Vaxcyte Reports Second Quarter 2023 Financial Results and Provides Business Update

August 8, 2023

-- Advanced Ongoing VAX-24 Phase 2 Infant Study to Second Stage, Dosing First New Participants in July 2023; Topline Data from Primary Immunization Series Expected by 2025 --

-- Completed Phase 2 VAX-24 Adult Program for the Prevention of Invasive Pneumococcal Disease (IPD); Topline Phase 3 Data Expected in 2025 --

-- VAX-31 Adult Investigational New Drug (IND) Application Clearance Expected in Fourth Quarter of 2023; Topline Phase 1/2 Data Expected in 2024 --

-- $1.4 Billion in Cash, Cash Equivalents and Investments as of June 30, 2023, Including Net Proceeds of $545.3 Million from April Public Offering --

SAN CARLOS, Calif., Aug. 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 second quarter ended June 30, 2023 and provided a business update.

“The need for vaccines that offer broader protection to prevent pneumococcal disease was recently reaffirmed by the Advisory Committee on Immunization Practices, and we believe the positive data from the VAX-24 adult Phase 2 clinical program support the potential best-in-class profile for our 24-valent PCV candidate to deliver broader coverage and improved immune responses compared to the standard-of-care,” said Grant Pickering, Chief Executive Officer and Co-founder of Vaxcyte. “Our strong balance sheet provides a solid foundation as we advance our PCV franchise and pipeline programs. We look forward to continued progress, including the finalization of our VAX-24 adult Phase 3 program and licensure requirements, and remain on track to deliver topline Phase 3 data in 2025.”

Key Second Quarter and Recent Highlights

- ***Completed VAX-24 Adult Phase 2 Program with Announcement of Positive Data in Adults 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. VAX-24, the Company’s lead, broad-spectrum 24-valent pneumococcal conjugate vaccine (PCV) candidate, is being studied for the prevention of IPD. In the Phase 2 study in adults aged 65 and older, VAX-24 demonstrated robust opsonophagocytic activity (OPA) immune responses across all 24 serotypes at all doses studied, confirming the prior Phase 2 adult study results. The VAX-24 2.2mcg dose, which Vaxcyte plans to advance to Phase 3, showed an overall improvement in immune responses vs. Prevnar 20® (PCV20) relative to the results from the prior Phase 2 study in adults aged 50-64. The six-month safety data from both studies showed safety and tolerability results for VAX-24 similar to PCV20 at all doses studied. Additionally, the prespecified pooled immunogenicity analyses of data from both adult Phase 2 studies showed the VAX-24 2.2mcg dose met the OPA non-inferiority criteria(1) for all 20 serotypes common with PCV20 and the superiority criteria(2) for the four additional VAX-24 serotypes.

- ***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 were enrolled and dosed in Stage 2 of the study in July 2023. Additionally, in agreement with the U.S. Food and Drug Administration (FDA), Vaxcyte amended the study protocol for Stage 2, changing the study comparator to PCV20, which is currently the broadest-spectrum PCV recommended by the Advisory Committee on Immunization Practices.

- ***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 offering expenses

payable by Vaxcyte and excluding the exercise of any pre-funded warrants.

- ***Published New VAX-GI Preclinical Data and Received NIH Grants:*** A paper entitled, "A Novel Shigella O-Polysaccharide–IpaB Conjugate Vaccine Elicits Robust Antibody Responses and Confers Protection against Multiple Shigella Serotypes," was published in the April 2023 edition of *mSphere* featuring new preclinical data for VAX-GI, Vaxcyte's novel Shigella vaccine candidate. These data demonstrated that with Vaxcyte's cell-free technology, the Company believes it can produce the central antigen in VAX-GI, IpaB, at substantially improved yields, allowing for commercial-scale production of the target vaccine. Additionally, this research showed that the vaccine candidate was efficacious in preclinical models of Shigella infection. Shigella, which has no available preventative treatment, affects an estimated 188 million people worldwide each year and results in approximately 164,000 deaths. This vaccine candidate is being developed in collaboration with the University of Maryland, Baltimore as well as with partial funding from two National Institutes of Health research (R01) grants totaling $7.2 million.

In Memoriam

"In early July, we were saddened by the sudden passing of Michael E. Kamarck, Ph.D., a member of our Board of Directors. Mike was a luminary in the biopharmaceutical industry, with long-standing, major contributions in vaccine and therapeutic product development and manufacturing that spanned over four decades. His desire to improve the lives of people around the world was evident through this commitment to public health and his support of companies large and small, on which he left a lasting mark. Mike's compassionate nature extended far beyond his work as a beloved husband, father, grandfather and friend. We extend our deepest condolences to his family and all those he impacted throughout his life," said Mr. Pickering.

Anticipated Key Milestones

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

- ***VAX-24 Adult Program:***
  - Several regulatory interactions to finalize the Company's Phase 3 clinical program and Biologics License Application submission requirements including:
    - An End-of-Phase 2 meeting with the FDA regarding the adult Phase 3 clinical program expected in the fourth quarter of 2023.
    - Discussions afforded by the Breakthrough Therapy designation granted by the FDA, including meetings regarding the Company's CMC strategy 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:***
  - Clearance of the adult IND application by the FDA in the fourth quarter of 2023 following submission.
  - Topline safety, tolerability and immunogenicity data from the Phase 1/2 study in adults in 2024.

Second Quarter 2023 Financial Results

- ***Cash Position:*** Cash, cash equivalents and investments were $1,440.8 million as of June 30, 2023, compared to $957.9 million as of December 31, 2022. The June 30, 2023 amount includes the $545.3 million in net proceeds from the follow-on offering completed in April 2023.
- ***Research & Development (R&D) Expenses:*** R&D expenses were $72.7 million for the three months ended June 30, 2023 as compared to $38.5 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 $14.5 million for the three months ended June 30, 2023 as compared to $9.4 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 June 30, 2023, net loss was $68.3 million, compared to $48.5 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, including the viability and market opportunity of Vaxcyte's Shigella vaccine candidate; the timing and availability of data for the VAX-24 adult and infant studies and related regulatory interactions; the timing of the 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; 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 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 June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Operating expenses:				
Research and development (1)	$ 72,691	$ 38,469	$ 130,771	$ 70,147
General and administrative (1)	14,456	9,417	27,567	16,960
Total operating expenses	87,147	47,886	158,338	87,107
Loss from operations	(87,147)	$ (47,886)	(158,338)	(87,107)
Other income (expense), net:				
Interest expense	-	(2)	-	(2)
Interest income	16,451	399	26,844	533
Grant income	2,464	690	3,119	850
Foreign currency transaction (losses) gains	(107)	(1,733)	(426)	(1,792)
Total other income (expense), net	18,808	(646)	29,537	(411)
Net loss	$ (68,339)	$ (48,532)	$ (128,801)	$ (87,518)
Net loss per share, basic and diluted	$ (0.70)	$ (0.80)	$ (1.40)	$ (1.48)
Weighted-average shares outstanding, basic and diluted	98,057,870	60,818,778	92,165,076	59,192,182

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

Research and development	$ 5,911	$ 2,347	$ 10,438	$ 4,122
General and administrative	6,633	3,547	11,754	5,871
Total stock-based compensation expense	$ 12,544	$ 5,894	$ 22,192	$ 9,993

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

	June 30, 2023	December 31, 2022
Cash, cash equivalents and investments	$ 1,440,790	$ 957,925
Total assets	1,502,819	1,006,178
Total stockholders' equity	1,433,376	953,613