Vaxart Provides Business Update and Reports Full Year 2024 Financial Results

March 20, 2025

Initiated Phase 1 clinical trial evaluating its second-generation oral norovirus vaccine constructs with topline data expected as early as mid-2025

Continues per protocol follow-up for the COVID-19 Phase 2b 400-person sentinel cohort

Cash, cash equivalents and investments of $51.7 million as of December 31, 2024 provides runway through multiple development milestones and into the fourth quarter of 2025

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

SOUTH SAN FRANCISCO, Calif., March 20, 2025 (GLOBE NEWSWIRE) -- Vaxart, Inc. (Nasdaq: VXRT) today announced its business update and financial results for the full year 2024.

"Since our founding, Vaxart has been on a mission to transform global health with the goal of pioneering oral pill vaccines that can provide protection against common viral diseases safely and effectively," said Steven Lo, Chief Executive Officer of Vaxart. "Developing a safe vaccine that improves convenience and reduces the risk of illness or death compared to existing options, or creates a solution where no vaccine or treatment exists, is crucial for bolstering U.S. and global public health."

"We are making important progress on our mission by executing on our key milestones, highlighted by the initiation of our Phase 1 norovirus trial evaluating our second-generation oral vaccine candidate. We believe our second-generation candidate may be more potent than our first-generation candidate, which already demonstrated a favorable safety profile in multiple clinical trials, showed protection in a human challenge model, and elicited mucosal and systemic immunity in older adults. At the same time, we are continuing our efforts with the per protocol follow up for the 400-person sentinel cohort from our COVID-19 Phase 2b trial, and will further update on the BARDA award as events warrant," concluded Mr. Lo.

Recent Business Highlights

Norovirus Vaccine Developments

- In March 2025, Vaxart initiated its Phase 1, open label, dose ranging clinical trial evaluating its second-generation oral norovirus vaccine constructs head-to-head against its first-generation constructs. The study will measure safety and immune parameters that have correlated to protection in the completed norovirus challenge study, with topline data expected as early as mid-2025.
    - If the Phase 1 trial is successful, the next step, pending a partnership or other funding, would be to conduct a Phase 2b safety and immunogenicity study that could potentially begin as early as the second half of 2025 followed by an End of Phase 2 meeting with the U.S. Food and Drug Administration (FDA). A Phase 3 trial could then begin as early as 2026.

- In March 2025, Science Translational Medicine published the complete data from Vaxart's Phase 1b trial of its first-generation oral pill norovirus vaccine candidate in elderly adults (55-80 years).
    - Data from this study demonstrated strong and durable antibody responses and induction of norovirus-specific antibody and T cell responses, supporting the immunogenicity of the vaccine candidate in a patient population that often has age-related reductions in immune responses to injected vaccines.

COVID-19 Vaccine Developments

- In December 2024, Vaxart announced the 400-person sentinel cohort of the Phase 2b trial evaluating its COVID-19 vaccine candidate head-to-head against an approved mRNA comparator completed enrollment. Participants are monitored for up to 12 months post-vaccination to assess safety, immunogenicity, and efficacy for the sentinel cohort.
    - In January 2025, an independent Data Safety Monitoring Board (DSMB) recommended the study to proceed without modifications based on initial safety assessment the sentinel cohort's 30-day data.
- On February 21, 2025, Vaxart received an order from Advanced Technology International on behalf of the U.S. government directing that it stop work on all its efforts on the COVID-19 Phase 2b trial, with the exception that Vaxart may continue work associated with the per protocol follow-up for the 400-person cohort. Within 90 days of the order, the stop work order will either be canceled, extended, or work on this project will be terminated.

Influenza Program Developments

- Vaxart continues to advance its avian influenza program. Vaxart previously published data demonstrating protection in a preclinical model against avian influenza after oral immunization (Clin Vaccine Immunol 2013). Vaxart recently created a new avian influenza vaccine candidate to cover the latest clade 2.3.4.4b. Vaxart is in the process of conducting several preclinical studies to evaluate the new construct and preparing to manufacture it for clinical use. Vaxart intends to publish the results of the preclinical studies when complete.

Corporate Update

- In January 2025, Vaxart appointed Kevin Finney to Vaxart's Board of Directors. Mr. Finney is a seasoned healthcare executive and experienced board member who brings decades of industry leadership experience and operational expertise.

Financial Results for the Full Year Ended December 31, 2024

- Cash, cash equivalents and investments totaled $51.7 million as of December 31, 2024. Currently, Vaxart anticipates cash runway into the fourth quarter of 2025. After receiving the February 2025 stop work order related to the COVID Phase 2b trial, Vaxart implemented a restructuring plan that led to an approximately 10% reduction of Vaxart's workforce on a full-time equivalent basis.
- Vaxart reported a net loss of $66.9 million for the full year 2024, compared to $82.5 million for the full year 2023. Net loss per share for 2024 was $0.33, compared to a net loss of $0.57 per share for 2023.
- Revenue for the full year 2024 was $28.7 million, compared to $7.4 million for 2023. Revenue in 2024 was primarily from government contracts related to the BARDA contracts awarded in January and June 2024. 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 $74.2 million for 2024, compared to $68.1 million for 2023. The increase is primarily due to increases in clinical trial expenses related to Vaxart's COVID-19 vaccine candidate, an increase in manufacturing and preclinical expenses and facilities expenses, partially offset by a decrease in clinical trial expenses related to Vaxart's norovirus vaccine candidate and a decrease in stock-based compensation expense and personnel-related costs.
- General and administrative expenses were $20.8 million for 2024, compared to $22.6 million for 2023. The decrease is primarily due to a decrease in personnel-related costs, including stock-based compensation expenses, and directors' and officers' insurance costs, offset by increases in severance costs, recruiting costs 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 full year 2024 today, beginning at 4:30 p.m. ET.

The conference call can be accessed using the following information:

Webcast: Click here
Date: Thursday, March 20, 2025 – 4:30 p.m. ET
Domestic: (877) 407-0832
International: (201) 689-8433
Conference ID: 13751819

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; that the stop work order discussed above may result in further work on the COVID-19 Phase 2b trial being terminated; 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

	December 31, 2024 (Unaudited)	December 31, 2023 (1)
	(in thousands)	
Assets		
Cash and cash equivalents	$ 25,229	$ 34,755
Short-term investments	26,494	4,958
Accounts receivable	5,761	3,008
Unbilled receivable from government contracts	6,208	-
Prepaid expenses and other assets	5,407	3,741
Property and equipment, net	8,705	11,731
Prepaid clinical services, long-term	60,116	-
Right-of-use assets, net	20,404	24,840
Intangible assets, net	3,557	4,289
Goodwill	4,508	4,508
Total assets	$ 166,389	$ 91,830
Liabilities and stockholders' equity		
Accounts payable	$ 6,963	$ 1,584
Deferred government revenue	65,400	-
Accrued and other liabilities	11,817	5,927
Operating lease liability	17,526	20,088
Liability related to sale of future royalties	5,758	6,426
Total liabilities	107,464	34,025
Stockholders' equity	58,925	57,805
Total liabilities and stockholders' equity	$ 166,389	$ 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)

	Year Ended December 31, 2024 (Unaudited)	2023 (1)
	(in thousands, except share and per share amounts)	
Revenue	$ 28,700	$ 7,379
Operating expenses:		
Research and development	74,213	68,142
General and administrative	20,780	22,584
Total operating expenses	94,993	90,726
Operating loss	(66,293)	(83,347)
Other (expense) income, net	(395)	1,143
Loss before income taxes	(66,688)	(82,204)

Provision for income taxes	260	261
Net loss	$ (66,948)	$ (82,465)
Net loss per share, basic and diluted	$ (0.33)	$ (0.57)
Shares used in computing net loss per share, basic and diluted	202,137,531	144,819,781

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This press release was published by a CLEAR® Verified individual.

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