

**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 4, 2023

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

Common Stock, \$0.0001 par value

Trading symbol

VXRT

Name of each exchange on which registered

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 4, 2023, Vaxart, Inc. (the “Company”) issued a press release providing a business update and announcing its financial results for the quarter ended March 31, 2023. A copy of the press release is furnished as Exhibit 99.1 to this current report on Form 8-K (this “Form 8-K”) and is incorporated herein by reference.

The information in this Form 8-K, 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 the Company, 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 Number	Description
99.1	Press Release, dated May 4, 2023.
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 9, 2023

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

Vaxart Provides Business Update and Reports First Quarter 2023 Financial Results

On track to report key top line data from two Phase 2 norovirus vaccine studies mid-year and in Q3 2023

Continue to anticipate cash runway into Q2 2024

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

SOUTH SAN FRANCISCO, Calif., May 4, 2023 — Vaxart, Inc. (NASDAQ: VXRT) today announced its business update and financial results for the first quarter of 2023.

“During the first quarter, we continued to advance our norovirus oral pill vaccine program and remain on track to report two important clinical data readouts in 2023,” said Andrei Floroiu, Vaxart’s Chief Executive Officer. “Norovirus represents a significant public health issue with no approved vaccine, and it places a tremendous economic burden on society. More than 21 million people are infected in the U.S. each year, creating an annual disease burden of more than \$10 billion domestically.

“Our innovative approach to addressing this unmet medical need is supported by data from six completed norovirus clinical trials that have enrolled nearly 350 subjects. These data have shown immune responses from our vaccine to be strong, long-lasting, comparable to natural infection and similar in both elderly and young populations,” Mr. Floroiu added.

Recent Business Highlights**Norovirus Vaccine Developments**

- o In April 2023, Vaxart presented previously published research from its norovirus oral vaccine program at the World Vaccine Congress in Washington, D.C. Dr. James F. Cummings, Vaxart’s Chief Medical Officer, exhibited findings demonstrating potent serum and mucosal immune responses to norovirus with Vaxart’s oral bivalent norovirus vaccine candidate.
 - o In March 2023, Vaxart provided a detailed overview and reviewed data from its norovirus oral pill vaccine program during presentations at its sponsored norovirus Key Opinion Leader (KOL) event. Featured experts on the disease explained the current disease burden posed by norovirus, as well as its significant economic and societal costs that impact the U.S. on an annual basis. A replay of the KOL event is available [here](#).
 - o In February 2023, Vaxart initiated a Phase 2 dose-ranging study of its bivalent norovirus oral vaccine candidate and expects to report topline data from this study in mid-2023.
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COVID-19 Vaccine Developments

- Vaxart continues to conduct preclinical development of novel constructs for its COVID-19 oral vaccine candidate. Based on the mucosal cross-reactivity data reported to date in Vaxart's clinical studies of its COVID-19 vaccine candidates, the Company believes it may be able to create an oral pan-betacoronavirus vaccine. A pan-betacoronavirus vaccine may provide more effective and flexible protection, positioned to prevent both current and emerging coronavirus threats and other beta-coronaviruses, making it a valuable tool for pandemic preparedness.
- During the World Vaccine Congress, Dr. Sean Tucker, Vaxart's Founder and Chief Scientific Officer, presented previously published data from Vaxart studies demonstrating the platform's ability to block transmission and boost existing COVID-19 vaccines by oral tablet vaccination.

Anticipated 2023 Clinical Milestones

Vaxart continues to make progress on its anticipated milestones in 2023:

- Report topline data from the ongoing Phase 2 dose-ranging study of Vaxart's bivalent norovirus vaccine candidate in mid-2023.
- Report topline data from the ongoing Phase 2 challenge study of Vaxart's monovalent norovirus vaccine candidate in Q3 2023.
- Initiate Gates Foundation-funded clinical trial to evaluate the ability of Vaxart's norovirus vaccine candidate to induce antibodies in breast milk and transfer of antibodies to young infants.

Financial Results for the Three Months Ended March 31, 2023

- Vaxart ended the first quarter of 2023 with cash, cash equivalents, restricted cash and marketable securities of \$71.8 million, compared to \$95.7 million as of December 31, 2022. The decrease was primarily due to cash used in operations.
 - Vaxart reported a net loss of \$25.1 million for the first quarter of 2023, compared to \$25.1 million for the first quarter of 2022. Net loss per share for the first quarter of 2023 was \$0.19, compared to a net loss of \$0.20 per share in the first quarter of 2022.
 - Revenue for the first quarter of 2023 was \$675,000, compared to \$85,000 in the first quarter of 2022. The increase was due to revenue recognition for services rendered in relation to Vaxart's grant from the Gates Foundation and higher royalty revenue from sales of Inavir in Japan.
 - Research and development expenses were \$19.6 million for the first quarter of 2023, compared to \$18.2 million for the first quarter of 2022. The increase was mainly due to increases in headcount and related costs and clinical trial expenses related to the Company's norovirus vaccine candidate.
 - General and administrative expenses were \$6.6 million for the first quarter of 2023, compared to \$6.7 million for the first quarter of 2022.
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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 2023 today, beginning at 4:30 p.m. ET.

The conference call can be accessed using the following information:

Webcast: [Click here](#)

Date: Thursday, May 4, 2023 – 4:30 p.m. ET

Domestic: 888-272-8703

International: 713-481-1320

Conference ID: 13737884

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 norovirus, coronavirus, 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.

Contacts

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Vaxart, Inc.
Condensed Consolidated Balance Sheets

	March 31, 2023	December 31, 2022
	<u>(Unaudited)</u>	<u>(1)</u>
	<i>(in thousands)</i>	
Assets		
Cash, cash equivalents and restricted cash (2)	\$ 48,434	\$ 46,013
Investments in marketable debt securities	23,377	49,704
Accounts receivable	264	20
Prepaid and other assets	6,215	7,282
Property and equipment, net	14,373	15,585
Right-of-use assets, net	27,843	25,715
Intangible assets, net	4,837	5,020
Goodwill	4,508	4,508
Total Assets	<u>\$ 129,851</u>	<u>\$ 153,847</u>
Liabilities and stockholders' equity		
Accounts payable	\$ 3,882	\$ 5,514
Deferred grant revenue	1,603	2,000
Accrued and other liabilities	7,223	8,315
Operating lease liabilities	21,516	21,705
Liability related to sale of future royalties	5,874	5,716
Total liabilities	<u>40,098</u>	<u>43,250</u>
Stockholders' equity	89,753	110,597
Total liabilities and stockholders' equity	<u>\$ 129,851</u>	<u>\$ 153,847</u>

- (1) Derived from the audited consolidated financial statements of Vaxart, Inc. for the year ended December 31, 2022, included on the Form 10-K filed with the Securities and Exchange Commission on March 15, 2023.
- (2) Cash, cash equivalents and restricted cash includes \$1.6 million and \$2.0 million of restricted cash as of March 31, 2023 and December 31, 2022, respectively.

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

	Quarter Ended March 31,	
	2023	2022
	(Unaudited)	(1)
	<i>(in thousands, except share and per share amounts)</i>	
Revenue	\$ 675	\$ 85
Operating expenses:		
Research and development	19,622	18,203
General and administrative	6,625	6,658
Total operating expenses	26,247	24,861
Loss from operations	(25,572)	(24,776)
Other income and (expenses), net	461	(305)
Loss before income taxes	(25,111)	(25,081)
Provision for income taxes	29	20
Net loss	\$ (25,140)	\$ (25,101)
Net loss per share, basic and diluted	\$ (0.19)	\$ (0.20)
Shares used in computing net loss per share, basic and diluted	135,213,196	125,795,255

(1) Derived from the audited consolidated financial statements of Vaxart, Inc. for the year ended December 31, 2022, included on the Form 10-K filed with the Securities and Exchange Commission on March 15, 2023.