

# Orgenesis Enters Into R&D Agreement With The Fraunhofer IGB

WHITE PLAINS, N.Y.-- Orgenesis Inc. (OTCBB:ORGS) ("Orgenesis" or the "Company"), a development-stage company with a novel therapeutic technology dedicated to converting a patient's own liver cells into functioning insulin-producing cells as a treatment for diabetes, announced today that it has entered into a service agreement (the "Agreement") with the Fraunhofer Institute for Interfacial Engineering and Biotechnology ("Fraunhofer IGB"), a leading German contract research and development center for regenerative medicine.

The commencement of clinical studies of Advanced Medicinal Therapy Products ("ATMPs"), such as Orgenesis' autologous insulin-producing cell transplants, necessitates formal approval by the senior medical regulatory approval organizations. This approval requires manufacturing, processing and testing of ATMPs in accordance with current national regulations, including good manufacturing practice ("GMP").

Pursuant to the Agreement, the Fraunhofer IGB will explore a pilot process to manufacture human autologous insulin-producing cell transplants based on the Orgenesis technology. It is anticipated that the subsequent establishment of a fully GMP-compliant production process will, in turn, enable Orgenesis to obtain authorization for the production of clinical grade material to be used in a first-in-man study of the Company's diabetes treatment product candidate.

"The Fraunhofer IGB's expertise in developing manufacturing processes for ATMPs, combined with its ability to manufacture cell-based therapeutics in a clinical scale at its own certified GMP manufacturing unit, makes it an ideal R&D collaboration partner for Orgenesis as we continue to work towards initiating advanced stage trials of our technology," commented Jacob BenArie, CEO of Orgenesis.

"We are very excited to support Orgenesis in their development of a very promising new therapy for diabetes that overcomes the problem of donor shortage and removes the risk of transplant rejection. This project fits exactly into our strategy to support the translation of innovative tissue engineering technologies into the clinical application," commented by Dr. Martin Funk, head of the GMP unit at the Fraunhofer IGB.

## ***About Orgenesis Inc.***

Orgenesis (OTCBB:ORGS) is a development stage company with a novel therapeutic technology that employs a molecular and cellular approach directed at converting a patient's own liver cells into functional insulin producing cells, as a treatment for diabetes. The Company believes that converting the diabetic patient's own tissue into insulin-producing cells overcomes the problem of donor shortage and removes the risk of transplant rejection. If successful, this could mean the end of diabetes, as we now know it. For more information visit: [www.orgenesis.com](http://www.orgenesis.com).

## **About the Fraunhofer IGB**

The Fraunhofer Institute for Interfacial Engineering and Biotechnology IGB offers R&D solutions in the fields of medicine, pharmacy, chemistry, the environment and energy. Our competences comprise Interfacial Engineering and Materials Science, Molecular Biotechnology, Physical Process Technology, Environmental Biotechnology and Bioprocess Engineering, as well as Tissue Engineering. We offer solutions from market analysis through research & development through the finished product. For more information visit: [www.igb.fraunhofer.de](http://www.igb.fraunhofer.de)

## **Notice Regarding Forward-Looking Statements**

*This news release contains "forward-looking statements" which are not purely historical. Such forward-looking statements include, among other things, the expectations of management that our regeneration technology can be developed as therapeutic treatment for diabetes. No assurance can be given that any of the events anticipated by the forward-looking statements will occur or, if they do occur, what benefits the Company will obtain from them. Actual results could differ from those projected in any forward-looking statements due to numerous factors. Such factors include, among others, the inherent uncertainties associated with new projects and development stage companies, which include, without limitation, the potential failure of development candidates to advance through preclinical studies or demonstrate safety and efficacy in clinical testing and the ability to pass clinical trials so as to move on to the next phase, our ability to retain key employees and our ability to finance development or satisfy the rigorous regulatory requirements for new medical procedures. Competitors may develop better or cheaper alternatives to our products. These forward-looking statements are made as of the date of this news release, and we assume no obligation to update the forward-looking statements, or to update the reasons why actual results could differ from those projected in the forward-looking statements. Investors should refer to the risk factors disclosure outlined in our periodic reports filed from time-to-time with the Securities and Exchange Commission.*

On Behalf of the Board  
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