

March 10, 2020



# Orgenesis Provides Fiscal 2019 Year-End Results and Business Update; Outlines New Vertically Integrated Business Model and POCare Strategy Following Sale of Masthercell

*Reports 78% increase in revenue and 92% increase in gross profit for fiscal 2019*

*Generated over \$3.1 million in sales through POCare platform*

*Rapidly expanding POCare platform through new collaborations*

GERMANTOWN, Md., March 10, 2020 (GLOBE NEWSWIRE) -- [Orgenesis Inc. \(NASDAQ: ORGS\)](#) ("Orgenesis" or the "Company"), a vertically integrated biopharmaceutical company committed to lowering costs, accelerating commercialization, and transforming the delivery of life saving cell and gene therapies, today reported financial results for the year ended December 31, 2019 and provided a business update.

## **Fiscal Year 2019 Financial Highlights Include:**

- Revenues increased 78% to \$33.3 million compared to \$18.7 million for FY 2018
- Gross profit increased 92% to \$15.0 million compared to \$7.8 million for FY 2018
- Point-of-Care ("POCare") platform generated \$3.1 million in sales compared to zero for FY 2018
- Cash and cash equivalents totalled \$11.4 million as of December 31, 2019, which does not include approximately \$127 million net proceeds from the sale of the CDMO business in February 2020

Vered Caplan, CEO of Orgenesis, commented, "2019 was a truly transformational year for the Company. While we achieved strong company-wide revenue growth, more importantly, we generated \$3.1 million in sales through our newly launched POCare platform. We believe our POCare platform represents an attractive pathway for the future of the industry, and is poised for accelerated growth this year through industry partnerships that are currently underway with leading healthcare institutions around the world. In 2019, we signed collaborations with several leading research and healthcare institutions. Given this traction, I am pleased to report that we successfully sold our Masthercell Global, Inc. subsidiary, a contract development manufacturing organization (CDMO) for \$315 million, generating approximately \$127 million net proceeds to Orgenesis. Within 5 years of acquiring Masthercell, the CDMO segment revenue increased from a run-rate of just \$3 million to a run-rate of approximately \$30 million at the end of 2019, reflecting a compound annual growth rate of 59% under our leadership. We determined it was the right time to sell Masthercell in order to maximize value for our shareholders and accelerate the rollout of our

new business model.”

“The cell and gene therapy market faces several significant challenges that we believe our new business model directly addresses. In most cases, the costs of cell and gene therapies are prohibitive, as illustrated by recent CAR-T therapies, which range in the hundreds of thousands of dollars per patient, per year. Second, the development costs and timeline to bring these therapies from concept to market is long and expensive. Third, the current method of centralized manufacturing and distribution is challenging for these therapies, making it difficult for companies to scale and handle the logistics around living cells.”

“As a vertically integrated biotech company, our business model is designed to directly address and fundamentally transform the entire development, manufacturing, supply and commercialization of cell and gene therapies, which has the potential of accelerating the speed to market, lowering costs, and enhancing the delivery of cell and gene therapies. Our therapeutic pipeline consists of proprietary and licensed Advanced Therapy Medicinal Products (“ATMPs”). Supporting this therapeutic pipeline is our POCare platform, which consists of both our POCare Solutions and our POCare Network. The POCare solutions are an integrated suite of proprietary and in-licensed technologies designed to enable onsite development, production and administration of ATMPs within the patient care setting. The POCare Network is a growing network of affiliated pre-clinical and clinical-stage biopharmaceutical companies, research institutions and hospitals through which we are able to in license technologies or ATMPs and co-develop them with our partners. We support this network with regulatory, pre-clinical/clinical development and training services.”

“We intend to use the net proceeds generated from the Masthercell transaction to accelerate the rollout of our therapeutic pipeline, as well as our POCare platform in order to capitalize on the positive feedback from the industry. We have already established joint ventures with several leading universities and healthcare institutions in Asia, North America and Europe and we are in advanced discussions with a number of additional major institutions around the world. We believe this approach has the potential to transform the cell and gene therapy market by lowering the costs and expanding availability of these life-changing and life-saving therapies. We have built a highly scalable foundation that we believe is poised for long-term growth. We believe we are now strategically positioned within this rapidly emerging industry.”

The Company’s complete financial results are available in the Company’s Form 10-K filed with the Securities and Exchange Commission on March 9, 2020 which is available at [www.sec.gov](http://www.sec.gov) and on the Company’s [website](#). As a result of the Company’s change in its fiscal year end from November 30 to December 31, the Company is comparing the results for the twelve months ended December 31, 2019, to the twelve months ended November 30, 2018.

### **About Orgenesis**

Orgenesis is a vertically integrated biopharmaceutical company that is lowering costs, accelerating commercialization, and transforming the delivery of life saving cell and gene therapies. Orgenesis’ therapeutic pipeline consists of proprietary and licensed Advanced Therapy Medicinal Products (“ATMPs”). The Company’s Point of Care (POCare) Platform consists of: (a) POCare Solutions, an integrated suite of proprietary and in-licensed technologies designed to enable onsite production and administration of ATMPs within the patient care setting; and (b) POCare Network, a growing network of affiliated pre-clinical and clinical-stage biopharmaceutical companies, research institutions and hospitals through

which the Company in licenses technologies or ATMPs and out licenses ATMPs and POCare Solutions. The Company also provides regulatory, pre-clinical/clinical and training services to support regional partners within the POCare Network. Additional information is available at: [www.orgenesis.com](http://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, our reliance on, and our ability to grow, our point-of-care cell therapy platform, our ability to effectively use the net proceeds from the sale of Mathercell, our ability to achieve and maintain overall profitability, the development of our POCare strategy, the sufficiency of working capital to realize our business plans, the development of our trans-differentiation technology as therapeutic treatment for diabetes which could, if successful, be a cure for Type 1 Diabetes; our technology not functioning as expected; our ability to retain key employees; our ability to satisfy the rigorous regulatory requirements for new procedures; 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 December 31 2019, 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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