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): August 31, 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 7.01. Regulation FD Disclosure.

On September 1, 2022, Vaxart, Inc. (the "*Company*") issued a press release discussing top-line results from the first part of a two-part Phase 2 clinical study of the Company's Wuhan S-only COVID-19 pill vaccine candidate and announcing that it will hold a conference call and webcast on September 1, 2022, at 8:30 a.m. Eastern Time, to discuss that data. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information furnished under this Item 7.01 to this Current Report on Form 8-K, including Exhibit 99.1, shall not be deemed "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 other filing under the Securities Act of 1933, as amended, or the Exchange Act, regardless of any general incorporation language in such filing.

Item 8.01. Other Events.

On August 31, 2022, the Company issued a press release announcing that it named Ray Stapleton as the Company's Chief Technology Officer. A copy of the press release is filed as Exhibit 99.2 to this Current Report on Form 8-K.

Item 9.01. Financial Statements and Exhibits.

(d) *Exhibits*.

Exhibit	**Description**
99.1	Press Release, dated September 1, 2022.
99.2	Press Release, dated August 31, 2022.
104	Cover Page Interactive Data File (embedded within the 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: September 1, 2022

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

Exhibit 99.1

Vaxart Announces Positive Top-line Phase II Clinical Study Data Demonstrating Safety and Immunogenicity of Its Wuhan S-Only COVID-19 Pill Vaccine Candidate

— Study met primary safety and secondary immunogenicity endpoints —

— Boosted serum neutralizing antibodies in both naive and previously mRNA vaccinated subjects —

— Elicited cross-reactive mucosal responses in approximately 50% of subjects —

— Company to host conference call at 8:30 a.m. ET today —

SOUTH SAN FRANCISCO, Calif., September 1, 2022 (GLOBE NEWSWIRE) -- Vaxart, Inc. (NASDAQ: VXRT) today reported positive top-line data from the first part of a planned two-part Phase II study of its Wuhan S-only oral pill COVID-19 vaccine candidate, VXA-CoV2-1.1-S. The data demonstrate that the trial met its primary safety and secondary immunogenicity endpoints and will inform ongoing development of new Omicron-based vaccine constructs.

Serum neutralizing antibodies rose after oral vaccination, and the increases were particularly notable in subjects who had previously received an mRNA vaccine. Additionally, all subjects who had a mucosal immune response to the Wuhan-based vaccine had mucosal immune responses that cross-reacted with the Omicron variants, including BA 4/5, as well as other coronaviruses. Vaxart is the first company to advance an oral pill COVID-19 vaccine to Phase II clinical development.

“These Phase II data represent a very important milestone in the development of the world’s first COVID-19 pill vaccine,” said Dr. James F. Cummings, Vaxart’s Chief Medical Officer. “These data also demonstrate that a pill vaccine can induce strong serum antibody responses as well as mucosal and T cell responses. Unfortunately, for the past two years the emergence of new variants has outpaced the ability to update the currently approved injectable vaccines. We believe that activating multiple mechanisms of the immune system that can address emerging variants may help the global community get ahead of the immunologic curve of protection. It could transform how we fight this and future pandemics.”

"The results reported today clearly indicate that the S-only construct improved antibody responses compared with the data we previously generated for the S+N construct (VXA-CoV2-1), and also boosted immune responses in subjects who previously received an mRNA vaccine. These are the critical data we sought when this trial was initiated in October 2021,” said Dr. Sean Tucker, Vaxart's Founder and Chief Scientific Officer. “Additionally, the observed increase in mucosal IgA is very encouraging, and we believe that the positive findings for multiple immunologic responses may ultimately translate to enhanced protection against infection with, and/or transmission of, SARS-CoV-2.”

Study Key Findings

- The VXA-CoV2-1.1-S vaccine construct was safe and well-tolerated. No vaccine-related solicited grade 3 adverse events (AEs) and no vaccine-related serious adverse events (SAEs) were reported.
- Vaccination with VXA-CoV2-1.1-S increased levels of SARS-CoV-2-specific serum IgG and IgA antibodies at Days 29 and 57.
- The geometric mean titer (GMT) increase of SARS-CoV-2-specific serum neutralizing antibodies from Day 1 to Day 57 ranged by cohort between 1.2- and 2-fold, with higher increases for higher doses.

- Among 18-55 year-old subjects previously vaccinated with mRNA vaccines, the geometric mean titer (GMT) of SARS-CoV-2-specific serum neutralizing antibodies increased 1.6-fold, from 481 AU/ml at Day 1 to 778 AU/ml at Day 57. The subjects who had lower starting titers showed greater increases after oral boosting.
- Approximately 50% of all subjects, as well as 50% of subjects that previously received an mRNA vaccine, had at least a 1.5-fold increase in mucosal IgA antibodies.
- All subjects who had a mucosal response to Wuhan S from VXA-CoV2-1.1-S (a Wuhan-based vaccine) also had mucosal immune responses that cross-reacted with the Omicron variants, including BA 4/5, as well as other coronaviruses. This includes subjects that had previously received an mRNA-based vaccine.
- SARS-CoV-2-specific T cell responses were observed in the majority of subjects after the second dose of VXA-CoV2-1.1-S.

“These very exciting data support the great potential of our platform,” said Andrei Floroiu, Vaxart’s Chief Executive Officer. “We are now a step closer to the day when we could get vaccinated against COVID-19 with an oral pill vaccine that offers broad protection against current and future variants by harnessing multiple immune system mechanisms. I believe this is what transformative innovation looks like. We will continue working toward the promise of vaccinating more people around the world, faster, with more protective vaccines, with just a pill and a glass of water."

Clinical Trial Next Steps
As previously announced, Vaxart is evaluating new Omicron-based constructs as Omicron-only monovalent vaccine candidates and as bivalent candidates in combination with the Company’s Wuhan constructs. Vaxart will also compare the clinical results of its S-only and S+N constructs to determine the best path forward in developing a vaccine that can hinder viral infection and transmission for current and emerging variants. These constructs are expected to be evaluated in preclinical models this year and to advance to clinical trials in the first half of 2023. The Company expects to move forward with the best possible vaccine constructs for its planned COVID-19 Omicron challenge in the second half of 2023 with hVIVO, as well as larger trials in the U.S. and internationally.

Clinical Study Design
Part 1 of the open-label, Phase II study enrolled 66 healthy adult volunteers, including subjects who had or had not received prior mRNA COVID-19 vaccination, ages 18-55 years and 56-75 years. Subjects were randomized into six cohorts stratified by age, vaccination history and dose. Subjects received either a high or a low dose of VXA-CoV2-1.1-S on Day 1 and Day 29, and immune responses were assessed prior to vaccine administration on Day 1, Day 29 and on Day 57.

Conference Call Information
The Vaxart senior management team will host a conference call today, beginning at 8:30 a.m. ET.

The conference call can be accessed using the following information:
Webcast: Click here
Date: Thursday, September 1, 2022 – 8:30 a.m. ET
Domestic: 877-407-0832
International: 201-689-8433
Conference ID: 13732510

Investors may submit written questions in advance of the conference call to ir@vaxart.com. A replay of the webcast will be available on the Company's website at www.vaxart.com following the conclusion of the event.

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.

Please also refer to the 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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Exhibit 99.2

Vaxart Names Biotech Veteran Ray Stapleton Chief Technology Officer

Dr. Stapleton has more than 20 years of industry experience leading technical, quality and manufacturing operations at commercial and clinical stage biopharmaceutical companies

SOUTH SAN FRANCISCO, Calif., Aug. 31, 2022 (GLOBE NEWSWIRE) -- Vaxart, Inc. (NASDAQ: VXRT) announced today that it has named Ray Stapleton, Ph.D., as its Chief Technology Officer (CTO), effective immediately. Dr. Stapleton joins Vaxart from Genocea, where he served as CTO and Executive Vice President, working to develop next generation personalized immunotherapies in the forms of vaccines and cell therapies.

"Manufacturing is an important part of vaccine development, and we are excited to have a CTO with Ray's depth and breadth of professional experience join our executive team," said Andrei Floroiu, Vaxart's Chief Executive Officer. "We believe Ray will help us deliver on our vision of developing next generation oral pill vaccines that hold the promise of transforming how we're fighting infectious diseases globally."

"Vaxart's pill vaccines have the potential to revolutionize how the world gets vaccinated and I'm excited to be a part of the team working to advance Vaxart's manufacturing and key pipeline programs," Dr. Stapleton said. "I've spent my career working on cutting edge science and nothing is more rewarding than the opportunity to improve human health on a large scale."

Dr. Stapleton joined Genocea in January 2021, bringing more than 20 years of industry experience to the company, having led technical, quality and manufacturing operations at commercial and clinical stage biopharmaceutical companies.

Before that, he served as President and Chief Operating Officer of American Type Culture Collection (ATCC), as well as a member of the Board of Directors of both ATCC and ATCC Global. Prior to ATCC, Dr. Stapleton worked in senior manufacturing and technical operations roles at Iovance Biotherapeutics, Inc. and Synthetic Biologics, Inc. after spending 15 years in positions of increasing responsibility in Merck and Company's manufacturing organization.

At Merck, Dr. Stapleton led a complex science, technology, and engineering organization at a manufacturing site responsible for supporting Merck's $5 billion annual revenue vaccine business.

Dr. Stapleton earned a bachelor's degree in Biology from Mary Washington College in Fredericksburg, Virginia and received his PhD in Microbial Ecology from the University of Tennessee, Knoxville. He has served as peer reviewer for a half dozen scientific journals, co-authored 17 peer-reviewed manuscripts, and holds multiple patents.

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