



Organovo On Track to Establish Human 3D Disease Model in Inflammatory Bowel Disease in 2022

November 30, 2021

SAN DIEGO, Nov. 30, 2021 (GLOBE NEWSWIRE) -- Organovo Holdings, Inc. (Nasdaq: ONVO), today provided a business overview and progress update, and announced it is on track to establish its first models of inflammatory bowel disease in 2022 using its 3D bioprinting and other 3D tissue technologies.

In September 2020, Organovo began its new business strategy after the vote of the stockholders brought a new Board of Directors into control. Since that time, Organovo has rebuilt the R&D function of the company and begun its pursuit of novel drug therapies using its 3D bioprinting and other 3D biology techniques to model human intestinal diseases like ulcerative colitis and Crohn's disease. Organovo believes that using human cells in 3D tissue models of disease offers the opportunity to understand and treat disease in a superior way to the use of animal models.

Organovo has successfully hired and built a strong scientific team that has begun its efforts in short-term laboratory space. The company will be moving into its long-term new space next week, with approximately 8,051 sq. ft. of mixed lab and office plus 2,892 sq. ft. of dedicated office space. The company will continue growing its research efforts, including continued growth in its employee headcount.

Organovo plans to pursue novel drug therapies in inflammatory bowel disease (IBD) discovered in its 3D tissues. The company believes that this path offers strong promise because of inherent advantages in using 3D human tissues, which it believes offer the promise of finding drugs with a higher chance of success than those discovered using the prevailing paradigm of animal models. The company will build a pipeline of drug opportunities, with more than one drug program in IBD, and will be expanding in 2022 into at least one additional tissue area, beyond intestine, with another drug program. Multiple tissue types are being evaluated currently to select the best option for our next tissue.

Organovo is targeting filing multiple investigative new drug (IND) applications for novel drug therapies by 2025, with the opportunity to file the first as early as 2024.

The milestones along the path to putting novel drugs in the clinic include:

- Disease Model Building – establishing a 3D model for each specific disease
- Target Validation and Selection – demonstrating that a gene affects the disease in the company's 3D model and beginning a program to find a drug targeting that gene pathway to modulate disease
- Screening and Lead Compound Selection – conducting screens (for an oral compound, antibody, or another modality) to find various drug compounds that affect the target gene in a way that reduces the evidence of disease in the 3D models, and selecting the drug compound most promising for clinical studies
- Investigative New Drug (IND) Enabling Studies – performing the necessary work to show safety and efficacy sufficient to enter human clinical trials
- IND filings with FDA – providing the data package required by FDA to allow the initiation of Phase 1 clinical studies in humans with the company's novel drug candidates

Organovo plans to communicate its achievements as it approaches and hits its milestones for drug programs, and to provide information on its progress towards entering the clinic. The company believes that its results thus far suggest that it is on track to establish the necessary disease models of inflammatory bowel disease in 2022.

According to the Biotechnology Innovation Organization's 2021 report, only 7.9% of drugs that enter clinical trials are approved for human use. Organovo believes that it can achieve a significantly better success rate than that by using its 3D human tissue models of disease. By leveraging the prior investments in its bioprinting platform and investing in additional technologies, the company is positioning itself as a leader in the creation and use of innovative human 3D tissue models for drug discovery.

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.

"Clinical Development Success Rates and Contributing Factors 2011–2020". Feb. 2021. Co-publication by three organizations: Biotechnology Innovation Organization (BIO), PharmaIntelligence, and Quantitative Live Sciences (QLS). [ClinicalDevelopmentSuccessRates2011_2020.pdf \(bio.org\)](#)

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. These forward-looking statements include, among others, statements regarding the Company's expectations for establishing its first models of inflammatory bowel disease and the timing thereof, beliefs regarding the potential effectiveness of using human cells in 3D tissue models of disease and its potential superiority to the use of animal models, its plans to expand its research team and employee headcount, the Company's plans to pursue novel drug therapies in inflammatory bowel disease discovered in its 3D tissues and the potential promise thereof with respect to finding drugs with a higher chance of success, its expected timing for filing IND applications and the achievement of milestones with respect thereto. Any forward-looking statements contained herein are based on current expectations, but are subject to a number of risks and uncertainties, all of which are difficult to predict and many of which are beyond the Company's control and could cause its actual results to differ materially and adversely from those expressed in its forward-looking statements, including, but not limited to: risks related to the Company's belief that its use of innovative human 3D tissue models provides superior way to treat disease; risks that the Company may not move into the new office space or expand its research team or employee headcount as planned; risks that the Company fails to establish its first models of inflammatory bowel disease in 2022; risks that the Company fails to achieve any milestone along its way to obtain IND applications or to communicate its progress with respect thereto; and risks related to COVID-19. These risks and uncertainties and other factors are identified and described in more detail in the Company's filings with the SEC, including its Quarterly Report on Form 10-Q filed with the SEC on November 8, 2021. 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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Source: Organovo, Inc.