

**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): June 17, 2024

Vaxart, Inc.

(Exact name of registrant as specified in its charter)

Delaware (State or other jurisdiction of incorporation)	001-35285 (Commission File Number)	59-1212264 (IRS Employer Identification No.)
170 Harbor Way, Suite 300, South San Francisco, California (Address of principal executive offices)		94080 (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 7.01 Regulation FD Disclosure.

On June 17, 2024, Vaxart, Inc. (the “Company”) issued a press release providing a business update. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information in this Item 7.01, and Exhibit 99.1 attached hereto, is being furnished and shall not be deemed “filed” for the purposes of Section 18 of the Exchange Act, or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, regardless of any general incorporation language in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit	Description
99.1	Press Release, dated June 17, 2024.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

Vaxart Provides Business Update

— Cash runway extended into 2026 —

— Received one of the largest BARDA-funded Project NextGen Awards to date, up to \$453 million —

— Company well-capitalized to execute on multiple key clinical and regulatory milestones in COVID-19 and norovirus programs —

SOUTH SAN FRANCISCO, Calif., June 17, 2024 – Vaxart, Inc. (Nasdaq: VXRT) today provided business and cash runway updates as the Company continues to advance its oral pill vaccine platform.

Vaxart anticipates that net proceeds from the recent \$40 million offering, expected fees and reimbursements under its Project NextGen award of up to \$453 million, combined with its existing cash, cash equivalents and investments, will extend its cash runway into 2026, funding through multiple key clinical and regulatory milestones.

“The past week was especially important for Vaxart, because the combination of receiving one of the largest Project NextGen awards from BARDA and closing our \$40 million financing from leading institutional investors significantly strengthened the Company. These notable achievements enable us to pursue our goal of creating transformative oral pill vaccine candidates representing multibillion-dollar market opportunities and offering the world a better way to protect against disease,” said Steven Lo, Vaxart’s Chief Executive Officer.

“We appreciate the funding from the U.S. government and the support and confidence from investors who share our vision of a world where injectable vaccinations can be replaced by just a pill. It is our mission to improve public health by developing a groundbreaking oral tablet vaccine platform,” added Mr. Lo.

Vaxart is developing the most advanced oral pill vaccine platform that provides a more convenient formulation compared to injectable vaccines, generates both systemic and mucosal immune responses, and has a benign safety profile as shown in clinical trials to date. The Company believes mucosal immunity generated by its vaccine candidate is critical as it generates an immune response at the site of the infection and may also provide better protection against variants as viruses, such as SARS-CoV-2, continue to evolve and mutate.

COVID-19 Vaccine Next Steps

On June 13, Vaxart received a project award valued at up to \$453 million through the Rapid Response Partnership Vehicle (RRPV), a Consortium funded by the Biomedical Advanced Research and Development Authority (BARDA), part of the Administration for Strategic Preparedness and Response (ASPR) in the U.S. Department of Health and Human Services (HHS).

Funds from the BARDA award will be used to conduct a 10,000-subject Phase 2b comparative study evaluating Vaxart’s oral pill COVID-19 vaccine candidate against a U.S. Food and Drug Administration (FDA)-approved mRNA vaccine comparator. With manufacturing preparations substantially complete and funding in place, Vaxart plans to initiate enrollment in this trial as early as summer 2024, pending regulatory alignment. An interim analysis for vaccine efficacy compared to an approved mRNA comparator may occur as early as the first quarter of 2025.

The study 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.

This project has been funded with federal funds from HHS; Administration for Strategic Preparedness and Response (ASPR); BARDA, under Other Transaction Number: 75A50123D00005.

Norovirus Vaccine Next Steps

Vaxart is on track to receive feedback from FDA in mid-2024 on potential correlates of protection for norovirus, which will inform potential next steps, such as conducting a Phase 2b study and potentially a GII.4 challenge study. The Company will then determine the best way to progress its norovirus program by considering the regulatory feedback, clinical data on current constructs, and preclinical data generated on new constructs.

In April 2024, Vaxart announced positive topline results from the Phase 1 clinical trial evaluating its oral pill bivalent norovirus candidate in lactating mothers, with support from the Bill & Melinda Gates Foundation.

Other Programs

Vaxart continues to develop earlier stage programs, including seasonal influenza and human papillomavirus (HPV), and has begun efforts on avian flu in light of the recent bird flu outbreaks. Additional updates will be provided as these programs progress.

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 immunoncology 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 for the Phase 2b study, results from preclinical and clinical trials and the timing of such trials and 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 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, and the timing 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. 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:

FINN Partners

IR@vaxart.com