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): April 30, 2024

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 8.01 Other Events.

On April 30, 2024, Vaxart, Inc. issued a press release announcing it has completed the topline analysis for the Phase 1 clinical trial evaluating Vaxart, Inc.'s oral pill bivalent 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 April 30, 2024.
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: April 30, 2024

By: /s/ STEVEN LO
Steven Lo
President and Chief Executive Officer

Exhibit 99.1

Vaxart Announces Positive Results for Its Bivalent Norovirus Vaccine Candidate in Lactating Mothers

Antibody rise observed in lactating mothers and in their breast milk

Long-term goal is to provide protection to infants through passive antibody transfer

SOUTH SAN FRANCISCO, Calif., April 30, 2024 (GLOBE NEWSWIRE) – Vaxart, Inc. (Nasdaq: VXRT) today announced that it has completed the topline analysis for the Phase 1 clinical trial evaluating Vaxart's oral pill bivalent norovirus vaccine candidate.

The trial was focused on lactating mothers. Antibodies to norovirus rose on average 4.0 fold for the G1.1 virus strain and 6.0 fold for the GII.4 virus strain in the breast milk of lactating mothers who received the Vaxart vaccine candidate in the high dose group. There were no vaccine-related serious adverse events (SAEs) and no dose-limiting pharmacotoxicity.

"This is an important step forward as we drive toward a vaccine candidate that may make it possible for mothers to protect their children against this highly contagious – and potentially lethal – virus. It can be difficult to immunize the youngest of children mucosally because the immune system is still developing. Passive transfer of antibodies from mothers to infants via breast milk is an innovative approach to potentially improve infection resistance in infants," said Dr. James F. Cummings, Vaxart's Chief Medical Officer. "We would like to thank the study subjects for their participation in this novel and important clinical trial."

There is no approved vaccine against norovirus, which sickens approximately 21 million people in the United States each year, including the 15% of children under age 5 who contract norovirus annually. Approximately 3 million sets of parents are forced by this virus to miss work – approximately 2.2 days on average – to care for their children. The annual disease burden from norovirus is $10.6 billion in the United States alone.

Globally, norovirus has become the leading cause of pediatric gastroenteritis in health care settings in countries that have adopted a rotavirus vaccine program.[1] Pediatric deaths in the United States due to norovirus are rare, but they are much more common in the developing world.

This Phase I trial was conducted in South Africa (trial #20230307), and partially funded by the Bill & Melinda Gates Foundation. More complete results, including other immunogenicity measures, will be reported in a future scientific manuscript.

About the VXA-NVV-108 Clinical Trial

This Phase 1, multicenter, randomized, double-blind, placebo-controlled single dose, dose-ranging study is designed to evaluate the safety, tolerability, and immunogenicity of orally administered bivalent GI.1/GII.4 norovirus vaccine in healthy lactating females 18-43 years of age. The study enrolled 76 subjects at five sites in South Africa. Subjects were randomized into high- or medium-dose vaccine (N=30 for each arm) or placebo (N=16). The primary endpoint results were:

- Serum VP1-specific IgA rose an average of 5.6 fold in response to GI.1 and 4.4 fold in response to GII.4 in the high dose group, similar to the response observed in a previous Vaxart bivalent study conducted in adults 18-55 years of age in the United States.
- Breastmilk VP1-specific IgA rose on average 4.0 fold in response to G1.1 and 6.0 fold in response to GII.4 in the high dose group.
- The vaccine was well tolerated, with no SAEs, no adverse events of special interest (AESIs) and no new onset of chronic illness (NOCIs) observed through the active period.

Further information, including information about study funding, can be found in Vaxart's press release of December 1, 2022, as well as Vaxart's latest annual filing with the Securities and Exchange Commission.

[1] Shah and Hall, Infect Dis Clin North Am. 2018 Mar; 32(1): 103-118.

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 coronavirus, norovirus, and influenza, 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.

Contacts

Vaxart Media Relations:
Mark Herr
Vaxart, Inc.
mherr@vaxart.com
(203) 517-8957

Investor Relations:
Andrew Blazier
FINN Partners
IR@vaxart.com
(646) 871-8486