Vaxart Provides Business Update and Reports First Quarter 2022 Financial Results

May 9, 2022

Data from COVID-19 Phase II study and norovirus Phase IB study are expected in 2022

Ended the 1st Quarter with $157.0 million in cash, cash equivalents and marketable securities

SOUTH SAN FRANCISCO, Calif., May 09, 2022 (GLOBE NEWSWIRE) -- Vaxart, Inc. (NASDAQ: VXRT) issued its business update today for the first quarter of 2022, reporting continued progress on its oral vaccine candidates.

“We continue to make progress on our pipeline of potentially game changing oral tablet vaccine programs, with norovirus studies that will report results in the second quarter as well as our Phase II study for our COVID-19 program that will report results from the first part of the planned two-part study in the third quarter,” said Andrei Floroiu, Vaxart’s Chief Executive Officer. “Vaxart’s oral vaccine technology may address many public health challenges, including rapidly emerging COVID-19 variants because the cross-reactive nature of mucosal IgA response increases the likelihood of variant coverage.”

Recent Business Highlights

Preclinical and Clinical

COVID-19 Vaccine Developments

- In February 2022, Vaxart’s COVID-19 non-human primate study was published by bioRxiv. The study demonstrates that Vaxart’s S-only COVID-19 vaccine candidate, now being studied by Vaxart in Phase II trials, generated antibodies to the original COVID-19 virus strain and to the Beta, Delta, Alpha and Gamma variants of SARS-CoV-2 in the serum and nasal mucosa of non-human primates (NHPs).
    - Vaxart’s S-only candidate is believed to be the first vaccine candidate to demonstrate neutralizing antibody responses in mucosal sites, which is where primary infection occurs.
    - The candidate also induced a 1000-fold increase in nasal IgA responses to the variants, which may reduce community transmission.
- In April 2022, an article was published in *Vaccines* that highlights the potential of Vaxart’s oral tablet vaccine platform to transform vaccine strategies for respiratory viral pathogens.
    - The article discusses one of the chief advantages of oral vaccines, which is to induce an immune response in the mucosa, the first line of defense against invading respiratory pathogens.
    - The article also outlines how Vaxart’s oral tablet vaccine candidates are very well suited to transform global vaccination strategies by potentially removing cold-chain requirements and the necessity of administration by healthcare professionals, enabling rapid deployment of new vaccines to address novel pathogens.
- Vaxart now expects data from the dose selection portion of its two part dose-ranging and preliminary efficacy Phase II clinical trials of its oral tablet COVID-19 vaccine candidate to be available in the third quarter of 2022. This is an open-label dose and age escalation lead-in segment in naïve and previously vaccinated subjects.

Norovirus Vaccine Developments

- Vaxart has dosed all subjects in its Phase IB placebo-controlled, dose-ranging, repeat dose trial of its oral norovirus vaccine candidate in elderly subjects aged 55 to 80 years. This study is designed to evaluate the safety and immunogenicity of Vaxart's GI.1 vaccine candidate and results will be available in the second quarter of 2022.
- Vaxart launched a Phase II GI.1 norovirus challenge study in January 2022 to evaluate the safety and clinical efficacy of its oral vaccine candidate. This double blind, placebo-controlled study uses a safe, well-characterized challenge with norovirus GI.1 of volunteers vaccinated with our monovalent norovirus vaccine candidate. The study will yield data on efficacy, safety, and immune correlates of protection, with data expected to be reported in the first quarter of 2023.

2022 Planned Clinical Milestones

- Data from the first part of Vaxart’s two-part Phase II trial of its COVID-19 vaccine candidate is expected to be available in the third quarter of 2022.
- Vaxart’s international Phase IB and Phase II COVID-19 trials, including a placebo-controlled efficacy trial in India, are

anticipated to begin this year.

- Results from Vaxart's Phase IB trial of its norovirus vaccine candidate in elderly subjects are expected in the second quarter of 2022.

Financial Results for the Three Months Ended March 31, 2022

- Vaxart ended the first quarter with cash, cash equivalents and available-for-sale debt securities of $157.0 million, compared to $182.7 million as of December 31, 2021. The decrease was primarily due to $25.1 million of cash used in operations.
- The Company reported a net loss of $25.1 million for the first quarter of 2022, compared to $16.0 million for the first quarter of 2021. Net loss per share for the first quarter of 2022 was $0.20, compared to a net loss of $0.14 per share in the first quarter of 2021. The increase in net loss was primarily due to a significant increase in research and development expenses.
- Revenue for the first quarter of 2022 was $85,000, compared to $506,000 in the first quarter of 2021. The decrease was due to lower royalty revenue from sales of Inavir in Japan.
- Research and development expenses were $18.2 million for the first quarter of 2022, compared to $10.1 million for the first 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 $6.7 million for the first quarter of 2022, compared to $5.9 million the first quarter of 2021. The increase was mainly due to an increase in headcount and related costs.

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

	March 31, 2022 (Unaudited)	December 31, 2021 (1)
	(in thousands)	
Assets		
Cash and cash equivalents	$ 123,404	$ 143,745
Investments in debt securities	33,603	38,952
Accounts receivable	81	71
Prepaid and other assets	7,997	3,499
Property and equipment, net	7,629	6,601
Right-of-use assets, net	12,870	13,168
Intangible assets, net	10,286	10,624
Goodwill	4,508	4,508
Total assets	$ 200,378	$ 221,168
Liabilities and stockholders' equity		
Accounts payable	$ 4,017	$ 3,872
Operating lease liabilities	12,916	13,008
Liability related to sale of future royalties	11,791	11,522
Accrued and other liabilities	5,289	5,235
Total liabilities	34,013	33,637
Stockholders' equity	166,365	187,531
Total liabilities and stockholders' equity	$ 200,378	$ 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 March 31,	
	2022	2021
	(in thousands, except share and per share amounts)	
Revenue	$ 85	$ 506
Operating expenses:		
Research and development	18,203	10,073
General and administrative	6,658	5,944
Total operating expenses	24,861	16,017
Loss from operations	(24,776)	(15,511)
Other income (expense), net	(305)	(458)
Loss before income taxes	(25,081)	(15,969)
Provision for income taxes	20	38
Net loss	$ (25,101)	$ (16,007)
Net loss per share, basic and diluted	$ (0.20)	$ (0.14)
Shares used in computing net loss per share, basic and diluted	125,795,255	115,422,628

Source: Vaxart, Inc.