



Vaxart Reports Third Quarter 2020 Financial Results and Provides Business Update

November 12, 2020

Enrollment in Phase 1 for Oral COVID-19 Vaccine Trial Completed

Significant viral load reduction and strong antibody responses in COVID-19 hamster challenge model

Restarting the Norovirus program

SOUTH SAN FRANCISCO, Calif., Nov. 12, 2020 (GLOBE NEWSWIRE) -- Vaxart, Inc., a clinical-stage biotechnology company developing oral recombinant vaccines that are administered by tablet rather than by injection, today announced financial results for the third quarter of 2020 and provided a corporate update, including updates on its oral COVID-19 vaccine pre-clinical studies and clinical trials.

"To defeat the COVID-19 epidemic, we need not only effective vaccines, but effective vaccines that are easy to administer, store, and distribute. We need a practical global solution," said Andrei Floroiu, chief executive officer of Vaxart. "The strong pre-clinical data we generated and the clinical progress we have made strengthen our belief that our oral tablet COVID-19 vaccine will emerge as a global solution against the COVID-19 pandemic."

VXA-CoV2-1 is a single-dose COVID-19 tablet vaccine candidate that we believe can be conveniently distributed and administered without the need for cold-chain storage and distribution.

Unlike injectable vaccines, animal data indicate that VXA-CoV2-1 activates both systemic and mucosal immunity, a broader immune response that has the potential to offer superior protection against SARS-CoV-2. By leveraging over a decade's worth of work building Vaxart's platform technology, VXA-CoV2-1 is under investigation to assess its ability to provide durable immunity following a single dose with favorable tolerability.

Recent Business Highlights:

Pre-Clinical and Clinical Developments:

- Completed enrollment in the Company's Phase 1 study of VXA-CoV2-1, its oral tablet COVID-19 vaccine candidate.
- Reported COVID-19 Hamster Challenge Study data showing protection against COVID-19 in hamsters receiving two oral doses of Vaxart's oral vaccine. Animals were protected against systemic weight loss, lung weight gain, showed a 4-5 log reduction in lung viral load, and developed IgG titers above 10,000. Both oral and intranasal delivery of VXA-CoV2-1 (rAd-S-N) conferred similar protection against intranasal viral challenge on all these metrics.
- Posted *Preclinical studies of a recombinant adenoviral mucosal vaccine to prevent SARS-CoV-2 infection* to Biorxiv, which noted immunization with the vaccine candidate induced strong IgA response in the lungs of animals, indicative of a mucosal immune response.
- Restarted its Norovirus vaccine program with a booster study in subjects that were primed in the previously conducted Phase 1b Norovirus trial.

Manufacturing:

- Expanded collaboration with Kindred Biosciences for the manufacturing of our COVID-19 oral vaccine. Kindred's California plant will be responsible for scaling the COVID-19 clinical trial material into mid-size bioreactors and the Kansas plant will be responsible for manufacturing at 2000L scale in its single use bioreactors.
- Entered into a master services agreement with Attwill Vascular Technologies, LP for processing, lyophilizing, and tableting compounds for the Company's oral COVID-19 vaccine.

Corporate Developments:

Addition to the Board of Directors: In August, Vaxart appointed Karen J. Wilson to its Board of Directors. Ms. Wilson is a biopharmaceutical finance executive and board member with more than 30 years of industry and leadership experience in life sciences companies with relevant knowledge in finance, strategy, and risk management. She is a certified public accountant and holds a bachelor's degree in business from the University of California, Berkeley.

Financial Results for the Fiscal Period Ended September 30, 2020

- Vaxart reported a net loss of \$8.1 million for the third quarter of 2020 compared to \$5.3 million for the third quarter of 2019. The increase was mainly due to an increase in operating expenses. Net loss per share for the third quarter was \$0.08 in 2020 compared to \$0.32 in 2019, in part due to an increase in the number of shares outstanding.
- Vaxart ended the quarter with cash and cash equivalents of \$133.4 million compared to \$44.4 million as of June 30, 2020. The increase was primarily due to net proceeds of \$97.0 million for the issuance of common stock, partially offset by \$9.3 million of cash used in operations.

- Revenue for the third quarter was \$265,000 compared to \$454,000 in the third quarter of 2019. The decrease was principally due to a reduction in revenue from our contract with Janssen, for which activities were mostly completed between July 2019 and June 2020.
- Research and development expenses were \$4.6 million for the third quarter compared to \$3.7 million for the third quarter of 2019. The increase was mainly due to manufacturing expenses related to the COVID-19 vaccine candidate and higher stock-based compensation costs, partially offset by reductions in the cost of clinical trials for our norovirus vaccine candidate and in personnel costs after we ceased internal manufacturing as part of our December 2019 restructuring.
- General and administrative expenses were \$4.2 million for the third quarter compared to \$1.5 million for the third quarter of 2019. The increase was mainly due to higher legal fees and an increase in headcount, with higher stock-based compensation costs.

About Vaxart

Vaxart is a clinical-stage biotechnology company focused on developing oral tablet vaccines designed to generate mucosal and systemic immune responses that protect against a wide range of infectious diseases and have the potential to provide sterilizing immunity for diseases such as COVID-19. Vaxart believes that a room temperature stable tablet is easier to distribute, store and administer than injectable vaccines and may provide a significantly faster response to a pandemic than injectable vaccines, enabling a greater portion of the population to be protected. Vaxart's development programs include oral tablet vaccines that are designed to protect against coronavirus, norovirus, seasonal influenza and respiratory syncytial virus (RSV), as well as a therapeutic vaccine for human papillomavirus (HPV). For more information, please visit www.vaxart.com.

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 preclinical 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, KindredBio and AMS including their ability to produce bulk cGMP vaccines and the timing thereof; and Vaxart's expectations with respect to the important advantages it believes its oral vaccine platform can offer over injectable alternatives, particularly for mucosal pathogens such as norovirus, flu and RSV, as well as coronaviruses such as SARS, MERS and SARS-CoV-2. 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 recent outbreak of COVID-19; 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 Operation Warp Speed may not result in a positive financial impact on Vaxart's financial results 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, 2020	December 31, 2019
	(Unaudited)	(1)
	(in thousands)	
Assets		
Cash and cash equivalents	\$ 133,438	\$ 13,526
Accounts receivable	250	3,619
Prepaid and other assets	1,975	594

Property and equipment, net	662	210
Right-of-use assets, net	2,591	1,990
Intangible assets, net	15,794	17,093
Total assets	<u>\$ 154,710</u>	<u>\$ 37,032</u>

Liabilities and stockholders' equity

Accounts payable	\$ 1,871	\$ 852
Accrued and other liabilities	3,724	4,583
Liability related to sale of future royalties	14,706	16,332
Operating lease liabilities	<u>2,731</u>	<u>2,313</u>
Total liabilities	23,032	24,080
Stockholders' equity	<u>131,678</u>	<u>12,952</u>
Total liabilities and stockholders' equity	<u>\$ 154,710</u>	<u>\$ 37,032</u>

(1) Derived from the audited consolidated financial statements of Vaxart, Inc. for the year ended December 31, 2019, included on the Form 10-K filed with the Securities and Exchange Commission on March 19, 2020.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
<i>(in thousands, except share and per share amounts)</i>				
Revenue	<u>\$ 265</u>	<u>\$ 454</u>	<u>\$ 3,690</u>	<u>\$ 5,946</u>
Operating expenses:				
Research and development	4,616	3,713	11,272	11,249
General and administrative	4,190	1,455	10,076	4,856
Restructuring costs	<u>(952)</u>	<u>—</u>	<u>(849)</u>	<u>—</u>
Total operating expenses	<u>7,854</u>	<u>5,168</u>	<u>20,499</u>	<u>16,105</u>
Loss from operations	<u>(7,589)</u>	<u>(4,714)</u>	<u>(16,809)</u>	<u>(10,159)</u>
Other income and (expenses), net	(470)	(515)	(1,345)	(1,783)
Provision for income taxes	<u>(26)</u>	<u>(31)</u>	<u>(205)</u>	<u>(294)</u>
Net loss	<u>\$ (8,085)</u>	<u>\$ (5,260)</u>	<u>\$ (18,359)</u>	<u>\$ (12,236)</u>
Net loss per share, basic and diluted	<u>\$ (0.08)</u>	<u>\$ (0.32)</u>	<u>\$ (0.23)</u>	<u>\$ (0.96)</u>
Shares used in computing net loss per share, basic and diluted	<u>107,718,578</u>	<u>16,249,032</u>	<u>81,121,045</u>	<u>12,748,665</u>



Source: Vaxart, Inc.