Vaxart Provides Business Update and Reports Third Quarter 2022 Financial Results

November 8, 2022

Growing body of clinical evidence supports transformational potential of Vaxart's oral vaccine platform

Clinical trial programs on track for reporting key data milestones

Ended third quarter with $114.8 million in cash, cash equivalents and marketable securities

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

SOUTH SAN FRANCISCO, Calif., Nov. 08, 2022 (GLOBE NEWSWIRE) -- Vaxart, Inc. (NASDAQ: VXRT) issued its business update today for the third quarter of 2022, during which the Company made significant progress on its oral vaccine candidates.

"We are encouraged by the growing body of clinical evidence that supports the transformational potential of Vaxart's oral pill vaccine platform with positive data from both our leading programs, COVID-19 and norovirus," said Andrei Floroiu, Vaxart's Chief Executive Officer.

Dr. James Cummings, Vaxart's Chief Medical Officer, said, "During the third quarter, we announced positive top-line Phase II clinical study results for our Wuhan S-only COVID-19 pill vaccine candidate. These data are very encouraging, showing that Vaxart's vaccine candidate can trigger both serum and mucosal immunity and can boost responses in those having previously received mRNA vaccines. These results highlight the potential of mucosal immunity through remarkable cross-reactive responses. Our Wuhan vaccine candidate showed equally strong activity towards Omicron, something not seen with injectable vaccines. Additionally, we remain confident in our norovirus program, with encouraging recent data from our trial in elderly adults, which suggests similar activity as seen in younger adults. This is not often expected with vaccines and offers another potential source of differentiation for our oral pill vaccine candidate."

"Norovirus is a significant opportunity for Vaxart – with a $10 billion economic burden of disease in the U.S. alone and no approved vaccine against a disease that disproportionately affects older and pediatric populations. Vaxart has generated compelling clinical data across five norovirus trials. We are eagerly anticipating the upcoming results of our norovirus human challenge study at the end of the first quarter or at the start of the second quarter of 2023. We are increasing our focus on the norovirus program, with two additional clinical trials planned to start in the next six months," Mr. Floroiu added.

Vaxart's oral vaccine platform has the potential to transform the vaccination paradigm globally, by providing significant advantages compared to injectable vaccines. One of the Company's vaccine candidates was shown to be as protective as a leading injectable against a pandemic respiratory virus in a human flu challenge study. In addition, data from multiple programs suggest that by triggering mucosal immunity the platform could provide cross-reactivity against variants, reduce viral transmission, offer long duration of protection and offer a more tolerable safety profile.

"These potential advantages are in addition to those offered by the oral pill format, which could allow more people to be vaccinated painlessly, easily and faster all around the world. We are in a position to aggressively pursue our two leading clinical programs and are very excited looking into 2023 at the significant milestones for both programs – the readouts of two human challenge studies for norovirus and COVID-19," Mr. Floroiu concluded.

Recent Business Highlights

COVID-19 Vaccine Developments

- In September 2022, Vaxart reported positive top-line data from its Phase II COVID-19 trial supporting broad potential of the Company's COVID-19 vaccine candidates to tackle the challenges of an evolving virus that continues to overcome the immune protection provided by approved vaccines.
  - Vaxart is the only company with a mucosal vaccine candidate for COVID-19 that has produced Phase II clinical data that shows it stimulates mucosal immunity.
- In July 2022, the Company updated Phase I data showing Vaxart's Spike/Nucleocapsid (S+N) candidate stimulated SARS-CoV-2-specific IgA antibodies in saliva and nasal samples from human subjects and was cross-reactive to many different coronaviruses that are more divergent than circulating variants of SARS-CoV-2.

Norovirus Vaccine Developments

- In June 2022, Vaxart reported positive top-line data about its norovirus vaccine candidate.
  - The 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.
  - 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.

Corporate Updates

- Bolstered management and Board with three significant additions:
  - In August, named Ray Stapleton, Ph.D. as Chief Technology Officer.
    - Dr. Stapleton joins Vaxart from Genocea, where he served as CTO and Executive Vice President, working to develop next generation personalized immunotherapies in the forms of vaccines and cell therapies. His prior experience includes senior manufacturing and technical operations roles at a number of biotech companies after spending 15 years in positions of increasing responsibility in Merck and Company's manufacturing organization.
  - Also in August, appointed Elaine J. Heron, Ph.D. and W. Mark Watson to the Company's Board of Directors.
    - Dr. Heron currently serves on the boards of BioMarin Pharmaceutical, Inc., Palvella Therapeutics, Inc., Visgenx, Inc., and Watershed Medical, Inc. She also serves as an advisor to Kyto Technology and Life Science, Inc. Dr. Heron has over 35 years of experience in the life science research and biotech development sectors.
    - Mr. Watson is a Certified Public Accountant with more than 40 years of experience in public accounting and auditing, having spent his entire career from January 1973 to June 2013 at Deloitte Touche Tohmatsu and its predecessor, most recently as Central Florida Marketplace Leader.

Planned Clinical Milestones in the COVID-19 and Norovirus Pipelines

Vaxart continues to make progress on its expected milestones:

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

Financial Results for the Three Months Ended September 30, 2022

- Vaxart ended the third quarter with cash, cash equivalents and available-for-sale debt securities of $114.8 million, compared to $131.5 million as of June 30, 2022. The decrease was primarily due to $14.6 million of cash used in operations.

- The Company reported a net loss of $29.3 million for the third quarter of 2022, compared to $17.6 million for the third quarter of 2021. Net loss per share for the third quarter of 2022 was $0.23, compared to a net loss of $0.14 per share in the third quarter of 2021. The increase in net loss was primarily due to a significant increase in research and development costs.

- Research and development expenses were $22.5 million for the third quarter of 2022, compared to $12.4 million for the third 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 $7.0 million for the third quarter of 2022, compared to $5.0 million for the third quarter of 2021. The increase was mainly due to increases in headcount and related costs and in legal and professional costs.

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 2022 today, beginning at 4:30 p.m. ET.

The conference call can be accessed using the following information:

Webcast: Click here
Date: Tuesday, November 8, 2022 – 4:30 p.m. ET
Domestic: 888-437-3179
International: 862-298-0702
Conference ID: 13733692

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.

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

	September 30, 2022	December 31, 2021
	(Unaudited)	(1)
	(in thousands)	
Assets		
Cash and cash equivalents	$ 50,768	$ 143,745
Investments in debt securities	63,999	38,952
Accounts receivable	-	71
Prepaid and other assets	7,536	3,499
Property and equipment, net	12,280	6,601
Right-of-use assets, net	26,607	13,168
Intangible assets, net	9,611	10,624
Goodwill	4,508	4,508
Total assets	$ 175,309	$ 221,168
Liabilities and stockholders’ equity		
Accounts payable	$ 7,916	$ 3,872
Operating lease liabilities	22,168	13,008
Liability related to sale of future royalties	12,358	11,522
Accrued and other liabilities	10,560	5,235
Total liabilities	53,002	33,637
Stockholders’ equity	122,307	187,531
Total liabilities and stockholders’ equity	$ 175,309	$ 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 September 30,	Nine Months Ended September 30,

	2022	2021	2022	2021
	(in thousands, except share and per share amounts)			
Revenue	$ -	$ 200	$ 85	$ 818
Operating expenses:				
Research and development	22,466	12,409	60,595	33,219
General and administrative	6,960	5,042	22,939	16,136
Total operating expenses	29,426	17,451	83,534	49,355
Loss from operations	(29,426)	(17,251)	(83,449)	(48,537)
Other income and (expense), net	133	(311)	(340)	(1,080)
Loss before income taxes	(29,293)	(17,562)	(83,789)	(49,617)
Provision for income taxes	16	21	51	89
Net loss	$ (29,309)	$ (17,583)	$ (83,840)	$ (49,706)
Net loss per share, basic and diluted	$ (0.23)	$ (0.14)	$ (0.66)	$ (0.41)
Shares used in computing net loss per share, basic and diluted	126,889,718	123,984,141	126,374,424	120,110,780

Source: Vaxart, Inc.