Vaxart Provides Business Update and Full Year 2022 Financial Results

March 15, 2023

Prioritizing oral bivalent norovirus candidate, one of the most advanced norovirus vaccines in development

Will continue preclinical development of novel COVID-19 vaccine constructs to enhance cross-reactivity and potency with the goal of developing a pan-betacoronavirus vaccine

Portfolio prioritization extends cash runway into Q2 2024

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

SOUTH SAN FRANCISCO, Calif., March 15, 2023 (GLOBE NEWSWIRE) -- Vaxart, Inc. (NASDAQ: VXRT) issued its business update today for the full year 2022, during which Vaxart announced it is prioritizing development of the Company's bivalent norovirus candidate.

"After completing six norovirus clinical trials, we are encouraged by the robust immunogenicity data in both young adult and elderly populations and the encouraging safety profile of our oral norovirus program. We are therefore focusing our resources on our bivalent norovirus candidate and are excited about the two important upcoming data readouts from this program over the next two quarters. We believe this is the best strategy for advancing our oral vaccine platform while positioning Vaxart for future success," said Andrei Floroiu, Vaxart's Chief Executive Officer. "There currently is no approved vaccine against norovirus, which sickens approximately 21 million people each year in the U.S. alone[1] and is estimated to be responsible for more than $10 billion in annual disease burden[2]. The global annual burden is estimated at over $60 billion[3]. Vaxart is focused on providing an oral tablet vaccine to address this significant unmet need."

Recent Business Highlights

Norovirus Vaccine Developments

- As part of the prioritization of its norovirus program, Vaxart is expanding the ongoing Phase 2 GI.1 norovirus challenge study to include additional challenge cohorts. Vaxart believes the expanded dataset will improve the likelihood of identifying a correlate of protection between immune responses to the vaccine and a reduction in risk of norovirus infection and / or acute gastroenteritis.

- Vaxart expects that identifying novel correlates of protection may reduce the size and duration of a Phase 3 trial. With the inclusion of the additional cohorts, Vaxart expects to report topline efficacy data from its Phase 2 challenge study in Q3 2023.

- In February 2023, Vaxart initiated a Phase 2 dose-ranging study of its bivalent norovirus oral vaccine candidate and expects to report topline data from this study in mid-2023.

- In December 2022, Vaxart announced it will commence a new study of Vaxart's oral norovirus vaccine candidate focused on protecting breastfeeding mothers and their infants. The study has received significant funding and support from the Bill & Melinda Gates Foundation ("Gates Foundation") and is expected to be initiated in 2023.

COVID-19 Vaccine Development

- Vaxart continues to conduct preclinical development of novel constructs for its COVID-19 oral vaccine candidate. Based on the mucosal cross-reactivity data seen in Vaxart's clinical studies of its COVID-19 vaccine candidates, Vaxart believes it may be able to create an oral pan-betacoronavirus vaccine, which may provide improved protection against SARS-CoV-2 as the virus continues to evolve as well as protection against other types of betacoronaviruses, which include SARS-CoV-1 and Middle East respiratory syndrome coronavirus (MERS-CoV).

- Vaxart is postponing further COVID-19 clinical trials, including the Omicron Human Challenge Trial in the U.K. As Vaxart advances new vaccine candidates, it will determine the best development plan.

Corporate Updates

- Consistent with its prioritization, Vaxart reduced its workforce by 27 percent in Q1 2023.

- Vaxart has access to all cash and other deposits previously held at Silicon Valley Bank (SVB), and has decided to move

these deposits to larger financial institutions. The Company does not anticipate any material impact as a result of SVB's circumstances.

- Vaxart expects its cash on hand will extend into Q2 2024.
- Vaxart remains engaged in discussions with regulatory agencies, governments, non-governmental organizations and other potential strategic parties to maximize the value for all its vaccine candidates.
- In December 2022, Vaxart named Phillip Lee as Chief Financial Officer.
    - Mr. Lee has almost 15 years of strategic finance and advisory experience in the biotechnology industry. During his career, he has helped raise over $1 billion of capital and worked on more than $20 billion of M&A transactions, including partnerships, asset acquisitions, mergers, spin-offs and royalty monetization. Most recently, he was CFO and Chief Operating Officer at Clover Biopharmaceuticals and prior to that held finance leadership positions at several biotechnology companies.

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

- Report topline data from the ongoing Phase 2 challenge study of Vaxart's monovalent norovirus vaccine candidate in Q3 2023.
- Report topline data from the ongoing Phase 2 dose-ranging study of Vaxart's bivalent norovirus vaccine candidate in mid-2023.
- Initiate 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 Full Year Ended December 31, 2022

- Vaxart ended the year with cash, cash equivalents, restricted cash and marketable securities of $95.7 million.
- Vaxart reported a net loss of $107.8 million for the full year 2022, compared to $70.5 million for the full year 2021. Net loss per share for 2022 was $0.84, compared to $0.58 for 2021.
- Revenue in 2022 was $0.1 million, compared to $0.9 million in 2021. The decrease was principally due to lower royalty revenue from sales of Inavir in Japan.
- Research and development expenses were $81.1 million for 2022, compared to $48.7 million for 2021. The increase was mainly due to a larger headcount and related costs, and in higher manufacturing and clinical trial expenses related to our norovirus and COVID-19 vaccine candidates.
- General and administrative expenses were $29.4 million for 2022, compared to $21.9 million for 2021. The increase was mainly due to a larger headcount and related costs and higher 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 full year 2022 today, beginning at 4:30 p.m. ET.

The conference call can be accessed using the following information:
Webcast: Click here
Date: Wednesday, March 15, 2023 – 4:30 p.m. ET
Domestic: 888-407-0832
International: 201-689-8433
Conference ID: 13735958

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.

References

1) CDC Website Norovirus Section

2) Potential Clinical and Economic Value of Norovirus Vaccination in the Community Setting, Bartsch S et al., AJPM 2021

3) Global Economic Burden of Norovirus, Bartsch S et al., PLOS ONE 2016

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 vaccine candidates designed to protect against norovirus, coronavirus, seasonal influenza, and respiratory syncytial virus (RSV), as well as a therapeutic vaccine candidate 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 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

	December 31, 2022	December 31, 2021
	(Unaudited)	(1)
	(in thousands)	
Assets		
Cash, cash equivalents and restricted cash (2)	$ 46,013	$ 143,745
Investments in marketable debt securities	49,704	38,952
Accounts receivable	20	71
Prepaid and other assets	7,282	3,499
Property and equipment, net	15,585	6,601
Right-of-use assets, net	25,715	13,168
Intangible assets, net	5,020	10,624
Goodwill	4,508	4,508
Total Assets	$ 153,847	$ 221,168
Liabilities and stockholders' equity		
Accounts payable	$ 5,514	$ 3,872
Deferred grant revenue	2,000	-

Accrued and other liabilities	8,315	5,235
Operating lease liabilities	21,705	13,008
Liability related to sale of future royalties	5,716	11,522
Total liabilities	43,250	33,637
Stockholders' equity	110,597	187,531
Total liabilities and stockholders' equity	$ 153,847	$ 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.

(2) Cash, cash equivalents and restricted cash includes $2.0 million of restricted cash.

Vaxart, Inc.
Condensed Consolidated Statements of Operations

	Year Ended December 31,	
	2022	**2021**
	(Unaudited)	**(1)**
	(in thousands, except share and per share amounts)	
Revenue	$ 107	$ 892
Operating expenses:		
Research and development	81,054	48,749
General and administrative	29,386	21,890
Impairment of intangible assets	4,254	3,005
Total operating expenses	114,694	73,644
Loss from operations	(114,587)	(72,752)
Other income and (expenses), net	(64)	(1,400)
Gain on remeasurement of future royalty liability	6,960	3,789
Loss before income taxes	(107,691)	(70,363)
Provision for income taxes	67	107
Net loss	$ (107,758)	$ (70,470)
Net loss per share, basic and diluted	$ (0.84)	$ (0.58)
Shares used in computing net loss per share, basic and diluted	127,683,813	121,453,723

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Source: Vaxart, Inc.