

**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): February 25, 2021

Vaxart, Inc.

(Exact name of registrant as specified in its charter)

<u>Delaware</u> (State or other jurisdiction of incorporation)	<u>001-35285</u> (Commission File Number)	<u>59-1212264</u> (IRS Employer Identification No.)
<u>170 Harbor Way, Suite 300, South San Francisco, California</u> (Address of principal executive offices)		<u>94080</u> (Zip Code)

Registrant's telephone number, including area code: (650) 550-3500

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:

<u>Title of each class</u> Common stock, \$0.0001 par value	<u>Trading symbol</u> VXRT	<u>Name of each exchange on which registered</u> The Nasdaq Capital Market
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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 February 25, 2021, Vaxart, Inc. issued a press release announcing its financial results for the quarter and year ended December 31, 2020. A copy of this press release is furnished as Exhibit 99.1 to this report and is incorporated herein by reference.

The information in this report, including Exhibit 99.1 attached hereto, is being furnished and shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or subject to the liabilities of that section or Sections 11 and 12(a)(2) of the Securities Act of 1933, as amended. The information contained herein and in the accompanying Exhibit 99.1 shall not be deemed incorporated by reference into any filing with the U.S. Securities and Exchange Commission made by Vaxart, Inc., whether made before or after the date hereof regardless of any general incorporation language in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit	Description
99.1	<u>Press release, dated February 25, 2021, titled “Vaxart Provides Business Update and Reports Fourth Quarter and Full Year 2020 Financial Results”</u>

SIGNATURES

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

Dated: February 25, 2021

Vaxart, Inc.

By: /s/ ANDREI FLOROIU
Andrei Floroiu
President and Chief Executive Officer

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

- VXA-CoV2-1 oral COVID-19 vaccine candidate targeting both the S and N proteins is planned to advance to Phase 2 testing during Q2 2021
- Cash and cash equivalents of \$126.9 million as of December 31, 2020
- Conference call and webcast focused on our COVID-19 strategy scheduled for Tuesday, March 2, 2021 at 4:30pm ET

SOUTH SAN FRANCISCO, Calif. – February 25, 2021-- Vaxart, Inc. (Nasdaq: VXRT) a clinical-stage biotechnology company developing oral recombinant vaccines that are administered by tablet rather than by injection, today announced that it plans to initiate the first Phase 2 study of its oral COVID-19 vaccine candidate, VXA-CoV2-1, in 2Q 2021.

Vaxart made this announcement as it provided financial results for the fourth quarter and full year ended December 31, 2020 and provided a corporate update.

“Recently, we have seen the emergence of new SARS-Cov-2 strains, against which some of the leading injectable vaccines offer reduced protection. At the same time, it has become clear that mass vaccinations by needle take a long time, and new strains may emerge faster than many countries’ medical and governmental infrastructure can inject their populations. A better solution is needed given that COVID-19 may be a challenge for years to come,” said Andrei Floroiu, chief executive officer of Vaxart. “As a result of our scientists’ foresight to include both the S and N proteins, VXA-CoV2-1 could be protective against these newly emerging variant strains. We are very excited about the prospect of moving into Phase 2 not only as an oral COVID-19 vaccine candidate, but one with a differentiated mechanism, which could prove to be valuable globally in the fight against coronavirus.”

- VXA-CoV2-1 triggers mucosal immune responses in humans. Mucosal immunity is believed to be the first line of defense against airborne viruses, such as coronavirus and flu, and may also be important in reducing viral shedding and preventing transmission.
- VXA-CoV2-1 targets both the spike protein (S) and nucleoprotein (N). The N protein is more conserved (less prone to mutations) than the S protein, and therefore new viral variants may be less likely to escape protection.
- The N protein is also a good target for T-cell responses. Potent T-cell responses alone may offer multi-variant protection against severe COVID-19 illness.
- Vaxart is also advancing S-only vaccine candidates targeted specifically against variant strains, including one targeting the South African viral strain. These new candidates are expected to generate strong mucosal and serum antibody responses and may be complementary to the potent T-cell inducer VXA-CoV2-1. Vaxart has previously shown that a bivalent oral vaccine using its platform can induce immune responses without interference.

A conference call and webcast focused on our COVID-19 strategy will be held on Tuesday, March 2, 2021 at 4:30pm Eastern Time, Domestic: 877-407-0784, International: 201-689-8560, Conference ID: 13716984, Webcast: <http://public.viavid.com/index.php?id=143739>.

Recent Business Development Highlights:

Pre-Clinical and Clinical:

- VXA-CoV2-1 Phase 1 trial met its primary and secondary endpoints. The vaccine was generally well-tolerated, with no severe adverse events reported. Results from the trial were presented by Dr. Sean Tucker, Vaxart's Founder and Chief Scientific Officer, at the New York Academy of Sciences Symposium "The Quest for a COVID-19 Vaccine" in early February 2021. The presentation can be viewed on Vaxart's corporate website on the Investors page under "Events and Presentations".
- VXA-CoV2-1 triggered immune responses against SARS-CoV-2 antigens in a majority of subjects, including: CD8+ cytotoxic T-cell response to the S and N proteins (may contribute to long-lasting cross-reactive immunity), activation of B cells that will home to the mucosa, an increase in proinflammatory Th1 cytokines (responsible for creating a productive immune response against viral infection) and IgA responses.
- COVID-19 Hamster Challenge Study data showed that 100% of hamsters receiving two oral doses of Vaxart's recombinant adenoviral vaccine were protected against systemic weight loss, as well as lung weight gain. Conversely, all unvaccinated animals lost at least 8% of their body weight, and all showed evidence of lung disease as measured by relative weight gain in the lungs. Full results from the study will be published when data analysis is complete.
- Vaxart's norovirus vaccine program has been restarted with the addition of a booster dose administered more than 12 months post first vaccination in subjects who participated in the Phase 1b trial. Data are expected to be available in the first half of 2021. Additional studies planned for 2021 include a Phase 1 study in elderly adults age 65+ and a Norovirus Challenge study.

Manufacturing:

- Expanded collaboration with Kindred Biosciences for the manufacturing of VXA-CoV2-1 oral vaccine as well as other vaccine candidates. Under the terms of the expanded agreement, the California plant will be used for scaling the COVID-19 clinical trial material into mid-size bioreactors, and its Kansas plant will be used for manufacturing at a 2000L scale in its single use bioreactors.
- Vaxart entered into an agreement with Attwill Vascular Technologies, LP for processing and lyophilizing certain compounds and further tableting the lyophilized compounds for the Company's oral COVID-19 vaccine.

Corporate:

- Strengthened the organization, bringing the total number of full-time equivalents to 49 people (including consultants and contractors), by hiring in critical areas, including research, clinical, regulatory, manufacturing, and finance.

Cash Balance:

- Vaxart ended the year with cash and cash equivalents of \$126.9 million compared to \$13.5 million as of December 31, 2019. The increase was primarily due to receipts of \$97.0 million from the Company's \$100 million at-the-market facility entered into in July 2020, \$26.0 million from the exercise of warrants, \$9.2 million from the registered direct offering in March 2020, and \$4.9 million from the Company's \$250 million at-the-market facility entered into in October 2020 (October 2020 ATM), partially offset by \$23.8 million of cash used in operations.
 - Subsequent to year end, the Company has raised net proceeds of \$65.8 million from the issuance of common stock under the October 2020 ATM.
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Financial Results for the Three Months Ended December 31, 2020

- Vaxart reported a net loss of \$13.9 million for the fourth quarter of 2020 compared to \$6.4 million for the fourth quarter of 2019. Net loss per share for the fourth quarter of 2020 was \$0.13, unchanged from 2019 due to an increase in the weighted average number of shares outstanding.
- Revenue for the fourth quarter was \$356,000 compared to \$3.9 million in the fourth quarter of 2019. The decrease was principally due to a reduction in royalty revenue related to Inavir sales in Japan as a result of an abnormally low incidence of seasonal influenza, and a decline in contract revenue from Janssen which was substantially completed by September 30, 2020.
- Research and development expenses were \$8.6 million for the fourth quarter of 2020 compared to \$3.3 million for the fourth quarter of 2019. The increase was mainly due to manufacturing and clinical trial expenses related to the COVID-19 vaccine candidate.
- General and administrative expenses were \$5.1 million for the fourth quarter of 2020 compared to \$1.3 million for the fourth quarter of 2019. The increase was mainly due to higher legal and consulting, and an increase in headcount and related costs.
- There were no restructuring expenses for the fourth quarter of 2020 compared to \$4.9 million for the fourth quarter of 2019.

Financial Results for the Full Year 2020

- Vaxart reported a net loss of \$32.2 million for full year 2020 compared to \$18.6 million for full year 2019. Net loss per share for 2020 was \$0.36, down from \$0.86 for 2019 due to the increase in net loss being outweighed by the increase in the weighted average number of shares outstanding during 2020.
- Revenue in 2020 was \$4.0 million compared to \$9.9 million in 2019. The decrease was principally due to a reduction in royalty revenue related to Inavir sales in Japan due to abnormally low incidences of seasonal influenza in 2020, compared to higher-than-average incidences in 2019.
- Research and development expenses were \$19.9 million for 2020 compared to \$14.5 million for 2019. The increase was mainly due to higher preclinical, manufacturing and clinical trial expenses related to our COVID-19 vaccine candidate.
- General and administrative expenses were \$15.2 million for 2020 compared to \$6.2 million for 2019. The increase was mainly due to higher legal and consulting fees and an increase in headcount and related costs.
- Restructuring charges for 2019 were \$4.9 million, compared to a net reversal of \$849,000 in 2020, principally due to a settlement with Lonza for less than the total amount invoiced. No further restructuring charges or reversals are expected.

About Vaxart

Vaxart is a clinical-stage biotechnology company developing a range of oral recombinant vaccines based on its proprietary delivery platform. Vaxart vaccines are designed to be administered using tablets that can be stored and shipped without refrigeration and eliminate the risk of needle-stick injury. Vaxart believes that its proprietary tablet vaccine delivery platform is suitable to deliver recombinant vaccines, positioning the company to develop oral versions of currently marketed vaccines and to design recombinant vaccines for new indications. Its development programs currently include tablet vaccines designed to protect against coronavirus, Norovirus, seasonal influenza and respiratory syncytial virus (RSV), as well as a therapeutic vaccine for human papillomavirus (HPV), Vaxart's first immuno-oncology indication. Vaxart has filed broad domestic and international patents covering its proprietary technology and creations for oral vaccination using adenovirus and TLR3 agonists.

Note Regarding Forward-Looking Statements

This press release contains forward-looking statements that involve substantial risks and uncertainties. All statements, other than statements of historical facts, included in this press release regarding Vaxart's strategy, prospects, plans and objectives, results from pre-clinical and clinical trials, commercialization agreements and licenses, beliefs and expectations of management are forward-looking statements. These forward-looking statements may be accompanied by such words as "should," "believe," "could," "potential," "will," "expected," "plan" and other words and terms of similar meaning. Examples of such statements include, but are not limited to, statements relating to Vaxart's ability to develop and commercialize its product candidates and clinical results and trial data (including plans with respect to the COVID-19 vaccine product candidates); expectations relating to Vaxart's relationship with Emergent BioSolutions Inc., Kindred Biosciences and Attwill Medical Solutions Sterilflow, LP, including their ability to produce cGMP vaccines and the timing thereof; Vaxart's expectations with respect to the important advantages it believes its oral vaccine platform can offer over injectable alternatives, particularly for coronaviruses such as SARS, MERS and SARS-CoV-2; expectations regarding Vaxart's ability to develop effective vaccines against new and emerging variant strains; expectations regarding the timing and nature of future developments and announcements, including those related to trials and studies; the potential applicability of results seen in our preclinical studies or trials to those that may be seen in humans or clinical trials; the expected role of mucosal immunity in blocking transmission of COVID-19; and Vaxart's expectations with respect to the effectiveness of its product candidates, including Vaxart's potential role in mitigating the impact of COVID-19. Vaxart may not actually achieve the plans, carry out the intentions or meet the expectations or projections disclosed in the forward-looking statements and you should not place undue reliance on these forward-looking statements. Actual results or events could differ materially from the plans, intentions, expectations and projections disclosed in the forward-looking statements. Various important factors could cause actual results or events to differ materially from the forward-looking statements that Vaxart makes, including uncertainties inherent in research and development, including the ability to meet anticipated clinical endpoints, commencement and/or completion dates for clinical, regulatory submission dates, regulatory approval dates and/or launch dates, as well as the possibility of unfavorable new clinical data and further analyses of existing clinical data; the risk that clinical trial data are subject to differing interpretations and assessments by regulatory authorities; whether regulatory authorities will be satisfied with the design of and results from the clinical studies; decisions by regulatory authorities impacting labeling, manufacturing processes, and safety that could affect the availability or commercial potential of any product candidate, including the possibility that Vaxart's product candidates may not be approved by the FDA or non-U.S. regulatory authorities; that, even if approved by the FDA or non-U.S. regulatory authorities, Vaxart's product candidates may not achieve broad market acceptance; that a Vaxart collaborator may not attain development and commercial milestones; that Vaxart or its partners may experience manufacturing issues and delays due to events within, or outside of, Vaxart's or its partners control, including the recent outbreak of COVID-19; difficulties in production, particularly in scaling up initial production, including difficulties with production costs and yields, quality control, including stability of the product candidate and quality assurance testing, shortages of qualified personnel or key raw materials, and compliance with strictly enforced federal, state, and foreign regulations; that Vaxart may not be able to obtain, maintain and enforce necessary patent and other intellectual property protection; that Vaxart's capital resources may be inadequate; Vaxart's ability to resolve pending legal matters; Vaxart's ability to obtain sufficient capital to fund its operations on terms acceptable to Vaxart, if at all; the impact of government healthcare proposals and policies; competitive factors; and other risks described in the "Risk Factors" sections of Vaxart's Quarterly and Annual Reports filed with the SEC. Vaxart does not assume any obligation to update any forward-looking statements, except as required by law.

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Vaxart, Inc.
Condensed Consolidated Balance Sheets

	December 31, 2020	December 31, 2019
	(Unaudited)	(1)
	<i>(in thousands)</i>	
Assets		
Cash and cash equivalents	\$ 126,870	\$ 13,526
Accounts receivable	334	3,619
Prepaid and other assets	1,699	594
Property and equipment, net	1,480	210
Right-of-use assets, net	6,838	1,990
Intangible assets, net	15,361	17,093
Total assets	\$ 152,582	\$ 37,032
Liabilities and stockholders' equity		
Accounts payable	\$ 2,133	\$ 852
Accrued and other liabilities	4,908	4,583
Liability related to sale of future royalties	14,929	16,332
Operating lease liabilities	7,208	2,313
Total liabilities	29,178	24,080
Stockholders' equity	123,404	12,952
Total liabilities and stockholders' equity	\$ 152,582	\$ 37,032

(1) Derived from the audited consolidated financial statements of Vaxart, Inc. for the year ended December 31, 2019, included on the Form 10-K filed with the Securities and Exchange Commission on March 19, 2020.

Vaxart, Inc.
Condensed Consolidated Statements of Operations

	Three Months Ended December 31,		Year Ended December 31,	
	2020	2019	2020	2019
	(Unaudited)	(Unaudited)	(Unaudited)	(1)
	<i>(in thousands, except share and per share amounts)</i>			
Revenue	\$ 356	\$ 3,916	\$ 4,046	\$ 9,862
Operating expenses:				
Research and development	8,591	3,291	19,863	14,540
General and administrative	5,126	1,331	15,202	6,187
Restructuring and impairment charges and (reversals)	—	4,920	(849)	4,920
Total operating expenses	13,717	9,542	34,216	25,647
Loss from operations	(13,361)	(5,626)	(30,170)	(15,785)
Other income and expenses, net	(467)	(587)	(1,812)	(2,370)
Provision for income taxes	(33)	(196)	(238)	(490)
Net loss	\$ (13,861)	\$ (6,409)	\$ (32,220)	\$ (18,645)
Net loss per share, basic and diluted	\$ (0.13)	\$ (0.13)	\$ (0.36)	\$ (0.86)
Shares used in computing net loss per share, basic and diluted	109,663,940	47,744,463	88,295,762	21,569,523

(1) Derived from the audited consolidated financial statements of Vaxart, Inc. for the year ended December 31, 2019, included on the Form 10-K filed with the Securities and Exchange Commission on March 19, 2020.