



Vaxart Provides Business Update and Reports First Quarter 2024 Financial Results

May 13, 2024

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 (GLOBE NEWSWIRE) -- 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

Vaxart Media Relations:

Mark Herr
Vaxart, Inc.
mherr@vaxart.com
(203) 517-8957

Investor Relations:

Andrew Blazier
Finn Partners
IR@Vaxart.com
(646) 871-8486

Vaxart, Inc. Condensed Consolidated Balance Sheets

Assets

March 31,	December 31,
2024	2023
Unaudited	(1)
(in thousands)	

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
	<i>(in thousands, except share and per share amounts)</i>	
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



Source: Vaxart, Inc.