Vaxcyte Reports First Quarter 2023 Financial Results and Provides Business Update

May 8, 2023

-- Positive Data from VAX-24 Phase 2 Study in Adults Aged 65 and Older Demonstrated Robust Immune Responses Across all 24 Serotypes (ST) at all Doses, Confirming Prior Phase 2 Results in Adults Aged 50-64 --

-- Full Six-Month Safety Data from Both Adult Studies Demonstrated VAX-24 Safety and Tolerability Results Similar to PCV20 at All Doses Studied --

-- Dosed First Participants in Infant Phase 2 Study Evaluating VAX-24 for the Prevention of Invasive Pneumococcal Disease (IPD) --

-- VAX-31 Progressing with Adult Investigational New Drug (IND) Application Submission and Subsequent Clearance Announcement Expected in Second Half 2023 and Topline Phase 1/2 Data in 2024 --

-- $949.9 Million in Cash, Cash Equivalents and Investments as of March 31, 2023, Excluding Net Proceeds of $545.1 Million from Recent Public Offering --

SAN CARLOS, Calif., May 08, 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 first quarter ended March 31, 2023 and provided a business update.

“We believe the recently announced positive results from the Phase 2 study in adults aged 65 and older confirm the clinical potential of our lead vaccine candidate in the adult population and validate our carrier-sparing, cell-free platform,” said Grant Pickering, Chief Executive Officer and Co-founder of Vaxcyte. “These data support a potential best-in-class profile for VAX-24 as well as our goal of creating PCVs that provide broader coverage and better immune responses compared to the standard-of-care vaccines. We look forward to discussing our Phase 2 program results with regulators as we advance towards a Phase 3 pivotal study for VAX-24 from which we expect topline data in 2025.”

“With the recent follow-on equity offering, which generated approximately $545 million in net proceeds, our balance sheet is further strengthened,” said Andrew Guggenhime, President and Chief Financial Officer of Vaxcyte. “This allows us to expand our manufacturing capabilities as we continue advancing our PCV franchise, comprised of VAX-24 and VAX-31, our 31-valent PCV candidate for which we expect to submit and announce the subsequent clearance of our adult IND application in the second half of this year.”

Key First Quarter and Recent Highlights

- ***Reported Positive Data from Phase 2 Study of VAX-24 in Adults Aged 65 and Older and Full Six-Month Safety Data from Adult Phase 1/2 and Phase 2 Studies:*** In April 2023, Vaxcyte announced positive results from the VAX-24 Phase 2 study in adults aged 65 and older, as well as data from the full six-month safety assessment and prespecified pooled immunogenicity analyses from both the Phase 2 study in adults aged 65 and older and the prior Phase 1/2 study in adults aged 18-64 (Phase 1 portion adults aged 18-49, Phase 2 portion adults aged 50-64). VAX-24, the Company’s lead, broad-spectrum 24-valent pneumococcal conjugate vaccine (PCV) candidate, is being studied for the prevention of IPD.
    - ***VAX-24 Phase 2 Study in Adults Aged 65 and Older Results:***
        - In the Phase 2 study in adults aged 65 and older, VAX-24 showed robust immune responses across all 24 STs at all doses studied, confirming the prior Phase 2 study results in adults aged 50-64.
        - At the 2.2mcg dose, which Vaxcyte plans to advance to a pivotal Phase 3 study, VAX-24:
            - Met the opsonophagocytic activity (OPA) response non-inferiority criteria[(1)] for 18 of 20 STs common with Prevnar 20® (PCV20) and met the superiority criteria[(2)] for all four additional STs unique to VAX-24.
            - Showed an overall improvement in immune responses vs. PCV20 relative to the results from the Phase 2 study in adults aged 50-64 and higher geometric mean ratios for 16 of 20 STs common with PCV20.
    - ***Safety and Tolerability Findings from Both Adult Studies:***
        - The six-month safety data from both studies showed safety and tolerability results for VAX-24 similar to PCV20 at all doses studied.

- ***Findings from Prespecified Pooled Analyses:***
  - The pooled immunogenicity analyses of data from both Phase 2 adult studies for adults 50+ (n~225/group) and 60+ (n~100/group), which could serve as a precursor for the pivotal Phase 3 study target population, met the OPA response non-inferiority criteria for all 20 STs common with PCV20 and met the superiority criteria for the four additional STs unique to VAX-24.

- ***Completed Successful $575 Million Follow-On Financing:*** In April 2023, Vaxcyte completed an underwritten public offering of 13,030,000 shares of its common stock, which included the full exercise of the underwriters' option to purchase additional shares, at a public offering price of $41.00 per share and pre-funded warrants to purchase 1,000,000 shares of common stock at a public offering price of $40.999 per underlying share. The aggregate gross proceeds to Vaxcyte from the offering were $575.2 million, before deducting underwriting discounts and commissions and other estimated offering expenses payable by Vaxcyte, and excluding the exercise of any pre-funded warrants.

- ***Dosed First Participants in Infant Phase 2 Study Evaluating VAX-24 for the Prevention of IPD:*** In March 2023, Vaxcyte announced that the first participants were dosed in the Phase 2 study of VAX-24 in healthy infants. Vaxcyte's Phase 2 infant study is being conducted in two stages. Stage 1 of the study, which is now currently underway, is evaluating the safety and tolerability of a single injection of VAX-24 at three dose levels and compared to VAXNEUVANCE™ (PCV15) in approximately 48 infants in a dose-escalation approach. The Stage 2 portion will evaluate the safety, tolerability and immunogenicity of VAX-24 at the same three dose levels and compared to PCV15 (or PCV20 contingent on pending discussions with the U.S. Food & Drug Administration (FDA)) in approximately 750 infants. The study design includes a primary immunization series consisting of three doses followed by a subsequent booster dose. Topline safety, tolerability and immunogenicity data following the primary three-dose immunization series are expected by 2025.

- ***VAX-24 Granted Breakthrough Therapy Designation from FDA for the Prevention of IPD in Adults Aged 18 and Older:*** In January 2023, Vaxcyte announced that the FDA granted Breakthrough Therapy designation for VAX-24 for the prevention of IPD in adults. With Breakthrough Therapy designation, Vaxcyte will have access to all of the elements of the FDA's Fast Track program, as well as the ability to receive guidance and support from the FDA on an efficient drug development program and an organizational commitment from senior managers within the FDA. The FDA's decision was based on positive topline results from the Phase 1/2 proof-of-concept study of VAX-24 in adults 18-64 years of age.

Anticipated Key Milestones

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

- ***VAX-24 Adult Program:***
  - End-of-Phase 2 meeting with the FDA in the second half of 2023 to inform the conduct of the adult Phase 3 program.
  - 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:***
  - Submission of the adult IND application to the FDA and announcement of subsequent FDA clearance in the second half of 2023.
  - Topline safety, tolerability and immunogenicity data from the Phase 1/2 study in adults in 2024.

First Quarter 2023 Financial Results

- ***Cash Position:*** Cash, cash equivalents and investments were $949.9 million as of March 31, 2023, compared to $957.9 million as of December 31, 2022. The March 31, 2023 amount excludes the $545.1 million in estimated net proceeds from the follow-on offering completed in April 2023.

- ***Research & Development (R&D) Expenses:*** R&D expenses were $58.1 million for the three months ended March 31, 2023 as compared to $31.7 million for the same period in 2022. The increase was due primarily to higher product and clinical development expenses for Vaxcyte's VAX-24 program, as well as an increase in personnel-related expenses related to the growth in the number of R&D employees.

- ***General & Administrative (G&A) Expenses:*** G&A expenses were $13.1 million for the three months ended March 31, 2023 as compared to $7.5 million for the same period in 2022. The increase was due primarily to higher personnel-related expenses related to an increase in G&A employees to support the growth of the Company.

- ***Net Loss:*** For the three months ended March 31, 2023, net loss was $60.5 million, compared to $39.0 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. 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-31, a 31-valent PCV candidate; 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, 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; the timing and availability of data for VAX-24 adult and infant studies and related regulatory interactions; the timing of submission and clearance of an IND application for the VAX-31 adult program and the timing and availability of the Phase 1/2 topline data for such program; the potential benefits and opportunities available as a result of the Breakthrough Therapy designation for VAX-24 in adults; the ability to expand manufacturing capabilities; 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; 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 its Quarterly Report on Form 10-Q filed with the SEC on May 8, 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.

(1) Lower bound of the 2-sided 95% confidence interval of the OPA geometric mean 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 ratio is greater than 2.0.

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

	Three Months Ended March 31,	
	2023	**2022**
Operating expenses:		
Research and development (1)	$ 58,080	$ 31,678
General and administrative (1)	13,112	7,543
Total operating expenses	71,192	39,221
Loss from operations	(71,192)	(39,221)
Other income (expense), net:		
Interest income	10,393	134

Grant income	654	160
Realized losses on marketable securities	-	(65)
Foreign currency transaction (losses) gains	(317)	6
Total other income (expense), net	10,730	235
Net loss	$ (60,462)	$ (38,986)
Net loss per share, basic and diluted	$ (0.70)	$ (0.68)
Weighted-average shares outstanding, basic and diluted	86,206,817	57,547,808

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

Research and development	$ 4,527	$ 1,775
General and administrative	5,121	2,324
Total stock-based compensation expense	$ 9,648	$ 4,099

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

	March 31, 2023	December 31, 2022
Cash, cash equivalents and investments	$ 949,853	$ 957,925
Total assets	1,008,163	1,006,178
Total stockholders' equity	944,771	953,613