

**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, 2023

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))

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, \$0.0001 par value	ORGO	Nasdaq Capital Market

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.

Item 2.02 Results of Operations and Financial Condition.

On May 10, 2023, the Company announced via press release its results for the fiscal first quarter ended March 31, 2023. A copy of the Company's press release is hereby furnished to the Commission and incorporated herein by reference as Exhibit 99.1.

The information in the press release attached as Exhibit 99.1 is intended to be furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934 (the "Exchange Act") 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 or the Exchange Act, except as expressly set forth by specific reference in such filing.

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

Exhibit No.	Description
99.1	Press Release dated May 10, 2023
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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/ Lori Freedman

Name: Lori Freedman

Title: Vice President and General Counsel

Date: May 10, 2023

FOR IMMEDIATE RELEASE

Organogenesis Holdings Inc. Reports First Quarter 2023 Financial Results

CANTON, Mass., (May 10, 2023) -- 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 the first quarter ended March 31, 2023.

First Quarter 2023 Financial Results Summary:

- Net revenue of \$107.6 million for the first quarter of 2023, an increase of \$10.5 million compared to net revenue of \$97.1 million for the first quarter of 2022. Net revenue for the first quarter of 2023 consists of:
 - o Net revenue from Advanced Wound Care products of \$100.9 million, an increase of 12% from the first quarter of 2022.
 - o Net revenue from Surgical & Sports Medicine products of \$6.7 million, a decrease of 4% from the first quarter of 2022.
- Net loss of \$3.0 million for the first quarter of 2023, compared to a net loss of \$0.9 million for the first quarter of 2022, an increase of \$2.1 million.
- Adjusted net loss¹ of \$0.7 million for the first quarter of 2023, compared to an adjusted net income of \$1.0 million for the first quarter of 2022, a decrease of \$1.6 million.
- Adjusted EBITDA of \$3.8 million for the first quarter of 2023, compared to Adjusted EBITDA of \$5.0 million for the first quarter of 2022, a decrease of \$1.2 million.

“First quarter sales came in above the high-end of the guidance range we provided on our fourth quarter earnings call,” said Gary S. Gillheaney, Sr., President, Chief Executive Officer and Chair of the Board of Organogenesis. “Sales of Advanced Wound Care products drove the majority of the upside in the quarter, exceeding the high-end of our expectations in both the hospital outpatient and physician office settings. As expected, we leveraged our diversified portfolio and leadership position in Wound Care Centers and physician offices across the U.S. to deliver strong growth in Q1.

Mr. Gillheaney, Sr. continued: “We are proud of the team’s execution in Q1 and believe our ability to deliver results above the high-end of our guidance range represents another clear illustration that we have the right strategy to maximize our competitive position in the Advanced Wound Care market. We have increased our financial guidance as a result of the stronger-than-expected first quarter results and look forward to continued progress in 2023. We will continue to be a leader in the Advanced Wound Care space while improving our competitive positions in the Surgical & Sports Medicine and burn markets as we deliver on our mission to provide integrated healing solutions that substantially improve patient outcomes and lower the overall cost of care. We remain committed to educating the public on the benefits of the use of skin substitutes and improving access to clinically efficacious treatment options.”

¹Defined as GAAP net income (loss) adjusted to exclude the effect of amortization, restructuring charges, GPO settlement fee and the resulting income taxes on these items.

First Quarter 2023 Financial Results:

	Three Months Ended March 31,		Change	
	2023	2022	\$	%
	(in thousands, except for percentages)			
Advanced Wound Care	\$ 100,917	\$ 90,090	\$ 10,827	12 %
Surgical & Sports Medicine	6,725	7,027	(302)	(4 %)
Net revenue	<u>\$ 107,642</u>	<u>\$ 97,117</u>	<u>\$ 10,525</u>	<u>11 %</u>

Net revenue for the first quarter of 2023 was \$107.6 million, compared to \$97.1 million for the first quarter of 2022, an increase of \$10.5 million, or 11%. The increase in net revenue was driven by an increase of \$10.8 million, or 12% in Advanced Wound Care products partially offset by a decrease of \$0.3 million, or 4% in net revenue of Surgical & Sports Medicine products.

Gross profit for the first quarter of 2023 was \$81.0 million, or 75% of net revenue, compared to \$72.0 million, or 74% of net revenue for the first quarter of 2022, an increase of \$9.0 million, or 12%.

Operating expenses for the first quarter of 2023 were \$85.0 million compared to \$72.2 million for the first quarter of 2022, an increase of \$12.9 million, or 18%. R&D expense was \$11.2 million for the first quarter of 2023, compared to \$8.6 million in the first quarter of 2022, an increase of \$2.6 million, or 30%. Selling, general and administrative expenses were \$73.8 million for the first quarter of 2023, compared to \$63.6 million in the first quarter of 2022, an increase of \$10.3 million, or 16%.

Operating loss for the first quarter of 2023 was \$4.0 million, compared to an operating loss of \$0.1 million for the first quarter of 2022, a decrease of \$3.9 million.

Total other expense, net, for the first quarter of 2023 was \$0.6 million, compared to \$0.7 million for the first quarter of 2022, a decrease of \$0.1 million.

Net loss for the first quarter of 2023 was \$3.0 million, or \$(0.02) per share, compared to a net loss of \$0.9 million, or \$(0.01) per share, for the first quarter of 2022, an increase of \$2.1 million, or \$(0.01) per share.

Adjusted net loss of \$0.7 million for the first quarter of 2023, compared to adjusted net income of \$1.0 million for the first quarter of 2022, a decrease of \$1.6 million.

Adjusted EBITDA was \$3.8 million for the first quarter of 2023, compared to \$5.0 million for the first quarter of 2022, a decrease of \$1.2 million.

As of March 31, 2023, the Company had \$89.4 million in cash, cash equivalents and restricted cash and \$69.9 million in debt obligations, compared to \$103.3 million in cash, cash equivalents and restricted cash and \$70.8 million in debt obligations as of December 31, 2022.

Fiscal Year 2023 Guidance:

For the year ending December 31, 2023, the Company expects:

- Net revenue between \$454 million and \$466 million, representing an increase of approximately 1% to 3% year-over-year, as compared to net revenue of \$450.9 million for the year ended December 31, 2022.
 - o The 2023 net revenue guidance range assumes:
 - Net revenue from Advanced Wound Care products between \$424 million and \$432 million, an increase of 0% to 2% year-over-year as compared to net revenue of \$422.2 million for the year ended December 31, 2022.
 - Net revenue from Surgical & Sports Medicine products between \$30 million and \$34 million, an increase of approximately 5% to 19% year-over-year as compared to net revenue of \$28.7 million for the year ended December 31, 2022.
- Net income between \$3 million and \$11 million and adjusted net income between \$8 million and \$16 million.
- EBITDA between \$28 million and \$39 million and Adjusted EBITDA between \$38 million and \$49 million.

First Quarter Earnings Conference Call:

Financial results for the first fiscal quarter of 2023 will be reported after the market closes on Wednesday, May 10th. Management will host a conference call at 5:00 p.m. Eastern Time on May 10th to discuss the results of the quarter, and provide a corporate update with a question and answer session. Those who would like to participate may access the live webcast [here](#), or access the teleconference [here](#). 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, the webcast will be archived at investors.organogenesis.com for approximately one year.

ORGANOGENESIS HOLDINGS INC.
UNAUDITED CONSOLIDATED BALANCE SHEETS
(amounts in thousands, except share and per share data)

	March 31, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	\$ 88,694	\$ 102,478
Restricted cash	721	812
Accounts receivable, net	92,021	89,450
Inventory, net	25,539	24,783
Prepaid expenses and other current assets	9,847	5,086
Total current assets	216,822	222,609
Property and equipment, net	106,637	102,463
Intangible assets, net	19,560	20,789
Goodwill	28,772	28,772
Operating lease right-of-use assets, net	42,839	43,192
Deferred tax asset, net	30,014	30,014
Other assets	1,463	1,520
Total assets	\$ 446,107	\$ 449,359
Liabilities and Stockholders' Equity		
Current liabilities:		
Current portion of term loan	\$ 5,009	\$ 4,538
Current portion of operating lease obligations	12,160	11,708
Accounts payable	30,310	32,330
Accrued expenses and other current liabilities	28,597	26,447
Total current liabilities	76,076	75,023
Term loan, net of current portion	64,860	66,231
Operating lease obligations, net of current portion	40,325	41,314
Other liabilities	1,145	1,122
Total liabilities	182,406	183,690
Commitments and contingencies (Note 18)		
Stockholders' equity:		
Preferred stock, \$0.0001 par value; 1,000,000 shares authorized; none issued	-	-
Common stock, \$0.0001 par value; 400,000,000 shares authorized; 131,954,935 and 131,647,677 shares issued; 131,226,387 and 130,919,129 shares outstanding at March 31, 2023 and December 31, 2022, respectively.	13	13
Additional paid-in capital	312,573	310,957
Accumulated deficit	(48,885)	(45,301)
Total stockholders' equity	263,701	265,669
Total liabilities and stockholders' equity	\$ 446,107	\$ 449,359

ORGANOGENESIS HOLDINGS INC.
UNAUDITED CONSOLIDATED
STATEMENTS OF OPERATIONS
(amounts in thousands, except share and per share data)

	Three Months Ended March 31,	
	2023	2022
Net revenue	\$ 107,642	\$ 97,117
Cost of goods sold	26,607	25,080
Gross profit	81,035	72,037
Operating expenses:		
Selling, general and administrative	73,834	63,578
Research and development	11,202	8,587
Total operating expenses	85,036	72,165
Loss from operations	(4,001)	(128)
Other expense, net:		
Interest expense	(649)	(737)
Other income (expense), net	23	(3)
Total other expense, net	(626)	(740)
Net loss before income taxes	(4,627)	(868)
Income tax benefit (expense)	1,658	(45)
Net loss	\$ (2,969)	\$ (913)
Net loss, per share:		
Basic	\$ (0.02)	\$ (0.01)
Diluted	\$ (0.02)	\$ (0.01)
Weighted-average common shares outstanding		
Basic	131,083,841	128,788,721
Diluted	131,083,841	128,788,721

ORGANOGENESIS HOLDINGS INC.
UNAUDITED CONSOLIDATED
STATEMENT OF CASH FLOWS
(amounts in thousands, except share and per share data)

	Three Months Ended March 31,	
	2023	2022
Cash flows from operating activities:		
Net loss	\$ (2,969)	\$ (913)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:		
Depreciation	2,694	1,347
Amortization of intangible assets	1,230	1,221
Reduction in the carrying value of right-of-use assets	1,939	1,847
Non-cash interest expense	107	108
Deferred interest expense	122	151
Provision recorded for credit losses	243	40
Loss on disposal of property and equipment	63	-
Adjustment for excess and obsolete inventories	1,407	2,205
Stock-based compensation	1,914	1,303
Changes in operating assets and liabilities:		
Accounts receivable	(3,429)	2,942
Inventory	(2,163)	80
Prepaid expenses and other current assets	(4,774)	(2,165)
Operating leases	(2,122)	(1,751)
Accounts payable	(1,390)	(1,186)
Accrued expenses and other current liabilities	2,029	(3,828)
Other liabilities	22	10
Net cash provided by (used in) operating activities	(5,077)	1,411
Cash flows from investing activities:		
Purchases of property and equipment	(7,562)	(6,672)
Net cash used in investing activities	(7,562)	(6,672)
Cash flows from financing activities:		
Payments of term loan under the 2021 Credit Agreement	(938)	(469)
Payments of withholding taxes in connection with RSUs vesting	(298)	(488)
Proceeds from the exercise of stock options	-	291
Principal repayments of finance lease obligations	-	(99)
Net cash used in financing activities	(1,236)	(765)
Change in cash, cash equivalents and restricted cash	(13,875)	(6,026)
Cash, cash equivalents, and restricted cash, beginning of period	103,290	114,528
Cash, cash equivalents, and restricted cash, end of period	<u>\$ 89,415</u>	<u>\$ 108,502</u>
Supplemental disclosure of cash flow information:		
Cash paid for interest	\$ 1,271	\$ 627
Cash paid for income taxes	\$ 128	\$ 4
Supplemental disclosure of non-cash investing and financing activities:		
Purchases of property and equipment included in accounts payable and accrued expenses	\$ 1,986	\$ 1,869
Right-of-use assets obtained through operating lease obligations	\$ 1,586	\$ 171

Non-GAAP Financial 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 and adjusted net income to evaluate our operating performance and trends and make planning decisions. Our management believes Adjusted EBITDA and adjusted net income help 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 and adjusted net income provide useful information to investors and others in understanding and evaluating our operating results, enhancing the overall understanding of our past performance and prospects, and allowing for greater transparency with respect to key financial metrics used by our management in its financial and operational decision-making.

The following table presents a reconciliation of GAAP net income to non-GAAP EBITDA and non-GAAP Adjusted EBITDA, for the period presented:

	Three Months Ended	
	March 31,	
	2023	2022
	(Unaudited) (in thousands)	
Net loss	\$ (2,969)	\$ (913)
Interest expense, net	649	737
Income tax expense (benefit)	(1,658)	45
Depreciation	2,694	1,347
Amortization	1,230	1,221
EBITDA	(54)	2,437
Stock-based compensation expense	1,914	1,303
Restructuring charge (1)	1,908	264
Settlement fee (2)	-	1,000
Adjusted EBITDA	<u>\$ 3,768</u>	<u>\$ 5,004</u>

(1) Amounts reflect employee severance, retention and benefits as well as other exit costs associated with the Company's restructuring activities.

(2) Amounts reflect the fee the Company paid to a GPO to settle previously disputed GPO fees.

The following table presents a reconciliation of GAAP net loss to non-GAAP adjusted net income (loss), for the periods presented:

	Three Months Ended March 31,	
	2023	2022
	(Unaudited) (in thousands)	
Net loss	\$ (2,969)	\$ (913)
Amortization	1,230	1,221
Restructuring charge (1)	1,908	264
Settlement fee (2)	-	1,000
Tax on above	(847)	(621)
Adjusted net income (loss)	<u>\$ (678)</u>	<u>\$ 951</u>

(1) Amounts reflect employee severance, retention and benefits as well as other exit costs associated with the Company's restructuring activities.

(2) Amounts reflect the fee the Company paid to a GPO to settle previously disputed GPO fees.

The following table presents a reconciliation of projected GAAP net income to projected non-GAAP EBITDA and projected non-GAAP Adjusted EBITDA included in our guidance for the year ending December 31, 2023:

	Year Ending December 31,	
	2023L	2023H
Net income	\$ 3,200	\$ 10,900
Interest expense	3,300	3,300
Income tax expense	5,100	8,100
Depreciation	11,500	11,500
Amortization	4,900	4,900
EBITDA	<u>\$ 28,000</u>	<u>\$ 38,700</u>
Stock-based compensation expense	7,900	7,900
Restructuring charge	2,200	2,200
Adjusted EBITDA	<u>\$ 38,100</u>	<u>\$ 48,800</u>

The following table presents a reconciliation of projected GAAP net income to projected non-GAAP adjusted net income included in our guidance for the year ending December 31, 2023:

	Year Ending December 31,	
	2023L	2023H
Net income	\$ 3,200	\$ 10,900
Amortization	4,900	4,900
Restructuring charge	2,200	2,200
Tax on above	(1,900)	(1,900)
Adjusted net income	<u>\$ 8,400</u>	<u>\$ 16,100</u>

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, adjusted net revenue, net income, adjusted net income, EBITDA, and Adjusted EBITDA for fiscal 2023 and the breakdown of expected 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 impact of any changes to the reimbursement levels for the Company’s products; (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 may owe rebates to the federal government prospectively on certain of its products if more than a certain percentage of the product is not administered to a patient and is discarded (wasted) by providers; (6) the Company’s ability to raise funds to expand its business; (7) the Company has incurred losses in prior years and may incur losses in the future; (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; (10) the Company’s ability to maintain production of Affinity in sufficient quantities to meet demand; (11) any resurgence of the COVID-19 pandemic and its impact, if any, on the Company’s fiscal condition and results of operations; (12) the impact of the suspension of commercialization of: (a) ReNu and NuCel in connection with the expiration of the FDA’s enforcement grace period for HCT/Ps on May 31, 2021 and (b) Dermagraft in the second quarter of 2022 pending transition of manufacturing to a new manufacturing facility or a third-party manufacturer; and (13) 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, 2022 and its subsequently filed periodic reports. 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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