# 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): May 13, 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 2.02 Results of Operations and Financial Condition.**

On May 13, 2024, Vaxart, Inc. issued a press release announcing its financial results for the quarter ended March 31, 2024. A copy of this press release is furnished as Exhibit 99.1 to this report and is incorporated herein by reference.

The information in this report, including Exhibit 99.1 attached hereto, is being furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or subject to the liabilities of that section or Sections 11 and 12(a)(2) of the Securities Act of 1933, as amended. The information contained herein and in the accompanying Exhibit 99.1 shall not be deemed incorporated by reference into any filing with the U.S. Securities and Exchange Commission made by Vaxart, Inc., whether made before or after the date hereof 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 May 13, 2024, titled "Vaxart Provides Business Update and Reports First Quarter 2024 Financial Results". |
| 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: May 13, 2024

By: /s/ STEVEN LO
Steven Lo
President and Chief Executive Officer

**Exhibit 99.1**

**Vaxart Provides Business Update and Reports First Quarter 2024 Financial Results**

*Positive results from Phase 1 norovirus study in lactating mothers indicate the potential of Vaxart's oral pill vaccine candidate to protect or reduce the effect of the disease in infants*

*Expects to initiate Phase 2b study evaluating Vaxart's oral pill XBB COVID-19 vaccine against an approved mRNA vaccine comparator as early as the second quarter of 2024*

*Anticipates meeting with the FDA in mid-2024 to evaluate clinical data and discuss next steps for its norovirus program*

*Conference call today at 4:30 p.m. ET*

SOUTH SAN FRANCISCO, Calif., May 13, 2024 — Vaxart, Inc. (Nasdaq: VXRT) today announced its business update and financial results for the first quarter of 2024.

"We are pleased that we achieved an important milestone in our norovirus clinical program, delivering positive topline results from the Phase 1 trial of our oral pill bivalent norovirus candidate focused on lactating mothers," said Steven Lo, Vaxart's Chief Executive Officer. "We look forward to additional data from this study that will further inform future pediatric studies for this indication. We have also made significant progress and remain on track to initiate a Phase 2b study evaluating our XBB COVID-19 vaccine candidate as early as this quarter.

"We are excited about the potential for our oral pill vaccine technology, not only for the Company but for the benefit of society. We believe the data we have generated to date are compelling and demonstrate our vaccines' potential to address the serious, ongoing impact of many infectious diseases on the most vulnerable populations," Lo added. "Recent preclinical data suggests our COVID-19 XBB construct showed a more robust immunogenic response compared with our previous constructs. With a potentially superior construct, we are exploring whether certain changes we implemented in this vaccine candidate will also be beneficial for other indications in our pipeline."

**Recent Business Highlights**

**COVID-19 Vaccine Developments**

- Vaxart is preparing for a 10,000-subject, Phase 2b clinical study evaluating Vaxart's oral pill XBB COVID-19 vaccine candidate against an approved mRNA vaccine comparator. The preparations are being supported by a United States Biomedical Advanced Research and Development Authority ("BARDA") contract for $9.27 million as part of BARDA's "Project NextGen" initiative.
  - The Company anticipates initiating the Phase 2b trial as early as the second quarter of 2024.

**Norovirus Vaccine Developments**

- 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.
  - Antibodies to norovirus rose on average 4.0 fold in response to the GI.1 virus strain and 6.0 fold in response to the GII.4 virus strain in the breastmilk of lactating mothers who received the Vaxart vaccine candidate in the high dose group.
- Vaxart plans to meet with the U.S. Food and Drug Administration ("FDA") in mid-2024 to discuss data on correlates of protection. These data will inform potential next steps, such as potentially conducting a Phase 2b study and potentially a GII.4 challenge study.

**Financial Results for the First Quarter Ended March 31, 2024**

- Cash, cash equivalents and investments totaled $36.7 million as of March 31, 2024. The Company did not receive any cash payments from BARDA in the first quarter of 2024. Currently, Vaxart anticipates cash runway into late fourth quarter of 2024.
- Vaxart reported a net loss of $24.4 million for the first quarter of 2024, compared to $25.1 million for the first quarter of 2023. Net loss per share for the first quarter of 2024 was $0.14, compared to a net loss per share of $0.19 for the first quarter of 2023.
- Revenue for the first quarter of 2024 was $2.2 million, compared to $0.7 million for the first quarter of 2023. Revenue in the first quarter of 2024 was primarily from revenue recognized for work performed under Vaxart's contract with BARDA and non-cash royalty revenue from sales of Inavir in Japan.
- Research and development expenses were $19.0 million for the first quarter of 2024, compared to $19.6 million for the first quarter of 2023. The decrease was primarily due to decreases in personnel related costs and clinical trial expenses related to Vaxart's norovirus vaccine candidate, partially offset by increased manufacturing costs, clinical trial costs related to its COVID-19 vaccine candidate and personnel stock-based expense.
- General and administrative expenses were $7.2 million for the first quarter of 2024, compared to $6.6 million for the first quarter of 2023. The increase was primarily due to an increase in personnel stock-based expense and recruiting costs, partially offset by decreases in directors' and officers' insurance and legal fees.

**Conference Call**

The Vaxart senior management team will host a conference call to discuss the business update and financial results for the first quarter of 2024 today, beginning at 4:30 p.m. ET.

The conference call can be accessed using the following information:

Webcast: Click here
Date: Monday, May 13, 2024 – 4:30 p.m. ET
Domestic: 877-407-0832
International: 201-689-8433
Conference ID: 13745591

Investors may submit written questions in advance of the conference call to ir@vaxart.com.

A replay of the webcast will be available for 30 days on Vaxart's website at www.vaxart.com following the conclusion of the event.

**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 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 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 such trials and 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.

**Contacts**

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**Vaxart, Inc.**
**Condensed Consolidated Balance Sheets**

| | March 31, 2024 Unaudited | December 31, 2023 (1) |
|---|---|---|
| | *(in thousands)* | |
| **Assets** | | |
| Cash and cash equivalents | $ 26,735 | $ 34,755 |
| Investments in marketable debt securities | 9,929 | 4,958 |
| Accounts receivable | 556 | 3,008 |
| Prepaid expenses and other assets | 7,981 | 3,741 |
| Property and equipment, net | 11,102 | 11,731 |
| Right-of-use assets, net | 23,753 | 24,840 |
| Intangible assets, net | 4,106 | 4,289 |
| Goodwill | 4,508 | 4,508 |
| Total assets | $ 88,670 | $ 91,830 |
| | | |
| **Liabilities and stockholders' equity** | | |
| Accounts payable | $ 3,978 | $ 1,584 |
| Accrued and other liabilities | 5,289 | 5,927 |
| Operating lease liability | 19,490 | 20,088 |
| Liability related to sale of future royalties | 4,223 | 6,426 |
| Total liabilities | 32,980 | 34,025 |
| Stockholders' equity | 55,690 | 57,805 |
| Total liabilities and stockholders' equity | $ 88,670 | $ 91,830 |

(1) Derived from the audited consolidated financial statements of Vaxart, Inc. for the year ended December 31, 2023, included on the Form 10-K filed with the Securities and Exchange Commission on March 14, 2024.

**Vaxart, Inc.**
**Condensed Consolidated Statements of Operations**
**(Unaudited)**

| | Three Months Ended March 31, | |
|---|---|---|
| | **2024** | **2023** |
| | *(in thousands, except share and per share amounts)* | |
| **Revenue** | $ 2,181 | $ 675 |
| Operating expenses: | | |
| Research and development | 19,013 | 19,622 |
| General and administrative | 7,238 | 6,625 |
| Total operating expenses | 26,251 | 26,247 |
| **Operating loss** | (24,070) | (25,572) |
| Other income (expense), net | (302) | 461 |
| **Loss before income taxes** | (24,372) | (25,111) |
| Provision for income taxes | 45 | 29 |
| **Net loss** | $ (24,417) | $ (25,140) |
| **Net loss per share, basic and diluted** | $ (0.14) | $ (0.19) |
| Shares used in computing net loss per share, basic and diluted | 168,811,095 | 135,213,196 |