

**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): March 18, 2020

Vaxart, Inc.

(Exact name of registrant as specified in its charter)

| | | |
|--|--|--|
| <u>Delaware</u> (State or other jurisdiction of incorporation) | <u>001-35285</u> (Commission File Number) | <u>59-1212264</u> (IRS Employer Identification No.) |
| <u>385 Oyster Point Boulevard, Suite 9A, South San Francisco, California</u> (Address of principal executive offices) | | <u>94080</u> (Zip Code) |

Registrant's telephone number, including area code: (650) 550-3500

**290 Utah Ave. Suite 200, South San Francisco, California, 94080
(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, \$0.10 par value | VXRT | 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 March 19, 2020, Vaxart, Inc. issued a press release announcing its financial results for the quarter and year ended December 31, 2019, and provided a corporate update. 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 8.01. Other Events.

On March 18, 2019, Vaxart, Inc. issued a press release announcing that it has entered into an agreement with Emergent BioSolutions Inc. A copy of the press release is filed as Exhibit 99.2 hereto and is incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit Description

- | | |
|------|--|
| 99.1 | Press release, dated March 19, 2020, titled “Vaxart Announces Fourth Quarter and Full Year 2019 Financial Results and Provides Corporate Update”. |
| 99.2 | Press release, dated March 18, 2020, titled “Vaxart Announces it Entered into an Agreement with Emergent Biosolutions for the Development and Manufacturing of Oral Coronavirus (COVID-19) Vaccine Candidate”. |
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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: March 19, 2020

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



**Vaxart Announces Fourth Quarter and Full Year 2019 Financial Results
and Provides Corporate Update**

Company Focuses on COVID-19 Program, the First Oral Coronavirus Vaccine

Raised total of \$19.8 Million from a Registered Direct Offering and Warrant Exercises during Q1 2020

SOUTH SAN FRANCISCO, Calif.-- (BUSINESS WIRE) - March 19, 2020-- 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 fourth quarter and full year ended December 31, 2019, and provided a corporate update.

“SARS CoV-2, the coronavirus that causes COVID-19, is primarily transmitted by viral particles that enter through the nose, mouth or eyes, and cause a respiratory infection,” said Wouter Latour, MD, chief executive officer of Vaxart Inc. “Unlike injectable vaccines, our oral vaccines have been shown to protect against respiratory infection based on mucosal immunity, the first line of defense for such infections. This could be essential for an effective vaccine that protects the population from COVID-19. In addition, the Vaxart vaccine would be administered using a room temperature-stable tablet, an enormous logistical advantage in large vaccination campaigns.”

“This outbreak is a call to duty for all of us here at Vaxart and we are highly focused on the development of the COVID-19 vaccine,” Dr. Latour continued. “Accordingly, we have put several vaccine programs on hold, including the norovirus vaccine program for which we recently successfully completed a Phase 1 study and for which we are actively seeking a development partner, as well as our therapeutic HPV vaccine program. The Janssen-partnered Universal Flu program is fully active and on track to be completed in the coming weeks.”

All Vaxart vaccines are based on its oral Vector-Adjuvant platform, VAAST™. In a recent clinical study published in the *Lancet Infectious Diseases*, the Company demonstrated that the Vaxart oral H1 influenza tablet vaccine primarily protected against infection based on mucosal immunity, in contrast to the injectable flu vaccine that protected primarily through systemic immunity.

In January, Vaxart initiated a program to develop a coronavirus vaccine candidate based on its VAAST™ platform and is currently producing multiple research grade COVID-19 vaccine candidates to be evaluated in a preclinical model. In addition, Vaxart announced this week that it had entered into an agreement with Emergent BioSolutions Inc. Per the agreement, development services are to begin immediately and upon Vaxart’s election, Emergent is expected to produce bulk cGMP vaccine in time for a Phase 1 clinical study to begin early in the second half of 2020.

Other Corporate Updates:

- The Universal Influenza vaccine collaboration with Janssen is proceeding as planned and remains on schedule to provide results in 1H 2020, barring delays due to the Coronavirus outbreak.
- Published results from the H1 seasonal influenza oral tablet vaccine challenge study in the *Lancet Infectious Diseases*. The study demonstrated that Vaxart's oral tablet influenza vaccine generated a 39 percent reduction in clinical disease relative to placebo, compared to a 27 percent reduction by Fluzone. It also reduced infection rates by 47 percent, compared to 43 percent by Fluzone.
- Restructured the manufacturing and process development departments resulting in, among other things, a reduction in headcount.
- Raised approximately \$9.8 million in net proceeds from the exercise of Warrants during the first quarter of 2020 to date.
- Completed a registered direct offering in March 2020, through which Vaxart raised aggregate gross proceeds of \$10.0 million from the sale of 4.0 Million shares of common stock and warrants to purchase 2.0 million shares of common stock that are exercisable for \$2.50 per share.
- Regained compliance with the continuing listing standards of The Nasdaq Capital Market.

Financial Results for the Three Months Ended December 31, 2019

- Vaxart reported a net loss of \$6.4 million for the fourth quarter of 2019 compared to \$4.9 million for the fourth quarter of 2018. The principal reason for the increase was a charge of \$4.9 million for restructuring, partially offset by an increase in revenue and a reduction in research and development expenditure.
- Revenue for the quarter was \$3.9 million compared to \$1.8 million in the fourth quarter of 2018. The increase was mostly due to non-cash royalty revenue related to the sale of future royalties.
- For the quarter ended December 31, 2019, royalty revenue from Inavir increased by \$2.2 million, or 148%, compared to the quarter ended December 31, 2018.

Financial Results for the Full Year 2019

- Vaxart reported a net loss of \$18.6 million for 2019 compared to \$18.3 million for 2018. The principal reason for the increase was the absence of a bargain purchase gain of \$6.8 million, partially offset by an increase in revenue of \$5.7 million.
- Revenue for the year was \$9.9 million compared to \$4.2 million in 2018. The increase was mostly due to \$3.5 million of 2018 revenue having been recorded in the pre-Merger period of January 1-February 13, 2018 and increased royalty revenue from Inavir in the fourth quarter of 2019.
- Research and development expenses were \$14.5 million for 2019 compared to \$17.3 million for 2018. The decrease was mainly due to the absence of clinical trials costs for teslexivir and HHS BARDA contract costs and a reduction in pre-clinical research costs, partially offset by higher manufacturing and clinical trial costs incurred in Vaxart's norovirus program.
- General and administrative expenses were \$6.2 million for the year compared to \$6.7 million for 2018. The decrease was mainly due to reductions in legal fees and other costs associated with becoming a public company.

- Other operating expenses were \$4.9 million for 2019 due to restructuring costs related to the suspension of Vaxart’s manufacturing operations, compared to \$2.0 million for 2018, which related to the impairment of intangible assets related to teslexivir and the sublease of Vaxart’s premises in Georgia.
- Vaxart ended the year with cash and cash equivalents of \$13.5 million compared to \$11.5 million at December 31, 2018. The increase was primarily due to funds raised via issuances of equity totaling \$19.8 million during 2019, partially offset by cash used in operations totaling \$13.1 million and the repayment of debt for \$3.8 million.

About Vaxart

Vaxart is a clinical-stage biotechnology company primarily 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 coronavirus, 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.

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, 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 (including plans with respect to the proposed coronavirus vaccine program); Vaxart’s intention to continue its efforts to advance its oral tablet seasonal flu vaccine; 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, as well as coronaviruses such as SARS, MERS and the virus that recently emerged in China. 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, 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.

Contact

Brant Biehn
Vaxart Inc
650 550 3500
IR@vaxart.com

Vaxart, Inc.
Condensed Consolidated Balance Sheets

| | <u>December 31, 2019</u> | <u>December 31, 2018</u> |
|---|--------------------------|--------------------------|
| | (Unaudited) | (1) |
| | <i>(in thousands)</i> | |
| Assets | | |
| Cash and cash equivalents | \$ 13,526 | \$ 11,506 |
| Accounts receivable | 3,619 | 1,796 |
| Prepaid and other assets | 594 | 1,446 |
| Property and equipment, net | 210 | 1,066 |
| Right-of-use assets, net | 1,990 | — |
| Intangible assets, net | 17,093 | 19,413 |
| Total Assets | <u>\$ 37,032</u> | <u>\$ 35,227</u> |
| Liabilities and stockholders' equity | | |
| Accounts payable | \$ 852 | \$ 962 |
| Accrued and other liabilities | 4,583 | 1,675 |
| Liability related to sale of future royalties | 16,332 | 17,741 |
| Secured promissory note | — | 3,611 |
| Operating lease liabilities | 2,313 | — |
| Total liabilities | <u>24,080</u> | <u>23,989</u> |
| Stockholders' equity | 12,952 | 11,238 |
| Total liabilities and stockholders' equity | <u>\$ 37,032</u> | <u>\$ 35,227</u> |

(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

| | <u>Three Months Ended December 31,</u> | | <u>Year Ended December 31,</u> | |
|--|---|--------------------|--------------------------------|--------------------|
| | <u>2019</u> | <u>2018</u> | <u>2019</u> | <u>2018</u> |
| | <u>(Unaudited)</u> | <u>(Unaudited)</u> | <u>(Unaudited)</u> | <u>(1)</u> |
| | <i>(in thousands, except share and per share amounts)</i> | | | |
| Revenue | \$ 3,916 | \$ 1,767 | \$ 9,862 | \$ 4,159 |
| Operating expenses: | | | | |
| Research and development | 3,291 | 4,474 | 14,540 | 17,275 |
| General and administrative | 1,331 | 1,226 | 6,187 | 6,681 |
| Restructuring and impairment charges | 4,920 | 253 | 4,920 | 1,959 |
| Total operating expenses | 9,542 | 5,953 | 25,647 | 25,915 |
| Loss from operations | (5,626) | (4,186) | (15,785) | (21,756) |
| Bargain purchase gain | — | 100 | — | 6,760 |
| Other income and expenses, net | (587) | (736) | (2,370) | (2,902) |
| Provision for income taxes | (196) | (80) | (490) | (109) |
| Net loss | <u>\$ (6,409)</u> | <u>\$ (4,902)</u> | <u>\$ (18,645)</u> | <u>\$ (18,007)</u> |
| Net loss attributable to common stockholders | <u>\$ (6,409)</u> | <u>\$ (4,902)</u> | <u>\$ (18,645)</u> | <u>\$ (18,346)</u> |
| Net loss per share, basic and diluted | <u>\$ (0.13)</u> | <u>\$ (0.69)</u> | <u>\$ (0.86)</u> | <u>\$ (2.90)</u> |
| Shares used in computing net loss per share, basic and diluted | <u>47,744,463</u> | <u>7,141,189</u> | <u>21,569,523</u> | <u>6,316,065</u> |

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VAXART ANNOUNCES IT ENTERED INTO AN AGREEMENT WITH EMERGENT BIOSOLUTIONS FOR DEVELOPMENT AND MANUFACTURING OF ORAL CORONAVIRUS (COVID-19) VACCINE CANDIDATE

Oral Vaccines based on Proprietary VAAST™ Platform Offer Potential Key Advantages
in Global Quest to Develop Coronavirus Vaccine

SOUTH SAN FRANCISCO, Calif., March 18, 2020 – Vaxart, Inc. (Nasdaq: VXRT), a clinical-stage biotechnology company developing oral recombinant vaccines administered by tablet rather than by injection, announced today that it has entered into an agreement with Emergent BioSolutions Inc. (NYSE: EBS), whereby Emergent will deploy its molecule-to-market contract development and manufacturing (CDMO) services to help develop and manufacture Vaxart’s experimental oral vaccine candidate for coronavirus disease (COVID-19). Vaxart’s oral recombinant vaccine candidate is based on its proprietary VAAST™ platform.

“I’m pleased that we are joining forces with an experienced manufacturer such as Emergent to help advance our oral COVID-19 vaccine to the clinic,” said Wouter Latour, MD, chief executive officer of Vaxart. “We believe an oral vaccine administered using a room temperature-stable tablet may offer enormous logistical advantages in the roll-out of a large vaccination campaign, and Emergent is a great partner to help in this endeavor.”

Under the terms of the agreement, development services will begin immediately, and upon Vaxart’s election, Emergent is expected to produce bulk cGMP vaccine allowing Vaxart to initiate a Phase 1 clinical study early in the second half of 2020. Emergent will provide development services out of its Gaithersburg, MD location and manufacture drug substance at its Bayview facility in Baltimore, MD, designated a Center for Innovation in Advanced Development and Manufacturing (CIADM) by the U.S. Department of Health and Human Services.

“Emergent is pleased to deploy our nimble CDMO expertise to support fellow innovators, like Vaxart, and advance an experimental COVID-19 vaccine candidate,” said Syed T. Husain, senior vice president and CDMO business unit head at Emergent BioSolutions. “We look forward to applying our broad molecule-to-market services, including our ability to work with a multitude of delivery systems, execute under expedited timelines, and meet Vaxart’s potential need for future scalability and large-scale capacity for commercial quantities.”

About Coronavirus

The 2019 Novel Coronavirus (COVID-19) is a virus (more specifically, a coronavirus) identified as the cause of an outbreak of respiratory illness first detected in Wuhan, China. Early on, many of the patients in the outbreak in Wuhan, China reportedly had some link to a large seafood and animal market, suggesting animal-to-person spread. However, a growing number of patients reportedly have not had exposure to animal markets, indicating person-to-person spread is occurring. At this time, it’s unclear how easily or sustainably this virus is spreading between people. The latest situation summary updates are available on CDC’s web page 2019 Novel Coronavirus, Wuhan, China.

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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 Vaxart's expectations and plans with respect to its product development programs (including plans with respect to the proposed Coronavirus vaccine program); Vaxart's ability to develop and commercialize its product candidates and expectations with respect to clinical results and trial data; 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, as well as coronaviruses such as SARS, MERS and the virus that recently emerged in China. 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, including Vaxart's decision whether or not to proceed with the development program after the initial evaluation phase; the success of the planned development program; the timing of and ability to obtain and maintain regulatory approvals by the FDA or non-U.S. regulatory authorities for Vaxart's product candidates; even if approved by the FDA or non-U.S. regulatory authorities, Vaxart's product candidates may not achieve broad market acceptance; 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.

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