UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): August 08, 2022

Vaxcyte, Inc.

(Exact name of Registrant as Specified in Its Charter)

Delaware	**01-39323**	**46-4233385**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

825 Industrial Road **Suite 300** **San Carlos, California**	**94070**
(Address of Principal Executive Offices)	**(Zip Code)**

Registrant's Telephone Number, Including Area Code: 650 837-0111

Not Applicable
(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	**Trading Symbol(s)**	**Name of each exchange on which registered**
Common Stock, $0.001 par value per share	PCVX	The NASDAQ Stock Market LLC

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 2.02 Results of Operations and Financial Condition.

On August 8, 2022, Vaxcyte, Inc. issued a press release announcing its financial results for the quarter ended June 30, 2022. The full text of the press release is furnished as Exhibit 99.1 to this report on Form 8-K and is incorporated herein by reference.

The information in this Item 2.02 and Item 9.01, including Exhibit 99.1, shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference into any registration statement or other document filed under the Securities Act of 1933, as amended or the Exchange Act, except as shall be expressly set forth by specific reference in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	Description
99.1	Press Release of Vaxcyte, Inc., dated August 8, 2022
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Date: August 8, 2022

By: /s/ Andrew Guggenhime

Andrew Guggenhime
President and Chief Financial Officer

Exhibit 99.1

Vaxcyte Reports Second Quarter 2022 Financial Results and Provides Business Update

-- Completed Enrollment of Phase 2 Portion of Phase 1/2 Clinical Proof-of-Concept Study Evaluating Safety, Tolerability and Immunogenicity of VAX-24 in Adults --

-- Announcement of Topline Results from the Phase 1 and Phase 2 Portions of the VAX-24 Proof-of-Concept Study Expected in October or November 2022 --

-- First Participants Dosed in Separate VAX-24 Phase 2 Clinical Study in Adults 65 Years and Older, with Topline Data Expected in the First Half of 2023 --

-- Received FDA Fast Track Designation for VAX-24 in Adults --

-- Completed Successful Pre-IND Meeting with FDA Regarding VAX-24 Pediatric Program, Supporting Path to Proceed Directly into Infants --

--$361.4 Million in Cash, Cash Equivalents and Investments as of June 30, 2022 --

SAN CARLOS, Calif., August 8, 2022 – 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, 2022 and provided a business update.

“Completing enrollment of the Phase 2 portion of our clinical proof-of-concept study in adults is a significant milestone in the advancement of VAX-24, our 24-valent pneumococcal conjugate vaccine (PCV), putting us on track to announce the topline safety, tolerability and immunogenicity results, versus the standard-of-care, in October or November of this year,” said Grant Pickering, Chief Executive Officer and Co-founder of Vaxcyte. “We expect this study, if successful, to be a driver of further activity across our PCV franchise, including the initiation of a VAX-24 study in infants and advancement of VAX-XP, our PCV candidate with an expanded breadth of coverage of greater than 30 strains.”

Mr. Pickering continued, “We believe the positive feedback from the FDA regarding both the adult and pediatric VAX-24 clinical programs, including receiving Fast Track designation in adults, supports an expedited path to deliver the broadest-spectrum PCV designed to prevent this serious disease. With significant upcoming milestones for the VAX-24 program, as well as across our pipeline, we expect continued, meaningful progress in the coming months.”

Recent Highlights

- ***Completed Enrollment of Phase 2 Portion of VAX-24 Phase 1/2 Clinical Proof-of-Concept Study in Adults:*** In July 2022, Vaxcyte announced the completion of enrollment in the Phase 2 portion of the ongoing Phase 1/2 clinical proof-of-concept study in adults 18-64 years of age. VAX-24 was designed to prevent invasive pneumococcal disease (IPD) and deliver the broadest-spectrum PCV.

- The VAX-24 Phase 1/2 clinical proof-of-concept study (VAX-24 Study 101, NCT05266456) is a randomized, observer-blind, dose-finding, controlled study designed to evaluate the safety, tolerability and immunogenicity of VAX-24 in healthy adults 18-64 years of age.
- The Phase 1 portion of the study is evaluating safety and tolerability of a single injection of VAX-24 at three dose levels and compared to Prevnar 20™ in 64 healthy adults 18 to 49 years of age.
- The Phase 2 portion is evaluating the safety, tolerability and immunogenicity of a single injection of VAX-24 at three dose levels and compared to a single injection of Prevnar 20™ in approximately 800 healthy adults 50 to 64 years of age. The prespecified immunogenicity endpoints of the Phase 2 portion of the study include an assessment of the induction of antibody responses, using opsonophagocytic activity (OPA) and immunoglobulin G (IgG), at each of the three VAX-24 doses and compared to Prevnar 20™ and, for the additional four serotypes contained in VAX-24 and Pneumovax® 23, but not in Prevnar 20™, the percentage of subjects that experience a four-fold rise in antibody titers.
- Participants in the study will be evaluated for safety through six months after vaccination.
- The study enrolled subjects at 13 sites in the United States.

- ***Initiated Separate VAX-24 Phase 2 Clinical Study in Adults 65 Years and Older:*** In July 2022, Vaxcyte dosed the first participants in a separate Phase 2 study in adults 65 years of age and older. This study is intended to further build the body of clinical evidence to support the potential of VAX-24 as the broadest-spectrum PCV in adults.
  - This VAX-24 Phase 2 clinical study (VAX-24 Study 102, NCT05297578) is a randomized, observer-blind, dose-finding, controlled study designed to evaluate the safety, tolerability and immunogenicity of VAX-24 in approximately 200 healthy adults 65 years of age and older.
  - The study is evaluating the safety, tolerability and immunogenicity of a single injection of VAX-24 at three dose levels and compared to a single injection of Prevnar 20™. The prespecified immunogenicity endpoints of the study include an assessment of the induction of antibody responses, using OPA and IgG, at each of the three VAX-24 doses and compared to Prevnar 20™ and, for the additional four serotypes contained in VAX-24 and Pneumovax® 23, but not in Prevnar 20™, the percentage of subjects that experience a four-fold rise in antibody titers.
  - Participants in the study will be evaluated for safety through six months after vaccination.
  - The study is currently being conducted at approximately 20 sites in the United States.

- ***Received FDA Fast Track Designation for VAX-24 in Adults:*** In early 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. Companies with products receiving Fast

Track designation are eligible for more frequent meetings with the FDA to discuss the drug's development plan and ensure collection of data needed to support drug approval and more frequent written communication from the FDA about things such as the design of proposed clinical trials. Finally, these companies may also be eligible for Accelerated Approval and Priority Review, if relevant criteria are met.

- ***Completed Successful Pre-Investigational New Drug (IND) Meeting with FDA Regarding VAX-24 Pediatric Development Program***: In July 2022, the Company successfully completed a pre-IND meeting with the FDA regarding the pediatric clinical program for VAX-24. Vaxcyte received positive written feedback from the FDA supporting the initiation of a pediatric study that proceeds directly into infants contingent on satisfactory topline safety, tolerability and immunogenicity results from the ongoing 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 a potentially best-in-class PCV, VAX-24, to the pediatric population, which represents the largest portion of the pneumococcal vaccine market in the United States.

- ***Published New Research Supporting the Potential of Vaxcyte's Technology Platform:*** The paper, *"Non-Native Amino Acid Click Chemistry-Based Technology for Site-Specific Polysaccharide Conjugation to a Bacterial Protein Serving as Both Carrier and Vaccine Antigen,"* published in the July 2022 edition of the journal *ACS Omega*, demonstrates the potential advantages of Vaxcyte's site-specific conjugation technology, the XpressCF™ cell-free protein synthesis platform, over random conjugation associated with the limitations of traditional chemistry. Specifically, this study used the Company's platform technology to preserve B-cell and T-cell epitopes that are critical for generating T-cell help and protective immune responses against Group A Streptococcus (Strep). Key findings from this study, which received the American Chemical Society Editor's Choice Award, include:
  - The XpressCF™ platform produced a streptolysin O (SLO) protein containing several non-native amino acids to facilitate site-specific conjugation to the polyrhamnose backbone of the Group A Strep carbohydrate to form a conjugate vaccine.
  - This vaccine candidate produced robust antibody responses and generated functional antibodies against both conserved Group A Strep virulence factors.
  - Additionally, this vaccine candidate also provided protection against systemic Group A Strep challenge, whereas conventional conjugation technologies showed a marked decrease in immunogenicity when employing the same immunogens.

Anticipated Key Milestones

- ***VAX-24:***
  - ***Phase 1/2 Study in Adults Aged 18-64:*** The Phase 1/2 clinical proof-of-concept study is now fully enrolled and the Company expects to announce topline safety and tolerability results from the Phase 1 portion of the study and safety, tolerability and immunogenicity results from the Phase 2 portion of the study in October or November 2022.

- ***Phase 2 Study in Adults Aged 65 and Older:*** The first participants have been dosed in the separate Phase 2 study in adults 65 years of age and older and topline safety, tolerability and immunogenicity results from this study are expected in the first half of 2023.

- ***Pediatric IND Application:*** Vaxcyte also anticipates submitting its first VAX-24 pediatric IND application to the FDA in the first half of 2023, subject to satisfactory topline results from the ongoing VAX-24 Phase 1/2 clinical proof-of-concept study in adults 18 to 64 years of age.

- ***VAX-XP:*** Vaxcyte continues to progress VAX-XP, the Company's PCV candidate with an expanded breadth of coverage of greater than 30 strains, and expects to provide guidance for the anticipated submission of its IND application in adults to the FDA following the announcement of the topline results from the ongoing VAX-24 Phase 1/2 study in adults aged 18 to 64.

- ***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 in the second half 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.

Second Quarter 2022 Financial Results

- ***Cash Position:*** Cash, cash equivalents and investments were $361.4 million as of June 30, 2022, compared to $273.1 million as of December 31, 2021.

- ***Research & Development (R&D) Expenses:*** R&D expenses were $38.5 million for the three months ended June 30, 2022 as compared to $17.7 million for the same period in 2021. The increase was due primarily to higher product and clinical development expenses attributable to the VAX-24 Phase 1/2 clinical proof-of-concept study, VAX-XP IND readiness activities and VAX-24 Phase 3 readiness activities, which were partially offset by a decrease in VAX-24 IND readiness activities; an increase in personnel-related expenses as a result of headcount growth; and an increase in facility-related and other allocated expenses.

- ***General & Administrative (G&A) Expenses:*** G&A expenses were $9.4 million for the three months ended June 30, 2022 as compared to $6.1 million for the same period in 2021. The increase was due primarily to an increase in personnel-related expenses.

- ***Net Loss:*** For the three months ended June 30, 2022, the net loss was $48.5 million, compared to $23.7 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 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™ 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 an expanded breadth of coverage of greater than 30 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 improvement upon the standard-of-care, the ability to deliver a potentially best-in-class PCV and the achievement of clinical proof-of-concept; the process and timing of anticipated future development, milestones and momentum of Vaxcyte's vaccine candidates; the timing, availability and outcome of topline data for the VAX-24 Phase 1/2 clinical proof-of-concept study and Phase 2 clinical study; the demand for Vaxcyte's vaccine candidates; and other statements that are not historical fact. The words "believe," "could," "expect," "may," "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 August 8, 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.

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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,	
	2022	2021	2022	2021
Operating expenses:				
Research and development [1]	$ 38,469	$ 17,651	$ 70,147	$ 34,909
General and administrative [1]	9,417	6,079	16,960	11,964
Total operating expenses	47,886	23,730	87,107	46,873
Loss from operations	(47,886)	(23,730)	(87,107)	(46,873)
Other income (expense), net:				
Interest expense	(2)	(7)	(2)	(7)
Interest income	399	93	533	155
Grant income	690	378	850	378
Realized gain on marketable securities	—	1	—	1
Foreign currency transaction gains (losses)	(1,733)	(414)	(1,792)	1,447
Total other income (expense), net	(646)	51	(411)	1,974
Net loss	$ (48,532)	$ (23,679)	$ (87,518)	$ (44,899)
Net loss per share, basic and diluted	$ (0.80)	$ (0.46)	$ (1.48)	$ (0.87)
Weighted-average shares outstanding, basic and diluted	60,818,778	51,508,340	59,192,182	51,342,585

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

Research and development	$ 2,347	$ 982	$ 4,122	$ 1,665
General and administrative	3,547	1,787	5,871	2,969
Total stock-based compensation expense	$ 5,894	$ 2,769	$ 9,993	$ 4,634

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

	June 30, 2022	December 31, 2021
Cash, cash equivalents and investments	$ 361,361	$ 273,087
Total assets	411,619	324,337
Total stockholders' equity	366,500	284,018