Vaxart Provides Business Update and Reports Second Quarter 2023 Financial Results

August 3, 2023

On track to report topline data from Phase 2 GI.1 norovirus vaccine challenge study in Q3 2023

Cash runway extended into Q3 2024

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

SOUTH SAN FRANCISCO, Calif., Aug. 03, 2023 (GLOBE NEWSWIRE) -- Vaxart, Inc. (Nasdaq: VXRT) today announced its business update and financial results for the second quarter of 2023.

“During the second quarter, we continued to advance our oral pill vaccine programs and deliver on our planned timelines for this year,” said Andrei Floroiu, Vaxart’s Chief Executive Officer. “Positive preliminary topline data from our Phase 2 bivalent norovirus vaccine candidate builds on the growing body of evidence supporting Vaxart’s platform and the potential advantages of mucosal vaccination.

“We are excited about the potential for our norovirus vaccine program, the only one formulated for oral administration and delivery to the gastrointestinal system,” Mr. Floroiu continued. “We anticipate reporting topline data from our GI.1 norovirus challenge study during the third quarter, which will help inform the next steps for this program.”

Recent Business Highlights

Norovirus Vaccine Developments

- In July 2023, Vaxart reported positive preliminary topline data from the Phase 2 dose-ranging clinical trial of its oral pill bivalent norovirus vaccine candidate.
  - The study met all primary endpoints, as the vaccine was well-tolerated with robust immunogenicity.
  - Data from this study and from Vaxart’s forthcoming norovirus challenge study will help inform selection of the dose to be used in a larger Phase 2b study. These studies are expected to enable an End-of-Phase 2 meeting with the U.S. Food and Drug Administration (FDA) to discuss plans for a Phase 3 trial.
  - Vaxart now has obtained robust immunogenicity data from seven clinical trials in both young adults and elderly populations.
  - These trials have shown a favorable safety profile, as the vaccine candidates have been well tolerated with no vaccine related serious adverse events.

COVID-19 Vaccine Developments

- Vaxart continues to progress its COVID-19 vaccine program and believes the cross-reactivity of the current constructs suggests a pathway for developing a pan-betacoronavirus vaccine. The Company is assessing next steps.

Anticipated 2023 Clinical Milestones
Vaxart continues to make progress on its anticipated milestones in 2023:

- Topline data from the ongoing Phase 2 challenge study of Vaxart’s GI.1 norovirus vaccine candidate is expected in Q3 2023.
- Initiation of a Bill & Melinda Gates Foundation-funded clinical trial to evaluate the ability of Vaxart’s norovirus vaccine candidate to induce antibodies in breast milk and transfer of antibodies to young infants.

Financial Results for the Three Months Ended June 30, 2023

- Vaxart ended the second quarter of 2023 with cash, cash equivalents, restricted cash and marketable securities of $67.9 million, compared to $71.8 million as of March 31, 2023. The decrease was primarily due to cash used in operations, which was partially offset by $13.6 million of net proceeds from a public offering completed in June 2023. The offering extends the Company’s expected cash runway into the third quarter of 2024.
- Vaxart reported a net loss of $22.6 million for the second quarter of 2023, compared to $29.4 million for the second quarter of 2022. Net loss per share for the second quarter of 2023 was $0.16, compared to a net loss of $0.23 per share in the second quarter of 2022.
- Revenue for the second quarter of 2023 was $1.4 million, compared to no revenue in the second quarter of 2022.

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 $18.8 million for the second quarter of 2023, compared to $19.9 million for the second quarter of 2022. The decrease was primarily due to decreases in manufacturing costs, personnel-related costs and clinical trial expenses related to the Company's COVID-19 vaccine candidates, partially offset by increased clinical trial expenses related to its norovirus vaccine candidates.
- General and administrative expenses were $5.6 million for the second quarter of 2023, compared to $9.3 million for the second quarter of 2022. The decrease is primarily due to a decrease in litigation settlement cost, legal and professional fees 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 second quarter of 2023 today, beginning at 4:30 p.m. ET.

The conference call can be accessed using the following information:

Webcast: Click here
Date: Thursday, August 3, 2023 – 4:30 p.m. ET
Domestic: 877-407-0832
International: 201-689-8433
Conference ID: 13739413

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 norovirus, coronavirus, seasonal influenza, and respiratory syncytial virus (RSV), 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

	June 30, 2023 (Unaudited)	December 31, 2022 (1)
	(in thousands)	
Assets		
Cash, cash equivalents and restricted cash[2]	$ 43,277	$ 46,013
Investments in marketable debt securities	24,628	49,704
Accounts receivable	29	20
Prepaid and other assets	4,835	7,282
Property and equipment, net	13,918	15,585
Right-of-use assets, net	26,804	25,715
Intangible assets, net	4,654	5,020
Goodwill	4,508	4,508
Total Assets	$ 122,653	$ 153,847
Liabilities and stockholders' equity		
Accounts payable	$ 4,199	$ 5,514
Deferred grant revenue	275	2,000
Accrued and other liabilities	6,312	8,315
Operating lease liabilities	20,996	21,705
Liability related to sale of future royalties	5,798	5,716
Total liabilities	37,580	43,250
Stockholders' equity	85,073	110,597
Total liabilities and stockholders' equity	$ 122,653	$ 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 $0.3 million and $2.0 million of restricted cash as of June 30, 2023 and December 31, 2022, respectively.

Vaxart, Inc.
Condensed Consolidated Statements of Operations
(Unaudited)

	3 Months Ended June 30,		6 Months Ended June 30,	
	2023	2022	2023	2022
	(in thousands, except share and per share amounts)			
Revenue	$ 1,358	$ -	$ 2,033	$ 85
Operating expenses:				
Research and development	18,813	19,926	38,435	38,129
General and administrative	5,598	9,321	12,223	15,979
Total operating expenses	24,411	29,247	50,658	54,108
Loss from operations	(23,053)	(29,247)	(48,625)	(54,023)
Other income and (expenses), net	522	(168)	983	(473)
Loss before income taxes	(22,531)	(29,415)	(47,642)	(54,496)
Provision for income taxes	19	15	48	35
Net loss	$ (22,550)	$ (29,430)	$ (47,690)	$ (54,531)
Net loss per share, basic and diluted	$ (0.16)	$ (0.23)	$ (0.35)	$ (0.43)
Shares used in computing net loss per share, basic and diluted	139,594,238	126,428,298	137,403,416	126,111,777

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Source: Vaxart, Inc.