Vaxart Provides Business Update and Reports Full Year 2023 Financial Results

March 14, 2024

Significant progress made in preparing for a Phase 2b study evaluating Vaxart's oral pill XBB COVID-19 vaccine against an approved mRNA vaccine comparator

Topline data from Phase 1 norovirus study in lactating mothers expected in mid-2024

Steven Lo appointed President, Chief Executive Officer and Board Member

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

SOUTH SAN FRANCISCO, Calif., March 14, 2024 (GLOBE NEWSWIRE) -- Vaxart, Inc. (Nasdaq: VXRT) today announced its business update and financial results for the full year 2023.

"We are excited to welcome Steve Lo as Vaxart's President and Chief Executive Officer. Steve brings extensive biopharma leadership experience, and we look forward to his contributions in executing on our strategy and creating value for our shareholders," said Dr. Michael Finney, Vaxart's Interim Chief Executive Officer.

"Steve's arrival comes as we made important progress on our oral vaccine platform in 2023. We now have established proof of concept in two challenge studies, for both respiratory and GI viruses," Dr. Finney said. "Our recent COVID-19 BARDA Project NextGen contract award is supportive of our differentiated approach. Our oral pill vaccines offer several advantages compared with injectables, including the ability to vaccinate more people faster, easier and painlessly. Steve's leadership will guide Vaxart in accelerating the development of a platform that has the potential to revolutionize how people are vaccinated."

Recent Business Highlights

COVID-19 Vaccine Developments

- The United States Biomedical Advanced Research and Development Authority (BARDA) awarded Vaxart a $9.27 million contract in January to prepare for a 10,000-subject, Phase 2b clinical study evaluating the Company's oral pill XBB COVID-19 vaccine candidate against an approved mRNA vaccine comparator as part of its "Project NextGen" initiative designed to support the development of vaccines and treatments to stay ahead of COVID-19.
    - Vaxart believes the Phase 2b trial may initiate as soon as the second quarter of 2024.
- In February 2024, Vaxart published preclinical non-human primate (NHP) data showing strong cross-reactive immune responses, thus demonstrating the potential of its COVID-19 vaccine to protect against multiple SARS-CoV-2 variants of concern (VOC).

Norovirus Vaccine Developments

- Vaxart plans to meet with the U.S. Food and Drug Administration ("FDA") in the second quarter of 2024 to discuss data on correlates of protection, which will inform potential next steps, such as potentially conducting a Phase 2b study and potentially a GII.4 challenge study.
    - The Company expects the Phase 2b study will generate sufficient safety data to have an End-of-Phase 2 meeting with the FDA. The End-of-Phase 2 meeting will allow the Company to gain concurrence on the scope and design of the Phase 3 pivotal efficacy study in adults over 18 years of age.
- In December 2023, Vaxart completed enrollment in the Phase 1 norovirus study in lactating mothers. With support from the Bill & Melinda Gates Foundation, the study is designed to evaluate the ability of Vaxart's norovirus vaccine candidate to induce antibodies in breast milk and transfer of antibodies to young infants.
    - The Company expects to announce topline results in mid-2024.

Corporate Update

- In March 2024, Vaxart appointed Mr. Lo as President and Chief Executive Officer and a member of the Board of Directors, effective March 18, 2024. Dr. Finney will continue to serve as Chair of the Board of Directors.

Financial Results for the Full Year Ended December 31, 2023

- Cash, cash equivalents and investments totaled $39.7 million as of December 31, 2023. This cash balance does not include approximately $15 million in net proceeds raised in early 2024 from a registered direct offering and at-the-market

equity offerings. Currently, the Company anticipates cash runway into the fourth quarter of 2024.

- Vaxart reported a net loss of $82.5 million for the full year 2023, compared to $107.8 million for the full year 2022. Net loss per share for 2023 was $0.57, compared to a net loss of $0.84 per share for 2022.
- Revenue for the full year 2023 was $7.4 million, compared to $0.1 million for 2022. Revenue in 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 $68.1 million for 2023, compared to $81.1 million for 2022. The decrease is primarily due to decreases in manufacturing costs, personnel related costs and clinical trial expenses related to Vaxart's COVID-19 vaccine candidates, partially offset by increased facilities and depreciation expense.
- General and administrative expenses were $22.6 million for 2023, compared to $29.4 million for 2022. The decrease is primarily due to decreases in legal and professional fees, litigation settlement costs and directors' and officers' insurance, 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 full year 2023 today, beginning at 4:30 p.m. ET.

The conference call can be accessed using the following information:

Webcast: Click here
Date: Thursday, March 14, 2024 – 4:30 p.m. ET
Domestic: 877-407-0832
International: 201-689-8433
Conference ID: 13744368

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, 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

	December 31, 2023 (Unaudited)	December 31, 2022 (1)
	(in thousands)	
Assets		
Cash, cash equivalents and restricted cash [2]	$ 34,755	$ 46,013
Investments in marketable debt securities	4,958	49,704
Accounts receivable	3,008	20
Prepaid expenses and other assets	3,741	7,282
Property and equipment, net	11,731	15,585
Right-of-use assets, net	24,840	25,715
Intangible assets, net	4,289	5,020
Goodwill	4,508	4,508
Total assets	$ 91,830	$ 153,847
Liabilities and stockholders' equity		
Accounts payable	$ 1,584	$ 5,514
Deferred grant revenue	-	2,000
Accrued and other liabilities	5,927	8,315
Operating lease liability	20,088	21,705
Liability related to sale of future royalties	6,426	5,716
Total liabilities	34,025	43,250
Stockholders' equity	57,805	110,597
Total liabilities and stockholders' equity	$ 91,830	$ 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 $0 and $2.0 million of restricted cash as of December 31, 2023 and December 31, 2022, respectively.

Vaxart, Inc.
Condensed Consolidated Statement of Operations

	Year Ended December 31, 2023 (Unaudited)	Year Ended December 31, 2022 (1)
	(in thousands, except share and per share amounts)	
Revenue	$ 7,379	$ 107
Operating expenses:		
Research and development	68,142	81,054
General and administrative	22,584	29,386
Impairment of intangible assets	-	4,254
Total operating expenses	90,726	114,694
Operating loss	(83,347)	(114,587)
Other income (expense), net	1,143	6,896
Loss before income taxes	(82,204)	(107,691)

Provision for income taxes	261	67
Net loss	$ (82,465)	$ (107,758)
Net loss per share, basic and diluted	$ (0.57)	$ (0.84)
Shares used in computing net loss per share, basic and diluted	144,819,781	127,683,813

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Source: Vaxart, Inc.