
**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, 2018**

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)	41-1301878 (I.R.S. Employer Identification No.)
13631 Progress Blvd., Suite 400, Alachua, FL (Address of Principal Executive Offices)	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)

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 October 26, 2018, the registrant had 38,672,871 shares of common stock outstanding.

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Forward-Looking Statements

From time to time, in reports filed with the U.S. Securities and Exchange Commission (the "SEC") (including this 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" or "our") 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 we are active, as well as our business plans. Words such as "expects", "anticipates", "intends", "plans", "believes", "seeks", "estimates", "projects", "forecasts", "continue", "may", "should", "will", variations of such words and similar expressions are intended to identify such forward-looking statements. The forward-looking statements may include, without limitation, statements regarding our growth, our 2018 and 2019 guidance, product development, product potential, financial performance, sales growth, product adoption, market awareness of our products, data validation, our visibility at and sponsorship of conferences and educational events. The forward-looking statements are subject to risks and uncertainties, which may cause results to differ materially from those set forth in the statements. Forward-looking statements in this Form 10-Q should be evaluated together with the many uncertainties that affect the Company's business and its market, particularly those discussed in the risk factors and cautionary statements in the Company's filings with the SEC, including as described in "Risk Factors" included in Item 1A of this Form 10-Q. 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 the Company assumes no responsibility to update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law.

PART 1 — FINANCIAL INFORMATION

ITEM 1 — FINANCIAL STATEMENTS

AxoGen, Inc.
Condensed Consolidated Balance Sheets
(unaudited)

	September 30, 2018	December 31, 2017
Assets		
Current assets:		
Cash and cash equivalents	\$ 25,629,057	\$ 36,506,624
Investments	100,740,344	—
Accounts receivable, net of allowance for doubtful accounts of \$737,000 and \$461,000, respectively	13,990,477	11,064,720
Inventory	10,949,045	7,315,942
Prepaid expenses and other	1,477,419	853,381
Total current assets	152,786,342	55,740,667
Property and equipment, net	7,673,263	2,197,039
Intangible assets	1,198,131	936,992
Total assets	\$ 161,657,736	\$ 58,874,698
Liabilities and Shareholders' Equity		
Current liabilities:		
Borrowings under revolving loan agreement	\$ —	\$ 4,000,000
Accounts payable and accrued expenses	11,956,797	8,952,061
Current maturities of long term obligations	35,962	735,017
Contract liabilities, current	22,540	31,668
Total current liabilities	12,015,299	13,718,746
Long Term Obligations, net of current maturities and deferred financing fees	38,314	19,809,772
Other long-term liabilities	76,002	95,514
Contract liabilities	48,694	68,631
Total liabilities	12,178,309	33,692,663
Shareholders' equity:		
Common stock, \$0.01 par value per share; 100,000,000 shares authorized; 38,672,216 and 34,350,329 shares issued and outstanding	386,722	343,503
Additional paid-in capital	294,589,477	153,167,817
Accumulated deficit	(145,496,772)	(128,329,285)
Total shareholders' equity	149,479,427	25,182,035
Total liabilities and shareholders' equity	\$ 161,657,736	\$ 58,874,698

See notes to condensed consolidated financial statements.

AxoGen, Inc.
Condensed Consolidated Statements of Operations
(unaudited)

	<u>Three Months Ended</u>		<u>Nine Months Ended</u>	
	<u>September 30,</u> <u>2018</u>	<u>September 30,</u> <u>2017</u>	<u>September 30,</u> <u>2018</u>	<u>September 30,</u> <u>2017</u>
Revenues	\$22,660,139	\$16,046,253	\$ 60,504,496	\$43,455,390
Cost of goods sold	3,464,010	2,504,278	9,282,605	6,697,127
Gross profit	19,196,129	13,541,975	51,221,891	36,758,263
Costs and expenses:				
Sales and marketing	14,653,307	9,466,496	41,148,567	27,515,266
Research and development	3,306,856	1,795,292	7,966,535	4,727,551
General and administrative	6,070,547	3,778,612	16,751,038	10,659,756
Total costs and expenses	24,030,710	15,040,400	65,866,140	42,902,573
Loss from operations	(4,834,581)	(1,498,425)	(14,644,249)	(6,144,310)
Other income (expense):				
Investment income	727,115	—	883,665	—
Interest expense	5,964	(577,941)	(1,123,861)	(1,639,874)
Interest expense — deferred financing costs	—	(46,110)	(81,329)	(136,711)
Loss on extinguishment of debt	—	—	(2,186,114)	—
Other expense	(126)	(1,603)	(15,598)	(25,388)
Total other expense	732,953	(625,654)	(2,523,237)	(1,801,973)
Net Loss	<u>\$(4,101,628)</u>	<u>\$(2,124,079)</u>	<u>\$(17,167,486)</u>	<u>\$(7,946,283)</u>
Weighted average common shares outstanding				
— basic and diluted	38,504,810	33,286,211	36,582,261	33,146,546
Loss per common share — basic and diluted	<u>\$ (0.11)</u>	<u>\$ (0.06)</u>	<u>\$ (0.47)</u>	<u>\$ (0.24)</u>

See notes to condensed consolidated financial statements.

AxoGen, Inc.
Condensed Consolidated Statements of Cash Flows
(unaudited)

	Nine Months Ended	
	September 30, 2018	September 30, 2017
Cash flows from operating activities:		
Net loss	\$ (17,167,486)	\$ (7,946,283)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	574,684	346,839
Amortization of intangible assets	58,550	60,459
Amortization of deferred financing costs	81,329	136,711
Loss on disposal of equipment	1,361	—
Loss on extinguishment of debt	2,186,114	—
Provision for bad debt	297,563	83,733
Provision for inventory write down	876,656	999,698
Changes in investment gains and losses	(375,101)	—
Share-based compensation	5,981,229	2,491,992
Change in assets and liabilities:		
Accounts receivable	(3,223,320)	(2,232,090)
Inventory	(4,509,760)	(2,239,801)
Prepaid expenses and other	(624,038)	(60,108)
Accounts payable and accrued expenses	3,004,736	70,365
Contract and other liabilities	(48,577)	99,367
Net cash used in operating activities	(12,886,060)	(8,189,118)
Cash flows from investing activities:		
Purchase of property and equipment	(6,052,269)	(616,432)
Purchase of investments	(103,865,243)	—
Sale of investments	3,500,000	—
Acquisition of intangible assets	(319,689)	(182,953)
Net cash used for investing activities	(106,737,201)	(799,385)
Cash flows from financing activities:		
Proceeds from issuance of common stock	132,963,000	—
Cash paid for equity offering	(256,770)	—
Borrowing on revolving loan	26,253,043	41,553,210
Payments on revolving loan and prepayment penalties	(30,488,886)	(41,578,233)
Repayments of long-term debt and prepayment penalties	(22,502,114)	(15,589)
Debt issuance costs	—	(29,472)
Proceeds from exercise of stock options	2,777,421	1,085,279
Net cash provided by financing activities	108,745,694	1,015,195
Net increase (decrease) in cash and cash equivalents	(10,877,567)	(7,973,308)
Cash and cash equivalents, beginning of year	36,506,624	30,014,405
Cash and cash equivalents, end of period	\$ 25,629,057	\$ 22,041,097
Supplemental disclosures of cash flow activity:		
Cash paid for interest	\$ 1,321,920	\$ 1,631,795

See notes to condensed consolidated financial statements.

AxoGen, Inc.
Notes to Condensed Consolidated Financial Statements
(unaudited)

Unless the context otherwise requires, all references in these Notes to “AxoGen,” “the Company,” “we,” “us” and “our” refer to AxoGen, Inc. and its wholly owned subsidiaries AxoGen Corporation (“AC”), AxoGen Processing Corporation, and AxoGen Europe GmbH.

1. Basis of Presentation

The accompanying unaudited condensed consolidated financial statements include the accounts of the Company as of September 30, 2018 and December 31, 2017 and for the three and nine-month periods ended September 30, 2018 and 2017. 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 of America (“US GAAP”) and should be read in conjunction with the audited financial statements of the Company for the year ended December 31, 2017, which are included in the Company’s Annual Report on Form 10-K as of and for the year ended December 31, 2017. The interim condensed consolidated financial statements are unaudited and in the opinion of management, reflect all adjustments necessary for a fair presentation of results for the periods presented. Results for interim periods are not necessarily indicative of results for the full year. All intercompany accounts and transactions have been eliminated in consolidation.

Certain prior year amounts in the interim condensed consolidated financial statements have been reclassified to match the current year’s presentation, and include other long-term liabilities of \$95,514 as of December 31, 2017 and provision for inventory write down of \$1.0 million for the nine months ended September 30, 2017.

2. Summary of Significant Accounting Policies

Revenue Recognition

On January 1, 2018, the Company adopted Financial Accounting Standards Board (FASB) Accounting Standards Codification (ASC) No. 606, Revenue from Contracts with Customers, utilizing the modified retrospective method applied to contracts that were not completed. The adoption of the standard did not have a material impact on the timing and amounts of our revenue, processes or internal controls. Upon adoption, we did not have any material remaining performance obligations, significant judgements, or material costs to obtain or fulfill contracts with our customers.

The Company enters into contracts to sell and distribute products and services to hospitals and surgical facilities for use in caring for patients with peripheral nerve damage or discontinuity. Revenue is recognized when the Company has met its performance obligations pursuant to its contracts with its customers in an amount that we expect to be entitled to in exchange for the transfer of control of the products and services to our customers. In the case of products or services sold to a customer under a distribution or purchase agreement, the Company has no further performance obligations and revenue is recognized at the point control transfers which occurs either when: i) the product is shipped via common carrier; or ii) the product is delivered to the customer or distributor, in accordance with the terms of the agreement.

A portion of the Company’s product revenue is generated from consigned inventory maintained at hospitals and distributors, and also from inventory physically held by field sales representatives. For these types of products sales, the Company retains control until the product has been used or implanted, at which time revenue is recognized.

The Company elected to account for shipping and handling activities as a fulfillment cost rather than a separate performance obligation. Amounts billed to customers for shipping and handling are included as part of the transaction price and recognized as revenue when control of the underlying products is transferred to the customer. The related shipping and freight charges incurred by the Company are included in the cost of goods sold.

The Company operates in a single reportable segment of peripheral nerve repair, offers similar products to its customers, and enters into consistently structured arrangements with similar types of customers. As such, the Company does not disaggregate revenue from contracts with customers as the nature, amount, timing and uncertainty of revenue and cash flows does not materially differ within and among the contracts with customers.

The contract with the customer states the final terms of the sale, including the description, quantity, and price of each implant distributed. The payment terms and conditions in our contracts vary; however, as a common business practice, payment terms are typically due in full within 30 to 60 days of delivery. Since the customer agrees to a stated price in the contract that does not vary over the contract term, the contracts do not contain any material types of variable consideration, and contractual rights of return are not material. The Company has several contracts with distributors in international markets which include consideration paid to the customer in exchange for distinct marketing and other services. We can reasonably estimate the fair value of such services and record such consideration paid to the customer as a reduction to revenue from the contracts with those distributor customers.

In connection with our AcroVal® Neurosensory and Motor Testing System, we sell extended warranty and service packages to some of our customers who purchase this evaluation and measurement tool, and the prepayment of these extended warranties represent contract liabilities until the performance obligations are satisfied ratably over the term of the contract. The sale of the aforementioned extended warranty represents the only performance obligation the Company satisfies over time and creates the contract liability disclosed below. The opening and closing balances of our contract receivables and liabilities are as follows:

	Contract Balances		
	Net Receivables	Contract Liabilities, Current	Contract Liabilities, Long-Term
Opening, January 1, 2018	\$ 11,064,720	\$ 31,668	\$ 68,631
Closing, September 30, 2018	13,990,477	22,540	48,694
Increase (decrease)	2,925,757	(9,128)	(19,937)

Concentrations of credit risk with respect to accounts receivable are limited because a large number of geographically diverse customers make up the Company's customer base, thus spreading the trade credit risk. The Company further controls credit risk through credit approvals and monitoring procedures.

Investments

The Company invests primarily in U.S. Government securities, corporate bonds, commercial paper and asset-backed securities and classifies all investments as available-for-sale. Investments are recorded at fair value. The Company has elected the fair value option (FVO) for all of its available-for-sale investments. The FVO election results in all changes in unrealized gains and losses being included in investment income in the Condensed Consolidated Statements of Operations.

During June 2018, the Company began investing in available-for-sale securities, and as of June 30, 2018, the fair market value of these securities and interest receivable was approximately \$81.8 million. These available-for-sale securities should have been presented as investments as of June 30, 2018; however, they were reported as cash and cash equivalents in the June 30, 2018 Condensed Consolidated Balance Sheet that was presented in the Company's Form 10-Q. Purchases of investments reported in the September 30, 2018 Condensed Consolidated Statement of Cash Flows includes approximately \$81.8 million of purchases that were made during June 2018, that were not previously reported as investments.

Income Taxes

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 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 the Internal Revenue Service include the years ended December 31, 2015 through 2017; however, there currently are no examinations in process.

Use of Estimates

The preparation of consolidated financial statements in conformity with US GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the consolidated financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ materially from those estimates.

Loss Per Share of Common Stock

Basic and diluted net loss per share is computed in accordance with FASB ASC No. 260, Earnings Per Share, by dividing the net loss by the weighted average number of common shares outstanding during the period. Since the Company has experienced net losses for all periods presented, net loss per share excludes the effect of 2,931,360 and 2,022,731 stock options and restricted stock shares as of September 30, 2018 and 2017 because they are anti-dilutive. Therefore, the number of shares calculated for basic net loss per share is also used for the diluted net loss per share calculation.

Recent Accounting Pronouncements

In May 2014, the FASB issued a new standard on revenue recognition which outlines a single comprehensive model to use in accounting for revenue arising from contracts with customers and supersedes most current revenue recognition guidance, including industry-specific guidance. The core principle of the revenue model is that an entity should recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. The standard was designed to create greater comparability for financial statement users across industries and jurisdictions and also requires enhanced disclosures. The standard could be applied retrospectively to each prior period presented or retrospectively with the cumulative effect recognized as of the adoption date. We adopted the standard on January 1, 2018 utilizing the modified retrospective method. The adoption of this standard did not have a material impact on our consolidated financial statements, other than the enhanced disclosure included in Note 2.

In February 2016, the FASB issued ASU No. 2016-02, Leases (Topic 842). This update will increase transparency and comparability among organizations by recognizing lease assets and lease liabilities on the balance sheet and disclosing key information about leasing arrangements. This update is effective for annual and interim reporting periods beginning after December 15, 2018, including interim periods within those fiscal years. Early adoption is permitted. We have begun our assessment of the impact of adopting ASU 2016-02, and expect to complete that process during the fourth quarter of 2018. We expect the adoption of ASU 2016-02 to result in an increase in right-of-use assets and lease liabilities on our consolidated statement of financial position related to our leases that are currently classified as operating leases, primarily for office and lab space.

In August 2016, the FASB issued ASU No. 2016-15, Classification of Certain Cash Receipts and Cash Payments (Topic 230). The ASU was issued intending to reduce diversity in practice in how certain cash receipts and cash payments are presented and classified in the Consolidated Statement of Cash Flows by providing guidance on eight specific cash flow issues. We prospectively adopted the standard on January 1, 2018. The adoption of this standard did not have a material impact on our consolidated financial statements.

In November 2016, the FASB issued ASU No. 2016-18, Statement of Cash Flows (Topic 230), guidance that a statement of cash flows explains the change during the period in the total of cash, cash equivalents, and amounts generally described as restricted cash or restricted cash equivalents. We prospectively adopted the standard on January 1, 2018. The adoption of this standard did not have a material impact on our consolidated Statement of Cash Flows.

In May 2017, the FASB issued ASU No. 2017-09, Compensation – Stock Compensation (Topic 718): Scope of Modification Accounting. ASU 2017-09 provides clarity on which changes to the terms or conditions of share-based payment awards require entities to apply the modification accounting provisions required in Topic 718. We prospectively adopted the standard on January 1, 2018. The adoption of this standard did not have a material impact on our consolidated financial statements.

In June 2018, the FASB issued ASU No. 2018-07, which supersedes ASC 505-50 and expands the scope of ASC 718 to include all share-based payment arrangements related to the acquisition of goods and services from both nonemployees and employees. As result, most of the guidance in ASC 718 associated with employee share-based payments, including most of its requirements related to classification and measurement, applies to nonemployee share-based payment arrangements. This update is effective for annual and interim reporting periods beginning after December 15, 2018, including interim periods within those fiscal years. Early adoption is permitted. We do not expect this standard will have a material impact on our consolidated financial statements.

In July 2018, the FASB issued ASU No. 2018-11, Targeted Improvements to ASC 842, Leases. ASU 2018-11 provided entities with the ability to elect not to recast the comparative periods presented when adopting ASC 842. We are currently evaluating our lease and other agreements to assess the impact this standard will have on our consolidated financial statements and disclosure.

In August 2018, the FASB issued ASU No. 2018-15, Guidance on Cloud Computing Arrangements. ASU 2018-15 provides guidance on implementation costs incurred in a cloud computing arrangement (CCA) that is a service contract and aligns the accounting for such costs with the guidance on capitalizing costs associated with developing or obtaining internal-use software. Specifically, the ASU amends ASC 350 to include in its scope implementation costs of a CCA that is a service contract and clarifies that a customer should apply ASC 350-40 to determine which implementation costs should be capitalized. This update is effective for annual and interim reporting periods beginning after December 15, 2019, including interim periods within those fiscal years. Early adoption is permitted. We are currently evaluating the impact this standard will have on our consolidated financial statements.

The Company's management has reviewed and considered all other recent accounting pronouncements and believe there are none that could potentially have a material impact on the Company's consolidated financial condition, results of operations, or disclosures.

3. Inventories

Inventories are comprised of unprocessed tissue, work-in-process, Avance® Nerve Graft, AxoGuard® Nerve Connector, AxoGuard® Nerve Protector, Avive® Soft Tissue Membrane, AcroVal® Neurosensory and Motor Testing System, AxoTouch® Two-Point Discriminator and supplies and are valued at the lower of cost (first-in, first-out) or net realizable value and consist of the following:

	<u>September 30, 2018</u>	<u>December 31, 2017</u>
Finished goods	\$ 8,324,019	\$5,489,360
Work in process	346,159	470,187
Raw materials	<u>2,278,867</u>	<u>1,356,395</u>
Inventories	<u>\$10,949,045</u>	<u>\$7,315,942</u>

For the three months ended September 30, 2018 and 2017, the Company had inventory write-downs of \$295,000 and \$319,000, respectively, and for the nine months ended September 30, 2018 and 2017, the Company had inventory write-downs of \$877,000 and \$1.0 million, respectively, relating primarily to product obsolescence.

4. Fair Value of Investments

The Company has elected the FVO for all investments in debt securities. Fair value is defined as the price that would be received upon the sale of an asset or paid to transfer a liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value maximize the use of observable inputs and minimize the use of unobservable inputs. The fair value hierarchy defines a three-level valuation hierarchy for classification and disclosure of fair value measurements as follows:

Level 1 – Quoted prices in active markets for identical assets or liabilities.

Level 2 – Inputs other than Level 1 that are observable, either directly or indirectly, such as quoted prices for similar assets or liabilities; quoted prices in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.

Level 3 – Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

The Company classifies cash equivalents and investments according to the hierarchy of techniques used to determine fair value based on the types of inputs.

The following table represents the Company's fair value hierarchy for its financial assets measured at fair value on a recurring basis as of September 30, 2018:

	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Other Unobservable Inputs (Level 3)	Total
Assets:				
Money market funds	\$ 14,881,346	\$ -	\$ -	\$ 14,881,346
U.S. government securities	17,865,780	-	-	17,865,780
Corporate bonds	-	65,873,445	-	65,873,445
Asset-backed securities	-	17,001,119	-	17,001,119
Total assets	<u>\$ 32,747,126</u>	<u>\$ 82,874,564</u>	<u>\$ -</u>	<u>\$ 115,621,690</u>

There were no changes in the levels or methodology of the measurement of financial assets or liabilities during the three and nine months ended September 30, 2018. The maturity date of all of the Company's investments is less than one year.

5. Property and Equipment

Property and equipment consist of the following:

	September 30, 2018	December 31, 2017
Furniture and equipment	\$ 1,646,271	\$ 1,381,595
Leasehold improvements	1,150,790	711,319
Processing equipment	2,334,959	1,839,800
Land	730,984	—
Projects in process	4,471,824	553,074
Less: accumulated depreciation and amortization	<u>(2,661,565)</u>	<u>(2,288,749)</u>
Property and equipment, net	<u>\$ 7,673,263</u>	<u>\$ 2,197,039</u>

Depreciation expense for the three months ended September 30, 2018 and 2017 was \$200,000 and \$129,000, respectively, and for the nine months ended September 30, 2018 and 2017 was \$575,000 and \$347,000, respectively.

6. Intangible Assets

The Company's intangible assets consist of the following:

	September 30, 2018	December 31, 2017
License agreements	\$1,033,591	\$1,007,566
Less: accumulated amortization	(535,762)	(485,585)
License agreements, net	\$ 497,829	\$ 521,981
Patents	753,567	459,903
Less: accumulated amortization	(53,265)	(44,892)
Patents, net	\$ 700,302	\$ 415,011
Intangible assets, net	\$1,198,131	\$ 936,992

License agreements are being amortized over periods ranging from 17-20 years. Certain patent costs of \$22,000 were being amortized over three years. As of September 30, 2018, those patents were fully amortized, and the remaining patents of \$745,000 are a combination of pending patent costs, \$69,000 of which is being amortized over periods up to 20 years. Amortization expense was approximately \$19,000 for each of the three months ended September 30, 2018 and 2017, respectively, and \$59,000 and \$60,000 for the nine months ended September 30, 2018 and 2017, respectively. As of September 30, 2018, future amortization of license agreements and patents (i) for the remainder of fiscal year 2018 is \$19,000, (ii) for the fiscal years 2019 through 2024 is expected to be \$75,000 per year, and (iii) after 2024 an aggregate \$60,000.

License Agreements

The Company has entered into multiple license agreements (together, the "License Agreements") with the University of Florida Research Foundation and the University of Texas at Austin. Under the terms of the License Agreements, the Company acquired exclusive worldwide licenses for underlying technology used in repairing and regenerating nerves. The licensed technologies include the rights to issued patents and patents pending in the United States and international markets. The effective term of the License Agreements extends through the term of the related patents and the agreements may be terminated by the Company with 60 days' prior written notice. Additionally, in the event of default, licensors may terminate an agreement if the Company fails to cure a breach after written notice. The License Agreements contain the key terms listed below:

- AxoGen pays royalty fees ranging from 1% to 3% under the License Agreements based on net sales of licensed products. One of the agreements also contains a minimum royalty of \$12,500 per quarter, which may include a credit in future quarters in the same calendar year for the amount the minimum royalty exceeds the royalty fees. Also, when AxoGen pays royalties to more than one licensor for sales of the same product, a royalty stack cap applies, capping total royalties at 3.75%;
- If AxoGen sublicenses technologies covered by the License Agreements to third parties, AxoGen would pay a percentage of sublicense fees received from the third party to the licensor. Currently, AxoGen does not sublicense any technologies covered by License Agreements. The Company is not considered a sub-licensee under the License Agreements and does not owe any sub-licensee fees for its own use of the technologies;
- AxoGen reimburses the licensors for certain legal expenses incurred for patent prosecution and defense of the technologies covered by the License Agreements; and
- Currently, under the University of Texas at Austin's agreement, AxoGen would owe a \$15,000 milestone fee upon receiving a Phase II Small Business Innovation Research or Phase II Small Business Technology Transfer grant involving the licensed technology. The Company has not received either grant and does not owe such a milestone fee. A milestone fee to the University of Florida Research Foundation of \$2,000 is due if AxoGen

receives FDA approval of its Avance® Nerve Graft, a milestone fee of \$25,000 is due upon the first commercial use of certain licensed technology to provide services to manufacture products for third parties and a milestone fee of \$10,000 is due upon the first use to manufacture products that utilize certain technology that is not currently incorporated into AxoGen products.

Royalty fees were approximately \$444,000 and \$319,000 during the three months ended September 30, 2018 and 2017, respectively, and approximately \$1.2 million and \$860,000 during the nine months ended September 30, 2018 and 2017, respectively, and are included in sales and marketing expense on the accompanying condensed consolidated statements of operations.

7. Accounts Payable and Accrued Expenses

Accounts payable and accrued expenses consist of the following:

	<u>September 30, 2018</u>	<u>December 31, 2017</u>
Accounts payable	\$ 4,787,561	\$3,237,962
Accrued expenses	1,521,195	1,770,956
Accrued compensation	5,648,041	3,943,143
Accounts Payable and Accrued Expenses	<u>\$11,956,797</u>	<u>\$8,952,061</u>

8. Term Loan Agreements and Long-Term Debt

Term Loan Agreement and Long-Term Debt consist of the following:

	<u>September 30,</u> <u>2018</u>	<u>December 31,</u> <u>2017</u>
Term Loan Agreement with MidCap Financial Trust (“MidCap”) for a total of \$21,000,000, net of \$554,100 unamortized deferred financing fees at December 31, 2017. Interest was payable monthly at 8.0% per annum plus the greater of LIBOR or 0.5%. As of September 30, 2018, the Term Loan was paid in full.	\$ —	\$20,445,900
Revolving Loan Agreement with MidCap for up to \$10,000,000 with borrowings based upon eligible accounts receivable and inventory. Interest was payable monthly at 4.5% per annum plus the greater of LIBOR or 0.5%. As of September 30, 2018, the Revolving Loan was paid in full.	—	4,000,000
Equipment Lease Agreement with Cisco Capital for a total lease amount of \$58,875 which has a 36 month term and requires no lease payments for the first three months of the lease and 33 equal payments of principal and interest until the end of the term. Interest on the lease is payable monthly at 3.5% per annum.	20,644	36,930
Equipment Lease Agreement with Raymond Leasing Corporation for a total lease amount of \$29,998 which has a 48 month term with equal payments for principal and interest until the end of the term. Interest on the lease is payable monthly at 6.7% per annum.	25,192	29,998
Equipment Lease Agreement with B&B Office Systems for a total lease amount of \$31,961 which has a 60 month term with equal payments for principal and interest until the end of the term. Interest on the lease is payable monthly at 8.5% per annum.	28,440	31,961
Total	<u>74,276</u>	<u>24,544,789</u>
Less current revolving loan	—	(4,000,000)
Less current maturities of long term debt	(35,962)	(735,017)
Long-term portion	<u>\$ 38,314</u>	<u>\$19,809,772</u>

Credit Facilities

MidCap Term Loan Agreement

On October 25, 2016 (the “Closing Date”), AxoGen and AC, each as borrowers, entered into a Credit and Security Agreement (Term Loan) (the “MC Term Loan Agreement”) with the lenders party thereto and MidCap Financial Trust (“MidCap”), as administrative agent and a lender. Under the MC Term Loan Agreement, MidCap provided the Company a term loan in the aggregate principal amount of \$21 million (the “Term Loan”) which had a maturity date of May 1, 2021 and required interest only payments through December 1, 2018, and thereafter, 30 monthly payments of principal and interest resulting in the Term Loan being fully paid by the maturity date. Interest was payable monthly at 8.0% per annum plus the greater of LIBOR or 0.5%. In addition to the interest charged on the Term Loan, the Company was also obligated to pay certain fees, including an annual agency fee of 0.25% of the aggregate principal amount of the Term Loan.

The Company had the option at any time to prepay the Term Loan in whole or in part, subject to certain conditions, a prepayment fee and a 5.0% exit fee as specified in the MC Term Loan Agreement. The prepayment fee was determined by multiplying the amount being prepaid by the following applicable percentage amount: (a) 3.0% during the first year following the Closing Date; (b) 2.0% during the second year following the Closing Date, and (c) 1.0% thereafter.

However, no prepayment fee would be due in the event the prepayment was a result of refinancing the Term Loan and Revolving Loan with MidCap or an affiliate of MidCap. On May 22, 2018, the Company paid \$22.5 million to prepay the Term Loan in full, which included exit and pre-payment fees of 5% and 2%, respectively, of the outstanding balance for a total of \$1.5 million. Included in the loss on extinguishment is the unamortized deferred financing costs associated with the Term Loan of \$473,000.

MidCap Revolving Loan Agreement

In addition, on October 25, 2016, AxoGen and AC, each as borrowers, also entered into a Credit and Security Agreement (Revolving Loan) (the "Revolving Loan Agreement") with the lenders party thereto and MidCap, as administrative agent and a lender. Under the Revolving Loan Agreement, MidCap agreed to lend to the Company up to \$10 million under a revolving credit facility (the "Revolving Loan") which amount could be drawn down by the Company based upon an available borrowing base which included certain accounts receivable and inventory. The Revolving Loan could be increased to up to \$15 million at the Company's request and with the approval of MidCap. The maturity date of the Revolving Loan was May 1, 2021. Interest was payable monthly at 4.5% per annum plus the greater of LIBOR or 0.5% on outstanding advances. In addition to the interest charged on the Revolving Loan, the Company was also obligated to pay certain fees, including a collateral management fee of 0.5% per annum of the principal amount outstanding on the Revolving Loan from time to time and an unused line fee of 0.5% per annum on the difference between the average amount outstanding on the Revolving Loan minus the total amount of the Revolving Loan commitment. The Revolving Loan was subject to a minimum balance, such that the Company paid the greater of: (i) interest accrued on the actual amount drawn under the Revolving Loan Facility; and (ii) interest accrued on 30% of the average borrowing base. If the Revolving Loan was terminated or permanently reduced prior to the maturity date, MidCap was owed a deferred revolving loan origination fee as specified in the Revolving Loan Agreement. No deferred revolving loan origination fee would be due in the event the Revolving Loan was paid in full or the termination of the revolving credit facility was a result of refinancing the Term Loan and Revolving Loan with MidCap or an affiliate of MidCap.

The MC Term Loan Agreement and the Revolving Loan Agreement each contained covenants that placed restrictions on AxoGen's operations, including, without limitation, covenants related to debt restrictions, investment restrictions, dividend restrictions, restrictions on transactions with affiliates and certain revenue covenants. MidCap, on behalf of the lenders under the agreements, had a first perfected security interest in the assets of the Company to guarantee the payment in full of the agreements. On May 22, 2018, the Company paid \$3.0 million to prepay the Revolving Loan in full, which included pre-payment fees of \$236,000.

Interest expense for the three months ended September 30, 2018 was zero, as compared to approximately \$578,000 for the three months ended September 30, 2017, and for the nine months ended September 30, 2018 and 2017, was approximately \$1.1 million and \$1.6 million, respectively.

Annual maturities of the Company's long-term obligations are as follows:

Year Ending December 31,	Amount
2018 (three months remaining)	\$ 10,404
2019	27,916
2020	13,817
2021	14,892
2022	7,247
TOTAL	<u>\$ 74,276</u>

9. Stock Incentive Plan

The Company maintains the AxoGen 2010 Stock Incentive Plan, as amended and restated (the “AxoGen Plan”), which allows for issuance of incentive stock options, non-qualified stock options, performance stock units (“PSUs”) and restricted stock units (“RSUs”) to employees, directors and consultants at exercise prices not less than the fair market value at the date of grant. At the 2017 Annual Meeting of Shareholders held on May 24, 2017, the AxoGen Plan was amended to increase the number of shares of common stock authorized for issuance under the AxoGen Plan to 7,700,000 shares. As of September 30, 2018, 1,246,405 shares of common stock were available for issuance under the AxoGen Plan.

At the 2017 Annual Meeting of Shareholders, the shareholders approved the adoption of the AxoGen 2017 Employee Stock Purchase Plan (the “2017 ESPP”), which allows for eligible employees to acquire shares of our common stock through payroll deductions at a discount from market value. The 2017 ESPP authorized a total of 600,000 shares of our common stock to be provided under the plan. As of September 30, 2018, 574,816 shares of common stock were available for issuance under the 2017 ESPP.

The options granted to employees prior to July 1, 2017 typically vest 25% one year after the grant date and 12.5% every six months thereafter for the remaining three-year period until fully vested after four years. The options granted to employees after July 1, 2017 typically vest 50% two years after the grant date and 12.5% every six months thereafter for the remaining two-year period until fully vested after four years. The options granted to directors and certain options granted from time to time to certain executive officers have vested ratably over two years, 25% per quarter over one year or had no vesting period. Options issued to consultants have vesting provisions based on the engagement ranging from no vesting to vesting over the service period ranging from three to four years. Options typically have terms ranging from seven to ten years.

The Company recognized stock-based compensation expense, which consisted of compensation expense related to employee stock options, PSUs, RSUs and the 2017 ESPP based on the value of share-based payment awards that are ultimately expected to vest during the period, of approximately \$2.2 million and \$919,000 for the three months ended September 30, 2018 and 2017, respectively, and approximately \$6.0 million and \$2.5 million for the nine months ended September 30, 2018 and 2017, respectively.

The Company estimates the fair value of each option award issued under such plans on the date of grant using a Multiple Point Black-Scholes option-pricing model which uses a weighted average of historical volatility and peer company volatility. The Company determines the expected life of each award giving consideration to the contractual terms, vesting schedules and post-vesting forfeitures. The Company uses the risk-free interest rate on the implied yield currently available on U.S. Treasury issues with an equivalent remaining term approximately equal to the expected life of the award.

The Company used the following weighted-average assumptions for options granted during the periods indicated:

Nine months ended September 30,	2018	2017
Expected term (in years)	6.22	6.16
Expected volatility	49.73 %	50.72 %
Risk free rate	2.69 %	2.07 %
Expected dividends	— %	— %

The Company granted stock-based awards for 323,670 shares of its common stock pursuant to the AxoGen Plan during the nine months ended September 30, 2018. The weighted average fair value of the awards granted at market during the nine months ended September 30, 2018 and 2017 was \$26.19 and \$6.77 per award, respectively.

At September 30, 2018, the total future stock compensation expense related to non-vested awards is expected to be approximately \$20.0 million.

10. Public Offering of Common Stock

On May 8, 2018, the Company entered into an underwriting agreement with Jefferies LLC and Leerink Partners LLC, as representatives of the several underwriters named therein (collectively, the “Underwriters”), pursuant to which the Company agreed to issue and sell 3,000,000 shares of the Company’s common stock in an underwritten registered public offering at an offering price of \$41.00 per share (the “2018 Offering”). The Company granted the Underwriters a 30-day option to purchase up to an aggregate of 450,000 additional shares of common stock, at the public offering price, less the underwriting discounts and commissions, which was exercised in full on May 9, 2018.

The 2018 Offering closed on May 11, 2018, and the Company received proceeds of approximately \$132.7 million from the sale of the shares (including the sale of 450,000 additional shares issued upon exercise of the Underwriters’ overallotment option), after deducting the underwriting discounts and commissions and estimated offering expenses.

11. Commitments and Contingencies

Operating Leases

The Company finances its use of certain facilities and equipment under committed lease arrangements provided by various institutions. Since the terms of these arrangements meet the accounting definition of operating lease agreements, the aggregate sum of future minimum lease payments is not reflected on the condensed consolidated balance sheet.

On September 20, 2018 (the “Heights Union Lease Effective Date”), the Company entered into an agreement with Heights Union, LLC, a Florida limited liability company (“Heights Union”), for the lease of 75,000 square feet of office space (the “Heights Union Premises”) in a 150,051 square foot office building that Heights Union intends to construct and complete on or before February 15, 2020, on an area of land in Tampa, Florida (the “Site”). Pursuant to the Heights Union Lease, the Company will use the Heights Union Premises for general office, medical laboratory, training and meeting purposes. Heights Union is expected to become the fee simple owner of the Site within sixty (60) days of the Heights Union Lease Effective Date. The Company has a termination right if Heights Union does not become the fee simple owner of the Site within such timeframe and, in such event, Heights Union will reimburse the Company for the Company’s actual expenses incurred in negotiating the Heights Union Lease, up to a maximum of \$100,000.

Estimated future minimum rental payments on the leases, including the lease agreement for the Heights Union Premises, are as follows:

Year Ending December 31,	Amount
2018 (three months remaining)	115,401
2019	401,876
2020	991,331
2021	2,729,840
2022	2,511,250
2023	2,574,000
Thereafter	31,510,500
TOTAL	<u>\$40,834,198</u>

Total rent expense for the Company’s leased office and lab space for the three months ended September 30, 2018 and 2017 was approximately \$141,000 and \$118,000, respectively, and for the nine months ended September 30, 2018 and 2017 was approximately \$358,000 and \$368,000, respectively.

Service Agreements

On August 6, 2015, AC entered into a License and Services Agreement (the “CTS Agreement”) with Community Blood Center (d/b/a Community Tissue Services) (“CTS”), Dayton, Ohio, an FDA registered tissue establishment.

Processing of the Avance® Nerve Graft pursuant to the CTS Agreement began in February 2016. The CTS Agreement is for a five-year term, subject to earlier termination by either party for cause (subject to the non-terminating party's right to cure, in certain circumstances), or without cause, upon 18 months' prior notice. Under the CTS Agreement, AC pays CTS a facility fee for clean room/manufacturing, storage and office space. CTS also provides services in support of AC's manufacturing such as routine sterilization of daily supplies, providing disposable supplies, microbial services and office support. During the three months ended September 30, 2018 and 2017, AxoGen paid license fees to CTS of approximately \$553,000 and \$347,000, respectively, and during the nine months ended September 30, 2018 and 2017, approximately \$1.4 million and \$1.0 million, respectively, and are included in cost of goods sold on the accompanying condensed consolidated statements of operations.

In August 2008, the Company entered into an agreement to distribute the AxoGuard® products worldwide in the field of peripheral nerve repair, and the parties subsequently amended the agreement on February 26, 2018. Pursuant to the February 2018 amendment, the agreement expires on September 30, 2027. The Cook Biotech agreement also requires certain minimum purchases, although through mutual agreement the parties have not established such minimums and to date have not enforced such provision, and establishes a formula for the transfer cost of the AxoGuard® products. Under the agreement, AxoGen provides purchase orders to Cook Biotech, and Cook Biotech fulfills the purchase orders.

In December 2011, the Company also entered into a Master Services Agreement for Clinical Research and Related Services. The Company was required to pay \$151,318 upon execution of this agreement and the remainder monthly based on activities associated with the execution of AxoGen's phase 3 pivotal clinical trial to support a biologics license application (BLA) for Avance® Nerve Graft.

Certain executive officers of the Company are parties to employment contracts. Such contracts have severance payments for certain conditions including change of control.

Concentrations

Vendor

Substantially all of AxoGen's revenue is currently derived from four products, Avance® Nerve Graft, AxoGuard® Nerve Protector, AxoGuard® Nerve Connector and Avive® Soft Tissue Membrane. AxoGen has an exclusive distribution agreement with Cook Biotech for the purchase of AxoGuard® which expires September 30, 2027. The Cook Biotech agreement also requires certain minimum purchases, although through mutual agreement the parties have not established such minimums and to date have not enforced such provision, and establishes a formula for the transfer cost of the AxoGuard® products.

The agreement allows for termination provisions for both parties. Although there are products that AxoGen believes it could develop or obtain that would replace the AxoGuard® products, the loss of the ability to sell the AxoGuard® products could have a material adverse effect on AxoGen's business until other replacement products would be available.

Processor

AxoGen is highly dependent on the continued availability of its processing facilities at CTS and could be harmed if the physical infrastructure of this facility is unavailable for any prolonged period of time. In addition, disruptions could lead to significant costs and reductions in revenues, as well as a potential harm to AxoGen's business reputation and financial results. The CTS agreement is for a five-year term, subject to earlier termination by either party at any time for cause (subject to the non-terminating party's right to cure, in certain circumstances), or without cause, upon 18 months' prior notice. Although AxoGen believes it can find and make operational a new leased facility in less than six months, the regulatory process for approval of facilities is time-consuming and unpredictable. AxoGen's ability to rebuild or find acceptable lease facilities could take a considerable amount of time and expense and could cause a significant disruption in service to its customers. AxoGen purchased a facility (the "APC") in Vandalia, Ohio in July 2018 located near AC's current leased processing facility for Avance® Nerve Graft and Avive® Soft Tissue Membrane. The APC is comprised

of a 70,000 square foot building on approximately 8.6 acres of land. It is expected that renovations to the APC will be completed by the third quarter of 2020 so that the APC can be included in our Biologics License Application (“BLA”) for the Avance® Nerve Graft. The capacity of the APC once operational, along with the ability for expansion, is expected to provide processing capabilities that will meet our intended sales growth. AxoGen believes the APC would meet its needs in the event of CTS lease termination, but, depending on timing, may not provide required processing space if the CTS facility was unavailable in the next 18 months. Although AxoGen has business interruption insurance which would, in instances other than lease termination, cover certain costs, it may not cover all costs nor help to regain AxoGen’s standing in the market.

12. Retirement Plan

AxoGen 401(k) Plan

The Company adopted the AxoGen 401(k) plan (the “401(k) Plan”) in December 2015 with contributions starting in January 2016. All full-time employees who have attained the age of 18 are eligible to participate in the 401(k) Plan. Eligibility is immediate upon employment and enrollment is available any time during employment. Participating employees may make annual pretax contributions to their accounts up to a maximum amount as limited by law. The 401(k) Plan requires the Company to make matching contributions of 3% on the first 3% of the employee’s annual salary and 1% of the next 2% of the employee’s annual salary as long as the employee participates in the 401(k) Plan. Both employee contributions and Company contributions vest immediately. Employer contributions to the 401(k) Plan for the three months ending September 30, 2018 and 2017 were approximately \$157,000 and \$114,000, respectively, and for the nine months ending September 30, 2018 and 2017 were approximately \$467,000 and \$320,000, respectively.

13. Subsequent Event

On October 26, 2018, the Company entered into an agreement (the “Ashley Avenue Lease”) for the lease of 14,647 square feet of commercial office space on the second floor of the building located at 1000 N. Ashley Drive, Tampa, Florida, 33602 (the “Ashley Avenue Premises”) from Ashley Avenue Associates I, LLC, a Delaware limited liability company (“Ashley”). Pursuant to the Ashley Avenue Lease, the Company will use the Ashley Avenue Premises for general office and meeting purposes on a short-term basis until the Heights Union Premises is completed and ready for occupancy. Under the terms of the Ashley Avenue Lease, the Company will lease the Ashley Avenue Premises for a period of twenty-four (24) months commencing on December 1, 2018; however, the Company has an option to terminate the lease after eighteen (18) months (i.e., as of May 31, 2020) by providing Ashley with four (4) months advance written notice. Annual base rent for the Ashley Avenue Premises will be \$380,000 for lease months 1 through 12 and \$392,000 for lease months 13 through 24. The Company will also be obligated to pay for its pro rata share of the building’s property taxes, utilities, insurance, administrative costs, common area maintenance and management fees, excluding any capital improvements or any damage due to fire, hurricane or other casualty. In addition, upon execution of the Ashley Avenue Lease, the Company shall pay to Ashley the sum of \$67,786 as a security deposit.

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

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, and AxoGen Europe GmbH.

OVERVIEW

We are a global leader in innovative surgical solutions for physical damage or discontinuity to peripheral nerves. We provide products and education to improve surgical treatment algorithms for peripheral nerve damage or discontinuity. Our portfolio of products includes Avance® Nerve Graft, an 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 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 injured peripheral nerves and reinforce the nerve reconstruction while preventing soft tissue attachments and Avive® Soft Tissue Membrane, a minimally processed human umbilical cord membrane that may be used as a resorbable soft tissue covering to separate tissues and modulate inflammation in the surgical bed. Along with these core surgical products, we also offer the AxoTouch® Two-Point Discriminator and AcroVal® Neurosensory and Motor Testing System. These evaluation and measurement tools assist healthcare professionals in detecting changes in sensation, assessing return of sensory, grip and pinch function, evaluating effective treatment interventions, and providing feedback to patients on peripheral nerve function. Our portfolio of products is available in the United States, Canada, the United Kingdom and several European and other international countries.

Revenue from the distribution of AxoGen’s nerve repair products, the Avance® Nerve Graft, AxoGuard® Nerve Connector, AxoGuard® Nerve Protector and Avive® Soft Tissue Membrane, in the United States is the main contributor to AxoGen’s total reported sales and has been the key component of our growth to date. AxoGen revenues continued to increase in the first nine months of 2018 compared to the same period of 2017 primarily as a result of revenue growth resulting from ongoing product penetration in active accounts, and to a lesser extent, the development and growth of new accounts.

We have experienced that surgeons initially are cautious adopters for 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 committee approval process, have at least one surgeon who has converted a portion of his or her treatment algorithms of peripheral nerve repair to the AxoGen portfolio and have ordered AxoGen products at least six times in the last 12 months. The number of active accounts at the end of the third quarter of 2018 was approximately 679, representing an increase of 21% compared to 563 at the end of the third quarter of 2017.

As such, revenue growth is primarily due to increased purchases from active accounts, followed by revenue growth from new accounts. Each new period of measurement is thus benefited from growth in active accounts which may include those that were new accounts in the prior measurement period. We have continued to broaden our sales and marketing focus which we expect to have a continuing positive contribution to our revenue growth in the long-term.

There have been no significant changes to our critical accounting policies from those disclosed in our 2017 Annual Report on Form 10-K except for the adoption of the new standard related to revenue recognition, as described in Note 2 to the interim unaudited condensed consolidated financial statements.

Results of Operations

Comparison of the Three Months Ended September 30, 2018 and 2017

Revenues

Revenues for the three months ended September 30, 2018 increased 41% to \$22.7 million as compared to \$16.0 million for the three months ended September 30, 2017. This increase was primarily the result of unit revenue growth in active accounts and, to a lesser extent, the establishment of new accounts, as well as a product price increase implemented earlier in 2018.

Gross Profit

Gross profit for the three months ended September 30, 2018 increased 42% to \$19.2 million as compared to \$13.5 million for the three months ended September 30, 2017. This increase was primarily attributable to the increased revenues. Gross margin increased slightly to 84.7% for the three months ended September 30, 2018 as compared to 84.4% for the same period in 2017.

Costs and Expenses

Total costs and expenses increased 60% to \$24.0 million for the three months ended September 30, 2018 as compared to \$15.0 million for the three months ended September 30, 2017, primarily due to increased sales activity, costs associated with increases in personnel to support our growth (including non-cash stock compensation of \$2.2 million), increases in research and development, which includes product development and clinical trial costs, and increased general expenses associated with our continuing organizational growth. As a percentage of total revenues, total cost and expenses increased to 106.0% for the three months ended September 30, 2018 as compared to 93.8% for the three months ended September 30, 2017, primarily as a result of the increase in total costs outpacing the increase in total revenues as we have continued to invest in the expansion of our commercial team, research and development activities, and infrastructure.

Sales and marketing expenses increased 55% to \$14.7 million for the three months ended September 30, 2018 as compared to \$9.5 million for the three months ended September 30, 2017. This increase was primarily due to increased compensation expenses related to our direct sales force as a result of continued hiring of additional personnel, increased commissions as a result of increased revenue and distribution, and market development activities. As a percentage of total revenues, sales and marketing expenses were 64.7% for the three months ended September 30, 2018 as compared to 59.4% for the three months ended September 30, 2017, primarily as a result of the continuing investment to expand our markets and commercial team.

General and administrative expenses increased 61% to \$6.1 million for the three months ended September 30, 2018 as compared to \$3.8 million for the three months ended September 30, 2017, primarily as the result of increased compensation (including non-cash stock compensation of \$1.2 million) and professional fees, and increased general expenses related to our continuing efforts to expand our resources to support our growth. As a percentage of total revenues, general and administrative expenses were 26.8% for the three months ended September 30, 2018 as compared to 23.8% for the three months ended September 30, 2017, primarily as a result of the increase in general and administrative expenses related to increased headcount to support our continuing growth.

Research and development expenses increased 84% to \$3.3 million for the three months ended September 30, 2018 as compared to \$1.8 million for the three months ended September 30, 2017. Research and development costs include our product and application development and clinical efforts substantially focused on our biologics license application (BLA) for the Avance® Nerve Graft, investigator-initiated studies and development of new products and product applications. This activity varies from quarter to quarter due to the timing of certain projects. The increase in expenses for the third quarter of 2018 related to expenditures to support our clinical activities and increased compensation from the hiring of additional personnel to support both clinical and new product development efforts. Although our products are developed for distribution in their current use, we continue to conduct development efforts focused on new products and new product applications. From time to time, we pursue research grants to support research and early product development. As a percentage of total revenues, research and development expenses for the three months ended

September 30, 2018 were 14.6% as compared to 11.2% for the three months ended September 30, 2017, as we continued to invest in growing our product development team and clinical studies.

Other Income and Expenses

For the three months ended September 30, 2018, we recognized \$727,000 of investment income from our asset management and cash investment sweep accounts that were opened during the second quarter of 2018. As a result of the prepayment in full of the Term Loan and Revolving Loan with MidCap during the second quarter of 2018, interest expense and deferred financing costs were eliminated for the three months ended September 30, 2018 as compared to \$578,000 and \$46,000, respectively, for the three months ended September 30, 2017.

Income Taxes

We had no income tax expenses or income tax benefit for each of the three months ended September 30, 2018 and 2017, due to the incurrence of net operating losses in each of these periods, the benefits of which have been fully reserved. We do not believe that there are any additional tax expenses or benefits currently available.

Comparison of the Nine Months Ended September 30, 2018 and 2017:

Revenues

Revenues for the nine months ended September 30, 2018 increased 39% to \$60.5 million as compared to \$43.5 million for the nine months ended September 30, 2017. This increase was primarily the result of revenue growth in active accounts due to penetration of our nerve repair platform in those accounts and, to a lesser extent, the establishment and growth of new accounts and a product price increase implemented earlier in the year in 2018.

Gross Profit

Gross profit for the nine months ended September 30, 2018 increased 39% to \$51.2 million as compared to \$36.8 million for the nine months ended September 30, 2017, primarily as a result of the increased revenues. Gross margin was relatively unchanged at 84.7% for the nine months ended September 30, 2018 as compared to 84.6% for the same period in 2017.

Costs and Expenses

Total cost and expenses increased 54% to \$65.9 million for the nine months ended September 30, 2018 as compared to \$42.9 million for the nine months ended September 30, 2017. These increases were due primarily to increased sales activity, expansion of our commercial team, ongoing clinical activities, increases in compensation (including non-cash stock compensation of \$6.0 million) and increased general expenses associated with our growth. As a percentage of revenue, total cost and expenses increased to 108.9% for the nine months ended September 30, 2018 as compared to 98.6% for the nine months ended September 30, 2017. Growth in expenses outpaced our revenue growth as we continued to invest in capability development across the organization, including our commercial organization, product development and clinical activities, and administrative expenses in support of growth.

Sales and marketing expenses increased 50% to \$41.1 million for the nine months ended September 30, 2018 as compared to \$27.5 million for the nine months ended September 30, 2017. This increase was primarily due to increased compensation expenses related to our direct sales force as a result of increased sales and hiring of additional personnel, and increased marketing and market development activity. As a percentage of revenues, sales and marketing expenses were 68.0% for the nine months ended September 30, 2018 as compared to 63.2% for the nine months ended September 30, 2017, primarily as a result of our expenses to increase our commercial team and activities outpacing increases in our sales revenues.

General and administrative expenses increased 57% to \$16.8 million for the nine months ended September 30, 2018 as compared to \$10.7 million for the nine months ended September 30, 2017. The increase was primarily the result of increased compensation (including non-cash stock compensation of \$3.3 million), professional fees and increased general expenses related to our continuing efforts to expand our resources to support our growth. As a percentage of

revenues, general and administrative expenses were 27.7% for the nine months ended September 30, 2018 as compared to 24.6% for the nine months ended September 30, 2017, as growth in expenses continued to outpace our revenue growth as we expand our infrastructure to support our organizational growth.

Research and development costs increased 69% to \$8.0 million for the nine months ended September 30, 2018 as compared to \$4.7 million for the nine months ended September 30, 2017. Research and development costs include our product and application development and clinical efforts substantially focused on our BLA for the Avance® Nerve Graft as well as investigator-initiated studies and development of new products and product applications. This activity varies from quarter to quarter due to the timing of certain projects. The increase in expenses for the first nine months of 2018 relates to expenditures for clinical study activities and increased compensation from the hiring of additional personnel to support both clinical and new product development projects. Although our products are developed for distribution in their current use, we continue to conduct development efforts focused on new products and new product applications. From time to time, we pursue research grants to support research and early product development. As a percentage of revenues, research and development expenses for the nine months ended September 30, 2018 were 13.2% as compared to 10.8% for the nine months ended September 30, 2017, as we continue to invest in new product development, personnel and our continuing clinical activities.

Other Income and Expenses

For the nine months ended September 30, 2018, we recognized \$884,000 of investment income from our asset management and cash investment sweep accounts that were opened during the second quarter of 2018. As a result of the prepayment in full of the Term Loan and Revolving Loan with MidCap during the second quarter of 2018, interest expense decreased 32% to \$1.1 million for the nine months ended September 30, 2018 as compared to \$1.6 million for the nine months ended September 30, 2017, and interest expense – deferred financing costs decreased 41% to approximately \$81,000 for the nine months ended September 30, 2018 as compared to approximately \$137,000 for the nine months ended September 30, 2017. For the nine months ended September 30, 2018, we incurred a loss on the extinguishment of the debt of \$2.2 million for exit, prepayment fees and the amortization of the remaining balance of the deferred financing costs.

Income Taxes

We had no income tax expenses or income tax benefit for each of the nine months ended September 30, 2018 and 2017, due to the incurrence of net operating losses in each of these periods, the benefits of which have been fully reserved. We do not believe that there are any additional tax expenses or benefits currently available.

Effect of Inflation

Inflation did not have a significant impact on the Company's net sales, revenues or income from continuing operations during 2018 or the fiscal years ended 2017, 2016 and 2015.

Liquidity and Capital Resources

Cash Flow Information

As of September 30, 2018, the Company had cash and cash equivalents of \$25.6 million, a decrease of \$10.9 million from \$36.5 million at December 31, 2017, primarily as a result of the proceeds, net of expenses, of \$132.7 million from the public offering of common stock completed in May 2018, \$120.0 million of which was invested in a custodial asset management account. As of September 30, 2018, the asset management account had a balance of \$115.6 million. Cash disbursements in the first nine months included \$2.5 million for the 2017 all-employee performance bonus and related costs, \$25.5 million for the prepayment in full of the Term Loan and Revolving Loan with MidCap, and \$5.0 million for the acquisition of the APC.

The Company had working capital of \$140.8 million and a current ratio of 12.7 at September 30, 2018, compared to working capital of \$42.0 million and a current ratio of 4.06 at December 31, 2017. The increase in working capital and the current ratio at September 30, 2018 as compared to December 31, 2017 was due primarily to the proceeds from the public offering, offset by use of working capital to fund operations including the payment of the 2017 performance

bonus and related costs, the prepayment of the Term Loan and Revolving Loan with MidCap, and the acquisition of the APC. The Company believes it has sufficient cash resources to meet its liquidity requirements for at least the next 12 months based on its expected level of operations.

AxoGen's future capital requirements depend on a number of factors including, without limitation, revenue increases consistent with its business plan, cost of products and acquisition and/or development of new products. AxoGen could face increasing capital needs. Such capital needs could be substantial depending on the extent to which AxoGen is unable to increase revenue.

If AxoGen needs additional capital in the future, it may raise additional funds through public or private equity offerings, debt financings or from other sources. The sale of additional equity would result in dilution to AxoGen's shareholders. There is no assurance that AxoGen will be able to secure funding on terms acceptable to it, 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 AxoGen as needed, AxoGen may be required to take certain actions, such as slowing sales and marketing expansion, delaying regulatory approvals or reducing headcount.

The Company's principal sources and uses of funds are explained below:

Cash used in operating activities

Operating activities for the nine months ended September 30, 2018 used \$12.9 million of cash as compared to using \$8.2 million of cash for operating activities for the nine months ended September 30, 2017. This increase in cash used for operating activities of approximately \$4.7 million was primarily attributable to higher net losses after adjusting for higher non-cash expenses, including stock-based compensation and depreciation in 2018 compared to 2017, coupled with the loss on extinguishment of our debt and increases in accounts receivable and inventory, which were partially offset by an increase in accounts payable and accrued expenses.

Cash used for investing activities

Investing activities for the nine months ended September 30, 2018 used \$106.7 million of cash as compared to using \$799,000 of cash for the nine months ended September 30, 2017. This increase in cash used for investing activities of \$105.9 million was principally attributable to the short-term investments in the asset management account, the acquisition of the APC, along with ongoing investments for capital equipment and leasehold improvements in our expanded corporate headquarters facility to support the continuing growth of our business.

Cash provided by financing activities

Financing activities for the nine months ended September 30, 2018 provided \$108.7 million of cash as compared to providing \$1.0 million of cash for the nine months ended September 30, 2017. The increase of \$107.7 million in cash provided by financing activities was primarily the result of the net proceeds of \$132.7 million from the public stock offering, offset by the \$26.7 million of payments on the Company's debt, including the prepayment of the Term Loan and Revolving Loan with MidCap and related fees. Proceeds from the exercise of stock options provided \$2.8 million and \$1.1 million of cash for the nine months ended September 30, 2018 and 2017, respectively.

Credit Facilities

On October 25, 2016 (the "Closing Date"), AxoGen and AC, each as borrowers, entered into a Credit and Security Agreement (Term Loan) (the "MC Term Loan Agreement") with the lenders party thereto and MidCap Financial Trust ("MidCap"), as administrative agent and a lender. Under the MC Term Loan Agreement, MidCap provided the Company a term loan in the aggregate principal amount of \$21 million (the "Term Loan") which had a maturity date of May 1, 2021 and required interest only payments through December 1, 2018, and thereafter, 30 monthly payments of principal and interest resulting in the Term Loan being fully paid by the maturity date. Interest was payable monthly at 8.0% per annum plus the greater of LIBOR or 0.5%. In addition to the interest charged on the Term Loan, the Company was also obligated to pay certain fees, including an annual agency fee of 0.25% of the aggregate principal amount of the Term Loan.

The Company had the option at any time to prepay the Term Loan in whole or in part, subject to certain conditions, a prepayment fee, and a 5.0% exit fee as specified in the MC Term Loan Agreement. The prepayment fee was determined by multiplying the amount being prepaid by the following applicable percentage amount: (a) 3.0% during the first year following the Closing Date; (b) 2.0% during the second year following the Closing Date, and (c) 1.0% thereafter. However, no prepayment fee would be due in the event the prepayment was a result of refinancing the Term Loan and Revolving Loan with MidCap or an affiliate of MidCap. On May 22, 2018, the Company paid \$22.5 million to prepay the Term Loan in full, which included exit and pre-payment fees of 5% and 2%, respectively, of the outstanding balance for a total of \$1.5 million. In addition to the prepayment fees, the Company charged to interest expense the unamortized deferred financing costs associated with the Term Loan of \$473,000.

In addition, on October 25, 2016, AxoGen and AC, each as borrowers, also entered into a Credit and Security Agreement (Revolving Loan) (the "Revolving Loan Agreement") with the lenders party thereto and MidCap, as administrative agent and a lender. Under the Revolving Loan Agreement, MidCap agreed to lend to the Company up to \$10 million under a revolving credit facility (the "Revolving Loan") which amount could be drawn down by the Company based upon an available borrowing base which included certain accounts receivable and inventory. The Revolving Loan could be increased to up to \$15 million at the Company's request and with the approval of MidCap. The maturity date of the Revolving Loan was May 1, 2021. Interest was payable monthly at 4.5% per annum plus the greater of LIBOR or 0.5% on outstanding advances. In addition to the interest charged on the Revolving Loan, the Company was also obligated to pay certain fees, including a collateral management fee of 0.5% per annum of the principal amount outstanding on the Revolving Loan from time to time and an unused line fee of 0.5% per annum on the difference between the average amount outstanding on the Revolving Loan minus the total amount of the Revolving Loan commitment. The Revolving Loan was subject to a minimum balance, such that the Company paid the greater of: (i) interest accrued on the actual amount drawn under the Revolving Loan Facility; and (ii) interest accrued on 30% of the average borrowing base. If the Revolving Loan was terminated or permanently reduced prior to the maturity date, MidCap was owed a deferred revolving loan origination fee as specified in the Revolving Loan Agreement. No deferred revolving loan origination fee would be due in the event the Revolving Loan was paid in full or the termination of the revolving credit facility was a result of refinancing the Term Loan and Revolving Loan with MidCap or an affiliate of MidCap.

The MC Term Loan Agreement and the Revolving Loan Agreement each contained covenants that placed restrictions on AxoGen's operations, including, without limitation, covenants related to debt restrictions, investment restrictions, dividend restrictions, restrictions on transactions with affiliates and certain revenue covenants. MidCap, on behalf of the lenders under the agreements, had a first perfected security interest in the assets of the Company to guarantee the payment in full of the agreements. On May 22, 2018, the Company paid \$3.0 million to prepay the Revolving Loan in full, which included pre-payment fees of \$236,000.

Material Commitments

The Company had no material commitments for capital expenditures at September 30, 2018.

Off-Balance Sheet Arrangements

AxoGen does not have any off-balance sheet arrangements.

Contractual Obligations

The following table summarizes our obligations with regard to our contractual obligations as of September 30, 2018, and the expected timing of maturities of those contractual obligations. These amounts include the expected future rental payments related to the conditional lease agreement with Heights Union, LLC, for office and lab facilities in Tampa, Florida. This table should be read in conjunction with the notes to the unaudited condensed consolidated financial statements included elsewhere in this quarterly report on Form 10-Q.

Contractual Obligations	Total	Less than 1 year	1-3 years	3-5 years	More than 5 years
Operating leases	\$40,834,198	\$ 115,401	\$ 1,393,207	\$5,241,090	\$34,084,500
Capital lease minimum lease payments	74,276	10,404	41,733	22,139	-
	<u>\$40,908,474</u>	<u>125,805</u>	<u>1,434,940</u>	<u>5,263,229</u>	<u>\$34,084,500</u>

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

The following discussion about our exposure to market risk of financial instruments contains forward-looking statements under the Private Securities Litigation Reform Act of 1995. Actual results may differ materially from those described due to a number of factors, including uncertainties associated with general economic conditions and conditions impacting our industry.

We are exposed to certain market risks in the ordinary course of business.

Financial instruments that potentially subject us to concentrations of credit risk consist primarily of cash and cash equivalents and accounts receivables. We maintain our accounts for cash and cash equivalents principally at one major bank and one investment firm in the United States. We have not experienced any losses on our deposits of our cash and cash equivalents.

With respect to accounts receivable, we perform credit evaluations of our customers and do not require collateral. There have been no material losses on accounts receivables. Concentrations of credit risk with respect to accounts receivable are limited because a large number of geographically diverse customers make up the Company's customer base, thus spreading the trade credit risk. The Company also controls credit risk through credit approvals and monitoring procedures.

We are subject to market risk from exposure to changes in interest rates based upon our investing and cash management activities. Changes in interest rates affect interest income earned on cash and cash equivalents. We have not entered into derivative transactions related to cash and cash equivalents. We do not expect changes in interest rates to have a material adverse effect on our income or our cash flows in 2018. However, we can give no assurance that interest rates will not significantly change in the future.

The value of the U.S. dollar compared to the Euro has little to no effect on our financial results. International business transactions are currently invoiced in U.S. dollars. As a result, the Company has minimal exposure related to exchange rate fluctuations.

In the United States, we sell our products directly to hospitals and clinics in the local currency. Revenue is recognized as disclosed in Note 2 - Summary of Significant Accounting Policies - Revenue Recognition in our Notes to the Unaudited Condensed Consolidated Financial Statements.

In all international markets, we distribute our products and services to independent distributors who, in turn, distribute and market to medical clinics. The revenue from the distribution of our products in these countries through independent distributors is denominated in United States dollars.

We do not believe our operations are currently subject to significant market risks for foreign currency exchange rates, commodity prices or other relevant market price risks of a material nature.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

The Company maintains “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 the design and operation of our disclosure controls and procedures as of September 30, 2018 and concluded that our disclosure controls and procedures were effective.

Changes in Internal Controls Over Financial Reporting

There have not been any changes in our internal control over financial reporting identified in management’s evaluation pursuant to Rules 13a-15(d) or 15d-15(d) of the Exchange Act during the three months ended September 30, 2018 that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II – OTHER INFORMATION

ITEM 1 – LEGAL PROCEEDINGS

From time to time, we may be a party to various lawsuits, claims and other legal proceedings that arise in the ordinary course of our business, some of which relate to some or all of certain of our patents. While it is not possible to determine the outcome of these matters, management does not expect that the ultimate costs to resolve these matters will materially adversely affect our business, financial position, or results of operations.

AxoGen and its subsidiaries are not a party to any material litigation as of September 30, 2018.

ITEM 1A - RISK FACTORS

The Company faces a number of risks and uncertainties. In addition to the other information in this report and the Company’s other filings with the SEC, readers should consider carefully the risk factors discussed in Part I “Item 1A. Risk Factors” in the Company’s 2017 annual report on Form 10-K. If any of these risks actually occur, the Company’s business, results of operations or financial condition could be materially adversely affected. Other than as described below, there have been no material changes to these risk factors since the filing of the Company’s 2017 annual report on Form 10-K.

AxoGen’s failure to comply with data protection laws and regulations could lead to government enforcement actions and significant penalties against AxoGen, and adversely impact AxoGen’s operating results.

European Union 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 European Union, which was formerly governed by the provisions of the European Union Data Protection Directive, was replaced with the European Union General Data Protection Regulation, or the GDPR, in May 2018. The GDPR, which is wide-ranging in scope, 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 European Union to the United States, provides an enforcement authority and imposes large penalties for noncompliance, including the potential for fines of up to €20 million or 4% of the annual global revenues of the noncompliant company, whichever is greater. The recent implementation of the GDPR has increased AxoGen's responsibility and liability in relation to personal data that AxoGen processes, including in clinical trials, and AxoGen 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 AxoGen's cost of doing business. In addition, new regulation or legislative actions regarding data privacy and security (together with applicable industry standards) may increase AxoGen's costs of doing business. In this regard, AxoGen expects that there will continue to be new proposed laws, regulations and industry standards relating to privacy and data protection in the United States, the European Union and other jurisdictions, and AxoGen cannot determine the impact such future laws, regulations and standards may have on its business.

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	Agreement for Purchase and Sale of Real Property, dated as of June 8, 2018, by and between AxoGen Corporation and ARC CRVANO001, LLC, a Delaware limited liability company (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K, filed on July 12, 2018).
**10.2	Executive Employment Agreement, dated as of September 4, 2018, by and between AxoGen Corporation and Angelo Scopelianos (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed on September 7, 2018).
10.3	Letter Agreement, effective as of September 20, 2018, by and between AxoGen Corporation and SNH Medical Office Properties Trust (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed on September 21, 2018).
10.4	Office Lease, dated September 20, 2018, by and between AxoGen, Inc. and AxoGen Corporation and Heights Union, LLC (incorporated by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K filed on September 21, 2018).
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.
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.

** Management contract or compensatory plan or arrangement

† Filed herewith.

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** Management contract or compensatory plan or arrangement

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†† Furnished herewith.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

AXOGEN, INC.

Dated: October 29, 2018

/s/ Karen Zaderej

Karen Zaderej
Chief Executive Officer
(Principal Executive Officer)

Dated: October 29, 2018

/s/ Peter J. Mariani

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

**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: October 29, 2018

/s/ Karen Zaderej
Karen Zaderej
Chief Executive Officer

**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: October 29, 2018

/s/ Peter J. Mariani

Peter J. Mariani
Chief Financial Officer

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 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: October 29, 2018

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

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