Organovo Achieves 3D Tissue Model for Crohn's Disease

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SAN DIEGO, May 17, 2022 (GLOBE NEWSWIRE) -- Organovo Holdings, Inc. (Nasdaq: ONVO), a three-dimensional (3D) biology company focused on delivering scientific and medical breakthroughs using novel technologies including 3D bioprinting, today announces that it has successfully advanced its first inflammatory bowel disease (IBD) model to the next step of target discovery and validation for Crohn's disease. Based on its internal data and scientific results, the company believes that its first IBD model correctly demonstrates key aspects of Crohn's patient biology that differ from a non-diseased state, and can be used to find and characterize therapeutics.

"A functional Crohn's disease model represents a milestone achievement for Organovo and a key next step on our path to finding novel drugs" said Jeff Miner, Ph.D., Organovo's Chief Scientific Officer, adding, "Our models attempt to mimic the architecture, cell diversity, and function of the human gut in healthy and disease states."

More than 1 million people in North America suffer from Crohn's and its prevalence is increasing globally. Because of its progressive nature, more than 70% will require at least one surgical intervention to relieve symptoms. Current drugs can slow progression in about 50% of patients, but none are curative. Defects in the intestinal lining and inflammation can lead to abdominal pain, severe diarrhea, fatigue, weight loss, malnutrition, and lower quality of life. Chronic inflammation leads to ulcers, fistulas and bowel obstructions caused by fibrosis. Organovo believes that its 3D tissue technologies are well suited to drug and target discovery in IBD because they contain a functional intestinal epithelium that is affected by disease and a stromal layer demonstrating disease-dependent fibrosis, key targets for therapy.

Organovo previously announced that it had updated its business model to capitalize on its human 3D tissue technologies in drug discovery, building disease models to find effective therapies that are more likely to succeed in the clinic than drugs discovered using animal models. We have focused on the creation of three-dimensional intestinal disease models to discover therapeutic opportunities that leverage the insights possible from the truer human biology achievable in 3D human disease models.

The drug discovery process using 3D tissues consists of several stages. Two steps that are uniquely important in Organovo's approach to drug discovery are creation of a disease model followed by target discovery and validation, each of which represents substantially de-risking a program. The steps involved in each require groundbreaking science that represents the application of tools specific to our approach. Organovo has now achieved the first of these two steps and is embarking on the second step. For this first step, there was no guarantee a suitable model could be achieved using 3D tools, and therefore we believe the achievement of a suitable model represents a strong step forward and lowering of risk. The next phase will be target identification and validation, which we intend to complete by the end of our fiscal year in March 2023. The remaining steps after validation of a target substantially resemble typical pharma development steps to advance a drug to Phase 1 clinical trials. Organovo is on track to have the Crohn's disease model being advanced at this time provide one of the validated targets to result in an investigative new drug (IND) application by 2025 in alignment with our previously communicated objective to have multiple INDs by that time.

Upon validation of targets, we believe the potential of using 3D models in a given application will be realized and that the use of 3D tissue technologies will be substantially de-risked. We expect to then begin medicinal chemistry to identify a small molecule drug candidate or a parallel process such as antibody development if the target would best be engaged with a monoclonal antibody or other modality. Medicinal chemistry, preclinical safety studies, and other common tasks that follow consist of fairly common practices across pharmaceutical development, and are not unique to 3D drug discovery, but can benefit greatly from the additional insights that can be provided by testing candidates in human tissue 3D models as the candidates are screened and developed. Since these steps are more typical, the risk profile is similar to traditional pharmaceutical development at these stages. However, upon entering the clinic and seeking evidence of efficacy in humans, we believe that our use of human 3D disease models to select drug candidates will result in significantly higher probability of success.

Organovo will seek to develop multiple pipeline programs and continues to expect to have multiple IND filings by 2025, which will allow us to progress innovative breakthrough drugs discovered in our 3D tissue systems into clinical trials. The company is working on additional IBD disease models representing different aspects of disease, each of which can represent a significant advancement over previous tools. Organovo will also seek to leverage validated targets and scientific knowledge from these disease models into business development deals and partnerships with pharmaceutical companies.

About Organovo

Organovo is an early-stage biotechnology company that is developing and utilizing highly customized 3D human tissues as dynamic models of healthy and diseased human biology for drug development. The company's proprietary technology is being used to build functional 3D human tissues that mimic key aspects of native human tissue composition, architecture, function and disease. Organovo's advances include cell type-specific compartments, prevalent intercellular tight junctions, and the formation of microvascular structures. Management believes these attributes can enable critical complex, multicellular disease models that can be used to develop clinically effective drugs for selected therapeutic areas.

Forward Looking Statements

Any statements contained in this press release that do not describe historical facts constitute forward-looking statements as that term is defined in the Private Securities Litigation Reform Act of 1995. Any forward-looking statements contained herein are based on current expectations, but are subject to a number of risks and uncertainties. These risks and uncertainties and other factors are identified and described in more detail in the Company's filings with the SEC, including its Annual Report on Form 10-K filed with the SEC on June 15, 2021, as such risk factors are updated in its most

recently filed Quarterly Report on Form 10-Q filed with the SEC on February 14, 2022. You should not place undue reliance on these forward-looking statements, which speak only as of the date that they were made. These cautionary statements should be considered with any written or oral forward-looking statements that the Company may issue in the future. Except as required by applicable law, including the securities laws of the United States, the Company does not intend to update any of the forward-looking statements to conform these statements to reflect actual results, later events or circumstances or to reflect the occurrence of unanticipated events.

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