UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 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, 2023

OR

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

For the transition period from _____ to_____

Commission file number: 001-36046

Axogen, Inc.

(Exact Name of Registrant as Specified in Its Charter)

Minnesota
(State or other jurisdiction of
incorporation or organization)

13631 Progress Blvd., Suite 400 Alachua, FL
(Address of principal executive offices)

41-1301878
(I.R.S. Employer
Identification No.)

32615
(Zip Code)

386-462-6800
(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	Name of each exchange on which registered
Common Stock, $0.01 par value	AXGN	The Nasdaq Stock 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 ☒

As of November 1, 2023, the registrant had 43,043,606 shares of common stock outstanding.

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Part I - Financial Information

Part II - Other Information

Forward-Looking Statements

From time to time, in reports filed with the U.S. Securities and Exchange Commission (the "SEC") (including this Quarterly Report on Form 10-Q), in press releases, and in other communications to shareholders or the investment community, Axogen, Inc. (including Axogen, Inc.'s wholly owned subsidiaries, Axogen Corporation, Axogen Processing Corporation and Axogen Europe GmbH, the "Company," "Axogen," "we," "our," or "us") may provide forward-looking statements, as defined in the Private Securities Litigation Reform Act of 1995, concerning possible or anticipated future results of operations or business developments. These statements are based on management's current expectations or predictions of future conditions, events, or results based on various assumptions and management's estimates of trends and economic factors in the markets in which the Company is active, as well as its business plans. Words such as "expects," "anticipates," "intends," "plans," "believes," "seeks," "estimates," "projects," "forecasts," "continue," "may," "should," "will," "goals," and variations of such words and similar expressions are intended to identify such forward-looking statements.

The forward-looking statements in this Form 10-Q include, but are not limited to the following:

- Our intention not to pursue regulatory approval for Avive and to focus efforts on Avive+ Soft Tissue Matrix™ ("Avive+");
- Our expectations regarding the timing of manufacturing of Avive+, our expectation to launch Avive+ in the first quarter of 2024, our ability to market Avive+, and our expectations that Avive+ will, and will continue to, be regulated solely under Section 361 of the Public Health Service Act;
- Our expectation that a Pre-BLA meeting with the FDA will occur in early first quarter 2024;
- Our expectation that our request to the Food and Drug Administration ("FDA") for a rolling biologics license application ("BLA") submission for Avance Nerve Graft will occur in the first quarter of 2024;
- Our expectation that the initial BLA submission for Avance Nerve Graft, if approved by the FDA, will begin, in the first quarter of 2024 with completion of the full submission by the second quarter of 2024;
- Our expectation that the BLA will be approved in the first half of 2025, subject to the rolling submission process being approved by the FDA;
- Our expectation that we will have have more than 30 teams trained in implant-based Resentation by the end of the year;
- Our expectation that we will reduce our utilization of Community Blood Center's ("CTS") clean rooms, storage, and office space for Avance in 2023, and continue to utilize CTS beyond 2023 for Avive+;
- Our belief that our existing cash and cash equivalents and investments, as well as cash provided by sales of our products will allow us to fund our operations through at least the next 12 months;
- Our belief that any losses resulting from any claims, lawsuits, and proceedings are adequately covered by insurance or indemnified and are not expected to result in a material adverse effect on the Company's financial condition, results of operation, or cash flow; and
- Our estimates concerning the mix of scheduled procedures and emergent trauma procedures and our belief that the growth in scheduled procedures will continue to outpace emergent trauma procedure growth and continue to become a larger mix of our revenue over time.

The forward-looking statements are and will be subject to risks and uncertainties, which may cause actual results to differ materially from those expressed or implied in such forward-looking statements. Forward-looking statements contained in this Quarterly Report on Form 10-Q should be evaluated together with the many risks and uncertainties that affect the Company's business and its market, particularly those discussed in the risk factors and cautionary statements set forth in the Company's filings with the SEC, including as described in "Risk Factors" included in Item 1A and "Risk Factor Summary" included in the Company's Annual Report on Form 10-K for the year ended December 31, 2022. Forward-looking statements are not guarantees of future performance, and actual results may differ materially from those projected. The forward-looking statements are representative only as of the date they are made and, except as required by applicable law, the Company assumes no responsibility to publicly update or revise any forward-looking statements, whether as a result of new information, future events, changed circumstances or otherwise.

PART 1 — FINANCIAL INFORMATION

ITEM 1 — FINANCIAL STATEMENTS

Axogen, Inc.
Condensed Consolidated Balance Sheets
(unaudited)
(In thousands, except share and per share amounts)

	September 30, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 31,094	$ 15,284
Restricted cash	6,002	6,251
Investments	1,494	33,505
Accounts receivable, net of allowance for doubtful accounts of $319 and $650, respectively	23,263	22,186
Inventory	23,019	18,905
Prepaid expenses and other	2,567	1,944
Total current assets	87,439	98,075
Property and equipment, net	89,030	79,294
Operating lease right-of-use assets	13,873	14,369
Intangible assets, net	4,288	3,649
Total assets	$ 194,630	$ 195,387
Liabilities and shareholders' equity		
Current liabilities:		
Accounts payable and accrued expenses	$ 25,550	$ 22,443
Current maturities of long-term lease obligations	1,096	1,310
Total current liabilities	26,646	23,753
Long-term debt, net of debt discount and financing fees	46,378	45,712
Long-term lease obligations	19,927	20,405
Debt derivative liabilities	3,869	4,518
Total liabilities	96,820	94,388
Commitments and contingencies - see Note 12		
Shareholders' equity:		
Common stock, 0.01 par value per share; 100,000,000 shares authorized; 43,039,399 and 42,445,517 shares issued and outstanding	430	424
Additional paid-in capital	374,783	360,155
Accumulated deficit	(277,403)	(259,580)
Total shareholders' equity	97,810	100,999
Total liabilities and shareholders' equity	$ 194,630	$ 195,387

See notes to condensed consolidated financial statements.

Axogen, Inc.
Condensed Consolidated Statements of Operations
(unaudited)
(In thousands, except share and per share amounts)

	Three Months Ended		Nine Months Ended	
	September 30, 2023	September 30, 2022	September 30, 2023	September 30, 2022
Revenues	$ 41,271	$ 36,959	$ 116,090	$ 102,420
Cost of goods sold	8,043	6,176	21,980	18,006
Gross profit	33,228	30,783	94,110	84,414
Costs and expenses:				
Sales and marketing	21,429	19,792	63,885	60,349
Research and development	6,989	7,050	21,032	20,347
General and administrative	8,835	8,796	27,461	27,817
Total costs and expenses	37,253	35,638	112,378	108,513
Loss from operations	(4,025)	(4,855)	(18,268)	(24,099)
Other income (expense):				
Investment income	367	186	1,151	172
Interest expense	(827)	(61)	(992)	(664)
Change in fair value of derivatives	402	469	649	1,155
Other expense	(6)	(57)	(363)	(97)
Total other (expense) income, net	(64)	537	445	566
Net loss	$ (4,089)	$ (4,318)	$ (17,823)	$ (23,533)
Weighted average common shares outstanding — basic and diluted	43,022,328	42,220,519	42,821,284	42,008,013
Loss per common share — basic and diluted	$ (0.10)	$ (0.10)	$ (0.42)	$ (0.56)

See notes to condensed consolidated financial statements.

Axogen, Inc.
Condensed Consolidated Statements of Cash Flows
(unaudited)
(In thousands)

	Nine Months Ended	
	September 30, 2023	**September 30, 2022**
Cash flows from operating activities:		
Net loss	$ (17,823)	$ (23,533)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	2,660	2,182
Amortization of right-of-use assets	826	1,303
Amortization of intangible assets	214	198
Amortization of debt discount and deferred financing fees	666	667
(Recovery of) provision for bad debt	(311)	566
Provision for inventory write-down	1,841	1,381
Change in fair value of derivatives	(649)	(1,155)
Investment (gains) loss	(660)	44
Stock-based compensation	13,091	11,437
Change in operating assets and liabilities:		
Accounts receivable	(766)	(3,695)
Inventory	(5,955)	(3,804)
Prepaid expenses and other	(623)	(828)
Accounts payable and accrued expenses	3,012	(870)
Operating lease obligations	(1,012)	(1,320)
Cash paid for interest portion of finance leases	(2)	(1)
Contract and other liabilities	(14)	—
Net cash used in operating activities	(5,505)	(17,428)
Cash flows from investing activities:		
Purchase of property and equipment	(12,409)	(13,456)
Purchase of investments	(10,203)	(24,607)
Proceeds from sale of investments	42,874	37,100
Cash payments for intangible assets	(732)	(1,028)
Net cash provided by (used in) investing activities	19,530	(1,991)
Cash flows from financing activities:		
Cash paid for debt portion of finance leases	(7)	(9)
Proceeds from exercise of stock options and ESPP stock purchases	1,543	990
Net cash provided by financing activities	1,536	981
Net increase (decrease) in cash, cash equivalents, and restricted cash	15,561	(18,438)
Cash, cash equivalents, and restricted cash, beginning of period	21,535	39,007
Cash, cash equivalents, and restricted cash, end of period	$ 37,096	$ 20,569
Supplemental disclosures of cash flow activity:		
Cash paid for interest, net of capitalized interest	$ 325	$ —
Supplemental disclosure of non-cash investing and financing activities:		
Acquisition of fixed assets in accounts payable and accrued expenses	$ 853	$ 2,090
Obtaining a right-of-use asset in exchange for a lease liability	$ 366	$ 920
Obtaining of property and equipment in exchange for a lease liability	$ —	$ 22
Acquisition of intangible assets in accounts payable and accrued expenses	$ 420	$ 177

See notes to condensed consolidated financial statements.

Axogen, Inc.
Condensed Consolidated Statements of Changes in Shareholders' Equity
(unaudited)
(In thousands, except share amounts)

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Shareholders' Equity
	Shares	Amount			
Three Months Ended September 30, 2023					
Balance at June 30, 2023	42,979,541	$ 430	$ 370,036	$ (273,314)	97,152
Net loss	—	—	—	(4,089)	(4,089)
Stock-based compensation	—	—	4,747	—	4,747
Issuance of restricted and performance stock units	59,858	—	—	—	—
Balance at September 30, 2023	43,039,399	$ 430	$ 374,783	$ (277,403)	$ 97,810
Nine Months Ended September 30, 2023					
Balance at December 31, 2022	42,445,517	$ 424	$ 360,155	$ (259,580)	$ 100,999
Net loss	—	—	—	(17,823)	(17,823)
Stock-based compensation	—	—	13,091	—	13,091
Issuance of restricted and performance stock units	356,236	4	(4)	—	—
Exercise of stock options and employee stock purchase plan	237,646	2	1,541	—	1,543
Balance at September 30, 2023	43,039,399	$ 430	$ 374,783	$ (277,403)	$ 97,810
Three Months Ended September 30, 2022					
Balance at June 30, 2022	42,134,504	$ 420	$ 351,117	$ (249,847)	$ 101,690
Net loss	—	—	—	(4,318)	(4,318)
Stock-based compensation	—	—	3,849	—	3,849
Issuance of restricted and performance stock units	55,934	1	(1)	—	—
Exercise of stock options and employee stock purchase plan	81,785	2	222	—	224
Balance at September 30, 2022	42,272,223	$ 423	$ 355,187	$ (254,165)	$ 101,445
Nine Months Ended September 30, 2022					
Balance at December 31, 2021	41,736,950	$ 417	$ 342,765	$ (230,632)	112,550
Net loss	—	—	—	(23,533)	(23,533)
Stock-based compensation	—	—	11,437	—	11,437
Issuance of restricted and performance stock units	315,275	3	(3)	—	—
Exercise of stock options and employee stock purchase plan	219,998	3	988	—	991
Balance at September 30, 2022	42,272,223	$ 423	$ 355,187	$ (254,165)	$ 101,445

See notes to condensed consolidated financial statements.

Axogen, Inc.
Notes to Condensed Consolidated Financial Statements
(unaudited)
(In thousands, except share and per share amounts)

1. Nature of Business

Axogen, Inc. (together with its wholly-owned subsidiaries, the "Company") was incorporated in Minnesota and is the leader in the science, development and commercialization of the technologies used for peripheral nerve regeneration and repair. The Company's products include Avance® Nerve Graft, Axoguard Nerve Connector®, Axoguard Nerve Protector®, Axoguard HA+ Nerve Protector, Axoguard Nerve Cap® and Axotouch® Two-Point Discriminator. The Company is headquartered in Florida. The Company has processing, warehousing, and distribution facilities in Texas and Ohio.

The Company manages its operations as a single operating segment. Substantially all of the Company's assets are maintained in the United States. The Company derives substantially all of its revenues from sales to customers in the United States.

2. Summary of Significant Accounting Policies

Please see Note 2 to the Company's consolidated financial statements included in the Company's Annual Report on Form 10-K for the year ended December 31, 2022, filed with the Securities and Exchange Commission ("SEC") on March 14, 2023, for a description of all significant accounting policies.

Basis of Presentation

The accompanying unaudited condensed consolidated financial statements include the accounts of the Company as of September 30, 2023, and December 31, 2022, and for the three and nine months ended September 30, 2023, and 2022. The Company's condensed consolidated financial statements have been prepared in accordance with the instructions to Form 10-Q and Rule 10-01 of Regulation S-X, and; therefore, do not include all information and footnotes necessary for a fair presentation of consolidated financial position, results of operations, and cash flows in conformity with accounting principles generally accepted in the United States ("U.S. GAAP") and should be read in conjunction with the audited financial statements of the Company for the year ended December 31, 2022, which are included in the Company's Annual Report on Form 10-K for the year ended December 31, 2022.

The interim condensed consolidated financial statements are unaudited, and in the opinion of management, reflect all adjustments, consisting only of normal recurring adjustments, necessary for a fair presentation of results for the periods presented. The results of operations for the three and nine months ended September 30, 2023, are not necessarily indicative of the results to be expected for the full year due primarily to the impact of the continued uncertainty of general economic conditions that may impact the Company's markets for the remainder of fiscal year 2023. All intercompany accounts and transactions have been eliminated in consolidation.

Cash and Cash Equivalents and Concentration

Cash and cash equivalents consist of short-term, highly liquid investments with original maturities of three months or less from the date of acquisition. Certain of the Company's cash and cash equivalents balances exceed Federal Deposit Insurance Corporation ("FDIC") insured limits or are invested in money market accounts with investment banks that are not FDIC-insured. The Company places its cash and cash equivalents in what they believe to be credit-worthy financial institutions. As of September 30, 2023, $30,344 of the cash and cash equivalents balance was in excess of FDIC limits.

Restricted Cash

Amounts included in restricted cash represent those required to be set aside to meet contractual terms of a lease agreement held by the Company.See Note 8 - Long-Term Debt, Net of Debt Discount and Financing Fees - Other Credit Facilities.

The following table provides a reconciliation of cash, cash equivalents, and restricted cash reported in the condensed consolidated balance sheets that sum to the total of the same amounts shown in the condensed consolidated statements of cash flows:

(In thousands)	September 30, 2023	December 31, 2022
Cash and cash equivalents	$ 31,094	$ 15,284
Restricted cash	6,002	6,251
Total cash, cash equivalents, and restricted cash shown in the statement of cash flows	$ 37,096	$ 21,535

Property and Equipment, Net

Property and equipment, net are stated at historical cost less accumulated depreciation and amortization. Additions and improvements that extend the lives of the assets are capitalized, while expenditures for repairs and maintenance are expensed as incurred. Leasehold improvements are amortized on a straight-line basis over the shorter of the asset's estimated useful life or the remaining lease term. Depreciation is calculated on a straight-line basis over the estimated useful lives of the assets ranging from three to thirty-nine years.

Gains or losses on the disposition of property and equipment are recorded in the period incurred and recorded in general and administrative expenses on the condensed consolidated statements of operations.

Capitalized Interest

The interest cost on capital projects, including facilities build-outs, is capitalized and included in the cost of the project. Capitalization begins with the first expenditure for the project and continues until the project is substantially complete and ready for its intended use. For the three and nine months ended September 30, 2023, and 2022, the Company capitalized $1,043 and $1,450, respectively, and $5,240 and $4,474, respectively, of interest expense into property and equipment.

Shipping and Handling

All shipping and handling costs, including facility and warehousing overhead, directly related to bringing the Company's products to their final selling destination are included in sales and marketing expense. Shipping and handling costs included in sales and marketing expense were $952 and $1,330, for the three months ended September 30, 2023, and 2022, respectively, and $3,693 and $3,863, for the nine months ended September 30, 2023, and 2022, respectively.

Recent Accounting Pronouncements

All other Accounting Standards Updates ("ASU's") issued and not yet effective as of December 31, 2022, and through the date of this report, were assessed and determined to be either not applicable or are expected to have minimal impact on the Company's current or future financial position or results of operations except for the following:

Accounting Pronouncements Recently Adopted

In December 2022, the Financial Accounting Standards Board issued ASU 2022-06 - Reference Rate Reform (Topic 848): Deferral of the Sunset Date of Topic 848 ("ASU 2022-06"). ASU 2022-06 amended Accounting Standards Codification 848 Reference Rate Reform and ASU 2020 - 4, Reference Rate Reform. The amendment in ASU 2022-06 defers the sunset date of Topic 848 from December 31, 2022, to December 31, 2024, after which entities will no longer be permitted to apply the relief in Topic 848. The new guidance provides optional expedients and exceptions for applying U.S. GAAP to contracts, hedging relationships and other transactions affected by reference rate reform if certain criteria are met. The amendments apply only to contracts and hedging relationships that reference the London Interbank Offered Rate ("LIBOR"), or another reference rate expected to be discontinued due to reference rate reform. The Company early adopted ASU 2022-06 in the second quarter of 2023 and the adoption of this accounting standard did not have an impact on the Company's condensed consolidated financial statements.

3. Inventory

Inventory consists of the following:

(in thousands)	September 30, 2023	December 31, 2022
Finished goods	$ 14,981	$ 12,651
Work in process	1,030	1,026
Raw materials	7,008	5,228
Inventory	$ 23,019	$ 18,905

The provision for inventory write-down is as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
(in thousands)	2023	2022	2023	2022
Provision for inventory write-down	$ 789	$ 452	$ 1,841	$ 1,381

4. Property and Equipment, Net

Property and equipment, net consist of the following:

(in thousands)	September 30, 2023	December 31, 2022
Land	$ 731	$ 731
Building	58,688	—
Leasehold improvements	15,482	15,482
Processing equipment	12,135	4,227
Furniture and equipment	8,697	5,316
Projects in process	6,122	63,703
Finance lease right-of-use assets	131	131
Property and equipment, at cost	101,986	89,590
Less: accumulated depreciation and amortization	(12,956)	(10,296)
Property and equipment, net	$ 89,030	$ 79,294

Depreciation expense is as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
(in thousands)	2023	2022	2023	2022
Depreciation expense	$ 1,154	$ 764	$ 2,660	$ 2,182

5. Intangible Assets, Net

Intangible assets consist of the following:

(in thousands)	September 30, 2023			December 31, 2022		
	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount
Amortizable intangible assets:						
Patents	$ 4,629	$ (763)	$ 3,866	$ 3,792	$ (621)	$ 3,170
License agreements	1,101	(1,086)	15	1,101	(1,014)	87
Total amortizable intangible assets	5,730	(1,849)	3,881	4,893	(1,635)	3,258
Unamortized intangible assets:						
Trademarks	407	—	407	391	—	391
Total intangible assets	$ 6,138	$ (1,849)	$ 4,288	$ 5,284	$ (1,635)	$ 3,649

Amortization expense is as follows:

(in thousands)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Amortization expense	$ 70	$ 66	$ 214	$ 198

As of September 30, 2023, future amortization of patents and license agreements is as follows:

Year Ending December 31,	(in thousands)
2023 (excluding the nine months ended September 30, 2023)	$ 56
2024	223
2025	223
2026	221
2027	218
Thereafter	2,940
Total	$ 3,881

License Agreements

The Company has various license agreements that require the payment of royalty fees.

Royalty fee expense included in sales and marketing expense is as follows:

(in thousands)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Royalty fee expense	$ 930	$ 848	$ 2,628	$ 2,287

6. Fair Value Measurement

The following tables present the Company's fair value hierarchy for its financial assets and liabilities measured at fair value on a recurring basis as of September 30, 2023, and December 31, 2022:

(in thousands)	September 30, 2023 (Level 1)	(Level 2)	(Level 3)	Total
Assets:				
Money market funds	$ 24,752	$ —	$ —	$ 24,752
U.S. government securities	1,494	—	—	1,494
Total assets	$ 26,246	$ —	$ —	$ 26,246
Liabilities:				
Debt derivative liabilities	$ —	$ —	$ 3,869	$ 3,869
Total liabilities	$ —	$ —	$ 3,869	$ 3,869

(in thousands)	December 31, 2022 (Level 1)	(Level 2)	(Level 3)	Total
Assets:				
Money market funds	$ 10,354	$ —	$ —	$ 10,354
U.S. government securities	12,316	—	—	12,316
Commercial paper	—	21,189	—	21,189
Total assets	$ 22,669	$ 21,189	$ —	$ 43,859
Liabilities:				
Debt derivative liabilities	$ —	$ —	$ 4,518	$ 4,518
Total liabilities	$ —	$ —	$ 4,518	$ 4,518

The changes in Level 3 liabilities measured at fair value on a recurring basis for the three and nine months ended September 30, 2023, were as follows (in thousands):

Three Months Ended September 30, 2023	
Balance, July 1, 2023	$ 4,271
Change in fair value included in net loss	(402)
Balance, September 30, 2023	$ 3,869

Nine Months Ended September 30, 2023	
Beginning Balance, January 1, 2023	$ 4,518
Change in fair value included in net loss	(649)
Ending Balance, September 30, 2023	$ 3,869

The changes in Level 3 liabilities measured at fair value on a recurring basis for the three and nine months ended September 30, 2022, were as follows (in thousands):

Three Months Ended September 30, 2022	
Balance July 1, 2022	$ 4,876
Change in fair value included in net loss	(469)
Balance, September 30, 2022	$ 4,407

Nine Months Ended September 30, 2022	
Beginning Balance, January 1, 2022	$ 5,562
Change in fair value included in net loss	(1,155)
Ending Balance, September 30, 2022	$ 4,407

The fair value of cash, restricted cash, accounts receivable, accounts payable and accrued expenses approximates the carrying values because of the short-term nature of these instruments. The carrying value and fair value of the Credit Facility were $46,378 and $51,135 at September 30, 2023, and $45,712 and $50,293 at December 31, 2022, respectively. See Note 8 - Long-Term Debt, Net of Debt Discount and Financing Fees.

The debt derivative liabilities are measured using a 'with and without' valuation model to compare the fair value of each tranche of the Credit Facility including the identified embedded derivative features and the fair value of a plain vanilla note with the same terms. The fair value of the Credit Facility including the identified embedded derivative features was determined using a probability-weighted expected return model based on four potential settlement scenarios for the financing agreement as disclosed in the table below. The estimated settlement value of each scenario, which would include any required make-whole payment, (see Note 8 - Long-Term Debt, Net of Debt Discount and Financing Fees), is then discounted to present value using a discount rate that is derived based on the initial terms of the financing agreement at issuance and corroborated utilizing a synthetic credit rating analysis.

The significant inputs that are included in the valuation of the debt derivative liability - first tranche include:

	September 30, 2023	December 31, 2022
Input		
Remaining term (years)	3.75 years	4.5 years
Maturity date	June 30, 2027	June 30, 2027
Coupon rate	9.5% - 13.3%	9.5% - 12.7%
Revenue participation payments	Maximum each year	Maximum each year
Discount rate	13.9% (1)	13.9% (1)
Probability of mandatory prepayment before 2024	5.0 % (1)	5.0 % (1)
Estimated timing of mandatory prepayment event before 2024	December 31, 2023 (1)	December 31, 2023 (1)
Probability of mandatory prepayment 2024 or after	15.0 % (1)	15.0 % (1)
Estimated timing of mandatory prepayment event 2024 or after	March 31, 2026 (1)	March 31, 2026 (1)
Probability of optional prepayment event	5.0 % (1)	5.0 % (1)
Estimated timing of optional prepayment event	December 31, 2025 (1)	December 31, 2025 (1)

(1) Represents a significant unobservable input

The significant inputs that are included in the valuation of the debt derivative liability - second tranche include:

	September 30, 2023	December 31, 2022
Input		
Remaining term (years)	4.75 years	5.5 years
Maturity date	June 30, 2028	June 30, 2028
Coupon rate	9.5% - 13.3%	9.5% - 12.7%
Revenue participation payments	Maximum each year	Maximum each year
Discount rate	17.18 % (1)	17.56 % (1)
Probability of mandatory prepayment before 2024	5.0% (1)	5.0% (1)
Estimated timing of mandatory prepayment event before 2024	December 31, 2023 (1)	December 31, 2023 (1)
Probability of mandatory prepayment 2024 or after	15.0% (1)	15.0% (1)
Estimated timing of mandatory prepayment event 2024 or after	March 31, 2026 (1)	March 31, 2026 (1)
Probability of optional prepayment event	5.0% (1)	5.0% (1)
Estimated timing of optional prepayment event	December 31, 2025 (1)	December 31, 2025 (1)

(1) Represents a significant unobservable input

7. Leases

The Company leases administrative, processing, research and distribution facilities through operating leases. Several of the leases include fixed payments, including rent and non-lease components such as common area or other maintenance costs.

Operating lease expense is as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
(in thousands)	2023	2022	2023	2022
Operating lease expense	$ 1,327	$ 1,337	$ 3,871	$ 4,100

Supplemental balance sheet information related to the operating and financing leases is as follows:

(In thousands, except lease term and discount rate)	September 30, 2023	December 31, 2022
Operating Leases		
Right-of-use operating assets	$ 13,873	$ 14,369
Current maturities of long-term lease obligations	$ 1,091	$ 1,303
Long-term lease obligations	$ 19,913	$ 20,387
Financing Leases		
Right-of-use financing leases [(1)]	$ 25	$ 41
Current maturities of long-term lease obligations	$ 5	$ 7
Long-term lease obligations	$ 14	$ 18
Weighted average operating lease term (in years):	10.4	11.0
Weighted average financing lease term (in years):	3.6	4.0
Weighted average discount rate operating leases	10.69%	10.58%
Weighted average discount rate financing leases	12.50%	11.91%

[(1)] Financing leases are included in property and equipment, net on the condensed consolidated balance sheets.

Future minimum lease payments under operating and financing leases at September 30, 2023, are as follows:

(In thousands)	
2023 (excluding nine months ended September 30, 2023)	$ 831
2024	3,313
2025	3,398
2026	3,412
2027	3,104
Thereafter	21,668
Total	35,726
Less: Imputed interest	(14,703)
Total lease liability	21,023
Less: Current lease liability	(1,096)
Long-term lease liability	$ 19,927

New leases

The Company accounts for new leases in accordance with ASC 842,*Leases*.

On May 9, 2023, the Company entered into a Commercial Lease with JA-Cole L.P., with an effective date of May 9, 2023 (the "2023 JA-Cole Lease"). The 2023 JA-Cole Lease is for an additional 2,500 square feet of office and warehouse facility located in Burleson, Texas. The Commercial Lease has a commencement date of September 1, 2023, and an expiration date of

September 30, 2027. The Company will value the 2023 JA-Cole Lease using a 13.9% incremental borrowing rate and record a right-of-use asset and a lease liability of $98 on the commencement date.

Lease modifications

The Company accounts for lease revisions as a lease modification in accordance with ASC 842, *Leases*, when the modification effectively terminates the existing lease and creates a new lease.

On May 9, 2023, the Company entered into a Commercial Lease Amendment ("Amendment") with JA-Cole L.P., with an effective date of May 1, 2023, pursuant to the original Commercial Leases dated April 21, 2015, as amended (the "2015 JA-Cole Lease"). The 2015 JA-Cole Lease is for 15,000 square feet of office and warehouse facility located in Burleson, Texas. The Amendment revised the commencement date to May 1, 2023, and the expiration date to April 30, 2030. The Company valued the 2015 JA-Cole Lease using a 13.1% incremental borrowing rate and recorded a right-of-use asset and a lease liability of $268 as a result of this amendment.

8. Long-Term Debt, Net of Debt Discount and Financing Fees

Long-term debt, net of debt discount and financing fees consists of the following:

(in thousands)	September 30, 2023	December 31, 2022
Credit Facility - first tranche	$ 35,000	$ 35,000
Credit Facility - second tranche	15,000	15,000
Less - unamortized debt discount and deferred financing fees	(3,622)	(4,288)
Long-term debt, net of debt discount and financing fees	$ 46,378	$ 45,712

Credit Facility

On June 29, 2023, the Company amended its Credit Facility with Oberland Capital and its affiliates TPC Investments II LP and Argo LLC (collectively, the "Lender"). The term loan agreement for the Credit Facility was amended to transition the base interest rate from three month LIBOR to Adjusted SOFR. The Company obtained the first tranche of $35,000 at closing on June 30, 2020. On June 30, 2021, the second tranche of $15,000 was drawn down by the Company.

Each tranche under the Credit Facility requires quarterly interest payments for seven years. Interest is calculated as 7.5% plus the greater of Adjusted SOFR or 2.0% (12.84% at September 30, 2023). Each tranche of the Credit Facility has a term of seven years from the date of issuance (with the first tranche issued on June 30, 2020, maturing on June 30, 2027, and the second tranche issued on June 30, 2021, maturing on June 30, 2028). In connection with the Credit Facility, the Company entered into a revenue participation agreement (the "Revenue Participation Agreement") with the Lender, which provided that, among other things, a quarterly royalty payment as a percentage of the Company's net revenues, up to $70 million in any given year, after April 1, 2021, ending on the date upon which all amounts owed under the Credit Facility have been paid in full. This structure results in approximately 1.0% per year of additional interest payments on the outstanding loan amount. The Company recorded $0 and $49 as interest expense for this Revenue Participation Agreement for the three months ended September 30, 2023, and 2022, respectively and $756 and $756 for the nine months ended September 30, 2023, and 2022, respectively. The Company pays the quarterly debt interest on the last day of the quarter and for the three months ended September 30, 2023, and 2022, paid $1,642 and $1,249, respectively, and $4,776 and $3,637 for the nine months ended September 30, 2023, and 2022, respectively, to the Lender. The Company capitalized interest of $1,043 and $1,450 for the three months ended September 30, 2023, and 2022, respectively, and $5,240 and $4,474 for the nine months ended September 30, 2023, and 2022, towards the costs to construct and retrofit the Axogen Processing Center ("APC Facility") in Vandalia, Ohio. See Note 12 - Commitments and Contingencies. To date, the Company has capitalized interest of $16,669 related to this project. The capitalized interest is recorded as part of property and equipment, net in the condensed consolidated balance sheets. As of September 30, 2023, the Company was in compliance with all financial covenants.

Embedded Derivatives

The fair values of the debt derivative liabilities were $3,869 and $4,518 at September 30, 2023, and December 31, 2022, respectively. See Note 6 - Fair Value Measurement.

Unamortized Debt Discount and Financing Fees

The unamortized debt discount consists of the remaining initial fair values of the embedded derivatives related to the Credit Facility.

The financing fees for the Credit Facility were $642 and were recorded as a contra liability to long-term debt on the consolidated balance sheet.

Amortization of debt discount and deferred financing fees for the three months ended September 30, 2023, and 2022 was $224 and $225, respectively, and $666 and $667 for the nine months ended September 30, 2023, and 2022, respectively.

Other Credit Facilities

The Company had restricted cash of $6,002 and $6,251 at September 30, 2023, and December 31, 2022, respectively. The September 30, 2023, balance includes a $6,000 irrevocable standby letter of credit and the December 31, 2022, balance included two irrevocable standby letters of credit for $6,000 and $250 representing collateral. During the third quarter ended September 30, 2023, the $250 letter of credit was terminated.

9. Stock-Based Compensation

The Company's stock-based compensation plans are described in Note 11. Stock-Based Compensation to the Company's consolidated financial statements included in the Company's Annual Report on Form 10-K for the year ended December 31, 2022.

During the fiscal year 2023, the following stock compensation was awarded to officers and employees. All awards were granted under the 2019 Amended and Restated Long-Term Incentive Plan ("2019 Plan"), with the exception of the inducement shares awarded as inducements material to new employees entering into employment with the Company in accordance with Nasdaq Listing Rule 5635(c)(4).

Type of Award	Quarter Awarded	Target Shares or Units	Weighted Average Grant Date Fair Value
Stock Options [1]	1st Quarter	1,046,800	$ 4.96
	2nd Quarter	2,200	$ 5.64
	3rd Quarter	175,188	$ 3.77
Restricted Stock Units [2][3]	1st Quarter	1,129,718	$ 8.39
	2nd Quarter	33,850	$ 9.06
	3rd Quarter	134,432	$ 6.85
Performance Stock Units [4]	1st Quarter	744,000	$ 8.27
Inducement Shares [5][6]			
Stock Options	1st Quarter	150,000	$ 4.92
Restricted Stock Units	1st Quarter	75,000	$ 8.16

[1] Options awarded to officers and employees during the first, second, and third quarter, vest over a four-year period.

[2] Restricted stock units awarded to officers and employees during the first, second, and third quarters vest over a four-year period. Upon vesting, the outstanding number of restricted stock units vested are converted into common stock.

[3] Restricted stock units, equal to one half of their annual compensation, were awarded to the Company's Board of Directors on September 1, 2023. Vesting occurs over a one-year period. Upon vesting, the outstanding number of restricted stock units vested are converted into common stock.

[4] Performance stock units were issued to officers and employees during the first quarter. Vesting occurs over a three-year performance period. Participants will earn from 0% to 150% upon achievement of the target depending on the attainment of specific revenue goals. The maximum number of units that can be issued under this award is 1,116,000.

[5] Inducement shares were issued totwo officers during the first quarter, to new employees entering into employment with the Company in accordance with Nasdaq Listing Rule 5635(c)(4). Vesting for both the stock options and restricted stock units are over a four-year period.

[6] No inducement shares were granted in the second or third quarter of 2023.

Total stock-based compensation expense is as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
(in thousands)	2023	2022	2023	2022
Stock-based compensation expense	$ 4,747	$ 3,849	$ 13,091	$ 11,437

10. Net Loss Per Common Share

The following reflects the net loss attributable to common shareholders and share data used in the basic and diluted earnings per share computations using the two-class method:

	Three Months Ended September 30,		Nine Months Ended September 30,	
(In thousands, except per share amounts)	2023	2022	2023	2022
Numerator:				
Net loss	$ (4,089)	$ (4,318)	$ (17,823)	$ (23,533)
Denominator:				
Weighted-average common shares outstanding (Basic)	43,022,328	42,220,519	42,821,284	42,008,013
Weighted-average common shares outstanding (Diluted)	43,022,328	42,220,519	42,821,284	42,008,013
Net loss per common share (Basic and Diluted)	$ (0.10)	$ (0.10)	$ (0.42)	$ (0.56)
Anti-dilutive shares excluded from the calculation of diluted earnings per share [1]				
Stock options	4,552,919	3,132,722	4,355,115	3,083,519
Restricted stock units	1,672,397	441,866	386,597	498,966

(1) These common equivalent shares are not included in the diluted per share calculations as they would be anti-dilutive if the Company was in a net income position.

11. Income Taxes

The Company has no recorded income tax expense or income tax benefit for the three and nine months ended September 30, 2023, and 2022 due to the generation of net operating losses, the benefits of which have been fully reserved.

The Company has not recorded current income tax expense due to the generation of net operating losses. Deferred income taxes are accounted for using the balance sheet approach, which requires recognition of deferred tax assets and liabilities for the expected future consequences of temporary differences between the financial reporting basis and the tax basis of assets and liabilities. A valuation allowance is provided when it is more likely than not that a deferred tax asset will not be realized. A full valuation allowance has been established on the deferred tax asset as it is more likely than not that a future tax benefit will not be realized. In addition, future utilization of the available net operating loss carryforward may be limited under Internal Revenue Code Section 382 as a result of changes in ownership.

The Company identifies and evaluates uncertain tax positions, if any, and recognizes the impact of uncertain tax positions for which there is a less than more likely than not probability of the position being upheld when reviewed by the relevant taxing authority. Such positions are deemed to be unrecognized tax benefits and a corresponding liability is established on the condensed consolidated balance sheet. The Company has not recognized a liability for uncertain tax positions. If there were an unrecognized tax benefit, the Company would recognize interest accrued related to unrecognized tax benefits in interest expense and penalties in operating expenses. The Company's remaining open tax years subject to examination by federal tax authorities include the years ended December 31, 2019, through 2022. However, for tax years 2004 through 2017, federal taxing authorities may examine and adjust loss carryforwards in the years in which those loss carryforwards are ultimately utilized.

12. Commitments and Contingencies

Service Agreements

The Company pays Community Blood Center, (d/b/a Community Tissue Service) ("CTS") a facility fee for the use of clean rooms, storage and office space and for services in support of its tissue processing including for routine sterilization of daily supplies, providing disposable supplies and microbial services, and office support. The Company paid $600 and $541 for the three months ended September 30, 2023, and 2022, respectively, and $1,911 and $1,785 during the nine months ended September 30, 2023, and 2022, respectively, related to the agreement with CTS. The agreement terminates on December 31, 2023, subject to earlier termination by either party at any time for cause, or without cause upon six months prior notice. The Company expects to reduce its utilization of CTS in the remainder of 2023 for Avance, and will continue to utilize CTS beyond 2023 for Avive +.

In December 2011, the Company entered into a Master Services Agreement for clinical research and related services. The Company was required to pay $151 upon execution of this agreement and the remainder monthly based on activities associated with the execution of the Company's phase 3 pivotal clinical trial to support the biologics license application ("BLA") for Avance Nerve Graft. Payments made under this agreement were $23 and $279 for the three months ended September 30, 2023, and 2022, respectively, and $191 and $963 for the nine months ended September 30, 2023, and 2022, respectively.

Axogen Processing Center Facility

The Company is highly dependent on the continued availability of its processing facilities at CTS and APC in Dayton, Ohio and could be harmed if the physical infrastructure of these facilities are unavailable for any prolonged period of time.

On July 31, 2018, the Company purchased the APC Facility in Vandalia, Ohio, located near the CTS processing facility where Avance Nerve Graft is currently processed. The APC Facility, when and if operational, will be the new processing facility for Avance Nerve Graft to provide continued capacity for growth and to support the transition of Avance Nerve Graft from a human cellular and tissue-based product to a biologic product. The APC Facility is comprised of a 107,000 square foot building on approximately 8.6 acres of land. The Company paid $731 for the land, and this is recorded as land within Property and equipment, net on the condensed consolidated balance sheets. The Company paid $4,300 for the building and this is recorded within Property and equipment, net on the condensed consolidated balance sheets.

On July 9, 2019, the Company entered into a Standard Form of Agreement Between Owner and Design-Builder with CRB Builders, L.L.C., (“CRB”), pursuant to which CRB will renovate and retrofit the APC Facility. For the three and nine months ended September 30, 2023, the Company recorded $808 and $4,047, respectively, related to renovations and design and build in projects in progress. The Company has recorded $50,401 to date related to this project. In addition to these project costs, the Company has capitalized interest of $1,043 and $5,240 for the three and nine months ended September 30, 2023. To date, the Company has capitalized interest of $16,669 related to this project. During the quarter ended September 30, 2023, the APC Facility was placed into service. These costs were recorded to their respective asset category in Property and equipment, net on the condensed consolidated balance sheet. Validation of the tissue processing center was completed and we began operations during the third quarter of this year. The costs related to the labs at APC are recorded in projects in process in Property and equipment, net on the condensed consolidated balance sheet.

The Company obtained certain economic development grants from state and local authorities totaling up to $2,685 including $1,250 of cash grants to offset costs to acquire and develop the APC Facility. The economic development grants are subject to certain job creation milestones through December 31, 2023, and have clawback clauses if the Company does not meet the job creation milestones The Company requested an extension from the grant authorities to extend the job creation milestones and received approval to extend the evaluation date to December 31, 2024, and the expiration date to December 31, 2026. As of September 30, 2023, the Company received $1,188 from the cash grants and has a grant receivable of $0 recorded in receivables on the condensed consolidated balance sheets.

Fair Value of the Debt Derivative Liabilities

The fair value of the debt derivative liabilities is $3,869 as of September 30, 2023. The fair value of the debt derivative liabilities was determined using a probability-weighted expected return model based upon the four potential settlement scenarios for the Credit Facility. The estimated settlement value of each scenario, which includes any required make-whole payment, is then discounted to present value using a discount rate that is derived based upon the initial terms of the Credit Facility at issuance and corroborated utilizing a synthetic rating analysis. The calculated fair values under the four scenarios are then compared to the fair value of a plain vanilla note, with the difference reflecting the fair value of the debt derivative liabilities. The Company estimated the make-whole payments required under each scenario according to the terms of the Credit

Facility to generate an internal rate of return equal to11.5% through the scheduled maturity dates, less the total of all quarterly interest and royalty payments previously paid to the Lender. The calculation utilized the XIRR function in Microsoft Excel as required by the Credit Facility. If the debt is not prepaid but instead is held to its scheduled maturities, the Company's estimate of the make-whole payment for the first tranche and second tranche of the Credit Facility due on June 30, 2027, and June 30, 2028, respectively, are approximately zero. The Company has consistently applied this approach since the inception of the debt agreement on June 30, 2020.

The Company is aware that the Lender may have an alternative interpretation of the calculation of the make-whole payments that the Company believes does not properly utilize the same methodology utilized by the XIRR function in Microsoft Excel as described in the Credit Facility. The Company estimates the top end of the range of the make-whole payments if the debt is held to scheduled maturity under an alternative interpretation to be approximately $8,000 for the first tranche of the Credit Facility due on June 30, 2027, and approximately $4,000 for the second tranche of the Credit Facility due on June 30, 2028. Further, if the debt is prepaid prior to the scheduled maturity dates and subject to the alternative interpretation, the make-whole payment would be larger than the amounts herein.

Legal Proceedings

The Company is and may be subject to various claims, lawsuits, and proceedings in the ordinary course of the Company's business. Such matters are subject to many uncertainties and outcomes are not predictable with assurance. While there can be no assurances as to the ultimate outcome of any legal proceeding or other loss contingency involving the Company, in the opinion of management, such claims are either adequately covered by insurance or otherwise indemnified, or are not expected individually or in the aggregate, to result in a material, adverse effect on the Company's financial condition, results of operations or cash flows. However, it is possible that the Company's results of operations, financial position and cash flows in a particular period could be materially affected by these contingencies.

ITEM 2 – MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion and analysis of the Company's financial condition and results of operations should be read in conjunction with our condensed consolidated financial statements and the related notes thereto appearing elsewhere in this report and our consolidated financial statements for the year ended December 31, 2022, included in our Annual Report on Form 10-K. All dollar amounts in the discussion and analysis, unless noted otherwise, are presented in thousands.

Unless the context otherwise requires, all references in this report to "Axogen," the "Company," "we," "us" and "our" refer to Axogen, Inc., and its wholly owned subsidiaries Axogen Corporation ("AC"), Axogen Processing Corporation, Axogen Europe GmbH and Axogen Germany GmbH.

OVERVIEW

We are the leading company focused specifically on the science, development, and commercialization of technologies for peripheral nerve regeneration and repair. We are passionate about providing the opportunity to restore nerve function and quality of life for patients with peripheral nerve injuries. We provide innovative, clinically proven, and economically effective repair solutions for surgeons and healthcare providers. Peripheral nerves provide the pathways for both motor and sensory signals throughout the body. Every day, people suffer traumatic injuries or undergo surgical procedures that impact the function of their peripheral nerves. Physical damage to a peripheral nerve or the inability to properly reconnect peripheral nerves can result in the loss of muscle or organ function, the loss of sensory feeling, or the initiation of pain.

Product Portfolio

- Avance® Nerve Graft, a biologically active off-the-shelf processed human nerve allograft for bridging severed peripheral nerves without the comorbidities associated with a second surgical site.
- Axoguard Nerve Connector®, a porcine (pig) submucosa extracellular matrix ("ECM") coaptation aid for tensionless repair of severed peripheral nerves.
- Axoguard Nerve Protector®, a porcine submucosa ECM product used to wrap and protect damaged peripheral nerves and reinforce the nerve reconstruction while preventing soft tissue attachments.
- Axoguard HA+ Nerve Protector™, is comprised of a processed porcine submucosa ECM base layer with a hyaluronate-alginate gel coating designed to provide short- and long-term protection for peripheral nerve injuries. The gel layer facilitates enhanced nerve gliding to aid in minimizing soft tissue attachments, while the base layer is remodeled into a long-term protective tissue layer.
- Axoguard Nerve Cap®, a porcine submucosa ECM product used to protect a peripheral nerve end and separate the nerve from the surrounding environment to reduce the development of symptomatic or painful neuroma.
- Axotouch® Two-Point Discriminator, used to measure the innervation density of any surface area of the skin.

Our portfolio of products is currently available in the United States, Canada, Germany, United Kingdom, Spain and several other European, Asian and Latin American countries.

Revenue from the distribution of our nerve repair products, Avance® Nerve Graft, Axoguard Nerve Connector®, Axoguard Nerve Protector®, Axoguard HA+ Nerve Protector™, and Axoguard Nerve Cap®, in the United States ("U.S.") is the main contributor to our total reported sales and have been the key component of our growth to date.

As previously announced, we suspended the market availability of Avive® Soft Tissue Membrane ("Avive") on June 1, 2021, to have discussions with the U.S. Food and Drug Administration ("FDA") about the appropriate regulatory classification and requirements for Avive. The suspension was not based on any known or reported safety or product performance issues or concerns with Avive. Based on preliminary feedback from FDA on the product classification and regulatory pathway, we have decided not to continue discussions with FDA and will not pursue regulatory approval for Avive. Therefore, we will not seek to return Avive to the market. We are working on developing a replacement product called Avive + that would not require a BLA and would fall under the criteria set forth in 21 CFR 1271.10(a) for regulation solely under Section 361 of the Public Health Service Act and the regulations in 21 CFR Part 1271. We seek to launch Avive+ in the first quarter of 2024. Products regulated solely under Section 361 of the Public Health Service Act are a product category under close scrutiny by FDA for compliance with the regulatory requirements and potentially subject to regulatory change in the future. Failure to comply with applicable

regulatory requirements could expose us to potential compliance actions by FDA or state regulators and could risk the commercial availability of the product.

We have observed that surgeons are initially cautious adopters of nerve repair products. Surgeons typically start with a few cases and then wait and review the results of these initial cases. Active accounts are usually past this wait period and have developed some level of product reorder. These active accounts have typically gone through the Value Analysis Committee approval process, have at least one surgeon who has converted a portion of his or her treatment algorithms of peripheral nerve repair to our portfolio and have ordered our products at least six times in the last twelve months. As of September 30, 2023, we had 1016 active accounts, an increase of 6.7% from 952 as of September 30, 2022, and an increase of 4.3% from 974 compared to June 30, 2023. Active accounts are approximately 85% of our revenue. The top 10% of these active accounts continue to represent approximately 40% of our revenue.

Core accounts are defined as accounts that have purchased at least $100,000 in the past twelve months. As of September 30, 2023, we had 372 core accounts, an increase of 12% from 331 as of September 30, 2022, and an increase of 7.2% from 347 compared to June 30, 2023. These core accounts represented approximately 65% of our revenue in the quarter, which increased from approximately 60% over the past several quarters.

Our business was originally anchored in emergent trauma and over the past several years we have introduced a number of new nerve repair applications that utilize our Avance and Axoguard product lines. These new applications share common characteristics that now lead us to think about our business along two primary categories, scheduled non-trauma (“Scheduled”) procedures, and emergent trauma (“Emergent”) procedures.

Scheduled procedures are generally characterized as procedures where a patient is seeking relief of a condition caused by a nerve defect or surgical procedure. These include breast reconstruction following a mastectomy, nerve reconstruction following the surgical removal of painful neuromas, oral and maxillofacial procedures, and nerve decompression.

The nature of Scheduled procedures affords patients the opportunity to actively search for treatment options and advocate for solutions that may improve quality of life following the procedure. For example, in breast reconstruction, this may include prioritizing neurotization as a part of their treatment plan. These procedures lend themselves to standardization of surgical techniques and more consistent nerve repair algorithms. In addition, these patients are likely to engage in extended follow-up evaluations with their physicians.

Emergent procedures generally result from injuries that initially present in an emergency room. These procedures are typically referred to and completed by a specialist either immediately or within a few days following the initial injury. Given the emergent and diverse nature of traumatic injuries, the required repair algorithm and procedure scheduling can be highly variable, and follow-up evaluations are generally inconsistent.

While the various applications can have unique surgeon customers, the procedures are often performed in the same accounts and use the same family of Axogen products. Scheduled procedures typically have a higher value of Axogen products used per procedure as compared to routine trauma; and, given the planned nature of these procedures, there is a higher level of predictability and are generally additive to our sales rep productivity.

Reporting by application has historically been challenging. However, we have recently developed improved analytical tools that we believe allow us to better monitor product utilization data within accounts and generate improved estimates of our revenue by application. We estimate revenue by application using the information received from hospitals and sales representatives based on assumptions regarding specific surgeon practice and account information. Accordingly, the accuracy of our estimates is subject to the limited data we receive and the accuracy of those assumptions.

We estimate that the mix of Scheduled and Emergent procedures for fiscal year 2022 was approximately 45% Scheduled and 55% Emergent. For the nine months ended September 30, 2023, the mix has shifted to approximately 50% Scheduled and 50% Emergent; and we expect Scheduled procedure growth will continue to outpace Emergent procedure growth and continue to become a larger mix of our revenue over time.

Summary of Operational and Business Highlights

- Revenues were $41,271 for the quarter ended September 30, 2023, an increase of $4,312 or 11.7% compared to the quarter ended September 30, 2022.
- We estimate revenues from Emergent procedures represented approximately half of total revenues for the quarter ended September 30, 2023, and grew in the mid-single digit percent percent range from the quarter ended September 30, 2022.
- We estimate revenues from Scheduled non-trauma procedures represented approximately half of total revenues for the quarter ended September 30, 2023, and grew approximately 20% from the quarter ended September 30, 2022.
- Gross profit was $33,228 for the quarter ended September 30, 2023, an increase of $2,445 or 7.9% compared to the quarter ended September 30, 2022.
- We had 116 and 115 direct sales representatives as of September 30, 2023, and December 31, 2022.
- The Company is continuing to expand its offering in the nerve protection market with the national launch of Axoguard HA+ Nerve Protector™ in August, and expects to launch Avive+ Soft Tissue Matrix™ in the first quarter of 2024
- We ended the quarter with over 200 peer-reviewed clinical publications featuring our nerve repair product portfolio.
- In August. the Company began processing tissue in the new, state-of-the-art APC facility, which provides for up to 3 times current capacity and was designed for future growth and expansion
- The Company continues to anticipate a Pre-BLA meeting with the FDA in the first quarter of 2024 where it will request utilization of a rolling submission process for the Biologics License Application (BLA) for Avance Nerve Graft which would begin later in the first quarter. The Company anticipates completing the submission in the second quarter of 2024 and believes this process will support BLA approval in the first half of 2025.
- The Company has exceeded its initial goal of training 20 new surgical teams on new techniques in implant-based Resensation® and now expects to have more than 30 teams trained by the end of this year.

Results of Operations

Comparison of the Three Months Ended September 30, 2023, and 2022

The following table sets forth, for the periods indicated, our results of operations expressed as dollar amounts and percentage of total revenue:

	Three Months Ended September 30,			
	2023		2022	
	Amount	% of Revenue	Amount	% of Revenue
	(dollars in thousands)			
Revenues	$ 41,271	100.0 %	$ 36,959	100.0 %
Cost of goods sold	8,043	19.5	6,176	16.7
Gross profit	33,228	80.5	30,783	83.3
Costs and expenses				
Sales and marketing	21,429	51.9	19,792	53.6
Research and development	6,989	16.9	7,050	19.1
General and administrative	8,835	21.4	8,796	23.8
Total costs and expenses	37,253	90.3	35,638	96.4
Loss from operations	(4,025)	(9.8)	(4,855)	(13.1)
Other income (expense):				
Investment income	367	0.9	186	0.5
Interest expense	(827)	(2.0)	(61)	(0.2)
Change in fair value of derivatives	402	1.0	469	1.3
Other expense	(6)	—	(57)	(0.2)
Total other (expense) income, net	(64)	(0.2)	537	1.5
Net loss	$ (4,089)	(9.9)%	$ (4,318)	(11.7)%

Revenues

Revenues for the three months ended September 30, 2023, increased $4,312 or 12% to $41,271 as compared to $36,959 for the three months ended September 30, 2022. The increase in revenue was driven by an increase in unit volume of 8%, and a 3.5% increase in prices.

Gross Profit

Gross profit for the three months ended September 30, 2023, increased $2,445 or 8% to $33,228 as compared to $30,783 for the three months ended September 30, 2022. Gross margin was 80.5% and 83.3% for the three months ended September 30, 2023, and 2022, respectively.

Costs and Expenses

Total costs and expenses increased $1,615 or 5% to $37,253 for the three months ended September 30, 2023, as compared to $35,638 for the three months ended September 30, 2022. The net increase in total costs and expenses was primarily the result of increased compensation costs of $1,024 and marketing programs of $747, professional services of $562, partially offset by reduction in research and development projects of $750.

Sales and marketing expenses increased $1,637 or 8% to $21,429 for the three months ended September 30, 2023, as compared to $19,792 for the three months ended September 30, 2022. This increase was primarily attributable to marketing programs of $747, compensation costs of $354, and travel of $304.

Research and development expenses decreased $61 or 1% to $6,989 for the three months ended September 30, 2023, as compared to $7,050 for the three months ended September 30, 2022. The decrease was primarily due to product development and clinical expenses. Product development costs include spending in a number of specific programs including the non-clinical

expenses related to the BLA for Avance Nerve Graft. Product development expenses represented approximately 62% and 50% of total research and development expense for the three months ended September 30, 2023, and 2022, respectively. Clinical trial expenses represented approximately 38% and 50% of total research and development expense the three months ended September 30, 2023, and 2022, respectively.

General and administrative expenses increased by $39 to $8,835 for the three months ended September 30, 2023, as compared to $8,796 for the three months ended September 30, 2022. The increase was primarily due to an increase in professional services of $605 and compensation costs of $178, partially offset by a decrease in bad debt expense of $290, insurance fees of $211, and other, net of $247.

Other Income and Expense

Other expense, net increased $601 or 112% to $64 for thethree months ended September 30, 2023, as compared to other income, net of $537 for the three months ended September 30, 2022. The net increase in other expense was due to an increase in interest expense of $766 partially offset by an increase in investment income of $181.

Investment income increased $181 to $367 for the three months ended September 30, 2023, as compared to an investment income of $186 for the three months ended September 30, 2022. This change was primarily due to an increase in interest rates.

Interest expense increased $766 to $827 for the three months ended September 30, 2023, as compared to $61 for the three months ended September 30, 2022. The increase was primarily due to capitalizing less interest expense related to the Credit Facility for the three months ended September 30, 2023. We recognized total interest expense of $1,866 and $1,474 in connection with the Credit Facility for the three months ended September 30, 2023, and 2022, respectively, of which $1,043 and $1,450 of this interest was capitalized to the construction costs of the APC Facility during the third quarter of 2023 and 2022, respectively.

Taxes

We had no income tax expense or benefit during the three months ended September 30, 2023, and 2022 due to the incurrence of net operating losses in each of these periods, the benefits of which have a full valuation allowance. We do not believe that there are any additional tax expenses or benefits currently available.

Comparison of the Nine Months Ended September 30, 2023, and 2022

The following table sets forth, for the periods indicated, our results of operations expressed as dollar amounts and percentage of total revenue:

	Nine Months Ended September 30,			
	2023		2022	
	Amount	% of Revenue	Amount	% of Revenue
	(dollars in thousands)			
Revenues	$ 116,090	100.0 %	$ 102,420	100.0 %
Cost of goods sold	21,980	18.9 %	18,006	17.6 %
Gross profit	94,110	81.1 %	84,414	82.4 %
Costs and expenses				
Sales and marketing	63,885	55.0 %	60,349	58.9 %
Research and development	21,032	18.1 %	20,347	19.9 %
General and administrative	27,462	23.7 %	27,817	27.2 %
Total costs and expenses	112,379	96.8 %	108,513	105.9 %
Loss from operations	(18,269)	(15.7)%	(24,099)	(23.53)
Other income (expense):				
Investment income (loss)	1,151	1.0 %	172	0.2 %
Interest expense	(992)	(0.9)%	(664)	(0.6)%
Change in fair value of derivatives	649	0.6 %	1,155	1.1 %
Other expense	(363)	(0.3)%	(97)	(0.1)%
Total other income, net	445	0.4 %	566	0.6 %
Net loss	$ (17,824)	(15.4)%	$ (23,533)	(23.0)%

Revenues

Revenues for nine months ended September 30, 2023, increased $13,670 or 13% to $116,090 as compared to $102,420 for the nine months ended September 30, 2022. The increase in revenue was driven by an increase in unit volume of 8% as well as a 4% increase in prices and 2% in product mix.

Gross Profit

Gross profit for the nine months ended September 30, 2023, increased $9,696 or 11% to $94,110 as compared to $84,414 for the nine months ended September 30, 2022. Gross margin was 81% and 82% for the nine months ended September 30, 2023, and 2022, respectively.

Costs and Expenses

Total costs and expenses increased $3,866 or 4% to $112,379 for the nine months ended September 30, 2023, as compared to $108,513 for the nine months ended September 30, 2022. The net increase in total costs and expenses was primarily the result of increased compensation costs of $4,198, marketing programs of $1,210 and travel costs of $533 partially offset by decreases in projects of $1,612 and other, net of $472.

Sales and marketing expenses increased $3,536 or 6% to $63,885 for the nine months ended September 30, 2023, as compared to $60,349 for the nine months ended September 30, 2022. This increase was primarily attributable to other services of $1,238, marketing programs of $1,209, compensation costs of $531 and travel of $508.

Research and development expenses increased $685 or 3% to $21,032 for the nine months ended September 30, 2023, as compared to $20,347 for the nine months ended September 30, 2022. The increase was primarily due to product development and clinical expenses. Product development costs include spending in a number of specific programs including the non-clinical expenses related to the BLA for Avance Nerve Graft. Product development expenses represented approximately 60% and 51%

of total research and development expense for the nine months ended September 30, 2023, and 2022, respectively. Clinical trial expenses represented approximately 40% and 49% of total research and development expense for the nine months ended September 30, 2023, and 2022, respectively.

General and administrative expenses decreased $355 or 1% to $27,462 for the nine months ended September 30, 2023, as compared to $27,817 for the nine months ended September 30, 2022. The decrease was primarily due to a reduction in bad debt expense of $877, insurance expense of $763, merchant fees of $743, professional services of $696, other, net of $384, occupancy related costs of $207 and travel of $94 partially offset by an increase in net compensation costs of $3,411.

Other Income and Expense

Other income, net decreased $121 to $445 for the nine months ended September 30, 2023, as compared to other income, net of $566 for the nine months ended September 30, 2022. The net decrease was driven by a reduction in the change in the fair value of the derivative of $506, an increase in interest expense of $326 and other expense of $266, partially offset by the increase in investment income of $979.

Investment income increased $979 to $1,151 for the nine months ended September 30, 2023, as compared to investment income of $172 for the nine months ended September 30, 2022. This change was primarily due to increased interest rates.

Interest expense increased $328 to $992 for the nine months ended September 30, 2023, as compared to $664 for the nine months ended September 30, 2022. The increase was primarily due to capitalizing the interest expense related to APC for the nine months ended September 30, 2023. We recognized total interest expense of $5,442 and $4,304 in connection with the Credit Facility for the nine months ended September 30, 2023, and 2022, respectively, of which $5,240 and $4,474 of this interest was capitalized to the construction costs of the APC Facility during the nine months ended September 30, 2023, and 2022, respectively. The increase in total interest expense over the prior period was the result of higher interest rates on the Credit Facility.

Income Taxes

We had no income tax expense or benefit during the nine months ended September 30, 2023, and 2022 due to the incurrence of net operating losses in each of these periods, the benefits of which have a full valuation allowance. We do not believe that there are any additional tax expenses or benefits currently available.

Critical Accounting Estimates

In preparing financial statements, we follow accounting principles generally accepted in the United States, which require us to make certain estimates and apply judgments that affect our financial position and results of operations. Management regularly reviews our accounting policies and financial information disclosures. A summary of significant accounting estimates that require the use of estimates and judgments in preparing the financial statements was provided in our 2022 Annual Report on Form 10-K. During the quarter covered by this report, there were no material changes to the accounting estimates and assumptions previously disclosed.

Liquidity and Capital Resources

As of September 30, 2023, our principal sources of liquidity were our cash and cash equivalents and investments totaling $32,588. Our cash equivalents are comprised primarily of a money market mutual fund and our investments consist of primarily short-term commercial paper and U.S. Treasuries. Our cash and cash equivalents and investments decreased $16,201 from $48,789 at December 31, 2022, primarily as a result of operating activities and renovating the APC Facility.

We had working capital of $60,793 and a current ratio of 3.3x at September 30, 2023, compared to working capital of $74,322 and a current ratio of 4.1x at December 31, 2022. The decrease in our working capital at September 30, 2023, as compared to December 31, 2022, was primarily due to cash used in operations and to renovate the APC Facility, which is included in non-current assets and used in operations. Based on current estimates, we believe that our existing cash and cash equivalents and investments, as well as cash provided by sales of our products will allow us to fund our operations through at least the next 12 months.

Cash Flow Information

The following table presents a summary of cash flows from operating, investing and financing activities:

(In thousands)	Nine Months Ended September 30, 2023	2022
Net cash (used in) provided by:		
Operating activities	$ (5,505)	$ (17,428)
Investing activities	19,530	(1,991)
Financing activities	1,536	981
Net increase (decrease) in cash, cash equivalents, and restricted cash	$ 15,561	$ (18,438)

Net Cash Used in Operating Activities

Net cash used in operating activities was $5,505 and $17,428 during the nine months ended September 30, 2023, and 2022, respectively. The favorable change in net cash used in operating activities of $11,923, or 68%, is due to the decrease in net loss of $5,710 and the net favorable change of $5,157 in working capital accounts.

Net Cash Provided by (Used in) Investing Activities

Net cash provided by investing activities for the nine months ended September 30, 2023, was $19,530 as compared to net cash used in investing activities of $1,991 for the nine months ended September 30, 2022, an increase of $21,521, or 1081%. The increase of net cash provided by investing activities is principally due to the increase in the net proceeds from the sale and purchase of investments totaling $20,178, the reduction in purchases of property and equipment of $1,047 and the reduction in purchases of intangible assets of $297 during the nine months ended September 30, 2023.

Net Cash Provided by Financing Activities

Net cash provided by financing activities was $1,536 and $981 for the nine months ended September 30, 2023, and 2022, respectively, an increase of $555. The favorable change in net cash provided by financing activities was primarily due to the increase in proceeds from the exercise of stock options of $552 during the nine months ended September 30, 2023.

Sources of Capital

Our expected future capital requirements may depend on many factors including expanding our customer base and sales force and timing and extent of spending in obtaining regulatory approval and introduction of new products. Additional sources of liquidity available to us include issuance of additional equity securities through public or private equity offerings, debt financings or from other sources. The sale of additional equity may result in dilution to our shareholders. There is no assurance that we will be able to secure funding on terms acceptable to us, or at all. The increasing need for capital could also make it more difficult to obtain funding through either equity or debt. Should additional capital not become available to us as needed, we may be required to take certain actions, such as slowing sales and marketing expansion, delaying regulatory approvals, or reducing headcount.

Contractual Obligations and Forward-Looking Cash Requirements

- Capital expenditures on an annual basis generally range from $3,000 to $5,000 as a use of cash.
- We lease facilities in Florida, Ohio and Texas, and as of September 30, 2023, our total remaining obligation related to operating and financing lease payments was $35,726, of which $3,303 is due in the next 12 months. See Note 7 - Leases.

Credit Facilities

As of September 30, 2023, we had $50,000 outstanding in indebtedness under a credit facility: $35,000 maturing on June 30, 2027, and $15,000 maturing on June 30, 2028. Quarterly interest only and revenue participation payments are due through each of the maturity dates. Interest is calculated as 7.5% plus the greater of three-month SOFR plus 0.1% ("Adjusted SOFR") or 2.0% (12.84% as of September 30, 2023). Revenue participation payments are calculated as a percentage of our net revenues, up to $70,000 in any given year, adding approximately 1.0% per year of additional interest payments on the outstanding indebtedness. Upon each maturity date or upon such date earlier repayment occurs, we will repay the principal balance and

provide a make-whole payment calculated to generate an internal rate of return to the lender equal to 11.5%, less the total of all quarterly interest and revenue participation payments previously paid. See Note 8 - Long-Term Debt, Net of Debt Discount and Financing Fees and Note 12 - Commitments and Contingencies.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

For a discussion of our market risks, refer to Item 7A, “Quantitative and Qualitative Disclosures about Market Risk,” included in our 2022 Annual Report on Form 10-K.

The amount of interest expense on the outstanding debt is based or Adjusted SOFR. Changes in the Adjusted SOFR rate may affect our interest expense associated with the Credit Facility. Based on the outstanding balance of the Credit Facility as of September 30, 2023, a hypothetical 100 basis point increase in the applicable rate would result in an increase to our annual interest expense of approximately $500.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

We maintain "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"), that are designed to ensure that information required to be disclosed by us in reports we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including our principal executive officer and principal financial officer, and Board of Directors, as appropriate, to allow timely decisions regarding required disclosure. In designing and evaluating our disclosure controls and procedures, management recognizes that disclosure controls and procedures, no matter how well conceived and operated, can provide only reasonable assurance of achieving the desired objectives, and we necessarily are required to apply our judgment in evaluating the cost-benefit relationship of possible disclosure controls and procedures.

Our management, including our principal executive officer and principal financial officer, evaluated the effectiveness of our disclosure controls and procedures as of September 30, 2023, and concluded that our disclosure controls and procedures were effective.

Changes in Internal Controls Over Financial Reporting

There were no changes in our internal control over financial reporting during the three months ended September 30, 2023, that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting (as defined in Rules 13a-15(d) or 15d-15(f) of the Exchange Act).

PART II –OTHER INFORMATION

ITEM 1 – LEGAL PROCEEDINGS

As disclosed in Note 12 - Commitments and Contingencies in the Notes to Condensed Consolidated Financial Statements included in this Quarterly Report on Form 10-Q, we are engaged in certain legal proceedings, and the disclosure set forth in Note 12 - Commitments and Contingencies relating to legal proceedings is incorporated herein by reference.

ITEM 1A - RISK FACTORS

There have been no material changes to the risk factors disclosed in our 2022 Annual Report on Form 10-K, except as set forth below. Any investment in our business involves a high degree of risk. Before making an investment decision, you should carefully consider the information we include in this Quarterly Report on Form 10-Q, including our unaudited interim condensed consolidated financial statements and accompanying notes, our Annual Report on Form 10-K for the year ended December 31, 2022, including our financial statements and related notes contained therein, and the additional information in the other reports we file with the Securities and Exchange Commission. These risks may result in material harm to our business and our financial condition and results of operations. In this event, the market price of our common stock may decline, and you could lose part or all of your investment. Additional risks that we currently believe are immaterial may also impair our business operations. Our business, financial conditions and future prospects and the trading price of our common stock could be harmed as a result of any of these risks.

We are currently operating in a period of economic uncertainty and capital markets disruption, which has been significantly impacted by geopolitical instability and tensions, Russia's ongoing invasion of Ukraine and illegal annexation of Ukrainian territories, and record inflation and could materially and adversely affect our business, financial condition and results of operations.

We are exposed to the risk of changes in social, geopolitical, legal, and economic conditions. The global economy has been, and may continue to be, negatively impacted by Russia’s invasion of Ukraine and illegal annexation of Ukrainian territories. The negative impacts arising from the war and sanctions and export restrictions imposed by various countries, including those imposed by Russia, may include reduced consumer demand, supply chain disruptions, increased cybersecurity risks, and increased costs for transportation, energy, and raw materials. Additionally, further escalation of trade tensions between the U.S. and China, escalation of tensions between China and Taiwan, further escalation in the conflict between the State of Israel and Hamas, as well as further escalation of tensions between the State of Israel and various countries in the Middle East and North Africa, could result in a global economic slowdown and long-term changes to global trade. Although we do not have material operations in Russia, Ukraine, China, Taiwan, Israel or other countries in the Middle East and North Africa, further escalation of geopolitical tensions could have a broader impact that expands into other markets where we have material operations, which may adversely affect our business, financial condition and results of operations.

Further, changes in domestic and global economic conditions, supply chain disruptions, labor shortages, as well as other stimulus and spending programs, have led to higher inflation, which is likely to lead to increased costs and may cause changes in fiscal and monetary policy. Additionally, our ability to access capital markets and other funding sources in the future may not be available on commercially reasonable terms, if at all. Impacts from inflationary pressures, such as increasing costs for research and development of our products, administrative and other costs of doing business, could adversely affect our business, financial condition and results of operations.

Additionally, our customers could experience financial and operational pressures as a result of labor shortages, the supply chain disruptions, and increased inflation, which could impact their ability to access capital markets and other funding sources, increase cost of funding, or impede their ability to comply with debt covenants, which in turn could impede their ability to provide patient care, conduct further research and development, marketing and commercialization efforts, or impact their profitability. To the extent that our customers continue to face such financial pressures, it could impact their willingness to spend on our products and services, which could adversely affect our business, financial condition and results of operations.

Although, to date, our business has not been materially impacted by Russia's ongoing invasion of Ukraine and illegal annexation of Ukrainian territories, geopolitical tensions between China and the U.S., geopolitical tensions between China and Taiwan, the escalation of the conflict between the State of Israel and Hamas, or record inflation, it is impossible to predict the extent to which our operations could be impacted in the short and long term, or the ways in which such matters may impact our business.

Our failure to protect our technology systems and comply with data protection laws and regulations could lead to government enforcement actions and significant penalties against us, and adversely impact our business, results of operations, financial condition, and prospects.

We rely on information technology systems, including technology from third-party vendors, to process, transmit and store electronic information in our day-to-day operations. Similar to other companies, the size and complexity of our information technology systems makes them vulnerable to a cyber-attack, malicious intrusion, breakdown, destruction, loss of data privacy, or other significant disruption. Our information systems require an ongoing commitment of resources to maintain, protect and enhance existing systems and develop new systems to keep pace with continuing changes in information processing technology, evolving systems and regulatory standards and the increasing need to protect patient and customer information. We expend significant resources to comply with applicable data privacy and security laws and regulations (together with applicable industry standards) and minimize the risk of security breaches, including deploying additional personnel and protection technologies, training employees annually, and engaging third-party experts and contractors. Significant and increasing investments of time and resources by management and Board have been, and will continue to be, required to anticipate and address cybersecurity risks and incidents. However, given that the techniques used to obtain unauthorized access or to sabotage systems change frequently, and often are not identified until they are launched against a target, we may be unable to anticipate these techniques or implement adequate preventative measures in time to stop a cyber incident. Any failure by us to maintain or protect our information technology systems and data integrity could result in the unauthorized access to patient data and personally identifiable information, theft of intellectual property or other misappropriation of assets, or otherwise compromise our confidential or proprietary information and disrupt our operations. Cyber-attacks, intrusions, or other breaches could adversely impact our business, results of operations, financial condition, and prospects and potentially subject us to fines and penalties.

In the U.S., federal and state privacy and security laws require certain of our operations to protect the confidentiality of personal information, including patient medical records and other health information. Limiting and/or restricting the use of certain personal data and information, as well as added transparency obligations to data subjects is becoming an increasing focus as evidenced by the implementation of the California Consumer Privacy Act ("CCPA") which became effective on January 1, 2020. In Europe, E.U. member states and other foreign jurisdictions, including Switzerland, have adopted data protection laws and regulations which impose significant compliance obligations. Moreover, the collection and use of personal health data in the E.U. is governed by the European Union General Data Protection Regulation ("GDPR"). The GDPR imposes several requirements relating to the consent of the individuals to whom the personal data relates, the information provided to the individuals, the security and confidentiality of the personal data, data breach notification and the use of third-party processors in connection with the processing of personal data. The GDPR also imposes strict rules on the transfer of personal data out of the E.U. to the U.S., provides an enforcement authority and imposes large penalties for noncompliance, including the potential for fines of up to 4% of the annual global revenue of the noncompliant company. The recent implementation of the GDPR has increased our responsibility and liability in relation to personal data that we process, including in clinical trials, and we may in the future be required to put in place additional mechanisms to ensure compliance with the GDPR, which could divert management's attention and increase our cost of doing business. Additionally, we expect that there will be other proposed laws, regulations and industry standards relating to privacy and data protection in the U.S., the E.U. and other jurisdictions, and we cannot determine the impact such future laws, regulations and standards may have on our business results of operations, financial condition, and prospects.

We are dependent on internal information and telecommunications systems, and any failure of these systems, including system security breaches, data protection breaches or other cybersecurity attacks, may negatively impact our business and results of operations.

Cyber-attacks and other tactics designed to gain access to and exploit sensitive information by breaching mission critical systems of large organizations are constantly evolving and have been increasing in sophistication in recent years. High profile security breaches leading to unauthorized release of sensitive information have occurred with increasing frequency at a number of major U.S. companies, despite widespread recognition of the cyber-attack threat and improved data protection methods. While to date we have not experienced a significant data loss, significant compromise or any material financial losses related to cybersecurity attacks, our systems, those of our customers, and those of our third-party service providers are under constant threat. Cybercrime, including phishing, social engineering, attempts to overload our servers with denial-of-service attacks, or similar disruptions from unauthorized access to our systems, could cause us critical data loss or the disclosure or use of personal or other confidential information. Outside parties may attempt to fraudulently induce employees to disclose personally identifiable information or other confidential information which could expose us to a risk of loss or misuse of this information. Although we incur significant expenses to minimize the risk of security breaches, given that the techniques used to obtain unauthorized access or to sabotage systems change frequently, and often are not identified until they are launched against a

target, we may be unable to anticipate these techniques of implement adequate preventive measures in time to stop or effectively mitigate a cyber incident.

We are dependent on internal information and telecommunications systems, and we are vulnerable to failure of these systems, including through system security breaches, data protection breaches or other cybersecurity attacks. If these events occur, the unauthorized disclosure, loss or unavailability of data and disruption to our business may have a material adverse effect on our reputation and harm our relationships with vendors and customers. Additionally, these events may lead to financial losses from remedial actions, or potential liability from fines, including in relation to noncompliance with the GDPR, as well as possible litigation and punitive damages. Failures of our internal information or telecommunications systems may prevent us from taking customer orders, shipping products and billing customers. Sales may also be impacted if our customers are unable to access our pricing and product availability information. The occurrence of any of these events could have a material adverse impact on our business and results of operations.

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.

ITEM 6 - EXHIBITS

Exhibit Number	Description
10.1	Amendment to the Nerve End Cap Commercial Supply Agreement dated as of August 4, 2023, among Axogen Corporation and Cook Biotech Incorporated (incorporated by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q, filed on August 8, 2023).
10.2	Amendment No. 3 to the Distribution Agreement dated as of August 4, 2023, among Axogen Corporation and Cook Biotech Incorporated. (incorporated by reference to Exhibit 10.3 to the Company's Quarterly Report on Form 10-Q, filed on August 8, 2023).
31.1†	Certification of Principal Executive Officer pursuant to Rules 13a-14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2†	Certification of Principal Financial Officer pursuant to Rules 13a-14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32††	Certifications of the Principal Executive Officer and Principal Financial Officer pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS†	XBRL Instance Document – The instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document.
101.SCH†	XBRL Taxonomy Extension Schema Document.
101.CAL†	XBRL Taxonomy Extension Calculation Linkbase Document.
101.DEF†	XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB†	XBRL Extension Labels Linkbase.
101.PRE†	XBRL Taxonomy Extension Presentation Linkbase Document.
104	Cover Page Interactive Data File – The cover pages do not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document

† Filed herewith.

†† Furnished herewith.

** Management contract or compensatory plan or arrangement.

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.

AXOGEN, INC.

Dated: November 7, 2023

/s/ Karen Zaderej

Karen Zaderej
Chief Executive Officer and President
(Principal Executive Officer)

Dated: November 7, 2023

/s/ Peter J. Mariani

Peter J. Mariani
Executive Vice President and Chief Financial Officer
(Principal Financial and Accounting Officer)

EXHIBIT 31.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER PURSUANT TO SECTION 302 OF

THE SARBANES-OXLEY ACT OF 2002

I, Karen Zaderej, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Axogen, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 7, 2023

/s/ Karen Zaderej
Karen Zaderej
Chief Executive Officer and President

EXHIBIT 31.2

CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER PURSUANT TO SECTION 302 OF

THE SARBANES-OXLEY ACT OF 2002

I, Peter J. Mariani, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Axogen, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 7, 2023

/s/ Peter J. Mariani
Peter J. Mariani
Chief Financial Officer

EXHIBIT 32

CERTIFICATION PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002 (SUBSECTIONS (A) AND (B) OF SECTION 1350, CHAPTER 63 OF TITLE 18, UNITED STATES CODE)

In connection with the Quarterly Report on Form 10-Q (the "Report") of Axogen, Inc. (the "Company"), Karen Zaderej, Chief Executive Officer and President of the Company and Peter J. Mariani, Chief Financial Officer of the Company, each certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, to the best of her/his knowledge that:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: November 7, 2023

/s/ Karen Zaderej
Karen Zaderej
Chief Executive Officer and President
(Principal Executive Officer)

/s/ Peter J. Mariani
Peter J. Mariani
Chief Financial Officer
(Principal Financial Officer)