

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-Q

(Mark One)

☒ QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the Quarterly Period Ended March 31, 2024

OR

☐ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

Commission File Number 001-37906

ORGANOGENESIS HOLDINGS INC.

(Exact Name of Registrant as Specified in Its Charter)

Delaware
(State or Other Jurisdiction of
Incorporation or Organization)

98-1329150
(I.R.S. 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
(Former name, former address and former fiscal year, if changed since last report)

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 (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☐	Accelerated filer	☒
Non-accelerated filer	☐	Smaller reporting company	☐
		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 provided pursuant to Section 13(a) of the Exchange Act ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

The number of shares of the registrant's Class A common stock outstanding as of April 30, 2024 was 132,572,465.

[Table of Contents](#)

Organogenesis Holdings Inc.
Quarterly Report on Form 10-Q
For the Quarterly Period Ended March 31, 2024

Table of Contents

	Page
PART I. FINANCIAL INFORMATION	4
Item 1. Unaudited Condensed Consolidated Financial Statements	4
Condensed Consolidated Balance Sheets	4
Condensed Consolidated Statements of Operations and Comprehensive Loss	5
Condensed Consolidated Statements of Stockholders' Equity	6
Condensed Consolidated Statements of Cash Flows	7
Notes to Condensed Consolidated Financial Statements	8
Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations	19
Item 3. Quantitative and Qualitative Disclosures About Market Risk	26
Item 4. Controls and Procedures	27
PART II. OTHER INFORMATION	28
Item 1. Legal Proceedings	28
Item 1A Risk Factors	28
Item 2. Unregistered Sales of Equity Securities and Use of Proceeds	28
Item 3. Defaults Upon Senior Securities	28
Item 4. Mine Safety Disclosures	29
Item 5. Other Information	29
Item 6. Exhibits	30
SIGNATURES	31

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q (this “Form 10-Q”) contains forward-looking statements. These statements may relate to, but are not limited to, expectations of our future results of operations, business strategies and operations, financing plans, potential growth opportunities, clinical development and commercialization of our product candidates, potential market opportunities and the effects of competition, as well as assumptions relating to the foregoing. Forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified. These risks and other factors include, but are not limited to, those listed under “Risk Factors.” In some cases, you can identify forward-looking statements by terminology such as “may,” “will,” “should,” “could,” “expect,” “plan,” “anticipate,” “believe,” “estimate,” “predict,” “intend,” “potential,” “might,” “would,” “continue” or the negative of these terms or other comparable terminology. These forward-looking statements are based on our management’s current expectations, estimates, forecasts and projections about our business and the industry in which we operate and our management’s beliefs and assumptions. These forward-looking statements are not guarantees of future performance or development and involve known and unknown risks, uncertainties and other factors that are in some cases beyond our control. As a result, any or all of our forward-looking statements in this Form 10-Q may turn out to be inaccurate. Factors that may cause actual results to differ materially from current expectations include, among other things, those listed under “Risk Factors” and discussed elsewhere in this Form 10-Q and in “Part I, Item 1A—Risk Factors” in our Annual Report on Form 10-K for the year ended December 31, 2023. These forward-looking statements speak only as of the date of this Form 10-Q. Except as required by law, we assume no obligation to update or revise these forward-looking statements for any reason, even if new information becomes available in the future. You should, however, review the factors and risks we describe in the reports we will file from time to time with the U.S. Securities and Exchange Commission (the “SEC”) after the date of this Form 10-Q.

As used herein, except as otherwise indicated by context, references to “we,” “us,” “our,” “the Company,” “Organogenesis” and “ORGO” will refer to Organogenesis Holdings Inc. and its subsidiaries.

PART I—FINANCIAL INFORMATION
Item 1. Unaudited Condensed Consolidated Financial Statements.

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

	March 31, 2024	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	\$ 88,626	\$ 103,840
Restricted cash	720	498
Accounts receivable, net	96,148	81,999
Inventories, net	27,694	28,253
Prepaid expenses and other current assets	13,979	10,454
Total current assets	227,167	225,044
Property and equipment, net	114,245	116,228
Intangible assets, net	14,970	15,871
Goodwill	28,772	28,772
Operating lease right-of-use assets, net	38,616	40,118
Deferred tax asset, net	28,002	28,002
Other assets	6,709	5,990
Total assets	<u>\$ 458,481</u>	<u>\$ 460,025</u>
Liabilities and Stockholders' Equity		
Current liabilities:		
Current portion of term loan	\$ 5,489	\$ 5,486
Current portion of finance lease obligations	1,103	1,081
Current portion of operating lease obligations - related party	8,543	8,413
Current portion of operating lease obligations	4,675	4,731
Accounts payable	23,230	30,724
Accrued expenses and other current liabilities	39,759	30,074
Total current liabilities	82,799	80,509
Term loan, net of current portion	59,371	60,745
Finance lease obligations, net of current portion	1,604	1,888
Operating lease obligations, net of current portion - related party	11,052	11,954
Operating lease obligations, net of current portion	24,383	25,053
Other liabilities	1,242	1,213
Total liabilities	180,451	181,362
Commitments and contingencies (Note 14)		
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; 133,267,888 and 132,044,944 shares issued; 132,539,340 and 131,316,396 shares outstanding at March 31, 2024 and December 31, 2023, respectively.	13	13
Additional paid-in capital	321,088	319,621
Accumulated deficit	(43,071)	(40,971)
Total stockholders' equity	278,030	278,663
Total liabilities and stockholders' equity	<u>\$ 458,481</u>	<u>\$ 460,025</u>

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

ORGANOGENESIS HOLDINGS INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(unaudited)
(amounts in thousands, except share and per share data)

	Three Months Ended March 31,	
	2024	2023
Net revenue	\$ 109,976	\$ 107,642
Cost of goods sold	28,696	26,607
Gross profit	81,280	81,035
Operating expenses:		
Selling, general and administrative	72,322	73,834
Research and development	12,810	11,202
Total operating expenses	85,132	85,036
Loss from operations	(3,852)	(4,001)
Other expense, net:		
Interest expense, net	(514)	(649)
Other income, net	23	23
Total other expense, net	(491)	(626)
Net loss before income taxes	(4,343)	(4,627)
Income tax benefit	2,243	1,658
Net loss and comprehensive loss	\$ (2,100)	\$ (2,969)
Net loss, per share:		
Basic and diluted	\$ (0.02)	\$ (0.02)
Weighted-average common shares outstanding		
Basic and diluted	131,861,772	131,083,841

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

ORGANOGENESIS HOLDINGS INC.
CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
(unaudited)
(amounts in thousands, except share data)

	Three Months Ended March 31, 2024				
	Common Stock		Paid-in Capital	Accumulat ed Deficit	Total Stockholders' Equity
	Shares	Amount			
Balance as of December 31, 2023	131,316,396	\$ 13	\$ 319,621	\$ (40,971)	\$ 278,663
Exercise of stock options	152,250	—	180	—	180
Vesting of RSUs, net of shares surrendered to pay taxes	1,070,694	—	(1,120)	—	(1,120)
Stock-based compensation expense	—	—	2,407	—	2,407
Net loss	—	—	—	(2,100)	(2,100)
Balance as of March 31, 2024	<u>132,539,340</u>	<u>\$ 13</u>	<u>\$ 321,088</u>	<u>\$ (43,071)</u>	<u>\$ 278,030</u>

	Three Months Ended March 31, 2023				
	Common Stock		Paid-in Capital	Accumulat ed Deficit	Total Stockholders' Equity
	Shares	Amount			
Balance as of December 31, 2022	130,919,129	\$ 13	\$ 310,957	\$ (45,301)	\$ 265,669
Cumulative-effect adjustment from adoption of ASU 2016-13, net of tax (Note 2)	—	—	—	(615)	(615)
Vesting of RSUs, net of shares surrendered to pay taxes	307,258	—	(298)	—	(298)
Stock-based compensation expense	—	—	1,914	—	1,914
Net loss	—	—	—	(2,969)	(2,969)
Balance as of March 31, 2023	<u>131,226,387</u>	<u>\$ 13</u>	<u>\$ 312,573</u>	<u>\$ (48,885)</u>	<u>\$ 263,701</u>

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

ORGANOGENESIS HOLDINGS INC.
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(unaudited, in thousands)

	Three Months Ended March 31,	
	2024	2023
Cash flows from operating activities:		
Net loss	\$ (2,100)	\$ (2,969)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	3,072	2,694
Amortization of intangible assets	901	1,230
Reduction in the carrying value of right-of-use assets	2,203	1,939
Non-cash interest expense	105	107
Deferred interest expense	122	122
Provision recorded for credit losses	968	243
Loss on disposal of property and equipment	347	63
Adjustment for excess and obsolete inventories	2,515	1,407
Stock-based compensation	2,407	1,914
Changes in operating assets and liabilities:		
Accounts receivable	(15,117)	(3,429)
Inventories	(4,670)	(2,163)
Prepaid expenses and other current assets and other assets	(4,315)	(4,774)
Operating leases	(2,199)	(2,122)
Accounts payable	(4,391)	(1,390)
Accrued expenses and other current liabilities	9,962	2,029
Other liabilities	28	22
Net cash used in operating activities	(10,162)	(5,077)
Cash flows from investing activities:		
Purchases of property and equipment	(2,222)	(7,562)
Net cash used in investing activities	(2,222)	(7,562)
Cash flows from financing activities:		
Payments of term loan under the 2021 Credit Agreement	(1,406)	(938)
Payments of withholding taxes in connection with RSUs vesting	(1,120)	(298)
Proceeds from the exercise of stock options	180	-
Principal repayments of finance lease obligations	(262)	-
Net cash used in financing activities	(2,608)	(1,236)
Change in cash, cash equivalents and restricted cash	(14,992)	(13,875)
Cash, cash equivalents, and restricted cash, beginning of period	104,338	103,290
Cash, cash equivalents, and restricted cash, end of period	\$ 89,346	\$ 89,415
Supplemental disclosure of cash flow information:		
Cash paid for interest	\$ 1,375	\$ 1,271
Cash paid for income taxes	\$ 35	\$ 128
Supplemental disclosure of non-cash investing and financing activities:		
Cumulative effect adjustment for adoption of ASU No. 2016-13 (Note 2)	\$ —	\$ 615
Purchases of property and equipment included in accounts payable and accrued expenses	\$ 786	\$ 1,986
Right-of-use assets obtained through operating lease obligations	\$ 701	\$ 1,586

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

ORGANOGENESIS HOLDINGS INC.

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(amounts in thousands, except share and per share data)

1. Nature of Business and Basis of Presentation

Organogenesis Holdings Inc. (“ORGO” or the “Company”) is a leading regenerative medicine company focused on the development, manufacture, and commercialization of solutions for the Advanced Wound Care and Surgical & Sports Medicine markets. Several of the existing and pipeline products in the Company’s portfolio have Premarket Application (“PMA”) approval, or Premarket Notification 510(k) clearance from the United States Food and Drug Administration (“FDA”). The Company’s customers include hospitals, wound care centers, government facilities, ambulatory surgery centers (“ASCs”) and physician offices. The Company has one operating and reportable segment.

Unaudited Interim Financial Information

The accompanying unaudited condensed consolidated financial statements have been prepared by management in accordance with generally accepted accounting principles in the United States (“GAAP”), pursuant to the rules and regulations of the Securities and Exchange Commission (“SEC”) for interim financial statements. Certain information and footnote disclosures normally included in financial statements prepared in accordance with GAAP have been condensed or omitted pursuant to such rules and regulations. However, the Company believes that the disclosures are adequate to make the information presented not misleading. These unaudited condensed consolidated financial statements should be read in conjunction with the audited consolidated financial statements and notes thereto, for the year ended December 31, 2023, included in the Company’s annual report on Form 10-K for the fiscal year ended December 31, 2023, which was filed with the SEC on February 29, 2024 (the “Annual Report”). The results for the three months ended March 31, 2024 are not necessarily indicative of the results to be expected for the year ending December 31, 2024, any other interim periods, or any future years or periods.

2. Summary of Significant Accounting Policies

The Company’s significant accounting policies are described in the Company’s audited consolidated financial statements as of and for the year ended December 31, 2023, and the notes thereto, which are included in the Annual Report. There have been no material changes to the significant accounting policies previously disclosed in the Annual Report.

These unaudited condensed consolidated financial statements include the accounts and results of operations of Organogenesis Holdings Inc. and its wholly-owned subsidiaries, Organogenesis Inc., Organogenesis GmbH (a Switzerland corporation) and Prime Merger Sub, LLC. All intercompany balances and transactions have been eliminated in consolidation.

From time to time, new accounting pronouncements are issued by the Financial Accounting Standards Board (“FASB”) or other standard setting bodies that the Company adopts as of the specified effective date. Unless otherwise discussed below, the Company does not believe that the adoption of recently issued standards have had or may have a material impact on its condensed consolidated financial statements or disclosures.

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities at the date of the financial statements and the reported results of operations during the reporting periods. In preparing the condensed consolidated financial statements, the estimates and assumptions that management considers to be significant and that present the greatest amount of uncertainty include: revenue recognition; sales returns and credit losses; inventory reserve; recognition and measurement of current and deferred income tax assets and liabilities; the assessment of recoverability of long-lived assets; and the valuation and recognition of stock-based compensation. Actual results and outcomes may differ significantly from those estimates and assumptions.

Concentration of Credit Risk

Financial instruments that potentially subject the Company to concentration of credit risk consist of cash and cash equivalents. The Company invests its cash equivalents in highly rated money market funds. Deposits may exceed federally insured limits, and the Company is exposed to credit risk on deposits in the event of default by the financial institutions to the extent account balances exceed the amount insured by the Federal Deposit Insurance Corporation (“FDIC”). However, the Company sweeps cash daily overnight and diversifies among financial institutions to reduce such exposure.

[Table of Contents](#)

Recently Issued Accounting Pronouncements Not Yet Adopted

In November 2023, the FASB issued ASU 2023-07, *Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures*, which requires public entities to disclose information about their reportable segments' significant expenses and other segment items on an interim and annual basis. Public entities with a single reportable segment are required to apply the disclosure requirements in ASU 2023-07, as well as all existing segment disclosures and reconciliation requirements in ASC 280. ASU 2023-07 is effective for fiscal years beginning after December 15, 2023, and for interim periods within fiscal years beginning after December 15, 2024, with early adoption permitted. The Company is currently evaluating the impact of adopting ASU 2023-07.

In December 2023, the FASB issued ASU 2023-09, *Income Taxes (Topic 740): Improvements to Income Tax Disclosures*, which requires public entities to disclose specific categories in the effective tax rate reconciliation, as well as additional information for reconciling items that exceed a quantitative threshold. ASU 2023-09 also requires all entities to disclose income taxes paid disaggregated by federal, state and foreign taxes, and further disaggregated for specific jurisdictions that exceed 5% of total income taxes paid, among other expanded disclosures. ASU 2023-09 is effective for fiscal years beginning after December 15, 2024, with early adoption permitted. The Company is currently evaluating the impact of adopting ASU 2023-09.

Correction of Immaterial Classification Error

Subsequent to the issuance of the consolidated financial statements as of and for the year ended December 31, 2023, the Company determined that as of December 31, 2023, it had incorrectly classified \$5,273 of accrued but unpaid lease obligations as current portion of operating lease obligations instead of as current portion of operating lease obligations - related party. As a result, the Company also incorrectly classified \$5,273 of operating lease obligations, net of current portion as operating lease obligations, net of current portion - related party. These misclassifications have been corrected in the accompanying condensed consolidated balance sheets and conform to the current period presentation of operating lease obligations. These reclassifications had no impact on reported results of operations, stockholders' equity, cash flows, total current liabilities, or total liabilities.

3. Revenue from Contracts with Customers

The Company generates revenue through the sale of Advanced Wound Care and Surgical & Sports Medicine products. There is a single performance obligation in all of the Company's contracts, which is the Company's promise to transfer the Company's products to customers based on specific payment and shipping terms in the arrangement. Product revenue is recognized when a customer obtains control of the Company's products which occurs at a point in time and may be upon shipment, procedure date, or delivery, based on the terms of the contract. Revenue is recorded net of a reserve for returns, discounts and Group Purchasing Organization ("GPO") rebates, which represent a direct reduction to the revenue recognized. These reductions are accrued at the time revenue is recognized, based upon historical experience and specific circumstances. For the three months ended March 31, 2024 and 2023, the Company recorded GPO fees of \$1,394 and \$1,424, respectively, as a direct reduction of revenue.

The following tables set forth revenue by product category:

	Three Months Ended March 31,	
	2024	2023
Advanced Wound Care	\$ 103,864	\$ 100,917
Surgical & Sports Medicine	6,112	6,725
Total net revenue	<u>\$ 109,976</u>	<u>\$ 107,642</u>

For all periods presented, net revenue generated outside the United States represented less than 1% of total net revenue.

4. Accounts Receivable, Net

Accounts receivable consisted of the following:

	March 31, 2024	December 31, 2023
Accounts receivable	\$ 103,623	\$ 88,859
Less — allowance for credit losses	<u>(7,475)</u>	<u>(6,860)</u>

\$	96,148	\$	81,999
----	--------	----	--------

[Table of Contents](#)

The Company's allowance for credit losses is comprised of the following:

	Three Months Ended March 31,	
	2024	2023
Balance at beginning of period	\$ 6,860	\$ 6,362
Cumulative effect of adopting ASU 2016-13	—	615
Additions (adjustments)	968	243
Write-offs	(356)	(299)
Recoveries	3	—
Balance at end of period	<u>\$ 7,475</u>	<u>\$ 6,921</u>

5. Inventories

Inventories, net of related reserves for excess and obsolescence, consisted of the following:

	March 31, 2024	December 31, 2023
Raw materials	\$ 13,341	\$ 12,988
Work in process	858	810
Finished goods	13,495	14,455
	<u>\$ 27,694</u>	<u>\$ 28,253</u>

Raw materials include various components used in the Company's manufacturing process. The Company's excess and obsolete inventory review process includes analysis of sales forecasts and historical sales as compared to inventory level, and working with operations to maximize recovery of excess inventory. During the three months ended March 31, 2024 and 2023, the Company charged \$2,515 and \$1,407, respectively, for inventory excess and obsolescence to cost of goods sold within the condensed consolidated statements of operations and comprehensive loss.

6. Property and Equipment, Net

Property and equipment consisted of the following:

	March 31, 2024	December 31, 2023
Leasehold improvements	\$ 62,129	\$ 60,819
Buildings	4,943	4,943
Furniture, computers and equipment	63,528	64,585
	130,600	130,347
Accumulated depreciation	(74,745)	(73,186)
Construction in progress	58,390	59,067
	<u>\$ 114,245</u>	<u>\$ 116,228</u>

Depreciation expense was \$3,072 and \$2,694 for the three months ended March 31, 2024 and 2023, respectively. Construction in progress primarily represents the ongoing ERP system implementation and the unfinished construction work on a purchased building located on the Company's Canton, Massachusetts campus and improvements at the Company's leased facilities in Canton and Norwood, Massachusetts.

[Table of Contents](#)

7. Goodwill and Intangible Assets

Goodwill was \$28,772 as of March 31, 2024 and December 31, 2023. There was no impairment of goodwill recorded during the three months ended March 31, 2024 and 2023.

Intangible assets consisted of the following as of March 31, 2024:

	Original Cost	Accumulated Amortization	Net Book Value
Developed technology	\$ 32,620	\$ (25,226)	\$ 7,394
Customer relationships	10,690	(3,786)	6,904
Patent	7,623	(7,623)	—
Independent sales agency network	4,500	(4,500)	—
Trade names and trademarks	2,080	(1,627)	453
Non-compete agreements	1,010	(791)	219
Total	<u>\$ 58,523</u>	<u>\$ (43,553)</u>	<u>\$ 14,970</u>

Intangible assets consisted of the following as of December 31, 2023:

	Original Cost	Accumulated Amortization	Net Book Value
Developed technology	\$ 32,620	\$ (24,666)	\$ 7,954
Customer relationship	10,690	(3,519)	7,171
Patent	7,623	(7,623)	—
Independent sales agency network	4,500	(4,500)	—
Trade names and trademarks	2,080	(1,590)	490
Non-compete agreements	1,010	(754)	256
Total	<u>\$ 58,523</u>	<u>\$ (42,652)</u>	<u>\$ 15,871</u>

Amortization of intangible assets, calculated on a straight-line basis or using an accelerated method, was \$901 and \$1,230 for the three months ended March 31, 2024 and 2023, respectively. The weighted average remaining useful lives for developed technology, trade names and trademarks, customer relationship, and non-compete agreements are 4.2 years, 4.2 years, 6.5 years, and 1.5 years, respectively, as of March 31, 2024.

8. Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consisted of the following:

	March 31, 2024	December 31, 2023
Personnel costs	\$ 24,078	\$ 18,287
Royalties	6,582	3,075
Accrued but unpaid lease obligations and interest	2,448	2,326
Accrued milestone payment (Note 14)	2,500	2,500
Accrued option payment (Note 14)	2,500	—
Accrued taxes	483	2,799
Other	1,168	1,087
	<u>\$ 39,759</u>	<u>\$ 30,074</u>

The accrued but unpaid lease obligations and the interest accrual on these obligations are related to the buildings in Canton, Massachusetts. See Note 13, *Leases*.

9. Restructuring

In order to reduce the Company's cost structure and improve operating efficiency, the Company has consolidated its manufacturing operations in various locations into Massachusetts facilities.

On February 3, 2023, the Company committed to a plan to restructure its workforce to increase productivity and enhance profitability. The reduction in force reduced the Company's headcount by 71 employees, or approximately 7% of all employees. The

[Table of Contents](#)

Company incurred a total charge of \$1,817 in the three months ended March 31, 2023 in connection with the restructuring, primarily consisting of severance payments. It was substantially completed as of March 31, 2023.

As a result of the restructuring activities, the Company incurred a total pre-tax charge of \$1,908 during the three months ended March 31, 2023. These charges were included in selling, general and administrative expenses in the condensed consolidated statements of operations and comprehensive loss. The liability related to the restructuring activities was \$280 and \$904 as of March 31, 2024 and December 31, 2023, respectively, and was included in accrued expenses and other current liabilities in the condensed consolidated balance sheets. The following tables provide a roll-forward of the restructuring liabilities.

	Total
Liability balance as of December 31, 2023	\$ 904
Cash disbursements and other adjustments	(624)
Liability balance as of March 31, 2024	\$ 280

	Employee	Other	Total
Liability balance as of December 31, 2022	\$ 1,010	\$ 182	\$ 1,192
Expenses	1,817	91	1,908
Cash disbursements and other adjustments	(1,740)	(273)	(2,013)
Liability balance as of March 31, 2023	\$ 1,087	\$ —	\$ 1,087

10. Debt Obligations

Debt obligations consisted of the following:

	March 31, 2024	December 31, 2023
Revolving Facility	\$ —	\$ —
Term loan	65,156	66,563
Less debt discount and debt issuance cost	(296)	(332)
Term loan, net of debt discount and debt issuance cost	\$ 64,860	\$ 66,231

2021 Credit Agreement

In August 2021, the Company, as borrower, its subsidiaries, as guarantors, and Silicon Valley Bank (“SVB”), and the several other lenders thereto (collectively, the “Lenders”) entered into a credit agreement, as amended (the “2021 Credit Agreement”), providing for a term loan facility not to exceed \$75,000 (the “Term Loan Facility”) and a revolving credit facility not to exceed \$125,000 (the “Revolving Facility” and, together with the Term Loan Facility, the “Facilities”). The Company’s obligations to the Lenders are secured by substantially all of the Company’s assets, including intellectual property. Capitalized terms used herein and not otherwise defined are defined as set forth in the 2021 Credit Agreement.

Advances made under the 2021 Credit Agreement may be either SOFR Loans or ABR Loans, at the Company’s option. For SOFR Loans, the interest rate is a per annum interest rate equal to the Adjusted Term SOFR plus an Applicable Margin between 2.00% to 3.25% based on the Total Net Leverage Ratio. For ABR Loans, the interest rate is equal to (1) the highest of (a) the Wall Street Journal Prime Rate, (b) the Federal Funds Rate plus 0.50% and (c) the Adjusted Term SOFR rate plus 1.0%, plus (2) an Applicable Margin between 1.00% to 2.25% based on the Total Net Leverage Ratio. On March 31, 2024, the applicable interest rate for outstanding borrowings is 7.64%.

The 2021 Credit Agreement requires the Company to make consecutive quarterly installment payments equal to the following: (a) from September 30, 2021 through and including June 30, 2022, \$469; (b) from September 30, 2022 through and including June 30, 2023, \$938; (c) from September 30, 2023 through and including June 30, 2025, \$1,406 and (d) from September 30, 2025 and the last day of each quarter thereafter until August 6, 2026 (the “Term Loan Maturity Date”), \$1,875. The remaining principal balance of

\$50,625 is also due on the Term Loan Maturity Date. The Company may prepay the Term Loan Facility. Once repaid, amounts borrowed under the Term Loan Facility may not be re-borrowed.

The Company must pay in arrears, on the first day of each quarter prior to August 6, 2026 (the “Revolving Termination Date”) and on the Revolving Termination Date, a fee for the Company’s non-use of available funds (the “Commitment Fee”). The

[Table of Contents](#)

Commitment Fee rate is between 0.25% to 0.45% based on the Total Net Leverage Ratio. The Company may elect to reduce or terminate the Revolving Facility in its entirety at any time by repaying all outstanding principal and unpaid accrued interest.

Under the 2021 Credit Agreement, the Company is required to comply with certain financial covenants including the Consolidated Fixed Charge Coverage Ratio and Consolidated Total Net Leverage Ratio, tested quarterly. In addition, the Company is also required to make representations and warranties and comply with certain non-financial covenants that are customary in loan agreements of this type, including restrictions on the payment of dividends, repurchase of stock, incurrence of indebtedness, dispositions and acquisitions.

The Company recorded debt issuance costs and related fees of \$604 in connection with entering into the Term Loan Facility, which are recorded as a reduction of the carrying value of the term loan on the accompanying condensed consolidated balance sheets. In connection with entering into the Revolving Facility, the Company recorded debt issuance costs and related fees of \$1,223, which are recorded as other assets. Both of these costs are being amortized to interest expense through the maturity date of the facilities.

As of March 31, 2024 and December 31, 2023, the Company had outstanding borrowings of \$65,156 and \$66,563 under the Term Loan Facility, respectively, and \$0 under the Revolving Facility with \$125,000 available for future revolving borrowings.

The future payments due under the Term Loan Facility as of March 31, 2024, are as follows for the calendar years ending December 31:

2024 (remaining nine months)	4,218
2025	6,563
2026	54,375
Total	<u>\$ 65,156</u>

11. Stockholders' Equity and Stock-Based Compensation

Common Stock

As of March 31, 2024, the issued shares of Class A common stock include 728,548 treasury shares that were reacquired in connection with the redemption of redeemable shares in March 2019.

Stock Incentive Plans

On November 28, 2018, the Board of Directors of the Company adopted, and on December 10, 2018 the Company's stockholders approved, the Organogenesis 2018 Equity Incentive Plan (the "2018 Plan"). At the adoption of the 2018 Plan, a total of 9,198,996 shares of Class A common stock was authorized to be issued (subject to adjustment in the case of any stock dividend, stock split, reverse stock split, or similar change in capitalization of the Company). In June 2022, the 2018 Plan was amended to increase the number of shares of Class A common stock reserved for issuance by 7,826,970 shares.

The Organogenesis 2003 Stock Incentive Plan (the "2003 Plan"), provided for the Company to issue restricted stock awards, or to grant incentive stock options or non-statutory stock options. Effective December 10, 2018, no additional awards may be made under the 2003 Plan.

Stock-Based Compensation Expense

Stock options awarded under the stock incentive plans expire 10 years after the grant date and typically vest over four or five years. Restricted stock units awarded typically vest over four years.

Stock-based compensation expense was \$2,407 and \$1,914 for the three months ended March 31, 2024 and 2023, respectively. The total amount of stock-based compensation expense was included within selling, general and administrative expenses on the condensed consolidated statements of operations and comprehensive loss.

Restricted Stock Units (RSUs)

The Company granted 1,766,615 and 3,192,372 time-based restricted stock units to its employees, executives and members of the Board of Directors in the three months ended March 31, 2024 and 2023, respectively. Each restricted stock unit represents the

contingent right to receive one share of the Company's Class A common stock. A majority of the restricted stock units will vest in four equal annual installments. The fair value of the restricted stock units was based on the fair market value of the Company's stock on the date of grant.

[Table of Contents](#)

The activity of restricted stock units is set forth below:

	Number of RSUs	Weighted Average Grant Date Fair Value
Unvested at December 31, 2023	3,898,331	\$ 3.54
Granted	1,766,615	3.43
Vested	(1,376,737)	3.63
Canceled/forfeited	(15,474)	5.52
Unvested at March 31, 2024	4,272,735	\$ 3.46

As of March 31, 2024, the total unrecognized compensation cost related to unvested restricted stock units expected to vest was \$10,968 and the weighted average remaining recognition period for unvested awards was 2.77 years.

Stock Options

The following table summarizes the Company's stock option activity since December 31, 2023:

	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Outstanding as of December 31, 2023	9,340,046	\$ 4.60	6.66	\$ 10,267
Granted	2,640,601	3.43	—	—
Exercised	(152,250)	1.18	—	254
Canceled/forfeited	(21,738)	5.85	—	7
Outstanding as of March 31, 2024	11,806,659	\$ 4.38	7.28	\$ 3,359
Options exercisable as of March 31, 2024	5,258,648	\$ 4.92	5.18	\$ 2,487
Options vested or expected to vest as of March 31, 2024	10,457,197	\$ 4.47	7.03	\$ 3,169

The stock options granted during the three months ended March 31, 2024 and 2023 were 2,640,601 and 3,554,528, respectively.

The aggregate intrinsic value of stock options is calculated as the difference between the exercise price of the stock options and the fair value of the Company's Class A common stock for those stock options that have exercise prices lower than the fair value of the Company's Class A common stock.

The weighted-average grant-date fair value per share of stock options granted during the three months ended March 31, 2024 and 2023 was \$1.89 and \$1.32, respectively. The total fair value of options vested during the three months ended March 31, 2024 and 2023 was \$3,669 and \$2,653, respectively.

As of March 31, 2024, the total unrecognized stock compensation expense related to unvested stock options expected to vest was \$9,218 and was expected to be recognized over a weighted-average period of 2.84 years.

12. Earnings per Share (EPS)

Basic EPS is calculated by dividing net income (loss) by the weighted-average number of shares outstanding during the period. Diluted EPS is calculated by dividing net income (loss) by the weighted-average number of shares outstanding plus the dilutive effect, if any, of outstanding equity awards using the treasury stock method which includes consideration of unrecognized compensation expenses as additional proceeds.

The Company's potentially dilutive securities include restricted stock units and stock options to purchase shares of Class A common stock. As the Company had a net loss in the periods presented, the potentially dilutive securities have been excluded from the computation of diluted net loss per share as the effect would be anti-dilutive. Therefore, the weighted-average number of common shares outstanding used to calculate both basic and diluted net loss per share attributable to common stockholders is the same for these periods. For the three months ended March 31, 2024 and 2023, the Company excluded 1,542,861 and 800,395 potential shares of Class A common stock, respectively, presented based on the diluted effects of options and restricted stock units outstanding at each

[Table of Contents](#)

period end, from the computation of diluted net loss per share attributable to the common stockholders for these periods. Basic and diluted net loss attributable to the Class A common stockholders was calculated as follows.

	Three Months Ended March 31,	
	2024	2023
Numerator:		
Net loss	\$ (2,100)	\$ (2,969)
Denominator:		
Weighted-average common shares outstanding — basic and diluted	131,861,772	131,083,841
Net loss per share—basic and diluted	<u>\$ (0.02)</u>	<u>\$ (0.02)</u>

13. Leases

The Company's leases consist primarily of real estate, equipment and vehicle leases.

The Company leases real estate for office, lab, warehouse and production space under noncancelable leases that expire at various dates through 2035, subject to the Company's options to terminate or renew certain leases for an additional five to ten years. The Company leases vehicles under operating leases for certain employees and has fleet services agreements for service on these vehicles. The minimum lease term for each newly leased vehicle is 367 days with renewal options. The Company may terminate the vehicle lease after the minimum lease term upon thirty days' prior notice. The Company also leases other equipment under noncancelable leases that expire at various dates through 2026.

On January 1, 2013, the Company entered into finance lease arrangements with 65 Dan Road SPE, LLC, 85 Dan Road Associates, LLC, Dan Road Equity I, LLC and 275 Dan Road SPE, LLC for office and laboratory space in Canton, Massachusetts (the "Related-Party Leases"). 65 Dan Road SPE, LLC, 85 Dan Road Associates, LLC, Dan Road Equity I, LLC and 275 Dan Road SPE, LLC are related parties as the owners of these entities are also directors, former directors and / or stockholders of the Company.

In August 2021, the Company purchased the building (the "275 Dan Road Building") under the lease with 275 Dan Road SPE, LLC for \$6,013 and the lease was terminated. The Company recorded an asset of \$4,943 to buildings within property and equipment, net, to account for the purchase of the leased asset.

The remaining three Related-Party Leases were set to terminate on December 31, 2022 and each contained a renewal option for a five-year period with a rental rate at the greater of (i) rent for the last year of the prior term, or (ii) the then fair market value. In November 2021, the Company exercised the option to extend the leases for an additional five years, and at such time, remeasured the right of use assets and lease liabilities based on its best estimate of the market rental rate in the renewal period and reassessed the classification for these leases. As a result, these leases were reclassified from finance leases to operating leases on the consolidated balance sheets as of December 31, 2021. In December 2022, the Company and the landlord finalized the market rental rate in the renewal period for these properties, resulting in an additional \$8,060 to be recorded as variable lease expenses over the renewal period.

Effective April 1, 2019, the Company agreed to accrue interest on accrued but unpaid lease obligations owed for rent in arrears to the owners of the buildings subject to the Related-Party Leases, at an interest rate equal to the rate charged under the 2019 Credit Agreement. The remaining accrued but unpaid lease obligation with respect to the 275 Dan Road Building was paid in five quarterly installments through January 3, 2023, and accordingly at March 31, 2024 and December 31, 2023, there is no remaining balance or accrued interest associated with the 275 Dan Road Building. The accrued but unpaid lease obligations as well as the related accrued interest with respect to the remaining three Related-Party Leases are shown below:

	March 31,	December
	2024	31, 2023
Principal portion of rent in arrears	\$ 5,273	\$ 5,273
Accrued interest on accrued but unpaid lease obligations	\$ 2,448	\$ 2,326

The accrued but unpaid lease obligations owed for rent in arrears on the three remaining Related-Party Leases was included in current portion of operating lease obligations on the condensed consolidated balance sheets, as of March 31, 2024 and December 31,

2023. The accrued interest on the accrued but unpaid lease obligations was included in accrued expenses and other current liabilities on the condensed consolidated balance sheets as of March 31, 2024 and December 31, 2023.

[Table of Contents](#)

The components of lease cost were as follows:

	Classification	Three Months Ended March 31,	
		2024	2023
Finance lease			
Amortization of right-of-use assets	COGS and SG&A	\$ 288	\$ —
Interest on lease liabilities	Interest Expense	57	—
Total finance lease cost		345	—
Operating lease cost	COGS, R&D, SG&A	2,203	2,291
Short-term lease cost	COGS, R&D, SG&A	661	758
Variable lease cost	COGS, R&D, SG&A	1,126	1,794
Total lease cost		<u>\$ 4,335</u>	<u>\$ 4,843</u>

Supplemental balance sheet information related to finance leases was as follows:

	March 31, 2024	December 31, 2023
Property and equipment, gross	\$ 3,454	\$ 3,454
Accumulated depreciation	(767)	(479)
Property and equipment, net	<u>\$ 2,687</u>	<u>\$ 2,975</u>

Supplemental cash flow information related to leases was as follows:

	Three Months Ended March 31,	
	2024	2023
Cash paid for amounts included in the measurement of lease liabilities:		
Operating cash flows for operating leases	\$ 2,715	\$ 2,468
Operating cash flows for finance leases	\$ 57	\$ —
Financing cash flows for finance leases	\$ 262	\$ —
	March 31, 2024	December 31, 2023
Weighted-average remaining lease term		
Finance leases	2.33	2.58
Operating leases	6.31	6.49
	March 31, 2024	December 31, 2023
Weighted-average discount rate		
Finance leases	7.91 %	7.91 %
Operating leases	4.75 %	4.71 %

[Table of Contents](#)

As of March 31, 2024, maturities of lease liabilities were as follows:

	Operating leases	Finance leases
2024 (remaining nine months)	\$ 7,580	\$ 959
2025	8,819	1,278
2026	7,657	737
2027	8,119	—
2028	3,580	—
Thereafter	15,108	—
Total lease payments	50,863	2,974
Less: interest	(7,483)	(267)
Total lease liabilities	<u>\$ 43,380</u>	<u>\$ 2,707</u>

14. Commitments and Contingencies

License and Manufacturing Agreement

In November 2023, the Company entered into a trademark license and manufacturing agreement with Vivex Biologics, Inc. (“Vivex”) to sell its CYGNUS Dual (“Dual”) and CYGNUS Matrix (“Matrix”) products, with the option to license the VIA Matrix (“VIA”) products.

The Company paid an upfront licensing fee to Vivex to sell Dual and Matrix, and also agreed to pay a fixed milestone payment for Dual in the event that its average sales price (“ASP”) is published by certain government agencies for a specified period of time. In addition, the Company is required to pay a low double digit royalty and a high single-digit royalty on the Net Sales of Dual and Matrix, respectively, during the royalty term, as defined in the agreement with Vivex. The royalty term is commensurate with the initial term of the contract and will continue for each subsequent renewal period. The initial term of the agreement expires on December 31, 2026 and can be renewed for up to five additional one-year terms.

The Company recorded \$5,000 in prepaid and other current assets and other assets for the payment of the upfront licensing fee, which is recognized as expense on a straight-line basis over the estimated life of the arrangement, which the Company determined to be three years, commensurate with the initial term of the contract. In December 2023, the Company recorded \$2,500 in prepaid and other current assets, other assets, and accrued expenses and other current liabilities for the milestone payment, as the Company determined it is probable of owing such payment to Vivex. In March 2024, the Company exercised the option to license VIA, and as such, as of March 31, 2024, the option payment of \$2,500 is included in accrued expenses and other current liabilities on the condensed consolidated balance sheets.

Royalties

The Company entered into a license agreement with a university for certain patent rights related to the development, use, and production of one of its advanced wound care products. Under this agreement, the Company incurred a royalty based on a percentage of net product sales, for the use of these patents until the patents expired, which was in November 2006.

In October 2017, the Company entered into a license agreement with a third party. Under the license agreement, the Company is required to pay royalties based on a percentage of net sales of the licensed product that occur, after December 31, 2017, through the expiration of the underlying patent in October 2026, subject to minimum royalty payment provisions.

The Company recorded total royalty expense of \$4,947 and \$1,440 during the three months ended March 31, 2024 and 2023, respectively, within selling, general and administrative expenses on the condensed consolidated statements of operations and comprehensive loss.

Legal Matters

In conducting its activities, the Company, from time to time, is subject to various claims and also has claims against others. In management’s opinion, the ultimate resolution of such claims would not have a material effect on the financial position, operating results or cash flows of the Company. The Company accrues for these claims when amounts due are probable and estimable.

15. Related Party Transactions

Lease obligations to affiliates, including accrued but unpaid lease obligations, purchase of an asset under a finance lease with an affiliate, and renewal of leases with affiliates are further described in Note 13, *Leases*.

16. Taxes

[Table of Contents](#)

The Company is principally subject to taxation in the United States. The Company has a history of net operating losses both federally and in various states and began utilizing those losses to offset current taxable income in 2020. As net operating loss carryovers become limited or are fully utilized, the Company will accrue current federal and state income tax expense. The Company's wholly owned Swiss subsidiary, Organogenesis GmbH, is subject to taxation in Switzerland and has a transfer pricing arrangement in place with Organogenesis Inc., its U.S. parent.

The income tax rate for the three months ended March 31, 2024 was 51.1%, an increase from the U.S. statutory rate of 21% primarily due to the tax adjustments related to executive compensation, and other nondeductible expenses. The income tax benefit for the three months ended March 31, 2024 and 2023 was \$2,243 and \$1,658, respectively.

[Table of Contents](#)

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations.

The following discussion and analysis should be read in conjunction with our financial statements and accompanying notes included in this Form 10-Q and the financial statements and accompanying notes thereto and Management's Discussion and Analysis of Financial Condition and Results of Operations included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2023, filed with the SEC, on February 29, 2024. Please refer to our cautionary note regarding forward-looking statements on page 3 of this Form 10-Q, which is incorporated herein by this reference.

Overview

We are a leading regenerative medicine company focused on the development, manufacture, and commercialization of solutions for the Advanced Wound Care and Surgical & Sports Medicine markets. Our products have been shown through clinical and scientific studies to support and in some cases accelerate tissue healing and improve patient outcomes. We are advancing the standard of care in each phase of the healing process through multiple breakthroughs in tissue engineering and cell therapy. Our solutions address large and growing markets driven by aging demographics and increases in comorbidities such as diabetes, obesity, and cardiovascular and peripheral vascular disease. We offer our differentiated products and in-house customer support to a wide range of health care customers including hospitals, wound care centers, government facilities, ambulatory surgery centers (ASCs) and physician offices. Our mission is to provide integrated healing solutions that substantially improve medical outcomes and the lives of patients while lowering the overall cost of care.

We offer a comprehensive portfolio of products in the markets we serve that address patient needs across the continuum of care. We have and intend to continue to generate data from clinical trials, real-world outcomes and health economics research that validate the clinical efficacy and value proposition offered by our products. Several of our existing and pipeline products in our portfolio have PMA approval, or 510(k) clearance from the FDA. Given the extensive time and cost required to conduct clinical trials and receive FDA approvals, we believe that our data and regulatory approvals provide us with a strong competitive advantage. Our product development expertise and multiple technology platforms provide a robust product pipeline, which we believe will drive future growth.

In the Advanced Wound Care market, we focus on the development and commercialization of advanced wound care products for the treatment of chronic and acute wounds in various treatment settings. We have a comprehensive portfolio of regenerative medicine products, capable of supporting patients from early in the wound healing process through wound closure regardless of wound type. Our Advanced Wound Care products include Apligraf for the treatment of venous leg ulcers (VLUs) and diabetic foot ulcers (DFUs); Dermagraft for the treatment of DFUs (manufacturing and distribution currently suspended pending transition to a new manufacturing facility or engagement of a third-party manufacturer); PuraPly AM and PuraPly XT as antimicrobial barriers and native, cross-linked ECM scaffolds for a broad variety of wound types; and Affinity, Novachor, NuShield, and CYGNUS placental allografts to address a variety of wound sizes and types as a protective barrier and ECM scaffold. We have a highly trained and specialized direct wound care sales force paired with comprehensive customer support services.

In the Surgical & Sports Medicine market, we are leveraging our broad regenerative medicine capabilities to address chronic and acute surgical wounds and tendon and ligament injuries. Our Sports Medicine products include NuShield for surgical applications in targeted soft tissue repairs; and Affinity, Novachor, PuraPly AM, PuraPly MZ, and PuraPly SX for management of open wounds in the surgical setting. We currently sell these products through independent agencies and our direct sales force.

In May 2024, we announced that our Phase 3 randomized control trial evaluating the safety and efficacy of ReNu, a cryopreserved amniotic suspension allograft (ASA) for the management of symptoms associated with knee osteoarthritis (OA), achieved its primary endpoint upon the analysis of positive top line data. ReNu demonstrated a statistically significant reduction in knee OA pain at six months post-treatment compared with the control group. A complete analysis of the data from the Phase 3 clinical trial is expected later in May 2024.

Dermagraft

As previously disclosed, manufacturing of Dermagraft was suspended in the fourth quarter of 2021 and sales of Dermagraft were suspended in the second quarter of 2022. We currently plan to transition our Dermagraft manufacturing to a new manufacturing facility or engage a third-party manufacturer, which we expect will result in substantial long-term cost savings. In the period when Dermagraft is not available, we expect that customers will be willing to substitute Apligraf for Dermagraft and that the suspension of Dermagraft sales will not have a material impact on our net revenue. However, if we do not realize the expected substantial long-term cost savings or if customers are unwilling to substitute Apligraf for Dermagraft during the period in which Dermagraft is unavailable, it could have an adverse effect on our net revenue and results of operations.

[Table of Contents](#)

Local Coverage Determinations

In August 2023, three Medicare Administrative Contractors (MACs) issued local coverage determinations (LCDs) eliminating coverage for DFUs and VLUs for over 130 products, including five of our commercially marketed products. The LCDs were scheduled to take effect on September 17, 2023, and subsequently delayed to October 1, 2023. Given the potential adverse impact these LCDs could have on patients and on our business, we worked with our advisors to convince the MACs to withdraw the LCDs and incurred legal expenses and compensation expenses related to retention for impacted sales employees. On September 28, 2023, the three MACs withdrew the LCDs. Notwithstanding the ultimate withdrawal of the LCDs, we believe that some of our customers elected to purchase covered products from our competitors, reducing our revenue for the third and fourth quarters of the year ended December 31, 2023.

Similarly, on April 25, 2024, seven MACs published proposed LCDs for skin substitute grafts/cellular and tissue-based products (CTPs) for the treatment of DFUs and VLUs in the Medicare population, that classify five of our commercially marketed product lines as “non-covered.” We are engaging with the MACs to provide clinical evidence for these non-covered products demonstrating their efficacy for the treatment of DFUs and VLUs, however there is no guarantee that the MACs will agree to cover these products in the final LCDs.

License And Manufacturing Agreement

In November 2023, we entered into a trademark license and manufacturing agreement with Vivex Biologics, Inc. (Vivex) to sell its CYGNUS Dual (Dual) and CYGNUS Matrix (Matrix) products, with the option to license its VIA Matrix (VIA) products. We paid an upfront licensing fee to Vivex to sell Dual and Matrix, and also agreed to pay a fixed milestone payment for Dual in the event that its average selling price (ASP) is published by certain government agencies for a specified period of time, for which we previously accrued because we determined that payment would be probable in December 2024. In March 2024, we exercised the option to license VIA.

In addition, the Company is required to pay a low double-digit royalty and a high single-digit royalty on the Net Sales of Dual and Matrix, respectively, during the royalty term, as defined in the agreement with Vivex. The royalty term is commensurate with the initial term of the contract and will continue for each subsequent renewal period. The initial term of the agreement expires on December 31, 2026 and can be renewed for up to five additional one-year terms.

We paid \$5.0 million in upfront licensing fees and accrued \$2.5 million for the milestone payment in the fourth quarter of 2023, and paid an additional \$2.5 million licensing fee for the VIA option in April 2024.

Components of Our Condensed Consolidated Results of Operations

In assessing the performance of our business, we consider a variety of performance and financial measures. We believe the items discussed below provide insight into the factors that affect these key measures.

Revenue

We derive our net revenue from our portfolio of Advanced Wound Care and Surgical & Sports Medicine products. We primarily sell our Advanced Wound Care products through direct sales representatives who manage and maintain the sales relationships with hospitals, wound care centers, government facilities, ASCs and physician offices. We primarily sell our Surgical & Sports Medicine products through third party agencies. As of March 31, 2024, we had approximately 250 direct sales representatives and approximately 157 independent agencies.

We recognize revenue from sales of our Advanced Wound Care and Surgical & Sports Medicine products when the customer obtains control of our product, which occurs at a point in time and may be upon procedure date, shipment, or delivery, based on the contractual terms of a contract. We record revenue net of a reserve for returns, discounts and Group Purchasing Organization (GPO) rebates, which represent a direct reduction to the revenue we recognize.

Several factors affect our reported revenue in any period, including product, payer and geographic sales mix, operational effectiveness, pricing realization, marketing and promotional efforts, the timing of orders and shipments, regulatory actions including healthcare reimbursement scenarios, competition and business acquisitions.

Cost of goods sold and gross profit

Cost of goods sold includes personnel costs, product testing costs, quality assurance costs, raw materials and product costs, manufacturing costs, and the costs associated with our manufacturing and warehouse facilities. The changes in our cost of goods sold correspond with the changes in sales units and are also affected by product mix.

[Table of Contents](#)

Gross profit is calculated as net revenue less cost of goods sold and generally increases as revenue increases. Our gross profit is affected by product and geographic sales mix, realized pricing of our products, the efficiency of our manufacturing operations, and the costs of materials used and fees charged by third-party manufacturers to produce our products. Regulatory actions, including healthcare reimbursement scenarios, which may require costly expenditures or result in pricing pressures, may decrease our gross profit.

Selling, general and administrative expenses

Selling, general and administrative expenses generally include personnel costs for sales, marketing, sales support, customer support, and general and administrative personnel, sales commissions, incentive compensation, insurance, professional fees, depreciation, amortization, bad debt expense, royalties, information systems costs, gain or loss on disposal of long-lived assets, and costs associated with our administrative facilities. We generally expect our selling, general and administrative expenses to continue to increase due to increased investments in market development and the geographic expansion of our sales forces as we drive for continued revenue growth.

Research and development expenses

Research and development expenses include expenses for clinical trials, personnel costs for our research and development personnel, expenses related to improvements in our manufacturing processes, enhancements to our currently available products, and additional investments in our product and platform development pipeline. We expense research and development costs as incurred. We generally expect that research and development expenses will increase as we continue to conduct clinical trials on new and existing products, move products through the regulatory pathway (e.g., seek biologics license application approval), add personnel to support product enhancements as well as to bring new products to market, and enhance our manufacturing process and procedures.

Other expense, net

Other expense, net consists primarily of interest expense, which is interest on our outstanding indebtedness, including amortization of debt discount and debt issuance costs, net of interest income recognized.

Income taxes

We account for income taxes using an asset and liability approach. Deferred income taxes reflect the net tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. Valuation allowances are provided when necessary to reduce net deferred tax assets to an amount that is more likely than not to be realized.

In determining whether a valuation allowance for deferred tax assets is necessary, we analyze both positive and negative evidence related to the realization of deferred tax assets including projected future taxable income, recent financial results and estimates of future reversals of deferred tax assets and liabilities. We maintain the position that our net U.S. deferred tax assets did not require a valuation allowance as of March 31, 2024 and December 31, 2023.

We account for uncertainty in income taxes recognized in the condensed consolidated financial statements by applying a two-step process to determine the amount of tax benefit to be recognized. First, the tax position must be evaluated to determine the likelihood that it will be sustained upon external examination by the taxing authorities. If the tax position is deemed more-likely-than-not to be sustained, the tax position is then assessed to determine the amount of benefit to recognize in the condensed consolidated financial statements. The amount of the benefit that may be recognized is the largest amount that has a greater than 50% likelihood of being realized upon ultimate settlement. The provision for income taxes includes the effects of any resulting tax reserves, or unrecognized tax benefits, that are considered appropriate as well as the related net interest and penalties.

[Table of Contents](#)

Results of Operations

The following table sets forth, for the periods indicated, our results of operations:

	Three Months Ended March 31,	
	2024	2023
	(Unaudited, in thousands)	
Net revenue	\$ 109,976	\$ 107,642
Cost of goods sold	28,696	26,607
Gross profit	81,280	81,035
Operating expenses:		
Selling, general and administrative	72,322	73,834
Research and development	12,810	11,202
Total operating expenses	85,132	85,036
Loss from operations	(3,852)	(4,001)
Other expense, net:		
Interest expense	(514)	(649)
Other income, net	23	23
Total other expense, net	(491)	(626)
Net loss before income taxes	(4,343)	(4,627)
Income tax benefit	2,243	1,658
Net loss	\$ (2,100)	\$ (2,969)

EBITDA and Adjusted EBITDA

Our management uses financial measures that are not in accordance with generally accepted accounting principles in the United States (non-GAAP), in addition to financial measures in accordance with generally accepted accounting principles in the United States (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 to evaluate our operating performance and trends and make planning decisions. Our management 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.

The following is a reconciliation of GAAP net loss to non-GAAP EBITDA and non-GAAP Adjusted EBITDA for each of the periods presented:

	Three Months Ended March 31,	
	2024	2023
	(Unaudited, in thousands)	
Net loss	\$ (2,100)	\$ (2,969)
Interest expense, net	514	649
Income tax benefit	(2,243)	(1,658)
Depreciation	3,072	2,694
Amortization	901	1,230
EBITDA	144	(54)
Stock-based compensation expense	2,407	1,914
Restructuring charge (1)	—	1,908

Adjusted EBITDA	\$	2,551	\$	3,768
-----------------	----	-------	----	-------

[Table of Contents](#)

- (1) Amounts reflect employee severance, retention and benefits as well as other exit costs associated with the Company's restructuring activities. See Note 9, *Restructuring*, to our condensed consolidated financial statements included in this Quarterly Report on Form 10-Q.

Comparison of Three Months Ended March 31, 2024 and 2023

Revenue

	Three Months Ended March 31,		Change	
	2024	2023	\$	%
	(in thousands, except for percentages)			
Advanced Wound Care	\$ 103,864	\$ 100,917	\$ 2,947	3 %
Surgical & Sports Medicine	6,112	6,725	(613)	(9 %)
Net revenue	\$ 109,976	\$ 107,642	\$ 2,334	2 %

Net revenue from our Advanced Wound Care products increased by \$2.9 million, or 3%, to \$103.9 million in the three months ended March 31, 2024, from \$100.9 million in the three months ended March 31, 2023. The increase in Advanced Wound Care net revenue was primarily attributable to an increase in product sales of certain of our products to our existing and new customers.

Net revenue from our Surgical & Sports Medicine products decreased by \$0.6 million, or 9% to \$6.1 million in the three months ended March 31, 2024 from \$6.7 million in the three months ended March 31, 2023. The decrease in Surgical & Sports Medicine net revenue was primarily due to a decrease in certain customer buying patterns.

Cost of goods sold and gross profit

	Three Months Ended March 31,		Change	
	2024	2023	\$	%
	(in thousands, except for percentages)			
Cost of goods sold	\$ 28,696	\$ 26,607	\$ 2,089	8 %
Gross profit	\$ 81,280	\$ 81,035	\$ 245	0 %

Cost of goods sold increased by \$2.1 million, or 8%, to \$28.7 million in the three months ended March 31, 2024, from \$26.6 million in the three months ended March 31, 2023. The increase in cost of goods sold in the three months ended March 31, 2024 was primarily due to an increase in sales volume as well as a shift in product mix.

Gross profit increased by \$0.2 million to \$81.3 million in the three months ended March 31, 2024 from \$81.0 million in the three months ended March 31, 2023. Gross profit remained consistent from the three months ended March 31, 2023 to the three months ended March 31, 2024, but decreased as a percentage of revenue, due to a shift in product mix.

Research and Development Expenses

	Three Months Ended March 31,		Change	
	2024	2023	\$	%
	(in thousands, except for percentages)			
Research and development	\$ 12,810	\$ 11,202	\$ 1,608	14 %

Research and development expenses increased by \$1.6 million, or 14%, to \$12.8 million in the three months ended March 31, 2024 from \$11.2 million in the three months ended March 31, 2023. The increase in research and development expenses was primarily due to expenses associated with clinical research and trials, primarily related to ReNu, and support of Biologics License Application (BLA) efforts.

Selling, General and Administrative Expenses

	Three Months Ended March 31,		Change	
	2024	2023	\$	%
	(in thousands, except for percentages)			
Selling, general and administrative	\$ 72,322	\$ 73,834	\$ (1,512)	(2%)

Selling, general and administrative expenses decreased by \$1.5 million, or 2%, to \$72.3 million in the three months ended March 31, 2024 from \$73.8 million in the three months ended March 31, 2023. The decrease in selling, general and administrative expenses was primarily due to a \$5.2 million reduction in headcount-related expenses, including \$1.9 million in severance expense incurred in the three months ended March 31, 2023 and not repeated in the three months ended March 31, 2024; partially offset by \$3.5 million in royalty expense.

Other Expense, net

Other expense, net, decreased by \$0.1 million, or 17%, to \$0.5 million in the three months ended March 31, 2024 from \$0.6 million in the three months ended March 31, 2023. Other expense, net is comprised primarily of interest expense, and the decrease is due to the decreased debt balance under the 2021 Credit Agreement.

Income Tax Benefit

	Three Months Ended March 31,		Change	
	2024	2023	\$	%
	(in thousands, except for percentages)			
Income tax benefit	\$ 2,243	\$ 1,658	\$ 585	35%

Income tax benefit increased by \$0.6 million, or 35%, to \$2.2 million in the three months ended March 31, 2024 from \$1.7 million in the three months ended March 31, 2023. The change in the income tax benefit is primarily attributable to a higher estimated effective tax rate for the twelve months ended December 31, 2024 resulting from a reduction in expected pre-tax income in 2024 compared to 2023.

Liquidity and Capital Resources

As of March 31, 2024, we had working capital of \$144.4 million, which included \$88.6 million in cash and cash equivalents. We also have \$125.0 million available for future revolving borrowings under our Revolving Facility (see Note 10, *Long-Term Debt Obligations* to our condensed consolidated financial statements included in this Quarterly Report on Form 10-Q). We expect that our cash on hand and other components of working capital as of March 31, 2024, availability under the 2021 Credit Agreement, plus net cash flows from product sales, will be sufficient to fund our operating expenses, capital expenditure requirements and debt service payments for at least 12 months beyond the filing date of this quarterly report.

Our primary uses of cash are working capital requirements, capital expenditure and debt service payments. Additionally, from time to time, we may use capital for acquisitions and other investing and financing activities. Working capital is used principally for our personnel as well as manufacturing costs related to the production of our products. Our working capital requirements vary from period to period depending on manufacturing volumes, the timing of shipments and the payment cycles of our customers and payers. Our capital expenditures consist primarily of building improvements, manufacturing equipment, and computer hardware and software.

To the extent additional funds are necessary to meet our long-term liquidity needs as we continue to execute on our business strategy, we anticipate that they will be obtained through additional equity or debt financings, other strategic transactions or a combination of these potential sources of funds. There can be no assurance that we will be able to obtain additional funds on terms acceptable to us, on a timely basis, or at all.

[Table of Contents](#)

Cash Flows

The following table summarizes our cash flows for each of the periods presented:

	Three Months Ended March 31,	
	2024	2023
	(in thousands)	
Net cash used in operating activities	\$ (10,162)	\$ (5,077)
Net cash used in investing activities	(2,222)	(7,562)
Net cash used in financing activities	(2,608)	(1,236)
Net change in cash, cash equivalents, and restricted cash	\$ (14,992)	\$ (13,875)

Operating Activities

During the three months ended March 31, 2024, net cash used in operating activities was \$10.2 million, resulting from our net loss of \$2.1 million and non-cash charges of \$12.6 million, partially offset by net cash used in connection with changes in our operating assets and liabilities of \$20.7 million. Net cash used in changes in our operating assets and liabilities included an increase in inventory of \$4.7 million, an increase in prepaid expenses and other current assets of \$4.3 million, an increase in accounts receivable of \$15.1 million, a decrease in operating lease liabilities of \$2.2 million, and a decrease in accounts payable of \$4.4 million, partially offset by an increase in accrued expenses and other liabilities of \$12.3 million.

During the three months ended March 31, 2023, net cash used in operating activities was \$5.1 million, resulting from our net loss of \$3.0 million and net cash used in connection with changes in our operating assets and liabilities of \$11.8 million, partially offset by non-cash charges of \$9.7 million. Net cash used in changes in our operating assets and liabilities included an increase in accounts receivable of \$3.4 million, an increase in inventory of \$2.2 million, an increase in prepaid expenses and other current assets of \$4.8 million, a decrease in operating leases liabilities of \$2.1 million, and a decrease in accounts payable of \$1.4 million, partially offset by an increase in accrued expenses and other liabilities of \$2.1 million.

Investing Activities

During the three months ended March 31, 2024, we used \$2.2 million of cash in investing activities consisting exclusively of capital expenditures.

During the three months ended March 31, 2023, we used \$7.6 million of cash in investing activities consisting exclusively of capital expenditures.

Financing Activities

During the three months ended March 31, 2024, net cash used in financing activities was \$2.6 million. This consisted of the payment of term loan of \$1.4 million, principal payments on finance lease obligations of \$0.2 million, and net cash payments associated with our stock awards activities of \$1.1 million.

During the three months ended March 31, 2023, net cash used in financing activities was \$1.2 million. This consisted of the payment of term loan and the stock awards activities.

Indebtedness

2021 Credit Agreement

In August 2021, we and our subsidiaries entered into a credit agreement with SVB and several other lenders, which we refer to as the 2021 Credit Agreement. The 2021 Credit Agreement, as amended, provides for a term loan facility not to exceed \$75.0 million (the Term Loan Facility) and a revolving credit facility not to exceed \$125.0 million (the Revolving Facility).

Advances made under the 2021 Credit Agreement may be either SOFR Loans or ABR Loans, at our option. For SOFR Loans, the interest rate is a per annum interest rate equal to the Adjusted Term SOFR plus an Applicable Margin between 2.00% to 3.25% based on the Total Net Leverage Ratio. For ABR Loans, the interest rate is equal to (1) the highest of (a) the Wall Street Journal Prime Rate, (b)

the Federal Funds Rate plus 0.50% and (c) the Adjusted Term SOFR rate plus 1.0%, *plus* (2) an Applicable Margin between 1.00% to 2.25% based on the Total Net Leverage Ratio. On March 31, 2024, the applicable interest rate for outstanding borrowings is 7.64%.

[Table of Contents](#)

The 2021 Credit Agreement requires us to make consecutive quarterly installment payments equal to the following: (a) from September 30, 2021 through and including June 30, 2022, \$0.5 million; (b) from September 30, 2022 through and including June 30, 2023, \$0.9 million; (c) from September 30, 2023 through and including June 30, 2025, \$1.4 million and (d) from September 30, 2025 and the last day of each quarter thereafter until August 6, 2026 (the Term Loan Maturity Date), \$1.9 million. The remaining principal balance of \$50.6 million is also due on the Term Loan Maturity Date. We may prepay the Term Loan Facility. Once repaid, amounts borrowed under the Term Loan Facility may not be re-borrowed.

We must pay in arrears, on the first day of each quarter prior to August 6, 2026 (the Revolving Termination Date) and on the Revolving Termination Date, a fee for our non-use of available funds (the Commitment Fee). The Commitment Fee rate is between 0.25% to 0.45% based on the Total Net Leverage Ratio. We may elect to reduce or terminate the Revolving Facility in its entirety at any time by repaying all outstanding principal and unpaid accrued interest.

Under the 2021 Credit Agreement, we are required to comply with certain financial covenants including the Consolidated Fixed Charge Coverage Ratio and Consolidated Total Net Leverage Ratio, tested quarterly. In addition, we are also required to make representations and warranties and comply with certain non-financial covenants that are customary in loan agreements of this type, including restrictions on the payment of dividends, repurchase of stock, incurrence of indebtedness, dispositions and acquisitions.

As of March 31, 2024, we were in compliance with the covenants under the 2021 Credit Agreement. We had outstanding borrowings of \$65.2 million under our Term Loan Facility and no borrowings outstanding under our Revolving Facility with \$125.0 million available for future revolving borrowings, respectively.

Critical Accounting Policies and Significant Judgments and Estimates

Our unaudited condensed consolidated financial statements have been prepared in accordance with GAAP. The preparation of unaudited condensed consolidated financial statements requires us to make estimates, assumptions and judgments that affect the reported amounts of assets, liabilities, and the disclosure at the date of the unaudited condensed consolidated financial statements, as well as revenue and expenses recorded during the reporting periods. Management bases its estimates, assumptions and judgments on historical experience and on various other factors that it believes to be reasonable under the circumstances. Different assumptions and judgments would change the estimates used in the preparation of our unaudited condensed consolidated financial statements, which, in turn, could materially change our results from those reported. Management evaluates its estimates, assumptions and judgments on an ongoing basis. Historically, our critical accounting estimates have not differed materially from actual results. However, if our assumptions change, we may need to revise our estimates, or take other corrective actions, either of which may also have a material adverse effect on our condensed consolidated statements of operations and comprehensive loss, liquidity and financial condition. See also our Annual Report on Form 10-K for the fiscal year ended December 31, 2023, for information about these accounting policies as well as a description of our other significant accounting policies.

Off-Balance Sheet Arrangements

We did not have, during the periods presented, and we do not currently have, any off-balance sheet arrangements, as defined in the rules and regulations of the SEC.

Recently Issued Accounting Pronouncements

We have reviewed all recently issued standards as disclosed in Note 2, *Summary of Significant Accounting Policies* to our condensed consolidated financial statements included in this Quarterly Report on Form 10-Q.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

During the three months ended March 31, 2024, there were no material changes to our market risk disclosures as set forth in Part II, Item 7A, “Quantitative and Qualitative Disclosures About Market Risk” in our Annual Report on Form 10-K for the fiscal year ended December 31, 2023.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our principal executive officer and principal financial officer, evaluated the effectiveness of our disclosure controls and procedures as of March 31, 2024. The term “disclosure controls and procedures,” as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the Exchange Act), means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the rules and forms promulgated by the SEC. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company’s management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

Based on that evaluation, our management, including our principal executive officer and principal financial officer, concluded that, as of March 31, 2024, our disclosure controls and procedures were ineffective because, as disclosed in the Company’s Annual Report for the fiscal year ended December 31, 2023, we did not design and maintain effective controls over information technology general controls and proper segregation of duties to support the proper initiation and recording of transactions and the resulting impact on business process controls and applications that rely on such data.

Management assessed the effectiveness of the Company’s internal control over financial reporting based on the criteria established in the SEC guidance on conducting such assessments as of the end of the period covered by this report. Management conducted the assessment based on certain criteria established in *Internal Control—Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission in 2013 (COSO framework). Although it has made progress in remediating the remaining material weakness, as a result of its assessment, management concluded that as of March 31, 2024, our internal control over financial reporting was ineffective based on the criteria of the COSO framework, and the continued existence of the material weakness described above.

Plans for Remediation of Material Weakness

Management has taken actions to remediate the deficiencies in its internal controls over financial reporting and implemented additional processes and controls designed to address the underlying causes associated with the above-mentioned material weakness. Management is committed to finalizing the remediation of the material weakness. Management’s internal control remediation efforts include the following:

- We finalized the plan to implement a new company-wide enterprise resource planning, (ERP) system to provide additional systematic controls and segregation of duties for our accounting processes, and anticipate the ERP system implementation to be completed throughout 2024 and 2025. We have implemented controls to mitigate existing risks where proper segregation within our existing ERP may not be feasible.
- An outside firm will continue to assist management with performing control operating effectiveness testing throughout the year.
- We regularly reported the results of control testing to the key stakeholders across our organization, including our audit committee, on testing progress and defined corrective actions, and we monitored and reported on the results of control remediation. We have strengthened our internal policies, processes, and reviews through these actions.
- We have continued working on documenting and remediating weaknesses and structuring the Company’s processes to meet Sarbanes-Oxley (SOX) 404(b) requirements.

As management continues to evaluate and work to improve our internal control over financial reporting, management may determine it is necessary to take additional measures to address the material weakness. However, we believe the above actions will be effective in remediating the remaining material weakness and we will continue to devote significant time and attention to these remediation efforts. Until the controls have been operating for a sufficient period of time and management has concluded, through testing, that these controls are executed consistently and operating effectively, the material weakness described above will continue to exist.

Changes in Internal Control Over Financial Reporting

There have been no changes in our internal control over financial reporting that occurred during the quarter ended March 31, 2024 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting other than those described above related to remediation efforts of the remaining material weakness. As the implementation of the new ERP system continues and our remediation efforts continue, we will change our processes and procedures, which in turn, could result in

[Table of Contents](#)

changes to our internal control over financial reporting. As such changes occur, we will evaluate quarterly whether such changes materially affect our internal control over financial reporting.

PART II – OTHER INFORMATION

Item 1. Legal Proceedings

On December 10, 2021, a class action complaint captioned *Somogyi v. Organogenesis Holdings Inc., et al.* was filed on behalf of a putative class of all purchasers of our securities against us and our Chief Executive Officer and Chief Financial Officer in the United States District Court for the Eastern District of New York (the Court). The Court appointed Donald Martin as lead plaintiff. Mr. Martin filed an amended complaint on October 24, 2022 that brought claims on behalf of a purported class of all purchasers of our securities from August 10, 2020 through August 9, 2022 and alleged violations of federal securities law in connection with alleged false and misleading statements with respect to, among other matters, revenue, sales growth and ability to compete in connection with our Affinity and PuraPly XT products. The amended complaint alleged violations of the Securities Exchange Act of 1934 and Rule 10b-5 promulgated thereunder, and sought unquantified damages as well as attorneys' fees, expert fees and other costs. On March 13, 2023, we filed our motion to dismiss the litigation for failure to state a claim upon which relief can be granted, and briefing was completed on May 30, 2023. On March 29, 2024, the Court granted, with prejudice, the Company's motion to dismiss all claims asserted and the plaintiffs did not appeal the Court's determination.

We are not a party to any other material legal proceedings. From time to time, we may become involved in litigation or other legal proceedings relating to claims arising from the ordinary course of business. These matters may include intellectual property, employment and other general claims. With respect to our outstanding legal matters, based on our current knowledge, we believe that the amount or range of reasonably possible loss will not, either individually or in the aggregate, have a material adverse effect on our business, consolidated financial position, results of operations, or cash flows. However, the outcome of such legal matters is inherently unpredictable and subject to significant uncertainties.

Item 1A. Risk Factors

Investing in our Class A common stock involves a high degree of risk. Our Annual Report on Form 10-K for the year ended December 31, 2023, includes a detailed discussion of our risk factors under the heading "Part I, Item 1A—Risk Factors." Except as set forth below, there have been no material changes from such risk factors during the quarter ended March 31, 2024. You should consider carefully the risk factors discussed in our Annual Report on Form 10-K for the year ended December 31, 2023, and all other information contained in or incorporated by reference in this Quarterly Report on Form 10-Q before making an investment decision. If any of the risks discussed in the Annual Report on Form 10-K for the year ended December 31, 2023, or herein actually occur, they may materially harm our business, financial condition, operating results, cash flows or growth prospects. As a result, the market price of our Class A common stock could decline, and you could lose all or part of your investment. Additional risks and uncertainties that are not yet identified or that we think are immaterial may also materially harm our business, financial condition, operating results, cash flows or growth prospects and could result in a complete loss of your investment.

Seven MACs recently published new proposed LCDs, for skin substitute grafts/CTPs for the treatment of DFUs and VLUs in the Medicare population that list certain of our products as non-covered. If the final LCDs include this non-coverage determination, it could, at least in the near term, have a material adverse effect on utilization of these products, our business and our revenue.

On April 25, 2024, seven MACs (CGS, WPS, NGS, Palmetto, Novitas, First Coast Services, and Noridian) published new proposed LCDs for skin substitute grafts/CTPs for the treatment of DFUs and VLUs in the Medicare population. While our Affinity, Apligraf and Dermagraft products remain covered, the LCDs classify our PuraPly, Novachor, TransCyte, NuShield and CYGNUS products as "non-covered." If the final LCDs do not include coverage for these products, it would present a significant amount of uncertainty, at least in the near term, regarding future revenue for these products. Although we are engaging with the MACs to provide clinical evidence for these non-covered products demonstrating their efficacy for the treatment of DFUs and VLUs, there is no guarantee that the MACs will agree to cover these products in the final LCDs. If these products are not covered in the final LCDs, it could, at least in the near term, materially and adversely impact utilization of these products, our business and our revenue.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

None.

Item 3. Defaults Upon Senior Securities

None.

[Table of Contents](#)

Item 4. Mine Safety Disclosures

Not Applicable.

Item 5. Other Information

During the three months ended March 31, 2024, no director or officer of the Company other than Antonio S. Montecalvo, the Company's Vice President, Health Policy, adopted or terminated a "Rule 10b5-1 trading arrangement" or "non-rule 10b5-1 trading arrangement," as each term is defined in item 408(a) of Regulation S-K. On March 16, 2024, Mr. Montecalvo adopted a trading plan intended to satisfy Rule 10b5-1(c) to sell up to 32,733 shares of the Company's Class A common stock and up to 250,000 shares of the Company's Class A common stock issuable upon exercise of vested options between June 14, 2024 and March 14, 2025, subject to certain conditions.

[Table of Contents](#)

Item 6. Exhibits

Exhibit number	Description
3.1	Certificate of Incorporation of Organogenesis Holdings Inc. (incorporated by reference to Exhibit 3.1 to the Company's Registration Statement on Form S-3/A (File No. 333-233621) filed with the SEC on September 16, 2019)
3.2	Certificate of Amendment of Certificate of Incorporation of Organogenesis Holdings Inc. (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K (File No. 001-37906) filed with the SEC on June 27, 2022)
3.3	Bylaws of Organogenesis Holdings Inc. (incorporated by reference to Exhibit 3.2 to the Company's Registration Statement on Form S-3/A (File No. 333-233621) filed with the SEC on September 16, 2019)
31.1†	Certification of Principal Executive Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2†	Certification of Principal Financial Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1†	Certification of Principal Executive Officer and Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101.INS†	Inline XBRL Instance Document XBRL
101.SCH†	Inline XBRL Taxonomy Extension Schema Document
101.CAL†	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF†	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB†	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE†	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104†	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)

† Filed herewith

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 thereunto duly authorized.

Dated: May 9, 2024

Organogenesis Holdings Inc.

(Registrant)

/s/ David Francisco

David Francisco
Chief Financial Officer

(Principal Financial and Accounting Officer)