Vaxart Provides Business Update and Reports Second Quarter 2022 Financial Results

August 8, 2022

Top-line data from COVID-19 Phase II study expected in the third quarter of 2022

Vaxart initiates work on vaccine candidates that directly target new omicron variants of concern

Positive data from norovirus trial in elderly show similar immunogenicity to younger adults

Ended second quarter with $131.5 million in cash, cash equivalents and marketable securities

SOUTH SAN FRANCISCO, Calif., Aug. 08, 2022 (GLOBE NEWSWIRE) -- In its business update today for the second quarter of 2022, Vaxart, Inc. (NASDAQ: VXRT) said it has begun working on vaccine candidate constructs that directly target new omicron variants of concern and is preparing to release top-line data in the third quarter of 2022 from its Phase II COVID-19 testing of a Wuhan strain vaccine construct.

“We continue to be very excited about the cross-reactivity of our current vaccine candidates, as seen in preclinical and early clinical studies,” said Andrei Floroiu, Chief Executive Officer. “The characteristics and prevalence of newer SARS-CoV-2 strains, along with our plans for a human omicron challenge study, led us to begin working on clinical vaccine candidates that directly target omicron variants of concern, which also conforms to recent Food and Drug Administration (FDA) guidance that boosters should target omicron BA.4/5.

“We plan to evaluate these new constructs both as omicron-only monovalent vaccine candidates and bivalent candidates in combination with our Wuhan constructs, and to compare the clinical results of our S-only and S+N constructs to determine the best path forward in developing a vaccine that can hinder viral infection and transmission for current and emerging variants. Our expectation is that the omicron vaccine candidates will be available to evaluate preclinically in the fourth quarter, and clinically in the first half of 2023. In addition, top-line Phase II results from our Wuhan S-only construct are expected in the third quarter of 2022.

“During the second quarter, we also continued to make progress on our norovirus program,” Floroiu said. “The data from our trial in elderly adults is very encouraging, as it suggests similar activity to that in younger adults, which is often not the case with injectable vaccines. This adds to the already compelling clinical data on this program and increases our confidence as we continue our development.”

Recent Business Highlights

COVID-19 Vaccine Developments

- Reported multiple data sets supporting the potential of Vaxart’s COVID-19 vaccine candidates to tackle the challenge of an evolving virus that evades immune protection provided by approved vaccines or natural infection.
    - In May 2022, announced data from a preclinical hamster study conducted by researchers at Duke University and published in *Science Translational Medicine*, which demonstrated that Vaxart’s S-only COVID-19 candidate reduced disease and airborne transmission.
    - In June 2022, announced preclinical data demonstrating that two COVID-19 vaccine candidates targeting either the SARS-CoV-2 spike (S) protein for Wuhan or S protein for omicron protected hamsters when challenged with the omicron BA.1 variant.
    - In July 2022, updated Phase I data showing Vaxart’s Spike/Nucleocapsid (S+N) candidate induced long-lasting mucosal IgA antibodies in saliva and nasal samples against SARS-CoV-2 and was cross-reactive to many different coronaviruses that are more divergent than circulating variants of SARS-CoV-2.
    - Earlier this year, Vaxart released non-human primate data that demonstrated that administration of Vaxart’s S-only or S+N COVID-19 vaccine candidates to the nasal mucosa of non-human primates produced significant increases in serum IgG and IgA and up to 1,000-fold increases in nasal IgA.
        - All vaccinated animals challenged with SARS-CoV-2 B.1.351 (beta variant) had a significant reduction in viral titers in the nasal passages compared to unvaccinated controls.
- In June 2022, established an agreement with hVIVO Services Limited, a subsidiary of Open Orphan, a research company specializing in human challenge clinical trials for infectious and respiratory disease products, under which hVIVO will conduct a characterization study and, if successful, develop a human challenge model based on the omicron variant of SARS-CoV-2, with the intent to conduct a subsequent Phase II Human Challenge Trial (HCT) of Vaxart’s oral COVID-19 vaccine candidate.

Norovirus Vaccine Developments

- In June 2022, Vaxart reported positive top-line data about its norovirus vaccine candidate. No vaccine exists in the United States to treat norovirus, a virus that causes up to 21 million cases, 109,000 hospitalizations and 900 deaths annually in the United States. The June data, from Vaxart’s Phase Ib trial in subjects aged 55-80, demonstrated that Vaxart’s oral

norovirus vaccine candidate stimulated a robust immune response across all doses, with a dose-dependent production of IgA antibody secreting cells.
    - Results were consistent with previous studies conducted in younger populations, which is typically not the case, as the immune system often weakens with age, and older people tend to have less robust responses to vaccination than younger people.

- Vaxart also reported in June 2022 on top-line data from a Phase I trial evaluating different boosting regimens with Vaxart's oral norovirus vaccine candidate. The data showed that the candidate was able to successfully boost antibody responses, with antibody responses trending better with administration spread out over three months versus a shorter interval.

  This data and previous results support the continued development of Vaxart's oral norovirus vaccine candidate in adult populations, including elderly adults, and add to the growing body of evidence supporting its clinical utility.

Planned Clinical Milestones in the COVID-19 and Norovirus Pipelines

- Selection of COVID-19 vaccine constructs expected in Q4 2022 with clinical trials to start in 1H 2023.
- After determining which COVID-19 vaccine candidate to advance, Vaxart anticipates updating its plans for its India trials.
- Planned start of Phase II trial of Vaxart's bivalent norovirus vaccine candidate in Q4 2022.
- Top-line data from ongoing Phase II norovirus challenge study expected at the end of Q1 2023 or early Q2 2023.
- Omicron Human Challenge Trial in the UK starting in the 2H 2023 using selected vaccine construct.

Financial Results for the Three Months Ended June 30, 2022

- Vaxart ended the second quarter with cash, cash equivalents and available-for-sale debt securities of $131.5 million, compared to $157.0 million as of March 31, 2022. The decrease was primarily due to $25.9 million of cash used in operations. The Company's existing funds are expected to be sufficient to fund its operations into the second half of 2023.

- The Company reported a net loss of $29.4 million for the second quarter of 2022, compared to $16.1 million for the second quarter of 2021. Net loss per share for the second quarter of 2022 was $0.23, compared to a net loss of $0.13 per share in the second quarter of 2021. The increase in net loss was primarily due to a significant increase in research and development expenses.

- Research and development expenses were $19.9 million for the second quarter of 2022, compared to $10.7 million for the second quarter of 2021. The increase was mainly due to increases in headcount and related costs, and in manufacturing and clinical trial expenses related to our COVID-19 and norovirus vaccine candidates.

- General and administrative expenses were $9.3 million for the second quarter of 2022, compared to $5.2 million for the second quarter of 2021. The increase was mainly due to the cost of settling shareholder litigation in June and increases in legal and professional costs and in headcount and related 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 2022 today, beginning at 4:30 p.m. ET.

The conference call can be accessed using the following information:

Webcast: Click here
Date: Monday, August 8, 2022 – 4:30 p.m. ET
Domestic: 877-407-0832
International: 201-689-8433
Conference ID: 13731641

Investors may submit written questions in advance of the conference call to ir@vaxart.com. A replay of the webcast will be available on the Company'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 tablets that can be stored and shipped without refrigeration and eliminate the risk of needle-stick injury. Vaxart believes that its proprietary tablet 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 tablet vaccines designed to protect against coronavirus, norovirus, 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.

About Norovirus
Norovirus is the leading cause of acute gastroenteritis that produces vomiting and diarrhea among people of all ages. The World Health Organization's (WHO) Product Development for Vaccines Advisory Committee has identified norovirus as a priority disease for vaccine development. The virus contributes up to 21 million cases, 109,000 hospitalizations and 900 deaths annually in the United States. Children under the age of 5 and adults over the age of 65 years are especially vulnerable to norovirus infection, with 15% of the children and 7.5% of the adults infected annually. Norovirus also has negative health economic impacts, which has been estimated to cost $10.65 billion annually in the United States alone.

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, 2022 (Unaudited)	December 31, 2021 (1)
	(in thousands)	
Assets		
Cash and cash equivalents	$ 91,468	$ 143,745
Investments in debt securities	40,018	38,952
Accounts receivable	—	71
Prepaid and other assets	13,742	3,499
Property and equipment, net	9,336	6,601
Right-of-use assets, net	12,433	13,168
Intangible assets, net	9,949	10,624
Goodwill	4,508	4,508
Total Assets	$ 181,454	$ 221,168
Liabilities and stockholders' equity		
Accounts payable	$ 5,007	$ 3,872
Operating lease liabilities	12,679	13,008
Liability related to sale of future royalties	12,033	11,522
Accrued and other liabilities	8,641	5,235
Total liabilities	38,360	33,637
Stockholders' equity	143,094	187,531
Total liabilities and stockholders' equity	$ 181,454	$ 221,168

(1) Derived from the audited consolidated financial statements of Vaxart, Inc. for the year ended December 31, 2021, included on the Form 10-K filed with the Securities and Exchange Commission on February 24, 2022.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
	(in thousands, except share and per share amounts)			
Revenue	$ —	$ 112	$ 85	$ 618

Operating expenses:				
Research and development	19,926	10,737	38,129	20,810
General and administrative	9,321	5,150	15,979	11,094
Total operating expenses	29,247	15,887	54,108	31,904
Loss from operations	(29,247)	(15,775)	(54,023)	(31,286)
Other income and (expenses), net	(168)	(311)	(473)	(769)
Loss before income taxes	(29,415)	(16,086)	(54,496)	(32,055)
Provision for income taxes	15	30	35	68
Net loss	$ (29,430)	$ (16,116)	$ (54,531)	$ (32,123)
Net loss per share, basic and diluted	$ (0.23)	$ (0.13)	$ (0.43)	$ (0.27)
Shares used in computing net loss per share, basic and diluted	126,428,298	120,925,570	126,111,777	118,174,099

Source: Vaxart, Inc.