
**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): **March 19, 2019**

Vaxart, Inc.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation)

001-35285
(Commission File No.)

59-1212264
(I.R.S. Employer Identification No.)

290 Utah Ave.
Suite 200
South San Francisco, California 94080
(Address of principal executive office)(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))

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 March 19, 2019, Vaxart, Inc. (the “Company”) issued a press release announcing the initiation of a Phase 1b bivalent norovirus vaccine clinical trial. A copy of the press release is filed as Exhibit 99.1 hereto and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

<u>Exhibit</u>	<u>Description</u>
99.1	Press release, dated March 19, 2019, titled "Vaxart Announces Initiation of Bivalent Norovirus Vaccine Phase 1b Clinical Trial".

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.

Date: March 19, 2019

By: /S/ WOUTER W. LATOUR, M.D.

Name: Wouter W. Latour, M.D.

Title: President and Chief Executive Officer



Vaxart Announces Initiation of Bivalent Norovirus Vaccine Phase 1b Clinical Trial

- First Dosing with Norovirus GII.4 Oral Tablet Vaccine Scheduled for Week of March 18 -

SOUTH SAN FRANCISCO, Calif., March 19, 2019 — Vaxart, Inc., a clinical-stage biotechnology company developing oral recombinant vaccines that are administered by tablet rather than by injection, today announced the initiation of a Phase 1b bivalent norovirus vaccine clinical trial.

“The initiation of the bivalent norovirus vaccine Phase 1b trial marks a significant step towards our goal of developing a vaccine that can protect the most vulnerable patients from this highly infectious disease,” said Wouter Latour, M.D., chief executive officer of Vaxart. “Norovirus infection disproportionately affects the elderly and the very young, and we believe an oral vaccine would be the optimal approach to prevent the significant morbidity and even mortality in these age groups.”

The bivalent norovirus vaccine Phase 1b trial consists of two parts, an open-label lead-in phase during which 6 subjects will be dosed with norovirus GII.4 vaccine, and a double-blind, placebo-controlled phase during which a total of 80 subjects will be randomized into four groups and dosed with either placebo, norovirus GI.1 vaccine, norovirus GII.4 vaccine or both norovirus vaccines. Both portions of the study are designed to evaluate safety and immunogenicity. Vaxart expects the first dosing of the randomized portion of the study to begin in April, subject to final review by the FDA. The Company expects to receive topline data from the Phase 1b clinical study in the second half of 2019.

In addition, the Company reported it remains on track to initiate the Phase 2 monovalent norovirus challenge study in the second quarter of 2019, with results expected in the second half of 2019.

About Norovirus

Norovirus is recognized as the leading cause of acute gastroenteritis in the United States. It is a common intestinal infection that typically lasts three to five days and is marked by diarrhea, vomiting, abdominal cramps, nausea and sometimes fever. Symptoms can be more severe in older adults and young children and may lead to serious complications including death. Norovirus causes frequent and widespread outbreaks in the military, food industry, travel industry, child care facilities, elderly homes and healthcare facilities.

The U.S. Centers for Disease Control and Prevention (CDC) estimates that norovirus causes approximately 19 to 21 million illnesses in the United States each year, resulting in 56,000 to 71,000 hospitalizations and 570 to 800 deaths, mostly among young children and older adults.

In a recent study by Johns Hopkins University and the CDC, researchers estimated global economic impact of norovirus disease at \$60 billion, \$34 billion of which occurred in high income countries, including the United States, Europe and Japan.

About Vaxart

Vaxart is a clinical-stage biotechnology company focused on developing oral recombinant protein vaccines based on its proprietary oral vaccine platform. Vaxart's vaccines are designed to generate broad and durable immune responses that protect against a wide range of infectious diseases and may also be useful for the treatment of chronic viral infections and cancer. Vaxart's vaccines are administered using a convenient room temperature-stable tablet, rather than by injection. Vaxart believes that tableted vaccines are easier to distribute and administer than injectable vaccines and have the potential to significantly increase vaccination rates. Vaxart's development programs include oral tablet vaccines that are designed to protect against norovirus, seasonal influenza and respiratory syncytial virus (RSV), as well as a therapeutic vaccine for human papillomavirus (HPV). For more information, please visit www.vaxart.com.

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 our 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 "believe," "could," "potential," "will" and other words and terms of similar meaning. Examples of such statements include, but are not limited to, statements relating to the Vaxart's ability to develop and commercialize its product candidates and clinical results and trial data; the expected timing of the initiation of the Phase 1 bivalent study and Phase 2 monovalent challenge study; and Vaxart's expectations with respect to the advantages it believes its oral vaccine platform can offer over injectable alternatives, particularly for mucosal pathogens such as norovirus, flu and RSV. Vaxart may not actually achieve the plans, carry out the intentions or meet the expectations or projections disclosed in our 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 factors could cause actual results or events to differ materially from these forward-looking statements, including Vaxart's ability to raise sufficient capital to fund the continued development of its product candidates and complete its planned studies and trials, 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 Vaxart may experience manufacturing issues and delays; 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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