Vaxart Reports First Quarter 2021 Financial Results and Provides Business Update

May 3, 2021

- *Vaxart to advance three oral tablet COVID-19 vaccine candidates to the clinic: VXA-CoV2-1 (includes both the S and the N proteins) into Phase II and two S-only constructs into Phase I/II*
- *Four clinical trials of the oral norovirus vaccine candidate to be initiated in 2021*
- *Cash, cash equivalents, and marketable securities of $177.3 million as of March 31, 2021*

SOUTH SAN FRANCISCO, Calif., May 03, 2021 (GLOBE NEWSWIRE) -- Vaxart, Inc. (Nasdaq: VXRT), a clinical-stage biotechnology company developing oral vaccines that are administered by room-temperature stable tablet rather than by injection, today reported financial results for the first quarter ended March 31, 2021 and provided a corporate update. As part of this update, the Company announced that it plans to initiate several clinical and pre-clinical COVID-19 vaccine studies as it continues the development of its multivariant COVID-19 vaccine candidate portfolio.

“The recent results of a poll we commissioned suggested that as many as 19 million more Americans would decide to get vaccinated against COVID-19 if the vaccine was administered as a pill instead of a needle injection — a number we expect to be much higher worldwide, particularly given the distribution advantages of a room-temperature stable tablet. That alone could potentially make a significant global impact,” said Andrei Floroiu, Chief Executive Officer of Vaxart.

“Additionally, we expect our vaccine to have a different profile – on safety, tolerability, and immunogenicity – than those of injectable vaccines,” added Floroiu. “Our vaccines employ a novel mechanism of action — validated by clinical results against flu — that is very different than those of injectable vaccines, thus offering the potential to complement, if not replace, injectable vaccines.”

Recent Business Highlights:

Clinical and Pre-Clinical:

COVID-19

- Vaxart announced the results from its VXA-CoV2-1 Phase I clinical trial in 35 subjects:
    - Generally well-tolerated with no severe adverse events reported.
    - Triggered multiple immune responses against SARS-CoV2 antigens, including:
        - Inducing a high percentage of responding CD8+ T cells against both Spike (S) and Nucleoprotein (N) proteins, which may provide long-lasting cross-reactive protection against current and future strains of the virus due to the vaccine’s more conserved target.
        - An increase in proinflammatory Th1 cytokines, which are responsible for orchestrating the immune response to viral infection.
    - As previously announced, later today Vaxart will provide new data comparing the T-cell responses induced by its VXA-CoV2-1 vaccine with those of other vaccines. The Company will also present new mucosal antibody data and review the recent Phase 1 clinical results that suggest VXA-CoV2-1 is potentially protective against new and future COVID-19 strains due to the vaccine’s more conserved target.
- Next steps
    - Pre-clinical studies:
        - Several studies with our S and N and S-only constructs in multiple animal models are ongoing or will begin soon, testing attributes of our vaccine candidates such as impact on infection, illness, shedding, transmission, and cross-variant protection.
    - Clinical studies:
        - A Phase II trial of VXA-CoV2-1, our vaccine encoding both the S and the N proteins, is expected to start mid-year 2021 instead of 2Q. The delay is due to manufacturing issues at the Baltimore contract manufacturing facility, the same facility where other COVID-19 vaccine manufacturers have also reported issues.
        - Manufacturing of our vaccines is currently underway at the Company’s other manufacturing partner, and at

our own GMP facility. We are also evaluating additional manufacturing partners both in the U.S. and abroad.

- Phase I/II studies of two S-only vaccine constructs targeting different variants are planned to begin in 3Q 2021.
- Boosting studies with previously vaccinated or infected subjects are also planned for 2H 2021.
- Trials in India and Latin America are expected to initiate in 2021.

Norovirus:

Norovirus is a highly infectious illness that affects around 20 million Americans annually, and it has an annual economic impact of approximately $10.5 billion in the United States. Vaxart plans to progress its oral norovirus vaccine program with the initiation of four clinical trials in 2021:

- A booster dose in a subset of subjects who participated in the prior Phase 1b bivalent study will assess the safety, tolerability and immunogenicity of this dose approximately 18 months after initial dosing. Dosing is completed, and results will be reported by mid-year 2021.
- A booster ranging trial designed to assess the safety, tolerability, immunogenicity, and efficacy of 2-dose vaccination schedule (4, 8, and 12 weeks apart) started recently.
- An age escalation trial in subjects over 65 years old designed to assess the safety, tolerability, immunogenicity, and efficacy of 2 dose levels of vaccine with a 2-dose vaccination schedule (4 weeks apart) planned to start in 3Q 2021.
- A Phase 2 challenge study is planned to start later this year.

Vaxart also released data from a poll it commissioned, which surveyed 1,500 subjects and found that as many as an additional 19 million Americans would decide to get vaccinated against COVID-19 if they had an oral tablet option.

- The poll suggested as many as an additional 4 million Black, 3 million rural, 2 million Hispanic and 1.5 million Asian Americans would take a pill COVID-19 vaccine.
- 7 in 10 said they would prefer taking a vaccine pill rather than getting injected with a vaccine.

Corporate:

- Vaxart appointed David Wheadon, M.D., to its Board of Directors. Dr. Wheadon is a health policy leader and physician with more than three decades of global experience in the pharmaceutical industry coordinating the interests of public companies, trade groups, and regulators.
- Rajesh Kapoor, Ph.D., joined Vaxart as the SVP Quality. Dr. Kapoor brings 30 years of domestic and international experience with small and large companies covering aseptic and non-aseptic Quality Operations encompassing vaccines, biologics, drugs, APIs, clinical Quality Assurance, and radiopharmaceuticals.

Cash, Cash Equivalents, and Marketable Securities Balance:

- Vaxart ended the quarter with cash, cash equivalents, and available-for-sale debt securities of $177.3 million, compared to $126.9 million as of December 31, 2020. The increase was primarily due to receipts of $65.7 million from the Company's $250 million at-the-market facility entered into in October 2020 and $1.9 million from the exercise of warrants and options, partially offset by $16.6 million of cash used in operations and $0.6 million spent on property and equipment.

Financial Results for the Three Months Ended March 31, 2021:

- Vaxart reported a net loss of $16.0 million for the first quarter of 2021 compared to $1.3 million for the first quarter of 2020. Net loss per share for the first quarter of 2021 was $0.14, compared to a net loss of $0.02 in the first quarter of 2020. The increase in net loss per share was due to the increase in net loss partially offset by the increase in the weighted average number of shares outstanding.
- Revenue for the first quarter of 2021 was $506,000 compared to $2.9 million in the first quarter of 2020. The decrease was principally due to a reduction in royalty revenue related to Inavir sales in Japan as a result of abnormally low incidences of seasonal influenza.
- Research and development expenses were $10.1 million for the first quarter of 2021 compared to $1.5 million for the first quarter of 2020. The increase was mainly due to manufacturing and clinical trial expenses related to the COVID-19 and norovirus vaccine candidates.
- General and administrative expenses were $5.9 million for the first quarter of 2021 compared to $2.0 million for the first quarter of 2020. The increase was mainly due to higher legal and insurance expenses, and 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. Its 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 immuno-oncology indication. Vaxart has filed broad domestic and international patents 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 pre-clinical and clinical trials, commercialization agreements and licenses, 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," "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 and clinical results and trial data (including plans with respect to the COVID-19 vaccine product candidates); expectations relating to Vaxart's relationship with Emergent BioSolutions, Inc., Kindred Biosciences and Attwill Medical Solutions Sterilflow, LP, including their ability to produce cGMP vaccines and the timing thereof; Vaxart's expectations with respect to the important advantages it believes its oral vaccine platform can offer over injectable alternatives, particularly for coronaviruses such as SARS, MERS and SARS-CoV-2; expectations regarding Vaxart's ability to develop effective vaccines against new and emerging variant strains; expectations regarding the timing and nature of future developments and announcements, including those related to trials and studies; the potential applicability of results seen in our preclinical studies or trials to those that may be seen in humans or clinical trials; the expected role of mucosal immunity in blocking transmission of COVID-19; and Vaxart's expectations with respect to the effectiveness of its product candidates, including Vaxart's potential role in mitigating the impact of COVID-19. 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, including the ongoing COVID-19 pandemic; 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
(in thousands)

	March 31, 2021 (Unaudited)	December 31, 2020 (1)
Assets		
Cash and cash equivalents	$ 157,311	$ 126,870
Investments in debt securities	19,939	—
Accounts receivable	700	334
Prepaid and other assets	4,393	1,699
Property and equipment, net	2,245	1,480
Right-of-use assets, net	6,350	6,838
Intangible assets, net	14,928	15,361
Total assets	$ 205,866	$ 152,582

Liabilities and stockholders' equity		
Accounts payable	$ 4,638	$ 2,133
Accrued and other liabilities	3,298	4,908
Liability related to sale of future royalties	15,061	14,929
Operating lease liabilities	6,634	7,208
Total liabilities	29,631	29,178
Stockholders' equity	176,235	123,404
Total liabilities and stockholders' equity	$ 205,866	$ 152,582

(1) Derived from the audited consolidated financial statements of Vaxart, Inc. for the year ended December 31, 2020, included on the Form 10-K filed with the Securities and Exchange Commission on February 25, 2021

Vaxart, Inc.
Condensed Consolidated Statements of Operations
(Unaudited)
(in thousands, except share and per share amounts)

	Three Months Ended March 31,	
	2021	**2020**
Revenue	$ 506	$ 2,902
Operating expenses:		
Research and development	10,073	1,542
General and administrative	5,944	1,990
Restructuring costs	—	64
Total operating expenses	16,017	3,596
Loss from operations	(15,511)	(694)
Other income and (expenses), net	(458)	(450)
Provision for income taxes	(38)	(153)
Net loss	$ (16,007)	$ (1,297)
Net loss per share, basic and diluted	$ (0.14)	$ (0.02)
Shares used in computing net loss per share, basic and diluted	115,422,628	60,677,145

Source: Vaxart, Inc.