



## Organovo Introduces 3D Bioprinted Human Liver as Leading Therapeutic Tissue in Preclinical Development

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SAN DIEGO, Oct. 05, 2016 (GLOBE NEWSWIRE) -- Organovo Holdings, Inc. (NASDAQ:ONVO) ("Organovo"), a three-dimensional biology company focused on delivering scientific and medical breakthroughs using its 3D bioprinting technology, today announced its plan to develop 3D bioprinted human liver tissue for direct transplantation to patients. The Company is announcing its program to develop this therapeutic tissue based on the achievement of strong results in preclinical studies in animal models showing engraftment, vascularization and sustained functionality of its bioprinted liver tissue, including stable detection of liver-specific proteins and metabolic enzymes. Organovo expects to pursue this opportunity with a formal preclinical development program.

For patients in need of a liver transplant, no robust alternatives exist today. Approximately 17,000 patients are on the U.S. liver transplant waiting list, and only 6,000 liver transplants are performed each year. Organovo plans to develop clinical solutions in two initial areas. First, acute-on-chronic liver failure ("ACLF") is a recognized and distinct orphan disease entity encompassing an acute deterioration of liver function in patients with liver disease, which affects 150,000 patients annually in the United States. Second, pediatric metabolic liver diseases represent another orphan disease indication where a bioprinted liver tissue patch may show therapeutic benefits. The total addressable market opportunity for these initial indication areas exceeds \$3 billion. Assuming development progresses according to its current plan, Organovo intends to submit an Investigational New Drug ("IND") application to the U.S. Food and Drug Administration ("FDA") for its therapeutic liver tissue in three to five years. As appropriate, Organovo will pursue breakthrough therapy designation, clinical development outside the United States, and other opportunities to help accelerate time to market.

Keith Murphy, Organovo's CEO, will be presenting bioprinted human liver as the first therapeutic tissue being advanced in the Company's portfolio at the 2016 Cell & Gene Meeting on the Mesa in La Jolla, Ca. Mr. Murphy will speak today at 5 p.m. PT, and the presentation will be both webcast live and available for replay at <http://www.meetingonthemesa.com/webcast/>. The Company also expects to present more detailed preclinical results at upcoming scientific conferences.

"We're excited to introduce an implantable bioprinted liver tissue as the first preclinical candidate in our therapeutic tissue portfolio, and see the early results as extremely promising," said Keith Murphy, CEO, Organovo. "The scientific and commercial progress we have already made with ExVive™ Human Liver Tissue in drug toxicity testing has given us a firm foundation upon which to build a larger tissue for transplant. Advancing our first therapeutic tissue into preclinical development is an important milestone for Organovo, and it speaks to the power of our technology platform in addressing multiple applications, including preclinical safety, disease modeling and tissue replacement products for surgical implantation. We believe that 3D bioprinted tissues have an opportunity to provide options for patients who suffer from liver disorders."

"Organovo's approach is designed to overcome many of the challenges that cell therapies and conventional tissue engineering have struggled to address, including limited engraftment and significant migration of cells away from the liver," said Eric Michael David, M.D., J.D., chief strategy officer and executive vice president of preclinical development, Organovo. "In our preclinical studies, we deliver a patch of functional tissue directly to the liver, which integrates well, remains on the liver and maintains functionality. We believe our tissues have the potential to extend the lives of patients on liver transplant lists, or those who do not qualify for transplants due to other factors."

"Supply issues are a constant and growing challenge in transplant medicine and liver has the second highest transplant need among all organs," said David A. Gerber, M.D., FACS, Professor of Surgery and Chief of Transplant Surgery, UNC School of Medicine. "New solutions in development, such as 3D bioprinted human tissues, have the potential to create tissues that could augment and extend organ function to give more time to those patients on transplant waiting lists. Moreover, we are continuing to push the boundaries and understand how to scale 3D bioprinting and tissue engineering to develop larger tissues." Dr. Gerber serves as an advisor to Organovo on its liver therapeutic tissue preclinical development program.

Dr. John Geibel, Vice Chairman of Surgery, Director of Surgical Research, and Professor of Surgery and Cellular and Molecular Physiology at Yale University, added, "There are many conditions in areas such as liver, kidney, gastrointestinal, vascular, and lung disease where supplying a tissue patch may be curative, or bridge a patient a few more years before they need a transplant. The promise of 3D bioprinting human tissues to address these unmet needs is significant." Organovo and the Methuselah Foundation support Organovo's bioprinter for therapeutic research at Yale's Department of Surgery.

The Company continues to conduct early research on other tissues for therapeutic use in direct surgical applications. Liver tissue, having ranked highly in an initial strategic assessment performed by Organovo considering technical feasibility, commercial opportunity, clinical, regulatory, and reimbursement factors, has moved forward most quickly as the Company's first program for preclinical development. Preclinical 'proof-of-concept' is currently being pursued in additional areas, building on the breadth of Organovo's leading bioprinting expertise.

### About Organovo Holdings, Inc.

Organovo designs and creates functional, three-dimensional human tissues for use in medical research and therapeutic applications. The Company develops 3D human tissue models through internal development and in collaboration with pharmaceutical, academic and other partners. Organovo's 3D human tissues have the potential to accelerate the drug discovery process, enabling treatments to be developed faster and at lower cost. The Company's ExVive Human Liver and Kidney Tissues are used in toxicology and other preclinical drug testing. The Company also actively conducts early research on specific tissues for therapeutic use in direct surgical applications. In addition to numerous scientific publications, the Company's technology has been featured in The Wall Street Journal, Time Magazine, The Economist, Forbes, and numerous other media outlets. Organovo is changing the shape of life science research and transforming medical care. Learn more at [www.organovo.com](http://www.organovo.com).

### 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 forward-looking statements include, but are not limited to, statements regarding the Company's development plans and timeline for its human liver tissue, potential therapeutic uses for its human liver tissue, and the ability of the Company to complete the additional preclinical studies required to submit an IND for its human liver tissue, including having the necessary resources and achieving the required results. The factors that could cause the Company's actual future results to differ materially from current expectations include, but are not limited to, risks and uncertainties relating to the Company's ability to develop, market and sell products and services based on its technology; the expected benefits and efficacy of the Company's products, services and technology; the market acceptance of the Company's products and services; the Company's business, research, product development, regulatory approval, marketing and distribution plans and strategies; the Company's ability to successfully complete the contracts and recognize the revenue represented by the contracts included in its previously reported total contract bookings and secure additional contracted collaborative relationships; the final results of the Company's preclinical studies may be different from the Company's studies or interim preclinical data results and may not support further clinical development of its therapeutic tissues; the Company may not successfully complete the required preclinical and clinical trials required to obtain regulatory approval for its therapeutic tissues on a timely basis or at all; and the Company's ability to secure additional financing to support its long-term development plans. These 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 9, 2016 and its Quarterly Report on Form 10-Q filed with the SEC on August 4, 2016. 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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