Vaxart Provides Business Update and Reports Third Quarter 2021 Financial Results

November 4, 2021

Four clinical trials for COVID-19 and norovirus oral tablet vaccine candidates are currently ongoing

Company now operates two GMP manufacturing plants to support rapid clinical advancement of pipeline programs

Ended the quarter with $204 million in cash, cash equivalents and marketable securities

SOUTH SAN FRANCISCO, Calif., Nov. 04, 2021 (GLOBE NEWSWIRE) -- Vaxart, Inc. (NASDAQ: VXRT) issued its business update today for the third quarter of 2021, reporting strong forward momentum in developing its oral vaccine platform consisting of tablet vaccines that it believes may revolutionize public health.

During the third quarter, Vaxart started the first Phase II trial of its investigational COVID-19 oral tablet vaccine and dosed its first subjects. Vaxart expects the full data set from this study to be available in Q1 2022.

Duke University published the results of its study of Vaxart's COVID-19 vaccine candidate, finding that Vaxart's oral tablet vaccine reduced the airborne transmission of SARS-CoV-2 virus in a hamster preclinical model.

The Company also expanded its research and manufacturing capabilities, enhancing its ability to advance its pipeline of vaccine candidates.

"Vaxart made significant progress this quarter toward its goal of developing a next-generation oral tablet COVID-19 vaccine," said Andrei Floroiu, Vaxart's Chief Executive Officer. "We have started our United States Phase II trial and anticipate beginning international trials in the near future. This is an important milestone, as our candidate is the only oral COVID-19 vaccine to progress to Phase II trials in the U.S."

"Our view has been that an oral tablet vaccine could transform how the world is protected from COVID-19 and other infections because they are easy to distribute and administer. Now we added evidence suggesting the differentiated mucosal mechanism of action could be yet another improvement over injectable alternatives," added Mr. Floroiu.

"The progress we made in our vaccine research this quarter was significant," said Dr. Sean Tucker, Vaxart's founder and Chief Scientific Officer. "We already learned from an earlier human influenza challenge study that our oral flu vaccine candidate inhibited the shedding of viral RNA better than injectable vaccines. Our published hamster study showed that our vaccine candidate can reduce transmission of SARS-CoV-2, even when there is infection breakthrough in a vaccinated subject."

"The implications are significant because existing injected vaccines do not always protect against viral shedding and transmission to other people. A vaccine that reduces shedding and reduces the probability of infection could make a big difference in protecting lives and public health."

Recent Business Highlights

Corporate Developments

- Vaxart recently brought online its own GMP manufacturing facility and is now producing vaccines at two GMP plants. This has allowed the Company to manufacture all of the COVID-19 vaccine oral tablets for the clinical trials started and planned to start this year, and to begin manufacturing vaccines for its upcoming norovirus Phase II trials.
- Vaxart scaled up its research, quality and manufacturing capabilities, increasing its R&D employee headcount by more than 35% during the quarter.
- The Company created two advisory boards, the Scientific and Clinical Advisory Board and the Manufacturing and Quality Advisory Board, to provide expertise as the Company grows its scientific and manufacturing capabilities.
- Vaxart named Dr. James F. Cummings as its Chief Medical Officer. Dr. Cummings is a board-certified infectious disease physician with extensive experience in vaccine, drug and diagnostics development, and will help guide the Company's development of its vaccines.
- Widely respected biotech executive Dr. Julie Cherrington joined Vaxart's Board of Directors, deepening the pool of expertise on its board.

Preclinical and Clinical

Clinical COVID-19 Vaccine Developments

Vaxart made significant progress in Q3 2021 to advance its transformative approach to vaccines.

- Vaxart began dosing subjects in October for its Phase II clinical trial in the United States, which is expected to enroll 96

subjects.
    - The Company expects data from this study to be available during Q1 2022.
    - The study will be conducted with subjects split evenly between COVID-19 naïve and mRNA vaccinated subjects.
- During Q4 2021, Vaxart expects to start Phase Ib clinical testing in India.
- The Company expects to launch additional international clinical trials in 1H 2022.

Preclinical COVID-19 Vaccine Developments

- A Duke University-led study published in bioRxiv in October showed that Vaxart's investigational oral tablet vaccine candidate reduced the airborne transmission of SARS-CoV-2 virus in a hamster model.
    - These results are consistent with those from Vaxart's Phase II human flu challenge study, which showed that Vaxart's oral tablet flu vaccine was better at reducing shedding than the injectable flu vaccine comparator.
    - Vaxart's preclinical study also demonstrated that the Company's oral vaccine platform induces robust systemic and mucosal responses.
        - The study suggested that mucosal vaccines may protect not only vaccinated, but also unvaccinated animals.
- Vaxart will submit the results of its nonhuman primate study for publication in Q4 2021. Results from that study prompted Vaxart to move forward with its S-only vaccine candidate in Phase II clinical trials. This S-only vaccine candidate produced better antibody responses and cross-reactivity against all variants tested than Vaxart's S+N vaccine candidate.

Norovirus Vaccine Developments

Norovirus is a highly infectious illness that affects around 20 million Americans annually, with an annual economic impact of approximately $10.5 billion in the United States.

- Vaxart has almost completed enrollment in its Phase Ib placebo-controlled, dose-ranging, repeat dose trial investigating 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 vaccine candidate.
- The Company anticipates completing enrollment in its norovirus VXA-G1.1-104 study in Q4 2021.
- Vaxart is also conducting an additional norovirus vaccine study to evaluate the optimal timing for boost administration under VXA-NVV-105. This study has completed enrollment.
    - The Company expects initial data to be available from these studies in Q1 2022 and more complete data by Q2 2022.
- Vaxart is preparing to launch its norovirus challenge study in Q1 2022 to evaluate the safety and clinical efficacy of its oral vaccine candidate.

Manufacturing Updates

- As noted above, Vaxart is now producing vaccines at two GMP manufacturing plants in California, including its own GMP manufacturing facility.
- As a result, Vaxart has produced the tablets for its Phase II and Phase Ib COVID-19 studies and is starting to produce norovirus vaccine for additional clinical studies.

Financial Results for the Three Months Ended September 30, 2021

- Vaxart ended the quarter with cash, cash equivalents and available-for-sale debt securities of $204.0 million, compared to $198.9 million as of June 30, 2021. The increase was primarily due to net receipts of $20.3 million from the Company's $250 million at-the-market facility entered into in October 2020 and $0.3 million from the exercise of warrants and options, partially offset by $14.2 million of cash used in operations and $1.3 million spent on property and equipment.
- The Company reported a net loss of $17.6 million for the third quarter of 2021, compared to $8.1 million for the third quarter of 2020. Net loss per share for the third quarter of 2021 was $0.14, compared to a net loss of $0.08 per share in the third quarter of 2020. The increase in net loss per share was primarily due to the increase in net loss, resulting from a significant increase in research and development expenses.
- Revenue for the third quarter of 2021 was $200,000, compared to $265,000 in the third quarter of 2020. The decrease was due to lower royalty revenue from sales of Inavir in Japan.

- Research and development expenses were $12.4 million for the third quarter of 2021, compared to $4.6 million for the third quarter of 2020. 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 $5.0 million for the third quarter of 2021, compared to $4.2 million for the third quarter of 2020. 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," "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, 2021	December 31, 2020
	(Unaudited)	(1)
	(in thousands)	
Assets		
Cash and cash equivalents	$ 167,231	$ 126,870
Investments in debt securities	36,720	—
Accounts receivable	190	334
Prepaid and other assets	5,269	1,699
Property and equipment, net	5,427	1,480
Right-of-use assets, net	12,237	6,838
Intangible assets, net	14,062	15,361
Total assets	$ 241,136	$ 152,582

Liabilities and stockholders' equity		
Accounts payable	$ 3,745	$ 2,133
Accrued and other liabilities	4,543	4,908
Liability related to sale of future royalties	15,158	14,929
Operating lease liabilities	12,742	7,208
Total liabilities	36,188	29,178
Stockholders' equity	204,948	123,404
Total liabilities and stockholders' equity	$ 241,136	$ 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)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	**2020**	**2021**	**2020**
	(in thousands, except share and per share amounts)			
Revenue	$ 200	$ 265	$ 818	$ 3,690
Operating expenses:				
Research and development	12,409	4,616	33,219	11,272
General and administrative	5,042	4,190	16,136	10,076
Restructuring costs	—	(952)	—	(849)
Total operating expenses	17,451	7,854	49,355	20,499
Loss from operations	(17,251)	(7,589)	(48,537)	(16,809)
Other income and (expenses), net	(311)	(470)	(1,080)	(1,345)
Loss before income taxes	(17,562)	(8,059)	(49,617)	(18,154)
Provision for income taxes	21	26	89	205
Net loss	$ (17,583)	$ (8,085)	$ (49,706)	$ (18,359)
Net loss per share, basic and diluted	$ (0.14)	$ (0.08)	$ (0.41)	$ (0.23)
Shares used in computing net loss per share, basic and diluted	123,984,141	107,718,578	120,110,780	81,121,045

Source: Vaxart, Inc.