on equity offering, which generated approximately $651 million in net proceeds, our balance sheet is further strengthened as we advance our pipeline of novel vaccines. We anticipate multiple VAX-24 milestones, including the topline results from a second Phase 2 study in older adults and the initiation of a Phase 2 study in infants, in the first half of 2023. Additionally, we are progressing VAX-XP, our PCV candidate with 31 strains of coverage, and expect to submit an adult IND application in the second half of 2023."

Recent Highlights

- ***Reported Positive Topline Data from VAX-24 Phase 1/2 Proof-of-Concept Study in Adults Aged 18-64:*** In October 2022, Vaxcyte announced positive topline results from the Phase 1/2 clinical proof-of-concept study evaluating the safety, tolerability and immunogenicity of VAX-24 in healthy adults aged 18-64.

- ***Safety and Tolerability Findings:***
  - VAX-24 demonstrated a safety and tolerability profile similar to PCV20 at all doses studied.
  - Frequently reported local and systemic reactions were generally mild-to-moderate, resolving within several days of vaccination, and were similar across all cohorts, including PCV20. No serious adverse events or new onset chronic illnesses were considered to be related to study vaccines.
  - The full six-month safety follow-up is ongoing for the Phase 2 portion of the study.

- ***Immunogenicity Findings:***
  - VAX-24 demonstrated robust opsonophagocytic activity (OPA) and immunoglobulin G (IgG) immune responses for all 24 serotypes at all doses studied (1.1mcg, 2.2mcg, 2.2mcg/4.4mcg), each of which could advance into Phase 3.
  - The VAX-24 2.2mcg dose met or exceeded the established regulatory immunogenicity standards for all 24 serotypes and is the dose the Company expects to advance into Phase 3.
  - At the 2.2mcg dose, VAX-24 met the standard OPA response non-inferiority criteria[(1)] for all 20 serotypes common with PCV20, of which 16 serotypes achieved higher immune responses and four serotypes reached statistical significance for superiority.
  - At all three doses, VAX-24 met the standard superiority criteria[(2)] for all four serotypes unique to VAX-24.

- ***Received FDA Fast Track Designation for VAX-24 in Adults:*** In August 2022, the Company announced that the U.S. Food and Drug Administration (FDA) granted Fast Track designation to VAX-24 in adults ages 18 and older. The Fast Track designation is an FDA process that has been designed to facilitate the development and expedite the review of drugs, including vaccines, that treat or prevent serious conditions and fill an unmet medical need.

- ***Completed Successful Pre-IND Meeting with FDA Regarding VAX-24 Pediatric Program, Supporting Path to Proceed Directly into Infants:*** In August 2022, Vaxcyte also announced that it had received positive written feedback from the FDA supporting the initiation of a pediatric study that proceeds directly into infants, contingent on the satisfactory topline safety, tolerability and immunogenicity results from the VAX-24 Phase 1/2 clinical proof-of-concept study in adults 18 to 64 years of age. This approach provides the Company with an accelerated clinical path to deliver VAX-24 to the pediatric population, which represents the largest portion of the pneumococcal vaccine market in the United States.

- ***Confirmed VAX-XP Serotype Composition and Expected IND Submission Timing:*** In October 2022, Vaxcyte unveiled the serotype composition for VAX-XP, the follow-on vaccine in its carrier-sparing PCV franchise, which is designed to contain 31 serotypes that collectively cover approximately 95% of the circulating strains causing IPD in adults in the United States. VAX-XP has the potential to become the broadest-spectrum PCV as it is designed to incorporate all 24 strains in VAX-24 along with an additional seven strains (15A, 16F, 23A, 23B, 7C, 31, and 35B) associated with high case-fatality rates, antibiotic resistance and meningitis. Expanding coverage to address newly circulating strains of IPD as well as the strains included in current vaccines, which have documented pathogenicity and propensity for circulation, is vital for the continued prevention of this serious disease and the avoidance of rebound rates that have historically occurred when coverage has been withdrawn.

- ***Completed Successful $690 Million Follow-On Offering:*** In October 2022, Vaxcyte completed an underwritten public offering of 17,812,500 shares of common stock, which included the full exercise of the underwriters' option to purchase an additional 2,812,500 shares, at a public offering price of $32.00 per share and pre-funded warrants to purchase 3,750,000 shares of common stock at a public offering price of $31.999 per underlying share. The aggregate net proceeds to Vaxcyte from this offering were approximately $650.7 million after deducting underwriting discounts and commissions and other offering expenses payable by Vaxcyte.

- ***Expanded Executive Leadership Team with Key Appointments:*** In October 2022, the Company announced the appointment of Mark Wiggins as Chief Business Officer and Jakub Simon, M.D., as Chief Medical Officer. Both Mr. Wiggins and Dr. Simon are accomplished industry leaders who bring vast expertise that will support the continued growth and advancement of the Company.

Anticipated Key Milestones

- ***VAX-24 Adult Program:***
  - Topline safety, tolerability and immunogenicity data from the Phase 2 study in adults 65 and older are anticipated in the first half of 2023.
  - Final results with the 6-month safety data from the two Phase 2 adult studies are anticipated in the first half of 2023.
  - Following the receipt of the final safety reports from the two adult Phase 2 studies, regulatory interactions to inform the Phase 3 program are anticipated in the second half of 2023.
  - Topline safety, tolerability and immunogenicity data from the Phase 3 non-inferiority study in adults are expected in 2025.

- ***VAX-24 Pediatric Program:***
  - The infant IND application submission and the Phase 2 study initiation are both anticipated in first half of 2023.
  - Topline safety, tolerability and immunogenicity data from the infant Phase 2 study following the primary 3-dose immunization series are expected by 2025. The study design will include a primary immunization series consisting of three doses followed by a subsequent booster dose.

- ***VAX-XP Adult Program:***

  - The IND application submission for VAX-XP is anticipated in the second half of 2023.
  - Topline safety, tolerability and immunogenicity data from a Phase 1/2 study in adults are expected in 2024.

- ***VAX-A1:*** Vaxcyte continues to advance development of VAX-A1, a novel conjugate vaccine designed to prevent infections caused by Group A Strep bacteria, and expects to provide guidance for its anticipated IND application submission to the FDA by the end of 2022.

- ***VAX-PG:*** Vaxcyte expects to nominate a final vaccine candidate for VAX-PG, its novel therapeutic vaccine designed to treat periodontal disease, by the end of 2022.

Third Quarter 2022 Financial Results

- ***Cash Position:*** Cash, cash equivalents and investments were $366.2 million as of September 30, 2022, compared to $273.1 million as of December 31, 2021. This amount excludes the approximately $650.7 million in estimated net proceeds from the follow-on offering completed in October 2022.

- ***Research & Development (R&D) Expenses:*** R&D expenses were $47.7 million for the three months ended September 30, 2022 as compared to $20.4 million for the same period in 2021. The increase was due primarily to increases in VAX-24 Phase 3 and VAX-XP IND readiness activities; the initiations of the VAX-24 Phase 1/2 clinical proof-of-concept study in adults 18-64 years of age and VAX-24 Phase 2 clinical study in adults 65 years and older; and increases in personnel-related expenses and facility-related and other allocated expenses.

- ***General & Administrative (G&A) Expenses:*** G&A expenses were $10.9 million for the three months ended September 30, 2022 as compared to $6.5 million for the same period in 2021. The increase was due primarily to personnel-related expenses.

- ***Net Loss:*** For the three months ended September 30, 2022, the net loss was $57.9 million, compared to $26.6 million for the same period in 2021.

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 pneumococcal conjugate vaccine being developed for the prevention of IPD. Vaxcyte is re-engineering the way highly complex vaccines are made through modern synthetic techniques, including advanced chemistry and the XpressCF^{TM} 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-XP, a PCV with coverage of 31 strains; VAX-A1, a prophylactic vaccine candidate designed to prevent Group A Strep infections; and VAX-PG, a therapeutic vaccine candidate designed to slow or stop the progression of periodontal disease. 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, including breadth of coverage, the ability to deliver a potentially best-in-class PCV and the 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 Phase 2 and Phase 3 studies and related regulatory interactions; the timing and submission of an IND application for the VAX-24 Phase 2 infant study and the availability of Phase 2 topline results; the timing and submission of an IND application for the VAX-XP adult program and the timing and availability of the Phase 1/2 topline data for such program; the potential for VAX-XP to become the broadest-spectrum PCV; the timing of guidance for an IND application for VAX-A1; the timing of a nomination of a final vaccine candidate for VAX-PG; the demand for Vaxcyte's vaccine candidates; and other statements that are not historical fact. The words "anticipate," "believe," "could," "expect," "intend," "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; impacts of COVID-19; 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, without limitation, its Quarterly Report on Form 10-Q filed with the SEC on November 7, 2022 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.

(1) Lower bound of the 2-sided 95% confidence interval of the OPA geometric mean titer ratio is greater than 0.5.
(2) 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 Day 29 is greater than 10%, and lower bound of the 2-sided 95% confidence interval of the OPA geometric mean titer ratio is greater than 2.0.

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Condensed Statements of Operations
(in thousands, except share and per share amounts)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	**2021**	**2022**	**2021**
Operating expenses:				
Research and development (1)	$ 47,679	$ 20,428	$ 117,825	$ 55,337
General and administrative (1)	10,898	6,523	27,858	18,487
Total operating expenses	58,577	26,951	145,683	73,824
Loss from operations	(58,577)	(26,951)	(145,683)	(73,824)
Other income (expense), net:				
Interest expense	-	-	(2)	(7)
Interest income	1,190	90	1,723	245
Grant income	157	299	1,006	677
Realized gain on marketable securities	-	1	-	2
Foreign currency transaction gains (losses)	(687)	(54)	(2,479)	1,393
Total other income (expense), net	660	336	248	2,310
Net loss	$ (57,917)	$ (26,615)	$ (145,435)	$ (71,514)
Net loss per share, basic and diluted	$ (0.93)	$ (0.51)	$ (2.42)	$ (1.39)
Weighted-average shares outstanding, basic and diluted	61,989,347	52,187,303	60,166,583	51,627,249

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

Research and development	$ 2,682	$ 1,023	$ 6,804	$ 2,688
General and administrative	3,966	1,914	9,837	4,883
Total stock-based compensation expense	$ 6,648	$ 2,937	$ 16,641	$ 7,571

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

	September 30, 2022	**December 31, 2021**
Cash, cash equivalents and investments	$ 366,203	$ 273,087
Total assets	412,065	324,337
Total stockholders' equity	359,311	284,018