

**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): **June 6, 2023**

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:

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 8.01 Other Events.

On June 6, 2023, Vaxart, Inc. issued a press release providing an update on its norovirus vaccine candidate. A copy of the press release is filed as Exhibit 99.1 hereto and, other than the quotes by Dr. James F. Cummings, is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit	Description
99.1	Press Release, dated June 6, 2023.
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: June 6, 2023

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

Vaxart Announces Last Subject Dosed in Phase 2 Trial of its Bivalent Norovirus Candidate, and All Subjects Challenged in Phase 2 Challenge Study of Monovalent Norovirus Candidate

No Vaccine Related Serious Adverse Events (SAEs) reported to date

On track to report topline data from two Phase 2 norovirus vaccine studies over the next 3 months

SOUTH SAN FRANCISCO, Calif., June 06, 2023 (GLOBE NEWSWIRE) – Vaxart, Inc. (Nasdaq: VXRT) today announced that the last subject has completed dosing in the Phase 2 clinical trial of its oral pill bivalent norovirus vaccine candidate. In addition, all patients have been challenged in its challenge study of its G.1.1 monovalent vaccine candidate. No vaccine related SAEs have been reported to date in either trial, consistent with the safety profile observed in all our norovirus trials.

“We look forward to announcing key topline data of both Phase 2 trials for our norovirus candidates in the coming months as we continue to make timely progress in these studies,” said Dr. James F. Cummings, Vaxart’s Chief Medical Officer. “Both trials now are fully enrolled, and all subjects have been dosed and no vaccine-related SAEs reported in either study. Data from these Phase 2 trials will inform the next steps for our clinical development strategy for these potentially promising vaccine candidates.”

Vaxart continues to expect to report topline data from the ongoing Phase 2 dose-ranging study (NCT05626803) of its bivalent norovirus vaccine candidate in mid-2023. The primary endpoints are safety and immunogenicity, with the objective of determining dose levels for Phase 3 development.

The Company also expects to report topline data from the ongoing Phase 2 challenge study (NCT05212168) of Vaxart’s G1.1 monovalent norovirus vaccine candidate during Q3 2023. Primary endpoints include safety and reduction in acute gastroenteritis (AGE) caused by norovirus infection, while additional endpoints include reduction in AGE severity, reduction in shedding, and immunogenicity, with the objective of determining efficacy against norovirus G1.1-induced AGE.

Norovirus is the leading cause of acute viral gastroenteritis in all age groups in the U.S. However, there are no approved vaccines for noroviruses. In the U.S. alone, the annual disease burden from norovirus is \$10.5 billion, as on average norovirus causes 19 to 21 million cases of AGE, infects 15% of all children under the age of 5, and leads to 465,000 emergency department visits, 109,000 hospitalizations, and 900 deaths.

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 pills that can be stored and shipped without refrigeration and eliminate the risk of needle-stick injury. Vaxart believes that its proprietary pill 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 pill vaccines designed to protect against norovirus, coronavirus, 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 and the timing of such results, 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 the timing of receiving and reporting such 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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