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**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, 2017**

**OR**

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

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission file number: **001-36046**

**AxoGen, Inc.**

(Exact Name of Registrant as Specified in Its Charter)

Minnesota

(State or Other Jurisdiction of  
Incorporation or Organization)

41-1301878

(I.R.S. Employer  
Identification No.)

13631 Progress Blvd., Suite 400, Alachua, FL

(Address of Principal Executive Offices)

32615

(Zip Code)

386-462-6800

(Registrant's Telephone Number, Including Area Code)

**Not Applicable**

(Former Name, Former Address and Former Fiscal Year, if Changed Since Last Report)

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

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

Large accelerated filer

Accelerated filer

Non-accelerated filer  (Do not check if a smaller reporting company)

Smaller reporting company

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

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

As of October 30, 2017, the registrant had 33,456,091 shares of common stock outstanding.

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### Forward-Looking Statements

From time to time, in reports filed with the U.S. Securities and Exchange Commission (the "SEC") (including this Form 10-Q), in press releases, and in other communications to shareholders or the investment community, AxoGen, Inc. (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 2017 and 2018 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, 2017 (unaudited)	December 31, 2016
<b>Assets</b>		
<b>Current assets:</b>		
Cash and cash equivalents	\$ 22,041,097	\$ 30,014,405
Accounts receivable, net of allowance for doubtful accounts of approximately \$335,000 and \$272,000, respectively	10,200,560	8,052,203
Inventory	6,698,943	5,458,840
Prepaid expenses and other	571,912	511,804
<b>Total current assets</b>	<b>39,512,512</b>	<b>44,037,252</b>
<b>Property and equipment, net</b>	<b>1,763,840</b>	<b>1,494,247</b>
<b>Intangible assets</b>	<b>951,473</b>	<b>828,979</b>
	<b>\$ 42,227,825</b>	<b>\$ 46,360,478</b>
<b>Liabilities and Shareholders' Equity</b>		
<b>Current liabilities:</b>		
Borrowings under revolving loan agreement	\$ 4,000,000	\$ 4,025,023
Accounts payable and accrued expenses	7,072,530	7,002,165
Current maturities of long term obligations	21,596	20,899
Deferred revenue, current	43,576	33,282
<b>Total current liabilities</b>	<b>11,137,702</b>	<b>11,081,369</b>
<b>Long Term Obligations, net of current maturities and deferred financing fees</b>	<b>20,356,698</b>	<b>20,265,745</b>
<b>Deferred lease</b>	<b>105,261</b>	<b>--</b>
<b>Deferred revenue</b>	<b>76,027</b>	<b>92,215</b>
<b>Total liabilities</b>	<b>31,675,688</b>	<b>31,439,329</b>
<b>Shareholders' equity:</b>		
Common stock, \$0.01 par value per share; 50,000,000 shares authorized; 33,393,804 and 33,008,865 shares issued and outstanding	333,938	330,088
Additional paid-in capital	136,048,305	132,474,884
Accumulated deficit	(125,830,106)	(117,883,823)
<b>Total shareholders' equity</b>	<b>10,552,137</b>	<b>14,921,149</b>
	<b>\$ 42,227,825</b>	<b>\$ 46,360,478</b>

See notes to condensed consolidated financial statements.

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

	<u>Three Months Ended</u>		<u>Nine Months Ended</u>	
	<u>September 30, 2017</u>	<u>September 30, 2016</u>	<u>September 30, 2017</u>	<u>September 30, 2016</u>
<b>Revenues</b>	\$ 16,046,253	\$ 11,205,224	\$ 43,455,390	\$ 29,698,866
<b>Cost of goods sold</b>	2,504,278	1,697,443	6,697,127	4,637,446
<b>Gross profit</b>	13,541,975	9,507,781	36,758,263	25,061,420
<b>Costs and expenses:</b>				
Sales and marketing	9,466,496	7,090,059	27,515,266	20,076,297
Research and development	1,795,292	1,118,358	4,727,551	3,033,521
General and administrative	3,778,612	2,481,051	10,659,756	7,362,063
<b>Total costs and expenses</b>	15,040,400	10,689,468	42,902,573	30,471,881
<b>Loss from operations</b>	<u>(1,498,425)</u>	<u>(1,181,687)</u>	<u>(6,144,310)</u>	<u>(5,410,461)</u>
<b>Other income (expense):</b>				
Interest expense	(577,941)	(1,089,134)	(1,639,874)	(3,255,574)
Interest expense — deferred financing costs	(46,110)	(31,748)	(136,711)	(95,254)
Other (expense)	(1,603)	(2,804)	(25,388)	(22,871)
<b>Total other income (expense)</b>	<u>(625,654)</u>	<u>(1,123,686)</u>	<u>(1,801,973)</u>	<u>(3,373,699)</u>
<b>Net Loss</b>	<u>\$(2,124,079)</u>	<u>\$(2,305,373)</u>	<u>\$(7,946,283)</u>	<u>\$(8,784,160)</u>
Weighted Average Common Shares outstanding — basic and diluted	33,286,211	30,152,279	33,146,546	30,075,715
<b>Loss Per Common share — basic and diluted</b>	<u>\$ (0.06)</u>	<u>\$ (0.08)</u>	<u>\$ (0.24)</u>	<u>\$ (0.29)</u>

*See notes to condensed consolidated financial statements.*

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

	Nine Months Ended September 30,	
	2017	2016
<b>Cash flows from operating activities:</b>		
Net loss	\$ (7,946,283)	\$(8,784,160)
Adjustments to reconcile net loss to net cash used for operating activities:		
Depreciation	346,839	263,133
Amortization of intangible assets	60,459	48,050
Amortization of deferred financing costs	136,711	95,253
Provision for bad debt	83,733	80,934
Stock-based compensation	2,491,992	1,046,364
Interest added to note payable	—	199,124
Change in assets and liabilities:		
Accounts receivable	(2,232,090)	(2,302,701)
Inventory	(1,240,103)	(1,036,859)
Prepaid expenses and other	(60,108)	(260,786)
Accounts payable and accrued expenses	70,365	864,267
Deferred liabilities	99,367	5,727
<b>Net cash used for operating activities</b>	<b>(8,189,118)</b>	<b>(9,781,654)</b>
<b>Cash flows from investing activities:</b>		
Purchase of property and equipment	(616,432)	(612,974)
Acquisition of intangible assets	(182,953)	(157,491)
<b>Net cash used for investing activities</b>	<b>(799,385)</b>	<b>(770,465)</b>
<b>Cash flows from financing activities:</b>		
Borrowing on revolving loan	41,553,210	—
Payments on revolving loan	(41,578,233)	—
Repayments of long-term debt	(15,589)	—
Debt issuance costs	(29,472)	—
Proceeds from exercise of stock options	1,085,279	645,864
<b>Net cash provided by financing activities</b>	<b>1,015,195</b>	<b>645,864</b>
Net decrease in cash and cash equivalents	(7,973,308)	(9,906,255)
<b>Cash and cash equivalents, beginning of year</b>	<b>30,014,405</b>	<b>25,909,500</b>
<b>Cash and cash equivalents, end of period</b>	<b>\$ 22,041,097</b>	<b>\$16,003,245</b>
<b>Supplemental disclosures of cash flow activity:</b>		
Cash paid for interest	\$ 1,631,795	\$ 3,031,528

*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. its wholly owned subsidiary AxoGen Corporation (“AC”) and its wholly owned subsidiary AxoGen Europe GmbH, which was established in the fourth quarter of 2016.

**1. Basis of Presentation**

The accompanying condensed consolidated financial statements include the accounts of AxoGen, Inc. (the “Company” or “AxoGen”) and its wholly owned subsidiaries, AxoGen Corporation (“AC”) and AxoGen Europe GmbH, established in the fourth quarter of 2016, as of September 30, 2017 and December 31, 2016 and for the three and nine month periods ended September 30, 2017 and 2016. The Company’s condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America (“USGAAP”) and should be read in conjunction with the audited financial statements of the Company for the year ended December 31, 2016, which are included in the Company’s Annual Report on Form 10-K as of and for the year ended December 31, 2016. 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. AxoGen is the leading company focused specifically on the science, development and commercialization of technologies for peripheral nerve regeneration and repair. We are passionate about restoring nerve function and quality of life to patients with peripheral nerve injuries by providing innovative, clinically proven and economically effective repair solutions for surgeons and health care providers. Peripheral nerves provide the pathways for both motor and sensory signals throughout the body. Every day, people suffer traumatic injuries or undergo surgical procedures that impact the function of their peripheral nerves. Damage to a peripheral nerve can result in the loss of muscle or organ function, the loss of sensory feeling, or the initiation of pain.

AxoGen’s 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, AxoGuard® Nerve Protector, a porcine submucosa ECM product used to wrap and protect injured peripheral nerves and reinforce the nerve reconstruction while preventing soft tissue attachments, and Avive® Soft Tissue Membrane, a minimally processed human umbilical cord membrane that may be used as a resorbable soft tissue covering to separate tissue layers and modulate inflammation in the surgical bed. Along with these core surgical products, AxoGen also offers AcroVal® Neurosensory & Motor Testing System and AxoTouch® Two-Point Discriminator. These evaluation and measurement tools assist health care 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.

Avance® Nerve Graft and Avive® Soft Tissue Membrane are processed in the United States by AxoGen at its processing facility in Dayton, Ohio. 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 delivered to the customer or distributor, at which time title passes to the customer or distributor, provided, however, that in the case of revenues from consigned sales, delivery is determined when the product is utilized in a surgical procedure. Once a product is delivered, the Company has no further performance obligations. Delivery is defined as delivery 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. 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 receivables due to our past successful experience in collectability. Specific accounts that are deemed uncollectible are reserved at 100% of their outstanding balance. In the event that we exhaust all collection efforts and deem an account uncollectible, we would subsequently write off the account. The allowance for doubtful accounts reserve balance was approximately \$335,000 and \$272,000 at September 30, 2017 and December 31, 2016, 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 and monitoring procedures.

#### **Inventories**

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

We regularly review the inventory status to determine the expected reserve level required. The Company policy is to monitor the shelf life of its products and reserve amounts based on the expiration date of the finished goods inventory. We also reserve a portion of raw materials based on our historical experience of tissue that fails during the inspection and debridement stage due to medical history, serology compliance or poor quality.

### **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, 2014 through 2016; however, 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**

The Company measures all employee stock-based compensation awards using a fair value method and records such expense in its consolidated financial statements. The estimated value of the portion of the award that is ultimately expected to vest, taking into consideration estimated forfeitures based on the Company's historical forfeiture rate, is recognized as expense over the requisite service periods in the Company's consolidated statements of operations. The Company estimates the grant date fair value of stock option awards generally on the date of grant using the Black-Scholes option pricing model.

With respect to performance stock units ("PSUs"), the number of shares that vest and are issued to the recipient is based upon the Company's performance as measured against specified targets over the measurement period. The fair value of the PSUs is based on the Company's closing stock price on the grant date and its estimate of achieving such performance targets. See further discussion and disclosures in Note 9: "Stock Incentive Plan."

### **Use of Estimates**

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

### **Earnings (Loss) Per Share of Common Stock**

There were no dilutive instruments as of September 30, 2017 and 2016. The basic and diluted weighted average shares outstanding were 33,286,211 and 30,152,279 shares for the three months ended September 30, 2017 and 2016, respectively, and 33,146,546 and 30,075,715 shares for the nine months ended September 30, 2017 and 2016, respectively.



Basic and diluted net loss per share of common stock for all periods presented is computed by dividing the net loss attributable to common shareholders by the weighted-average number of shares of common stock outstanding and common stock equivalents outstanding, when dilutive. Potentially dilutive common stock equivalents include shares of common stock which would potentially be issued pursuant to stock warrants and stock options. Common stock equivalents are not included in determining the fully diluted loss per share if their effect is antidilutive.

### **Recent Accounting Pronouncements**

In May 2014, the Financial Accounting Standards Board (the “FASB”) issued a new standard on revenue recognition which outlines a single comprehensive model to use in accounting for revenue arising from contracts with customers and supersedes most current revenue recognition guidance, including industry-specific guidance. The core principle of the revenue model is that an entity should recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. The standard is designed to create greater comparability for financial statement users across industries and jurisdictions and also requires enhanced disclosures. The guidance will be effective for annual reporting periods beginning after December 15, 2017, including interim periods within that reporting period. The standard may be applied retrospectively to each prior period presented or retrospectively with the cumulative effect recognized as of the adoption date. During the quarter ended September 30, 2017, we completed the evaluation of the new standard and a related assessment and review of a representative sample of existing revenue contracts with our customers on our most significant revenue streams. Based upon this assessment, we do not believe there will be a material change to the timing of our revenue recognition. However, during the fourth quarter of 2017 we will continue our preparation for adopting the standard and periodically brief our Audit Committee on our progress. It is likely we will be required to provide additional disclosures in the notes to the consolidated financial statements upon adoption. We have not yet determined the effect of the ASU on our internal control over financial reporting or other changes in business practices and processes but will do so in the design and implementation phase to occur during the remainder of 2017. Additionally, we have not made a decision on which adoption method to utilize. Our evaluation of ASU 2014-09 is ongoing.

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 August 2016, the FASB issued ASU No. 2016-15, Classification of Certain Cash Receipts and Cash Payments (Topic 230). The ASU was issued intending to reduce diversity in practice in how certain cash receipts and cash payments are presented and classified in the Consolidated Statement of Cash Flows by providing guidance on eight specific cash flow issues. The new guidance is effective for fiscal years and interim periods within those years beginning after December 15, 2017 with early adoption permitted. We do not believe the adoption of this standard will have a material impact on our consolidated financial statements.

In November 2016, the FASB issued ASU No. 2016-18, Statement of Cash Flows (Topic 230), guidance that a statement of cash flows explains the change during the period in the total of cash, cash equivalents, and amounts generally described as restricted cash or restricted cash equivalents. The new guidance is effective for fiscal years beginning after December 15, 2017 with early adoption permitted. We do not believe the adoption of this guidance will have a material impact on our Statement of Cash Flows.

In May 2017, the FASB issued ASU 2017-09, “Compensation – Stock Compensation (Topic 718): Scope of Modification Accounting.” ASU 2017-09 provides clarity on which changes to the terms or conditions of share-based payment awards require entities to apply the modification accounting provisions required in Topic 718. ASU 2017-09 is effective for all entities for annual reporting periods beginning after December 15, 2017, with early adoption permitted, including adoption in any interim period for which financial statements have not yet been issued. The Company does not

expect that the adoption of ASU 2017-09 will have a material impact on the Company's results of operations and financial condition.

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

#### 4. Inventories

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

	<b>September 30, 2017</b>	<b>December 31, 2016</b>
Finished goods	\$5,157,260	\$4,132,036
Work in process	306,942	205,116
Raw materials	<u>1,234,741</u>	<u>1,121,688</u>
<b>Inventories</b>	<b><u>\$6,698,943</u></b>	<b><u>\$5,458,840</u></b>

Inventories are net of reserve of approximately \$642,000 and \$960,000 at September 30, 2017 and December 31, 2016, respectively.

#### 5. Property and Equipment

Property and equipment consist of the following:

	<b>September 30, 2017</b>	<b>December 31, 2016</b>
Furniture and equipment	\$ 1,436,733	\$ 1,270,173
Leasehold improvements	711,319	447,650
Processing equipment	1,763,764	1,577,561
Less: accumulated depreciation and amortization	<u>(2,147,976)</u>	<u>(1,801,137)</u>
<b>Property and equipment, net</b>	<b><u>\$ 1,763,840</u></b>	<b><u>\$ 1,494,247</u></b>

#### 6. Intangible Assets

The Company's intangible assets consist of the following:

	<b>September 30, 2017</b>	<b>December 31, 2016</b>
License agreements	\$1,003,512	\$ 984,342
Patents	461,712	308,212
Less: accumulated amortization	<u>(513,751)</u>	<u>(463,575)</u>
<b>Intangible assets, net</b>	<b><u>\$ 951,473</u></b>	<b><u>\$ 828,979</u></b>

License agreements are being amortized over periods ranging from 17-20 years. Patent costs of \$22,000 were being amortized over three years. As of September 30, 2017, those patents were fully amortized, and the remaining patents of \$461,712 are pending patent costs and are being amortized over periods up to 20 years. Amortization expense was approximately \$19,000 and \$16,000 for the three months ended September 30, 2017 and 2016, respectively, and

approximately \$60,000 and \$48,000 for the nine months ended September 30, 2017 and 2016, respectively. As of September 30, 2017, future amortization of license agreements and patents (i) for the remainder of fiscal year 2017 is \$19,000, (ii) for the fiscal years 2018 through 2022 is expected to be \$74,000 per year, and (iii) after 2022 an aggregate \$563,000.

### **License Agreements**

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

- AxoGen pays royalty fees ranging from 1% to 3% under the License Agreements based on net sales of licensed products. One of the agreements also contains a minimum royalty of \$12,500 per quarter, which may include a credit in future quarters in the same calendar year for the amount the minimum royalty exceeds the royalty fees. Also, when AxoGen pays royalties to more than one licensor for sales of the same product, a royalty stack cap applies, capping total royalties at 3.75%;
- If AxoGen sublicenses technologies covered by the License Agreements to third parties, AxoGen would pay a percentage of sublicense fees received from the third party to the licensor. Currently, AxoGen does not sublicense any technologies covered by License Agreements. The Company is not considered a sub-licensee under the License Agreements and does not owe any sub-licensee fees for its own use of the technologies;
- AxoGen reimburses the licensors for certain legal expenses incurred for patent prosecution and defense of the technologies covered by the License Agreements; and
- Currently, under the University of Texas at Austin’s agreement, AxoGen would owe a \$15,000 milestone fee upon receiving a Phase II Small Business Innovation Research or Phase II Small Business Technology Transfer grant involving the licensed technology. The Company has not received either grant and does not owe such a milestone fee. A milestone fee to the University of Florida Research Foundation of \$2,000 is due if AxoGen receives FDA approval of its Avance® Nerve Graft, a milestone fee of \$25,000 is due upon the first commercial use of certain licensed technology to provide services to manufacture products for third parties and a milestone fee of \$10,000 is due upon the first use to manufacture products that utilize certain technology that is not currently incorporated into AxoGen products.

Royalty fees were approximately \$319,000 and \$214,000 during the three months ended September 30, 2017 and 2016, respectively, and approximately \$860,000 and \$583,000 during the nine months ended September 30, 2017 and 2016, respectively, and are included in sales and marketing expense on the accompanying condensed consolidated statements of operations.

## 7. Accounts Payable and Accrued Expenses

Accounts payable and accrued expenses consist of the following:

	September 30, 2017	December 31, 2016
Accounts payable	\$2,104,119	\$3,614,015
Accrued expenses	1,361,769	804,691
Accrued compensation	3,606,642	2,583,459
<b>Accounts Payable and Accrued Expenses</b>	<b><u>\$7,072,530</u></b>	<b><u>\$7,002,165</u></b>

## 8. Term Loan Agreements and Long-Term Debt

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

	September 30, 2017	December 31, 2016
Term Loan Agreement with MidCap Financial Trust (“MidCap”) for a total of \$21,000,000, net of \$663,946 of unamortized deferred financing fees at September 30, 2017, and \$771,185 at December 31, 2016. Interest is payable monthly at 8.0% per annum plus the greater of LIBOR or 0.5% which as of September 30, 2017 resulted in a 8.5% rate.	\$20,336,054	\$20,228,815
Revolving Loan Agreement with MidCap for up to \$10,000,000 with borrowings based upon eligible accounts receivable and inventory. Interest is payable monthly at 4.5% per annum plus the greater of LIBOR or 0.5% which as of September 30, 2017 resulted in a 5.0% rate.	4,000,000	4,025,023
Equipment Lease Agreement with Cisco Capital for a total lease amount of \$58,875 which has a 36 month term and requires no lease payments for the first three months of the lease and 33 equal payments of principal and interest until the end of the term. Interest on the lease is payable monthly at 3.5% per annum.	42,240	57,829
Total	24,378,294	24,311,667
Less current revolving loan	(4,000,000)	(4,025,023)
Less current maturities of long term debt	(21,596)	(20,899)
<b>Long-term portion</b>	<b><u>\$20,356,698</u></b>	<b><u>\$20,265,745</u></b>

### Credit Facilities

#### **Three Peaks Term Loan Agreement and Revenue Interest Agreement**

On November 12, 2014, AxoGen, as borrower, and AC, as guarantor, entered into that certain Term Loan Agreement (the “Three Peaks Term Loan Agreement”), dated November 12, 2014, by and among AxoGen, as borrower, AC, as guarantor, 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, as administrative and collateral agent for the lenders. Under the Three Peaks Term Loan Agreement, Three Peaks provided AxoGen a term loan of \$25 million which had a six-year term and required interest only payments and a final principal payment due at the end of the term. Interest was payable quarterly at 9.0% per annum plus the greater of LIBOR or 1.0% which as of November 13, 2014 resulted in a 10% rate.

In addition, on November 12, 2014, AxoGen entered into that certain Revenue Interest Agreement (the "Revenue Interest Agreement") with Three Peaks. Royalty payments were 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.

On October 26, 2016, the Three Peaks Term Loan Agreement and Revenue Interest Agreement were paid in full and the Company had no further obligations pursuant to such agreements.

#### **MidCap Term Loan Agreement**

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

The Company has the option at any time to prepay the Term Loan in whole or in part, subject to certain conditions, a prepayment fee, and a 5.0% exit fee as specified in the MC Term Loan Agreement. The prepayment fee is determined by multiplying the amount being prepaid by the following applicable percentage amount: (a) 3.0% during the first year following the Closing Date; (b) 2.0% during the second year following the Closing Date, and (c) 1.0% thereafter. However, no prepayment fee is due in the event the prepayment is a result of refinancing the Term Loan and Revolving Loan with MidCap or an affiliate of MidCap.

#### **MidCap Revolving Loan Agreement**

In addition, on October 25, 2016, AxoGen and AC, each as borrowers, also entered into a Credit and Security Agreement (Revolving Loan) (the "Revolving Loan Agreement") with the lenders party thereto and MidCap, as administrative agent and a lender. Under the Revolving Loan Agreement, MidCap agreed to lend to the Company up to \$10 million under a revolving credit facility (the "Revolving Loan") which amount 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. 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. 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 0.5% per annum of the principal amount outstanding on the Revolving Loan from time to time and an unused line fee of 0.5% per annum on the difference between the average amount outstanding on the Revolving Loan minus the total amount of the Revolving Loan commitment. The Revolving Loan 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 as specified in the Revolving Loan Agreement. 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 Term Loan and Revolving Loan with MidCap or an affiliate of MidCap.

The MC Term Loan Agreement and the Revolving Loan Agreement each contain covenants that place restrictions on AxoGen's operations, including, without limitation, covenants related to debt restrictions, investment restrictions, dividend restrictions, restrictions on transactions with affiliates and certain revenue covenants. MidCap, on behalf of the lenders under the agreements, has a first perfected security interest in the assets of the Company to guarantee the payment in full of the agreements. Upon the payment in full to MidCap and the lenders of the Term Loan Agreement and Revolving Loan Agreement, the Company would have no further obligations to MidCap or the lenders under the Term Loan Agreement or the Revolving Loan Agreement. As of September 30, 2017, we were in compliance with the loan covenants.

The Company used the aggregate proceeds of \$25 million from the Term Loan and the Revolving Loan to pay the outstanding indebtedness owed to Three Peaks and the other lenders to terminate the Three Peaks Term Loan Agreement and the Revenue Interest Agreement. Expenses and fees of approximately \$800,000 to complete the negotiation and documentation of the 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.

Interest expense for the year ended December 31, 2016 was approximately \$5,386,000 compared to \$3,989,000 for the year ended December 31, 2015. The 2016 amount includes a final payment to Three Peaks of approximately \$2,447,000 inclusive of prepayment fees and accrued interest through October 25, 2016. In addition, as a result of the accounting treatment for the Three Peaks transaction, the Company had previously recorded a total of \$747,000 of deferred interest charges which were offset against these prepayment fees. The net impact of these transactions resulted in a net interest charge of approximately \$1,700,000 in the year which was included in interest expense for the year ended December 31, 2016. Additionally, as the result of the extinguishment of the debt facility with Three Peaks, the Company wrote off approximately \$750,000 of prepaid financing fees to interest expense – deferred financing costs in 2016.

As of September 30, 2017, the Term Loan had an outstanding balance of \$21.0 million, with an interest rate of 8.5%. Also, at September 30, 2017, the borrowing base under the Revolving Loan Agreement was approximately \$6,879,000 and the Company had an outstanding balance on the Revolving Loan facility of \$4,000,000 with an interest rate of 5.0%.

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

<b>Year Ending December 31</b>	<b>Amount</b>
2017	\$ 5,310
2018	1,421,834
2019	8,415,096
2020	8,400,000
2021	2,800,000
	<u>21,042,240</u>
Less unamortized debt issuance costs	(663,946)
<b>TOTAL</b>	<b>\$ 20,378,294</b>

## **9. Stock Incentive Plan**

The Company maintains the AxoGen 2010 Stock Incentive Plan, as amended and restated (the "AxoGen Plan"), which allows for issuance of incentive stock options, non-qualified stock options, performance stock units (PSU) and restricted stock awards (RSU) to employees, directors and consultants at exercise prices not less than the fair market value at the date of grant. At the 2016 Annual Meeting of Shareholders, the AxoGen Plan was amended to increase the number of shares of common stock authorized for issuance under the AxoGen Plan to 5,500,000 shares. Additionally, at the 2017 Annual Meeting of Shareholders held on May 24, 2017, the AxoGen Plan was amended to increase the number of shares of common stock authorized for issuance under the AxoGen Plan to 7,700,000 shares. At the 2017 Annual Meeting of Shareholders, the shareholders approved the adoption of the AxoGen 2017 Employee Stock Purchase Plan (the "2017 ESPP"), which allows for eligible employees to acquire shares of our common stock through payroll deductions at a discount from market value. The 2017 ESPP authorized a total of 600,000 shares of our common stock with the first offering period expected to begin January 1, 2018.

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

The Company recognized stock-based compensation expense of \$919,026 and \$293,575 for the three months ended September 30, 2017 and 2016, respectively, and \$2,491,992 and \$1,046,364 for the nine months ended September 30, 2017 and 2016, respectively, which consisted of compensation expense related to employee stock options, PSUs and RSUs based on the value of share-based payment awards that are ultimately expected to vest during the period.

The Company estimates the fair value of each option award issued under such plans on the date of grant using the 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 the Company's merger with LecTec Corporation in 2011 (the "Merger"), and based on the Company's common stock for periods subsequent to the Merger. However, for options granted on and after December 29, 2016 the Company began using a Multiple Point Black-Scholes option-pricing model which uses a weighted average of historical volatility and peer company volatility. The Company determines the expected life giving consideration to the contractual terms, vesting schedules and post-vesting forfeitures. The Company uses the risk-free interest rate on the implied yield currently available on U.S. Treasury issues with an equivalent remaining term approximately equal to the expected life of the award.

The Company used the following weighted-average assumptions for options granted during the nine months ended September 30:

<u>Nine months ended September 30,</u>	<u>2017</u>	<u>2016</u>
Expected term (in years)	6.16	4.00
Expected volatility	50.72 %	61.71 %
Risk free rate	2.07 %	1.22 %
Expected dividends	— %	— %

The Company granted stock options to purchase 635,525 shares of its common stock pursuant to the AxoGen Plan, for the nine months ended September 30, 2017. The weighted average fair value of options granted at market during the nine months ended September 30, 2017 and 2016 was \$6.77 and \$3.00 per option, respectively

At September 30, 2017, the total future stock compensation expense related to non-vested awards is expected to be approximately \$9,086,000.

## **10. Public Offering of Common Stock**

On October 7, 2016, AxoGen entered into an underwriting agreement with JMP Securities LLC, as representative of the several underwriters (collectively, the "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. Pursuant to the underwriting agreement, the Company also granted the Underwriters a 30-day option to purchase up to an additional 350,000 shares of common stock, which the 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 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 \$18.67 million from the sale of 2,683,334 shares of common stock, which includes the additional 350,000 shares of common stock, after deducting the underwriting discounts and commissions and estimated offering expenses.

## **11. Commitments and Contingencies**

### **Operating Leases**

On March 16, 2016, AxoGen entered into the Fourth Amendment to Lease ("Fourth Amendment") with SNH Medical Office Properties Trust ("SNH"). SNH is the landlord of AC's currently leased 11,761 square foot corporate headquarters facility at 13631 Progress Boulevard, Suite 400, Alachua, Florida 32615 (the "Current Premises") pursuant to that certain lease dated as of February 6, 2007, as amended (the "Existing SNH 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 Existing SNH Lease will be extended to approximately five years from the Occupancy Date (as defined in the Fourth Amendment) which was 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. AxoGen’s annual cost of such property ranges from approximately \$248,000 to \$332,000 per year.

On October 25, 2013, AC entered into a commercial lease with Ja-Cole L.P. (“Ja-Cole”). Under the terms of the commercial lease, AxoGen occupied 5,400 square feet of warehouse/office space in its Burleson, Texas Distribution Facility until November 30, 2016 at an annual cost of \$43,200. On April 21, 2015, AxoGen entered into a new commercial lease, as amended by the addendum on such date (as amended, the “Ja-Cole Lease”), with Ja-Cole. The new commercial lease superseded and replaced the original lease with Ja-Cole dated October 25, 2013. Under the terms of the Ja-Cole Lease, AxoGen leased an additional 2,100 square feet of warehouse space at the Distribution Facility. The Ja-Cole Lease is for a three-year term expiring April 21, 2018. On October 25, 2016, AC entered into Commercial Lease Amendment 2 (the “Ja-Cole Amendment”) to the Ja-Cole Lease. Under the terms of the Ja-Cole Amendment, AxoGen leased an additional 2,500 square feet of warehouse/office space at the Distribution Facility. The Distribution Facility now comprises a total of 10,000 square feet, all of which, pursuant to the Ja-Cole Amendment, will be leased until March 31, 2019. The annual rental cost of the entire Distribution Facility is now approximately \$88,000. The Burleson facility houses raw material storage and product distribution while allowing same day fulfillment of orders for both coasts of the United States.

On January 23, 2017, AC entered into a lease (the “New SNH Lease”) for a five year term commencing April 1, 2017 with SNH Medical Office Properties Trust, a Maryland real estate investment trust (“SNH”), for 1,431 square feet at 13709 Progress Boulevard, Alachua, Florida 32615. Pursuant to the New SNH Lease, AC is to use the space for general office and biomedical research uses. SNH is the landlord of AC’s currently leased corporate headquarters facility at 13631 Progress Boulevard, Alachua, Florida 32615. AC’s additional annual cost of the Premises range from approximately \$25,800 to \$29,000 over the life of the lease.

In addition, AxoGen leases space and maintains records at certain other facilities, including the Company’s prior corporate headquarters at 1407 South Kings Highway, Texarkana, Texas 75501.

Estimated future minimum rental payments on the leases are as follows:

<b>Year Ending December 31</b>	<b>Amount</b>
2017 (9 months ended)	\$ 98,835
2018	437,900
2019	182,250
2020	165,116
2021	86,638
TOTAL	<u>\$ 970,739</u>

Total rent expense for the Company’s leased office and lab space for the nine months ended September 30, 2017 and 2016 was approximately \$368,000 and \$340,000, respectively.

### **Service Agreements**

From 2009 to February 2016, AxoGen processed and packaged Avance® Nerve Graft using its employees and equipment located at LifeNet Health, Virginia Beach, Virginia (“LifeNet Health”). Business requirements of LifeNet Health led to their need for additional space and they notified AxoGen that AxoGen would need to transition out of the Virginia Beach facility on or before February 27, 2016. On August 6, 2015, AxoGen entered into a License and Services Agreement



with Community Blood Center (d/b/a Community Tissue Services) (“CTS”), Dayton, Ohio, an FDA registered tissue establishment. Processing of the Avance® Nerve Graft pursuant to the CTS agreement began in February 2016. The CTS agreement is for a five-year term, subject to earlier termination by either party for cause, or after August 6, 2017 without cause, upon 18 months’ notice. Under the CTS agreement, AxoGen pays CTS a facility fee for clean room/manufacturing, storage and office space. CTS also provides services in support of AxoGen’s manufacturing such as routine sterilization of daily supplies, providing disposable supplies, microbial services and office support.

In August 2008, the Company entered into an agreement to distribute the AxoGuard® products worldwide in the field of peripheral nerve repair, and the parties subsequently amended the agreement in March, 2012. The agreement expires in August 2022. The Cook Biotech agreement also requires certain minimum purchases, although through mutual agreement the parties have not established such minimums and to date have not enforced such provision, and establishes a formula for the transfer cost of the AxoGuard® products. Under the agreement, AxoGen provides purchase orders to Cook Biotech, and Cook Biotech fulfills the purchase orders.

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

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

## **12. Retirement Plan**

### **AxoGen 401(k) Plan**

The Company adopted the AxoGen 401(k) plan (the “401(k) Plan”) in December 2015 with contributions starting in January 2016. All full-time employees who have attained the age of 18 are eligible to participate in the 401(k) Plan. Eligibility is immediate upon employment and enrollment is available any time during employment. Participating employees may make annual pretax contributions to their accounts up to a maximum amount as limited by law. The 401(k) Plan requires the Company to make matching contributions of 3% on the first 3% of the employee’s annual salary and 1% of the next 2% of the employee’s annual salary as long as the employee participates in the 401(k) Plan. Both employee contributions and Company contributions vest immediately. The Company contributed approximately \$334,000 in matching funds during 2016. Employer contributions to the 401(k) Plan for the three months ending September 30, 2017 and 2016 were approximately \$114,000 and \$76,000, respectively, and for the nine months ending September 30, 2017 and 2016 were approximately \$320,000 and \$247,000, respectively.

## **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. its wholly owned subsidiary AxoGen Corporation (“AC”) and its wholly owned subsidiary AxoGen Europe GmbH, which was established in the fourth quarter of 2016.

### **OVERVIEW**

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

AxoGen's 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, AxoGuard® Nerve Protector, a porcine submucosa ECM product used to wrap and protect injured peripheral nerves and reinforce the nerve reconstruction while preventing soft tissue attachments, and Avive® Soft Tissue Membrane, a minimally processed human umbilical cord membrane that may be used as a resorbable soft tissue covering to separate tissue layers and modulate inflammation in the surgical bed. Along with these core surgical products, AxoGen also offers AcroVal™ Neurosensory & Motor Testing System and AxoTouch® Two-Point Discriminator. These evaluation and measurement tools assist health care 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 AxoGen’s nerve repair products, the Avance® Nerve Graft, AxoGuard® Nerve Connector, AxoGuard® Nerve Protector and Avive® Soft Tissue Membrane, in the United States is the main contributor to AxoGen’s total reported sales and has been the key component of our growth to date. We estimate that there are approximately 5,100 accounts (e.g., hospitals, specialty surgery centers) performing nerve repair across the United States.

We have experienced that surgeons initially are cautious adopters for nerve repair products. Surgeons typically start with a few cases and then wait and review the results of these initial cases which can take from six to twelve months, or longer. Active accounts are usually past their initial wait period and have developed some level of product reorder. These active accounts have typically gone through their buying committee approval process, have at least one surgeon who has converted a portion of his or her treatment algorithms of nerve repair so as to use at least one of AxoGen’s products and have ordered such product(s) at least six times within the last twelve months prior to the review date. The number of active accounts at the end of the third quarter of 2017 were approximately 563, representing an increase of 36% compared to the third quarter of 2016.

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

## Results of Operations

### *Comparison of the Three Months Ended September 30, 2017 and 2016*

#### Revenues

Revenues for the three months ended September 30, 2017 increased 42.9% to \$16.0 million as compared to \$11.2 million for the three months ended September 30, 2016. We continued to experience growth in the number of active accounts, as well as product portfolio penetration in those accounts and, to a lesser extent, the establishment of new accounts, which drove our revenue growth in terms of units.

#### Gross Profit

Gross profit for the three months ended September 30, 2017 increased 42.1% to \$13.5 million as compared to \$9.5 million for the three months ended September 30, 2016. This increase is primarily attributable to the increased revenues. Gross margin decreased slightly to 84.4% for the three months ended September 30, 2017 as compared to 84.9% for the same period in 2016 primarily due to manufacturing yield variances and product mix.

#### Costs and Expenses

Total costs and expenses increased 40.2% to \$15.0 million for the three months ended September 30, 2017 as compared to \$10.7 million for the three months ended September 30, 2016, primarily due to increased sales activity, costs associated with increases in personnel to support our growth (including non-cash stock compensation), increases in research and development, which includes our RECON clinical trial, and increased general expenses associated with our continuing growth. As a percentage of total revenue, total cost and expenses decreased to 93.8% for the three months ended September 30, 2017 as compared to 95.5% for the comparable three months ended September 30, 2016, primarily as a result of the total revenue increase outpacing the increase in total costs in expenses.

Sales and marketing expenses increased 33.8% to \$9.5 million for the three months ended September 30, 2017 as compared to \$7.1 million for the three months ended September 30, 2016. This increase was primarily due to increased compensation expenses related to our direct sales force as a result of continued increased sales and hiring of additional personnel, increased commissions to independent distributors as a result of increased sales, and increased marketing research activity to drive market penetration. As a percentage of total revenue, sales and marketing expenses were 59.4% for the three months ended September 30, 2017 as compared to 63.4% for the three months ended September 30, 2016, primarily as a result of the total revenue increase continuing to outpace the increase in sales and marketing expenses.

General and administrative expenses increased 52.0% to \$3.8 million for the three months ended September 30, 2017 as compared to \$2.5 million for the three months ended September 30, 2016, primarily as the result of increased compensation (including non-cash stock compensation) and recruiting fees, and increased general expenses related to our growth. As a percentage of total revenues, general and administrative expenses were 23.8% for the three months ended September 30, 2017 as compared to 22.3% for the three months ended September 30, 2016, primarily as a result of the increase in general and administrative expenses outpacing the increase in total revenue.

Research and development expenses increased 63.6% to \$1.8 million for the three months ended September 30, 2017 as compared to \$1.1 million for the three months ended September 30, 2016. Research and development costs include our product development and clinical efforts substantially focused on our biologics license application (BLA) for the Avance® Nerve Graft as well as efforts in support of the RANGER Registry, investigator initiated studies and development of new products and product applications. This activity varies from quarter to quarter due to the timing of certain projects. The increase in expenses for the third quarter of 2017 relates to expenditures for such clinical activity and increased compensation and recruiting fees. Although our products are developed for sale in their current use, we continue to conduct development efforts focused on new products and new product applications. We are active in pursuing research grants to support research and early product development. As a percentage of total revenue, research and development expenses for the three months ended September 30, 2017 were 11.2% as compared to 10.0% for the three months ended September 30, 2016, as we continued to invest in our product development pipeline and clinical studies.

### Other Income and Expenses

Interest expense decreased 47.5% to \$578,000 for the three months ended September 30, 2017 as compared to \$1.1 million for the three months ended September 30, 2016, due to the lower interest rate as a result of the refinancing of our debt facility in October 2016.

Interest expense – deferred financing costs increased 43.8% to \$46,000 for the three months ended September 30, 2017 as compared to \$32,000 for the three months ended September 30, 2016, due to the deferred financing costs associated with the new debt facility being amortized over a shorter term than our previous debt facility.

### Income Taxes

We had no income tax expenses or income tax benefit for each of the three months ended September 30, 2017 and 2016 due to the incurrence of net operating losses in each of these periods.

*Comparison of the Nine Months Ended September 30, 2017 and 2016:*

### Revenues

Revenues for the nine months ended September 30, 2017 increased 46.5% to \$43.5 million as compared to \$29.7 million for the nine months ended September 30, 2016. This increase was primarily the result of continued unit revenue growth in active accounts and, to a lesser extent, the establishment of new accounts, as well as the product price increase we implemented in March 2017 across all of our product lines.

### Gross Profit

Gross profit for the nine months ended September 30, 2017 increased 46.6% to \$36.8 million as compared to \$25.1 million for the nine months ended September 30, 2016. This increase was primarily attributable to the increased revenues. Gross margin improved slightly to 84.6% for the nine months ended September 30, 2017 as compared to 84.5% for the same period in 2016.

### Costs and Expenses

Total cost and expenses increased 40.7% to \$42.9 million for the nine months ended September 30, 2017 as compared to \$30.5 million for the nine months ended September 30, 2016. These increases were due primarily to increased sales activity, costs associated with increases in compensation (including non-cash stock compensation), increases in research and development, which includes our RECON clinical trial, and increased general expenses associated with our continuing growth. As a percentage of total revenue, total costs and expenses decreased to 98.6% for the nine months ended September 30, 2017 as compared to 102.7% for the nine months ended September 30, 2016, primarily as a result of the total revenue increase outpacing the increase in total costs in expenses.

Sales and marketing expenses increased 36.8% to \$27.5 million for the nine months ended September 30, 2017 as compared to \$20.1 million for the nine months ended September 30, 2016, primarily due to increased compensation expenses related to our direct sales force as a result of increased sales and hiring of additional personnel, increased commissions to independent distributors as a result of increased sales, the expansion of our surgeon education program, and increased marketing activity. As a percentage of total revenue, sales and marketing expenses were 63.2% for the nine months ended September 30, 2017 as compared to 67.7% for the nine months ended September 30, 2016, primarily as a result of the total revenue increase continuing to outpace the increase in sales and marketing expenses.

General and administrative expenses increased 44.6% to \$10.7 million for the nine months ended September 30, 2017 as compared to \$7.4 million for the nine months ended September 30, 2016. The increase was primarily the result of increased compensation (including non-cash stock compensation) and recruiting, professional fees and increased general expenses related to our growth. As a percentage of total revenue, general and administrative expenses decreased slightly to 24.6% for the nine months ended September 30, 2017 as compared to 24.9% for the nine months ended September 30, 2016, primarily as a result of the increase in total revenue outpacing the increase in general and administrative expenses.

Research and development costs increased 56.7% to \$4.7 million in the nine months ended September 30, 2017 as compared to \$3.0 million for the nine months ended September 30, 2016. Research and development costs include our product development and clinical efforts substantially focused on our BLA for the Avance® Nerve Graft as well as efforts in support of the RANGER Registry, investigator initiated studies and development of new products and product applications. This activity varies from period to period due to the timing of certain projects. The increase in expenses for the first nine months of 2017 relates to expenditures for such clinical activity, including increased personnel to support both clinical and product development activity, offset by certain projects that have been completed. Although our products are developed for sale in their current use, we continue to conduct development efforts focused on new products and new product applications. We are active in pursuing research grants to support research and early product development. As a percentage of revenues, research and development expenses for the nine months ended September 30, 2017 were 10.8% as compared to 10.1% for the nine months ended September 30, 2016, as we continued to invest in our product development pipeline and clinical studies.

#### Other Income and Expenses

Interest expense decreased 51.5% to \$1.6 million for the nine months ended September 30, 2017 as compared to \$3.3 million for the nine months ended September 30, 2016. This decrease was due to the lower interest rate as a result of the refinancing of our debt facility in October 2016.

Interest expense – deferred financing costs increased 44.2% to \$137,000 for the nine months ended September 30, 2017 as compared to \$95,000 for the nine months ended September 30, 2016, due to the deferred financing costs associated with the new debt facility being amortized over a shorter term than our previous debt facility.

#### Income Taxes

We had no income tax expenses or income tax benefit for each of the nine months ended September 30, 2017 and 2016 due to the incurrence of net operating loss in both of these periods.

#### **Effect of Inflation**

Inflation has not had a significant impact on the Company's operations or cash flow during 2017 or the fiscal years ended 2016, 2015 and 2014.

#### **Liquidity and Capital Resources**

##### Cash Flow Information

As of September 30, 2017, the Company had cash and cash equivalents of \$22.0 million, a decrease of \$8.0 million from \$30.0 million at December 31, 2016. Cash disbursements in the first nine months included a \$1.2 million payment of the 2016 all-employee performance bonus accrual.

The Company had working capital of \$28.4 million and a current ratio of 3.55 at September 30, 2017, compared to working capital of \$33.0 million and a current ratio of 3.97 at December 31, 2016. The decrease in working capital and the current ratio at September 30, 2017 as compared to December 31, 2016 was due primarily to the use of working capital to fund operations including the increase in inventory and accounts receivable. The Company believes it has sufficient cash resources to meet its liquidity requirements for at least the next 12 months based on its expected level of operations.

AxoGen's future capital requirements depend on a number of factors, including, without limitation, continued adoption of its products by surgeons and growth of its revenues, continued expansion and development of its direct sales force, expenses associated with its surgeon education programs, maintaining its gross margins, expenses related to its 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.

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, 2017 used \$8.2 million of cash as compared to using \$9.8 million of cash for operating activities for the nine months ended September 30, 2016. This decrease in cash used for operating activities of approximately \$1.6 million is primarily attributable to lower net losses after adjusting for higher non-cash expenses, including stock-based compensation and depreciation in 2017 compared to 2016.

Cash used for investing activities

Investing activities for the nine months ended September 30, 2017 used \$799,000 of cash as compared to using \$770,000 of cash for the nine months ended September 30, 2016. This increase in cash used for investing activities of \$29,000 is principally attributable to ongoing investments for capital equipment and intellectual property for the growth of our business.

Cash provided by financing activities

Financing activities for the nine months ended September 30, 2017 provided \$1.0 million of cash as compared to providing \$646,000 of cash for the nine months ended September 30, 2016. These amounts were primarily attributable to proceeds from the exercise of stock options.

Credit Facilities

On November 12, 2014, AxoGen, as borrower, and AC, as guarantor, entered into that certain Term Loan Agreement (the "Three Peaks Term Loan Agreement"), with Three Peaks Capital S.a.r.l. ("Three Peaks"), an indirect wholly-owned subsidiary of Oberland Capital Healthcare Master Fund LP, as administrative and collateral agent for the lenders. Under the Three Peaks Term Loan Agreement, Three Peaks provided AxoGen a term loan of \$25 million which had a six-year term and required interest only payments and a final principal payment due at the end of the term. Interest was payable quarterly at 9.0% per annum plus the greater of LIBOR or 1.0% which as of November 13, 2014 resulted in a 10% rate. AxoGen had to maintain certain covenants including limiting new indebtedness, restriction of the payment of dividends and maintain certain levels of revenue. Three Peaks had a first perfected security interest in the assets of AxoGen.

In addition, on November 12, 2014, AxoGen entered into that certain Revenue Interest Agreement (the "Revenue Interest Agreement") with Three Peaks. Royalty payments were 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.

On October 26, 2016, the Three Peaks Term Loan Agreement and Revenue Interest Agreement were paid in full and the Company had no further obligations pursuant to such agreements.

On October 25, 2016, AxoGen and AC, each as borrowers, entered into a Credit and Security Agreement (the "MC Term Loan Agreement") with the lenders party thereto and MidCap Financial Trust ("MidCap"), as administrative agent and a lender. Under the MC Term Loan Agreement, MidCap provided the Company a term loan in the aggregate principal amount of \$21 million (the "Term Loan") which 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 Term Loan being fully paid by the maturity date. Interest is payable monthly at 8.0% per annum plus the greater of LIBOR or 0.5%. Additionally, AxoGen and AC, each as borrowers, also entered into a Credit and Security Agreement (the "Revolving Loan Agreement") with the lenders party thereto and MidCap, as administrative agent and a lender. Under the Revolving Loan Agreement, MidCap agreed to lend to the Company up to \$10 million under a revolving credit facility (the "Revolving Loan") which amount 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. 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.

Under the MidCap Term Loan Agreement and the Revolving Loan Agreement, the Company must maintain certain covenants including, but not limited to, 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 MC Term Loan and Revolving Loan. Upon the payment in full to MidCap and the lenders of the MC Term Loan and Revolving Loan, the Company would have no further obligations to MidCap or the lenders under the MC Term Loan or the Revolving Loan or the Revolving Loan Agreement.

The Company used the aggregate proceeds of \$25 million from the Term Loan and the Revolving Loan to pay the outstanding indebtedness owed to Three Peaks and the other lenders to terminate the Three Peaks Term Loan Agreement and the Revenue Interest Agreement. Expenses and fees of approximately \$800,000 to complete the negotiation and documentation of the 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.

As of September 30, 2017, the Term Loan facility had an outstanding balance of \$21.0 million, with an interest rate of 8.5%. Also, at September 30, 2017, the Borrowing Base (as defined in the Revolving Loan Agreement) under the Revolving Loan Agreement was approximately \$6.9 million and the Company had an outstanding balance on the Revolving Loan facility of \$4.0 million with an interest rate of 5.0%.

#### **Public Offering of Common Stock**

On October 7, 2016, AxoGen entered into an underwriting agreement (the "Underwriting Agreement") with JMP Securities LLC, as representative of the several underwriters (collectively, the "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. Pursuant to the Underwriting Agreement, the Company also granted the Underwriters a 30-day option to purchase up to an additional 350,000 shares of common stock, which the 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 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 \$18.67 million from the sale of 2,683,334 shares of common stock, which includes the additional 350,000 shares of common stock, after deducting the underwriting discounts and commissions and estimated offering expenses. The Company intends to use, and has been using, the net proceeds from the 2016 Offering for general working capital purposes and expanded development of nerve repair markets. However, the Company's management retains broad discretion over the allocation of the net proceeds.

#### **Material Commitments**

At September 30, 2017, the Company had entered into an agreement with a local commercial general contractor for the expansion of its headquarters facility in Alachua, Florida to remodel and finish additional leased space adjacent to its current facility for \$285,000, which it expects to complete by December 31, 2017.

#### **Off-Balance Sheet Arrangements**

AxoGen does not have any off-balance sheet arrangements.

### **ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

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

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

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

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

We are subject to market risk from exposure to changes in interest rates based upon our financing, investing and cash management activities. Changes in interest rates affect interest income earned on cash and cash equivalents and interest expense on long term and revolving credit arrangements. We have not entered into derivative transactions related to cash and cash equivalents or debt. Our borrowings under our term loan and credit facilities expose us to market risk related to changes in interest rates. As of September 30, 2017, our long term debt was approximately \$21.0 million with an interest rate of 8.0% per annum plus the greater of LIBOR or 0.5% and our revolving loan was \$4.0 million with an interest rate of 4.5% per annum plus the greater of LIBOR or 0.5%. We do not expect changes in interest rates to have a material adverse effect on our income or our cash flows in 2017. However, we can give no assurance that interest rates will not significantly change in the future.

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

In the United States, we sell our products directly to hospitals and clinics in the local currency. Revenue is recognized as disclosed in Note 3 - Summary of Significant Accounting Policies - Revenue Recognition in our Notes to Condensed Consolidated Financial Statements.

In all international markets, we sell our products to independent distributors who, in turn, sell to medical clinics. These sales of our products in these countries through independent distributors are denominated in United States dollars.

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

#### **ITEM 4. CONTROLS AND PROCEDURES**

##### **Evaluation of Disclosure Controls and Procedures**

The Company maintains "disclosure controls and procedures" as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), that are designed to ensure that information required to be disclosed by us in reports we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including our principal executive officer and principal financial officer, and Board of Directors, as appropriate, to allow timely decisions regarding required disclosure. In designing and evaluating our disclosure controls and procedures, management recognizes that disclosure controls and procedures, no matter how well conceived and operated, can provide only reasonable assurance of achieving the desired objectives, and we necessarily are required to apply our judgment in evaluating the cost-benefit relationship of possible disclosure controls and procedures.



Our management, including our principal executive officer and principal financial officer, evaluated the effectiveness of the design and operation of our disclosure controls and procedures as of September 30, 2017 and concluded that our disclosure controls and procedures were still not effective as of such date due to the same material weaknesses in internal control over financial reporting described in Annual Report on Form 10-K for the year ended December 31, 2016 (the “2016 Annual Report”).

#### **Changes in Internal Controls Over Financial Reporting**

During the three months ended September 30, 2017, the Company made the following changes to the design of its internal controls over financial reporting:

- Improved procedures to test, evaluate and document the assumptions utilized in significant estimates; and
- Enhanced the scope and procedures of the testing and documentation of quarterly cycle counts of consignment inventory.

We believe these changes in internal controls over financial reporting address the material weaknesses relating to the design and operation of key controls around the use of judgment and calculations of significant estimates, as well as quarterly cycle count procedures related to consigned inventories, described in our 2016 Annual Report. Although these changes have been made, the material weaknesses or deficiencies will not be considered remediated until the applicable remedial controls operate for a sufficient period of time and management has concluded, through testing, that these controls are operating effectively. Weaknesses or deficiencies in our internal control over financial reporting may be identified when we assess the effectiveness of the Company’s internal control over financial reporting as of December 31, 2017, or during the audit by our independent registered public accounting firm of the Company’s internal control over financial reporting as of December 31, 2017.

Other than such changes, there were no other changes in our internal control over financial reporting identified in management’s evaluation pursuant to Rules 13a-15(d) or 15d-15(d) of the Exchange Act during the period covered by this Form 10-Q that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

## **PART II – OTHER INFORMATION**

### **ITEM 1 – LEGAL PROCEEDINGS**

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

AxoGen and its subsidiaries are not a party to any material litigation as of September 30, 2017.

### **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 2016 Annual Report. 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 since the filing of the 2016 Annual Report.

### **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*	Executive Employment Agreement dated as of July 17, 2017, by and between AxoGen Corporation and Jon S. Gingrich (incorporated by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K/A, filed on July 20, 2017).
10.2*	Form of Non-Qualified Stock Option Inducement Award Agreement to be granted by AxoGen, Inc. to Jon S. Gingrich on July 17, 2017 (incorporated by reference to Exhibit 10.2 of the Registrant's Current Report on Form 8-K/A, filed on July 20, 2017).
31.1†	Certification of Principal Executive Officer pursuant to Rules 13a-14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2†	Certification of Principal Financial Officer pursuant to Rules 13a-14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32††	Certifications of the Principal Executive Officer and Principal Financial Officer pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	XBRL Instance Document.
101.SCH	XBRL Taxonomy Extension Schema Document.
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document.
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB	XBRL Extension Labels Linkbase.
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document.

\* Management contract or compensatory plan or arrangement.

† Filed herewith.

†† Furnished herewith.

**EXHIBIT INDEX**

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† 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 1, 2017

/s/ Karen Zaderej

Karen Zaderej  
Chief Executive Officer  
(Principal Executive Officer)

Dated: November 1, 2017

/s/ Peter J. Mariani

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

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

I, Karen Zaderej, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of AxoGen, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 1, 2017

/s/ Karen Zaderej  
Karen Zaderej  
Chief Executive Officer

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

I, Peter J. Mariani, certify that:

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

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

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

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

- a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
- b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
- c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
- d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

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

- a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
- b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 1, 2017

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

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**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 1, 2017

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

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

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