

November 5, 2020



Orgenesis Third Quarter 2020 Revenue Increases 40% Reflecting Continued Progress of POCare Platform

Reports rapid advancement of therapeutic pipeline

Announces new semi-automated cell and gene therapy processing units

Reports cash and cash equivalents of \$88.8 million as of September 30, 2020

GERMANTOWN, Md., Nov. 05, 2020 (GLOBE NEWSWIRE) -- [Orgenesis Inc. \(NASDAQ: ORGS\)](#) ("Orgenesis" or the "Company"), a global biotech company working to unlock the full potential of cell and gene therapies, today provides a business update for the third quarter of 2020. Revenue increased 40% to \$1.7 million compared to \$1.2 million for the third quarter of 2019. The Company also reported approximately \$88.8 million of cash and cash equivalents as of September 30, 2020.

Vered Caplan, CEO of Orgenesis, stated, "Orgenesis continues to gain traction with a disruptive, point of care strategy for potentially commercializing life-changing treatments at reduced costs for large numbers of patients. In Q3 2020, we expanded the POCare Platform to include new POCare Therapeutics, Technologies, and a growing global Network."

"Orgenesis recently completed an [acquisition of Koligo Therapeutics, Inc., a regenerative medicine company, including substantially all of the assets of Tissue Genesis, LLC](#). This acquisition helped to expand our therapeutic and technology resources, while adding a highly experienced US team to help further bolster Orgenesis' POCare Network in the US."

"On the therapeutic front, Orgenesis is focused on several key verticals, including immunology, anti-viral, and metabolic/auto-immune diseases. A near-term goal is expanding the availability of KYSLECEL[®] from the recent Koligo acquisition. KYSLECEL is commercially available in the United States for chronic and recurrent acute pancreatitis. We are also planning patient recruitment for a phase 2 randomized clinical trial of KT-PC-301, subject to FDA review and clearance of an investigational new drug (IND) application. KT-PC-301 is an autologous clinical development stage cell therapy candidate for COVID-19-related Acute Respiratory Distress Syndrome, which we also acquired as part of the Koligo acquisition. Additionally, Orgenesis is preparing for a Phase 2 study of [Ranpirnase for the treatment of conditions caused by human papilloma virus](#) pending a planned IND submission to the FDA.

"Orgenesis intends to leverage our network of regional partners to advance the development and commercialization of our therapeutic pipeline. Towards this end, our partners have committed to funding the clinical programs. In turn, Orgenesis typically grants its partners geographic rights in exchange for future royalties, and a partnership with Orgenesis to support the supply of the targeted therapies. Through this unique model, Orgenesis has

already signed contracts, which we expect to generate over \$40 million in revenue over the next three years, if fully realized. There are also plans to continue to develop, license and form partnerships around a variety of POCare Technologies to support work in areas such as Tumor Infiltrating Lymphocytes (TILS), CAR-T, CAR-NK, dendritic cell therapies, and mesenchymal stem cell (MSC) based therapies.”

“Finally, Orgenesis is ready to announce advancements on proprietary, cell and gene processing units and labs that are being developed using first-in-class automation technologies. Orgenesis Mobile Processing Units & Labs (“OMPULs”) are designed to provide an economical industrial alternative for our POCare Network partners to produce cell and gene therapies at the point of care. Orgenesis intends to roll these OMPULs out in centers that we are establishing across the US, Europe, Asia, and the Middle East.”

The Company’s complete financial results are available in the Company’s Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on November 5, 2020 which is available at www.sec.gov and on the Company’s [website](#).

About Orgenesis

Orgenesis is a global biotech company working to unlock the full potential of cell and gene therapies (CGTs) in an affordable and accessible format at the point of care. The Orgenesis POCare Platform is comprised of three enabling components: a pipeline of licensed **POCare Therapeutics** that are processed and produced in closed, automated **POCare Technology** systems across a collaborative **POCare Network**. Orgenesis identifies promising new therapies and leverages its POCare Platform to provide a rapid, globally harmonized pathway for these therapies to reach and treat large numbers of patients at lowered costs through efficient, scalable, and decentralized production. The POCare Network brings together patients, doctors, industry partners, research institutes and hospitals worldwide to achieve harmonized, regulated clinical development and production of the therapies. Learn more about the work Orgenesis is doing at www.orgenesis.com.

Notice Regarding Forward-Looking Statements

The information in this release is as of November 5, 2020. Orgenesis assumes no obligation to update forward-looking statements contained in this release as a result of new information or future events or developments. This release contains forward looking statements about Orgenesis, Koligo, Koligo’s technology, and potential development and business opportunities of Koligo and Orgenesis, each of which involve substantial risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statements. Risks and uncertainties include, among other things, uncertainties regarding the commercial success of the Company’s products; the uncertainties inherent in research and development, including the ability to meet anticipated clinical endpoints, commencement and/or completion dates for our clinical trials, regulatory submission dates, regulatory approval dates and/or launch dates, as well as the possibility of unfavorable new clinical data and further analyses of existing clinical data; the risk that clinical trial data are subject to differing interpretations and assessments by regulatory authorities; whether regulatory authorities will be satisfied with the design of and results from our clinical studies; whether and when any such regulatory authorities may approved the Company’s development products, and, if approved, whether such product candidates will be commercially successful; decisions by regulatory authorities impacting labeling, manufacturing processes, safety and/or other matters that could affect the availability or

commercial potential of the Company's products; uncertainties regarding the impact of COVID-19 on the Company's business, operations and financial results and competitive developments.

A further description of risks and uncertainties can be found in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2019 and in its subsequent reports on Form 10-Q, including in the sections thereof captioned "Risk Factors" and "Forward-Looking Information," as well as in its subsequent reports on Form 8-K, all of which are filed with the U.S. Securities and Exchange Commission and available at www.sec.gov.

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Source: Orgenesis Inc.