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): November 2, 2023

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 November 2, 2023, Vaxart, Inc. issued a press release announcing its financial results for the quarter ended September 30, 2023. 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 November 2, 2023, titled "Vaxart Provides Business Update and Reports Third Quarter 2023 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: November 2, 2023

By: /s/ ANDREI FLOROIU
Andrei Floroiu
President and Chief Executive Officer

Exhibit 99.1

Vaxart Provides Business Update and Reports Third Quarter 2023 Financial Results

Norovirus challenge study topline results indicate the potential of Vaxart's oral pill vaccine candidate to reduce rates of norovirus infection, norovirus acute gastroenteritis and viral shedding
Clinical proof of concept for the Company's oral pill vaccine platform now established in two human challenge studies for norovirus and influenza
Conference call today at 4:30 p.m. ET

SOUTH SAN FRANCISCO, Calif., November 2, 2023 — Vaxart, Inc. (Nasdaq: VXRT) today announced its business update and financial results for the third quarter of 2023.

“During the third quarter, we took important steps toward validating our mucosal vaccine platform with the release of topline data from two Phase 2 trials of our norovirus program,” said Andrei Floroiu, Vaxart’s Chief Executive Officer. “Data from our Phase 2 challenge study indicated that our monovalent norovirus candidate has the potential to reduce norovirus infection, norovirus acute gastroenteritis, and viral shedding and also stimulates norovirus-specific antibody responses and neutralizing antibodies.

“With the rise in norovirus infections this year, we believe the totality of our norovirus vaccine data highlights the potential to address this need and the significant disease burden that norovirus causes,” Floroiu added. “We are currently conducting additional analyses of our norovirus data with the objectives of defining the timing of a larger Phase 2b study and identifying ways to reduce the size and duration of a subsequent Phase 3 registration study.”

Recent Business Highlights

Norovirus Vaccine Developments

- In October 2023, Vaxart dosed the first subject in its Phase 1 clinical trial evaluating the Company’s oral pill norovirus vaccine candidate focused on lactating mothers. The study is designed to investigate immunity in the breastmilk of nursing mothers who have received vaccine.
- In October 2023, Vaxart senior management presented at the World Vaccine Congress Europe 2023 in Barcelona, Spain.
  - Dr. Sean Tucker, Vaxart’s Founder and Chief Scientific Officer, presented on transmission-blocking strategies via oral pill vaccination and mucosal immune induction.
  - Dr. James F. Cummings, Vaxart’s Chief Medical Officer, discussed protection against norovirus infection from an oral pill vaccine candidate in humans.
- In September 2023, Vaxart announced topline data from the Phase 2 challenge study of its monovalent norovirus oral pill vaccine candidate.
  - The study met five of six primary endpoints.
  - The results showed a statistically significant 29% relative reduction in the rate of norovirus infection, a 21% relative reduction in the rate of norovirus acute gastroenteritis that was not statistically significant, and an 85% relative reduction in viral shedding. The latter was a prespecified study endpoint in the vaccinated cohort compared with placebo.
  - Vaxart believes this reduction in shedding could potentially have an impact on transmission and have important public health benefits.
- In July 2023, Vaxart reported preliminary positive topline data from the dose-ranging Phase 2 clinical trial of its oral pill bivalent norovirus vaccine candidate.
- Vaxart now has demonstrated robust immunogenicity data in eight clinical trials including both young adults and elderly populations.
- The Company’s norovirus oral vaccine candidate has shown an attractive safety profile in trials and has been well tolerated with no vaccine-related serious adverse events.

COVID-19 Vaccine Developments

- Vaxart continues to progress its COVID-19 vaccine program and believes the cross-reactivity of the current constructs suggests a pathway for developing a pan-betacoronavirus vaccine. The Company is assessing next steps.

Financial Results for the Three Months Ended September 30, 2023

- Vaxart ended the third quarter of 2023 with cash, cash equivalents, restricted cash and marketable securities of $53.0 million, compared to $67.9 million as of June 30, 2023. The Company continues to anticipate it has cash runway into the third quarter of 2024.
- Vaxart reported a net loss of $17.4 million for the third quarter of 2023, compared to $29.3 million for the third quarter of 2022. Net loss per share for the third quarter of 2023 was $0.11 per share, compared to a net loss of $0.23 per share in the third quarter of 2022.
- Revenue for the third quarter of 2023 was $2.1 million, compared to no revenue in the third quarter of 2022. Revenue in the third quarter of 2023 was primarily from revenue recognized for work performed under Vaxart’s grant from the Bill & Melinda Gates Foundation and non-cash royalty revenue from increased sales of Inavir in Japan.
- Research and development expenses were $15.0 million for the third quarter of 2023, compared to $22.5 million for the third quarter of 2022. The decrease is primarily due to decreases in manufacturing costs, personnel related costs and clinical trial expenses related to our COVID-19 vaccine candidates, partially offset by increased depreciation expense.
- General and administrative expenses were $4.9 million for the third quarter of 2023, compared to $7.0 million for the third quarter of 2022. The decrease is primarily due to a decrease in legal and professional fees, directors' and officers' insurance and personnel related costs, partially offset by an increase in personnel stock-based costs.

Conference Call

The Vaxart senior management team will host a conference call to discuss the business update and financial results for the third 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, November 2, 2023 – 4:30 p.m. ET
Domestic: 877-407-0832
International: 201-689-8433

Conference ID: 13741880

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, and seasonal 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 constructs 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.

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Vaxart, Inc.
Condensed Consolidated Balance Sheets

	September 30, 2023 (Unaudited)	December 31, 2022 (1)
	(in thousands)	
Assets		
Cash, cash equivalents and restricted cash (2)	$ 33,238	$ 46,013
Investments in marketable debt securities	19,799	49,704
Accounts receivable	424	20
Prepaid expenses and other assets	4,522	7,282
Property and equipment, net	12,926	15,585
Right-of-use assets, net	25,753	25,715
Intangible assets, net	4,472	5,020
Goodwill	4,508	4,508
Total assets	$ 105,642	153,847
Liabilities and stockholders' equity		
Accounts payable	$ 1,339	$ 5,514
Deferred grant revenue	79	2,000
Accrued and other liabilities	6,269	8,315
Operating lease liability	20,459	21,705
Liability related to sale of future royalties	5,975	5,716
Total liabilities	34,121	43,250
Stockholders' equity	71,521	110,597
Total liabilities and stockholders' equity	$ 105,642	$ 153,847

(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 $79,000 and $2.0 million of restricted cash as of September 30, 2023 and December 31, 2022, respectively.

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

	3 Months Ended September 30,		9 Months Ended September 30,	
	2023	**2022**	**2023**	**2022**
	(in thousands, except share and per share amounts)			
Revenue	$ 2,101	$ —	$ 4,134	$ 85
Operating expenses:				
Research and development	15,002	22,466	53,437	60,595
General and administrative	4,921	6,960	17,144	22,939
Total operating expenses	19,923	29,426	70,581	83,534
Loss from operations	(17,822)	(29,426)	(66,447)	(83,449)
Other income (expense), net	461	133	1,444	(340)
Loss before income taxes	(17,361)	(29,293)	(65,003)	(83,789)
Provision for income taxes	39	16	87	51
Net loss	$ (17,400)	$ (29,309)	$ (65,090)	$ (83,840)
Net loss per share, basic and diluted	$ (0.11)	$ (0.23)	$ (0.45)	$ (0.66)
Shares used in computing net loss per share, basic and diluted	152,026,112	126,889,718	145,810,175	126,374,424