Orgenesis Inc.
Form 8-K
April 29, 2019

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): **April 29, 2019**

ORGENESIS INC.

(Exact name of registrant as specified in its charter)

Nevada	**000-54329**	**98-0583166**
(State or other jurisdiction of incorporation)	(Commission File Number)	(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 (*see* General Instruction A.2. below):

[ ] 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))

Indicate by check mark whether the registrant is an emerging growth company as defined in as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b -2 of this chapter).

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chapter).

Emerging growth company [ ]

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. [ ]

Item 8.01 Other Events.

On April 29, 2019, Orgenesis Inc. (the Company) announced that it has received Institutional Review Board (IRB) approval to collect liver biopsies from patients at Rambam Medical Center located in Haifa, Israel for a planned study to confirm the suitability of liver cells for personalized cell replacement therapy for patients with insulin-dependent diabetes resulting from total or partial pancreatectomy. The liver cells are intended to be bio-banked for potential future clinical use.

The goal of the proposed study, entitled Collection of Human Liver Biopsy and Whole Blood Samples from Type 1 Diabetes Mellitus (T1DM), Total or Partial Pancreatectomy Patients for Potential use as an Autologous Source for Insulin Producing Cells in Future Clinical Studies, is to confirm the suitability of the liver cells for personalized cell replacement therapy, as well as eligibility of patients to participate in a future clinical study, as defined by successful Autologous Insulin Producing (AIP) cell production from their own liver biopsy. The secondary objective of the study is to evaluate patients' immune response to AIPs based on the patient s blood samples and followed by subcutaneous implantation into the patients' arm which would represent the first human trial. The Company has developed a novel technology based on technology licensed from Tel Hashomer Medical Research Infrastructure and Services Ltd., utilizing liver cells as a source for AIP cells as replacement therapy for islet transplantation.

During the study, liver samples will be collected and then processed and stored in specialized, clinical grade, tissue banks for potential clinical use. The study will enroll 20 patients and is expected to commence May 2019. The propagated cells will be maintained in a tissue bank and are intended to be utilized in a future clinical study, in which the cells will be transdifferentiated and administered back to the patients as a potential treatment. This personalized autologous process will be performed under our Autologous Point of Care (POCare) model in which the patient liver samples are processed, cryopreserved and potentially re-injected, all in the medical center under clinical grade/GMP level conditions.

This Current Report on Form 8-K contains forward-looking statements relating to the proposed study. Undue reliance should not be placed on these forward-looking statements because they involve known and unknown risks, uncertainties and other factors that are, in some cases, beyond the Company s control and that could materially affect actual results. The Company expressly disclaims any intent or obligation to update these forward-looking statements, except as required by law.

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.

Date: April 29, 2019 By: /s/ Neil Reithinger
Neil Reithinger
Chief Financial Officer, Treasurer and Secretary