

**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): March 29, 2021

VAXCYTE, INC.

(Exact name of Registrant as Specified in Its Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-39323

46-4233385
(IRS Employer
Identification No.)

(Commission File Number)

353 Hatch Drive
Foster City, California
(Address of Principal Executive Offices)

94404
(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 March 29, 2021, Vaxcyte, Inc. issued a press release announcing its financial results for the quarter and full year ended December 31, 2020. 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 March 29, 2021



Vaxcyte Reports Fourth Quarter and Full Year 2020 Financial Results and Provides Business Update

FOSTER CITY, Calif., March 29, 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 fourth quarter and full year ended December 31, 2020 and provided a business update.

“The past year has been transformational for Vaxcyte and I am pleased with the multiple milestones we have achieved on the path to submit our Investigational New Drug (IND) application for VAX-24, our 24-valent pneumococcal conjugate vaccine (PCV), the progress of our other pipeline programs, and the addition of new leadership team members,” said Grant Pickering, Chief Executive Officer and Co-founder of Vaxcyte. “While our team has completed several additional key steps to support the IND application submission for VAX-24, in light of the combination of ongoing work to manufacture the 24 conjugated drug substances, capacity constraints at our contract manufacturing organization and, to a lesser degree, the impact of the COVID-19 pandemic, we are changing the expected timing of our VAX-24 IND application submission to between January and June 2022.”

Pickering continued, “As further confirmation of the progress of our pipeline vaccines and the potential benefits of our technology platform, we are today announcing new immunogenicity data for VAX-XP, our PCV candidate with an expanded breadth of coverage, and the final vaccine candidate nomination for VAX-A1.”

Key 2020 and 2021 Highlights to Date

- **Achieved VAX-24 Manufacturing Milestones:** Vaxcyte achieved several key manufacturing milestones for VAX-24 in preparation for the anticipated IND application submission and Phase 1/2 clinical study initiation. These include completion of: the good manufacturing practice (GMP) batches of the eCRM® protein carrier; the GMP batches of the 24 pneumococcal polysaccharides; the first two stages of the GMP batches for the 24 conjugated drug substances; the drug product batches used in the good laboratory practice (GLP) toxicology studies; and the drug product batches that will serve as the source of the lead lot stability data for the IND application.
 - **Progressed and Reported New Data for VAX-XP Program:** As part of its strategy to maximize the optionality and value of its PCV franchise, Vaxcyte has continued to advance VAX-XP, its broader-spectrum PCV candidate designed to cover at least 30 strains. Today, Vaxcyte announced new data for VAX-XP that further demonstrate the potential benefits of Vaxcyte’s scalable technology platform and the reproducibility of data with conjugates produced at larger scale. Results from a preclinical proof-of-concept study showed that in rabbit models for VAX-XP compared to more than 30 different pneumococcal serotypes, including all of those contained in Prevnar 13, the VAX-XP IgG immune responses were superior to polysaccharide-only serotypes and comparable to Prevnar 13 in the common 13 strains.
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- **Advanced and Published Data for VAX-A1 Program:** Vaxcyte advanced VAX-A1, its novel conjugate vaccine candidate designed to prevent infections from Group A Strep, a human pathogen causing pharyngitis, or strep throat, and certain severe invasive infections such as sepsis, toxic shock syndrome and necrotizing fasciitis. Based on the progress of the program, and consistent with target timelines, Vaxcyte nominated the final VAX-A1 vaccine candidate in the first quarter of 2021. In January 2021, Vaxcyte announced the publication of preclinical data in the journal *Infectious Microbes & Diseases*, which showed that VAX-A1 demonstrated meaningful protection against systemic and soft tissue infection after challenge with no evidence of cross-reactivity with human tissue. Additionally, at the end of 2020, Vaxcyte completed the initial funding period under its Cooperative Agreement with CARB-X and is now in the process of submitting its proposal to CARB-X for the next funding period of the agreement.
- **Completed Initial Public Offering (IPO) and Series D Financing:** In June 2020, Vaxcyte completed its IPO of 17,968,750 shares of common stock, which included the full exercise of the underwriters' option to purchase 2,343,750 additional shares, at a public offering price of \$16.00 per share, resulting in aggregate net proceeds of \$264.0 million. In March 2020, Vaxcyte completed its Series D convertible preferred stock financing, raising aggregate net proceeds of \$109.9 million.
- **Strengthened Leadership Team and Advisory Board with Key Appointments:** During 2020, Vaxcyte added several key leaders, including Andrew Guggenlime, President and Chief Financial Officer, and appointed Halley Gilbert to its board of directors, each bringing over 20 years of biotechnology leadership experience. In 2021, Vaxcyte added William Hausdorff, PhD to its Scientific Advisory Board. Dr. Hausdorff has worked on the development, clinical evaluation, registration, implementation and post-marketing assessment of a variety of vaccines over the past 30 years. Since 2018, Dr. Hausdorff has served as the Lead, Public Health Value Propositions for Vaccines at PATH, a global organization that works to accelerate health equity by bringing together public institutions, businesses, social enterprises, and investors to solve the world's most pressing health challenges. Prior to joining PATH, he worked for 12 years at GlaxoSmithKline (GSK) Vaccines, eight years at Wyeth Vaccines and was previously at the Centers for Disease Control and Prevention. In his roles at GSK Vaccines and Wyeth Vaccines, he was involved in the development of Synflorix® and Prevnar 13®, respectively. Dr. Hausdorff received his PhD in Biology from The Johns Hopkins University and his BA in Biology from Carleton College.

Anticipated Key Milestones

- **VAX-24:** Vaxcyte expects to submit an IND application for VAX-24 to the U.S. Food and Drug Administration between January and June 2022. Vaxcyte expects to announce topline data from the ensuing Phase 1/2 clinical study between late 2022 and early 2023.
- **VAX-A1:** Following the nomination of its final vaccine candidate for VAX-A1 in the first quarter of 2021, Vaxcyte plans to initiate IND-enabling studies in the second half of 2021.
- **VAX-PG:** Vaxcyte expects to nominate a final vaccine candidate for VAX-PG, its novel therapeutic vaccine designed to treat periodontal disease, in the second half of 2021.

Fourth Quarter and Full Year 2020 Financial Results

- **Cash Position:** Cash and cash equivalents were \$386.2 million as of December 31, 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 \$14.7 million for the three months ended December 31, 2020 and \$73.6 million for the full year 2020 as compared to \$13.4 million and \$45.6 million, respectively, for the same periods in 2019. The increase for the year ended December 31, 2020 was due primarily to an increase in manufacturing expenses and outsourced research services related to Vaxcyte's VAX-24 program.
- **General & Administrative (G&A) Expenses:** G&A expenses were \$4.8 million for the three months ended December 31, 2020 and \$16.0 million for the full year 2020 as compared to \$2.5 million and \$8.5 million, respectively, for the same periods in 2019. The increase for the year ended December 31, 2020 was due primarily to an increase in personnel-related and directors and officers insurance expenses.
- **Net Loss:** For the three months and year ended December 31, 2020, net loss was \$20.7 million and \$89.2 million, respectively, compared to \$14.6 million and \$50.3 million for the same periods in 2019.

Conference Call and Webcast

Vaxcyte will host a conference call and webcast to discuss this announcement today, March 29, 2021 at 4:30 p.m. ET / 1:30 p.m. PT. To participate in the conference call, please dial (833) 519-1403 (domestic) or (270) 215-9736 (international) and refer to conference ID 1497487. A live audio webcast will be available in the Investors & Media section of the Company's website at www.vaxcyte.com. A replay of the webcast will be available for 30 days following the call.

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 are based on Vaxcyte's current beliefs and expectations. Such statements include, but are not limited to, statements related to: the preventative 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; the timing and availability of topline data for VAX-24; the initiation of IND-enabling activities for VAX-A1; the nomination of a final vaccine candidate for VAX-PG; and other statements that are not historical fact. 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; Vaxcyte’s reliance on third-party manufacturers; 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; sufficiency of cash and other funding to support Vaxcyte’s development programs and other operating expenses; and the ongoing COVID-19 pandemic, which could materially and adversely affect Vaxcyte’s business and operations. These and other risks are described more fully in Vaxcyte’s filings with the Securities and Exchange Commission (SEC), including its Annual Report on Form 10-K filed with the SEC on March 29, 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 December 31,		Year Ended December 31,	
	2020	2019	2020	2019
Operating expenses:				
Research and development (1)	\$ 14,661	\$ 13,381	\$ 73,564	\$ 45,607
General and administrative (1)	4,792	2,456	16,017	8,546
Total operating expenses	<u>19,453</u>	<u>15,837</u>	<u>89,581</u>	<u>54,153</u>
Loss from operations	(19,453)	(15,837)	(89,581)	(54,153)
Other income (expense), net				
Interest expense	—	(7)	(7)	(40)
Interest income	32	94	244	632
Grant income	326	184	2,478	237
Foreign currency transaction losses	(1,642)	280	(2,351)	(135)
Change in fair value of the redeemable convertible preferred stock tranche liability	—	665	—	3,185
Total other income (expense), net	<u>(1,284)</u>	<u>1,216</u>	<u>364</u>	<u>3,879</u>
Net loss and comprehensive loss	<u>\$ (20,737)</u>	<u>\$ (14,621)</u>	<u>\$ (89,217)</u>	<u>\$ (50,274)</u>
Net loss per share, basic and diluted	<u>\$ (0.41)</u>	<u>\$ (3.69)</u>	<u>\$ (3.02)</u>	<u>\$ (13.25)</u>
Weighted-average shares outstanding, basic and diluted	<u>50,964,294</u>	<u>3,965,166</u>	<u>29,545,810</u>	<u>3,795,090</u>

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

Research and development	\$ 779	\$ 106	\$ 1,861	\$ 368
General and administrative	1,155	269	3,573	817
Total stock-based compensation expense	<u>\$ 1,934</u>	<u>\$ 375</u>	<u>\$ 5,434</u>	<u>\$ 1,185</u>

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

	December 31, 2020	December 31, 2019
Cash and cash equivalents	\$ 386,200	\$ 58,976
Total assets	392,826	65,698
Redeemable convertible preferred stock	—	160,310
Total stockholders' equity (deficit)	345,843	(106,373)