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): September 27, 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 1.01. Entry into a Material Definitive Agreement.

On September 27, 2024, Vaxart, Inc. (the "Company") entered into Modification No. 3 (the "Modification") to the ATI-RRPV Project Award Agreement No. 001 dated June 13, 2024 (the "Project Agreement") with Advanced Technology International, the Rapid Response Partnership Vehicle's Consortium Management Firm funded by the Biomedical Advanced Research and Development Authority ("BARDA") of the U.S. Department of Health and Human Services. As previously disclosed, pursuant to the Project Agreement, the Company will receive funding to conduct a Phase 2b comparative study (the "Trial") evaluating the Company's oral pill XBB COVID-19 vaccine candidate against an mRNA vaccine comparator approved by the U.S. Food and Drug Administration.

The Modification (i) increased the total estimated ceiling for the funding to the Company to approximately $456.1 million, representing an increase of approximately $3.2 million, and (ii) increased the total amount of funding currently allotted to the Trial and available for payment to approximately $96.5 million, representing an increase of approximately $30.8 million. A portion of the additional funding is for the Company to commence manufacturing of a vaccine construct targeting the KP.2 strain.

On September 27, 2024, BARDA also informed the Company that it could proceed with the sentinel portion of the Trial pursuant to the Project Agreement. Pursuant to the Modification, the Trial is to begin with a sentinel cohort of 400 individuals using the Company's XBB vaccine and an mRNA XBB comparator.

The foregoing description of the Modification does not purport to be complete and is qualified in its entirety by reference to the full text of the Modification, which will be filed as an exhibit to the Company's next periodic report.

Item 8.01. Other Events.

On September 30, 2024, the Company issued a press release announcing the initiation of the sentinel portion of the Trial. A copy of the press release is attached to this Current Report on Form 8-K as Exhibit 99.1 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 September 30, 2024.
104	Cover Page Interactive Data File (embedded within Inline XBRL document).

Forward-Looking Statements

Statements contained or incorporated by reference in this Current Report on Form 8-K which relate to other than strictly historical facts, such as statements about the Company's expectations with respect to clinical and regulatory development plans for its product candidates, the data to be derived in the Company's ongoing and planned clinical trials, the timing of funding pursuant to the Project Agreement and/or the Modification, additional funding of the Trial under the Project Agreement and/or the Modification, and the structure, design, and objectives of the Trial. 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, risks and uncertainties associated with the Company's ability to achieve milestones and deliverables under the Project Agreement and achieve successful results in the Trial, the Company's continuing operating losses, and other risks detailed in the Company's most recent Annual Report on Form 10-K and other filings with the U.S. Securities and Exchange Commission. The Company undertakes no obligation to publicly update or revise any forward-looking statements, other than as may be required under applicable law.

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: September 30, 2024

By: */s/ Steven Lo*
Steven Lo
President and Chief Executive Officer

Exhibit 99.1

Vaxart Announces Initiation of Sentinel Cohort for Phase 2b Study Evaluating Its COVID-19 Oral Pill Vaccine Candidate

— 400 subject sentinel portion of Phase 2b study will evaluate the safety, immunogenicity and efficacy of Vaxart's next generation oral pill COVID-19 vaccine compared to an approved mRNA vaccine comparator —

— The sentinel cohort is being funded as part of the Phase 2b NextGen COVID-19 clinical trial, valued at up to $456 million through the Rapid Response Partnership Vehicle under the U.S. government's Project NextGen —

SOUTH SAN FRANCISCO, Calif., September 30, 2024 – Vaxart, Inc. (Nasdaq: VXRT) today announced the initiation of the sentinel cohort of its Phase 2b clinical trial evaluating Vaxart's oral pill COVID-19 vaccine candidate against an approved mRNA vaccine comparator.

"Initiating the sentinel cohort is a strong step toward Vaxart's goal of developing a vaccine that may bring us closer to a sustainable solution to the persistent threat of COVID-19," said Dr. James F. Cummings, Vaxart's Chief Medical Officer. "We continue to progress toward our goal of conducting the Phase 2b study and look forward to the results of our mucosal technology's first head-to-head comparison against an approved mRNA vaccine for this virus."

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 against an approved mRNA COVID-19 injectable vaccine in adults previously immunized against COVID-19 infection.

The trial consists of two parts and will enroll healthy adults 18 years and older in the United States. The first part, for which funding is now approved, is a sentinel cohort comprised of 400 participants, with 200 receiving Vaxart's COVID-19 vaccine candidate and 200 receiving an approved mRNA vaccine comparator. Once an independent Data and Safety Monitoring Board (DSMB) and FDA review the 30-day safety data of the 400 participants, the second part of the trial will proceed to enroll 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 full Phase 2b trial will measure efficacy for symptomatic and asymptomatic disease, systemic and mucosal immune induction, and the incidence of adverse events. The primary endpoint is relative efficacy of Vaxart's COVID-19 vaccine candidate compared to an approved mRNA comparator for the prevention of symptomatic disease. 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 the Biomedical Advanced Research and Development Authority (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. 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, 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.

Contact

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