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): January 13, 2025

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 January 13, 2025, Vaxart, Inc. (the "Company") issued a press release announcing that an independent Data Safety Monitoring Board recommended that the Company's Phase 2b clinical trial evaluating its oral pill COVID-19 vaccine candidate against an approved mRNA vaccine comparator proceed without any modifications.

On January 14, 2025, the Company issued a press release, providing business updates on its COVID-19, norovirus, and influenza programs, as well as other matters.

Copies of the press releases are attached herewith as Exhibits 99.1 and 99.2 to this Current Report on Form 8-K and, other than the quotes by Steven Lo and Dr. James F. Cummings, are incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

Exhibit No.	Description
99.1	Press Release dated January 13, 2025.
99.2	Press Release dated January 14, 2025.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: January 21, 2025

VAXART, INC.

/s/ Phillip Lee
Phillip Lee
Chief Financial Officer

Exhibit 99.1

Vaxart Announces Favorable DSMB Review of Sentinel Cohort from COVID-19 Phase 2b Clinical Trial

Independent Data Safety Monitoring Board (DSMB) recommends study to proceed without modifications based on initial safety assessment of 400 participant 30-day data

The company plans to progress the trial to enrollment of 10,000 participants, upon favorable review from the U.S. Food and Drug Administration (FDA) and upon Biomedical Advanced Research and Development Authority (BARDA) approval

SOUTH SAN FRANCISCO, Calif., January 13, 2025 – Vaxart, Inc. (Nasdaq: VXRT) today announced that an independent DSMB, which conducted a planned review of the 30-day safety data from a sentinel cohort of 400 participants in its COVID-19 Phase 2b trial, has recommended that the study continue without any modifications.

"We are pleased with the DSMB recommendation, an important step forward in conducting our head-to-head study versus an mRNA comparator," said Dr. James F. Cummings, Vaxart's Chief Medical Officer. "We look forward to the next steps of review of the safety data by the FDA and approval from BARDA before advancing the Phase 2b trial to the second part that will measure both safety and efficacy."

The FDA is reviewing the 30-day safety data from the sentinel cohort, and, upon favorable review as well as BARDA's approval, the study will progress by enrolling approximately 10,000 participants. The trial will strive to enroll participants in line with U.S. demographics, as well as including at least 25% over the age of 65.

The Phase 2b trial is a double-blind, multi-center, randomized, comparator-controlled study to determine the relative efficacy, safety, and immunogenicity of Vaxart's oral pill COVID-19 vaccine candidate compared to an approved mRNA COVID-19 injectable vaccine, in adults previously immunized against COVID-19 infection.

Funding for this award was received under Project NextGen, a $5 billion initiative led by BARDA and the National Institute of Allergy and Infectious Diseases (NIAID) to accelerate and streamline the development of the next generation of innovative COVID-19 vaccines, therapeutics, and enablers. Vaxart's project award through the Rapid Response Partnership Vehicle (RRPV) is valued at up to $460.7 million. This project has been funded with federal funds from the U.S. Department of Health and Human Services (HHS); Administration for Strategic Preparedness and Response (ASPR); BARDA, under Other Transaction (OT) number 75A50123D00005.

As a pioneer of oral vaccines, Vaxart was the first U.S. company to complete a Phase 2 clinical trial of an oral vaccine for COVID-19.

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, receipt of funding from BARDA, results from preclinical and clinical trials and the timing of such results as well as the outcome of the review of such results by regulatory authorities, 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.

Contact

Vaxart Media and Investor Relations:
Matt Steinberg
FINN Partners
IR@vaxart.com
(646) 871-8481

Exhibit 99.2

Vaxart Highlights Progress of COVID-19, Norovirus and Influenza Programs

COVID-19 Phase 2b study poised to initiate 10,000 participant portion of trial pending U.S. Food and Drug Administration (FDA) review of sentinel cohort 30-day safety data

Norovirus program to proceed with Phase 1 study following scientific advisory board and FDA feedback; Trial to initiate the first half of 2025 with topline data expected as early as mid-2025

New avian influenza vaccine candidate being tested in preclinical studies

SOUTH SAN FRANCISCO, Calif., January 14, 2025 — Vaxart, Inc. (Nasdaq: VXRT) today provided business updates as the Company continues to advance its oral pill vaccine platform.

“We continue to execute on our lead COVID-19 and norovirus programs as evidenced by the advancement of both programs toward key milestones,” said Steven Lo, Vaxart’s Chief Executive Officer. “Starting with our COVID-19 program, we believe that the favorable review of the 30-day sentinel cohort safety data of our Phase 2b trial by an independent DSMB has us well-positioned to initiate the 10,000-participant portion of the trial following a positive review from the FDA as well as approval from BARDA to proceed.”

“Regarding our norovirus program, after a thorough review of the constructive feedback from the FDA on our GI.1 norovirus candidate, discussions with advisors and infectious disease experts, and promising preclinical data on our second-generation constructs, we believe that performing a Phase 1 trial substantially improves our chance of success. The trial will compare the second-generation constructs to our first-generation constructs, providing us with supporting data to rapidly proceed with the best candidate,” added Mr. Lo.

“We proved efficacy against a robust controlled human infection using our first-generation norovirus construct and identified important immune markers that track with norovirus protection,” said James F. Cummings, MD, Vaxart’s Chief Medical Officer. “Our second-generation constructs induced stronger immune responses in preclinical models. As a result, our next clinical study will evaluate these next generation constructs head-to-head against our first-generation constructs to verify this robust response.”

“Through the tireless work of our dedicated team, we are now prepared to advance our two lead programs. At the same time, we will explore value creating partnerships and non-dilutive funding options to sustain our continued momentum and extend our cash runway,” concluded Mr. Lo.

COVID-19 Program Developments
An independent Data and Safety Monitoring Board (DSMB) recommended the continuation of the Phase 2b study. The DSMB reviewed 30-day safety data of the sentinel cohort of a Phase 2b clinical trial evaluating Vaxart’s oral pill COVID-19 vaccine candidate against an approved mRNA vaccine comparator.

The FDA is reviewing the 30-day safety data from the sentinel cohort, and, upon favorable review, the study will progress following the Biomedical Advanced Research and Development Authority’s (BARDA’s) approval to the second part of the trial by enrolling approximately 10,000 participants. The primary efficacy analysis will be performed when all participants have either discontinued or completed a study visit 12 months post-vaccination.

Funding for this award was received under Project NextGen, a $5 billion initiative led by BARDA and the National Institute of Allergy and Infectious Diseases (NIAID) to accelerate and streamline the development of the next generation of innovative COVID-19 vaccines, therapeutics, and enablers. Vaxart's project award through the Rapid Response Partnership Vehicle (RRPV) is valued at up to $460.7 million. This project has been funded with federal funds from the U.S. Department of Health and Human Services (HHS); Administration for Strategic Preparedness and Response (ASPR); BARDA, under Other Transaction (OT) number 75A50123D00005.

Norovirus Program Developments
Vaxart will proceed with a Phase 1, open label, dose ranging clinical trial evaluating its second-generation oral norovirus vaccine constructs head-to-head against its first-generation constructs. The study will measure safety and immune parameters that have correlated to protection in the completed norovirus challenge study. The Phase 1 trial is expected to initiate in the first half of 2025 with topline data expected as early as mid-2025.

If the Phase 1 trial is successful, the next step, pending a partnership or other funding, would be to conduct a Phase 2 safety and immunogenicity study that could potentially begin as early as the second half of 2025 followed by an End of Phase 2 meeting with the FDA. A Phase 3 trial could then begin as early as 2026.

Influenza Program Developments
Vaxart continues to advance its avian influenza program. The Company previously published data demonstrating protection in a preclinical model against avian influenza after oral immunization (Clin Vaccine Immunol 2013). Vaxart recently created a new avian influenza vaccine candidate to cover the latest clade 2.3.4.4b. The Company is in the process of conducting several preclinical studies to evaluate the new construct and preparing to manufacture it for clinical use. Vaxart will publish the results of the preclinical studies when complete.

Cash Runway Update
Vaxart expected fees and reimbursements under its Project NextGen award of up to $460.7 million, combined with its existing cash, cash equivalents and investments, provides the Company with cash runway into 2026, funding multiple key clinical and regulatory milestones.

Vaxart will explore various strategies to extend its cash runway through business development partnerships and non-dilutive funding options with the goal of achieving its upcoming clinical and regulatory milestones and maximizing shareholder value.

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, receipt of funding from BARDA, future cash runway and funding milestones, the results of the FDA's review of any trials, studies, or data, results from preclinical and clinical trials and the timing of such results and such 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 receipt of funding from BARDA for the Phase 2b study (or for any other purpose); Vaxart's ability to develop and commercialize its product candidates, including its vaccine booster products; Vaxart's expectations regarding clinical results and trial data, including their design, and the timing of such trials and of receiving and reporting such clinical results and trial data; Vaxart's expectations regarding timing of enrollment in studies; and Vaxart's expectations with respect to the effectiveness of its product candidates and the potential of its vaccine pill platform. 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 U.S. Securities and Exchange Commission. Vaxart does not assume any obligation to update any forward-looking statements, except as required by law.

Contact

Vaxart Media and Investor Relations
Matt Steinberg
FINN Partners
IR@vaxart.com
(646) 871-8481