Organogenesis Commends Final LCDs

November 14, 2024

Organogenesis Pleased to Lead Collaborative Effort to Support Data-Driven Policy on Local Coverage Determination

CANTON, Mass., November 14, 2024 -- Organogenesis Holdings Inc. (Nasdaq: ORGO), a leading regenerative medicine company focused on the development, manufacture, and commercialization of product solutions for the Advanced Wound Care and Surgical and Sports Medicine markets, commends today's decision by the U.S. Centers for Medicare & Medicaid Services (CMS) on local coverage determination (LCD) based on peer-reviewed and evidence-based data of clinical efficacy. The LCD covers skin substitute grafts/cellular and tissue-based products (CTP) for the treatment of diabetic foot ulcers (DFU) and venous leg ulcers (VLU) in the Medicare population and is now set to become effective on February 12, 2025.

"Today's LCD decision recognizes the importance of clinical trial data and real-world evidence in shaping policies that affect all patients," stated Gary S. Gillheeney, Sr., President, Chief Executive Officer, and Chair of the Board of Organogenesis. "We are proud of our work to bring wound care stakeholders together to inform this new policy."

Organogenesis offers 4 products for DFUs, including NuShield, and 2 for VLUs. "We are pleased to have NuShield added to the list of covered products. These products have demonstrated safety and efficacy in clinical trials as well as in patient care settings. We believe CMS' evidence-based approach is a long-term positive step for Organogenesis and the industry," concluded Gillheeney.

Forward-Looking Statements

This release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. These forward-looking statements relate to expectations or forecasts of future events. Forward-looking statements may be identified by the use of words such as "forecast," "intend," "seek," "target," "anticipate," "believe," "expect," "estimate," "plan," "outlook," and "project" and other similar expressions that predict or indicate future events or trends or that are not statements of historical matters. Such forward-looking statements include statements relating to the Company's expected revenue, net income (loss), Adjusted net income, EBITDA, and Adjusted EBITDA for fiscal 2024 and the breakdown of expected revenue in both its Advanced Wound Care and Surgical & Sports Medicine categories. Forward-looking statements with respect to the operations of the Company, strategies, prospects, and other aspects of the business of the Company are based on current expectations that are subject to known and unknown risks and uncertainties, which could cause actual results or outcomes to differ materially from expectations expressed or implied by such forward-looking statements. These factors include, but are not limited to: (1) the impact of any changes to the coverage and reimbursement levels for the Company's products (including as a result of the recently proposed LCDs); (2) the Company faces significant and continuing competition, which could adversely affect its business, results of operations and financial condition; (3) rapid technological change could cause the Company's products to become obsolete and if the Company does not enhance its product offerings through its research and development efforts, it may be unable to effectively compete; (4) to be commercially successful, the Company must convince physicians that its products are safe and effective alternatives to existing treatments and that its products should be used in their procedures; (5) the Company's ability to raise funds to expand its business; (6) the Company has incurred losses in the current period and prior periods and may incur losses in the future; (7) changes in applicable laws or regulations; (8) the possibility that the Company may be adversely affected by other economic, business, and/or competitive factors; (9) the Company's ability to maintain production or obtain supply of its products in sufficient quantities to meet demand; (10) any resurgence of the COVID-19 pandemic and its impact, if any, on the Company's fiscal condition and results of operations; (11) the impact of the suspension of commercialization of: (a) ReNu and NuCel in connection with the expiration of the FDAs enforcement grace period for HCT/Ps on May 31, 2021 and (b) Dermagraft in the second quarter of 2022 pending transition of manufacturing to a new manufacturing facility or a third-party manufacturer; (12) whether the Company is able to obtain regulatory approval for and successfully commercialize ReNu; and (13) other risks and uncertainties described in the Company's filings with the Securities and Exchange Commission, including Item 1A (Risk Factors) of the Company's Form 10-K for the year ended December 31, 2023 and its subsequently filed periodic reports. You are cautioned not to place undue reliance upon any forward-looking statements, which speak only as of the date made. Although it may voluntarily do so from time to time, the Company undertakes no commitment to update or revise the forward-looking statements, whether as a result of new information, future events or otherwise, except as required by applicable securities laws.

About Organogenesis Holdings Inc.
Organogenesis Holdings Inc. is a leading regenerative medicine company focused on the development, manufacture, and commercialization of solutions for the advanced wound care and surgical and sports medicine markets. Organogenesis offers a comprehensive portfolio of innovative regenerative products to address patient needs across the continuum of care. For more information, visit www.organogenesis.com.

Investor Inquiries: ICR Healthcare Mike Piccinino, CFA OrganoIR@westwicke.com Press and Media Inquiries: Organogenesis communications@organo.com