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Orgenesis Reports 85% Increase in Revenue and 139% Increase in Gross Profit for Fiscal 2018

Expands POCare platform through a variety of valuable collaboration agreements

GERMANTOWN, Md., Feb. 14, 2019 (GLOBE NEWSWIRE) -- Orgenesis Inc. (NASDAQ: ORGS), a developer, manufacturer and service provider of advanced cell therapies, today reported financial results and provided a business update for the fiscal year ended November 30, 2018.

Fiscal Year 2018 Financial Highlights Include:

- Revenues increased 85% to $18.7 million compared to $10.1 million for FY 2017
- Gross profit increased 139% to $7.8 million compared to $3.3 million for FY 2017
- Gross margin increased to 42.0% from 32.5%
- CDMO segment achieved operating profit of $4.0 million
- Finished with cash and cash equivalents of $16.1 million as of November 30, 2018
- Working capital surplus as of November 30, 2018 increased to $13.2 million compared to $(9.6) million as of November 30, 2017
- Shareholders' equity was $28.7 million as of November 30, 2018 compared to $14.1 million as of November 30, 2017

Vered Caplan, CEO of Orgenesis, commented, "We are pleased to report strong growth, increased gross profit and solid gross margin improvement in fiscal 2018. At the same time, we continue to strengthen our balance sheet and had over $16 million of cash at the end of the fiscal year, along with a significant improvement in shareholders' equity. In addition, our contract development and manufacturing organization (CDMO) segment, Masthercell Global ("Masthercell"), generated $22.6 million in sales, and an operating profit of $4 million on a standalone basis. While we continue to grow Masthercell's backlog and customer base, one of our key challenges in fiscal 2018 was ramping up to meet the growing global demand. To address these capacity constraints, we recently launched a new production wing of 6,458 square feet (600 square meters) at our Belgium site, which provides Masthercell with five additional state-of-the-art, late stage and commercial ready clean rooms. In total, we have more than doubled our manufacturing capacity in 2018, which positions us for continued strong growth in 2019. In addition, we recently announced expansion plans into the United States with plans to build a new 30,000 square foot (2,787 square meter) manufacturing facility in Houston, Texas. The new facility will allow Masthercell to expand its global presence."

"We are also making tremendous progress in advancing our point-of-care ("POCare") cell

therapy platform, in which we are actively in-licensing technologies and building collaborations with a variety of pre-clinical and clinical-stage biopharmaceutical companies and research and healthcare institutes, with a goal to bring Advanced Therapy Medicinal Products (ATMPs) to patients, by leveraging our technical, regulatory and commercial expertise. Towards this end, we recently announced the opening of new offices and laboratories at Accessia Pharma in Liège, Belgium for our Belgian subsidiary, Orgenesis SPRL, in order to support our growing POCare cellular therapy platform. In addition, we have partnered with local companies to expand our POCare activity to Japan and India. Importantly, we have already entered agreements that will begin generating revenue within this segment."

"As an example of our progress, we recently announced a collaboration with MangoGen Pharma Inc., initially focused on the pre-clinical development of insulin producing cells (IPC) using MangoGen's advanced gene delivery platform. In support of this program, we were awarded a grant from the Canada-Israel Industrial R&D Foundation (CIIRDF) to fund this project. We also announced a licensing and collaboration agreement with BGN Technologies, an affiliate of Ben-Gurion University of the Negev (BGU), to advance the research and development of BGU's dissolvable carriers for cell culturing, in which we received the exclusive, worldwide rights to make, develop and commercialize technologies utilizing dissolvable carriers for cell culturing. This unique technology has the potential to significantly reduce the cost and complexity of manufacturing for our cell therapy programs. We entered into a collaboration agreement with the New York Blood Center (NYBC), one of the largest independent, community-based blood centers in the world to collect, process, test, cryopreserve and biobank sampling materials, including liver biopsies for use as source of autologous insulin producing (AIP) cells for patients that may be eligible for future clinical trials. We also announced two important agreements with Hemogenyx Pharmaceuticals and its subsidiary, Immugenyx. The first collaboration is focused on the development and commercialization of Hemogenyx' Human Postnatal Hemogenic Endothelial (Hu-PHEC) technology, a cell replacement product candidate that is designed to generate cancer-free, patient-matched blood stem cells after transplantation into the patient. The second collaboration is focused on the development and commercialization of Immugenyx' advanced hematopoietic chimeras (AHC), a new type of humanized mouse with a functional human immune system, as an in vivo platform for disease modelling, drug and cell therapy development. Looking ahead, we are advancing a number of additional such agreements that have the potential to significantly enhance our POCare cellular therapy platform, which we look forward to announcing in the coming weeks and months."

About Orgenesis

Orgenesis is a biotechnology company specializing in the development, manufacturing and provision of technologies and services in the cell and gene therapy industry. The Company operates through two platforms: (i) a point-of-care ("POCare") cell therapy platform ("PT") and (ii) a Contract Development and Manufacturing Organization ("CDMO") platform conducted through its subsidiary, Masthercell Global. Through its PT business, the Company's aim is to further the development of Advanced Therapy Medicinal Products ("ATMPs") through collaborations and in-licensing with other pre-clinical and clinical-stage biopharmaceutical companies and research and healthcare institutes to bring such ATMPs to patients. The Company out-licenses these ATMPs

through regional partners to whom it also provides regulatory, pre-clinical and training services to support their activity in order to reach patients in a point-of-care hospital setting. Through the Company's CDMO platform, it is focused on providing contract manufacturing and development services for biopharmaceutical companies. The CDMO platform operates through Masthercell Global, which currently consists of MaSTherCell in Belgium, Atvio in Israel and subsidiaries in South Korea and in the United States, each having unique know-how and expertise for manufacturing in a multitude of cell types. Additional information is available at: www.orgenesis.com.

Notice Regarding Forward-Looking Statements

This press release contains forward-looking statements which are made pursuant to the safe harbor provisions of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities and Exchange Act of 1934, as amended. These forward-looking statements involve substantial uncertainties and risks and are based upon our current expectations, estimates and projections and reflect our beliefs and assumptions based upon information available to us at the date of this release. We caution readers that forward-looking statements are predictions based on our current expectations about future events. These forward-looking statements are not guarantees of future performance and are subject to risks, uncertainties and assumptions that are difficult to predict. Our actual results, performance or achievements could differ materially from those expressed or implied by the forward-looking statements as a result of a number of factors, including, but not limited to, the success of our reorganized CDMO operations, the success of our partnership with Great Point Partners, our ability to achieve and maintain overall profitability, the sufficiency of working capital to realize our business plans, the development of our POCare strategy, our transdifferentiation technology as therapeutic treatment for diabetes which could, if successful, be a cure for Type 1 Diabetes, the technology behind our in-licensed ATMPs not functioning as expected, our ability to retain key employees, our competitors developing better or cheaper alternatives to our products and the risks and uncertainties discussed under the heading "RISK FACTORS" in Item 1A of our Annual Report on Form 10-K for the fiscal year ended November 30, 2018, and in our other filings with the Securities and Exchange Commission. We undertake no obligation to revise or update any forward-looking statement for any reason.

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