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): November 18, 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 8.01. Other Events.

Grant from the Bill & Melinda Gates Foundation

On November 18, 2022, Vaxart, Inc. (the "*Company*") entered into a Grant Agreement (the "*Grant Agreement*") with the Bill & Melinda Gates Foundation ("*BMGF*"), pursuant to which the Company expects to receive approximately $3.46 million (the "*Grant*") to partially fund a new study of the Company's oral pill norovirus vaccine candidate focused on protecting breastfeeding mothers and their infants (the "*Study*"). Under the Grant Agreement, the Company agreed to a global access commitment for use of its vaccine candidate, if proven effective and approved, in breastfeeding mothers from low- and middle-income countries. The Grant Agreement is set to expire on September 15, 2024. Receipt by the Company of the Grant is subject to all of the terms and conditions of the Grant Agreement.

On December 1, 2022, the Company issued a press release discussing the commencement of the Study and the Grant. A copy of the press release is attached as Exhibit 99.1 to this Current Report on Form 8-K (this "*Form 8-K*") and incorporated by reference herein.

Notice Regarding Conclusion of SEC Inquiry

As previously disclosed, the Securities and Exchange Commission (the "*SEC*") advised the Company that it was the subject of an informal, non-public fact-finding inquiry by the SEC (the "*Inquiry*"). Additional information regarding the Inquiry can be found in the Company's prior filings, including the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2021 and filed with the SEC on February 24, 2022.

On November 29, 2022, the Company's legal counsel received a notice from the SEC (the "*Notice*") stating: "We have concluded the investigation as to your client Vaxart, Inc. Based on the information we have as of this date, we do not intend to recommend an enforcement action by the Commission against Vaxart, Inc." The Notice was provided under the guidelines set forth in the final paragraph of Securities Act Release No. 5310.

Forward-Looking Statements

Statements contained or incorporated by reference in this Form 8-K which relate to other than strictly historical facts, such as statements about the Company's plans and strategies are forward-looking statements. The words "believe," "expect," "intend," "anticipate," "estimate," "project," and similar expressions identify forward-looking statements that speak only as of the date of this Current Report on Form 8-K. Investors are cautioned that such statements involve risks and uncertainties that could cause actual results to differ materially from historical or anticipated results due to many factors including, but not limited to, whether any or all of the funding from the Grant is received by the Company, the Company's continuing contractual and common law indemnity obligations to current and former officers and directors, the Company's continuing operating losses, the possibility that the Company's product candidates may not be approved by the U.S. Food and Drug Administration or non-U.S. regulatory authorities, uncertainty of market acceptance if the Company eventually produces a commercially viable vaccine, reliance on third party manufacturers, accumulated deficit, future capital needs, uncertainty of capital funding, the Company's ability to meet anticipated clinical endpoints, commencement dates, and/or completion dates for clinical trials, competition, limited marketing and manufacturing experience, and other risks detailed in the Company's most recent Annual Report on Form 10-K and other filings with the SEC. The Company undertakes no obligation to publicly update or revise any forward-looking statements.

Item 9.01. Financial Statements and Exhibits.

(d) *Exhibits*.

Exhibit	**Description**
99.1	Press Release, dated December 1, 2022.
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: December 6, 2022

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

Exhibit 99.1

Vaxart Announces Collaborative Funding from Leading Foundation to Study Its Norovirus Vaccine Candidate in Breastfeeding Mothers

Funding and support provided by Bill & Melinda Gates Foundation

Study will focus on determining the ability of oral vaccine tablets to induce breast milk antibodies and transfer of antibodies to young infants

SOUTH SAN FRANCISCO, Calif., December 1, 2022 – Vaxart, Inc. (Nasdaq: VXRT) today announced it will commence a new study of Vaxart's oral pill norovirus vaccine candidate focused on protecting breastfeeding mothers and their infants.

The study will receive significant funding and support from the Bill & Melinda Gates Foundation ("Gates Foundation"). This funding follows Vaxart's previous collaboration with Duke University on a pre-clinical COVID-19 transmission study also funded by the Gates Foundation.

"Currently, there are no approved vaccines that prevent norovirus, which is responsible for a $10.5 billion annual disease burden in the United States alone. Vaxart's oral norovirus vaccine pill may make it possible for mothers to protect their infants against this highly contagious disease that has serious health consequences," said Dr. James Cummings, Vaxart's Chief Medical Officer. "We believe this is just one part of the broader promise of our norovirus vaccine program, which could be of great benefit to at-risk populations such as the elderly, children under age 5, the military, first responders and healthcare workers, both here in the U.S. and globally."

The study will examine whether Vaxart's vaccine candidate induces antibodies in the breast milk of lactating mothers and whether infants up to 6 months of age can acquire those antibodies. Vaxart believes there are potential advantages to this approach. Young children have an immature immune system that makes them particularly susceptible to highly contagious diseases, and direct immunization can be challenging. Passive transfer of antibodies from mother to infant that are induced in milk may protect breastfeeding infants from infectious pathogens.

"By triggering mucosal immunity in addition to protecting those vaccinated, our vaccines may also reduce transmission - the key mechanism by which viral infections spread, further increasing their overall effect on the broader population. This study investigates inducing mucosal immunity at an important site that ultimately might result in positively impacting transmission," said Andrei Floroiu, Vaxart's Chief Executive Officer. "We are pleased with the funding and support from the Gates Foundation, which will help realize the potential impact of our vaccine technology on global public health."

Norovirus sickens approximately 21 million people in the United States each year, and 15% of children under age 5 catch norovirus annually. This would translate into about 3 million sets of parents needing to take time from work (approximately 2.2 days on average) to care for their children. Globally, in countries that have adopted a rotavirus vaccine program, norovirus has become the leading cause of pediatric gastroenteritis in health care settings.[1] Pediatric deaths in the United States due to norovirus are rare, but much more common in the developing world.

As a grant recipient, Vaxart has agreed to a global access commitment for use of its vaccine candidate, if proven effective and approved, in breastfeeding mothers from low- and middle-income countries.

Vaxart is also currently studying its norovirus vaccine candidate in a challenge study that will provide the vaccine 30 days before exposure to actual norovirus, and then determine whether people get infected or have severe gastroenteritis.

[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, 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, 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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