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): November 10, 2021

VAXCYTE, INC.

(Exact name of Registrant as Specified in Its Charter)

Delaware	**001-39323**	**46-4233385**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**
353 Hatch Drive **Foster City, California**		**94404**
(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

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 November 10, 2021, Vaxcyte, Inc. issued a press release announcing its financial results for the quarter ended September 30, 2021. 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 November 10, 2021
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.

VAXCYTE, INC.

Date: November 10, 2021

By: /s/ Andrew Guggenhime

Andrew Guggenhime
President and Chief Financial Officer

Exhibit 99.1

Vaxcyte Reports Third Quarter 2021 Financial Results and Provides Business Update

-- Company Expects to Submit VAX-24 IND Application to FDA in Q1 2022 --

-- Completed Manufacture of VAX-24 GMP Drug Product and GLP Toxicology Study --

FOSTER CITY, Calif., November 10, 2021 – Vaxcyte, Inc. (Nasdaq: PCVX), 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, 2021 and provided a business update.

“We continue to make meaningful progress with the IND-enabling activities for VAX-24, our lead, 24-valent pneumococcal conjugate vaccine (PCV) candidate, having completed both the manufacture of the GMP drug product and the GLP toxicology study,” said Grant Pickering, Chief Executive Officer and Co-founder of Vaxcyte. “With these steps successfully completed, we are pleased to share that we currently expect to submit the VAX-24 IND application to the FDA in the first quarter of 2022.”

Mr. Pickering continued, “As we make important strides with VAX-24, bringing us closer to clinical proof-of-concept, the public health community continues to affirm the need for a PCV that offers broader protection to prevent pneumococcal disease. Our PCV franchise, consisting of VAX-24 and VAX-XP, with expanded breadth of coverage of greater than 30 strains, was designed with this in mind and has the potential to deliver the broadest protection to this very serious disease.”

Recent Highlights

- ***Advanced VAX-24 Investigational New Drug (IND)-Enabling Activities:*** Vaxcyte continues to make significant progress with VAX-24, including the recent completion of the formal release of the 24 good manufacturing practice (GMP) conjugated drug substances (DS), the good laboratory practice (GLP) non-clinical toxicology study and the manufacture (formulation, fill and finish) of the GMP drug product (DP).

- ***Presented Preclinical Data Supporting the Potential of VAX-XP:*** The poster, *“Development of a Next Generation 30+ Valent Pneumococcal Conjugate Vaccine (VAX-XP) Using Site-Specific Carrier Protein Conjugation,”* presented at IDWeek 2021, evaluated the immunogenicity of VAX-XP, Vaxcyte’s PCV candidate with an expanded breadth of coverage, in New Zealand white rabbits. The key study findings presented include:
    - VAX-XP showed conjugate-like immune responses for all 31 serotypes, as demonstrated by IgG immune responses 14 days after both an initial and booster dose that were superior to polysaccharide-based vaccines and comparable to Prevnar 13®.

- All serotypes in VAX-XP elicited a T-cell dependent immune response as demonstrated by the increase in IgG titers post-boost.

- ***Initiated VAX-A1 IND-Enabling Activities:*** Vaxcyte continues to advance development of VAX-A1, a novel conjugate vaccine designed to prevent infections caused by Group A *Streptococcus pyogenes* (Strep) bacteria. Following the nomination of its final VAX-A1 vaccine candidate in the first quarter of 2021, the Company initiated IND-enabling studies in the second half of 2021, consistent with prior guidance.
- ***Enhanced Board of Directors with Appointment of Four Industry Veterans:*** In October 2021, the Company appointed Dr. Carlos Paya, who serves as the Board Chair, and Dr. Michael Kamarck to its board of directors. This followed the September 2021 board appointments of Annie Drapeau and Teri Loxam. These accomplished industry leaders have deep experience across the biopharmaceutical and vaccine industries and will provide additional skills and expertise as the Company advances and scales its business.

- ***Appointed Harp Dhaliwal as Senior Vice President, Commercial Manufacturing & Supply Chain*****:** In October 2021, Harp Dhaliwal joined as Senior Vice President of Commercial Manufacturing and Supply Chain and a member of the executive team. Mr. Dhaliwal has 25 years of experience in engineering, operations strategy, manufacturing and supply chain, with significant expertise in the healthcare industry. During his career, he has led commercial manufacturing and supply chain for multiple products. Most recently, Mr. Dhaliwal served as Senior Vice President of Supply Chain, Manufacturing and Procurement at Dermira and transitioned to Eli Lilly following the company's acquisition. In this role, he supported Dermira's first product launch and successfully transitioned the cGMP manufacturing network from clinical to commercial. Previously, Mr. Dhaliwal was the Head of Manufacturing and Supply Chain at Medivation, an oncology-focused company. Following Pfizer's acquisition of Medivation, Mr. Dhaliwal led the operations integration. Previously, Mr. Dhaliwal had a long career at Biogen where he ultimately served as Biogen's Chief Procurement Officer, responsible for managing $3 billion of enterprise-wide spend. While at Biogen, he was also instrumental in transforming the manufacturing network, initiating the biosimilar business and other strategic initiatives. Mr. Dhaliwal has an MBA in Science and Technology from Queen's University and a Bachelor of Chemical Engineering from the University of British Columbia.

- ***Expanded Scientific Advisory Board with Appointment of Dr. Emmanuel Hanon:*** In July 2021, Vaxcyte added Dr. Emmanuel Hanon, a healthcare veteran and the Global Head of R&D for Viome, to its Scientific Advisory Board. Previously, Dr. Hanon spent 20 years at GlaxoSmithKline (GSK) in R&D roles of increasing responsibility, most recently serving as Senior Vice President, Head of Vaccine R&D and a member of GSK's Vaccine Executive Team. In this role, he oversaw more than 3,500 employees across 50 countries dedicated to the discovery, development and management activities for GSK's vaccine efforts. Additionally, Dr. Hanon was responsible for the shared science and technology platforms supporting the entire vaccine business, managing technical development, clinical immunology and preclinical stages of vaccine development. While at GSK, he contributed to the innovation of many vaccines targeting human papilloma virus, malaria, tuberculosis, seasonal and pandemic influenza, shingles, meningitis and RSV. Dr. Hanon has a Ph.D. in Immunology, Virology, and Vaccinology and a Doctorate in Veterinary Medicine from the University of Liège.

Anticipated Key Milestones

- ***VAX-24:*** The Company currently expects to submit the VAX-24 IND application to the FDA in the first quarter of 2022, following the anticipated completion of the remaining drug product testing and release, as well as documentation of stability. Vaxcyte continues to anticipate announcing topline data from the ensuing Phase 1/2 clinical proof-of-concept study in adults between late 2022 and early 2023.
- ***VAX-PG:*** Vaxcyte expects to nominate a final vaccine candidate for VAX-PG, its novel therapeutic vaccine designed to treat periodontal disease, in the first half of 2022.

Third Quarter 2021 Financial Results

- ***Cash Position:*** Cash, cash equivalents and investments were $318.3 million as of September 30, 2021, compared to $386.2 million as of December 31, 2020.
- ***Research & Development (R&D) Expenses:*** R&D expenses were $20.4 million for the three months ended September 30, 2021 as compared to $16.4 million for the same period in 2020. The increase was due primarily to personnel-related expenses, facility-related and other allocated expenses, and R&D consumables related to VAX-24 and VAX-XP.
- ***General & Administrative (G&A) Expenses:*** G&A expenses were $6.5 million for the three months ended September 30, 2021 as compared to $4.9 million for the same period in 2020. The increase was due primarily to an increase in personnel-related and other expenses to support public company operations.

- ***Net Loss:*** Net loss was $26.6 million for the three months ended September 30, 2021 as compared to $21.0 million for the same period in 2020.

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. Vaxcyte's pipeline also includes VAX-XP, a PCV with an expanded breadth of coverage of at least 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 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 benefit of Vaxcyte's vaccine candidates; the process and timing of anticipated future development of Vaxcyte's vaccine candidates, including the timing and submission of an IND application for VAX-24 and the initiation of the VAX-24 Phase 1/2 clinical

proof-of-concept study thereafter; the timing and availability of topline data for VAX-24; the completion of the drug product testing and release, as well as documentation of stability, for VAX-24; the 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 "believe," "could," "expect," "may," "potential," "should," "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 10, 2021 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)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	**2020**	**2021**	**2020**
Operating expenses:				
Research and development (1)	$ 20,428	$ 16,410	$ 55,337	$ 58,903
General and administrative (1)	6,523	4,898	18,487	11,225
Total operating expenses	26,951	21,308	73,824	70,128
Loss from operations	(26,951)	(21,308)	(73,824)	(70,128)
Other income (expense), net:				
Interest expense	—	—	(7)	(7)
Interest income	90	33	245	212
Grant income	299	787	677	2,152
Realized gain on marketable securities	1	—	2	—
Foreign currency transaction gains (losses)	(54)	(530)	1,393	(709)
Total other income (expense), net	336	290	2,310	1,648
Net loss	$ (26,615)	$ (21,018)	$ (71,514)	$ (68,480)
Net loss per share, basic and diluted	$ (0.51)	$ (0.41)	$ (1.39)	$ (3.06)
Weighted-average shares outstanding, basic and diluted	52,187,303	50,895,358	51,627,249	22,354,212

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

Research and development	$ 1,023	$ 558	$ 2,688	$ 1,081
General and administrative	1,914	1,280	4,883	2,418
Total stock-based compensation expense	$ 2,937	$ 1,838	$ 7,571	$ 3,499

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

	September 30, 2021	**December 31, 2020**
Cash, cash equivalents and investments	$ 318,311	$ 386,200
Total assets	354,068	392,826
Total stockholders' equity	305,956	345,843