
**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 September 30, 2022

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 November 1, 2022 was 130,915,099.

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Organogenesis Holdings Inc.
Quarterly Report on Form 10-Q
For the Quarterly Period Ended September 30, 2022

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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, 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, 2021. 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 Consolidated Financial Statements.

ORGANOGENESIS HOLDINGS INC.
CONSOLIDATED BALANCE SHEETS
(unaudited)

(amounts in thousands, except share and per share data)

	September 30, 2022	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	\$ 107,250	\$ 113,929
Restricted cash	771	599
Accounts receivable, net	93,115	82,460
Inventory, net	24,683	25,022
Prepaid expenses and other current assets	4,707	4,969
Total current assets	230,526	226,979
Property and equipment, net	97,012	79,160
Intangible assets, net	22,010	25,673
Goodwill	28,772	28,772
Operating lease right-of-use assets, net	45,369	49,144
Deferred tax asset, net	31,994	31,994
Other assets	1,589	1,537
Total assets	<u>\$ 457,272</u>	<u>\$ 443,259</u>
Liabilities and Stockholders' Equity		
Current liabilities:		
Deferred acquisition consideration	\$ -	\$ 1,436
Current portion of term loan	5,004	2,656
Finance lease obligations	-	200
Current portion of operating lease obligations	12,155	11,785
Accounts payable	37,952	29,339
Accrued expenses and other current liabilities	34,162	37,289
Total current liabilities	89,273	82,705
Term loan, net of current portion	67,600	70,769
Operating lease obligations, net of current portion	42,981	46,893
Other liabilities	1,090	1,557
Total liabilities	200,944	201,924
Commitments and contingencies (Note 18)		
Stockholders' equity:		
Preferred stock, \$0.0001 par value; 1,000,000 shares authorized; none issued	-	-
Common stock, \$0.0001 par value; 400,000,000 shares authorized; 131,643,647 and 129,408,740 shares issued; 130,915,099 and 128,680,192 shares outstanding at September 30, 2022 and December 31, 2021, respectively.	13	13
Additional paid-in capital	309,102	302,155
Accumulated deficit	(52,787)	(60,833)
Total stockholders' equity	256,328	241,335
Total liabilities and stockholders' equity	<u>\$ 457,272</u>	<u>\$ 443,259</u>

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

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Net revenue	\$ 116,859	\$ 113,753	\$ 335,377	\$ 339,501
Cost of goods sold	26,177	26,167	77,909	81,602
Gross profit	90,682	87,586	257,468	257,899
Operating expenses:				
Selling, general and administrative	79,328	62,369	215,515	182,950
Research and development	9,575	8,953	28,367	22,482
Total operating expenses	88,903	71,322	243,882	205,432
Income from operations	1,779	16,264	13,586	52,467
Other expense, net:				
Interest expense	(572)	(1,482)	(2,039)	(6,383)
Loss on extinguishment of debt	-	(1,883)	-	(1,883)
Other income (expense), net	5	(19)	(19)	(4)
Total other expense, net	(567)	(3,384)	(2,058)	(8,270)
Net income before income taxes	1,212	12,880	11,528	44,197
Income tax expense	(997)	(303)	(3,482)	(990)
Net income	<u>\$ 215</u>	<u>\$ 12,577</u>	<u>\$ 8,046</u>	<u>\$ 43,207</u>
Net income, per share:				
Basic	<u>\$ 0.00</u>	<u>\$ 0.10</u>	<u>\$ 0.06</u>	<u>\$ 0.34</u>
Diluted	<u>\$ 0.00</u>	<u>\$ 0.09</u>	<u>\$ 0.06</u>	<u>\$ 0.32</u>
Weighted-average common shares outstanding				
Basic	130,903,160	128,546,301	129,784,890	128,219,674
Diluted	132,232,954	133,850,216	132,555,265	133,766,004

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

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

Three and Nine Months Ended September 30, 2022					
	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount			
Balance as of June 30, 2022	130,885,369	13	307,374	(53,002)	254,385
Exercise of stock options	19,064	-	28	-	28
Vesting of RSUs, net of shares surrendered to pay taxes	10,666	-	(2)	-	(2)
Stock-based compensation expense	-	-	1,702	-	1,702
Net income	-	-	-	215	215
Balance as of September 30, 2022	<u>130,915,099</u>	<u>\$ 13</u>	<u>\$ 309,102</u>	<u>\$ (52,787)</u>	<u>\$ 256,328</u>
Balance as of December 31, 2021 (as reported)	128,680,192	\$ 13	\$ 302,155	\$ (60,133)	\$ 242,035
Adjustment due to settlement of GPO fee dispute	-	-	-	(700)	(700)
Balance as of December 31, 2021 (as adjusted)	128,680,192	13	302,155	(60,833)	241,335
Exercise of stock options	1,864,961	-	2,070	-	2,070
Vesting of RSUs, net of shares surrendered to pay taxes	166,461	-	(648)	-	(648)
Issuance of common stock associated with business acquisition	203,485	-	828	-	828
Stock-based compensation expense	-	-	4,697	-	4,697
Net income	-	-	-	8,046	8,046
Balance as of September 30, 2022	<u>130,915,099</u>	<u>\$ 13</u>	<u>\$ 309,102</u>	<u>\$ (52,787)</u>	<u>\$ 256,328</u>
Three and Nine Months Ended September 30, 2021					
	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount			
Balance as of June 30, 2021	128,283,241	\$ 13	\$ 299,038	\$ (124,405)	\$ 174,646
Exercise of stock options	353,420	-	910	-	910
Stock-based compensation expense	-	-	1,041	-	1,041
Net income	-	-	-	12,577	12,577
Balance as of September 30, 2021	<u>128,636,661</u>	<u>\$ 13</u>	<u>\$ 300,989</u>	<u>\$ (111,828)</u>	<u>\$ 189,174</u>
Balance as of December 31, 2020	127,731,833	13	296,830	(155,035)	141,808
Exercise of stock options	716,927	-	2,115	-	2,115
Vesting of RSUs, net of shares surrendered to pay taxes	187,901	-	(737)	-	(737)
Stock-based compensation expense	-	-	2,781	-	2,781
Net income	-	-	-	43,207	43,207
Balance as of September 30, 2021	<u>128,636,661</u>	<u>\$ 13</u>	<u>\$ 300,989</u>	<u>\$ (111,828)</u>	<u>\$ 189,174</u>

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

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

	Nine Months Ended September 30,	
	2022	2021
Cash flows from operating activities:		
Net income	\$ 8,046	\$ 43,207
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation	4,331	4,010
Amortization of intangible assets	3,662	3,726
Amortization of operating lease right-of-use assets	5,483	4,117
Non-cash interest expense	326	236
Deferred interest expense	428	1,331
Provision recorded for doubtful accounts	855	2,367
Loss on disposal of property and equipment	4,412	1,397
Adjustment for excess and obsolete inventories	7,621	8,045
Stock-based compensation	4,697	2,781
Change in fair value of Earnout liability	-	(3,985)
Loss on extinguishment of debt	-	1,883
Changes in operating assets and liabilities:		
Accounts receivable	(11,510)	(20,147)
Inventory	(7,282)	(9,741)
Prepaid expenses and other current assets	1	(98)
Operating leases	(5,250)	(4,179)
Accounts payable	5,261	5,237
Accrued expenses and other current liabilities	(4,061)	6,765
Other liabilities	39	(2,922)
Net cash provided by operating activities	17,059	44,030
Cash flows from investing activities:		
Purchases of property and equipment	(23,242)	(25,993)
Net cash used in investing activities	(23,242)	(25,993)
Cash flows from financing activities:		
Repayments under the 2019 Credit Agreement	-	(70,000)
Proceeds from term loan under the 2021 Credit Agreement, net of debt discount and issuance cost	-	73,174
Payments of term loan under the 2021 Credit Agreement	(938)	(469)
Payments of withholding taxes in connection with RSUs vesting	(648)	(737)
Proceeds from the exercise of stock options	2,070	2,115
Principal repayments of finance lease obligations	(200)	(2,099)
Payment to extinguish debt	-	(1,620)
Payment of deferred acquisition consideration	(608)	(483)
Net cash used in financing activities	(324)	(119)
Change in cash, cash equivalents and restricted cash	(6,507)	17,918
Cash, cash equivalents, and restricted cash, beginning of period	114,528	84,806
Cash, cash equivalents, and restricted cash, end of period	<u>\$ 108,021</u>	<u>\$ 102,724</u>
Supplemental disclosure of cash flow information:		
Cash paid for interest	\$ 1,787	\$ 5,830
Cash paid for income taxes	\$ 974	\$ 582
Supplemental disclosure of non-cash investing and financing activities:		
Purchases of property and equipment included in accounts payable and accrued expenses	\$ 5,547	\$ 1,523
Right-of-use assets obtained through operating lease obligations	\$ 1,708	\$ 30,639
Shares issued for deferred acquisition consideration	\$ 828	\$ -

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

ORGANOGENESIS HOLDINGS INC.

NOTES TO UNAUDITED 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 service centers (“ASCs”) and physician offices. The Company has one operating and reportable segment.

COVID-19 pandemic

The coronavirus (COVID-19) pandemic around the world, and particularly in the United States, continues to present risks to the Company. Although conditions have improved in the United States in recent months, on October 13, 2022, the U.S. Secretary of Health and Human Services extended the COVID-19 public health emergency declaration through at least January 11, 2023. While the COVID-19 pandemic has not materially adversely affected the Company’s financial results and business operations through the third quarter ended September 30, 2022, the Company is unable to predict the impact that COVID-19 will have on its financial position and operating results because of the numerous uncertainties created by the unprecedented nature of the pandemic.

The Company is closely monitoring the evolving impact of the pandemic on all aspects of its business. The Company has implemented a number of measures designed to protect the health and safety of its employees, support its customers and promote business continuity.

2. Summary of Significant Accounting Policies

The Company’s significant accounting policies are described in Note “2. Significant Accounting Policies” to the Consolidated Financial Statements included in the Company’s Annual Report on Form 10-K for the fiscal year ended December 31, 2021, as amended (the “Annual Report”). There have been no material changes to the significant accounting policies previously disclosed in the Annual Report.

Unaudited Interim Financial Information

The accompanying unaudited consolidated financial statements have been prepared by management in accordance with GAAP and the rules and regulations of the SEC regarding interim financial reporting. Accordingly, they do not include all the information and footnotes required by generally accepted accounting principles for complete financial statements. While we believe that the disclosures presented are adequate in order to make the information not misleading, these unaudited quarterly financial statements should be read in conjunction with the financial statements and notes thereto included in the Annual Report.

The unaudited 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. The Company considers events or transactions that occur after the balance sheet date but before the financial statements are issued to provide additional evidence relative to certain estimates or to identify matters that require additional disclosure. In the opinion of management, the unaudited consolidated financial statements reflect all adjustments of a normal recurring nature necessary for a fair presentation of the Company’s financial position, results of operations and cash flows at the dates and for the periods indicated. The results for the nine months ended September 30, 2022 are not necessarily indicative of the results to be expected for the year ending December 31, 2022, any other interim periods, or any future years or periods.

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, disclosure of contingent assets and liabilities at the date of the financial statements and the reported results of operations during the reporting periods. In preparing the consolidated financial statements, the estimates and assumptions that management consider 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 and indefinite lived assets (including intangible assets); assessing

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impairment of goodwill; valuation of assets and liabilities that use unobservable inputs; and the valuation and recognition of stock-based compensation. Actual results and outcomes may differ significantly from those estimates and assumptions.

Revision to Previously Issued Financial Statements

In August 2022, the Company reached an agreement with a Group Purchasing Organization (“GPO”) to settle previously disputed GPO fees for \$3,300. The Company identified that part of the settlement fee should have been accrued as of March 31, 2022 and December 31, 2021. This error resulted in an overstatement of revenue and understatement of accrued expenses and other current liabilities and accumulated deficit in the financial statements included in the Company’s quarterly reports on Form 10-Q and the Company’s Annual Report previously filed with the SEC. The Company assessed the materiality of this error on prior period financial statements in accordance with the SEC Staff Accounting Bulletin Number 99, Materiality, and ASC 250-10, Accounting Changes and Error Corrections. The Company determined that this error was not material to the financial statements of any prior annual or interim period. There was no impact to the quarter ended September 30, 2022. To correct the immaterial misstatement, the Company revised its previously issued financial statements as follows:

CONSOLIDATED BALANCE SHEETS	March 31, 2022			December 31, 2021		
	As Previously Reported	Adjustments	As Revised	As Previously Reported	Adjustments	As Revised
Accrued expenses and other current liabilities	\$ 32,419	\$ 1,700	\$ 34,119	\$ 36,589	\$ 700	\$ 37,289
Total current liabilities	\$ 76,792	\$ 1,700	\$ 78,492	\$ 82,005	\$ 700	\$ 82,705
Total liabilities	\$ 193,044	\$ 1,700	\$ 194,744	\$ 201,224	\$ 700	\$ 201,924
Accumulated deficit	\$ (60,046)	\$ (1,700)	\$ (61,746)	\$ (60,133)	\$ (700)	\$ (60,833)
Total stockholders’ equity	\$ 243,228	\$ (1,700)	\$ 241,528	\$ 242,035	\$ (700)	\$ 241,335

CONSOLIDATED STATEMENTS OF OPERATIONS	Three Months Ended March 31, 2022			Year Ended December 31, 2021		
	As Previously Reported	Adjustments	As Revised	As Previously Reported	Adjustments	As Revised
Net revenue	\$ 98,117	\$ (1,000)	\$ 97,117	\$ 468,059	\$ (700)	\$ 467,359
Gross profit	\$ 73,037	\$ (1,000)	\$ 72,037	\$ 353,860	\$ (700)	\$ 353,160
Income from operations	\$ 872	\$ (1,000)	\$ (128)	\$ 72,918	\$ (700)	\$ 72,218
Net income before income taxes	\$ 132	\$ (1,000)	\$ (868)	\$ 63,786	\$ (700)	\$ 63,086
Net income	\$ 87	\$ (1,000)	\$ (913)	\$ 94,902	\$ (700)	\$ 94,202

CONSOLIDATED STATEMENTS OF CASH FLOWS	Three Months Ended March 31, 2022			Year Ended December 31, 2021		
	As Previously Reported	Adjustments	As Revised	As Previously Reported	Adjustments	As Revised
Net income / (loss)	\$ 87	\$ (1,000)	\$ (913)	\$ 94,902	\$ (700)	\$ 94,202
Changes in operating assets and liabilities:						
Accrued expenses and other current liabilities	\$ (4,828)	\$ 1,000	\$ (3,828)	\$ 8,654	\$ 700	\$ 9,354

Revenue by Product Category:	Three Months Ended March 31, 2022			Year Ended December 31, 2021		
	As Previously Reported	Adjustments	As Revised	As Previously Reported	Adjustments	As Revised
Advanced Wound Care	\$ 90,950	\$ (860)	\$ 90,090	\$ 430,839	\$ (602)	\$ 430,237
Surgical & Sports Medicine	\$ 7,167	\$ (140)	\$ 7,027	\$ 37,220	\$ (98)	\$ 37,122
Net revenue	\$ 98,117	\$ (1,000)	\$ 97,117	\$ 468,059	\$ (700)	\$ 467,359

Miscellaneous Items	Three Months Ended March 31, 2022			Year Ended December 31, 2021		
	As Previously Reported	Adjustments	As Revised	As Previously Reported	Adjustments	As Revised
GPO fees	\$ 619	\$ 1,000	\$ 1,619	\$ 2,963	\$ 700	\$ 3,663
PuraPly revenue	\$ 53,300	\$ (500)	\$ 52,800	\$ 198,400	\$ (350)	\$ 198,050

Recently Issued Accounting Pronouncements Not Yet Adopted

In June 2016, the FASB issued ASU 2016-13, *Financial Instruments—Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments* (“ASU 2016-13”). Subsequent to the issuance of ASU 2016-13, the FASB has issued the following updates: ASU 2018-19, *Codification Improvements to Topic 326, Financial Instruments—Credit Losses*, ASU 2019-04, *Codification Improvements to Topic 326, Financial Instruments—Credit Losses, Topic 815, Derivatives and Hedging, and Topic 825, Financial Instruments*, ASU 2019-05, *Financial Instruments—Credit Losses (Topic 326)—Targeted Transition Relief* and ASU 2019-11, *Codification Improvements to Topic 326, Financial Instruments—Credit Losses*. The objective of ASU 2016-13 and all the related updates is to provide financial statement users with more decision-useful information about the expected credit losses on financial instruments and other commitments to extend credit held by a reporting entity at each reporting date. The amendments in this ASU replace the incurred loss impairment methodology in current GAAP with a methodology that reflects expected credit losses and requires consideration of a broader range of reasonable and supportable information to inform credit loss estimates. ASU 2016-13 and the related updates are effective for fiscal years, and interim periods within those years, beginning after December 15, 2019 for public business entities excluding entities eligible to be smaller reporting companies and for fiscal years, and interim periods within those years, beginning after December 15, 2022 for all other entities. Early adoption is permitted. As the Company was a smaller reporting company when the standard was issued, the Company took advantage of the extended transition period and will adopt this standard and the related improvements on January 1, 2023 by recognizing a cumulative-effect adjustment to retained earnings for any impact. The Company evaluated the effects of adopting ASU 2016-13 and the related improvements and does not expect a material impact on the Company’s consolidated financial statements.

In March 2020, the FASB issued ASU No. 2020-04, *Reference Rate Reform (Topic 848): Facilitation of the Effects of Reference Rate Reform on Financial Reporting* (“ASU 2020-04”). ASU 2020-04 provides temporary optional expedients and exceptions to the US GAAP guidance on contract modifications and hedge accounting to ease the financial reporting burdens related to the expected market transition from the London Interbank Offered Rate (LIBOR) and other interbank offered rates to alternative reference rates. In January 2021, the FASB issued ASU No. 2021-01, *Reference Rate Reform (Topic 848): Scope* (“ASU 2021-01”), to clarify certain optional expedients and exceptions in Topic 848 for contract modifications and hedge accounting to apply to derivatives that are affected by the discounting transition. Both ASU 2020-04 and ASU 2021-01 are effective upon issuance through December 31, 2022. The Company’s debt agreement that utilizes LIBOR has conventional LIBOR replacement language. Since the debt agreement has not discontinued the use of LIBOR, this ASU is not yet effective for the Company. To the extent the interest rate changes to the rate specified in the debt agreement, the Company will utilize the relief in this ASU. The Company evaluated the effects of adopting the provisions of ASU 2020-04 and ASU 2021-01 and does not expect a material impact on the Company’s consolidated financial statements.

3. Acquisition

On September 17, 2020 (the “Acquisition Date”), the Company acquired certain assets and assumed certain liabilities of CPN Biosciences, LLC (“CPN”) pursuant to an asset purchase agreement dated July 24, 2020. CPN offered a physician office management solution and advanced wound care products.

The aggregate consideration amounted to \$19,024 as of the Acquisition Date, consisting of \$6,427 in cash, 2,151,438 shares of the Company’s Class A common stock with a fair value of \$8,815, and contingent consideration (the “Earnout”) with a fair value of \$3,782. On the Acquisition Date, the Company paid \$5,820 in cash and issued 1,947,953 shares of the Company’s Class A common stock. The remaining consideration of \$1,436 was held back and was released in April 2022 by the Company paying \$608 in cash and issuing 203,485 shares of the Company’s Class A common stock to the former equity holders of CPN.

The Company was obligated to pay the Earnout to CPN’s former equity holders if CPN’s legacy product revenue in the Earnout Period (July 1, 2021 to June 30, 2022), exceeded CPN’s 2019 revenue. The amount of the Earnout, if any, would be equal to 70% of the excess and would be payable 60 days after the expiration of the Earnout Period. As of the conclusion of the Earnout Period on June 30, 2022, the Company calculated the Earnout liability to be \$0. During the Earnout Period, the Company assessed the fair value of the Earnout liability at each reporting period. Subsequent changes in the estimated fair value of the liability were reflected in earnings until the liability was settled. See Note “5. Fair Value Measurement of Financial Assets and Liabilities”.

4. Revenue

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. The entire transaction price reflects a single performance obligation. 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 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 September 30, 2022 and 2021, the Company recorded GPO fees of \$1,183 and \$794, respectively, as a direct reduction of revenue. For the nine months ended September 30, 2022 and 2021, the Company recorded GPO fees of \$5,136 and \$2,323, respectively, as a direct reduction of revenue.

In August 2022, the Company reached an agreement with a GPO to settle previously disputed GPO fees for \$3,300. The settlement fee was included in the GPO fees as a direct reduction of revenue. The Company recorded \$1,600 of the settlement fee during the three months ended June 30, 2022, and has revised the historical financial statements to include \$1,000 of the settlement fee in the three months ended March 31, 2022 and \$700 of the settlement fee during the year ended December 31, 2021. As such, the previously issued financial statements were revised accordingly. See Note "2. Summary of Significant Accounting Policies".

The following tables set forth revenue by product category:

	Three Months Ended September 30,	
	2022	2021
Advanced Wound Care	\$ 109,514	\$ 107,341
Surgical & Sports Medicine	7,345	6,412
Total net revenue	<u>\$ 116,859</u>	<u>\$ 113,753</u>

	Nine Months Ended September 30,	
	2022	2021
Advanced Wound Care	\$ 313,395	\$ 309,485
Surgical & Sports Medicine	21,982	30,016
Total net revenue	<u>\$ 335,377</u>	<u>\$ 339,501</u>

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

5. Fair Value Measurement of Financial Assets and Liabilities

Earnout Liability

In connection with accounting for the CPN acquisition on September 17, 2020, the Company recorded an Earnout liability of \$3,782 on the Acquisition Date, representing the fair value of contingent consideration payable upon the achievement of a certain revenue target. The Earnout liability was classified as a Level 3 measurement within the fair value hierarchy for which fair value was derived from inputs that were unobservable and significant to the overall fair value measurement. The fair value of such Earnout liability was estimated using a Monte Carlo simulation model that utilized key assumptions including forecasted revenues and volatilities of the underlying financial metrics during the Earnout Period. The Earnout Period ended on June 30, 2022 and the Company calculated the Earnout liability to be \$0. Before its settlement, the Company assessed the fair value of the Earnout liability at each reporting period. Any subsequent changes in the estimated fair value of the liability were reflected in selling, general and administrative expenses until the liability was settled. For more information about the Earnout liability, refer to Note "3. Acquisition".

As of December 31, 2021, the Earnout liability was \$0 as a result of the Company's assessment of the near-term market for the CPN product portfolio. The following table provides a roll-forward of the fair value of the Company's Earnout liability, for which fair value was determined using Level 3 inputs until the end of the Earnout Period on June 30, 2022.

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	Nine Months Ended September 30,	
	2022	2021
Beginning balance	\$ -	\$ 3,985
Change in fair value	-	(3,985)
Ending balance	\$ -	\$ -

The Company did not have any financial assets and liabilities measured at fair value on a non-recurring basis as of September 30, 2022 and December 31, 2021.

6. Accounts Receivable, Net

Accounts receivable consisted of the following:

	September 30, 2022	December 31, 2021
Accounts receivable	\$ 98,693	\$ 87,613
Less — allowance for doubtful accounts	(5,578)	(5,153)
	<u>\$ 93,115</u>	<u>\$ 82,460</u>

The Company's allowance for doubtful accounts was comprised of the following:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Balance at beginning of period	\$ 5,022	\$ 4,132	\$ 5,153	\$ 2,669
Additions	733	868	855	2,367
Write-offs	(177)	(472)	(430)	(508)
Balance at end of period	<u>\$ 5,578</u>	<u>\$ 4,528</u>	<u>\$ 5,578</u>	<u>\$ 4,528</u>

7. Inventories

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

	September 30, 2022	December 31, 2021
Raw materials	\$ 10,958	\$ 9,023
Work in process	1,146	991
Finished goods	12,579	15,008
	<u>\$ 24,683</u>	<u>\$ 25,022</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 September 30, 2022 and 2021, the Company charged \$2,393 and \$3,367, respectively, for inventory excess and obsolescence to cost of goods sold within the consolidated statements of operations. During the nine months ended September 30, 2022 and 2021, the Company charged \$7,621 and \$8,045, respectively, for inventory excess and obsolescence to cost of goods sold within the consolidated statements of operations.

8. Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consisted of the following:

	September 30, 2022	December 31, 2021
Subscriptions	\$ 3,009	\$ 2,745
Conferences and marketing expenses	224	538
Deposits	853	1,216
Insurance	585	358
Other	36	112
	<u>\$ 4,707</u>	<u>\$ 4,969</u>

Deposits are funds held by vendors which are expected to be released within twelve months and therefore they are recorded as current assets.

9. Property and Equipment, Net

Property and equipment consisted of the following:

	September 30, 2022	December 31, 2021
Leasehold improvements	\$ 36,939	\$ 30,531
Buildings	4,943	4,943
Furniture, computers and equipment	56,675	53,959
	98,557	89,433
Accumulated depreciation	(62,038)	(57,729)
Construction in progress	60,493	47,456
	<u>\$ 97,012</u>	<u>\$ 79,160</u>

Depreciation expense was \$1,456 and \$1,937 for the three months ended September 30, 2022 and 2021. Depreciation expense was \$4,331 and \$4,010 for the nine months ended September 30, 2022 and 2021. Construction in progress primarily represents 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. The increase in the construction in progress is a result of the Company's ongoing efforts to consolidate its manufacturing operations in various locations into Massachusetts facilities to reduce the Company's cost structure and improve operating efficiency.

During the three and nine months ended September 30, 2022, the Company recorded a charge of \$4,200 for the sale and donation of some equipment related to the construction in progress in one of its Canton, Massachusetts facilities. The disposal was the result of a change in the design of the construction plan for the manufacturing facility and the determination that this equipment was no longer compatible with the ongoing design. In the same quarter, the Company decided to pause the construction of this manufacturing facility due to the inflation and market conditions that adversely impacted construction projects across the biotechnology and life sciences industries. In connection with this decision, the Company recorded a charge of \$632 as cancellation fees to various vendors. These charges were included in selling, general and administrative expenses on the consolidated statements of operations for the three and nine months ended September 30, 2022.

This facility is part of the primary assets in the Company's OI East asset group. The Company considered the equipment disposal and construction pause, among other things, to be triggering events under ASC 360. The triggering events indicated that the Company's long-lived assets might be impaired. The Company performed a recoverability test on the OI East asset group in accordance with ASC 360, *Property, Plant and Equipment*. The estimated undiscounted cash flow directly attributable to the asset group exceeded the carrying value of the asset group. Therefore, no impairment was identified.

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10. Goodwill and Intangible Assets

Goodwill was \$28,772 as of September 30, 2022 and December 31, 2021.

Identifiable intangible assets consisted of the following as of September 30, 2022:

	Original Cost	Accumulated Amortization	Net Book Value
Developed technology	\$ 32,620	\$ (20,301)	\$ 12,319
Trade names and trademarks	2,080	(1,340)	740
Customer relationships	10,690	(2,183)	8,507
Independent sales agency network	4,500	(4,500)	-
Patent	7,623	(7,623)	-
Non-compete agreements	1,010	(566)	444
Total	<u>\$ 58,523</u>	<u>\$ (36,513)</u>	<u>\$ 22,010</u>

Identifiable intangible assets consisted of the following as of December 31, 2021:

	Original Cost	Accumulated Amortization	Net Book Value
Developed technology	\$ 32,620	\$ (17,709)	\$ 14,911
Trade names and trademarks	2,080	(1,183)	897
Customer relationship	10,690	(1,381)	9,309
Independent sales agency network	4,500	(4,500)	-
Patent	7,623	(7,623)	-
Non-compete agreements	1,010	(454)	556
Total	<u>\$ 58,523</u>	<u>\$ (32,850)</u>	<u>\$ 25,673</u>

Amortization of intangible assets, calculated on a straight-line basis or using an accelerated method, was \$1,220 and \$1,240 for the three months ended September 30, 2022 and 2021, respectively, and \$3,662 and \$3,726 for the nine months ended September 30, 2022 and 2021, respectively.

11. Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consisted of the following:

	September 30, 2022	December 31, 2021
Personnel costs	\$ 21,003	\$ 26,865
Royalties	3,544	3,458
Accrued but unpaid lease obligations and interest	2,973	3,963
Accrued settlement fee	1,650	700
Other	4,992	2,303
	<u>\$ 34,162</u>	<u>\$ 37,289</u>

The accrued but unpaid lease obligations and the interest accrual on these obligations are related to the buildings in Canton, Massachusetts. See Note “17. Leases”. See Note “4. Revenue” for accrued settlement fee.

12. Restructuring

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

On October 21, 2020, the Company committed to a plan to restructure the workforce and operations in its La Jolla, California facilities. The restructuring involved 65 employees and was substantially completed as of December 31, 2021, with certain facility and storage activities continuing through 2024.

On March 9, 2022, the Company committed to a plan to restructure the workforce and operations in its Birmingham, Alabama facilities. The restructuring is expected to be completed by the end of 2022 and will result in a charge of approximately \$3.0 million,

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of which approximately \$2.0 million is attributable to the retention benefits associated with approximately 25 employees and the remaining \$1.0 million is related to the other exit activities, including but not limited to contract termination, decommission and transportation of certain fixed assets. As employees are required to provide future services, employee retention and other benefit-related costs are expensed over the service period.

As a result of the restructuring activities, the Company incurred a pre-tax charge of \$611 and \$1,010 during the three months ended September 30, 2022 and 2021, respectively, and \$1,518 and \$2,876 during the nine months ended September 30, 2022 and 2021, respectively. These charges were included in selling, general and administrative expenses in the consolidated statements of operations. The liability related to the restructuring activities was \$1,110 and \$3,168 as of September 30, 2022 and December 31, 2021, respectively, and was included in accrued expenses and other current liabilities in the consolidated balance sheets. The following table provides a roll-forward of the restructuring liability.

	Employee	Other	Total
Liability balance as of June 30, 2022	\$ 638	\$ 23	\$ 661
Expenses	486	125	611
Payments	(18)	(144)	(162)
Liability balance as of September 30, 2022	<u>\$ 1,106</u>	<u>\$ 4</u>	<u>\$ 1,110</u>

	Employee	Other	Total
Liability balance as of December 31, 2021	\$ 2,517	\$ 651	\$ 3,168
Expenses	1,124	394	1,518
Payments	(2,535)	(1,041)	(3,576)
Liability balance as of September 30, 2022	<u>\$ 1,106</u>	<u>\$ 4</u>	<u>\$ 1,110</u>

13. Long-Term Debt Obligations

Long-term debt obligations consisted of the following:

	September 30, 2022	December 31, 2021
Line of credit	\$ -	\$ -
Term loan	73,125	74,062
Less debt discount and debt issuance cost	(521)	(637)
Term loan, net of debt discount and debt issuance cost	\$ 72,604	\$ 73,425

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 (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”). 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 Eurodollar Loans or ABR Loans, at the Company’s option. For Eurodollar Loans, the interest rate is a per annum interest rate equal to LIBOR 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 LIBOR rate plus 1.0%, *plus* (2) an Applicable Margin between 1.00% to 2.25% based on the Total Net Leverage Ratio.

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

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day of each quarter thereafter until August 6, 2026 (the “Term Loan Maturity Date”), \$1,875. 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 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 had outstanding borrowings of \$73,125 and \$74,062 under the Term Loan Facility and \$0 under the Revolving Facility with \$125,000 available for future revolving borrowings as of September 30, 2022 and December 31, 2021, respectively. Because the Lenders did not withdraw the September payment of \$938 until early October, the Term Loan balance as of September 30, 2022 was the same as at June 30, 2022. 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 Company’s consolidated balance sheets. In connection with 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.

Future payments of the 2021 Credit Agreement, as of September 30, 2022, are as follows for the calendar years ending December 31:

2022	\$	1,875
2023		4,687
2024		5,625
2025		6,563
2026		54,375
Total	\$	<u>73,125</u>

2019 Credit Agreement

In March 2019, the Company, its subsidiaries and SVB, and the several other lenders thereto entered into a credit agreement, as amended (the “2019 Credit Agreement”), providing for a term loan facility of \$40,000 and a revolving credit facility of up to \$60,000. Both facilities were set to mature in 2024. The interest rate for the term loan facility was a floating per annum interest rate equal to the greater of 3.75% above the Wall Street Journal Prime Rate and 9.25%. The interest rate for advances under the revolving facility was a floating per annum interest rate equal to the greater of the Wall Street Journal Prime Rate and 5.50%. If the Company elected to prepay the loan or terminate the facilities, the Company was required to pay a certain percentage of the outstanding principal as a prepayment fee. A final payment fee (the “Final Payment”) of 6.5% multiplied by the original aggregate principal amount of term loan facility was due upon the earlier to occur of the maturity date of the term loan or prepayment of all outstanding principal.

In August 2021, upon entering into the 2021 Credit Agreement, the Company paid an aggregate amount of \$70,559 due under the 2019 Credit Agreement, including unpaid principal, accrued interest, the Final Payment and a prepayment fee, with proceeds from the 2021 Credit Agreement, and the 2019 Credit Agreement was terminated. Upon termination of the 2019 Credit Agreement, the Company recognized \$1,883 as loss on the extinguishment of the loan for the year ended December 31, 2021.

14. Stockholders’ Equity

Common Stock

As of September 30, 2022, 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.

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As of September 30, 2022 and December 31, 2021, the Company reserved the following shares of Class A common stock for future issuance:

	September 30, 2022	December 31, 2021
Shares reserved for issuance for outstanding options	6,006,265	6,596,969
Shares reserved for issuance for outstanding restricted stock units	1,406,393	764,871
Shares reserved for issuance for future grants	11,346,343	5,644,691
Total shares of authorized common stock reserved for future issuance	<u>18,759,001</u>	<u>13,006,531</u>

15. Stock-Based Compensation

Stock Incentive Plans-the 2018 Plan

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 and Incentive Plan (the "2018 Plan"). The purposes of the 2018 Plan are to provide long-term incentives and rewards to the Company's employees, officers, directors and other key persons (including consultants), to attract and retain persons with the requisite experience and ability, and to more closely align the interests of such employees, officers, directors and other key persons with the interests of the Company's stockholders.

The 2018 Plan authorizes the Company's Board of Directors or a committee of not less than two independent directors (in either case, the "Administrator") to grant the following types of awards: non-statutory stock options; incentive stock options; restricted stock awards; restricted stock units; stock appreciation rights; unrestricted stock awards; performance share awards; and dividend equivalent rights. The 2018 Plan is administered by the Company's Board of Directors.

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.

Stock Incentive Plans-the 2003 Plan

The Organogenesis 2003 Stock Incentive Plan (the "2003 Plan"), provides for the Company to issue restricted stock awards, or to grant incentive stock options or non-statutory stock options. Incentive stock options may be granted only to the Company's employees. Restricted stock awards and non-statutory stock options may be granted to employees, members of the Board of Directors, outside advisors and consultants of the Company.

Effective December 10, 2018, no additional awards may be made under the 2003 Plan and as a result (i) any shares in respect of stock options that are expired or terminated under the 2003 Plan without having been fully exercised will not be available for future awards; (ii) any shares in respect of restricted stock that are forfeited to, or otherwise repurchased by the Company, will not be available for future awards; and (iii) any shares of Class A common stock that are tendered to the Company by a participant to exercise an award will not be available for future awards.

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 \$1,702 and \$1,041 for the three months ended September 30, 2022 and 2021, respectively, and was \$4,697 and \$2,781 for the nine months ended September 30, 2022 and 2021, respectively. The total amount of stock-based compensation expense was included within selling, general and administrative expenses on the consolidated statements of operations.

Restricted Stock Units (RSUs)

The Company granted 979,257 and 299,352 time-based restricted stock units to its employees, executives and the Board of Directors in the nine months ended September 30, 2022 and 2021, 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.

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The activity of restricted stock units is set forth below:

	Number of Shares	Weighted Average Grant Date Fair Value
Unvested at December 31, 2021	764,871	\$ 7.52
Granted	979,257	7.56
Vested	(245,326)	7.30
Canceled/Forfeited	(92,409)	7.03
Unvested at September 30, 2022	1,406,393	\$ 7.62

As of September 30, 2022, the total unrecognized compensation cost related to unvested restricted stock units expected to vest was \$6,510 and the weighted average remaining recognition period for unvested awards was 2.75 years.

Stock Option Valuation

The stock options granted during the nine months ended September 30, 2022 and 2021 were 1,418,224 and 1,069,658, respectively. The assumptions that the Company used to determine the grant-date fair value of stock options granted during these periods were as follows, presented on a weighted-average basis:

	September 30, 2022	September 30, 2021
Risk-free interest rate	1.92 %	0.83 %
Expected term (in years)	6.25	6.22
Expected volatility	50.66 %	39.31 %
Expected dividend yield	0.0 %	0.0 %
Exercise price	\$ 8.03	\$ 13.57
Underlying stock price	\$ 7.87	\$ 13.57

These assumptions resulted in an estimated weighted-average grant-date fair value per share of stock options granted during the nine months ended September 30, 2022 and 2021 of \$3.94 and \$5.32, respectively.

Stock Option Activity

The following table summarizes the Company's stock option activity since December 31, 2021:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Outstanding as of December 31, 2021	6,596,969	\$ 4.10	5.20	\$ 38,524
Granted	1,418,224	8.03		
Exercised	(1,864,961)	1.11		8,475
Canceled / forfeited	(143,967)	6.54		
Outstanding as of September 30, 2022	6,006,265	5.90	6.39	3,031
Options exercisable as of September 30, 2022	3,153,644	3.61	4.40	3,031
Options vested or expected to vest as of September 30, 2022	5,480,939	\$ 5.63	6.16	\$ 3,031

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 total fair value of options vested during the nine months ended September 30, 2022 and 2021 was \$2,082 and \$592, respectively.

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As of September 30, 2022, the total unrecognized stock compensation expense related to unvested stock options expected to vest was \$6,373 and was expected to be recognized over a weighted-average period of 2.84 years.

16. Earnings (Loss) 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.

A reconciliation of the numerator and denominator used in the calculation of the basic and diluted net income (loss) attributable to the Class A common stockholders is as follows.

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Numerator:				
Net Income (loss)	\$ 215	\$ 12,577	\$ 8,046	\$ 43,207
Denominator:				
Weighted average common shares outstanding —basic	130,903,160	128,546,301	129,784,890	128,219,674
Dilutive effect of restricted stock units	113,163	458,642	174,946	498,105
Dilutive effect of options	1,216,631	4,845,273	2,595,429	5,048,225
Weighted-average common shares outstanding—diluted	132,232,954	133,850,216	132,555,265	133,766,004
Earnings (loss) per share—basic	\$ 0.00	\$ 0.10	\$ 0.06	\$ 0.34
Earnings (loss) per share—diluted	\$ 0.00	\$ 0.09	\$ 0.06	\$ 0.32

For the three and nine months ended September 30, 2022, outstanding stock-based awards of 4,382,912 and 3,482,463 were excluded from the diluted EPS calculation as they were anti-dilutive. For the three and nine months ended September 30, 2021, outstanding stock-based awards of 956,466 were excluded from the diluted EPS calculation as they were anti-dilutive.

17. Leases

The Company leases are primarily 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 operating leases that expire at various dates through 2025.

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. 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 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 fixed asset, net in accordance with ASC 842-20-40-2 *Purchase of the Underlying Asset* to account for the purchase of the leased asset. Other than the lease with 275 Dan Road SPE, LLC which was terminated in August 2021, the remaining three 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. The Company exercised the option to extend the leases for an additional five years in November 2021 and is currently negotiating the rental rate for those properties with the landlord. The Company used its best estimate to calculate the lease assets and liabilities in the renewal period and reassessed the classification for these leases according to ASC 842-10-25-1 *Lease Classification*. As a result, these leases were reclassified from finance leases to operating leases. The related finance lease assets and liabilities were reclassified to operating lease right-of-use assets and operating lease obligations on the consolidated balance sheet as of December 31, 2021. Due to the competitive real estate market for biotechnology companies in Massachusetts, the negotiated rental rate could differ materially from management's estimates, which may significantly increase the lease assets and lease liabilities currently reported on the consolidated financial statements.

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The Company owes some accrued but unpaid lease obligations under the aforementioned leases as detailed in the section below. Effective April 1, 2019, the Company agreed to accrue interest on the accrued but unpaid lease obligations at an interest rate equal to the rate charged under the 2019 Credit Agreement. These accrued but unpaid lease obligations as well as the accrued interest on these obligations were subordinated to the 2019 Credit Agreement. With the termination of the 2019 Credit Agreement and the execution of the 2021 Credit Agreement (see Note “13. Long-Term Debt Obligations”) in August 2021, these obligations are no longer subordinated to the Company’s existing loans.

In connection with the purchase of the 275 Dan Road Building in August 2021, the Company paid 50% of the accrued but unpaid lease obligations associated with this building and the accrued interest thereof. The remaining balance is being paid in five quarterly installments ending on January 3, 2023. The interest on the balance of the accrued but unpaid lease obligations associated with the 275 Dan Road Building was reduced to an annual simple rate of 4.5%.

The accrued but unpaid lease obligations as well as the related interest accruals are shown below.

	September 30, 2022	December 31, 2021
Principal portion of rent in arrears	6,285	7,246
Unpaid operating and common area maintenance costs	-	558
Total accrued but unpaid lease obligations	6,285	7,804
Accrued interest on accrued but unpaid lease obligations	1,961	1,938

The principal portion of rent in arrears was included in the short-term portion of operating lease obligations other than the balance related to the 275 Dan Road Building that was included in accrued expenses and other current liabilities on the consolidated balance sheets as of September 30, 2022 and December 31, 2021. The unpaid operating and common area maintenance costs, and the accrued interest on the accrued but unpaid lease obligations were included in accrued expenses and other current liabilities on the consolidated balance sheets as of September 30, 2022 and December 31, 2021.

The components of lease cost were as follows:

		Nine Months Ended September 30,	
Classification		2022	2021
Finance lease			
Amortization of right-of-use assets	COGS and SG&A	\$ 213	\$ 1,396
Interest on lease liabilities	Interest Expense	7	879
Total Finance lease cost		220	2,275
Operating lease cost	COGS, R&D, SG&A	7,197	4,872
Short-term lease cost	COGS, R&D, SG&A	2,180	2,172
Variable lease cost	COGS, R&D, SG&A	3,564	3,753
Total lease cost		<u>\$ 13,161</u>	<u>\$ 13,072</u>

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

	September 30, 2022	December 31, 2021
Property and equipment, gross	\$ 1,174	\$ 1,174
Accumulated depreciation	(1,174)	(961)
Property and equipment, net	<u>\$ -</u>	<u>\$ 213</u>
Finance lease obligations	<u>\$ -</u>	<u>\$ 200</u>

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Supplemental cash flow information related to leases was as follows:

	Nine Months Ended September 30,	
	2022	2021
Cash paid for amounts included in the measurement of lease liabilities:		
Operating cash flows for operating leases	6,964	4,933
Operating cash flows for finance leases	7	1,327
Financing cash flows for finance leases	200	2,099
Right-of-use assets obtained in exchange for lease obligations		
Operating leases	1,708	30,639
Finance leases	-	-
	September 30, 2022	December 31, 2021
Weighted-average remaining lease term		
Finance leases	-	0.45
Operating leases	7.67	8.22
	September 30, 2022	December 31, 2021
Weighted-average discount rate		
Finance leases	-	11.30 %
Operating leases	4.62 %	4.51 %

As of September 30, 2022, maturities of lease liabilities were as follows:

	Operating leases
2022 (remaining 3 months)	\$ 7,628
2023	8,565
2024	7,521
2025	7,694
2026	7,489
Thereafter	26,615
Total lease payments	65,512
Less: interest	(10,376)
Total lease liabilities	\$ 55,136

18. Commitments and Contingencies

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. Accrued royalties totaled \$1,187 as of September 30, 2022 and December 31, 2021, respectively, and were classified as part of accrued expenses and other current liabilities on the Company's consolidated balance sheets. There was no royalty expense incurred during the three and nine months ended September 30, 2022 or 2021 related to this agreement.

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 royalty expense of \$1,875 and \$1,707 during the three months ended September 30, 2022 and 2021, respectively, and \$5,580 and \$4,062 during the nine months ended September 30, 2022 and 2021, respectively, within selling, general and administrative expenses on the consolidated statements of operations.

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. The Company accrued \$150 as of September 30, 2022 and December 31, 2021, for certain pending lawsuits.

19. Related Party Transactions

Lease obligations to affiliates, including accrued but unpaid lease obligations, and purchase of an asset under a finance lease with an affiliate are further described in Note "17. Leases".

During 2010, the Company's Board of Directors approved a loan program that permitted the Company to make loans to three executives of the Company (the "Employer Loans") to (i) provide them with liquidity ("Liquidity Loans") and (ii) fund the exercise of vested stock options ("Option Loans"). Two of the executives left the Company in 2014. The Employer Loans matured with all principal and accrued interest due on the tenth anniversary of the issuance date of each subject loan. Interest on the Employer Loans was at various rates ranging from 2.30% - 3.86% per annum, compounded annually. The Employer Loans were secured by shares of the Company's Class A common stock held by the former executives. With respect to the Liquidity Loans, the Company had no personal recourse against the borrowers beyond the pledged shares. As of December 31, 2020, Liquidity Loans and Option Loans to one former executive were outstanding with an aggregate principal balance of \$100 and \$334, respectively. During the three months ended March 31, 2021, this former executive paid off the outstanding principal balance of his Employer Loans and the related interest receivable. As a result, the Company recorded \$179 as a recovery of the previously reserved related party receivables within selling, general and administrative expenses on the consolidated statements of operations for the three months ended March 31, 2021. The \$334 of the repaid principal balance of the Option Loans was recorded to equity.

20. Taxes

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. 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 nine months ended September 30, 2022 varied from the U.S. statutory rate of 21% primarily due to the tax adjustments related to executive compensation, other permanent tax adjustments, and discrete items. Income tax expense for the nine months ended September 30, 2022 was \$3,482, which included a discrete tax expense of \$39 related primarily to the interest on certain uncertain tax positions. Income tax expense for the nine months ended September 30, 2021 was \$990, which included a discrete tax expense of \$31 related to the interest on certain uncertain tax positions.

The Company examines all positive and negative evidence to estimate whether sufficient future taxable income in the U.S. will be generated to permit the use of existing deferred tax assets. In the fourth quarter of 2021, the Company released the valuation allowance recorded against its U.S. deferred tax assets. Upon reviewing the positive evidence of net operating loss utilization, cumulative profits, and forecasted taxable income, the Company believed that it was more likely than not that these United States deferred tax assets would be utilized. There are no material deferred tax assets in the other jurisdictions. On a quarterly basis, the Company reassesses the need for a valuation allowance on deferred income tax assets, weighing positive and negative evidence to assess the recoverability of the deferred tax assets. After assessing both the positive and negative evidence, including net operating loss utilization, cumulative profits, and forecasted taxable income, the Company determined that it is more likely than not the U.S. deferred assets will be realized in full. As such, the Company has not recorded a valuation allowance against its U.S. deferred tax assets as of September 30, 2022 and December 31, 2021.

21. Subsequent Events

The Company has evaluated subsequent events through November 9, 2022, the date on which these consolidated financial statements were issued and has determined that there are no such events to report.

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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, 2021, filed with the SEC, on March 1, 2022, as amended. Please refer to our note regarding forward-looking statements on page 3 of this Form 10-Q, which is incorporated herein by this reference.

Overview

Organogenesis 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. 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, cardiovascular and peripheral vascular disease and smoking. 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 service 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 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 currently suspended pending transition to Massachusetts); PuraPly AM as an antimicrobial barrier for a broad variety of wound types; and the Affinity, Novachor and NuShield wound coverings to address a variety of wound sizes and types. 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 focus on products that support the healing of musculoskeletal injuries, including degenerative conditions such as osteoarthritis and tendonitis. We are leveraging our regenerative medicine capabilities in this attractive, adjacent market. Our Surgical & Sports Medicine products include NuShield for surgical application in targeted soft tissue repairs; and Affinity, Novachor, PuraPly AM and PuraPly MZ for management of open wounds in the surgical setting. We currently sell these products through independent agencies and our growing direct sales force.

For the nine months ended September 30, 2022, we generated \$335.4 million of net revenue and \$8.0 million of net income compared to \$339.5 million of net revenue and \$43.2 million of net income for the nine months ended September 30, 2021. While we reported net income for the most recent two years, we have incurred significant losses since inception and we may incur operating losses in the future as we expend resources as part of our efforts to grow our organization to support the planned expansion of our business. As of September 30, 2022, we had an accumulated deficit of \$52.8 million. Our primary sources of capital to date have been from sales of our products, borrowings from related parties and institutional lenders and proceeds from the sale of our Class A common stock. We operate as one segment of regenerative medicine.

COVID-19 pandemic

The emergence of the coronavirus (COVID-19) around the world, and particularly in the United States, continues to present risks to the Company. Although conditions have improved in the United States in recent months, on October 13, 2022, the U.S. Secretary of Health and Human Services extended the COVID-19 public health emergency declaration through at least January 11, 2023. While the COVID-19 pandemic has not materially adversely affected our financial results and business operations through the third quarter ended September 30, 2022, we are unable to predict the impact that COVID-19 will have on our financial position and operating results because of the numerous uncertainties created by the unprecedented nature of the pandemic. We continue to closely monitor the evolving impact of the pandemic on all aspects of our business. We have implemented a number of measures designed to protect the health and safety of our employees, support our customers and promote business continuity. We continue to evaluate the

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Company's liquidity position, communicate with and monitor the actions of our customers and suppliers, and review our near-term financial performance as we manage the Company through this period of continued uncertainty.

End of Enforcement Grace Period for ReNu and NuCel

On November 16, 2017, the FDA issued a final guidance document entitled, "Regulatory Considerations for Human Cells, Tissues, and Cellular and Tissue-Based Products: Minimal Manipulation and Homologous Use", or 361 HCT/P Guidance, which provided the FDA's thinking on how to apply the existing regulatory criteria for regulation as a Section 361 HCT/P. The 361 HCT/P Guidance clarified the FDA's views about the criteria that differentiate those products subject to regulation under Section 361 of the Public Health Service Act from those considered to be drugs, devices, and/or biological products subject to licensure under Section 351 and related regulations. The 361 HCT/P Guidance originally indicated that the FDA was providing a 36-month enforcement grace period to allow time for distributors of HCT/Ps to make any regulatory submissions and obtain any premarket approvals necessary to comply with the guidance. In July 2020, the FDA announced that the enforcement grace period would be extended until May 31, 2021 as a result of the challenges presented by the COVID-19 public health emergency. On April 21, 2021, the FDA reaffirmed that the enforcement grace period would end on May 31, 2021, at which time we ceased commercial distribution of ReNu and NuCel. We are continuing to conduct clinical studies of ReNu to support FDA approval of a Biologics License Application for the treatment of knee osteoarthritis and, based on favorable feasibility studies, we believe ReNu has potential as a treatment for additional osteoarthritis and tissue regeneration applications. Accordingly, we have decided to focus on clinical development of ReNu and we discontinued clinical development of NuCel.

Dermagraft

As part of our long-term plan to consolidate manufacturing operations in Massachusetts, 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 Massachusetts, which we expect will result in substantial long-term cost savings. In the period when Dermagraft is not available (possibly for a few years), 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.

Components of Our 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 September 30, 2022, we had approximately 365 direct sales representatives and approximately 150 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 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. We expect our cost of goods sold to increase due primarily to the anticipated increase in sales volumes driven by the expansion of our sales force and sales territories, expansion of our product portfolio offerings, and the number of healthcare facilities that offer our products.

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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 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. Our research and development expenses also include expenses for clinical trials. 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

Interest expense—Interest expense consists of interest on our outstanding indebtedness, including amortization of debt discount and debt issuance costs, net of interest income recognized.

Loss on the extinguishment of debt—In August 2021, upon entering into the 2021 Credit Agreement, we paid an aggregate amount of \$70.6 million associated with the termination of the 2019 Credit Agreement, including unpaid principal, accrued interest, the Final Payment and a prepayment fee. We recognized \$1.9 million as loss on the extinguishment of the loan for the nine months ended September 30, 2021.

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. In addition, we consider whether it is more likely than not that the tax position will be sustained on examination by taxing authorities based on the technical merits of the position. Based on a consideration of the factors discussed above, we have determined that our net U.S. deferred tax assets do not require a valuation allowance as of September 30, 2022 and December 31, 2021.

We account for uncertainty in income taxes recognized in the 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 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.

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Results of Operations

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
	(in thousands)		(in thousands)	
Net revenue	\$ 116,859	\$ 113,753	\$ 335,377	\$ 339,501
Cost of goods sold	26,177	26,167	77,909	81,602
Gross profit	90,682	87,586	257,468	257,899
Operating expenses:				
Selling, general and administrative	79,328	62,369	215,515	182,950
Research and development	9,575	8,953	28,367	22,482
Total operating expenses	88,903	71,322	243,882	205,432
Income from operations	1,779	16,264	13,586	52,467
Other expense, net:				
Interest expense	(572)	(1,482)	(2,039)	(6,383)
Loss on extinguishment of debt	-	(1,883)	-	(1,883)
Other expense, net	5	(19)	(19)	(4)
Total other expense, net	(567)	(3,384)	(2,058)	(8,270)
Net income before income taxes	1,212	12,880	11,528	44,197
Income tax expense	(997)	(303)	(3,482)	(990)
Net income	\$ 215	\$ 12,577	\$ 8,046	\$ 43,207

EBITDA and Adjusted EBITDA

Our management uses financial measures that are not in accordance with generally accepted accounting principles in the United States, or GAAP, in addition to financial measures in accordance with GAAP to evaluate our operating results. These non-GAAP financial measures should be considered supplemental to, and not a substitute for, our reported financial results prepared in accordance with GAAP. Our management uses Adjusted EBITDA 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 income to non-GAAP EBITDA and non-GAAP Adjusted EBITDA for each of the periods presented:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
	(Unaudited) (in thousands)			
Net income	\$ 215	\$ 12,577	\$ 8,046	\$ 43,207
Interest expense, net	572	1,482	2,039	6,383
Income tax expense	997	303	3,482	990
Depreciation	1,456	1,937	4,331	4,010
Amortization	1,220	1,240	3,662	3,726
EBITDA	4,460	17,539	21,560	58,316
Stock-based compensation expense	1,702	1,041	4,697	2,781
Recovery of certain notes receivable from related parties (1)	-	-	-	(179)
Change in fair value of Earnout (2)	-	(927)	-	(3,985)
Restructuring charge (3)	611	1,010	1,518	2,876
Loss on extinguishment of debt (4)	-	1,883	-	1,883
Write-off of certain assets (5)	4,200	1,104	4,200	1,104
Facility construction project pause (6)	632		632	

Settlement fee (7)	-	-	2,600	-
Adjusted EBITDA	<u>\$ 11,605</u>	<u>\$ 21,650</u>	<u>\$ 35,207</u>	<u>\$ 62,796</u>

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- (1) Amount reflects the collection of certain notes receivable from related parties previously reserved. See Note “19. Related Party Transactions”.
- (2) Amounts reflect the change in the fair value of the Earnout liability in connection with the CPN acquisition. See Note “3. Acquisition”.
- (3) Amounts reflect employee retention and benefits as well as other exit costs associated with the Company’s restructuring activities. See Note “12. Restructuring”.
- (4) Amounts reflect the loss recognized on the extinguishment of the 2019 Credit Agreement upon repayment. See Note “13. Long-Term Debt Obligations”.
- (5) Amount in 2021 reflects the write-off of certain design and consulting fees previously capitalized related to the construction in progress in one of the Company’s Canton, Massachusetts facilities. Amount in 2022 reflects the disposal of certain equipment related to the same facility. See Note “9. Property and Equipment, Net”.
- (6) Amounts reflect the cancellation fees incurred in connection with the Company’s decision to pause one of its manufacturing facility construction projects.
- (7) Amount reflects the fee the Company agreed to pay to a GPO to settle previously disputed GPO fees. See Note “4. Product and Geographic Sales”.

Comparison of Three and Nine Months Ended September 30, 2022 and 2021

Revenue

	Three Months Ended September 30,		Change	
	2022	2021	\$	%
	(in thousands, except for percentages)			
Advanced Wound Care	\$ 109,514	\$ 107,341	\$ 2,173	2 %
Surgical & Sports Medicine	7,345	6,412	933	15 %
Net revenue	<u>\$ 116,859</u>	<u>\$ 113,753</u>	<u>\$ 3,106</u>	<u>3 %</u>

	Nine Months Ended September 30,		Change	
	2022	2021	\$	%
	(in thousands, except for percentages)			
Advanced Wound Care	\$ 313,395	\$ 309,485	\$ 3,910	1 %
Surgical & Sports Medicine	21,982	30,016	(8,034)	(27 %)
Net revenue	<u>\$ 335,377</u>	<u>\$ 339,501</u>	<u>\$ (4,124)</u>	<u>(1 %)</u>

Net revenue from our Advanced Wound Care products in the three and nine months ended September 30, 2022 was \$109.5 million and \$313.4 million, respectively, increased slightly compared to the net revenue of \$107.3 million and \$309.5 million in the three and nine months ended September 30, 2021, respectively. The slight increase in Advanced Wound Care net revenue was primarily attributable to the expanded sales force, increased sales to existing and new customers, and increased adoption of our PuraPly line extensions, partially offset by the decrease of our Dermagraft product revenue, the sales of which were suspended in the three months ended June 30, 2022, and the settlement fee with a GPO recorded as a direct reduction of revenue in the three and nine months ended September 30, 2022.

Net revenue from our Surgical & Sports Medicine products increased by \$0.9 million, or 15%, to \$7.3 million in the three months ended September 30, 2022 from \$6.4 million in the three months ended September 30, 2021 primarily due to the increased PuraPly revenue as discussed below. Net revenue from our Surgical & Sports Medicine products decreased by \$8.0 million, or 27%, to \$22.0 million in the nine months ended September 30, 2022 from \$30.0 million in the nine months ended September 30, 2021. The decrease in Surgical & Sports Medicine net revenue was primarily due to the continued impact of the suspension of marketing of our ReNu and NuCel products in connection with the expiration of the FDA’s enforcement grace period on May 31, 2021.

Included within net revenue is PuraPly revenue of \$63.7 million and \$57.0 million for the three months ended September 30, 2022 and 2021, respectively, and \$185.9 million and \$135.9 million for the nine months ended September 30, 2022 and 2021, respectively. The continued increase in PuraPly revenue in the three and nine months ended September 30, 2022 was due to the expanded sales force, expanded sites of care, and increased adoption, by existing and new customers, of our PuraPly line extensions.

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Cost of goods sold and gross profit

	Three Months Ended September 30,		Change	
	2022	2021	\$	%
	(in thousands, except for percentages)			
Cost of goods sold	\$ 26,177	\$ 26,167	\$ 10	0 %
Gross profit	\$ 90,682	\$ 87,586	\$ 3,096	4 %

	Nine Months Ended September 30,		Change	
	2022	2021	\$	%
	(in thousands, except for percentages)			
Cost of goods sold	\$ 77,909	\$ 81,602	\$ (3,693)	(5 %)
Gross profit	\$ 257,468	\$ 257,899	\$ (431)	(0 %)

Cost of goods sold in the three months ended September 30, 2022 was \$26.2 million, which is relatively consistent with the cost of goods sold in the three months ended September 30, 2021. Cost of goods sold decreased by \$3.7 million or 5% to \$77.9 million in the nine months ended September 30, 2022 from \$81.6 million in the nine months ended September 30, 2021. The decrease in cost of goods sold was primarily due to decreased sales volume in our Surgical & Sports Medicine products.

Gross profit increased by \$3.1 million, or 4%, to \$90.7 million in the three months ended September 30, 2022, from \$87.6 million in the three months ended September 30, 2021. The increase in gross profit resulted primarily from a shift in product mix to our higher gross margin products. Gross profit in the nine months ended September 30, 2022 was \$257.5 million, which is a slight decrease compared to the gross profit of \$257.9 million in the nine months ended September 30, 2021. The decrease in gross profit resulted primarily from decreased sales volume in Surgical & Sports Medicine products and increased manufacturing-related costs, partially offset by a shift in product mix to our higher gross margin products.

Research and Development Expenses

	Three Months Ended September 30,		Change	
	2022	2021	\$	%
	(in thousands, except for percentages)			
Research and development	\$ 9,575	\$ 8,953	\$ 622	7 %

	Nine Months Ended September 30,		Change	
	2022	2021	\$	%
	(in thousands, except for percentages)			
Research and development	\$ 28,367	\$ 22,482	\$ 5,885	26 %

Research and development expenses increased by \$0.6 million, or 7%, to \$9.6 million in the three months ended September 30, 2022 from \$9.0 million in the three months ended September 30, 2021. Research and development expenses increased by \$5.9 million, or 26%, to \$28.4 million in the nine months ended September 30, 2022 from \$22.5 million in the nine months ended September 30, 2021. The increase in research and development expenses was primarily due to increased headcount associated with our existing Advanced Wound Care and Surgical & Sports Medicine products, an increase in product costs associated with our pipeline products not yet commercialized and an increase in the clinical study and related costs necessary to seek regulatory approvals for certain of our products.

Selling, General and Administrative Expenses

	Three Months Ended September 30,		Change	
	2022	2021	\$	%
	(in thousands, except for percentages)			
Selling, general and administrative	\$ 79,328	\$ 62,369	\$ 16,959	27 %

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	Nine Months Ended September 30,		Change	
	2022	2021	\$	%
	(in thousands, except for percentages)			
Selling, general and administrative	\$ 215,515	\$ 182,950	\$ 32,565	18 %

Selling, general and administrative expenses increased by \$17.0 million, or 27%, to \$79.3 million in the three months ended September 30, 2022 from \$62.4 million in the three months ended September 30, 2021. The increase in selling, general and administrative expenses was primarily due to a \$3.4 million increase related to additional headcount, primarily in our direct sales force, a \$6.5 million increase related to increased travel and marketing programs amid the relaxed COVID-19 travel restrictions, a \$4.2 million charge related to disposal of certain equipment related to the construction in progress in one of the Company's Canton, Massachusetts facilities, and a \$3.6 million increase in legal, royalty and consulting costs associated with the ongoing operations of our business and the ERP system implementation. In addition, in the three months ended September 30, 2021, the Company recorded a \$0.9 million reduction to the selling, general and administrative expenses related to the CPN Earnout fair value adjustments. These increases were partially offset by a \$1.6 million miscellaneous decrease.

Selling, general and administrative expenses increased by \$32.6 million, or 18%, to \$215.5 million in the nine months ended September 30, 2022 from \$183.0 million in the nine months ended September 30, 2021. The increase in selling, general and administrative expenses was primarily due to a \$13.8 million increase related to additional headcount, primarily in our direct sales force, a \$8.6 million increase related to increased travel and marketing programs amid the relaxed COVID-19 travel restrictions, a \$4.2 million charge related to disposal of certain equipment related to the construction in progress in one of the Company's Canton Massachusetts facilities, and a \$5.7 million increase in legal, royalty and consulting costs associated with the ongoing operations of our business and the ERP system implementation. In addition, in the nine months ended September 30, 2021, the Company recorded a \$4.0 million reduction to the selling, general and administrative expenses related to the CPN Earnout fair value adjustments. These increases were partially offset by a \$2.6 million miscellaneous decrease and a \$1.2 million decrease in restructuring costs due to the smaller scale of the restructuring activities associated with closing the Birmingham office in 2022 as compared to the restructuring activities associated with closing the La Jolla office in 2021.

Other Expense, net

	Three Months Ended September 30,		Change	
	2022	2021	\$	%
	(in thousands, except for percentages)			
Interest expense, net	\$ (572)	\$ (1,482)	\$ 910	(61 %)
Loss on extinguishment of debt	-	(1,883)	1,883	(100 %)
Other income (expense), net	5	(19)	24	(126 %)
Total other expense, net	\$ (567)	\$ (3,384)	\$ 2,817	(83 %)

	Nine Months Ended September 30,		Change	
	2022	2021	\$	%
	(in thousands, except for percentages)			
Interest expense, net	\$ (2,039)	\$ (6,383)	\$ 4,344	(68 %)
Loss on extinguishment of debt	-	(1,883)	1,883	(100 %)
Other expense, net	(19)	(4)	(15)	375 %
Total other expense, net	\$ (2,058)	\$ (8,270)	\$ 6,212	(75 %)

Other expense, net, decreased by \$2.8 million, or 83%, to \$0.6 million in the three months ended September 30, 2022 from \$3.4 million in the three months ended September 30, 2021. Other expense, net, decreased by \$6.2 million or 75% to \$2.1 million in the nine months ended September 30, 2022 from \$8.3 million in the nine months ended September 30, 2021. The decrease in interest expense in 2022 resulted from the lower interest rate for the borrowings under the 2021 Credit Agreement. Loss on extinguishment of debt of \$1.9 million in 2021 was related to loss recognized on the extinguishment of the 2019 Credit Agreement upon repayment in August 2021.

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Income Tax Expense

	Three Months Ended September 30,		Change	
	2022	2021	\$	%
	(in thousands, except for percentages)			
Income tax expense	\$ (997)	\$ (303)	\$ (694)	229 %

	Nine Months Ended September 30,		Change	
	2022	2021	\$	%
	(in thousands, except for percentages)			
Income tax expense	\$ (3,482)	\$ (990)	\$ (2,492)	252 %

Income tax expense increased by \$0.7 million, or 229%, to \$1.0 million in the three months ended September 30, 2022 from \$0.3 million in the three months ended September 30, 2021. Income tax expense increased by \$2.5 million, or 252% to \$3.5 million in the nine months ended September 30, 2022 from \$1.0 million in the nine months ended September 30, 2021. The increase in income tax expense was attributed to the increase in the effective rate from 2.24% in the nine months ended September 30, 2021 to 30.2% in the nine months ended September 30, 2022 due to the release of the valuation allowance in the three months ended December 31, 2021.

Liquidity and Capital Resources

Since our inception, we have funded our operations and capital expenditures through cash flows from product sales, loans from affiliates and entities controlled by certain of our affiliates, third-party debt and proceeds from the sale of our capital stock. As of September 30, 2022, we had an accumulated deficit of \$52.8 million and working capital of \$141.3 million which included \$107.3 million in cash and cash equivalents. We also have \$125.0 million available for future revolving borrowings under our Revolving Facility (see Note “13. Long-Term Debt Obligations”). For the nine months ended September 30, 2022, we reported \$335.4 million in net revenue, \$8.0 million in net income and \$17.1 million of cash inflows from operating activities. We expect that our cash on hand and other components of working capital as of September 30, 2022, 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.

We continue to closely monitor ongoing developments in connection with the COVID-19 pandemic, which may negatively affect our commercial prospects, cash position and access to capital in fiscal 2022 or beyond. We will continue to assess our cash and other sources of liquidity and, if circumstances warrant, we will make appropriate adjustments to our operating plan.

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.

Cash Flows

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

	Nine Months Ended September 30,	
	2022	2021
	(in thousands)	
Net cash provided by operating activities	\$ 17,059	\$ 44,030
Net cash used in investing activities	(23,242)	(25,993)
Net cash used in financing activities	(324)	(119)
Net change in cash, cash equivalents, and restricted cash	\$ (6,507)	\$ 17,918

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Operating Activities

During the nine months ended September 30, 2022, net cash provided by operating activities was \$17.1 million, resulting from our net income of \$8.0 million and non-cash charges of \$31.8 million, partially offset by net cash used in connection with changes in our operating assets and liabilities of \$22.8 million. Net cash used in changes in our operating assets and liabilities included an increase in accounts receivable of \$11.5 million, an increase in inventory of \$7.3 million, a decrease in operating leases liabilities of \$5.3 million, and a decrease in accrued expenses and other current liabilities of \$4.0 million, partially offset by an increase in accounts payable of \$5.3 million.

During the nine months ended September 30, 2021, net cash provided by operating activities was \$44.0 million, resulting primarily from our net income of \$43.2 million and non-cash charges of \$25.9 million, partially offset by net cash used in connection with changes in our operating assets and liabilities of \$25.1 million. Cash used in changes in our operating assets and liabilities included an increase in accounts receivable of \$20.1 million, an increase in inventory of \$9.7 million, and a decrease in operating leases and other liabilities of \$7.1 million, all of which were partially offset by an increase in accounts payable, accrued expenses and other current liabilities of \$12.0 million.

Investing Activities

During the nine months ended September 30, 2022, we used \$23.2 million of cash in investing activities solely consisting of capital expenditures.

During the nine months ended September 30, 2021, we used \$26.0 million of cash in investing activities solely consisting of capital expenditures.

Financing Activities

During the nine months ended September 30, 2022, net cash used in financing activities was \$0.3 million. This consisted primarily of the payment of term loan and finance lease obligations of \$1.1 million and the payment of \$0.6 million related to the CPN deferred acquisition consideration, partially offset by the net receipts of \$1.4 million in connection with the stock awards activities.

During the nine months ended September 30, 2021, net cash used in financing activities was \$0.1 million. This consisted primarily of the repayment of borrowings of \$70.0 million under the 2019 Credit Agreement, the payment of \$1.6 million to extinguish the loan, the payment of finance lease obligations of \$2.1 million, the payment of \$1.7 million related to other financing activities. The net cash used in financing activities was principally offset by \$73.2 million in net proceeds from the 2021 Credit Agreement and \$2.1 million in proceeds from the exercise of stock options.

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 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 Eurodollar Loans or ABR Loans, at our option. For Eurodollar Loans, the interest rate is a per annum interest rate equal to LIBOR 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 LIBOR rate plus 1.0%, *plus* (2) an Applicable Margin between 1.00% to 2.25% based on the Total Net Leverage Ratio.

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. 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.

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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 September 30, 2022, we were in compliance with the covenants under the 2021 Credit Agreement. We had outstanding borrowings under the Revolving Facility and Term Loan Facility of the 2021 Credit Agreement of \$0.0 million and \$73.1 million, respectively.

2019 Credit Agreement

In March 2019, we, our subsidiaries and SVB, and the several other lenders thereto entered into a credit agreement, as amended (the “2019 Credit Agreement”), providing for a term loan facility of \$40.0 million and a revolving credit facility of up to \$60.0 million. Both facilities were set to mature in 2024. The interest rate for the term loan facility was a floating per annum interest rate equal to the greater of 3.75% above the Wall Street Journal Prime Rate and 9.25%. The interest rate for advances under the revolving facility was a floating per annum interest rate equal to the greater of the Wall Street Journal Prime Rate and 5.50%. If we elected to prepay the loan or terminate the facilities, we were required to pay a certain percentage of the outstanding principal as a prepayment fee. A final payment fee (the “Final Payment”) of 6.5% multiplied by the original aggregate principal amount of term loan facility was due upon the earlier to occur, the maturity date of the term loan or prepayment of all outstanding principal.

In August 2021, upon entering into the 2021 Credit Agreement, we paid an aggregate amount of \$70.6 million due under the 2019 Credit Agreement, including unpaid principal, accrued interest, the Final Payment and a prepayment fee, with proceeds from the 2021 Credit Agreement, and the 2019 Credit Agreement was terminated. Upon termination of the 2019 Credit Agreement, the Company recognized \$1.9 million as loss on the extinguishment of the loan for the year ended December 31, 2021.

Critical Accounting Policies and Significant Judgments and Estimates

Our unaudited consolidated financial statements have been prepared in accordance with GAAP. The preparation of our unaudited 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 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 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 consolidated statements of operations, liquidity and financial condition. See also our Annual Report on Form 10-K for the fiscal year ended December 31, 2021, as amended, 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 consolidated financial statements included in this Quarterly Report on Form 10-Q.

Item 3. Quantitative and Qualitative Disclosures about Market Risk.

We are exposed to various market risks, including fluctuations in interest rates and variability in currency exchange rates. We have established policies, procedures and internal processes governing our management of market risk and the use of financial instruments to manage our exposure to such risk.

Interest Rate Risk

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As of September 30, 2022, we had \$73.1 million in borrowings outstanding under our term loan facility and no borrowings outstanding under our revolving credit facility, respectively. Borrowings under the term loan facility and revolving credit facility bear interest at variable rates. Based on the principal amounts outstanding as of September 30, 2022, an immediate 10% change in the interest rate would not have a material impact on our debt related obligations, financial position or results of operations.

Foreign Currency and Market Risk

The majority of our employees and our major operations are currently located in the United States. The functional currency of our foreign subsidiary in Switzerland is the U.S. dollar. We have, in the normal course of business, engaged in contracts with contractors or other vendors in a currency other than the U.S. dollar. To date, we have had minimal exposure to fluctuations in foreign currency exchange rates as the time period from the date that transactions are initiated and the date of payment or receipt of payment is generally of short duration. Accordingly, we believe we do not have a material exposure to foreign currency risk.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Material Weaknesses on Internal Control over Financial Reporting

The Company's management, with the participation of its principal executive officer and principal financial officer, evaluated the effectiveness of its disclosure controls and procedures as of September 30, 2022. 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.

Because of inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions or that the degree of compliance with the policies or procedures may deteriorate. Accordingly, even effective internal control over financial reporting can only provide reasonable assurance of achieving their control objectives.

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. As a result of this assessment, management concluded that, as of September 30, 2022, our internal control over financial reporting was not effective based on those criteria.

As disclosed in the Company's Annual Report for the fiscal year ended December 31, 2021, as amended, our management team identified the following material weakness in our internal control over financial reporting: we did not design and maintain formal accounting, business operations, and information technology policies, procedures and controls to achieve complete, accurate and timely financial accounting, reporting and disclosures, including (i) formalized policies and procedures for reviews over account reconciliations, journal entries, and other accounting analyses, memos and procedures to ensure completeness and accuracy of information used in these review controls and (ii) controls to support the objectives of proper segregation of the initiation of transactions, the recording of transactions, and the custody of assets.

Although management has made significant progress in remediating this material weakness, management concluded that the material weakness described above continued to exist as of September 30, 2022.

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:

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- We are planning the implementation of a new company-wide enterprise resource planning, or ERP, system to provide additional systematic controls and segregation of duties for our accounting processes. We anticipate that the ERP system will go live in 2023.
- We have continued to train and cross train our employees on their internal control responsibilities and how to best support the Company if personnel turnover issues within their departments occur. We have also supplemented our internal resources with third-party resources, where necessary.
- We have continued to engage an outside firm 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 the organization, including the audit committee, on testing progress and defined corrective actions, and we monitored and reported on the results of control remediation. Through these actions, we have continued to strengthen our internal policies, processes, and reviews.
- We implemented a new control to ensure that significant transactions are identified and effectively communicated so that they are properly and timely reported.

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 material weaknesses 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 September 30, 2022 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. However, as the implementation of the new ERP system continues, we will change our processes and procedures, which in turn, could result in 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 appointed Donald Martin as lead plaintiff. Mr. Martin filed an amended complaint on October 24, 2022 that brings claims on behalf of a purported class of all purchasers of our securities from August 10, 2020 through August 9, 2022 and alleges 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 complaint alleges violations of the Securities Exchange Act of 1934 and Rule 10b-5 promulgated thereunder, and seeks unquantified damages as well as attorneys' fees, expert fees and other costs. The action is in the early stages of litigation. We believe the claims are without merit and intend to vigorously contest them.

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, 2021, as amended, includes a detailed discussion of our risk factors under the heading "Part I, Item 1A—Risk Factors." There have been no material changes from such risk factors during the quarter ended September 30, 2022. You should consider carefully the risk factors discussed in our Annual Report on Form 10-K for the year ended December 31, 2021, as amended, 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, 2021, as amended, or

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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.

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

None.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosures

Not Applicable.

Item 5. Other Information

None.

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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: November 9, 2022

Organogenesis Holdings Inc.

(Registrant)

/s/ David Francisco

David Francisco
Chief Financial Officer

(Principal Financial and Accounting Officer)