
**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): **May 10, 2019**

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))

Indicate by check mark whether the registrant is an emerging growth company 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).

Emerging growth company

If an emerging growth company, indicate by checkmark 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. []

Securities registered pursuant to Section 12(b) of the Act:

Title of each class

Trading Symbol(s)

Name of each exchange on which registered

Common Stock

ORGS

The Nasdaq Capital Market

ITEM 2.02 RESULTS OF OPERATIONS AND FINANCIAL CONDITION

On May 9, 2019, Orgenesis Inc. (the "Company") issued a press release announcing its results of operations and financial condition as well as a business update for the quarter ended March 31, 2019. A copy of the press release is attached hereto as Exhibit 99.1 to this Current Report on Form 8-K and incorporated herein by reference.

In accordance with General Instruction B.2 of Form 8-K, the information in this Current Report on Form 8-K under this heading, including the related Exhibit 99.1, shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, except as shall be expressly set forth in such a filing.

ITEM 9.01 FINANCIAL STATEMENTS AND EXHIBITS.

(d) Exhibits.

[99.1](#) [Press Release of Orgenesis Inc. dated May 9, 2019.](#)

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
May 10, 2019



Orgenesis First Quarter 2019 Revenue Increases 177% to a Record \$7.3 Million

Company Expands Point of Care Platform; Benefits from Growing Cell and Gene Therapy Market

GERMANTOWN, MD – May 9, 2019 – **Orgenesis Inc. (NASDAQ: ORGS)** (“Orgenesis” or the “Company”), a developer, manufacturer and service provider of advanced cell therapies, today reported financial results and provided a business update for the fiscal first quarter ended March 31, 2019. As a result of the Company’s change in its fiscal year end from November 30 to December 31, the Company is reporting a December 2018 fiscal month transition period and is comparing the results for the three months ended March 31, 2019, to the three months ended February 28, 2018.

Fiscal Q1 2019 financial highlights include:

- Revenue increased 177% to \$7.3 million, as compared to \$2.6 million for the three months ended February 28, 2018
- Gross profit increased 198% to \$3.0 million, as compared to \$992,000 for the three months ended February 28, 2018
- Ended quarter with \$14.4 million of cash and approximately \$21.4 million of shareholders’ equity

Vered Caplan, CEO of Orgenesis, commented, “Our financial performance is indicative of the rapid growth in the cell and gene therapy market. The revenue increase we are experiencing at Orgenesis is a direct result of the expanding capacity of our Contract Development and Manufacturing Organization (“CDMO”) business to meet the growing demand by providing high quality services to our client base.”

“We have made significant strides with respect to our Point of Care (“POCare”) platform,” said Ms. Caplan. “We have aligned ourselves with key regional partners in order to establish a network of leading healthcare facilities to enable our autologous cell therapy platform. This division is driving further value for Orgenesis shareholders through collaboration and out licensing agreements. We believe this additional value will become increasingly visible in our future financial performance.”

“We achieved strong year-over-year revenue growth of 177%, with revenue increasing to a record \$7.3 million for the first quarter of 2019. In order to meet the growing demand for our CDMO services, we are establishing a new, state-of-the-art production site within the Gosselies Biopark in Belgium, which will expand our CDMO capacity with the goal of serving the needs of commercial-stage customers. We are also establishing a new 30,000 square foot manufacturing facility in Houston, Texas, to dramatically expand our presence within North America,” said Caplan.

Through its POCare platform, Orgenesis continues to align with regional partners in order to establish a network of leading healthcare facilities to develop autologous cell and gene therapies. Orgenesis recently entered into an out licensing and collaboration agreement with HekaBio K.K. for Japan. Orgenesis entered into an agreement with TheraCell for the clinical development and commercialization of cell and gene therapies in certain European countries and recently announced an agreement with Columbia University to develop a cellular vaccination product platform for pancreatic, hepatic and cholangiocarcinoma cancers. Orgenesis also partnered with ExcellaBio for exosome related technologies, as well as Digilab to develop industrial 3D printing capability for cellular structures and tissues for clinical use.

About Orgenesis

Orgenesis is a biotechnology company specializing in the development, manufacturing and provision of technologies and services in the cell and gene therapy industry. The Company operates through two platforms: (i) a POCare cell therapy platform ("PT") and (ii) a CDMO platform conducted through its subsidiary, Masthercell Global. Through its PT business, the Company's aim is to further the development of Advanced Therapy Medicinal Products ("ATMPs") through collaborations and in-licensing with other pre-clinical and clinical-stage biopharmaceutical companies and research and healthcare institutes to bring such ATMPs to patients. The Company out-licenses these ATMPs through regional partners to whom it also provides regulatory, pre-clinical and training services to support their activity in order to reach patients in a point-of-care hospital setting. Through the Company's CDMO platform, it is focused on providing contract manufacturing and development services for biopharmaceutical companies. The CDMO platform operates through Masthercell Global, which currently consists of MaSTherCell in Belgium, Atvio in Israel and subsidiaries in South Korea and in the United States, each having unique know-how and expertise for manufacturing in a multitude of cell types. Additional information is available at: www.orgenesis.com.

Notice Regarding Forward-Looking Statements

This press release contains forward-looking statements which are made pursuant to the safe harbor provisions of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities and Exchange Act of 1934, as amended. These forward-looking statements involve substantial uncertainties and risks and 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, the success of our reorganized CDMO operations, the success of our partnership with Great Point Partners, our ability to achieve and maintain overall profitability, the sufficiency of working capital to realize our business plans, the development of our transdifferentiation 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 procedures; our competitors developing better or cheaper alternatives to our products and the risks and uncertainties discussed under the heading "RISK FACTORS" in Item 1A of our Annual Report on Form 10-K for the fiscal year ended November 30, 2018, 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 for Orgenesis:

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(tables follow)

CONDENSED CONSOLIDATED BALANCE SHEETS
(U.S. Dollars in Thousands)
(Unaudited)

Assets	As of		
	March 31, 2019	December 31, 2018	November 30, 2018
CURRENT ASSETS:			
Cash and cash equivalents	\$ 14,361	\$ 14,612	\$ 16,064
Restricted cash	401	387	392
Accounts receivable, net	5,975	3,226	4,151
Prepaid expenses and other receivables	986	1,132	913
GPP receivable, see note 5	-	6,600	6,600
Grants receivable	217	441	441
Inventory	1,992	1,660	1,736
Total current assets	23,932	28,058	30,297
NON-CURRENT ASSETS:			
Deposits	569	143	85
Loans to related party, see note 5	2,033	1,012	1,007
Property and equipment, net	12,783	12,458	11,901
Intangible assets, net	15,823	16,642	16,700
Operating lease right-of-use assets	14,354	-	-
Goodwill	15,002	15,266	15,165
Other assets	274	297	292
Total non-current assets	60,838	45,818	45,150
TOTAL ASSETS	\$ 84,770	\$ 73,876	\$ 75,447

CONDENSED CONSOLIDATED BALANCE SHEETS (Cont'd)
(U.S. Dollars in Thousands)
(Unaudited)

	As of		
	March 31, 2019	December 31, 2018	November 30, 2018
Liabilities and Equity			
CURRENT LIABILITIES:			
Accounts payable	\$ 5,522	\$ 4,583	\$ 3,804
Accrued expenses and other payables	1,525	1,499	2,060
Employees and related payables	3,034	3,052	3,006
Related parties	92	-	-
Advance payments on account of grant	1,510	1,603	1,724
Short-term loans and current maturities of long-term loans	631	641	647
Contract liabilities	7,533	5,175	5,317
Current maturities of long-term finance leases	232	226	209
Current maturities of operating leases	1,291	-	-
Current maturities of convertible loans	382	382	378
Total current liabilities	<u>21,752</u>	<u>17,161</u>	<u>17,145</u>
LONG-TERM LIABILITIES:			
Non-current operating leases	11,816	-	-
Loans payable	1,510	1,633	1,662
Convertible loans	1,242	1,214	1,038
Retirement benefits obligation	304	280	265
Deferred taxes	1,578	1,656	1,702
Long-term finance leases	641	661	638
Other long-term liabilities	293	297	195
Total long-term liabilities	<u>17,384</u>	<u>5,741</u>	<u>5,500</u>
TOTAL LIABILITIES	<u>39,136</u>	<u>22,902</u>	<u>22,645</u>
COMMITMENTS			
REDEEMABLE NON-CONTROLLING INTEREST	24,233	24,224	24,153
EQUITY:			
Common stock of \$0.0001 par value, 145,833,334 shares authorized, 16,102,000, 15,540,333 and 14,951,783 shares issued and outstanding as of March 31, 2019, December 31, 2018 and November 30, 2018, respectively	2	2	1
Additional paid-in capital	94,049	90,597	88,082
Receipts on account of shares to be allotted	-	-	2,253
Accumulated other comprehensive income	185	669	425
Accumulated deficit	(73,474)	(65,163)	(62,411)
Equity attributable to Orgenesis Inc.	20,762	26,105	28,350
Non-controlling interest	639	645	299
Total equity	<u>21,401</u>	<u>26,750</u>	<u>28,649</u>
TOTAL LIABILITIES AND EQUITY	<u>\$ 84,770</u>	<u>\$ 73,876</u>	<u>\$ 75,447</u>

ORGENESIS INC.
CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS
(U.S. Dollars in Thousands, Except Share and Loss Per Share Amounts)
(Unaudited)

	Three Months Ended		Transition Period One- Month Ended
	March 31, 2019	February 28, 2018	December 31, 2018
REVENUES	\$ 7,301	\$ 2,636	\$ 1,852
COST OF REVENUES	4,344	1,644	1,221
GROSS PROFIT	2,957	992	631
RESEARCH AND DEVELOPMENT EXPENSES, net	5,150	766	1,431
AMORTIZATION OF INTANGIBLE ASSETS	517	436	179
SELLING, GENERAL AND ADMINISTRATIVE EXPENSES	5,600	3,344	1,984
OTHER INCOME, net	(37)	(316)	-
OPERATING LOSS	8,273	3,238	2,963
FINANCIAL EXPENSES, net	140	2,681	27
SHARE IN NET INCOME OF ASSOCIATED COMPANY	-	(46)	-
LOSS BEFORE INCOME TAXES	8,413	5,873	2,990
TAX (INCOME) EXPENSES	37	(396)	(83)
NET LOSS	8,450	5,477	2,907
NET INCOME (LOSS) ATTRIBUTABLE TO NON- CONTROLLING INTERESTS (INCLUDING REDEEMABLE)	(139)	134	(163)
NET LOSS ATTRIBUTABLE TO ORGENESIS INC.	<u>8,311</u>	<u>5,611</u>	<u>2,744</u>
LOSS PER SHARE:			
Basic	<u>\$ 0.55</u>	<u>\$ 0.52</u>	<u>\$ 0.19</u>
Diluted	<u>\$ 0.55</u>	<u>\$ 0.52</u>	<u>\$ 0.19</u>
WEIGHTED AVERAGE NUMBER OF SHARES USED IN COMPUTATION OF BASIC AND DILUTED EARNINGS (LOSS) PER SHARE:			
Basic	<u>15,571,568</u>	<u>10,775,877</u>	<u>15,423,040</u>
Diluted	<u>15,571,568</u>	<u>10,775,877</u>	<u>15,423,040</u>
COMPREHENSIVE LOSS:			
Net loss	\$ 8,450	\$ 5,477	\$ 2,907
Other comprehensive (income) loss - translation adjustments	484	(707)	(244)
Comprehensive loss	8,934	4,770	2,663
Comprehensive (income) loss attributed to non-controlling interests (including redeemable)	(139)	134	(163)
COMPREHENSIVE LOSS ATTRIBUTED TO ORGENESIS INC.	<u>\$ 8,795</u>	<u>\$ 4,904</u>	<u>\$ 2,500</u>