

**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

ORGANOGENESIS HOLDINGS INC.

(Exact Name of Registrant as specified in its charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-37906
(Commission
File Number)

98-1329150
(IRS Employer
Identification No.)

85 Dan Road
Canton, MA
(Address of principal executive offices)

02021
(Zip Code)

(781) 575-0775
(Registrant's telephone number, including area code)

Not Applicable
(Registrant's name or former address, if change 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 check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards 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
Class A Common Stock, \$0.001 par value	ORGO	Nasdaq Capital Market

Item 2.02 Results of Operations and Financial Condition.

On May 10, 2019, Organogenesis Holdings Inc. announced via press release its results for the first fiscal quarter ended March 31, 2019. A copy of Organogenesis Holdings' press release is hereby furnished to the Commission and incorporated herein by reference as Exhibit 99.1.

Item 9.01 Financial Statements and Exhibits.**(d) Exhibits**

<u>Exhibit No.</u>	<u>Description</u>
99.1	<u>Press release dated May 10, 2019, entitled "Organogenesis Holdings Inc. Reports First Quarter 2019 Financial Results"</u>

SIGNATURE

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

Organogenesis Holdings Inc.

By: /s/ Timothy M. Cunningham

Name: Timothy M. Cunningham

Title: Chief Financial Officer

Date: May 10, 2019



FOR IMMEDIATE RELEASE

Organogenesis Holdings Inc. Reports First Quarter 2019 Financial Results

CANTON, Mass. (May 10, 2019) – Organogenesis Holdings Inc. (Nasdaq: ORGO), a leading regenerative medicine company focused on the development, manufacture, and commercialization of product solutions for the Advanced Wound Care and Surgical & Sports Medicine markets, today reported financial results for its first quarter ended March 31, 2019.

First Quarter 2019 Financial Summary:

- Net revenue of \$57.1 million for the first quarter of 2019, up 60.8% compared to net revenue of \$35.5 million for the first quarter of 2018. Net revenue comprised:
 - Net revenue from Advanced Wound Care products of \$47.8 million, up 63.7% from the first quarter of 2018.
 - Net revenue from Surgical & Sports Medicine products of \$9.3 million, up 47.2% from the first quarter of 2018.
- Net revenue from the sale of PuraPly products of \$25.4 million for the first quarter of 2019, up 139.1% from the first quarter of 2018.
- Net revenue from the sale of non-PuraPly products of \$31.7 million for the first quarter of 2019, up 27.3% from the first quarter of 2018.
- Net loss was \$15.7 million, compared to a net loss of \$22.5 million for the first quarter of 2018.
- Adjusted EBITDA loss of \$9.4 million, compared to Adjusted EBITDA loss of \$17.3 million for the first quarter of 2018.

First Quarter 2019 and Recent Highlights:

- On March 4, 2019, the Company presented a new case series published in *Plastic and Reconstructive Surgery - Global Open* suggesting that PuraPly® Antimicrobial (PuraPly AM) positively affects the course of healing in a variety of complex, chronic wounds that were previously unresponsive to treatment.
- On March 14, 2019, the Company entered into a new credit agreement with Silicon Valley Bank and MidCap Financial, providing an aggregate principal amount of \$100 million consisting of a \$60 million term loan and a \$40 million revolving credit facility.
- On March 14, 2019, Jack Farr, MD, Medical Director of the Cartilage Research Center of Indiana presented clinical trial results demonstrating the effectiveness of ReNu® in treating symptoms associated with knee osteoarthritis at the American Academy of Orthopedic Surgeons Annual Meeting.
- On May 1, 2019, the Company announced that it received an Innovative Technology contract from Vizient, Inc. for its portfolio of Advanced Wound Care and Surgical & Sports Medicine products.

“2019 is off to a strong start,” said Gary S. Gillheeney, Sr., President and Chief Executive Officer of Organogenesis. “We delivered significant year-over-year revenue growth across both our Advanced Wound Care and Surgical & Sports Medicine portfolios driven by strong sales of our PuraPly and amnion products. With successful execution

against our commercial strategy, we leveraged PuraPly's pass through advantage to gain new PuraPly accounts, drive customer and clinician adoption of PuraPly deeper into existing accounts, and drive sales of our other products into accounts that had previously only purchased PuraPly. Strong execution from our sales team also drove penetration of our amnion products into existing and new accounts despite suspension of Affinity production in Q1 2019. Additionally, we grew our customer base across both our Advanced Wound Care and Surgical & Sports Medicine portfolios, and continued to build our commercial infrastructure by adding direct sales representatives and agencies. Based on our solid first quarter financial results and our expectation for continued strong commercial execution, we have increased our 2019 full year financial guidance."

Mr. Gillheeney, Sr. continued: "We remain committed to delivering on our mission to provide integrated healing solutions that substantially improve medical outcomes and the lives of patients, while lowering the overall cost of care. To that end, we recently announced that we received an 'Innovative Technology' contract from Vizient, Inc., the largest health care performance improvement company in the country as part of Vizient's move to value-based care."

Net Revenue Summary:

The following table represents revenue by product grouping for the three months ended March 31, 2019:

<i>(In thousands)</i>	Three Months Ended March 31,		Increase/Decrease	
	2019	2018	\$ Change	% Change
Advanced Wound Care	\$47,844	\$29,223	\$18,621	63.7%
Surgical & Sports Medicine	9,279	6,306	2,973	47.2%
Net revenue	<u>\$57,123</u>	<u>\$35,529</u>	<u>\$21,594</u>	<u>60.8%</u>

First Quarter 2019 Results:

Net revenue for the first quarter of 2019 was \$57.1 million, compared to \$35.5 million for the first quarter of 2018, an increase of \$21.6 million, or 60.8%. The increase in net revenue was driven by a \$18.6 million increase in net revenue of Advanced Wound Care products and a \$3.0 million increase in net revenue of Surgical & Sports Medicine products, representing growth of 63.7% and 47.2%, respectively, compared to the first quarter of 2018. The increase in Advanced Wound Care net revenue was primarily attributable to additional sales personnel, PuraPly regaining pass-through reimbursement status for the two-year period effective October 1, 2018 and the continued growth in adoption of our amnion products. The increase in Surgical & Sports Medicine revenue was primarily due to the expansion of the sales force and penetration of existing and new customer accounts. Net revenue of PuraPly products for the first quarter of 2019 was \$25.4 million, compared to \$10.6 million for the first quarter of 2018, an increase of \$14.8 million, or 139.1%. Net revenue of PuraPly products represented approximately 45% of net revenue in the first quarter of 2019, compared to 30% of net revenue in the first quarter of 2018.

Gross profit for the first quarter of 2019 was \$40.1 million or 70.3% of net revenue, compared to \$21.0 million, or 59.1% of net revenue, for the first quarter of 2018, an increase of \$19.1 million, or 91.1%. The improvement in gross profit and gross profit margin percentage resulted primarily from a more favorable product mix of revenue in the first quarter of 2019, PuraPly regaining pass-through reimbursement status, and volume-based manufacturing efficiencies.

Operating expenses for the first quarter of 2019 were \$52.3 million, compared to \$41.0 million for the first quarter of 2018, an increase of \$11.3 million, or 27.5%. The increase in operating expenses in the first quarter of 2019 as compared to the first quarter of 2018 was driven primarily by higher selling, general and administrative expenses which increased to \$48.9 million, compared to \$38.2 million in the first quarter of 2018, an increase of \$10.7 million, or 28.1%. The increase in selling, general and administrative expenses is primarily due to additional headcount, predominantly in the direct sales force, higher sales commissions and increased marketing and promotional expenses for the Company's products. R&D expense was \$3.4 million for the first quarter of 2019, compared to \$2.8 million in the first quarter of 2018, an increase of \$0.5 million, or 19.4%. The increase in R&D was driven by additional headcount and continued and new investment in clinical programs.

Operating loss for the first quarter of 2019 was \$12.1 million, compared to an operating loss of \$20.0 million for the first quarter of 2018, a decrease of \$7.9 million, or 39.3%. Total other expenses, net, for the first quarter of 2019 were \$3.5 million, compared to \$2.5 million for the first quarter of 2018, an increase of \$1.0 million, or 41.5%. The increase was driven primarily by a \$1.9 million non-cash loss on the extinguishment of debt and entering into the Company's new \$100 million credit agreement with Silicon Valley Bank and MidCap Financial.

Net loss for the first quarter of 2019 was \$15.7 million, or \$0.17 per share, compared to a net loss of \$22.5 million, or \$0.35 per share, for the first quarter of 2018, a decrease of \$6.8 million, or 30.3%.

As of March 31, 2019, the Company had \$30.6 million in cash and \$88.1 million in debt obligations, of which \$17.4 million were capital lease obligations, compared to \$21.3 million in cash and \$59.3 million in debt obligations, of which \$17.7 million were capital lease obligations, as of December 31, 2018.

Fiscal Year 2019 Revenue Guidance:

The Company is updating its fiscal year 2019 revenue expectations. For the twelve months ending December 31, 2019, the Company expects:

- Net revenue of between \$249 million and \$262 million, representing growth of approximately 29% to 35% year-over-year, as compared to net revenue of \$193.4 million for the twelve months ended December 31, 2018.
- The 2019 net revenue forecast assumes:
 - Net revenue from Advanced Wound Care products of between \$219 million and \$229 million, representing growth of approximately 33% to 39% year-over-year as compared to net revenue of \$164.3 million for the twelve months ended December 31, 2018.
 - Net revenue from Surgical & Sports Medicine products of between \$30 million and \$33 million, representing growth of approximately 3% to 13% year-over-year as compared to net revenue of \$29.1 million for the twelve months ended December 31, 2018.
 - The 2019 net revenue guidance range also assumes that net revenue from the sale of PuraPly products will represent between \$96 million and \$103 million of net revenue, representing growth of approximately 38% to 48% year-over-year, as compared to net revenue of \$69.8 million for the twelve months ended December 31, 2018.

Conference Call:

Management will host a conference call at 8:00 a.m. Eastern Time on May 10 to discuss the results of the quarter with a question and answer session. Those who would like to participate may dial 866-795-3142 (409-937-8908 for international callers) and provide access code 4572798. A live webcast of the call will also be provided on the investor relations section of the Company's website at investors.organogenesis.com.

For those unable to participate, a replay of the call will be available for two weeks at 855-859-2056 (404-537-3406 for international callers); access code 4572798. The webcast will be archived at investors.organogenesis.com.

Forward-Looking Statements

This release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. These forward-looking statements relate to expectations or forecasts of future events. Forward-looking statements may be identified by the use of words such as “forecast,” “intend,” “seek,” “target,” “anticipate,” “believe,” “expect,” “estimate,” “plan,” “outlook,” and “project” and other similar expressions that predict or indicate future events or trends or that are not statements of historical matters. Such forward-looking statements include statements relating to the Company’s expected revenue for fiscal 2019 and the breakdown of such revenue in both its Advanced Wound Care and Surgical & Sports Medicine categories as well as the estimated revenue contribution of its PuraPly products. Forward-looking statements with respect to the operations of the Company, strategies, prospects and other aspects of the business of the Company are based on current expectations that are subject to known and unknown risks and uncertainties, which could cause actual results or outcomes to differ materially from expectations expressed or implied by such forward-looking statements. These factors include, but are not limited to: (1) the Company has incurred significant losses since inception and anticipates that it will incur substantial losses for the foreseeable future; (2) the Company faces significant and continuing competition, which could adversely affect its business, results of operations and financial condition; (3) rapid technological change could cause the Company’s products to become obsolete and if the Company does not enhance its product offerings through its research and development efforts, it may be unable to effectively compete; (4) to be commercially successful, the Company must convince physicians that its products are safe and effective alternatives to existing treatments and that its products should be used in their procedures; (5) the Company’s ability to raise funds to expand its business; (6) the impact of any changes to the reimbursement levels for the Company’s products and the impact to the Company of the loss of preferred “pass through” status for PuraPly AM and PuraPly on October 1, 2020; (7) the Company’s ability to maintain compliance with applicable Nasdaq listing standards; (8) changes in applicable laws or regulations; (9) the possibility that the Company may be adversely affected by other economic, business, and/or competitive factors; and (10) other risks and uncertainties described in the Company’s filings with the Securities and Exchange Commission, including Item 1A (Risk Factors) of the Company’s Form 10-K for the year ended December 31, 2018. You are cautioned not to place undue reliance upon any forward-looking statements, which speak only as of the date made. Although it may voluntarily do so from time to time, the Company undertakes no commitment to update or revise the forward-looking statements, whether as a result of new information, future events or otherwise, except as required by applicable securities laws.

About Organogenesis Holdings Inc.

Organogenesis Holdings Inc. is a leading regenerative medicine company offering a portfolio of bioactive and acellular biomaterials products in advanced wound care and surgical biologics, including orthopedics and spine. Organogenesis’s comprehensive portfolio is designed to treat a variety of patients with repair and regenerative needs. For more information, visit www.organogenesis.com.

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ORGANOGENESIS HOLDINGS INC.

CONSOLIDATED BALANCE SHEETS

(in thousands, except share and per share amounts)

	March 31, 2018	December 31, 2018
Assets		
Current assets:		
Cash	\$ 30,561	\$ 21,291
Restricted cash	102	114
Accounts receivable, net	32,509	34,077
Inventory	17,972	13,321
Prepaid expenses and other current assets	3,918	2,328
Total current assets	85,062	71,131
Property and equipment, net	39,454	39,623
Notes receivable from related parties	496	477
Intangible assets, net	24,592	26,091
Goodwill	25,539	25,539
Deferred tax asset	238	238
Other assets	1,072	579
Total assets	<u>\$ 176,453</u>	<u>\$ 163,678</u>
Liabilities and Stockholders' Equity		
Current liabilities:		
Deferred acquisition consideration	\$ 5,000	\$ 5,000
Redeemable common stock liability	—	6,762
Current portion of notes payable	—	2,545
Current portion of capital lease obligations	2,337	2,236
Accounts payable	24,575	19,165
Accrued expenses and other current liabilities	20,395	20,388
Total current liabilities	52,307	56,096
Line of credit	30,984	26,484
Notes payable, net of current portion	—	12,578
Term loan	39,635	—
Deferred rent, net of current portion	179	130
Capital lease obligations, net of current portion	15,109	15,418
Other liabilities	5,680	5,931
Total liabilities	<u>143,894</u>	<u>116,637</u>
Commitments and contingencies (Note 13)		
Stockholders' equity:		
Common stock, \$0.0001 par value; 400,000,000 shares authorized at March 31, 2019 and December 31, 2018; 92,044,587 and 91,261,413 shares issued at March 31, 2019 and December 31, 2018, respectively. 91,316,039 and 91,261,413 outstanding at March 31, 2019 and December 31, 2018, respectively.	9	9
Additional paid-in capital	178,124	177,272
Accumulated deficit	(145,574)	(130,240)
Total stockholders' equity	<u>32,559</u>	<u>47,041</u>
Total liabilities and stockholders' equity	<u>\$ 176,453</u>	<u>\$ 163,678</u>

ORGANOGENESIS HOLDINGS INC.

CONSOLIDATED STATEMENTS OF OPERATIONS

(in thousands, except share and per share amounts)

	Three Months Ended March 31,	
	2019	2018
	(in thousands)	
Net revenue	\$ 57,123	\$ 35,529
Cost of goods sold	16,980	14,521
Gross profit	40,143	21,008
Operating expenses:		
Selling, general and administrative	48,893	38,165
Research and development	3,371	2,824
Total operating expenses	52,264	40,989
Loss from operations	(12,121)	(19,981)
Other income (expense), net:		
Interest expense	(1,797)	(2,429)
Interest income	19	19
Change in fair value of warrants	—	(74)
Loss on the extinguishment of debt	(1,862)	—
Other income, net	132	5
Total other income (expense), net	(3,508)	(2,479)
Net loss before income taxes	(15,629)	(22,460)
Income tax expense	(37)	(28)
Net loss	\$ (15,666)	\$ (22,488)
Net loss per share – basic and diluted	\$ (0.17)	\$ (0.35)
Weighted average common shares outstanding – basic and diluted	90,604,107	64,320,931

	Three Months Ended March 31,	
	2019	2018
	(in thousands)	
Net loss	\$ (15,666)	\$ (22,488)
Interest expense, net	1,778	2,410
Income tax expense	37	28
Depreciation	902	872
Amortization	1,498	917
EBITDA	\$ (11,451)	\$ (18,261)
Stock-based compensation expense	224	317
Change in contingent consideration forfeiture asset	—	589
Change in fair value of warrant liability	—	74
Loss on extinguishment of debt	1,862	—
Adjusted EBITDA	\$ (9,365)	\$ (17,281)

ORGANOGENESIS HOLDINGS INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS

(in thousands)

	Three Months Ended March 31,	
	2019	2018
Cash flows from operating activities:		
Net loss	\$ (15,666)	\$ (22,488)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	902	872
Amortization of intangible assets	1,498	917
Non-cash interest expense	170	239
Non-cash interest income	(19)	(20)
Non-cash rent expense	49	14
Benefit recorded for sales returns and doubtful accounts	(76)	(208)
Provision recorded for inventory reserve	520	1,482
Stock-based compensation	224	317
Change in fair value of warrant liability	—	73
Loss on extinguishment of debt	1,862	—
Changes in fair value of forfeiture rights	—	589
Changes in operating assets and liabilities:		
Accounts receivable	2,474	7,547
Inventory	(5,339)	(2,282)
Prepaid expenses and other current assets	(963)	(1,352)
Accounts payable	4,882	9,706
Accrued expenses and other current liabilities	176	(789)
Accrued interest—affiliate debt	—	797
Other liabilities	(252)	129
Net cash used in operating activities	(9,558)	(4,457)
Cash flows from investing activities:		
Purchases of property and equipment	(317)	(65)
Net cash used in investing activities	(317)	(65)
Cash flows from financing activities:		
Line of credit borrowings	4,500	3,075
Proceeds from term loan	40,000	—
Repayment of notes payable	(17,585)	(10)
Proceeds from the exercise of stock options	—	44
Redemption of redeemable common stock	(6,762)	—
Principal repayments of capital lease obligations	(209)	(18)
Payment of debt issuance costs	(811)	(9)
Net cash provided by financing activities	19,133	3,082
Change in cash and restricted cash	9,258	(1,440)
Cash and restricted cash, beginning of period	21,405	2,358
Cash and restricted cash, end of period	<u>\$ 30,663</u>	<u>\$ 918</u>
Supplemental disclosure of cash flow information:		
Cash paid for interest	\$ 1,627	\$ 1,650
Cash paid for income taxes	\$ 58	\$ 1
Supplemental disclosure of non-cash investing and financing activities:		
Debt issuance costs included in accounts payable	\$ 113	\$ —
Purchases of property and equipment in accounts payable and accrued expenses	\$ 415	\$ 715
Exercise of common stock warrants included in prepaids and other current assets	\$ 628	\$ —

Use of Non-GAAP Measures

Our management uses financial measures that are not in accordance with generally accepted accounting principles in the United States, or GAAP, in addition to financial measures in accordance with GAAP to evaluate our operating results. These non-GAAP financial measures should be considered supplemental to, and not a substitute for, our reported financial results prepared in accordance with GAAP. Our management uses Adjusted EBITDA principally as a measure of our operating performance and believes Adjusted EBITDA helps identify underlying trends in our business that could otherwise be masked by the effect of the items that we exclude. Accordingly, we believe that Adjusted EBITDA provides useful information to investors and others in understanding and evaluating our operating results, enhancing the overall understanding of our past performance and future prospects, and allowing for greater transparency with respect to key financial metrics used by our management in its financial and operational decision-making.

We define EBITDA as net income (loss) before depreciation and amortization, net interest expense and income taxes and we define Adjusted EBITDA as EBITDA, further adjusted for the impact of certain items that we do not consider indicative of our core operating performance. These items consist of non-cash equity compensation, mark to market adjustments on our warrant liabilities, change in fair value of interest rate swaps and our contingent asset and liabilities, write-off of deferred offering costs, Avista merger transaction costs and loss on the extinguishment of debt. We have presented Adjusted EBITDA in this press release because it is a key measure used by our management and Board of Directors to understand and evaluate our operating performance, generate future operating plans and make strategic decisions regarding the allocation of capital. In particular, we believe that the exclusion of certain items in calculating Adjusted EBITDA can produce a useful measure for period-to-period comparisons of our business.

Our Adjusted EBITDA is not prepared in accordance with GAAP, and should not be considered in isolation of, or as an alternative to, measures prepared in accordance with GAAP. There are a number of limitations related to the use of Adjusted EBITDA rather than net income (loss), which is the most directly comparable GAAP equivalent. Some of these limitations are:

- Adjusted EBITDA excludes stock-based compensation expense, as stock-based compensation expense has recently been, and will continue to be for the foreseeable future, a significant recurring expense for our business and an important part of our compensation strategy;
- Adjusted EBITDA excludes depreciation and amortization expense and, although these are non-cash expenses, the assets being depreciated may have to be replaced in the future;
- Adjusted EBITDA excludes net interest expense, or the cash requirements necessary to service interest, which reduces cash available to us;
- Adjusted EBITDA excludes the impact of the changes in the fair value of our warrant liability, our contingent consideration forfeiture asset, and the fair value of interest rate swaps;
- Adjusted EBITDA excludes the write-off of deferred offering costs, as well as merger transaction costs, consisting primarily of legal and professional fees;
- Adjusted EBITDA excludes the loss on extinguishment of debt, which is a non-cash loss related to the write-off of unamortized debt issuance costs upon repayment of affiliate and third-party debt, and related prepayment penalties;
- Adjusted EBITDA excludes income tax expense (benefit); and
- Other companies, including companies in our industry, may calculate Adjusted EBITDA differently, which reduces its usefulness as a comparative measure.

Because of these limitations, we consider, and you should consider, Adjusted EBITDA together with other operating and financial performance measures presented in accordance with GAAP. A reconciliation of Adjusted EBITDA to net loss, the most directly comparable measure calculated in accordance with GAAP, has been included herein.

	Three Months Ended March 31,	
	2019	2018
	(in thousands)	
Net loss	\$ (15,666)	\$ (22,488)
Interest expense, net	1,778	2,410
Income tax expense	37	28
Depreciation	902	872
Amortization	1,498	917
EBITDA	<u>\$ (11,451)</u>	<u>\$ (18,261)</u>
Stock-based compensation expense	224	317
Change in contingent consideration forfeiture asset	—	589
Change in fair value of warrant liability	—	74
Loss on extinguishment of debt	1,862	—
Adjusted EBITDA	<u>\$ (9,365)</u>	<u>\$ (17,281)</u>

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