

**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): August 9, 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 August 9, 2023, the Company announced via press release its results for the fiscal second quarter ended June 30, 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 August 9, 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: Chief Administrative and Legal Officer

Date: August 9, 2023

FOR IMMEDIATE RELEASE

Organogenesis Holdings Inc. Reports Second Quarter 2023 Financial Results; Withdraws Fiscal Year 2023 Guidance

CANTON, Mass., (August 9, 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 second quarter ended June 30th, 2023.

Second Quarter 2023 Financial Results Summary:

- Net revenue of \$117.3 million for the second quarter of 2023, a decrease of \$4.1 million compared to net revenue of \$121.4 million for the second quarter of 2022. Net revenue for the second quarter of 2023 consists of:
 - o Net revenue from Advanced Wound Care products of \$110.1 million, a decrease of 3% from the second quarter of 2022.
 - o Net revenue from Surgical & Sports Medicine products of \$7.2 million, a decrease of 5% from the second quarter of 2022.
- Net income of \$5.3 million for the second quarter of 2023, compared to a net income of \$8.7 million for the second quarter of 2022, a decrease of \$3.4 million.
- Adjusted net income¹ of \$6.1 million for the second quarter of 2023, compared to an adjusted net income of \$11.3 million for the second quarter of 2022, a decrease of \$5.2 million.
- Adjusted EBITDA of \$15.4 million for the second quarter of 2023, compared to Adjusted EBITDA of \$18.6 million for the second quarter of 2022, a decrease of \$3.2 million.

“Second quarter total net revenue came in above the high-end of the guidance range we provided on our first quarter earnings call,” said Gary S. Gillheeny, Sr., President, Chief Executive Officer and Chair of the Board of Organogenesis. “As expected, we leveraged our diversified portfolio and leadership position in Wound Care Centers and physician offices across the U.S. to deliver better-than-expected revenue and profitability performance in Q2.”

Mr. Gillheeny continued: “The recently published local coverage determinations (LCDs) from Novitas, First Coast Services and CGS to limit coverage for treatment of diabetic foot ulcers (DFU) and venous leg ulcers (VLU) to include only Apligraf and Dermagraft, presents a significant amount of uncertainty regarding the revenue outlook for a number of our products in these regions. Further uncertainty remains as it relates to potential impact on demand for our products when used for treatment of non-DFU/VLU wounds. As such, we are withdrawing the fiscal year 2023 guidance, previously provided on May 10, 2023. We believe that the five commercialized products that were listed as ‘not covered’ were improperly excluded from the list of ‘covered’ products and we are engaging with all relevant parties in advance of the effective date of these LCDs on September 17, 2023.”

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.

Second Quarter 2023 Financial Results:

	Three Months Ended June 30,		Change	
	2023	2022	\$	%
			(in thousands, except for percentages)	
Advanced Wound Care	\$ 110,075	\$ 113,791	\$ (3,716)	(3 %)
Surgical & Sports Medicine	7,241	7,610	(369)	(5 %)
Net revenue	\$ 117,316	\$ 121,401	\$ (4,085)	(3 %)

Net revenue for the second quarter of 2023 was \$117.3 million, compared to \$121.4 million for the second quarter of 2022, a decrease of \$4.1 million, or 3%. The decrease in net revenue was driven by a decrease of \$3.7 million, or 3% in net revenue for Advanced Wound Care products and a decrease of \$0.4 million, or 5%, in net revenue for Surgical & Sports Medicine products.

Gross profit for the second quarter of 2023 was \$91.0 million, or 78% of net revenue, compared to \$94.7 million, or 78% of net revenue for the second quarter of 2022, a decrease of \$3.7 million.

Operating expenses for the second quarter of 2023 were \$81.3 million compared to \$82.8 million for the second quarter of 2022, a decrease of \$1.6 million. R&D expense was \$10.9 million for the second quarter of 2023, compared to \$10.2 million for the second quarter of 2022, an increase of \$0.7 million. Selling, general and administrative expenses were \$70.3 million for the second quarter of 2023, compared to \$72.6 million for the second quarter of 2022, a decrease of \$2.3 million.

Operating income for the second quarter of 2023 was \$9.7 million, compared to operating income of \$11.9 million for the second quarter of 2022, a decrease of \$2.2 million.

Total other expense, net, for the second quarter of 2023 was \$0.6 million, compared to \$0.8 million for the second quarter of 2022, a decrease of \$0.2 million.

Net income for the second quarter of 2023 was \$5.3 million, or \$0.04 per share, compared to net income of \$8.7 million, or \$0.07 per share, for the second quarter of 2022, a decrease of \$3.4 million, or \$0.03 per share.

Adjusted net income of \$6.1 million for the second quarter of 2023, compared to adjusted net income of \$11.3 million for the second quarter of 2022, a decrease of \$5.2 million.

Adjusted EBITDA was \$15.4 million for the second quarter of 2023, compared to \$18.6 million for the second quarter of 2022, a decrease of \$3.2 million.

As of June 30th, 2023, the Company had \$89.5 million in cash, cash equivalents and restricted cash and \$69.0 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.

First Half 2023 Results

The following table represents net revenue by product grouping for the six months ended June 30, 2023 and June 30, 2022, respectively:

	Six Months Ended June 30,		Change	
	2023	2022	\$	%
			(in thousands, except for percentages)	
Advanced Wound Care	\$ 210,992	\$ 203,881	\$ 7,111	3%
Surgical & Sports Medicine	13,966	14,637	(671)	(5%)
Net revenue	<u>\$ 224,958</u>	<u>\$ 218,518</u>	<u>\$ 6,440</u>	<u>3%</u>

Net revenue for the six months ended June 30, 2023 was \$225.0 million, compared to \$218.5 million for the six months ended June 30, 2022, an increase of \$6.4 million, or 3%. The increase in net revenue was driven by an increase of \$7.1 million, or 3% in net revenue for Advanced Wound Care products. This is partially offset by a decrease of \$0.7 million, or 5% in net revenue for Surgical & Sports Medicine products.

Gross profit for the six months ended June 30, 2023 was \$172.0 million, or 76% of net revenue, compared to \$166.8 million, or 76% of net revenue, for the six months ended June 30, 2022, an increase of \$5.2 million.

Operating expenses for the six months ended June 30, 2023 were \$166.3 million, compared to \$155.0 million for the six months June 30, 2022, an increase of \$11.3 million. R&D expense was \$22.1 million for the six months ended June 30, 2023, compared to \$18.8 million in the six months ended June 30, 2022, an increase of \$3.3 million. Selling, general and administrative expenses were \$144.2 million for the six months ended June 30, 2023, compared to \$136.2 million in the six months ended June 30, 2022, an increase of \$8.0 million.

Operating income for the six months ended June 30, 2023 was \$5.7 million, compared to operating income of \$11.8 million for the six months ended June 30, 2022, a decrease of \$6.1 million.

Total other expenses, net, for the six months ended June 30, 2023 were \$1.2 million, compared to \$1.5 million for the six months ended June 30, 2022, a decrease of \$0.3 million.

Net income of \$2.3 million for the six months ended June 30, 2023 or \$0.02 per share, compared to net income of \$7.8 million, or \$0.06 per share for the six months ended June 30, 2022, a decrease of \$5.5 million, or \$0.04, per share.

Adjusted net income for the six months ended June 30, 2023 was \$5.4 million compared to \$12.2 million, for the six months ended June 30, 2022, a decrease of \$6.7 million.

Adjusted EBITDA of \$19.2 million for the six months ended June 30, 2023, compared to an Adjusted EBITDA of \$23.6 million, for the six months ended June 30, 2022, a decrease of \$4.4 million.

Fiscal Year 2023 Guidance:

The Company is withdrawing its previously announced fiscal year 2023 guidance, originally issued on May 10, 2023, due to the uncertainty resulting from the potential impact of the recently published local coverage determinations from Novitas, First Coast Services and CGS to limit coverage for treatment of diabetic foot ulcers (DFU) and venous leg ulcers (VLU) to include only Apligraf and Dermagraft. The Company is currently unable to predict the impact that the recently published local coverage determinations will have on its financial position and operating results.

Second Quarter Earnings Conference Call:

Financial results for the second fiscal quarter of 2023 will be reported after the market closes on August, 9th. Management will host a conference call at 5:00 p.m. Eastern Time on August 9th 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](#). The live webcast can also be accessed via the company's website at investors.organogenesis.com. The webcast will be archived on the company website for one year.

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

	June 30, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	\$ 88,917	\$ 102,478
Restricted cash	591	812
Accounts receivable, net	93,615	89,450
Inventory, net	25,364	24,783
Prepaid expenses and other current assets	7,948	5,086
Total current assets	216,435	222,609
Property and equipment, net	111,825	102,463
Intangible assets, net	18,330	20,789
Goodwill	28,772	28,772
Operating lease right-of-use assets, net	43,544	43,192
Deferred tax asset, net	30,014	30,014
Other assets	1,393	1,520
Total assets	\$ 450,313	\$ 449,359
Liabilities and Stockholders' Equity		
Current liabilities:		
Current portion of term loan, net of debt issuance costs	\$ 5,480	\$ 4,538
Current portion of finance lease obligations	209	-
Current portion of operating lease obligations	12,592	11,708
Accounts payable	27,390	32,330
Accrued expenses and other current liabilities	27,784	26,447
Total current liabilities	73,455	75,023
Term loan, net of current portion and debt issuance costs	63,489	66,231
Finance lease obligations, net of current portion	402	-
Operating lease obligations, net of current portion	40,495	41,314
Other liabilities	1,190	1,122
Total liabilities	179,031	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; 132,040,400 and 131,647,677 shares issued; 131,311,852 and 130,919,129 shares outstanding at June 30, 2023 and December 31, 2022, respectively.	13	13
Additional paid-in capital	314,838	310,957
Accumulated deficit	(43,569)	(45,301)
Total stockholders' equity	271,282	265,669
Total liabilities and stockholders' equity	\$ 450,313	\$ 449,359

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Net revenue	\$ 117,316	\$ 121,401	\$ 224,958	\$ 218,518
Cost of goods sold	26,316	26,652	52,923	51,732
Gross profit	91,000	94,749	172,035	166,786
Operating expenses:				
Selling, general and administrative	70,317	72,609	144,151	136,187
Research and development	10,938	10,205	22,140	18,792
Total operating expenses	81,255	82,814	166,291	154,979
Income from operations	9,745	11,935	5,744	11,807
Other expense, net:				
Interest expense	(594)	(730)	(1,243)	(1,467)
Other income (expense), net	28	(21)	51	(24)
Total other expense, net	(566)	(751)	(1,192)	(1,491)
Net income before income taxes	9,179	11,184	4,552	10,316
Income tax expense	(3,863)	(2,440)	(2,205)	(2,485)
Net income	<u>\$ 5,316</u>	<u>\$ 8,744</u>	<u>\$ 2,347</u>	<u>\$ 7,831</u>
Net income, per share:				
Basic	<u>\$ 0.04</u>	<u>\$ 0.07</u>	<u>\$ 0.02</u>	<u>\$ 0.06</u>
Diluted	<u>\$ 0.04</u>	<u>\$ 0.07</u>	<u>\$ 0.02</u>	<u>\$ 0.06</u>
Weighted-average common shares outstanding				
Basic	<u>131,293,398</u>	<u>129,635,682</u>	<u>131,189,405</u>	<u>129,214,541</u>
Diluted	<u>133,066,010</u>	<u>132,600,579</u>	<u>132,475,908</u>	<u>132,705,206</u>

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

	Six Months Ended June 30,	
	2023	2022
Cash flows from operating activities:		
Net Income	\$ 2,347	\$ 7,831
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation	4,922	2,875
Amortization of intangible assets	2,459	2,442
Reduction in the carrying value of right-of-use assets	3,893	3,649
Non-cash interest expense	215	217
Deferred interest expense	245	291
Provision recorded for credit losses	190	122
Loss on disposal of property and equipment	65	196
Adjustment for excess and obsolete inventories	3,464	5,228
Stock-based compensation	4,213	2,995
Changes in operating assets and liabilities:		
Accounts receivable	(4,970)	(6,485)
Inventory	(4,045)	(3,441)
Prepaid expenses and other current assets	(2,874)	(1,839)
Operating leases	(4,178)	(3,472)
Accounts payable	(3,535)	2,671
Accrued expenses and other current liabilities	1,091	(1,697)
Other liabilities	67	23
Net cash provided by operating activities	3,569	11,606
Cash flows from investing activities:		
Purchases of property and equipment	(15,061)	(12,840)
Net cash used in investing activities	(15,061)	(12,840)
Cash flows from financing activities:		
Payments of term loan under the 2021 Credit Agreement	(1,875)	(938)
Payments of withholding taxes in connection with RSUs vesting	(332)	(646)
Proceeds from the exercise of stock options	-	2,042
Principal repayments of finance lease obligations	(83)	(200)
Payment of deferred acquisition consideration	-	(608)
Net cash used in financing activities	(2,290)	(350)
Change in cash, cash equivalents and restricted cash	(13,782)	(1,584)
Cash, cash equivalents, and restricted cash, beginning of period	103,290	114,528
Cash, cash equivalents, and restricted cash, end of period	\$ 89,508	\$ 112,944
Supplemental disclosure of cash flow information:		
Cash paid for interest	\$ 2,608	\$ 1,041
Cash paid for income taxes	\$ 3,022	\$ 974
Supplemental disclosure of non-cash investing and financing activities:		
Purchases of property and equipment included in accounts payable and accrued expenses	\$ 1,882	\$ 6,546
Right-of-use assets obtained through lease obligations	\$ 4,253	\$ 364
Shares issued for deferred acquisition consideration	\$ -	\$ 828

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
	(Unaudited) (in thousands)		(in thousands)	
Net Income	\$ 5,316	\$ 8,744	\$ 2,347	\$ 7,831
Amortization	1,229	1,221	2,459	2,442
Restructuring charge (adjustment) (1)	(126)	643	1,782	907
Settlement fee (2)	-	1,600	-	2,600
Tax on above	(298)	(935)	(1,145)	(1,606)
Adjusted net income	<u>\$ 6,121</u>	<u>\$ 11,273</u>	<u>\$ 5,443</u>	<u>\$ 12,174</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.

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, 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. 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 (including as a result of the recently published LCDs); (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 focused on the development, manufacture and commercialization of solutions for the advanced wound care and surgical and sports medicine markets. Organogenesis offers a comprehensive portfolio of innovative regenerative products to address patient needs across the continuum of care. For more information, visit www.organogenesis.com.

Investor Inquiries:

Westwicke Partners

Mike Piccinino, CFA

OrganoIR@westwicke.com

443-213-0500

Press and Media Inquiries:

Organogenesis

Ron O'Brien

communications@organo.com
