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 24, 2022

Vaxart, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**001-35285**	**59-1212264**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

170 Harbor Way, Suite 300, South San Francisco, California	**94080**
(Address of principal executive offices)	**(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:

Title of each class	Trading symbol	Name of each exchange on which registered
Common stock, $0.0001 par value	**VXRT**	**The Nasdaq Capital 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 February 24, 2022, Vaxart, Inc. issued a press release announcing its financial results for the quarter and year ended December 31, 2021. 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	Press release, dated February 24, 2022, titled "Vaxart Provides Business Update and Reports Fourth Quarter and Full Year 2021 Financial Results".
104	Cover Page Interactive Data File (embedded within Inline XBRL document).

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.

Vaxart, Inc.

Dated: February 24, 2022

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

Exhibit 99.1

Vaxart Provides Business Update and Reports Fourth Quarter and Full Year 2021 Financial Results

Company begins 2022 with multiple active programs with data readouts expected this year

Initial data from COVID-19 Phase II study expected in the first half of 2022 and data from several norovirus studies also expected this year

Ended 2021 with $182.7 million in cash, cash equivalents and marketable securities

SOUTH SAN FRANCISCO, Calif., Feb. 24, 2022 — Vaxart, Inc. (NASDAQ: VXRT) issued its business update today for the fourth quarter and full year 2021, reporting forward momentum for the Company, including its oral norovirus and COVID-19 vaccine candidates.

Vaxart said it expected further material progress across its programs in 2022.

“Vaxart made significant progress in 2021 that has us well-positioned to achieve several important milestones in 2022,” said Andrei Floroiu, Vaxart’s Chief Executive Officer. “Our potentially transformative oral vaccine programs continued to advance in clinical development. Patient dosing is underway in our U.S. Phase II COVID-19 trial and we have started a Phase II monovalent norovirus GI.1 challenge study.”

“We have improved our manufacturing capacity, added to our research and manufacturing ranks, and hired top leadership talent,” Floroiu said. “We anticipate building on 2021’s momentum, and are excited about the continued progress we expect to make in 2022, including launching the international clinical studies of our COVID-19 vaccine.”

“In 2021, we generated exciting preclinical and clinical data,” said Dr. Sean Tucker, Vaxart’s founder and Chief Scientific Officer. “A hamster challenge study showed that our oral COVID-19 vaccine candidate has the potential ability to reduce transmission of SARS-CoV-2, and a Phase I study showed that our vaccine candidate produced broad cross-reactive T cell and IgA responses against both SARS-CoV-2 and other coronaviruses. Therefore, we believe that our COVID-19 vaccine candidate may be reactive against SARS-CoV-2 variants. In 2022, we are planning to conduct additional trials that may highlight the advantages of triggering mucosal immunity as well as of other aspects of our platform.”

Recent Business Highlights

Preclinical and Clinical

COVID-19 Vaccine Developments

- During the fourth quarter of 2021, Vaxart began Phase II clinical trials of its oral tablet COVID-19 vaccine in the U.S. Vaxart dosed its first subject in late October 2021.
    - The U.S. portion of the trial is a randomized open-label dose and age escalation lead-in segment in naïve and previously vaccinated subjects. Vaxart expects data from this portion of the trial to be available during the first half of 2022.
- In October 2021, a Duke University-led study showed Vaxart’s COVID-19 vaccine candidate reduced the airborne transmission of SARS-CoV-2 virus in an animal model and suggested the vaccine candidate would trigger superior mucosal protection.
    - The study’s findings, published by bioRxiv, are consistent with those from Vaxart’s Phase II human flu challenge study published in 2020, which showed Vaxart’s oral tablet flu vaccine was better at reducing shedding than the injectable flu vaccine competitor.
- In February 2022, Vaxart’s COVID-19 non-human primate study was published by bioRxiv. The study demonstrates that Vaxart’s S-only COVID-19 clinical vaccine candidate, now being studied by Vaxart in Phase II trials, generated antibodies to the original COVID-19 virus strain and to the Beta, Delta, Alpha and Gamma variants of SARS-CoV-2 in the serum and nasal mucosa of non-human primates (NHPs).

- Vaxart also announced it would test the cross-reactivity of its oral tablet COVID-19 vaccine candidate against the Omicron SARS-CoV-2 variant in two different studies now expected to begin in March 2022.
    - In the first study, Vaxart will test the activity of its Phase II COVID-19 oral vaccine candidate against Omicron by analyzing mucosal and serum samples from subjects to whom the vaccine was administered in Vaxart's current COVID-19 vaccine Phase II trials.
    - In the second study, Vaxart will conduct an animal Omicron challenge study to assess how its current Phase II COVID-19 vaccine candidate performs in comparison to an Omicron-specific vaccine candidate, which Vaxart is currently developing.
    - Results from Phase I clinical testing and earlier preclinical testing support Vaxart's belief that its vaccine candidates may be reactive against Omicron.

Norovirus Vaccine Developments

- Vaxart completed enrollment in its Phase IB placebo-controlled, dose-ranging, repeat dose trial investigating its oral norovirus vaccine candidate in elderly subjects aged 55 to 80 years. This study is designed to evaluate the safety and immunogenicity of Vaxart's GI.1 vaccine candidate.
    - The Company expects initial data from this study to be available in the first quarter of 2022 and more complete data to be available by the second quarter of 2022.
- Vaxart is conducting an additional GI.1 norovirus vaccine study to evaluate the optimal timing for boost administration under VXA-NVV-105. This study has completed enrollment.
    - The Company expects initial data from this study to be available in the first quarter of 2022 and more complete data to be available in the first half of 2022.
- Vaxart launched a Phase II GI.1 norovirus challenge study in January 2022 to evaluate the safety and clinical efficacy of its oral vaccine candidate. This double blind, placebo-controlled study uses a safe, well-characterized challenge with norovirus GI.1 of volunteers vaccinated with our monovalent norovirus vaccine. The study will yield data on efficacy, safety and immune correlates of protection, with data to be reported in the first quarter of 2023.

Manufacturing Updates

- During the fourth quarter of 2021, Vaxart purchased its second clinical manufacturing facility and will be producing vaccines at two plants in parallel. Vaxart expects its manufacturing facilities to produce oral tablet vaccines required for Vaxart's planned clinical trials in 2022.

Corporate Developments

- A new Stanford study published in Cell Host and Microbe found that protection against influenza infection may be achieved through mechanisms other than the development of serum antibodies. The Phase II study demonstrated that VXA-A1.1, an investigational oral tablet flu vaccine under development by Vaxart, had cellular correlates of protection against influenza infection.
- Vaxart grew its full-time employee headcount from 28 to 110 during 2021, expanding its research, manufacturing and quality groups as well as its management team to better advance its pipeline of vaccine programs.
- In February 2022, Vaxart appointed industry veteran Edward B. Berg as the Company's first in-house General Counsel. Mr. Berg has practiced law for more than 30 years and has represented Fortune 500 and mid-cap companies in biotechnology, pharmaceuticals and life sciences.

2022 Planned Milestones

Vaxart anticipates the progress and momentum of 2021 will continue into 2022:

- Initial data from Vaxart's Phase II COVID-19 vaccine trials is expected to be available in the first half of 2022.
- The Company's international Phase IB and Phase II COVID-19 trials, including a placebo-controlled efficacy trial in India, are anticipated to begin this year.
- Results from two norovirus trials that Vaxart began in 2021 are expected in the first half of 2022.

Financial Results for the Three Months Ended December 31, 2021

- Vaxart ended the year with cash, cash equivalents and available-for-sale debt securities of $182.7 million, compared to $204.0 million as of September 30, 2021. The decrease was primarily due to $15.8 million of cash used in operations and $4.8 million spent on a business acquisition.

- The Company reported a net loss of $20.8 million for the fourth quarter of 2021, compared to $13.9 million for the fourth quarter of 2020. Net loss per share for the fourth quarter of 2021 was $0.17, compared to a net loss of $0.13 per share in the fourth quarter of 2020. The increase in net loss per share was primarily due to a significant increase in research and development expenses.

- Revenue for the fourth quarter of 2021 was $74,000, compared to $356,000 in the fourth quarter of 2020. The decrease was due to lower royalty revenue from sales of Inavir in Japan.

- Research and development expenses were $15.5 million for the fourth quarter of 2021, compared to $8.6 million for the fourth quarter of 2020. The increase was mainly due to increases in headcount and related costs and in manufacturing and clinical trial expenses related to our COVID-19 and norovirus vaccine candidates.

- General and administrative expenses were $5.8 million for the fourth quarter of 2021, compared to $5.1 million for the fourth quarter of 2020. The increase was mainly due to an increase in headcount and related costs.

Financial Results for the Full Year Ended December 31, 2021

- Vaxart reported a net loss of $70.5 million for full year 2021, compared to $32.2 million for full year 2020. Net loss per share for 2021 was $0.58, compared to $0.36 for 2020.

- Revenue in 2021 was $892,000, compared to $4.0 million in 2020. The decrease was principally due to lower royalty revenue from sales of Inavir in Japan.

- Research and development expenses were $48.7 million for 2021 compared to $19.9 million for 2020. The increase was mainly due to increases in headcount and related costs and in manufacturing and clinical trial expenses related to our COVID-19 and norovirus vaccine candidates.

- General and administrative expenses were $21.9 million for 2021 compared to $15.2 million for 2020. The increase was mainly due to increases in personnel costs, D&O insurance and legal and professional fees.

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. Vaxart's 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 immune-oncology indication. Vaxart has filed broad domestic and international patent applications 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 preclinical and clinical trials, commercialization agreements and licenses, and 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," “anticipate,” "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, including its vaccine booster products; Vaxart's expectations regarding clinical results and trial data; and Vaxart's expectations with respect to the effectiveness of its product candidates. 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 trials, 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; 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, 2021 (Unaudited)	December 31, 2020 (1)
	(in thousands)	
Assets		
Cash and cash equivalents	$ 143,745	$ 126,870
Investments in debt securities	38,952	—
Accounts receivable	71	334
Prepaid and other assets	3,499	1,699
Property and equipment, net	6,601	1,480
Right-of-use assets, net	13,168	6,838
Intangible assets, net	10,624	15,361
Goodwill	4,508	—
Total assets	$ 221,168	$ 152,582
Liabilities and stockholders' equity		
Accounts payable	$ 3,872	$ 2,133
Accrued and other liabilities	5,235	4,908
Liability related to sale of future royalties	11,522	14,929
Operating lease liabilities	13,008	7,208
Total liabilities	33,637	29,178
Stockholders' equity	187,531	123,404
Total liabilities and stockholders' equity	$ 221,168	$ 152,582

(1) Derived from the audited consolidated financial statements of Vaxart, Inc. for the year ended December 31, 2020, included on the Form 10-K filed with the Securities and Exchange Commission on February 25, 2021.

Vaxart, Inc.
Condensed Consolidated Statements of Operations

	Three Months Ended December 31,		Year Ended December 31,	
	2021	2020	2021	2020
	(Unaudited)	(Unaudited)	(Unaudited)	(1)
	(in thousands, except share and per share amounts)			
Revenue	$ 74	$ 356	$ 892	$ 4,046
Operating expenses:				
Research and development	15,530	8,591	48,749	19,863
General and administrative	5,754	5,126	21,890	15,202
Impairment of intangible assets	3,005	—	3,005	—
Restructuring cost reversal	—	—	—	(849)
Total operating expenses	24,289	13,717	73,644	34,216
Loss from operations	(24,215)	(13,361)	(72,752)	(30,170)
Other income (expense), net	3,469	(467)	2,389	(1,812)
Loss before income taxes	(20,746)	(13,828)	(70,363)	(31,982)
Provision for income taxes	18	33	107	238
Net loss	$ (20,764)	$ (13,861)	$ (70,470)	$ (32,220)
Net loss per share, basic and diluted	$ (0.17)	$ (0.13)	$ (0.58)	$ (0.36)
Shares used in computing net loss per share, basic and diluted	125,482,555	109,663,940	121,453,723	88,295,762

(1) Derived from the audited consolidated financial statements of Vaxart, Inc. for the year ended December 31, 2020, included on the Form 10-K filed with the Securities and Exchange Commission on February 25, 2021.