Vaxart Provides Business Update and Reports Third Quarter 2024 Financial Results

November 13, 2024

Expects to complete enrollment of the 400-participant sentinel cohort for the COVID-19 Phase 2b study in November 2024

Solid financial position enables Vaxart to attain multiple regulatory and clinical milestones

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

SOUTH SAN FRANCISCO, Calif., Nov. 13, 2024 (GLOBE NEWSWIRE) -- Vaxart, Inc. (Nasdaq: VXRT) today announced its business update and financial results for the third quarter of 2024.

"Our successful initiation of sentinel cohort dosing is a testament to our rapid execution in helping to ensure that we remain on track to meet the milestones of our Biomedical Advanced Research Development Authority (BARDA) contract," said Steven Lo, Vaxart's Chief Executive Officer. "We are pleased to be nearing completion of enrollment of the sentinel cohort. Then, if the U.S. Food and Drug Administration (FDA) and independent Data and Safety Monitoring Board's (DSMB's) 30-day safety data review is favorable, we will initiate the 10,000-participant portion of the Phase 2b trial. Our continued progress brings us closer to our goal of demonstrating advantages of our mucosal technology against an approved mRNA vaccine."

"On our norovirus program, we received constructive feedback from the FDA on our proposed correlate of protection and are evaluating next steps," Mr. Lo added. "Additionally, our scientific team created potentially more potent norovirus GI.1 and GII.4 constructs compared to the constructs previously evaluated in our clinical trials. We are excited about the potential these improvements may yield and remain committed to moving forward with our norovirus program."

Recent Business Highlights

COVID-19 Vaccine Developments

- In September 2024, Vaxart initiated the 400-participant sentinel cohort of its Phase 2b trial to evaluate Vaxart's oral pill COVID-19 vaccine candidate against an approved mRNA vaccine comparator. The sentinel cohort is being funded as part of the Phase 2b NextGen COVID-19 clinical trial, valued at up to $456 million through the Rapid Response Partnership Vehicle under the U.S. government's Project NextGen.
    - Enrollment of the sentinel cohort is expected to be completed in November 2024. The 30-day safety data of the sentinel cohort will then be reviewed by the independent DSMB and the FDA.
    - If the review of safety data by the DSMB and FDA is favorable, Vaxart expects the study to progress to the second part of the trial in early 2025 by enrolling approximately 10,000 participants.
    - The primary efficacy analysis will be performed when all participants have either discontinued or completed a study visit 12 months post-vaccination.

Norovirus Vaccine Developments

- In the second half of 2024, Vaxart held productive conversations with the FDA on its data for potential correlates of protection and next steps for Vaxart's norovirus program.
    - Based on the latest feedback, the FDA requested new clinical data before proceeding with further review of Vaxart's potential correlate.
    - Vaxart created additional norovirus GI.1 and GII.4 constructs that may be more potent than the constructs being evaluated in clinical trials. Vaxart is discussing regulatory feedback, clinical data on current constructs, and preclinical data generated on its new constructs with certain key opinion leaders in determining the best way to progress its norovirus program.

- In October 2024, Vaxart presented clinical research demonstrating the potential of its norovirus oral pill vaccine candidate at IDWeek.

Other Programs

- In August 2024, preclinical data was published in *Vaccines,* demonstrating the potential of Vaxart's mucosal vaccine technology platform in enabling therapeutic vaccination against HPV-related cervical dysplasia.

Financial Results for the Third Quarter Ended September 30, 2024

- Cash, cash equivalents and investments totaled $58.7 million as of September 30, 2024. Vaxart continues to anticipate cash runway into 2026.

- Vaxart reported a net loss of $14.1 million for the third quarter of 2024, compared to $17.4 million for the third quarter of 2023. Net loss per share for the third quarter of 2024 was $0.06, compared to a net loss per share of $0.11 for the third

quarter of 2023.

- Revenue for the third quarter of 2024 was $4.9 million, compared to $2.1 million for the third quarter of 2023. Revenue in the third quarter of 2024 was primarily from government contracts related to the BARDA contracts awarded in January 2024 and June 2024. 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 $15.1 million for the third quarter of 2024, compared to $15.0 million for the third quarter of 2023. The R&D expenses in the latest quarter were primarily due to increases in clinical trial expenses related to Vaxart's COVID-19 vaccine candidate and preclinical expenses across multiple programs and facilities expenses, partially offset by decreases in clinical trial expenses related to Vaxart's norovirus vaccine candidate, stock-based compensation expenses and personnel-related costs, and manufacturing expenses.

- General and administrative expenses were $4.3 million for the third quarter of 2024, compared to $4.9 million for the third quarter of 2023. The decrease was primarily due to decreases in stock-based compensation expense and directors' and officers' insurance costs, partially offset by increases in legal and other professional fees.

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 2024 today, beginning at 4:30 p.m. ET.

The conference call can be accessed using the following information:

Webcast: Click here
Date: Wednesday, November 13, 2024 – 4:30 p.m. ET
Domestic: (877) 407-0832
International: (201) 689-8433
Conference ID: 13749666

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, receipt of funding from BARDA, 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 receipt of funding from BARDA for the Phase 2b study (or for any other purpose); Vaxart's ability to develop and commercialize its product candidates, including its vaccine booster products; Vaxart's expectations regarding clinical results and trial data, including their design, and the timing of such trials and of receiving and reporting such clinical results and trial data; Vaxart's expectations regarding timing of enrollment in studies; and Vaxart's expectations with respect to the effectiveness of its product candidates and the potential of its vaccine pill platform. 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 U.S. Securities and Exchange Commission. 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, 2024 (Unaudited)	December 31, 2023 (1)
		(in thousands)
Assets		
Cash and cash equivalents	$ 22,035	$ 34,755
Investments in marketable debt securities	36,676	4,958
Accounts receivable	591	3,008
Unbilled receivable from government contracts	3,085	-
Prepaid expenses and other assets	4,911	3,741
Property and equipment, net	9,476	11,731
Long-term prepaid clinical services	60,116	-
Right-of-use assets, net	21,536	24,840
Intangible assets, net	3,740	4,289
Goodwill	4,508	4,508
Total assets	$ 166,674	$ 91,830
Liabilities and stockholders' equity		
Accounts payable	$ 2,524	$ 1,584
Deferred government revenue	65,447	-
Accrued and other liabilities	7,185	5,927
Operating lease liability	18,201	20,088
Liability related to sale of future royalties	4,875	6,426
Total liabilities	98,232	34,025
Stockholders' equity	68,442	57,805
Total liabilities and stockholders' equity	$ 166,674	$ 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 September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
	(in thousands, except share and per share amounts)			
Revenue	$ 4,933	$ 2,101	$ 13,515	$ 4,134
Operating expenses:				
Research and development	15,066	15,002	51,559	53,437
General and administrative	4,342	4,921	16,757	17,144
Total operating expenses	19,408	19,923	68,316	70,581
Operating loss	(14,475)	(17,822)	(54,801)	(66,447)
Other income (expense), net	413	461	(78)	1,444
Loss before income taxes	(14,062)	(17,361)	(54,879)	(65,003)
Provision for income taxes	18	39	84	87
Net loss	$ (14,080)	$ (17,400)	$ (54,963)	$ (65,090)
Net loss per share, basic and diluted	$ (0.06)	$ (0.11)	$ (0.28)	$ (0.45)
Shares used in computing net loss per share, basic and diluted	227,452,883	152,026,112	193,655,660	145,810,175

Source: Vaxart, Inc.