



Vaxart Provides Business Update and Reports Second Quarter 2024 Financial Results

August 8, 2024

BARDA Project NextGen contract to support a Phase 2b trial potentially positions Vaxart's oral pill vaccine platform as a next-generation approach to combating COVID-19 and future pandemic threats

Solid financial position enables Vaxart to execute on multiple regulatory and clinical milestones

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

SOUTH SAN FRANCISCO, Calif., Aug. 08, 2024 (GLOBE NEWSWIRE) -- Vaxart, Inc. (Nasdaq: VXRT) today announced its business update and financial results for the second quarter of 2024.

"We achieved meaningful progress on our clinical, regulatory and operational goals during the first half of 2024," said Steven Lo, Vaxart's Chief Executive Officer. "Most significant was one of the largest Biomedical Advanced Research Development Authority (BARDA) contracts awarded to date for our COVID-19 program under Project NextGen, providing up to \$453 million to support a Phase 2b trial, which will evaluate our oral pill vaccine candidate against an approved mRNA injectable vaccine. We also reported positive Phase 1 data from our bivalent norovirus vaccine candidate in lactating mothers and extended our cash runway.

"Through our focus on execution and continued constructive conversations with the U.S. Food and Drug Administration (FDA), we are well-positioned to initiate our COVID Phase 2b trial in the near-term and determine next steps in advancing our norovirus program," Lo added. "Infectious diseases remain at the forefront of health challenges facing society, and we believe that by unlocking the potential of our oral pill vaccine platform, we will have a solution that can solve some of the greatest global health problems today."

Recent Business Highlights

COVID-19 Vaccine Developments

- In June 2024, Vaxart received a project award valued at up to \$453 million through the Rapid Response Partnership Vehicle's Consortium Management Firm funded by BARDA, in the U.S. Department of Health and Human Services. Funds from the BARDA award will be used to conduct a 10,000-subject Phase 2b comparative study evaluating Vaxart's oral pill COVID-19 vaccine candidate against an FDA-approved mRNA vaccine comparator.
 - Vaxart plans to initiate enrollment in this trial as early as the second half of 2024, pending regulatory alignment with FDA.
 - An interim analysis for vaccine efficacy compared to an approved mRNA comparator may occur when 255 symptomatic COVID-19 cases have been observed.
 - 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

- Vaxart is in discussions with the FDA regarding our data for potential correlates of protection.
 - After initial feedback, Vaxart is in the process of submitting additional requested information to the FDA and will determine next steps, such as potentially conducting a Phase 2b study and / or a GII.4 challenge study, based on discussions with the FDA.

Financial Results for the Second Quarter Ended June 30, 2024

- Cash, cash equivalents and investments totaled \$62.6 million as of June 30, 2024. Subsequent to the close of the quarter, Vaxart received a payment of approximately \$64.7 million related to the BARDA contract awarded in June 2024. Proceeds will be used to continue study start-up activities for the COVID-19 Phase 2b clinical trial. Vaxart continues to anticipate cash runway into 2026.
- Vaxart reported a net loss of \$16.5 million for the second quarter of 2024, compared to \$22.6 million for the second quarter of 2023. Net loss per share for the second quarter of 2024 was \$0.09, compared to a net loss per share of \$0.16 for the second quarter of 2023.
- Revenue for the second quarter of 2024 was \$6.4 million, compared to \$1.4 million for the second quarter of 2023. Revenue in the second quarter of 2024 was primarily from government contracts related to the BARDA contract awarded

in January 2024. Revenue in the second quarter of 2023 was primarily from revenue recognized for work performed under Vaxart's grant from the Bill & Melinda Gates Foundation.

- Research and development expenses were \$17.5 million for the second quarter of 2024, compared to \$18.8 million for the second quarter of 2023. The decrease was primarily due to decreases in clinical trial expenses related to Vaxart's norovirus vaccine candidate, stock-based compensation expense, and personnel-related costs, partially offset by increases in clinical trial expenses and pre-clinical expenses related to Vaxart's COVID-19 vaccine candidate.
- General and administrative expenses were \$5.2 million for the second quarter of 2024, compared to \$5.6 million for the second quarter of 2023. The decrease was primarily due to decreases in stock-based compensation expense and personnel-related costs and directors' and officers' insurance costs, partially offset by increases in legal and professional fees.

Conference Call

The Vaxart senior management team will host a conference call to discuss the business update and financial results for the second 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: Thursday, August 8, 2024 – 4:30 p.m. ET

Domestic: 866-682-6100

International: 862-298-0702

Conference ID: 13747081

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 for the Phase 2b study, 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

	<u>June 30,</u>		<u>December 31,</u>	
	<u>2024</u>		<u>2023</u>	
	(Unaudited)		(1)	
	(in thousands)			
Assets				
Cash and cash equivalents	\$	43,285	\$	34,755
Investments in marketable debt securities		19,308		4,958
Accounts receivable		1,088		3,008
Unbilled receivable from government contracts		3,689		-
Prepaid expenses and other assets		5,016		3,741
Property and equipment, net		10,280		11,731
Right-of-use assets, net		22,652		24,840
Intangible assets, net		3,923		4,289
Goodwill		4,508		4,508
Total assets	\$	113,749	\$	91,830
Liabilities and stockholders' equity				
Accounts payable	\$	3,587	\$	1,584
Accrued and other liabilities		7,016		5,927
Operating lease liability		18,855		20,088
Liability related to sale of future royalties		4,277		6,426
Total liabilities		33,735		34,025
Stockholders' equity		80,014		57,805
Total liabilities and stockholders' equity	\$	113,749	\$	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)

	<u>Three Months Ended June 30,</u>		<u>Six Months Ended June 30,</u>	
	<u>2024</u>	<u>2023</u>	<u>2024</u>	<u>2023</u>
	(in thousands, except share and per share amounts)			
Revenue	\$	6,401	\$	1,358
Operating expenses:				
Research and development		17,480		18,813
General and administrative		5,177		5,598
Total operating expenses		22,657		24,411
Operating loss		(16,256)		(23,053)
Other (expense) income, net		(189)		522
Loss before income taxes		(16,445)		(22,531)
Provision for income taxes		21		19
Net loss	\$	(16,466)	\$	(22,550)
Net loss per share, basic and diluted	\$	(0.09)	\$	(0.16)
Shares used in computing net loss per share, basic and diluted		184,703,003		139,594,238
			\$	(40,883)
			\$	(47,690)
			\$	(0.23)
			\$	(0.35)
		176,757,049		137,403,416



Source: Vaxart, Inc.