

---

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

**FORM 8-K**

**CURRENT REPORT**

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): **March 8, 2017**

**ORGENESIS INC.**

(Exact name of registrant as specified in its charter)

**Nevada**  
(State or other jurisdiction  
of incorporation)

**000-54329**  
(Commission File  
Number)

**98-0583166**  
(IRS Employer  
Identification No.)

**20271 Goldenrod Lane, Germantown, MD 20876**  
(Address of principal executive offices) (Zip Code)

Registrant's telephone number, including area code: **(480) 659-6404**

**Not Applicable**  
(Former name or former address, if changed since last report.)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a -12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d -2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e -4(c))
-

**Item 8.01. Other Events**

On March 8, 2017, Orgenesis Inc. (the “Company”) issued a press release announcing a shareholder update for the fiscal year ended November 30, 2016.

A copy of the press release is attached hereto as Exhibit 99 and is incorporated herein by reference.

**Item 9.01. Financial Statements and Exhibits**

Exhibit N. Description

99.1 [Press Release issued March 8, 2017](#)

The press release may contain a hypertext link to information on our website. The information on our websites is not incorporated by reference into this Current Report on Form 8-K and does not constitute a part of this Form 8-K.

---

## SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

### **ORGENESIS INC.**

By:

/s/ Neil Reithinger

Neil Reithinger

Chief Financial Officer, Treasurer and Secretary

March 8, 2017

---



**For Immediate Release**

**Orgenesis Provides Update Regarding AIP Cell-Based Therapy for Type 1 Diabetes,  
MaSTherCell Cell Manufacturing Subsidiary and Overall Financial Condition**

**GERMANTOWN, MD – March 8, 2017 – Orgenesis Inc. (OTCQB: ORGS)**, a vertically-integrated biopharmaceutical company with expertise and unique experience in cell therapy development and manufacturing, today provided a business update from the Company’s CEO, Vered Caplan. The Company also reported that revenue for the fiscal year ending November 30, 2016 increased 115% to \$6.4 million from \$3.0 million in fiscal 2015 due to growth of MaSTherCell, the Company’s cell therapy manufacturing subsidiary.

Vered Caplan, CEO of Orgenesis, commented, “2016 was a transformative year for the Company and we continue to be very encouraged by the outlook for the business. A summary of our accomplishments are as follows:

- Through our Israeli subsidiary, we continue to advance our unique cell-based therapy, the Autologous Insulin Producing (“AIP”) cells, into clinical development. AIP cells utilize the technology of ‘cellular transdifferentiation’ to transform an autologous adult liver cell into a fully functional and physiologically glucose-responsive insulin-producing cell. Because the AIP cells are autologous, this benefit should be achieved and maintained without the need for concomitant immunosuppressive therapy. Diabetes is one of the most challenging health problems globally, incurring staggering health, societal, and economic impact. We believe our platform technology will provide Type 1 diabetes patients with long-term insulin independence, which would transform the lives of patients suffering from this debilitating disease.”

- Through our wholly-owned CDMO subsidiary, MaSTherCell, we are establishing a global reputation as a premier service provider in the regenerative medicine industry. While academic and industrial research has greatly advanced scientific development in the sector, industrialization and manufacturing expertise remains insufficient. We plan to fill this gap by providing two types of services to our customers: (i) process and assay development and optimization services; and (ii) current Good Manufacturing Practices (cGMP) contract manufacturing services. In 2016, MaSTherCell entered agreements with a number of the leading pharmaceutical and biotech companies, as well as research institutions and hospitals involved in cutting-edge cell therapy companies. As the industry continues to mature and a growing number of cell therapy companies approach commercialization, we believe that MaSTherCell is well positioned to serve as an external manufacturing source for a wide array of cell therapy companies.”

- We entered into several strategic partnerships and joint venture agreements in 2016. In March, we entered into a Joint Venture Agreement with CureCell, pursuant to which we are collaborating in the contract development and manufacturing of cell therapy products in Korea. In May 2016, Orgenesis Ltd, our Israeli subsidiary, entered into a pharma Cooperation and Project Funding Agreement (CPFA) with KORIL and CureCell, whereby KORIL will provide funding for a joint research and development project for the use of AIP cells for the treatment of diabetes. Also in May 2016, we entered into a joint venture agreement with Atvio Biotech Ltd., an Israeli company, to collaborate in the contract development and manufacturing of cell and virus therapy products in the field of regenerative medicine.”

---

- We secured a number of grants in 2016 to advance our platform through non-dilutive funding. In April 2016, Orgenesis SPRL, our Belgian subsidiary, received formal approval from DGO6 for a budgeted €1.3 million (\$1.5 million) support program for the development of our technology for Type 1 diabetes. In October 2016, Orgenesis SPRL received formal approval from the DGO6 for a budgeted €12.3 million (\$12.8 million) support program for the GMP production of AIP cells for two clinical trials that are scheduled to be performed in Germany and Belgium.”

- We were successful in raising additional capital in 2016, and have since secured an additional commitment from an institutional investor for \$16 million, payable periodically through August 2018, with the first payment of \$1 million already received in February 2017. We believe this latest investment, which was consummated at a premium to market at the time of the agreement, is further validation of both our technology and our business model.”

“Looking ahead, through our Israeli subsidiary, we look forward to rapidly advancing our proprietary and patented AIP technology for diabetes through the regulatory and clinical pathway. We also look forward to accelerating growth in our MaSTherCell subsidiary as we expand organically around the world, and as pilot projects mature into commercialization partnerships with leading pharmaceutical and biotech company. We also plan to apply our expertise to emerging technologies in other cell therapy markets in areas such as cell-based cancer immunotherapies and neurodegenerative diseases. We appreciate the continued support of our shareholders and look forward to providing further updates in the near future.”

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

Orgenesis is a vertically-integrated biopharmaceutical company with expertise and unique experience in cell therapy development and manufacturing. Through its Israeli subsidiary, Orgenesis Ltd., Orgenesis is a pioneer in the development of technology designed to successfully reprogram human liver cells into glucose-responsive, fully functional, Insulin Producing Cells (IPCs). Orgenesis believes that converting the diabetic patient's own tissue into insulin-producing cells has the potential to overcome the significant issues of donor shortage, cost and exposure to chronic immunosuppressive therapy associated with islet cell transplantation. In addition, through its Belgian subsidiary, MaSTherCell S.A., a global Contract Development and Manufacturing Organization (CDMO), Orgenesis is able to deliver optimized process industrialization capacities to cell therapy companies, and speed up the arrival of their therapies onto the market. From technology selection to business modeling, GMP manufacturing, process development, quality management and assay development, MaSTherCell's teams are fully committed to helping our customers fulfill their objective of providing sustainable and affordable therapies to their patients. The company operates in a validated and flexible facility located in the strategic center of Europe within the Walloon healthcare cluster, Biowin. This integrated approach supports Orgenesis's business philosophy of bringing to market significant life-improving medical treatments. For more information, visit [www.orgenesis.com](http://www.orgenesis.com).

---

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

*This press release contains forward-looking statements that involve substantial uncertainties and risks. These forward-looking statements 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 ability to raise working capital to support our business, the sufficiency of working capital to realize our business plans, our ability to raise the working capital needed to fund the commitments of our CDMO business, various joint ventures, development projects and the effect on these efforts of the going concern qualification in our financial statements; the progress to and timing of clinical trials for our AIP technology, the successful integration of our clinical and CDMO strategy; the development of our regeneration 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 medical procedures; our competitors developing better or cheaper alternatives to our products and the risks and uncertainties discussed under the heading "RISK FACTORS" in Item 1 of our Annual Report on Form 10-K for the fiscal year ended November 30, 2016, 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.*

###

**Contact:**

David Waldman  
Crescendo Communications, LLC  
(212) 671-1020 x301  
orgs@crescendo-ir.com

---