Table of Contents

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, 2016**

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	**41-1301878**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
13631 Progress Blvd., Suite 400, Alachua, FL	**32615**
(Address of principal executive offices)	(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 and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted 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 and post such files). YES ☒ NO ☐

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

Large accelerated filer ☐ Accelerated filer ☐

Non-Accelerated filer ☐ (Do not check if a smaller reporting company) Smaller reporting company ☒

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

As of November 2, 2016, the registrant had 32,898,115 shares of common stock outstanding.

Table of Contents

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. (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 2016 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

	September 30, 2016	December 31, 2015
	(unaudited)	
Assets		
Current assets:		
Cash and cash equivalents	$ 16,003,245	$ 25,909,500
Accounts receivable, net of allowance for doubtful accounts of approximately $249,000 and $192,000 respectively	7,004,756	4,782,989
Inventory	4,970,819	3,933,960
Prepaid expenses and other	685,711	424,925
Total current assets	28,664,531	35,051,374
Property and equipment, net	1,320,711	970,870
Intangible assets	787,523	678,082
	$ 30,772,765	$ 36,700,326
Liabilities and Shareholders' Equity		
Current liabilities:		
Accounts payable and accrued expenses	$ 4,559,394	$ 3,695,127
Current deferred revenue	36,032	14,118
Total current liabilities	4,595,426	3,709,245
Note Payable - Revenue Interest Purchase Agreement	24,996,070	24,701,693
Long Term Deferred Revenue	77,610	93,797
Total liabilities	29,669,106	28,504,735
Shareholders' equity:		
Common stock, $0.01 par value per share; 50,000,000 shares authorized; 30,209,036 and 29,984,591 shares issued and outstanding	302,090	299,846
Additional paid-in capital	113,058,408	111,368,424
Accumulated deficit	(112,256,839)	(103,472,679)
Total shareholders' equity	1,103,659	8,195,591
	$ 30,772,765	$ 36,700,326

See notes to condensed consolidated financial statements.

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

	Three Months Ended		Nine Months Ended	
	September 30, 2016	September 30, 2015	September 30, 2016	September 30, 2015
Revenues	$ 11,205,224	$ 8,153,675	$ 29,698,866	$ 19,522,244
Cost of goods sold	1,697,443	1,410,416	4,637,446	3,433,138
Gross profit	9,507,781	6,743,259	25,061,420	16,089,106
Costs and expenses:				
Sales and marketing	7,090,059	5,512,613	20,076,297	14,257,397
Research and development	1,118,358	936,015	3,033,521	2,343,450
General and administrative	2,481,051	2,212,457	7,362,063	6,103,058
Total costs and expenses	10,689,468	8,661,085	30,471,881	22,703,905
Loss from operations	(1,181,687)	(1,917,826)	(5,410,461)	(6,614,799)
Other income (expense):				
Interest expense	(1,089,134)	(1,042,258)	(3,255,574)	(3,060,779)
Interest expense — deferred financing costs	(31,748)	(31,419)	(95,254)	(96,375)
Other income (expense)	(2,804)	12,645	(22,871)	27,021
Total other income (expense)	(1,123,686)	(1,061,032)	(3,373,699)	(3,130,133)
Net Loss	$(2,305,373)	$(2,978,858)	$(8,784,160)	$(9,744,932)
Weighted Average Common Shares outstanding — basic and diluted	30,152,279	26,841,060	30,075,715	24,778,123
Loss Per Common share — basic and diluted	$ (0.08)	$ (0.11)	$ (0.29)	$ (0.39)

See notes to condensed consolidated financial statements.

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

	Nine Months Ended September 30,	
	2016	2015
Cash flows from operating activities:		
Net loss	$ (8,784,160)	$ (9,744,932)
Adjustments to reconcile net loss to net cash used for operating activities:		
Depreciation	263,133	142,038
Amortization of intangible assets	48,050	34,009
Amortization of deferred financing costs	95,253	96,375
Provision for bad debt	80,934	—
Stock-based compensation	1,046,364	1,031,218
Interest added to note payable	199,124	451,590
Change in assets and liabilities:		
Accounts receivable	(2,302,701)	(1,770,494)
Inventory	(1,036,859)	(488,135)
Prepaid expenses and other	(260,786)	(180,862)
Accounts payable and accrued expenses	864,267	1,655,114
Deferred revenue	5,727	(16,187)
Net cash used for operating activities	(9,781,654)	(8,790,266)
Cash flows from investing activities:		
Purchase of property and equipment	(612,974)	(353,093)
Acquisition of intangible assets	(157,491)	(92,184)
Net cash used for investing activities	(770,465)	(445,277)
Cash flows from financing activities:		
Proceeds from issuance of common stock	—	30,970,735
Debt issuance costs	—	(180,142)
Proceeds from exercise of stock options	645,864	164,626
Net cash provided by financing activities	645,864	30,955,219
Net increase (decrease) in cash and cash equivalents	(9,906,255)	21,719,676
Cash and cash equivalents, beginning of year	25,909,500	8,215,791
Cash and cash equivalents, end of period	$16,003,245	$29,935,467
Supplemental disclosures of cash flow activity:		
Cash paid for interest	$ 3,031,528	$ 1,949,381

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 subsidiary AxoGen Corporation ("AC").

1. Basis of Presentation

The accompanying condensed consolidated financial statements include the accounts of AxoGen, Inc. (the "Company" or "AxoGen") and its wholly owned subsidiary AxoGen Corporation ("AC") as of September 30, 2016 and December 31, 2015 and for the three and nine month periods ended September 30, 2016 and 2015. The Company's condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("GAAP") and should be read in conjunction with the audited financial statements of the Company for the year ended December 31, 2015, which are included in the Company's Annual Report on Form 10-K as of and for the year ended December 31, 2015. 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 significant intercompany accounts and transactions have been eliminated in consolidation.

2. Organization and Business

Business Summary

We are a global leader in innovative surgical solutions for peripheral nerve injuries. Our portfolio of products includes Avance® Nerve Graft, an off-the-shelf processed human nerve allograft for bridging severed 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 nerves, and 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. Along with these core surgical products, AxoGen also offers AxoTouch™ Two-Point Discriminator and AcroVal™ Neurosensory & 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 nerve function. The AxoGen portfolio of products is available in the United States, Canada, the United Kingdom and several European and international countries.

Avance® Nerve Graft is processed in the United States by AxoGen. AxoGuard® Nerve Connector and AxoGuard® Nerve Protector are manufactured in the United States by Cook Biotech Incorporated and are distributed worldwide exclusively by AxoGen. The AcroVal™ Neurosensory and Motor Testing System and AxoTouch™ Two Point Discriminator are contract manufactured by Viron Technologies, LLC. (formerly Cybernetics Research Laboratories) ("Viron") Tucson, Arizona. Viron supplies the AcroVal™ and AxoTouch™ unpackaged and they are packaged at AxoGen's distribution facility in Burleson, Texas. AxoGen maintains its corporate offices in Alachua, Florida and is the parent company of its wholly owned operating subsidiary, AC.

3. Summary of Significant Accounting Policies

Revenue Recognition

Revenue is recognized when persuasive evidence of an arrangement exists, the price is fixed and determinable, delivery has occurred and there is a reasonable assurance of collection of the sales proceeds. Revenues for manufactured products and products sold to a customer or under a distribution agreement are recognized when the product is shipped to the customer or distributor, at which time title passes to the customer or distributor. Once a product is shipped, the Company has no further performance obligations. Shipped product is defined as shipment to a customer location or segregation of product into a contracted distribution location. At such time, this product cannot be sold to any other

customer. Fees charged to customers for shipping are recognized as revenues when products are shipped to the customer, distributor or end user. In the case of revenues from consigned sales, revenue is determined when the product is utilized in a surgical procedure. Revenues from research grants are recognized in the period the associated costs are incurred.

Cash and Cash Equivalents and Concentration

For purposes of the statement of cash flows, the Company considers all highly liquid debt instruments purchased with a maturity of three months or less to be cash equivalents. Cash and cash equivalents are maintained at financial institutions and, at times, balances may exceed federally insured limits. The Company has never experienced any losses related to these balances and does not believe it is exposed to any significant credit risk on cash and cash equivalents.

Accounts Receivable and Concentration of Credit Risk

Accounts receivable are carried at the original invoice amount less an estimate made for doubtful accounts based on a review of all outstanding amounts on a monthly basis. Management determines the allowance for doubtful accounts by regularly evaluating individual customer receivables and considering a customer's financial condition, credit history and current economic conditions. Accounts receivable are written off when deemed uncollectible. Recoveries of accounts receivable previously written off are recorded when received.

We regularly review all accounts that exceed 60 days from the invoice date and based on an assessment of current credit worthiness, estimate the portion, if any, of the balance that will not be collected. The analysis excludes certain government related receivables due to our past successful experience in collectability. Specific accounts that are deemed uncollectible are reserved at 100% of their outstanding balance. The remaining balances outstanding over 60 days have a percentage applied by aging category (5% for balances 61-90 days and 20% for balances over 90 days aged), based on a historical valuation that allows us to calculate the total reserve required. The reserve balance was determined by applying a percentage to the cumulative balance between 60 and 90 days and a higher percentage to the balance over 90 days. In the event that we exhaust all collection efforts and deem an account uncollectible, we would subsequently write off the account. The write off process involves approval by senior management based on the write off amount. The allowance for doubtful accounts reserve balance was approximately $249,000 and $192,000 at September 30, 2016 and December 31, 2015, respectively.

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, credit limits and monitoring procedures.

Inventories

Inventories are comprised of implantable tissue, nerve grafts, Avance® Nerve Graft, AxoGuard® Nerve Connector, AxoGuard® Nerve Protector, and supplies that are valued at the lower of cost (first-in, first-out) or market and consist of the following:

	September 30, 2016	December 31, 2015
Finished goods	$3,343,110	$2,732,823
Work in process	224,803	237,108
Raw materials	1,402,906	964,029
	$4,970,819	$3,933,960

Inventories were net of reserve of approximately $858,000 and $711,000 at September 30, 2016 and December 31, 2015, respectively.

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, 2012 through 2015; there currently are no examinations in process.

Fair Value of Financial Instruments

The respective carrying value of certain on-balance-sheet financial instruments approximated their fair values due to the short-term nature of these instruments. These financial instruments include cash, accounts receivable, accounts payable and accrued expenses. The fair value of the Company's long-term debt approximates its carrying value based upon current rates available to the Company.

Share-Based Compensation

Stock-based compensation cost related to stock options granted under the AC 2002 Stock Option Plan (the "2002 Plan") and AxoGen 2010 Stock Incentive Plan (the "2010 Plan" and, together with the 2002 Plan, the "Plans") (see Note 8) is measured at grant date, based on the fair value of the award, and is recognized as an expense over the employee's requisite service period. The Company estimates the fair value of each option award issued under the Plans on the date of grant using a Black-Scholes-Merton option-pricing model that uses the assumptions noted in the table below. The Company estimates the volatility of its common stock at the date of grant based on the volatility of comparable peer companies which are publicly traded, for the periods prior to there being a market for the Company's common stock, and based on the Company's common stock for periods subsequent to having an established market for the stock. The Company determines the expected life based on historical experience with similar awards, 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 has never paid any cash dividends on its common stock, is restricted from paying dividends pursuant to its debt commitments and does not anticipate paying any cash dividends in the foreseeable future. The Company used the following weighted-average assumptions for options granted during the nine months ended September 30:

Nine months ended September 30,	2016	2015
Expected term (in years)	4	4
Expected volatility	61.71 %	75.45 %
Risk free rate	1.22 %	1.27 %
Expected dividends	— %	— %

The Company estimates forfeitures when recognizing compensation expense and this estimate of forfeitures is adjusted over the requisite service period based on the extent to which actual forfeitures differ, or are expected to differ, from such estimates. Changes in estimated forfeitures are recognized through a cumulative catch-up adjustment, which is recognized in the period of change, and also impact the amount of unamortized compensation expense to be recognized

in future periods. The Company did not apply a forfeiture allocation to its unvested options outstanding during the nine months ended September 30, 2016 and 2015 as they were deemed insignificant.

Use of Estimates

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

Recent Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board, or 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 is designed to create greater comparability for financial statement users across industries and jurisdictions and also requires enhanced disclosures. The guidance was scheduled to become effective for fiscal years, and interim periods within those years, beginning after December 15, 2016; however, on July 9, 2015, the FASB decided to delay the effective date of the new revenue standard by one year. The proposed deferral may permit early adoption, but would not allow adoption any earlier than the original effective date of the standard. We are currently evaluating the impact this standard will have on our consolidated financial statements.

In June 2014, the FASB issued updated guidance related to stock compensation. The amendment requires that a performance target that affects vesting and that could be achieved after the requisite period, be treated as a performance condition. The updated guidance became effective for annual reporting periods and interim periods within those annual periods beginning after December 15, 2015. The Company has one such stock option grant that is based on quarterly performance conditions and the vesting and compensation expense is measured subsequent to the end of each quarter over a two year period. If the performance condition is met the vesting and compensation expense is recognized on the measurement date.

In April 2015, the FASB issued Accounting Standard Update (“ASU”) No. 2015-03, "Simplifying the Presentation of Debt Issuance Costs" ("ASU 2015-03") which changes the presentation of debt issuance costs in financial statements to present such costs as a direct deduction from the related debt liability rather than as an asset. ASU 2015-03 became effective for public companies during interim and annual reporting periods beginning after December 15, 2015. Early adoption is permitted. The Company adopted this standard in the first quarter of 2016 on a retrospective basis. (See note 7)

In November 2015, the FASB issued an ASU to simplify the presentation of deferred income taxes. The amendments in this ASU require that deferred tax liabilities and assets be classified as noncurrent in a classified statement of financial position. The amendments in these ASU may be applied either prospectively to all deferred tax liabilities and assets or retrospectively to all periods presented and are effective for interim and annual reporting periods beginning after December 15, 2016. Earlier application is permitted for all entities as of the beginning of an interim or annual reporting period. We are currently evaluating the impact this standard will have on our consolidated financial statements.

In January 2016, the FASB, issued ASU 2016-01 “Recognition and Measurement of Financial Assets and Financial Liabilities,” which requires that most equity instruments be measured at fair value, with subsequent changes in fair value recognized in net income. The pronouncement also impacts the financial liabilities under the fair value option and the presentation and disclosure requirements for financial instruments. The ASU does not apply to equity method investments or investments in consolidated subsidiaries. The new standard will be effective for us for the year ending December 31, 2017, with early adoption permitted and amendments to be applied as a cumulative-effect adjustment to the balance sheet in the year of adoption. We are currently evaluating the impact this standard will have on our consolidated financial statements.

In February 2016, the FASB issued ASU 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 are currently evaluating the impact this standard will have on our consolidated financial statements.

In March 2016, the FASB issued ASU No. 2016-09, Compensation - Stock Compensation (Topic 718), Improvements to Employee Share-Based Payment Accounting. The ASU was issued as part of the FASB Simplification Initiative and involves several aspects of accounting for shared-based payment transactions, including the income tax consequences, options to elect forfeiture accounting policy either by the number of awards that are expected to vest (current GAAP) or account for forfeitures when they occur, and classification on the statement of cash flows. The guidance is effective for annual periods beginning after December 15, 2016, and interim periods within those annual periods. Early adoption is permitted for any entity in any interim or annual period. If an entity early adopts the amendments in an interim period, any adjustments should be reflected as of the beginning of the fiscal year that includes that interim period. An entity that elects early adoption must adopt all of the amendments in the same period. We are currently evaluating the impact this standard will have on our consolidated financial statements.
In August 2016, the FASB issued ASU No. 2016-15, Classification of Certain Cash Receipts and Cash Payments (Topic 230). The ASU was issued intended 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. The new guidance is effective for fiscal years and interim periods within those years beginning after December 15, 2017 with early adoption 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 we believe there are none that could potentially have a material impact on the Company’s consolidated financial condition, results of operations, or disclosures.

4. Property and Equipment

Property and equipment consist of the following:

	September 30, 2016	December 31, 2015
Furniture and equipment	$ 1,240,987	$ 1,186,815
Leasehold improvements	490,214	346,642
Processing equipment	1,790,989	1,375,759
Less: accumulated depreciation and amortization	(2,201,479)	(1,938,346)
Property and equipment, net	$ 1,320,711	$ 970,870

5. Intangible Assets

The Company’s intangible assets consist of the following:

	September 30, 2016	December 31, 2015
License agreements	$ 923,269	$ 897,594
Patents	311,812	179,997
Less: accumulated amortization	(447,558)	(399,509)
Intangible assets, net	$ 787,523	$ 678,082

License agreements are being amortized over periods ranging from 17-20 years. Patent costs were being amortized over three years. As of September 30, 2016, the patents were fully amortized, and the remaining patents of $311,812 were pending patent costs and were not amortizable. Amortization expense was approximately $16,000 and $11,000 for the three months ended September 30, 2016 and 2015, respectively, and approximately $48,000 and $34,000 for the nine months ended September 30, 2016 and 2015, respectively. As of September 30, 2016, future amortization of license agreements for the remainder of this year and the next seven years is expected to be $16,000 for 2016, $64,000 for 2017 through 2022 and $75,000 for 2023.

License Agreements

The Company has entered into multiple license agreements (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 $214,000 and $162,000 during the three months ended September 30, 2016 and 2015, respectively, and approximately $583,000 and $379,000 for the nine months ended September 30, 2016 and 2015, respectively, and are included in sales and marketing expense on the accompanying condensed consolidated statements of operations.

6. Accounts Payable and Accrued Expenses

Accounts payable and accrued expenses consist of the following:

	September 30, 2016	December 31, 2015
Accounts payable	$1,892,839	$2,090,874
Miscellaneous accruals	262,645	15,183
Accrued compensation	2,403,910	1,589,070
Accounts Payable and Accrued Expenses	$4,559,394	$3,695,127

7. Term Loan Agreement

Term Loan Agreement consists of the following:

	September 30, 2016	December 31, 2015
Term Loan and Revenue Interest Agreement with Three Peaks Capital S.a.r.l. for a total term loan amount of $25,000,000 which has a six year term and requires interest only payments and a final principal payment due at the end of the term. Interest is payable quarterly at 9.00% per annum plus the greater of LIBOR or 1.0% which as of September 30, 2016 and December 31, 2015 resulted in a 10% rate. The Revenue Interest Agreement is for a period of ten years. Royalty payments are based on a royalty rate of 3.75% of revenues up to a maximum of $30 million in revenues in any 12 month period.	$24,996,070	$24,701,693
Long-term portion	$24,996,070	$24,701,693

In the first quarter of 2016, the Company adopted ASU 2015-03, "Simplifying the Presentation of Debt Issuance Costs." ASU 2015-03 requires debt issuance costs related to recognized debt liabilities to be presented in the balance sheet as a direct deduction from the debt liability rather than an asset. Accordingly, as of September 30, 2016, approximately $750,000 of deferred debt issuance costs were presented as a direct deduction within Long-Term Debt on the Company's Condensed Consolidated Balance Sheets. Furthermore, the Company reclassified approximately $846,000 of deferred debt issuance costs from Other Assets – Deferred Financing Costs to Long-Term Debt as of December 31, 2015.

Term Loan Agreement and Revenue Interest Agreement

On November 12, 2014 (the "Signing Date"), AxoGen, as borrower, and AC, as guarantor, entered into a term loan agreement (the "Term Loan Agreement") with the lenders party thereto and Three Peaks Capital S.a.r.l. ("Three Peaks"), an indirect wholly-owned subsidiary of Oberland Capital Healthcare Master Fund LP ("Oberland"), as administrative and collateral agent for the lenders thereto. Under the Term Loan Agreement, Three Peaks provided to AxoGen a term loan of $25 million (the "Term Loan") which has a six year term and requires interest only payments and a final principal payment due at the end of the term. Interest is payable quarterly at 9.00% per annum plus the greater of LIBOR or 1.0% which as of November 13, 2014 ("the Closing Date") resulted in a 10% interest rate. AxoGen has to comply with certain covenants including limiting new indebtedness, restricting the payment of dividends and maintaining certain levels of revenue. Three Peaks has a first perfected security interest in the assets of AxoGen.

In addition, AxoGen entered into a 10 year Revenue Interest Agreement (the "Revenue Interest Agreement") with Three Peaks. Royalty payments are based on a royalty rate of 3.75% of AxoGen's revenues up to a maximum of $30 million in revenues in any 12 month period. AxoGen has to comply with certain covenants including those covenants under the Term Loan.

Under the Term Loan Agreement, AxoGen has the option at any time to prepay the Term Loan, in whole or in part, and the Royalty Interest Agreement, defined below, by making the following payment, and Three Peaks has the right to

demand the following payment upon a change of control of AxoGen, sale of a majority of AxoGen's assets or a material adverse change to AxoGen: (i) on or prior to the first anniversary of the applicable Closing Date, 120% of the outstanding principal amount of the Term Loan or any portion being prepaid; (ii) after the first anniversary but no later than the second anniversary of the applicable Closing Date, 135% of the outstanding principal amount of the Term Loan or any portion being prepaid; (iii) after the second anniversary but no later than the third anniversary of the applicable Closing Date, 150% of the outstanding principal amount of the Term Loan or any portion being prepaid; or (iv) after the third anniversary of the applicable Closing Date, an amount generating an internal rate of return of 16.25% of the outstanding principal amount of the Term Loan or any portion being prepaid. In all cases, the amount due is reduced by the sum of interest and principal previously paid and all amounts received under the Revenue Interest Agreement. In each such case AxoGen will also owe an additional 3% of the originally advanced Term Loan amount. Upon payment to Three Peaks, AxoGen would have no further obligations to Three Peaks under the Term Loan or the Revenue Interest Agreement.

In connection with the Term Loan Agreement, on the Signing Date, the Company and AC, its wholly owned subsidiary, entered into a Security Agreement (the "Security Agreement") with Three Peaks, pursuant to which each of the Company and AC grants to Three Peaks a security interest in certain collateral as specified in the Security Agreement to guarantee the payment in full when due of the secured obligations. In the event of default per the terms of the Term Loan Agreement, Three Peaks would have the ability to foreclose on the pledged collateral and the Company and AC would not be able to continue its current business if such foreclosure occurred.

Also in connection with the above transaction, the Company sold 1,375,969 shares of its common stock to Three Peaks for a total of $3.55 million ("Three Peaks Equity Sale") at a price of $2.58 per share. Pursuant to the equity purchase provisions in the Three Peaks Term Loan Agreement, in the event that, prior to November 12, 2016, we sell our securities at a lower price per share than the $2.58 per share paid by Three Peaks, or where the terms of such subsequent sale are otherwise more favorable, then in such case we have agreed to match the more favorable terms of such subsequent sale with respect to the shares purchased by Three Peaks. A subsequent sale does not include the issuance of securities or options to our employees, officers, directors or consultants pursuant to our approved employee option pool or any other employee stock purchase or option plan existing as of November 12, 2014.

The Company records interest using its best estimate of the effective interest rate. This estimate takes into account both the rate on the Term Loan Agreement and the rate associated with the 10 year Revenue Interest Agreement with Three Peaks. The effective interest rate is based on actual payments to date, projected future revenues and the projected royalty payments and the quarterly interest payments due on the Term Loan Agreement. From time to time, AxoGen will reevaluate the expected cash flows and may adjust the effective interest rate. Determining the effective interest rate requires judgment and is based on significant assumptions related to estimates of the amounts and timing of future revenue streams. Determination of these assumptions is highly subjective and different assumptions could lead to materially different outcomes.

See Note 12 Subsequent Events "Debt Refinancing"

8. Stock Options

The Company granted stock options to purchase 542,250 shares of its common stock pursuant to the 2010 Plan for the nine months ended September 30, 2016. Stock-based compensation expense was $293,575 and $334,593 for the three months ended September 30, 2016 and 2015, respectively and $1,046,364 and $1,031,218 for the nine months ended September 30, 2016 and 2015, respectively. From August 2015 through March 2016, we issued 739,000 stock options to certain officers, directors and employees under the 2010 Plan. The options were subject to shareholder approval to increase the number of shares authorized under the plan. On May 26, 2016, the shareholder approval was obtained and as a result we recognized stock-based compensation of $272,240 related to these options for the three months ended June 30, 2016. Total future stock compensation expense related to nonvested awards is expected to be approximately $2,761,000 at September 30, 2016.

9. Public Offerings of Common Stock

On February 5, 2015, AxoGen entered into an underwriting agreement (the "2015 Underwriting Agreement") with Wedbush Securities Inc. (the "2015 Underwriter") in connection with the offering, issuance and sale (the "February 2015 Offering") of 4,728,000 shares of the Company's common stock, at a price to the public of $2.75 per share. The Company also granted to the 2015 Underwriter a 30-day option to purchase up to an aggregate of 709,200 additional shares of the Company's common stock to cover over-allotments, if any, which option the 2015 Underwriter exercised in full.

As of February 13, 2015, the February 2015 Offering was completed with the sale of 5,437,200 shares of the Company's common stock, which included the full exercise of the over-allotment option, at $2.75 per share, resulting in gross proceeds to AxoGen from the February 2015 Offering of approximately $15.0 million, before deducting underwriting discounts and commissions and other estimated offering expenses payable by AxoGen estimated at approximately $1.4 million. The shares of Company common stock were listed on the NASDAQ Capital Market. The February 2015 Offering was made pursuant to the Company's effective shelf registration statement on Form S-3 (Registration No. 333-195588) previously filed with the SEC on April 30, 2014, and pursuant to the prospectus supplement and the accompanying prospectus describing the terms of the February 2015 Offering, dated February 5, 2015.

On August 26, 2015, the Company entered into a purchase agreement (the "Purchase Agreement") with Essex Woodlands Fund IX, L.P. ("Essex") for the purchase of 4,861,111 shares of the Company's common stock at a public offering price of $3.60 per share, raising approximately $17.5 million in gross proceeds (the "August 2015 Offering"). The expenses directly related to the August 2015 Offering were approximately $300,000 and were all paid as of December 31, 2015 by the Company. Such expenses include the Company's legal and accounting fees, printing expenses, transfer agent fees and miscellaneous fees and costs related to the August 2015 Offering. Proceeds from the August 2015 Offering are being used for sales and marketing and general working capital purposes. The Company has provided certain demand and "piggy-back" registration rights in connection with this sale of its common stock. The August 2015 Offering was made pursuant to the Company's effective shelf registration statement on Form S-3 (Registration No. 333-195588) previously filed with the SEC on April 30, 2014 and pursuant to the prospectus supplement and the accompanying prospectus describing the terms of the August 2015 Offering, dated August 26, 2015.

The August 2015 Offering was made pursuant to the Company's effective shelf registration statement on Form S-3 (Registration No. 333-195588) previously filed with the SEC on April 30, 2014, and pursuant to the prospectus supplement and the accompanying prospectus describing the terms of the Offering, dated August 26, 2015.

10. Commitments and Contingencies

Commercial Lease

On March 16, 2016, AC entered into the Fourth Amendment to Lease ("Fourth Amendment") with SNH Medical Office Properties Trust, a Maryland real estate investment trust ("SNH"). SNH is the landlord of AC's currently leased 11,761 square foot corporate headquarters facility in Alachua, Florida (the "Current Premises") pursuant to that certain lease dated as of February 6, 2007, as amended (the "Lease").

The Fourth Amendment expands the Current Premises by 7,050 square feet (the "Expansion Premises"). The Fourth Amendment also provides that the Expiration Date (as defined in the Fourth Amendment) of the Lease will be extended to approximately five years from the Occupancy Date (as defined in the Fourth Amendment) of the Expansion Premises, which Occupancy Date occurred in June 2016. The original expiration date of the Current Premises remains unchanged; provided, however, that AC shall have the right to extend the Current Premises Term (as defined in the Fourth Amendment) for three additional periods (the "Current Premises Extended Term"), the first such Current Premises Extended Term to commence on November 1, 2018 and end on October 31, 2019, the second such Current Premises Extended Term to commence on November 1, 2019 and end on October 31, 2020, and the third such Current Premises Extended Term to commence on November 1, 2020 and end on the Expiration Date. AC also has the right to extend the term of the then current Leased Premises (as defined in the Fourth Amendment) for an additional period of five years commencing on the day immediately after the Expiration Date. AC's additional annual cost of the Expansion Premises

will be approximately $123,000, $127,000, $131,000, $135,000 and $139,000 for years one through five, respectively, of the Lease, with year one commencing on the Occupancy Date.

Processing Agreement

Until February 2016, the Company was party to that certain Amended and Restated Nerve Tissue Processing Agreement (the "LifeNet Agreement") with LifeNet Health ("LifeNet"), whereby the Company processed and packaged Avance® Nerve Graft using its employees and equipment located at LifeNet in Virginia Beach, Virginia (the "Virginia Beach Facility"). As a result of business requirements of LifeNet and their need for additional space, on April 16, 2015 LifeNet notified the Company that it would need to transition out of the Virginia Beach Facility and the LifeNet Agreement was terminated effective February 27, 2016.

As a result of the termination of the LifeNet Agreement, on August 6, 2015 the Company entered into a License and Services Agreement (the "CTS Agreement") with Community Blood Center (d/b/a Community Tissue Services) ("CTS") whose headquarters are located in Dayton, Ohio. The CTS facility and CTS Agreement provides the Company a cost effective, quality controlled and licensed facility to process and package its Avance® Nerve Graft using the Company's employees and processing equipment. The processing that was performed at the Virginia Beach Facility has been transferred in its entirety to the CTS facility.

The CTS Agreement is for a five-year term, subject to earlier termination by either party for cause, or after the two-year anniversary of the CTS Agreement without cause, upon 18 months notice. Under the CTS Agreement, the Company pays CTS a facility fee for clean room/processing, storage and office space and CTS provides services in support of the Company's processing such as routine sterilization of daily supplies, providing disposable supplies, microbial services and office support. The service fee is based on a per donor batch rate. However, AxoGen could reproduce a manufacturing space that would meet its needs if it no longer continued its relationship with CTS. AxoGen's processing methods and process controls have been developed and validated to ensure product uniformity and quality. Pursuant to the CTS Agreement, AxoGen pays license fees on a monthly basis to CTS which total an annual amount of approximately $416,000.

11. 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 100% on the first 3% of the employee's annual salary and 50% of the next 2% of the employee's annual salary as long as the employee participates in the 401(k) Plan and contributes at least 5% of the annual salary. Both employee contributions and Company contributions vest immediately. Employer contributions to the 401(k) Plan for the three and nine months ending September 30, 2016, were approximately $76,000 and $247,000, respectively.

12. Subsequent Events

Public Offering

On October 7, 2016, the Company entered into an underwriting agreement (the "2016 Underwriting Agreement") with JMP Securities LLC, as representative of the several underwriters (collectively, the "2016 Underwriters"), to issue and sell 2,333,334 shares of the Company's common stock in an underwritten registered public offering (the "2016 Offering") at an offering price of $7.50 per share of common stock. Pursuant to the 2016 Underwriting Agreement, the Company also granted the 2016 Underwriters a 30-day option to purchase up to an additional 350,000 shares of common stock, which the 2016 Underwriters exercised in full on October 7, 2016. Five of the Company's directors and officers purchased an aggregate of approximately 32,666 shares of the Company's common stock in the 2016 Offering and such purchases were made on the same terms and conditions as purchases by the public in the 2016 Offering.

The 2016 Offering closed on October 13, 2016, and the Company received net proceeds of approximately $18.62 million from the sale of 2,683,334 shares of its common stock, which includes the additional 350,000 shares pursuant to the over-allotment option, after deducting the underwriting discounts and commissions and estimated offering expenses. The Company intends to use the net proceeds from the 2016 Offering for general working capital purposes and expanded development of nerve repair markets. However, the Company's management will retain broad discretion over the allocation of the net proceeds.

Burleson Texas Lease Amendment

On October 25, 2016, AC entered into Commercial Lease Amendment 2 (the "Amendment"), to the Commercial Lease dated April 1, 2016, with Ja-Cole L.P. dated October 25, 2016, as amended. Under the terms of the Amendment, AC leased an additional 2,500 square feet of warehouse/office space in Burleson, Texas (the "Burleson Facility"). The Burleson Facility will now comprise a total of 10,000 square feet, all of which, pursuant to the Amendment, will be leased until March 31, 2019. The annual rental cost of the entire Burleson Facility is now approximately $88,000. The Burleson Facility houses raw material storage and product distribution.

Debt Refinancing

Term Loan

On October 25, 2016 (the "Closing Date"), AxoGen and AC, each as borrowers, entered into a Credit and Security Agreement (Term Loan) (the "MidCap Term Loan Agreement") with the lenders party thereto and MidCap Financial Trust ("MidCap"), as administrative agent and a lender. Under the MidCap Term Loan Agreement, MidCap has agreed to lend to the Company a term loan in the aggregate principal amount of $21 million (the " MidCap Term Loan") which has a maturity date of May 1, 2021 and requires interest only payments through December 1, 2018, and thereafter, 30 monthly payments of principal and interest resulting in the MidCap Term Loan being fully paid by the maturity date. Interest is payable monthly at 8.00% per annum plus the greater of LIBOR or 0.5%, which, as of the Closing Date, resulted in an 8.5% rate. In addition to the interest charged on the MidCap Term Loan, the Company is also obligated to pay certain fees, including an annual agency fee of one quarter of one percent (0.25%) of the aggregate principal amount of the Term Loan.

Under the MidCap Term Loan Agreement, the Company has the option at any time to prepay the MidCap Term Loan in whole or in part, provided that prepayments shall be: (i) in an amount equal to $2,500,000 or a higher integral multiple of $1,000,000; and (ii) accompanied by certain prepayment and exit fees. There can be no more than three (3) partial voluntary prepayments allowed during the term of the MidCap Term Loan Agreement. MidCap and certain of the lenders have the right to demand prepayment, along with prepayment and exit fees upon an event of default which includes, but is not limited to: (i) default of the Revolving Loan as defined below; (ii) a change of control of the Company; (iii) sale of the majority of the Company's assets; or (iv) a material adverse change to the Company. The prepayment fee is determined by multiplying the amount being prepaid by the following applicable percentage amount: (a) three percent (3.0%) during the first year following the Closing Date; (b) two percent (2.0%) during the second year following the Closing Date, and (c) one percent (1.0%) thereafter. No Prepayment Fee is due in the event the prepayment is a result of refinancing the MidCap Term Loan and Revolving Loan with MidCap or an affiliate of MidCap. Upon any repayment of any portion of the MidCap Term Loan (whether voluntary, involuntary or mandatory), other than scheduled amortization payments, and on the final payment of principal of the MidCap Term Loan, an exit fee of five percent (5.0%) of the principal amount of the MidCap Term Loan is also owed based on the portion of any prepayment made and at maturity upon the original principal amount less any prepayments of the MidCap Term Loan.

The Company must maintain certain covenants including limiting new indebtedness, restrictions on the payment of dividends and maintaining certain levels of revenue. MidCap, on behalf of the lenders under the MidCap Term Loan Agreement, has a perfected security interest in the assets of the Company to guarantee the payment in full of the MidCap Term Loan. Upon the payment in full to MidCap and the lenders of the MidCap Term Loan, the Company would have no further obligations to MidCap or the lenders under the MidCap Term Loan Agreement.

Revolving Loan

On the Closing Date, 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 has agreed to lend to the Company up to $10 million under a revolving credit facility (the "Revolving Loan") which amount may be drawn down by the Company based upon an available borrowing base which includes certain accounts receivable and inventory. The Revolving Loan may be increased to up to $15 million at the Company's request and with the approval of MidCap. As of the Closing Date, the Company's borrowing base under the Revolving Loan provided availability of approximately $5.4 million of which the Company borrowed $4 million. The maturity date of the Revolving Loan is May 1, 2021. Interest is payable monthly at 4.5% per annum plus the greater of LIBOR or 0.5% on outstanding advances, which, as of the Closing Date, resulted in an 5.0% rate. In addition to the interest charged on the Revolving Loan, the Company is also obligated to pay certain fees, including a collateral management fee of one-half percent (0.5%) per annum of the principal amount outstanding on the Revolving Loan from time to time and an unused line fee of one-half percent (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 amount. The Revolving Loan is subject to a minimum balance, such that the Company pays 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 is terminated or permanently reduced prior to the maturity date, MidCap is owed a deferred revolving loan origination fee determined by multiplying the agreed total lending amount by the following applicable percentage amount: (a) three percent (3.0%) during the first year following the Closing Date; (b) two percent (2.0%) during the second year following the Closing Date, and (c) one percent (1.0%) thereafter. No deferred revolving loan origination fee is due in the event the Revolving Loan is paid in full or the termination of the revolving credit facility is a result of refinancing the MidCap Term Loan and Revolving Loan with MidCap or an affiliate of MidCap. Termination of the Revolving Loan may occur, at the option of MidCap and certain of the lenders, upon an event of default which includes, but is not limited to: (i) default in payment of the MidCap Term Loan; (ii) a change of control of the Company; (iii) sale of the majority of the Company's assets; or (iv) a material adverse change to the Company.

The Company must maintain certain covenants including limiting new indebtedness, restrictions on the payment of dividends and maintaining certain levels of revenue. MidCap, on behalf of the lenders under the Revolving Loan Agreement, has a first perfected security interest in the assets of the Company to guarantee the payment in full of the Revolving Loan. Upon the payment in full to MidCap and the lenders of the Revolving Loan, the Company would have no further obligations to MidCap or the lenders under the Revolving Loan or the Revolving Loan Agreement.

Use of Proceeds

The Company used the aggregate proceeds of $25 million from the MidCap Term Loan and the Revolving Loan to pay the outstanding indebtedness owed to Three Peaks and the other lenders to terminate the Term Loan Agreement and the Revenue Interest Agreement. Expenses and fees of approximately $700,000 to complete the negotiation and documentation of the MidCap Term Loan and the Revolving Loan and prepayment fees of approximately $2.3 million owed to Three Peaks were paid from the Company's own funds.

Pro Forma

After giving effect to the 2016 Offering and Midcap debt refinancing, the pro forma cash and debt, excluding accounts payable, of the Company as of September 30, 2016 was approximately $31.7 million and $25 million, respectively. This unaudited pro forma financial information of the Company is derived from applying the net proceeds from the 2016 Offering, Term Loan and Revolving Loan as described above, to the balance sheet of the Company as of September 30, 2016. In the opinion of the Company's management, all adjustments necessary to present fairly such unaudited pro forma financial information have been made based on the terms and structure of the transactions and in certain cases the estimated expenses of such transactions. This pro forma information is presented for illustrative purposes only and is not necessarily indicative of the actual results that would have occurred had the transactions taken place at September 30, 2016

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 subsidiary AxoGen Corporation ("AC").

OVERVIEW

We are a global leader in innovative surgical solutions for peripheral nerve injuries. Our portfolio of products includes Avance® Nerve Graft, an off-the-shelf processed human nerve allograft for bridging severed 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 nerves, and 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. Along with these core surgical products, AxoGen also offers AxoTouch™ Two-Point Discriminator and AcroVal™ Neurosensory & 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 nerve function. The AxoGen portfolio of products is available in the United States, Canada, the United Kingdom and several other European and international countries.

Revenue from the distribution of these products is the main contributor to AxoGen's total reported sales and has been the key component of its growth to date. AxoGen's revenues increased in the first nine months of 2016 compared to 2015 primarily as a result of increased product usage by active accounts and a price increase effective March 1, 2016. This increase is consistent with AxoGen's sales strategy of focusing largely on growing product usage in its active accounts and, to a lesser extent, the development of new accounts.

AxoGen has continued to broaden its sales and marketing activity. This activity is expected to result in additional revenue growth in the long term. In the near term, revenue growth lags behind the increased expenses for market development, such as hiring and training of new sales representatives and surgeon education programs.

Results of Operations

Comparison of the Three Months Ended September 30, 2016 and 2015

Revenues

Revenues for the three months ended September 30, 2016 increased 37.4% to approximately $11,205,000 as compared to approximately $8,154,000 for the three months ended September 30, 2015. This increase was primarily a result of our strategy of focusing largely on growing product usage in our active accounts and to a lesser extent the development of new accounts. A new account can become an active account with increased utilization and demonstrating six or more orders in a twelve month period. As such, revenue growth primarily occurs from increased purchasing 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. Finally, AxoGen recognized approximately $162,000 and $118,000 of grant revenue for the three months ended September 30, 2016 and 2015, respectively, which increase is a result of greater activity associated with grants that increased the associated billing by the Company.

Gross Profit

Gross profit for the three months ended September 30, 2016 increased 41.0% to approximately $9,508,000 as compared to approximately $6,743,000 for the three months ended September 30, 2015. Such increase in aggregate dollars was primarily attributable to the increased revenues in the third quarter of 2016, and to a lesser extent by an improvement in gross margin. Gross margin improved to 84.9% for the three months ended September 30, 2016 as compared to 82.7%

for the same period in 2015 as a result of processing efficiencies and favorable product mix as a result of changes both within and between product lines as gross profit differs by product.

Costs and Expenses

Total cost and expenses increased 23.4% to approximately $10,689,000 for the three months ended September 30, 2016 as compared to approximately $8,661,000 for the three months ended September 30, 2015. These increases were due primarily to increased sales and marketing activities, which includes the costs associated with an increased number of sales associates and an increased number of surgeon educational courses, costs associated with increased revenue, increased employee compensation expenses and increased research and development costs as the Company enrolls patients in its clinical trial for the Avance® Nerve Graft and develops new nerve repair products.

Sales and marketing expenses increased 28.6% to approximately $7,090,000 for the three months ended September 30, 2016 as compared to approximately $5,513,000 for the three months ended September 30, 2015. This increase was due primarily to the costs associated with the continued expansion of our direct sales force, increased commissions to independent distributors as a result of greater sales and the increase of surgeon education programs, and to a lesser extent increased support for both our direct sales force and independent distributors. As a percentage of total revenues, sales and marketing expenses were 63.3% for the three months ended September 30, 2016 compared to 67.6% for the three months ended September 30, 2015. Such lower sales and marketing expenses as a percentage of revenue were a result of the revenue increase outpacing increases in costs and expenses.

General and administrative expenses increased 12.2% to approximately $2,481,000 for the three months ended September 30, 2016 as compared to approximately $2,212,000 for the three months ended September 30, 2015. Such increase was primarily a result of increased expenses related to employee compensation and outside service fees. Also contributing, to a lesser extent, to the rise in such general and administrative expenses was an increase in bank charges related to sales activity. As a percentage of total revenues, general and administrative expenses were 22.1% for the three months ended September 30, 2016 as compared to 27.1% for the three months ended September 30, 2015. Such lower general and administrative expenses as a percentage of revenue were a result of the total revenue increase outpacing increases in costs and expenses.

Research and development expenses increased approximately 19.4% to approximately $1,118,000 for the three months ended September 30, 2016 as compared to approximately $936,000 for the three months ended September 30, 2015. Research and development costs include AxoGen's product development and clinical efforts including the Multicenter, Prospective, Randomized, Subject and Evaluator Blinded Comparative Study of Nerve Cuffs and Avance® Nerve Graft Evaluating Recovery Outcomes for the Repair of Nerve Discontinuities ("RECON") study, the phase 3 trial to support the Company's Biologic License Application ("BLA"). This activity varies from quarter to quarter due to the timing of certain projects and expenditures for RECON. It is expected that costs associated with RECON will increase as more subjects are enrolled in the trial over approximately the next two years and activity increases to prepare and submit the BLA at the completion of RECON. Although AxoGen's products are developed for sale in their current use, it does conduct research and product development efforts focused on new products and new applications for existing products. AxoGen is active in pursuing research grants to support some of this research. The expenses related to the Company's product pipeline development is expected to increase as it initiates more projects and products become ready for market. As a percentage of total revenues, research and development expenses for the three months ended September 30, 2016 were 10.0% as compared to 11.5% for the three months ended September 30, 2015.

Other Income and Expenses

Interest expense increased 4.5% to approximately $1,089,000 for the three months ended September 30, 2016 as compared to approximately $1,042,000 for the three months ended September 30, 2015. This increase was due to the difference in the interest generated by increased revenues related to the Revenue Interest Agreement with Three Peaks. As a result of the accounting treatment for the Three Peaks transaction, interest expense included approximately $22,000 and $743,000 for the three months ended September 30, 2016 and 2015, respectively, of non-cash expense that is based upon the terms of the Three Peaks transaction and increases in AxoGen revenues. Other than the $22,000 and $743,000 non-cash expense, the remaining $1,067,000 and $299,000 in interest expense for the three months ended September 30, 2016 and 2015, respectively, is related to cash paid for interest on the Term Loan Agreement.

Income Taxes

The Company had no income tax expenses or income tax benefit for each of the three months ended September 30, 2016 and 2015 due to the incurrence of net operating loss in each of these periods.

Comparison of the Nine Months Ended September 30, 2016 and 2015:

Revenues

Revenues for the nine months ended September 30, 2016 increased 52.1% to approximately $29,699,000 as compared to approximately $19,522,000 for the nine months ended September 30, 2015. This increase was primarily a result of our strategy of focusing largely on growing product usage in our active accounts and to a lesser extent the development of new accounts. A new account can become an active account with increased utilization and demonstrating six or more orders in a twelve month period. As such, revenue growth primarily occurs from increased purchasing 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. Finally, AxoGen recognized approximately $240,000 and $387,000 of grant revenue for the nine months ended September 30, 2016 and 2015, respectively, which decrease is a result of certain grants maturing and less activity being associated with them in the first six months of 2016 that could be billed by the Company.

Gross Profit

Gross profit for the nine months ended September 30, 2016 increased 55.8% to approximately $25,061,000 as compared to approximately $16,089,000 for the nine months ended September 30, 2015. Such increase in aggregate dollars was primarily attributable to the increased revenues in the first nine months of 2016, and to a lesser extent by an improvement in gross margin. Gross margin improved to 84.4% for the nine months ended September 30, 2016 as compared to 82.4% for the same period in 2015 as a result of processing efficiencies and changes in product mix as a result of changes both within and between product lines as gross profit differs by product.

Costs and Expenses

Total cost and expenses increased 34.2% to approximately $30,472,000 for the nine months ended September 30, 2016 as compared to approximately $22,704,000 for the nine months ended September 30, 2015. These increases were due primarily to sales and marketing activities including additional surgeon education programs employee compensation, facility costs, clinical and product development activity and general rise in costs of operating a larger organization.

Sales and marketing expenses increased 40.8% to approximately $20,076,000 for the nine months ended September 30, 2016 as compared to approximately $14,257,000 for the nine months ended September 30, 2015. This increase was due primarily to the costs associated with the continued expansion of the direct sales force, increased commissions to independent distributors as a result of greater sales, and the increase of surgeon education programs, and to a lesser extent increased support for both AxoGen's direct sales force and independent distributors. As a percentage of total revenues, sales and marketing expenses were 67.6% for the nine months ended September 30, 2016 compared to 73.0% for the nine months ended September 30, 2015. Such lower sales and marketing expenses as a percentage of total revenues were a result of the revenue increase outpacing increases in costs and expenses.

General and administrative expenses increased 20.6% to approximately $7,362,000 for the nine months ended September 30, 2016 as compared to approximately $6,103,000 for the nine months ended September 30, 2015. The increase was primarily a result of expenses related to employee compensation and outside services. Bank charges and insurance costs related to sales activity also increased. As a percentage of total revenues, general and administrative expenses were 24.8% for the nine months ended September 30, 2016 as compared to 31.3% for the nine months ended September 30, 2015. Such lower general and administrative expenses as a percentage of total revenues were a result of the revenue increase outpacing increases in costs and expenses.

Research and development costs increased 29.4% to approximately $3,034,000 in the nine months ended September 30, 2016 as compared to approximately $2,343,000 for the nine months ended September 30, 2015. Research and development costs include AxoGen's product development and clinical efforts including the RECON study, the phase 3

trial to support the Company's BLA. This activity varies from quarter to quarter due to the timing of certain projects and expenditures for RECON. It is expected that costs associated with RECON will increase as more subjects are enrolled in the trial over approximately the next two years and activity increases to prepare and submit the BLA at the completion of RECON. Although AxoGen's products are developed for sale in their current use, it does conduct research and product development efforts focused on new products and new applications for existing products. AxoGen is active in pursuing research grants to support some of this research. The expenses related to the Company's product pipeline development is expected to increase as it initiates more projects and products become ready for market. As a percentage of total revenues, research and development expenses for the nine months ended September 30, 2016 were 10.2% as compared to 12.0% for the nine months ended September 30, 2015.

Other Income and Expenses

Interest expense increased 6.37% to approximately $3,256,000 for the nine months ended September 30, 2016 as compared to approximately $3,061,000 for the nine months ended September 30, 2015. This increase was due to the difference in the interest generated by increased revenues related to the Revenue Interest Agreement with Three Peaks. As a result of the accounting treatment for the Three Peaks transaction, interest expense included approximately $224,000 and $1,111,000 for the nine months ended September 30, 2016 and 2015, respectively, of non-cash expense that is based upon the terms of the Three Peaks transaction and increases in AxoGen revenues. Other than the $224,000 and $1,111,000 non-cash expense, the remaining $3,032,000 and $1,950,000 in interest expense for the nine months ended September 30, 2016 and 2015, respectively, is related to cash paid for interest on the Term Loan Agreement.

Income Taxes

The Company had no income tax expenses or income tax benefit for each of the nine months ended September 30, 2016 and 2015 due to the incurrence of net operating loss in each of these periods.

Effect of Inflation

Inflation has not had a significant impact on the Company's operations or cash flow during 2016 or the fiscal years ended 2015 or 2014.

Liquidity and Capital Resources

Term Loan Agreement and Revenue Interest Agreement

On November 12, 2014, AxoGen, as borrower, and AC, as guarantor, entered into the Term Loan Agreement with the lenders party thereto and Three Peaks, an indirect wholly-owned subsidiary of Oberland, as administrative and collateral agent for the lenders party thereto. Under the Term Loan Agreement, Three Peaks provided to AxoGen the Initial Term Loan which has a six year term and requires interest only payments and a final principal payment due at the end of the term. Interest is payable quarterly at 9.00% per annum plus the greater of LIBOR or 1.0% which as of the Initial Closing Date resulted in a 10% interest rate. AxoGen has to comply with certain covenants including limiting new indebtedness, restricting the payment of dividends and maintaining certain levels of revenue. Three Peaks has a first perfected security interest in the assets of AxoGen.

In addition, AxoGen entered into a 10 year Revenue Interest Agreement with Three Peaks. Royalty payments are based on a royalty rate of 3.75% of AxoGen's revenues up to a maximum of $30 million in revenues in any 12 month period. AxoGen has to comply with certain covenants including those covenants under the Term Loan.

Under the Term Loan Agreement, AxoGen has the option at any time to prepay the Term Loan, in whole or in part, and the Royalty Interest Agreement by making the following payment, and Three Peaks has the right to demand the following payment upon a change of control of AxoGen, sale of a majority of AxoGen's assets or a material adverse change to AxoGen: (i) on or prior to the first anniversary of the applicable Closing Date, 120% of the outstanding principal amount of the Term Loan or any portion being prepaid; (ii) after the first anniversary but no later than the second anniversary of the applicable Closing Date, 135% of the outstanding principal amount of the Term Loan or any portion being prepaid; (iii) after the second anniversary but no later than the third anniversary of the applicable Closing Date, 150% of the outstanding principal amount of the Term Loan or any portion being prepaid; or (iv) after the third

anniversary of the applicable Closing Date, an amount generating an internal rate of return of 16.25% of the outstanding principal amount of the Term Loan or any portion being prepaid. In all cases, the amount due is reduced by the sum of interest and principal previously paid and all amounts received under the Revenue Interest Agreement. In each such case AxoGen will also owe an additional 3% of the originally advanced Term Loan amount. Upon payment to Three Peaks, AxoGen would have no further obligations to Three Peaks under the Term Loan or the Revenue Interest Agreement.

In connection with the Term Loan Agreement, on the Signing Date, the Company and AC entered into the Security Agreement with Three Peaks, pursuant to which each of the Company and AC grants to Three Peaks a security interest in certain collateral as specified in the Security Agreement to guarantee the payment in full when due of the secured obligations. In the event of default per the terms of the Term Loan Agreement, Three Peaks would have the ability to foreclose on the pledged collateral and the Company and AC would not be able to continue its current business if such foreclosure occurred.

Also in connection with the above transaction, the Company sold 1,375,969 shares of its common stock to Three Peaks for a total of $3.55 million at a price of $2.58 per share. Pursuant to the equity purchase provisions in the Three Peaks Term Loan Agreement, in the event that prior to November 12, 2016, we sell our securities at a lower price per share than the $2.58 per share paid by Three Peaks, or where the terms of such subsequent sale are otherwise more favorable, then in such case we have agreed to match the more favorable terms of such subsequent sale with respect to the shares purchased by Three Peaks. A subsequent sale does not include the issuance of securities or options to our employees, officers, directors or consultants pursuant to our approved employee option pool or any other employee stock purchase or option plan existing as of November 12, 2014.

As a result of the accounting treatment for the Three Peaks transaction, interest expense included approximately $22,000 and $743,000 for the three months ended September 30, 2016 and 2015, respectively, and approximately $224,000 and $1,111,000 for the nine months ended September 30, 2016 and 2015, respectively, of non-cash expense that is based upon the terms of the Three Peaks transaction and increases in AxoGen revenues. Other than the $224,000 and $1,111,000 non-cash expense, the remaining $3,032,000 and $1,950,000 in interest expense for the nine months ended September 30, 2016 and 2015, respectively, is related to cash paid for interest on the Term Loan Agreement.

The Company records interest using its best estimate of the effective interest rate. This estimate takes into account both the rate on the Term Loan Agreement and the rate associated with the 10 year Revenue Interest Agreement with Three Peaks. The effective interest rate is based on actual payments to date, projected future revenues and the projected royalty payments and the quarterly interest payments due on the Term Loan Agreement. From time to time, AxoGen will reevaluate the expected cash flows and may adjust the effective interest rate. Determining the effective interest rate requires judgment and is based on significant assumptions related to estimates of the amounts and timing of future revenue streams. Determination of these assumptions is highly subjective and different assumptions could lead to materially different outcomes.

The Company had no material commitments for capital expenditures at September 30, 2016.

Public Offerings of Common Stock

On February 5, 2015, AxoGen entered into the 2015 Underwriting Agreement with the 2015 Underwriter in connection with the February 2015 Offering. The Company also granted to the 2015 Underwriter a 30-day option to purchase up to an aggregate of 709,200 additional shares of its common stock to cover over-allotments, if any, which option the 2015 Underwriter exercised in full.

As of February 13, 2015, the February 2015 Offering was completed with the sale of 5,437,200 shares of the Company's common stock, which included the full exercise of the over-allotment option, at $2.75 per share, resulting in gross proceeds to AxoGen from the February 2015 Offering of approximately $15.0 million, before deducting underwriting discounts and commissions and other estimated offering expenses payable by AxoGen estimated at approximately $1.4 million. The shares of Company common stock were listed on the NASDAQ Capital Market. The February 2015 Offering was made pursuant to the Company's effective shelf registration statement on Form S-3 (Registration No. 333-195588) previously filed with the SEC on April 30, 2014, and pursuant to the prospectus supplement and the accompanying prospectus describing the terms of the February 2015 Offering, dated February 5, 2015.

On August 26, 2015, the Company entered into the Purchase Agreement with Essex for the purchase of 4,861,111 shares of the Company's common stock at a public offering price of $3.60 per share, raising approximately $17.5 million in gross proceeds before deducting expenses related to the August 2015 Offering. The expenses directly related to the August 2015 Offering were approximately $300,000 and were paid by the Company. Such expenses include the Company's legal and accounting fees, printing expenses, transfer agent fees and miscellaneous fees and costs related to the August 2015 Offering. Proceeds from the August 2015 Offering are being used for sales and marketing and general working capital purposes. The Company has provided certain demand and "piggy-back" registration rights in connection with this sale of the Company's common stock. The August 2015 Offering was made pursuant to the Company's effective shelf registration statement on Form S-3 (Registration No. 333-195588) previously filed with the SEC on April 30, 2014, and pursuant to the prospectus supplement and the accompanying prospectus describing the terms of the August 2015 Offering, dated August 26, 2015.

On October 7, 2016, the Company entered into the 2016 Underwriting Agreement with the 2016 Underwriters to issue and sell 2,333,334 shares of the Company's common stock in the 2016 Offering at an offering price of $7.50 per share of common stock. Pursuant to the 2016 Underwriting Agreement, the Company also granted the 2016 Underwriters a 30-day option to purchase up to an additional 350,000 shares of its common stock, which the 2016 Underwriters exercised in full on October 7, 2016. Five of the Company's directors and officers purchased an aggregate of approximately 32,666 shares of the Company's common stock in the 2016 Offering and such purchases were made on the same terms and conditions as purchases by the public in the 2016 Offering. The 2016 Offering closed on October 13, 2016, and the Company received net proceeds of approximately $18.62 million from the sale of 2,683,334 shares of its common stock, which includes the additional 350,000 shares pursuant to the over-allotment option, after deducting the underwriting discounts and commissions and estimated offering expenses. The Company intends to use the net proceeds from the 2016 Offering for general working capital purposes and expanded development of nerve repair markets. However, the Company's management will retain broad discretion over the allocation of the net proceeds.

Cash Flow Information

AxoGen had working capital of approximately $24.07 million and a current ratio of 6.24 at September 30, 2016, compared to working capital of $31.34 million and a current ratio of 9.45 at December 31, 2015. The decrease in working capital and the current ratio at September 30, 2016 as compared to December 31, 2015 was due primarily to the use of working capital to fund operations, including the purchase of certain equipment related to the distribution and processing facilities. The Company believes it has sufficient cash resources to meet its liquidity requirements for at least the next 12 months.

AxoGen's future capital requirements depend on a number of factors, including, without limitation, continued adoption of our products by surgeons and growth of our revenues, continued expansion and development of our direct sales force, expenses associated with our surgeon education programs, maintaining our gross margins, expenses related to our facilities for production and distribution of products and general market conditions. AxoGen could face increasing capital needs depending on the extent to which AxoGen is unable to increase revenues.

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.

During the nine months ended September 30, 2016, the Company had a net decrease in cash and cash equivalents of approximately $9,906,000 as compared to a net increase of cash and cash equivalents of approximately $21,720,000 for the nine months ended September 30, 2015. 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, 2016 used approximately $9,782,000 of cash as compared to using approximately $8,790,000 of cash for operating activities for the nine months ended September 30, 2015. This

increase in cash used for operating activities of approximately $992,000 is primarily attributable to the increase in accounts receivable, inventory and prepaid expenses accompanied by the net loss generated for the nine months ended September 30, 2016, offset by the increase in our accounts payable and accrued expenses.

Cash used for investing activities

Investing activities for the nine months ended September 30, 2016 used approximately $770,000 of cash as compared to using approximately $445,000 of cash for the nine months ended September 30, 2015. This increase in cash used for investing activities of approximately $325,000 is principally attributable to the non-recurrence of purchases of certain fixed assets for the expansion of the worldwide distribution facility in Burleson, Texas and purchase of certain fixed assets for the new processing facility in Dayton, Ohio.

Cash provided by financing activities

Financing activities for the nine months ended September 30, 2016 provided approximately $646,000 of cash as compared to providing approximately $30,955,000 of cash for the nine months ended September 30, 2015. The cash provided in the nine months ended September 30, 2015 was due to proceeds received from the February 2015 Offering and the August 2015 Offering.

Off-Balance Sheet Arrangements

AxoGen does not have any off-balance sheet arrangements.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Not Applicable.

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, 2016 and concluded that our disclosure controls and procedures were effective as of such date.

Changes in Internal Controls Over Financial Reporting

During the nine months ended September 30, 2016, there were no changes in the Company's internal control over financial reporting (as defined in Rule 13a-15(f) and 15d–15(f) under the Exchange Act) that have materially affected, or are reasonably likely to materially affect, the Company's 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.

The Company is not a party to any material litigation as of September 30, 2016.

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 Annual Report on Form 10-K as of and for the year ended December 31, 2015 (the "10-K"). If any of these risks actually occur, the Company's business, results of operations or financial condition could be materially adversely affected. There have been no material changes to these risk factors, other than provided as follows:

1. 10-K Risk Factor Entitled "Clinical trials can be long, expensive and ultimately uncertain which could jeopardize AxoGen's ability to obtain regulatory approval and continue to market its Avance® Nerve Graft product." An addition is made that: "The FDA completed on October 28, 2016 a routine audit of AxoGen's processing facility for compliance with 21 CFR Part 1271 and although AxoGen does not expect any material issues, and none were expressed by the FDA auditor, AxoGen will not know the outcome of the audit until the final report is issued".

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	Second Amendment to the Amended and Restated Standard Exclusive License Agreement No. A5140, effective as of July 5, 2016, by and between AxoGen Corporation and the University of Florida Research Foundation, Inc. (incorporated by reference to Exhibit 10.2.1 to the Company's Current Report on Form 8-K filed on July 11, 2016).
10.2	Commercial Lease Amendment 2, to Commercial Lease dated April 1, 2016, between AxoGen Corporation and Ja-Cole L.P. dated October 25, 2016. (incorporated by reference to Exhibit 10.2.1 to the Company's Current Report on Form 8-K filed on October 31, 2016).
31.1†	Certification of Principal Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2†	Certification of Principle Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32††	Certification 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.

†† 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 November 2, 2016

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

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

EXHIBIT INDEX

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* Management contract or compensatory plan or arrangement.

† Filed herewith.

†† Furnished herewith.

EXHIBIT 31.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Karen Zaderej, certify that:

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

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

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

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

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

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

Date: November 2, 2016

/s/ Karen Zaderej
Karen Zaderej
Chief Executive Officer

EXHIBIT 31.2

CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Peter J. Mariani, certify that:

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

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

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

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

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

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

Date: November 2, 2016

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

EXHIBIT 32

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

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

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

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

Dated: November 2, 2016

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

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