

**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 12, 2019

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.)

290 Utah Ave. Suite 200, 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, \$0.10 par value

Trading symbol

VXRT

Name of each exchange on which registered

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 12, 2019, Vaxart, Inc. issued a press release announcing its financial results for the quarter ended September 30, 2019. 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	<u>Press release, dated November 12, 2019, titled “Vaxart Announces Third Quarter 2019 Financial Results and Provides Corporate Update”.</u>

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Vaxart, Inc.

Dated: November 12, 2019

By: /s/ Wouter W. Latour, M.D.
Wouter W. Latour, M.D.
President and Chief Executive Officer



Vaxart Announces Third Quarter 2019 Financial Results and Provides Corporate Update

- \$9 million Underwritten Public Offering Closed -

- Oral Bivalent Norovirus Vaccine Meets Primary and Secondary Endpoints in Phase 1b Study -

SOUTH SAN FRANCISCO, Calif.-- (BUSINESS WIRE) - November 12, 2019-- Vaxart, Inc., a clinical-stage biotechnology company developing oral recombinant vaccines that are administered by tablet rather than by injection, today announced financial results for the third quarter ended September 30, 2019 and provided a corporate update.

“The positive topline results from the Phase 1b clinical trial were a major milestone for the norovirus program,” said Wouter Latour, M.D., chief executive officer of Vaxart. “The vaccine was well tolerated and elicited robust mucosal responses in 90 – 93% of subjects for the new norovirus GII component, and 78 – 86% for the norovirus GI component. This data suggests that our oral norovirus vaccine is likely to provide mucosal immunity in the intestine, the actual site of norovirus infection. We believe this is the optimal approach to protect against norovirus disease and puts Vaxart in a unique position to develop an effective oral vaccine targeting an estimated \$3+ billion US market.”

The CDC estimates that norovirus causes \$60 billion in global healthcare related costs annually.

Vaxart plans to focus its efforts and resources on progressing the clinical development of its oral tableted bivalent norovirus vaccine. The Company will also continue the development of its first therapeutic vaccine targeting cervical cancer and dysplasia caused by Human Papilloma Virus (HPV), and explore opportunities to apply its VAAST™ oral vaccine platform for indications such as influenza and RSV.

Recent Corporate Highlights:

- Vaxart’s Tableted Oral Bivalent Norovirus Vaccine Meets Primary and Secondary Endpoints in Phase 1b Study
 - The study met all primary endpoints for safety and demonstrated robust immunogenicity, with response rates of 90 – 93% for norovirus GII.4 and 78 – 86% for norovirus GI.1 as measured by IgA Antibody Secreting Cells (ASC), a key marker for mucosal immunity and a potential correlate of protection for norovirus disease.
- Manufacturing of Norovirus GI.1 and GII.4 vaccines is proceeding as planned at Lonza and the initiation of the Phase 2 Bivalent Norovirus study is on target for 2020.
- Research collaboration with Janssen’s Universal Influenza Vaccine Program is proceeding with results expected in 2020.
- Priced an underwritten public offering which closed in September. As of September 30, 2019, the aggregate gross proceeds were \$9.0 million.
- Vaxart presented a corporate overview and update to investors and strategic partners at the H.C. Wainwright 21st Annual Global Investment Conference, in New York City.

- Scientific meeting presentations:
 - *IDWeek – Washington, DC, Presentation Title: Oral Norovirus Vaccination in Humans Induces Plasmablast B Cell Expansion and Follicular T Cell Activation Comparable to Natural Infection*
 - *7th International Calicivirus Conference – Sydney, Australia, Presentation Title: Oral Vaccine to Prevent Norovirus Infection Induces Mucosal Homing Plasmablasts and T Follicular Cells in Humans*
 - *10th International Vaccines for Enteric Diseases Conference (VED 2019) – Lausanne, Switzerland, Presentation Title: Progress on the Development of an Oral, Bivalent Norovirus Vaccine*

In mid-November, Vaxart will be hosting a Key Opinion Leader Meeting in New York City on the Health Economics of Norovirus.

Financial Results for the Three Months Ended September 30, 2019

- Vaxart reported a net loss of \$5.3 million for the third quarter of 2019 compared to \$6.5 million for the third quarter of 2018. The principal reason for the decrease was a reduction in research and development expenditure.
- Vaxart ended the quarter with cash and cash equivalents of \$19.6 million compared to \$16.3 million at June 30, 2019. The increase was primarily due to the \$8.1 million net proceeds from equity financing, mostly from the underwritten offering in September 2019, partially offset by cash used in operations.
- Revenue for the quarter was \$454,000 compared to \$281,000 in the third quarter of 2018. The increase was mostly due to non-cash royalty revenue related to the sale of future royalties.
- Research and development expenses were \$3.7 million for the quarter compared to \$4.4 million for the third quarter of 2018. The decrease was mainly due to the absence of clinical trials costs for teslexivir and a reduction in amortization of intangibles, partially offset by higher clinical trial and manufacturing costs incurred in the Company's norovirus program.
- General and administrative expenses were \$1.5 million for the quarter compared to \$1.7 million for the third quarter of 2018. The decrease was mainly due to lower audit and accounting costs.

About Vaxart

Vaxart is a clinical-stage biotechnology company focused on developing oral recombinant protein vaccines based on its proprietary oral vaccine platform. Vaxart's vaccines are designed to generate broad and durable immune responses that protect against a wide range of infectious diseases and may also be useful for the treatment of chronic viral infections and cancer. Vaxart's vaccines are administered using a convenient room temperature-stable tablet, rather than by injection. Vaxart believes that tablet vaccines are easier to distribute and administer than injectable vaccines and have the potential to significantly increase vaccination rates. Vaxart's development programs include oral tablet vaccines that are designed to protect against norovirus, seasonal influenza and respiratory syncytial virus (RSV), as well as a therapeutic vaccine for human papillomavirus (HPV). For more information, please visit www.vaxart.com.

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 our strategy, prospects, plans and objectives, results from preclinical and clinical trials, commercialization agreements and licenses, beliefs and expectations of management are forward-looking statements. These forward-looking statements may be accompanied by such words as “believe,” “could,” “potential,” “will” and other words and terms of similar meaning. Examples of such statements include, but are not limited to, statements relating to the Vaxart’s ability to develop and commercialize its product candidates and clinical results and trial data; Vaxart’s plans to start a phase 2 study with its bivalent norovirus vaccine in 2020; Vaxart’s expectations with respect to its collaboration with Janssen and the timing of expected results in 2020; Vaxart’s intention to continue its efforts to advance its oral tablet vaccines for seasonal influenza, RSV and HPV; the ability of Lonza Houston to supply vaccine for Vaxart’s planned Phase 2 bivalent norovirus vaccine study in 2020; and Vaxart’s expectations with respect to the important advantages it believes its oral vaccine platform can offer over injectable alternatives, particularly for mucosal pathogens such as norovirus, flu and RSV. Vaxart may not actually achieve the plans, carry out the intentions or meet the expectations or projections disclosed in our 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, 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 Vaxart may experience manufacturing issues and delays; 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

	September 30, 2019	December 31, 2018
	(Unaudited)	(1)
	<i>(in thousands)</i>	
Assets		
Cash and cash equivalents	\$ 19,558	\$ 11,506
Accounts receivable	559	1,796
Prepaid and other assets	1,282	1,446
Property and equipment, net	1,469	1,066
Right-of-use assets, net	2,301	—
Intangible assets, net	17,526	19,413
Total Assets	\$ 42,695	\$ 35,227
Liabilities and stockholders' equity		
Accounts payable	\$ 1,049	\$ 962
Accrued and other liabilities	1,621	1,675
Liability related to sale of future royalties	16,154	17,741
Secured promissory note	2,454	3,611
Operating lease liabilities	2,514	—
Total liabilities	23,792	23,989
Stockholders' equity	18,903	11,238
Total liabilities and stockholders' equity	\$ 42,695	\$ 35,227

(1) Derived from the audited consolidated financial statements of Vaxart, Inc. for the year ended December 31, 2018, included on the Form 10-K filed with the Securities and Exchange Commission on February 6, 2019.

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

	<u>Three Months Ended September 30,</u>		<u>Nine Months Ended September 30,</u>	
	<u>2019</u>	<u>2018</u>	<u>2019</u>	<u>2018</u>
	<i>(in thousands, except share and per share amounts)</i>			
Revenue	\$ 454	\$ 281	\$ 5,946	\$ 2,392
Operating expenses:				
Research and development	3,713	4,381	11,249	12,801
General and administrative	1,455	1,674	4,856	5,455
Impairment charges	—	106	—	1,706
Total operating expenses	5,168	6,161	16,105	19,962
Loss from operations	(4,714)	(5,880)	(10,159)	(17,570)
Bargain purchase gain	—	—	—	6,660
Other income and (expenses), net	(515)	(668)	(1,783)	(2,166)
Provision for income taxes	(31)	—	(294)	(29)
Net loss	\$ (5,260)	\$ (6,548)	\$ (12,236)	\$ (13,105)
Net loss attributable to common stockholders	\$ (5,260)	\$ (6,548)	\$ (12,236)	\$ (13,444)
Net loss per share, basic and diluted	\$ (0.32)	\$ (0.92)	\$ (0.96)	\$ (2.23)
Shares used in computing net loss per share, basic and diluted	16,249,032	7,141,189	12,748,665	6,038,001