Vaxcyte Reports Third Quarter 2020 Financial Results and Provides Business Update

November 12, 2020

FOSTER CITY, Calif., Nov. 12, 2020 (GLOBE NEWSWIRE) -- Vaxcyte, Inc., formerly known as SutroVax, a next-generation vaccine company seeking to improve global health by developing superior and novel vaccines designed to prevent or treat some of the most common and deadly infectious diseases worldwide, today announced financial results for the third quarter ended September 30, 2020 and provided a business update.

"Vaxcyte continues to make steady progress in executing on our business objectives," said Grant Pickering, Chief Executive Officer and Co-founder of Vaxcyte. "We advanced several important manufacturing activities for VAX-24, our 24-valent investigational pneumococcal conjugate vaccine, or PCV, designed to prevent invasive pneumococcal disease, as we proceed toward our anticipated IND filing in the second half of next year. In addition, we continued to progress our pipeline vaccines, including VAX-XP, our PCV candidate with an expanded breadth of coverage of at least 30 strains, as part of our PCV franchise life cycle management strategy. We also were pleased to further strengthen our leadership team, as we approach the clinic, with the additions of Rom Colindres as Chief Medical Officer and Sue Fekete as Vice President, Regulatory Affairs."

Recent Highlights

- ***Advanced VAX-24 Manufacturing Activities:*** Vaxcyte progressed several manufacturing initiatives for VAX-24, including for the good manufacturing practices (GMP) batches of the 24 polysaccharide antigens and the GMP batches of the 24 conjugate drug substances.

- ***Appointed Romulo Colindres, MD, MPH as Chief Medical Officer:*** In November 2020, Vaxcyte appointed Romulo Colindres, MD, MPH as Chief Medical Officer. Prior to joining Vaxcyte, Dr. Colindres served in several roles at GlaxoSmithKline Vaccines and most recently served as an independent consultant and advisor to multiple biotechnology companies. From March 2007 to March 2019, Dr. Colindres served in roles of increasing responsibility at GlaxoSmithKline, including Head of Health Outcomes for GSK Vaccines Latin America, Head of Global Epidemiology for GSK Vaccines and, most recently, Vice President, Global Medical Affairs Lead, Zoster Vaccine, leading the medical team in the successful launch of Shingrix®, a recombinant adjuvanted herpes zoster vaccine. Prior to that, Dr. Colindres worked at the Centers for Disease Control and Prevention (CDC) as an Epidemic Intelligence Service Officer. He completed his residency at Children's National Medical Center in Washington, DC and was board certified in Pediatrics. Dr. Colindres received both his MD and MPH at The University of North Carolina, Chapel Hill, and his MBA from Duke University's Fuqua School of Business.

- ***Appointed Suzanna Fekete, MSc as Vice President, Regulatory Affairs:*** In October 2020, Vaxcyte appointed Suzanna Fekete, MSc as Vice President, Regulatory Affairs. Prior to joining Vaxcyte, Ms. Fekete served in roles of increasing responsibility at Takeda Vaccines since 2015, most recently as Vice President and Head, Global Regulatory Affairs. Ms. Fekete also served as Head, North American Regulatory Affairs at Novartis Vaccines and Diagnostics and held regulatory affairs leadership roles at multiple other pharmaceutical and biotechnology companies. Ms. Fekete received her MSc at the University of Wales.

Anticipated Milestones

Vaxcyte reaffirmed its previously issued guidance for its pipeline programs.

- ***VAX-24:*** Vaxcyte expects to submit an Investigational New Drug (IND) application for VAX-24 to the U.S. Food and Drug Administration (FDA) and initiate its Phase 1/2 clinical proof-of-concept study in the second half of 2021. Vaxcyte expects to announce topline data from this study in 2022.

- ***VAX-A1:*** In 2021, Vaxcyte expects to nominate a final vaccine candidate for VAX-A1, its novel conjugate vaccine designed to provide universal protection from infections caused by Group A Strep bacteria, which include pharyngitis, toxic shock syndrome and necrotizing fasciitis.

- ***VAX-PG:*** In 2021, Vaxcyte expects to nominate a final vaccine candidate for VAX-PG, its novel therapeutic vaccine designed to treat periodontal disease.

Third Quarter 2020 Financial Results

- ***Cash Position:*** Cash and cash equivalents were $397.0 million as of September 30, 2020, compared to $59.0 million as of December 31, 2019, an increase due to Vaxcyte's IPO in June 2020 and Series D financing in March 2020, which generated net proceeds of $264.0 million and $109.9 million, respectively.

- ***Research & Development (R&D) Expenses:*** R&D expenses were $16.4 million for the three months ended September 30, 2020 as compared to $9.6 million for the same period in 2019. The increase was due primarily to an increase in manufacturing expenses and outsourced research services related to the Company's VAX-24 program.

- ***General & Administrative (G&A) Expenses:*** G&A expenses were $4.9 million for the three months ended September 30, 2020 as compared to $2.5 million for the same period in 2019. The increase was due primarily to an increase in personnel-related and directors and officers insurance expenses.

- ***Net Loss:*** For the three months ended September 30, 2020, net loss was $21.0 million, compared to $11.3 million for the three months ended September 30, 2019.

About Vaxcyte

Vaxcyte is a next-generation vaccine company seeking to improve global health by developing superior and novel vaccines designed to prevent or treat some of the most common and deadly infectious diseases worldwide. The Company's cell-free protein synthesis platform, comprising the XpressCF™ platform, exclusively licensed from Sutro Biopharma, Inc., together with Vaxcyte's proprietary know-how, enables the design and production of protein carriers and antigens, the critical building blocks of vaccines, in ways that the Company believes conventional vaccine technologies currently cannot. Vaxcyte's lead vaccine candidate, VAX-24, is a preclinical, 24-valent broad-spectrum pneumococcal conjugate vaccine (PCV) being developed for the prevention of invasive pneumococcal disease (IPD). Vaxcyte's pipeline also includes VAX-XP, a PCV with an expanded breadth of coverage of at least 30 strains, including newly emerging strains responsible for IPD and antibiotic resistance; 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 by targeting the keystone pathogen responsible for this chronic, oral inflammatory disease. 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 process and timing of anticipated future development of Vaxcyte's vaccine candidates, including the submission of an IND and initiation of a Phase 1/2 study of VAX-24 in the second half of 2021 and the announcement of topline data in 2022; the nomination of a final vaccine candidate for VAX-A1 in 2021 and the nomination of a final vaccine candidate for VAX-PG in 2021. The words "anticipate," "believe," "continue," "could," "estimate," "expect," "intend," "may," "plan," "potential," "predict," "project," "should," "target," "will," "would" and similar expressions 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 12, 2020 or in other documents Vaxcyte subsequently files with or furnishes to the SEC. 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)
(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Operating expenses:				
Research and development [1]	$ 16,410	$ 9,630	$ 58,903	$ 32,225
General and administrative [1]	4,898	2,510	11,225	6,089
Total operating expenses	21,308	12,140	70,128	38,314

Loss from operations	(21,308)	(12,140)	(70,128)	(38,314)
Other income (expense), net				
Interest expense	—	(9)	(7)	(33)
Interest income	33	120	212	537
Grant income	787	54	2,152	54
Foreign currency transaction losses	(530)	(186)	(709)	(417)
Change in fair value of the redeemable convertible preferred stock tranche liability	—	844	—	2,520
Total other income (expense), net	290	823	1,648	2,661
Net loss and comprehensive loss	$ (21,018)	$ (11,317)	$ (68,480)	$ (35,653)
Net loss per share, basic and diluted	$ (0.41)	$ (2.93)	$ (3.06)	$ (9.54)
Weighted-average shares outstanding, basic and diluted	50,895,358	3,857,298	22,354,212	3,737,779

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

Research and development	$ 558	$ 88	$ 1,081	$ 262
General and administrative	1,280	178	2,418	548
Total stock-based compensation expense	$ 1,838	$ 266	$ 3,499	$ 810

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

	September 30, 2020	December 31, 2019
Cash and cash equivalents	$ 397,048	$ 58,976
Total assets	403,816	65,698
Redeemable convertible preferred stock	—	160,310
Total stockholders' equity (deficit)	364,075	(106,373)

Source: Vaxcyte, Inc.