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 3, 2021

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

N/A
(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.

Vaxart, Inc. (the "*Company*") estimates that its cash and cash equivalents as of December 31, 2020, was approximately $126.9 million, compared to $13.5 million and $11.5 million as of December 31, 2019 and 2018, respectively. The increase in 2020 is primarily due to $97 million received from the ATM facility in July 2020, $26 million from the exercise of warrants throughout the year, $9 million from the registered direct offering in February 2020, and $5 million from the ATM facility in October 2020 offset by $24 million used in operations. The Company estimates that its revenue for the year ending December 31, 2020 was approximately $4.0 million, compared to $9.9 million and $4.2 million for the years ended December 31, 2019 and 2018 respectively. The decrease was due primarily to the impact of COVID-19 on the royalty revenue stream from Daiichi for the Inavir product.

The Company's audited, consolidated financial statements as of December 31, 2020, are not yet available. Accordingly, the information presented above reflects the Company's preliminary estimates, subject to the completion of the Company's financial closing procedures and the annual audit of its financial statements by its auditors. As a result, these preliminary estimates may differ from the actual results that will be reflected in the Company's audited, consolidated financial statements for the fiscal year ended December 31, 2020 when they are completed and publicly disclosed. These preliminary estimates may change, and those changes may be material.

Because these financial results are only preliminary estimates and are based on information available to management as of the date of this report, these expectations could change. The Company's actual financial results as of December 31, 2020 are subject to the audit of the Company's financial statements as of and for such period, and are not indicative of future performance. The Company's independent registered public accountants have not audited, reviewed or performed any procedures with respect to such preliminary estimates and accordingly do not express an opinion or any other form of assurance with respect thereto.

Item 8.01 Other Events.

Preliminary Financial Information

The preliminary financial information disclosed under Item 2.02 above is incorporated herein by reference.

Janssen Research Collaboration Agreement

As previously disclosed, the Company entered into a research collaboration agreement (the "*Collaboration Agreement*") with Janssen Vaccines & Prevention B.V. ("*Janssen*") to evaluate the Company's proprietary oral vaccine platform for the Janssen universal influenza vaccine program. Under the agreement, the Company produced non-GMP oral vaccine containing certain proprietary antigens from Janssen and tested the product in a preclinical challenge model. The study has been completed, and recently the Company delivered the final report in connection with the Collaboration Agreement. Upon delivery of the report, Janssen has a three-month option to negotiate an exclusive worldwide license to the Company's technology encompassing the Janssen antigens. Janssen has not notified the Company whether it will exercise this option.

Non-Human Primate Study Update

As previously disclosed, the Company's oral COVID-19 vaccine was selected to participate in a non-human primate challenge ("*NHP*") study, organized by Operation Warp Speed and funded by the Biomedical Advanced Research and Development Authority ("*BARDA*") under contract with a research laboratory and in collaboration with USG partners. The Company recently received data from the NHP challenge study of its COVID-19 vaccine candidate. After reviewing the information provided by BARDA, the Company concluded that the study was unable to evaluate the Company's COVID-19 vaccine candidate because of oral vaccine delivery challenges in non-human primate model systems. The Company has significant previous experience with the NHP model and the difficulties of oral administration in this model. Therefore, the Company asked that an active control arm be included in the study, with a vaccine (norovirus) that has previously shown high immunogenicity in both NHP and clinical (human) studies, to validate that protocols and procedures were adequate for the NHP model. Data from the active control arm led the Company to conclude that the NHP study was unable to evaluate either vaccine.

Preliminary Data from Phase 1 Clinical Trial Evaluating Oral COVID-19 Tablet Vaccine Candidate

On February 3, 2021, the Company announced that preliminary data from its Phase 1 study of VXA-CoV2-1 showed that its oral COVID-19 tablet vaccine candidate was generally well-tolerated, and immunogenic as measured by multiple markers of immune responses to the SARS-CoV-2 antigens. On February 3, 2021, the Company issued a press release announcing this preliminary data and related matters. A copy of the press release is attached to this Current Report on Form 8-K as Exhibit 99.1.

Item 9.01 – Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press release, dated February 3, 2021

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 3, 2021

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

Exhibit 99.1

Vaxart Announces Positive Preliminary Data from Phase 1 Clinical Trial Evaluating Its Oral COVID-19 Tablet Vaccine Candidate

- *Study reached primary and secondary endpoints of safety and immunogenicity, respectively*
- *VXA-CoV2-1 induced potent $CD8^+$ T-cell responses*
- *VXA-CoV2-1 potentially protective against new and emerging COVID-19 strains*
- *Data to be presented today at the New York Academy of Sciences Symposium "The Quest for a COVID-19 Vaccine"*

SOUTH SAN FRANCISCO, Calif., February 3, 2021 – Vaxart, Inc., (NASDAQ: VXRT), a clinical-stage biotechnology company developing oral vaccines administered by tablet, today announced preliminary data from its Phase 1 study of VXA-CoV2-1 showing that its oral COVID-19 tablet vaccine candidate was generally well-tolerated, and immunogenic as measured by multiple markers of immune response to SARS-CoV-2 antigens.

"Our Phase I results highlight the importance of our differentiated vaccine design, as they suggest VXA-CoV2-1 could have broad activity against existing and future coronavirus strains. These results are timely, as we are seeing the emergence of new variants less responsive to first generation vaccines, thus making potential cross-reactivity another important advantage of next-generation vaccines," said Andrei Floroiu, Vaxart's Chief Executive Officer.

Vaxart's scientists recognized early the risk of variants of SARS-CoV-2 emerging and they designed a vaccine with the potential to be protective not only against the prevalent strain, but also against emerging mutations of the Spike (S) protein, by including both the S and N proteins. Virtually all other COVID-19 vaccines include just the S protein.

"These results, together with recent data from our peers, further raise our confidence in the success of VXA-CoV2-1 and the broad potential of our platform," continued Floroiu.

"We previously showed that our oral tablet vaccine technology worked to protect against flu – another airborne virus – as well as the leading injectable, but through a different mechanism, in a Phase II trial sponsored by BARDA. With COVID-19, we have now seen that many vaccine approaches— mRNA, protein, and viral vector, including three adenovirus vaccines – are protective, and that all available positive COVID-19 hamster challenge studies such as ours have translated into protection against COVID-19 in human trials," Floroiu said.

"These clinical data further differentiate our COVID-19 vaccine and enable us to meaningfully advance discussions with healthcare officials in the U.S. and around the world about how Vaxart may be able to help them fight back against COVID-19 with a transformative solution - a room-temperature stable oral vaccine that is not only easier to distribute and administer, but may also be more broadly protective," Floroiu added.

Sean Tucker, Ph.D., Vaxart's Chief Scientific Officer, will present the Phase 1 data as part of a clinical trial update at the New York Academy of Sciences Symposium "The Quest for a COVID-19 Vaccine" today at 1:15 p.m. ET. Register here to attend the symposium.

Preliminary Phase 1 trial results from a pooled analysis of all cohorts include:

VXA-CoV2-1 was generally well-tolerated:

- No severe adverse events were reported
- Adverse events were generally mild and primarily gastrointestinal in nature
- Including this study, a total of 495 subjects have now been dosed with our platform, with no serious adverse events reported

VXA-CoV2-1 triggered multiple immune responses against SARS-CoV-2 antigens, including:

- $CD8^+$ cytotoxic T-cell response to the viral Spike (S) protein, necessary for long-lasting cross-reactive immunity, higher than we have seen in any previous Vaxart clinical trial
- An increase in plasmablast cell number and an upregulation of the mucosal homing receptor, indicating activation of B cells that will home to the mucosa
- An increase in proinflammatory Th1 cytokines, responsible for orchestrating the immune response to viral infection
- IgA responses in serum and/or nasal swab samples in 100% of 2 dose subjects; neutralizing antibodies were not detected in serum and IgG responses were not detected in most subjects

“Viral variants with altered S proteins are becoming established in the population before the majority of people can be vaccinated. To end the pandemic, the world needs a vaccine that can provide long-lasting protection from emerging strains,” Dr. Tucker said.

“T-cells can provide long-lasting cross-reactive protection against current and emerging strains of the virus. Our vaccine induced a high percentage of responding $CD8^+$ T cells against both Spike (S) and Nucleoprotein (N) proteins, which may provide protection against variants with alterations in the faster-changing S protein. We expect that our vaccine will be less impacted by new variants than injectable vaccines,” Dr. Tucker added.

Vaxart expects to broaden its COVID-19 vaccine development plans, with efforts that could include:

- VXA-CoV2-1 in COVID-19 naïve subjects: Phase II studies to evaluate optimal dosing schedule, and to then assess efficacy against COVID-19
- VXA-CoV2-1 in previously vaccinated or exposed subjects: investigating single dose boosting protocol to broaden and strengthen immune responses

Clinical Trial design

The Phase I study (NCT04563702) was designed to evaluate the safety and immunogenicity of VXA-CoV2-1 vaccine with multiple dosing schedules. Subjects were divided into three cohorts. The first cohort (5 subjects) received two low doses of vaccine 29 days apart. The remaining cohorts (15 subjects each) received a single low or high dose of the vaccine. Safety and tolerability were monitored following vaccination as well as signs of immunogenicity, including general and SARs-CoV-2 specific immune responses.

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 has 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 preclinical 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 (including enrolling a sufficient number of subjects and manufacturing sufficient quantities of its product candidates) and commercialize its COVID-19 vaccine candidate and preclinical or clinical results and trial data (including plans with respect to the COVID-19 vaccine product candidates); expectations regarding the timing and nature of future announcements including, those related to clinical trials and results of preclinical studies; Vaxart's expectations with respect to the important advantages it believes its oral vaccine platform can offer over injectable alternatives, particularly for coronaviruses; the potential applicability of results seen in our preclinical studies or trials to those that may be seen in human studies 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 products or product candidates, including Vaxart's potential role in mitigating the impact of COVID-19 globally. 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 or preclinical studies, 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 and preclinical study 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 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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