

Orgenesis Inc.
Form 8-K
February 24, 2016

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): **February 18, 2016**

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))
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Item 8.01 Other Events.

On February 18, 2016, the Company, through its Israeli subsidiary Orgenesis Ltd. (Orgenesis Ltd.), entered into a Collaboration Agreement (the Collaboration Agreement) with Grand China Energy Group Limited with headquarters in Beijing, China (Grand China) to collaborate in carrying out clinical trials and marketing the Company's autologous insulin producing cell therapy product (API) in the Peoples Republic of China, Hong Kong and Macau (the Territory), based on achieving certain pre-market development milestones that include Grand China obtaining the requisite regulatory approvals for commercialization of the API, including performing all clinical and other testing required for market authorization in each jurisdiction in the Territory. Upon achieving the pre-market development milestones by Grand China, the parties will collaborate on marketing the products in the Territory. Grand China will bear all costs associated with the pre-marketing development efforts in the Territory, which is expected to last for approximately four years.

Subject to the completion of the pre-marketing development milestones, Orgenesis Ltd. has agreed to grant to Grand China, or a fully owned subsidiary thereof, under a separate sub-license agreement (the Sub-License Agreement), an exclusive sub-license to the intellectual property underlying the API solely for commercialization of the Company's products in each such jurisdiction in the Territory where all of the pre-marketing development required to commercialize the API product have been successfully completed by Grand China. Grand China has agreed to pay annual license fees, ongoing royalties based on net sales generated by Grand China and its sublicensees, milestone payments and sublicense fees. It is anticipated that the Sub-License Agreement will also contain, among other things, minimum sales requirements as well as other provisions common in licensing agreements for international biotech licensing agreements.

The Collaboration Agreement is terminable by Orgenesis Ltd. upon certain conditions, including, but not limited to, if the clinical trials necessary to obtain the pre-marketing approval are not commenced within 12 months of the date of the execution of the agreement or if all approvals necessary for the commencement of marketing in the Territory are not obtained within four years. The Collaboration Agreement is also terminable under certain limited conditions relating to a party's insolvency or bankruptcy related event or breach of a material term of the agreement and force majeure events.

This Current Report on Form 8-K contains forward-looking statements relating to the parties' collaboration plans. 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.

Item 9.01 Financial Statements and Exhibits.

None

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

February 24, 2016
