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, 2014

or

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

For the transition period from to

Commission file number: 001-36046

AxoGen, Inc.

(Exact name of registrant as specified in its charter)

Minnesota	**41-1301878**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
13631 Progress Blvd., Suite 400, Alachua, FL	**32615**
(Address of principal executive offices)	(Zip Code)

386-462-6800

(Registrant's telephone number, including area code)

Not Applicable

(Former name, former address and former fiscal year, if changed since last report)

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). YES ☒ NO ☐

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

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

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

As of November 13, 2014 the registrant had 19,487,530 shares of common stock outstanding.

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Forward-Looking Statements

From time to time, in reports filed with the Securities and Exchange Commission (including this Form 10-Q), in press releases, and in other communications to shareholders or the investment community, the Company may provide forward-looking statements 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", "may", "should", 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 product development, product potential, regulatory environment, sales and marketing strategies, liquidity, capital resources or operating performance. 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 Securities and Exchange Commission. 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.

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PART 1 — FINANCIAL INFORMATION

ITEM 1 — CONDENSED CONSOLIDATED FINANCIAL STATEMENTS AND NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

AxoGen, Inc.
Condensed Consolidated Balance Sheets

	September 30, 2014 (unaudited)	December 31, 2013
Assets		
Current assets:		
Cash and cash equivalents	$ 11,802,608	$ 20,069,750

Accounts receivable, net of allowance for doubtful accounts of approximately $69,000 and $59,000, respectively	2,743,041	1,893,699
Inventory	3,346,115	3,398,438
Prepaid expenses and other	100,923	296,719
Total current assets	17,992,687	25,658,606
Property and equipment, net	613,174	381,689
Intangible assets	576,382	570,396
Deferred financing costs	914,931	1,073,579
	$ 20,097,174	$ 27,684,270
Liabilities and Shareholders' Equity (Deficit)		
Current liabilities:		
Accounts payable and accrued expenses	$ 2,020,091	$ 2,083,942
Current Deferred Revenue	14,118	14,118
Total current liabilities	2,034,209	2,098,060
Note Payable — Revenue Interest Purchase Agreement	28,173,877	25,363,695
Long Term Deferred Revenue	75,168	85,882
Total liabilities	30,283,254	27,547,637
Commitments and contingencies		
Shareholders' equity (deficit):		
Common stock, $.01 par value; 50,000,000 shares authorized; 17,466,381 and 17,339,561 shares issued and outstanding	174,664	173,395
Additional paid-in capital	73,264,241	72,369,016
Accumulated deficit	(83,624,985)	(72,405,778)
Total shareholders' equity (deficit)	(10,186,080)	136,633
	$ 20,097,174	$ 27,684,270

See notes to condensed consolidated financial statements.

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

	Three Months Ended		Nine Months Ended	
	September 30, 2014	September 30, 2013	September 30, 2014	September 30, 2013
Revenues	$ 4,671,340	$ 2,957,462	$ 12,023,789	$ 7,962,683
Cost of goods sold	896,178	650,212	2,485,299	1,843,748
Gross profit	3,775,162	2,307,250	9,538,490	6,118,935
Costs and expenses:				
Sales and marketing	3,250,977	2,757,241	9,326,596	7,177,170
Research and development	681,230	593,643	2,049,603	1,498,904
General and administrative	1,645,859	1,233,360	5,254,082	4,237,738
Total costs and expenses	5,578,066	4,584,244	16,630,281	12,913,812
Loss from operations	(1,802,904)	(2,276,994)	(7,091,791)	(6,794,877)
Other income (expense):				
Interest expense	(1,380,470)	(1,214,603)	(3,963,885)	(3,505,869)
Interest expense—deferred financing costs	(55,217)	(61,216)	(158,648)	(146,648)
Other income (expense)	417	32	(4,886)	(696)
Total other income (expense)	(1,435,270)	(1,275,787)	(4,127,419)	(3,653,213)
Net loss	$ (3,238,174)	$ (3,552,781)	$ (11,219,210)	$ (10,448,090)
Weighted Average Common Shares outstanding — basic and diluted	17,466,097	14,320,113	17,437,373	12,205,863
Loss Per Common share - basic and diluted	$ (0.19)	$ (0.25)	$ (0.64)	$ (0.86)

See notes to condensed consolidated financial statements.

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AxoGen, Inc.
Condensed Consolidated Statements of Cash Flows

(unaudited)

	Nine Months Ended September 30,	
	2014	2013
Cash flows from operating activities:		
Net loss	$ (11,219,210)	$ (10,448,090)
Adjustments to reconcile net loss to net cash used for operating activities:		
Depreciation	111,390	60,869
Amortization of intangible assets	33,468	44,176
Amortization of deferred financing costs	158,648	146,648
Share-based compensation	701,697	534,673
Stock grants	60,125	—
Interest added to note	2,810,182	2,752,273
Change in assets and liabilities:		
Accounts receivable	(849,342)	(690,127)
Inventory	52,323	(308,955)
Prepaid expenses and other	195,796	9,821
Accounts payable and accrued expenses	(63,848)	(162,631)
Deferred revenue	(10,714)	—
Net cash used for operating activities	(8,019,485)	(8,061,343)
Cash flows from investing activities:		
Purchase of property and equipment	(342,875)	(66,564)
Acquisition of intangible assets	(39,454)	(50,262)
Net cash used for investing activities	(382,329)	(116,826)
Cash flows from financing activities:		
Proceeds from issuance of common stock	—	16,784,203
Proceeds from exercise of stock options	134,672	73,015
Net cash provided by financing activities	134,672	16,857,218
Net increase (decrease) in cash and cash equivalents	(8,267,142)	8,679,049
Cash and cash equivalents, beginning of year	20,069,750	13,907,401
Cash and cash equivalents, end of period	$ 11,802,608	$ 22,586,450
Supplemental disclosures of cash flow activity:		
Cash paid for interest	$ 1,154,738	$ 749,857

See notes to condensed consolidated financial statements.

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

1. Basis of Presentation

The accompanying condensed consolidated financial statements include the accounts of AxoGen, Inc. (the "Company" or "AxoGen") and its wholly owned subsidiary AxoGen Corporation ("AC") as of September 30, 2014 and December 31, 2013 and for the three month and nine month periods ended September 30, 2014 and 2013. The Company's condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America and should be read in conjunction with the audited financial statements of the Company for the year ended December 31, 2013, which are included in the Annual Report on Form 10-K as of and for the year ended December 31, 2013. 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

The Company is a leading medical technology company dedicated to peripheral nerve repair. AxoGen's portfolio of regenerative medicine products is available in the United States, Canada and several other countries and includes Avance® Nerve Graft, the only off-the-shelf commercially available processed nerve allograft for bridging severed nerves without the comorbidities associated with a second surgical site, AxoGuard® Nerve Connector, a porcine submucosa extracellular matrix ("ECM") coaptation aid for tensionless repair of severed nerves, and

AxoGuard® Nerve Protector, a porcine submucosa ECM product used to wrap and protect injured peripheral nerves and reinforce the nerve reconstruction while preventing soft tissue attachments.

Avance® Nerve Graft is processed in the United States by AxoGen. AxoGuard® Nerve Connector and AxoGuard® Nerve Protector are manufactured in the United States by Cook Biotech Incorporated, and are distributed worldwide exclusively by AxoGen. AxoGen maintains its corporate offices in Alachua, Florida and is the parent of its wholly owned operating subsidiary, AxoGen Corporation.

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 revenue 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

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has never experienced any losses related to these balances and does not believe it is exposed to any significant credit risk on cash and cash equivalents.

Accounts Receivable and Concentration of Credit Risk

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

We regularly review all accounts that exceed 60 days from the invoice date and based on an assessment of current credit worthiness, estimate the portion, if any, of the balance that will not be collected. The analysis excludes certain government related receivables due to our past successful experience in collectability. Specific accounts that are deemed uncollectible are reserved at 100% of their outstanding balance. The remaining balances outstanding over 60 days have a percentage applied by aging category (5% for balances 61-90 days and 20% for balances over 90 days aged), based on a historical valuation that allows us to calculate the total reserve required. The reserve balance was determined by applying a percentage to the cumulative balance between 60 and 90 days and a higher percentage to the balance over 90 days. In the event that we exhaust all collection efforts and deem an account uncollectible, we would subsequently write off the account. The write off process involves approval by senior management based on the write off amount. The allowance for doubtful accounts reserve balance was approximately $69,000 and $59,000 at September 30, 2014 and December 31, 2013, respectively.

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

Inventories

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

	September 30, 2014	December 31, 2013
	(unaudited)	
Finished goods	$ 2,116,046	$ 2,131,336
Work in process	221,362	235,966
Raw materials	1,008,707	1,031,136
	$ 3,346,115	$ 3,398,438

Inventories were net of reserve of approximately $383,000 and $383,000 at September 30, 2014 and December 31, 2013, respectively.

Income Taxes

The Company has not recorded current income tax expense due to the generation of net operating losses. Deferred income taxes are accounted for using the balance sheet approach which requires recognition of deferred tax assets and liabilities for the expected future consequences of temporary differences between the financial reporting basis and the tax basis of assets and liabilities. A valuation allowance is provided when it is more likely than not that a deferred tax asset will not be realized. A full valuation allowance has been established on the deferred tax asset as it is more likely than not that future tax benefit will not be realized. In

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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, 2010 through 2013; 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 and cash equivalents, accounts receivable and accounts payable and accrued expenses. The fair value of the Company's long-term debt approximates its carrying value based upon current rates available to the Company.

Share-Based Compensation

Stock-based compensation cost related to stock options granted under the AC 2002 Stock Option Plan and AxoGen 2010 Stock Incentive Plan is measured at grant date, based on the fair value of the award, and is recognized as an expense over the employee's requisite service period. The Company estimates the fair value of each option award issued under the Plan on the date of grant using a Black-Scholes-Merton option-pricing model that uses the assumptions noted in the table below. The Company estimates the volatility of its common stock at the date of grant based on the volatility of comparable peer companies which are publicly traded, for the periods prior to the merger, and based on the Company's common stock for periods subsequent to the merger. The Company determines the expected life based on historical experience with similar awards, giving consideration to the contractual terms, vesting schedules and post-vesting forfeitures. The Company uses the risk-free interest rate on the implied yield currently available on U.S. Treasury issues with an equivalent remaining term approximately equal to the expected life of the award. The Company has never paid any cash dividends on its common stock and does not anticipate paying any cash dividends in the foreseeable future. The Company used the following weighted-average assumptions for options granted during the nine months ended September 30:

Nine months ended September 30,	2014 (unaudited)	2013 (unaudited)
Expected term (in years)	4.0	4.0
Expected volatility	79.76%	83.27%
Risk free rate	1.23%	0.71%
Expected dividends	0.0%	0.0%

The Company estimates forfeitures when recognizing compensation expense and this estimate of forfeitures is adjusted over the requisite service period based on the extent to which actual forfeitures differ, or are expected to differ, from such estimates. Changes in estimated forfeitures are recognized through a cumulative catch-up adjustment, which is recognized in the period of change, and also impact the amount of unamortized compensation expense to be recognized in future periods. The Company did not apply a forfeiture allocation to its unvested options outstanding during the nine months ended September 30, 2014 and 2013 as they were deemed insignificant.

Use of Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported

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amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

Recent Accounting Pronouncements

On May 28, 2014, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2014-09, *Revenue from Contracts with Customers*. The core principle of the ASU is for companies to recognize revenue to depict the transfer of goods or services to customers in amounts that reflect the consideration, or payment, to which the company expects to be entitled in exchange for those goods or services. The ASU may also result in enhanced disclosures about revenue. For public entities, the ASU is effective for annual reporting periods beginning after December 15, 2016, including interim periods within that reporting period. Due to the recent date of issuance for this ASU, management is currently evaluating what impact, if any, the pronouncement will have on the Company's disclosures, its financial position or results from operations.

4. Property and Equipment

Property and equipment consist of the following:

	September 30, 2014 (unaudited)	December 31, 2013
Furniture and equipment	$ 825,690	$ 893,973
Leasehold improvements	285,698	53,864
Processing equipment	1,194,712	1,015,388
Less: accumulated depreciation and amortization	(1,692,926)	(1,581,536)
Property and equipment	$ 613,174	$ 381,689

5. Intangible Assets

The Company's intangible assets consist of the following:

	September 30, 2014 (unaudited)	December 31, 2013
License agreements	$ 838,586	$ 816,300
Patents	79,721	62,553
Less: accumulated amortization	(341,925)	(308,457)
Intangible assets, net	$ 576,382	$ 570,396

License agreements are being amortized over periods ranging from 17-20 years. Patent costs were being amortized over three years. As of December 31, 2013, the patents were fully amortized, the remaining patents of $79,721 were pending patent costs and were not amortizable. Amortization expense was approximately $11,000 and $15,000 for the three months and was approximately $33,000 and $44,000 for the nine months ended September 30, 2014 and 2013, respectively. As of September 30, 2014, future amortization of license

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agreements is expected to be approximately $15,000 for the remainder of 2014 and $48,000 for 2015 through 2018.

License Agreements

The Company has entered into multiple license agreements (the "License Agreements") with the University of Florida Research Foundation ("UFRF") and University of Texas at Austin ("UTA"). 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 one of the License Agreements, 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. Other milestone fees are due if AxoGen develops

certain pharmaceutical or medical device products under the License Agreements. No such products are currently under development.

Royalty fees were approximately $93,000 and $64,000 for the three months and were $238,000 and $169,000 for the nine months ended September 30, 2014 and 2013, and are included in sales and marketing expense on the accompanying condensed consolidated statements of operations.

6. Accounts Payable and Accrued Expenses

Accounts payable and accrued expenses includes $182,880 and $203,380 for accrued payroll at September 30, 2014 and December 31, 2013, respectively, $512,774 and $417,825 for accrued commissions at September 30, 2014 and December 31, 2013, respectively and $154,252 and $31,176 for accrued bonuses at September 30, 2014 and December 31, 2013, respectively.

7. Notes Payable

Notes Payable consists of the following:

	September 30, 2014 (unaudited)	December 31, 2013
Revenue Interest Purchase Agreement with PDL BioPharma, Inc. ("PDL") for aggregate of $20,800,000 with amounts payable monthly at 9.95% of Net Revenues through September 2014; and the greater of (i) 9.95% of product revenue or (ii) specific quarterly amounts varying from approximately $1.3 million to $2.5 million per quarter through September 2020. The minimum annual payment amounts are as follows: 2014 - $1,250,805, 2015 - $6,781,440, 2016 - $9,232,642, 2017 and 2018 - $9,000,000, 2019 - $9,063,000 and 2020 - $6,939,000.	$ 28,173,877	$ 25,363,695
Long-term Notes Payable	$ 28,173,877	$ 25,363,695

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Note Payable

On October 5, 2012, AxoGen entered into a Revenue Interests Purchase Agreement (the "Royalty Contract") with PDL BioPharma, Inc. ("PDL"), pursuant to which the Company sold to PDL the right to receive royalties equal to 9.95% of the Company's Net Revenues (as defined in the Royalty Contract) generated by the sale, distribution or other use of AxoGen's products Avance® Nerve Graft, AxoGuard® Nerve Connector and AxoGuard® Nerve Protector. Proceeds from the PDL transaction were used to fully repay the MidCap Loan, as defined below, and extinguish AxoGen's long-term debt obligations there under. The Royalty Contract has a term of eight years. Under the Royalty Contract, PDL is to receive royalty payments based on a royalty rate of 9.95% of the Company's Net Revenues, subject to certain agreed upon minimum payment requirements, currently anticipated to be operative, of approximately $1.3 to $2.5 million per quarter which begin in the fourth quarter of 2014 through the third quarter of 2020 as provided in the Royalty Contract. The total consideration PDL paid to the Company was $20,800,000 (the "Funded Amount"), including $19,050,000 PDL paid to the Company on October 5, 2012, and $1,750,000 PDL paid to the Company on August 14, 2012 pursuant to an Interim Revenue Interest Purchase Agreement between the Company and PDL, dated August 14, 2012 (the "Interim Royalty Contract"). Upon the closing (the "Closing") of PDL's purchase of the specified royalties described above, which was concurrent with the execution of the Royalty Contract, the Interim Royalty Contract was terminated.

The Company records interest using its best estimate of the effective interest rate. Currently the Company is accruing interest using the specified internal rate of return of the put option of 20%. From time to time, the Company will reevaluate the expected cash flows and may adjust the effective interest rate. Determining the effective interest rate requires judgment and is based on significant assumptions related to estimates of the amounts and timing of future revenue streams.

Put Option

Under the Royalty Contract, on October 5, 2016, or in the event of the occurrence of a material adverse event, our transfer of revenue interest or substantially all of our interest in the products or AxoGen's bankruptcy or material breach of the Royalty Contract, PDL may require AxoGen to repurchase the Assigned Interests at the "Put Price." The Put Price is equal to the sum of (i) an amount that, when paid to PDL, would generate a specified internal rate of return to PDL of 20% on the Funded Amount, taking into consideration payments made to PDL by the Company, and (ii) any "Delinquent Assigned Interest Payment" (as defined in the Royalty Contract) the Company owed to PDL.

Change of Control; Call Option

In addition, in the event of a "Change of Control" (as defined in the Royalty Contract), the Company must repurchase the assigned Interests from PDL for a repurchase price equal to the "Change of Control Price" on or prior to the third business day after the occurrence of the Change of Control. The Change of Control Price is equal to the sum of (i) an amount that, when paid to PDL, would generate a specified internal rate of return to PDL of thirty-two and one half percent (32.5%) on the Funded Amount, taking into consideration payments made to PDL by the Company, and (ii) any "Delinquent Assigned Interest Payment" (as defined in the Royalty Contract) the Company owed to PDL. In addition, at any time after October 5, 2016, the Company, at its option, can call the Royalty Contract for a price equal to the Change of Control Price.

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Board Designee

Under the Royalty Contract, during the term of the Royalty Contract, PDL is entitled to designate, and AxoGen shall appoint an individual designated by PDL, who shall serve on the Board of Directors of the Company (the "Board"). The PDL designee was elected at the Company's 2013 Annual Meeting of Shareholders. At each annual meeting thereafter during the term of the Royalty Contract, the Board shall nominate and recommend the PDL designee as a director nominee to serve on the Board until the next annual meeting and shall include such nomination in AxoGen's proxy statement for each annual meeting thereafter, provided that the election of the PDL designee is subject to shareholders' approval.

Should at any time there become a vacancy on the Board as a result of (i) the resignation, death or removal of the PDL designee or (ii) such PDL designee failing to obtain the requisite approval of the Company's shareholders at any annual or special meeting of the Company's shareholders and where no other individual is elected to such vacancy, PDL shall have the right to designate an individual to fill such vacancy, and AxoGen shall take such actions necessary to appoint, such individual to the Board.

On August 20, 2014, John McLaughlin, the PDL designee who was serving on the Board, delivered to us notice of his resignation as a member of the Board of Directors (the "Board") of AxoGen, Inc. (the "Company") effective as of the date of the notice. The Board accepted Mr. McLaughlin's notice of resignation. The Company notes that Mr. McLaughlin's resignation was not the result of any disagreement with the Company relating to the Company's operations, policies or practices. Mr. McLaughlin had served as a member of the Board since October 2012. PDL has informed the Company that it does not intend to appoint a replacement for Mr. McLaughlin at this time.

Preemptive Rights

Under the Royalty Contract, PDL has preemptive rights with respect to certain new issuances of AxoGen's equity securities and securities convertible, exchangeable or exercisable into such equity securities.

Restriction on Dividends

Under the Royalty Contract, during the period from the October 5, 2012 to December 4, 2016 (or the payment of the Put Price in the event PDL exercises its put option on or prior to December 4, 2016), AxoGen shall not, nor shall it permit any subsidiary to, declare, pay or make any dividend or distribution on any shares of the common stock or preferred stock of such entity (other than dividends or distributions payable in its stock, or split-ups or reclassifications of its stock) or apply any of its funds, property or assets to the purchase, redemption or other retirement of any common or preferred stock, or of any options to purchase or acquire any such shares of common or preferred stock of any such entity (collectively, "Restricted Payments"), except that: (i) each subsidiary may make direct or indirect Restricted Payments to the Company; and (ii) the Company and each subsidiary may purchase, redeem or otherwise acquire Equity Interests issued by it solely with the proceeds received from the substantially concurrent issue of new shares of its common stock or other common Equity Interests. For purposes of the Royalty Contract, "Equity Interests" of any person means any and all shares, rights to purchase, options, warrants, general, limited or limited liability partnership interests, member interests, participation or other equivalents of or interest in (regardless of how designated) equity of such entity, whether voting or nonvoting, including common stock, preferred stock, convertible securities or any other "equity security" (as such term is defined in Rule 3a11-1under the Securities Exchange Act of 1934, as amended).

Guarantee and Collateral Agreement

In connection with the Royalty Contract, on October 5, 2012, AxoGen and AC, entered into a Guarantee and Collateral Agreement (the "Guarantee and Collateral Agreement") with PDL, pursuant to which (i) AC unconditionally and irrevocably guarantees to PDL the prompt and complete payment and performance by AxoGen when due of the "Secured Obligations," which include the Company's obligations under the Royalty Contract, and any other obligations that AxoGen may owe to PDL under the Royalty Contract and other transaction documents; and (ii) each of the Company and AC grants to PDL a security interest in certain collateral as specified in the Guarantee and Collateral Agreement for the prompt and complete payment and performance when due of the Secured Obligations.

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8. Stock Options

The Company granted 476,250 options to purchase shares of stock pursuant to its 2010 Stock Incentive Plan for the nine months ended September 30, 2014. Stock-based compensation expense was $227,553 and $142,200 for the three months ended September 30, 2014 and 2013, respectively and $701,697 and $534,673 for the nine months ended September 30, 2014 and 2013, respectively. Total future stock compensation expense related to nonvested awards is expected to be approximately $1,508,000 at September 30, 2014.

9. Subsequent Events

On November 12, 2014, (the "Signing Date"), AxoGen, Inc. (the "Company" or "AxoGen"), as borrower, and the Company's wholly owned subsidiary AxoGen Corporation, as guarantor, entered into a term loan agreement (the "Term Loan Agreement") with the lenders

party thereto and Three Peaks Capital S.a.r.l. ("Three Peaks"), an indirect wholly owned subsidiary of Oberland Capital Healthcare Master Fund LP ("Oberland"), as administrative and collateral agent for the lenders. Under the Term Loan Agreement, Three Peaks has agreed to lend to AxoGen a term loan of $25 million (the "Initial Term Loan") which has a six year term and requires interest only payments and a final principal payment due at the end of the term. Interest is payable quarterly at 9.00% per annum plus the greater of LIBOR or 1.0% which as of November 13, 2014 ("the Initial Closing Date") resulted in a 10% rate. Under certain conditions, the Company has the option to draw an additional $7 million ("Subsequent Borrowing" and, together with the Initial Term Loan, the "Term Loan") during the period of April 1, 2016 through June 29, 2016 (the closing date of each such Subsequent Borrowing, a "Subsequent Closing Date" and, together with the Initial Closing Date, the "Closing Dates") under similar terms and conditions. The Company has to maintain certain covenants including limiting new indebtedness, restriction of the payment of dividends and maintain certain levels of revenue. Three peaks has a first perfected security interest in the assets of the Company.

As of the Signing Date, the Company also entered into a 10 year Revenue Interest Agreement ("Revenue Interest Agreement") with Three Peaks. Royalty payments are based on a royalty rate of 3.75% of the Company's revenues up to a maximum of $30 million in revenues in any 12 month period. In the event the Subsequent Borrowing is drawn, the royalty rate increases proportionally up to a maximum of 4.80%. The Company has to maintain certain covenants including those covenants under the Term Loan.

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

In addition, on the Initial Closing Date, the Company sold 1,375,969 shares of common stock to Three Peaks for a total of $3.55 million in cash ("Three Peaks Equity Sale") at a public offering price of $2.58 per share. The proceeds from the Initial Term Loan, the Three Peaks Equity Sale and $1.75 million of capital from the Company, were used to fully repay the Royalty Contract with PDL. The Company has no further obligations to PDL under the Royalty Contract.

In connection with the Term Loan Agreement, on the Signing Date, the Company and its wholly owned subsidiary. AxoGen Corporation ("AC"), entered into a Security Agreement (the "Security Agreement") with Three Peaks, pursuant to which each of the Company and AC grants to Three Peaks a security interest in certain collateral as specified in the Security Agreement to guarantee the payment in full when due of the Secured Obligations.

Subsequent to the closing of the Term Loan, also on the Initial Closing Date, the Company sold 643,382 shares of common stock for a total of $1.75 million to PDL ("PDL Equity Sale") at a public offering price of $2.72 per share pursuant to a Securities Purchase Agreement by and between the Company and PDL dated the Signing Date. The Company intends to use the proceeds from the PDL Equity Sale for general corporate purposes.

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

Unless the context otherwise requires, all references in this report to "AxoGen," "the Company," "we," "us" and "our" refer to AxoGen, Inc. and its wholly owned subsidiary AxoGen Corporation ("AC").

OVERVIEW

The Company is a leading medical technology company dedicated to peripheral nerve repair. AxoGen's portfolio of regenerative medicine products is available in the United States, Canada and several other countries and includes Avance® Nerve Graft, the only off-the-shelf commercially available processed nerve allograft for bridging severed nerves without the comorbidities associated with a second surgical site, AxoGuard® Nerve Connector, a ECM coaptation aid for tensionless repair of severed nerves, and AxoGuard® Nerve Protector, a porcine submucosa ECM product used to wrap and protect injured peripheral nerves and reinforce the nerve reconstruction while preventing soft tissue attachments.

Revenue from the distribution of these products is the main contributor to AxoGen's total reported sales and has been the key component of its growth to date. AxoGen revenues increased in third quarter 2014 compared to 2013 primarily as a result of the sales strategy to focus on growing sales and increasing product usage in existing accounts. AxoGen has continued to broaden and strengthen its sales and marketing activity with a focus on the execution of its sales operations. This is expected to have a continued positive contribution to its revenue growth in the long term.

Results of Operations

Comparison of the Three and Nine Months Ended September 30, 2014 and 2013

Revenues

Revenues for the three months ended September 30, 2014 increased 58.0% to approximately $4,671,000 as compared to approximately $2,957,000 for the three months ended September 30, 2013. Additionally, revenues for the nine months ended September 30, 2014 increased 51.0% to approximately $12,024,000 as compared to approximately $7,963,000 for the nine months ended September 30, 2013. This increase was primarily a result of the sales strategy to focus on growing sales and increasing product usage in existing accounts. In addition, AxoGen recognized approximately $57,000 and $175,000 of grant revenue for the three and nine months ended September 30, 2014, respectively, as compared to no such revenue in the corresponding time period in 2013.

Gross Profit

Gross profit for the three months ended September 30, 2014 increased 63.6% to approximately $3,775,000 as compared to approximately $2,307,000 for the three months ended September 30, 2013. Such increase in aggregate dollars was primarily attributable to the increased revenues in the third quarter of 2014. Gross margin improved to 80.8% for the three months ended September 30, 2014 as compared to 78.0% for the same period in 2013 as a result of price increases in March 2014, manufacturing efficiencies and changes in product mix.

Gross profit for the nine months ended September 30, 2014 increased 55.9% to approximately $9,538,000 as compared to approximately $6,119,000 for the nine months ended September 30, 2013. Such increase in aggregate dollars was primarily attributable to the increased revenues in the first nine months of 2014. Gross margin improved to 79.3% for the nine months ended September 30, 2014 as compared to 76.9% for the same period in 2013 as a result of price increases in March 2014 and changes in product mix.

Costs and Expenses

Total cost and expenses increased 21.7% to approximately $5,578,000 for the three months ended September 30, 2014 as compared to approximately $4,584,000 for the three months ended September 30, 2013. These

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increases were primarily due to increasing sales and marketing activities as revenues increased and increases in compensation as AxoGen hired additional personnel to meet its current and expected growth.

Total cost and expenses increased 28.8% to approximately $16,630,000 for the nine months ended September 30, 2014 as compared to approximately $12,914,000 for the nine months ended September 30, 2013. These increases were primarily due to increasing sales and marketing activities and increases in compensation as AxoGen hired additional personnel to meet its current and expected growth. To a lesser extent, these increases were also attributable to expenses associated with being a public company listed on NASDAQ, facility costs and research and development costs associated with the Company's preparation for its clinical trial.

Sales and marketing expenses increased 17.9% to approximately $3,251,000 for the three months ended September 30, 2014 as compared to approximately $2,757,000 for the three months ended September 30, 2013. This increase was primarily due to increased expenses related to AxoGen's direct sales force and independent distributors, sales training and surgeon education. As a percentage of revenues, sales and marketing expenses were 69.6% for the three months ended September 30, 2014 compared to 93.2% for the three months ended September 30, 2013. Such lower sales and marketing expenses as a percentage of revenue were a result of the revenue increase outpacing increases in costs and expenses.

Sales and marketing expenses increased 30.0% to approximately $9,327,000 for the nine months ended September 30, 2014 as compared to approximately $7,177,000 for the nine months ended September 30, 2013. This increase was primarily due to expansion of the direct sales force, increased support for both AxoGen's direct sales force and independent distributors, sales training and surgeon education. As a percentage of revenues, sales and marketing expenses were 77.6% for the nine months ended September 30, 2014 compared to 90.1% for the nine months ended September 30, 2013. Such lower sales and marketing expenses as a percentage of revenue were a result of the revenue increase outpacing increases in costs and expenses.

General and administrative expenses increased 33.5% to approximately $1,646,000 for the three months ended September 30, 2014 as compared to approximately $1,233,000 for the three months ended September 30, 2013. The increase was primarily a result of increased compensation including non-cash stock option compensation of approximately $84,000 and insurance expenses As a percentage of revenues, general and administrative expenses were 35.2% for the three months ended September 30, 2014 as compared to 41.7% for the three months ended September 30, 2013. Such lower general and administrative expenses as a percentage of revenue were a result of the revenue increase outpacing increases in costs and expenses.

General and administrative expenses increased 24.0% to approximately $5,254,000 for the nine months ended September 30, 2014 as compared to approximately $4,238,000 for the nine months ended September 30, 2013. The increase was primarily a result of increased compensation, including non-cash stock option compensation of approximately $167,000 and insurance expenses. As a percentage of revenues, general and administrative expenses were 43.7% for the nine months ended September 30, 2014 as compared to 53.2% for the nine months ended September 30, 2013. Such lower general and administrative expenses as a percentage of revenue were a result of the revenue increase outpacing increases in costs and expenses.

Research and development expenses increased approximately 14.6% to approximately $681,000 in the three months ended September 30, 2014 as compared to approximately $594,000 for the three months ended September 30, 2013. Research and development expenses

increased approximately 36.8% to approximately $2,050,000 in the nine months ended September 30, 2014 as compared to approximately $1,499,000 for the nine months ended September 30, 2013. Development includes AxoGen's product development and clinical efforts substantially focused on its biological license application ("BLA") for the Avance® Nerve Graft. A substantial portion of the increase in research and development expenses from 2013 to 2014 is related to expenditures for such clinical activity. Although AxoGen's products are developed for sale in their current use, it does conduct limited research and product development focused on new products and new applications to existing products. AxoGen has become more active in pursuing research grants to support this research. AxoGen's product pipeline development also contributed to a portion of the research and development expense increase in 2014, with grant revenue partially offsetting a portion of this activity.

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Other Income and Expenses

Interest expense increased 13.6% to approximately $1,380,000 for the three months ended September 30, 2014 as compared to approximately $1,215,000 for the three months ended September 30, 2013. Interest expense increased 13.1% to approximately $3,964,000 for the nine months ended September 30, 2014 as compared to approximately $3,506,000 for the nine months ended September 30, 2013. This increase was due to the increase in the interest related to the Royalty Contract from higher revenues and the interest accrued related to PDL. As a result of the accounting treatment for the PDL transaction, interest expense included approximately $890,000 and $923,000 for the three months ended September 30, 2014 and 2013, respectively, and approximately $2,809,000 and $2,756,000 for the nine months ended September 30, 2014 and 2013, respectively, of non-cash expense that is expected to be paid in the future based upon the terms of the PDL transaction and increases in AxoGen revenues. Other than the $2,809,000 and $2,756,000 non-cash expense, the remaining $1,155,000 and $750,000 in interest expense for the nine months ended September 30, 2014 and 2013, respectively, is related to cash paid for interest on the note payable.

Interest expense—deferred financing costs decreased 9.8% to approximately $55,000 for the three months ended September 30, 2014 as compared to approximately $61,000 for the three months ended September 30, 2013. Interest expense—deferred financing costs increased 8.2% to approximately $159,000 for the nine months ended September 30, 2014 as compared to approximately $147,000 for the nine months ended September 30, 2013. This increase is primarily due to higher deferred financing cost amortization associated with the PDL agreement from applying the effective interest rate method.

Income Taxes

The Company had no income tax expenses or income tax benefit for each of the three months and nine months ended September 30, 2014 and 2013 due to incurrence of net operating loss in each of these periods.

Effect of Inflation

Inflation has not had a significant impact on the Company's operations or cash flow.

Liquidity and Capital Resources

Note Payable

On October 5, 2012, AxoGen entered into the Royalty Contract with PDL. Proceeds from the PDL transaction were used to fully repay a prior credit facility and extinguish AxoGen's long-term debt obligations thereunder. Pursuant to the Royalty Contract the Company sold to PDL the right to receive specified royalties on the Company's Net Revenues (as defined in the Royalty Contract) generated by the sale, distribution or other use of the Company's products Avance® Nerve Graft, AxoGuard® Nerve Protector and AxoGuard® Nerve Connector (the "Acquired Revenues"). The Royalty Contract has a term of eight years. Under the Royalty Contract, PDL is to receive royalty payments currently paid weekly based on a royalty rate of 9.95% of the Company's Net Revenues (the "Assigned Interests"), subject to certain agreed upon minimum payment requirements which begin in the fourth quarter of 2014 as provided in the Royalty Contract. The total consideration PDL paid to the Company was $20,800,000 (the "Funded Amount"), including $19,050,000 PDL paid to the Company on October 5, 2012, and $1,750,000 PDL paid to the Company on August 14, 2012 pursuant to the Interim Royalty Contract. Upon the closing of PDL's purchase of the specified royalties described above, which was concurrent with the execution of the Royalty Contract, the Interim Royalty Contract was terminated. There are no financial covenants or other restrictions on the use of capital by AxoGen as a result of the Royalty Contract, however, PDL has a first perfected security interest in the Assigned Interests.

The Company had no material commitments for capital expenditures at September 30, 2014.

On November 12, 2014, (the "Signing Date"), AxoGen, Inc. (the "Company" or "AxoGen"), as borrower, and the Company's wholly owned subsidiary AxoGen Corporation, as guarantor, entered into a term loan agreement (the "Term Loan Agreement") with the lenders party thereto and Three Peaks Capital S.a.r.l. ("Three Peaks"), an indirect wholly owned subsidiary of Oberland Capital Healthcare Master Fund LP ("Oberland"), as administrative and collateral agent for the lenders. Under the Term Loan Agreement, Three Peaks has agreed to lend to AxoGen a term loan of $25 million (the "Initial Term Loan") which has a six year term and requires interest only payments and a final principal payment due at the end of the term. Interest is payable quarterly at 9.00% per annum plus the greater of LIBOR or 1.0% which as of November 13, 2014 ("the Initial Closing Date") resulted in a 10% rate. Under certain conditions, the Company has the option to draw an additional $7 million ("Subsequent Borrowing" and, together with the Initial Term Loan, the "Term Loan") during the period of April 1, 2016 through June 29, 2016 (the closing date of each such Subsequent Borrowing, a "Subsequent Closing Date" and, together with the Initial Closing Date, the "Closing Dates") under similar terms and conditions. The Company has to maintain certain covenants including limiting new indebtedness, restriction of the payment of dividends and maintain certain levels of revenue. Twin peaks has a first perfected

security interest in the assets of the Company.

As of the Signing Date, the Company also entered into a 10 year Revenue Interest Agreement ("Revenue Interest Agreement") with Three Peaks. Royalty payments are based on a royalty rate of 3.75% of the Company's revenues up to a maximum of $30 million in revenues in any 12 month period. In the event the

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Subsequent Borrowing is drawn, the royalty rate increases proportionally up to a maximum of 4.80%. The Company has to maintain certain covenants including those covenants under the Term Loan.

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

In addition, on the Initial Closing Date, the Company sold 1,375,969 shares of common stock to Three Peaks for a total of $3.55 million in cash ("Three Peaks Equity Sale") at a public offering price of $2.58 per share. The proceeds from the Initial Term Loan, the Three Peaks Equity Sale and $1.75 million of capital from the Company, were used to fully repay the Royalty Contract with PDL. The Company has no further obligations to PDL under the Royalty Contract.

In connection with the Term Loan Agreement, on the Signing Date, the Company and its wholly owned subsidiary, Axogen Corporation ("AC"), entered into a Security Agreement (the "Security Agreement") with Three Peaks, pursuant to which each of the Company and AC grants to Three Peaks a security interest in certain collateral as specified in the Security Agreement to guarantee the payment in full when due of the Secured Obligations.

Subsequent to the closing of the Term Loan, also on the Initial Closing Date, the Company sold 643,382 shares of common stock for a total of $1.75 million to PDL ("PDL Equity Sale") at a public offering price of $2.72 per share pursuant to a Securities Purchase Agreement by and between the Company and PDL dated the Signing Date. The Company intends to use the proceeds from the PDL Equity Sale for general corporate purposes.

Cash Flow Information

AxoGen had working capital of approximately $15.96 million and a current ratio of 8.85 at September 30, 2014, compared to working capital of $23.56 million and a current ratio of 12.23 at December 31, 2013. The decrease in working capital and the current ratio at September 30, 2014 as compared to December 31, 2013 was primarily due to the use of working capital for operations. The Company believes it has sufficient cash resources to meet its liquidity requirements for at least the next 12 months.

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

If AxoGen needs additional capital in the future, it may raise additional funds through public or private equity offerings, debt financings or from other sources. The sale of additional equity would result in dilution to AxoGen's shareholders. There is no assurance that AxoGen will be able to secure funding on terms acceptable to it, or at all. The increasing need for capital could also make it more difficult to obtain funding through either equity or debt. Should additional capital not become available to AxoGen as needed, AxoGen may be required to take certain action, such as, slowing sales and marketing expansion, delaying regulatory approvals or reducing headcount.

During the nine months ended September 30, 2014, the Company had a net decrease in cash and cash equivalents of approximately $8,267,000 as compared to a net increase of cash and cash equivalents of approximately $8,679,000 in the nine months ended September 30, 2013. The Company's principal sources and uses of funds are explained below:

Cash used in operating activities

The Company used approximately $8,019,000 of cash for operating activities in the nine months ended September 30, 2014, as compared to using approximately $8,061,000 of cash for operating activities in the nine months ended September 30, 2013. This decrease in cash used in operating activities is primarily attributed to the decrease in inventory offset by an increase in our accounts receivable associated with increased revenues.

Cash used for investing activities

Investing activities for the nine months ended September 30, 2014 used approximately $382,000 of cash as compared to using approximately $117,000 of cash in the nine months ended September 30, 2013. This increase in use is principally attributable to the purchase of certain fixed assets for the expansion of the headquarters office and the opening of the worldwide distribution facility in Burleson, Texas.

Cash provided by financing activities

Financing activities in the nine months ended September 30, 2014 provided approximately $135,000 of cash as compared to providing approximately $16,857,000 of cash in the nine months ended September 30, 2013. The cash provided in 2014 was due to proceeds received from the exercise of stock options where as the cash provide in 2013 was attributable to the underwritten public offering of our common shares completed in September 2013.

Off-Balance Sheet Arrangements

AxoGen does not have any off-balance sheet arrangements.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Not Applicable.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

The Company maintains "disclosure controls and procedures" as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, (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 Securities and Exchange Commission'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, 2014 and concluded that our disclosure controls and procedures were effective.

Changes in Internal Controls Over Financial Reporting

During the nine months ended September 30, 2014, there were no changes in the Company's internal control over financial reporting (as defined in Rule 13a-15(f) and 15d—15(f) under the Exchange Act) that have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

UNITED STATES
PART II —OTHER INFORMATION

ITEM 1 — Legal Proceedings

The Company is not a party to any material litigation as of September 30, 2014.

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 Securities and Exchange Commission, readers should consider carefully the risk factors discussed in Part I "Item 1A. Risk Factors" in the Company's Annual Report on Form 10-K as of and for the year ended December 31, 2013. There have been no material changes to

these risk factors. If any of these risks actually occur, the Company's business, results of operations or financial condition could be materially adversely affected.

ITEM 2 — UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

None.

ITEM 3 — DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4 MINE SAFETY DISCLOSURES

Not Applicable.

ITEM 5 — OTHER INFORMATION

None.

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ITEM 6 — EXHIBITS

Exhibit Number	Description
3.1	Amended and Restated Articles of Incorporation of AxoGen, Inc. (incorporated by reference to Appendix B to the Proxy Statement/Prospectus included as part of LecTec Corporation's Amendment No. 2 to Registration Statement on Form S-4 filed on August 29, 2011)
3.2	AxoGen, Inc. Amended and Restated Bylaws (incorporated by reference to Appendix C to the Proxy Statement/Prospectus included as part of LecTec Corporation's Amendment No. 2 to Registration Statement on Form S-4 filed on August 29, 2011).
*10.4.3	Fourth Amendment to Amended and Restated Nerve Tissue Processing Agreement, dated as of September 8, 2014, by and between AxoGen Corporation and LifeNet Health
31.1†	Certification of Principal Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2†	Certification of Principle Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32††	Certification Pursuant to 18 U.S.C. §1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS†	XBRL Instance Document.
101.SCH†	XBRL Taxonomy Extension Schema Document.
101.CAL†	XBRL Taxonomy Extension Calculation Linkbase Document.
101.DEF†	XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB†	XBRL Extension Labels Linkbase.
101.PRE†	XBRL Taxonomy Extension Presentation Linkbase Document.

† Filed herewith.

†† Furnished herewith.

* Confidential treatment has been requested as to certain portions, which portions have been omitted and filed separately with the Securities and Exchange Commission.

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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 13, 2014

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

/s/ Lee R. Johnston, Jr.
Lee R. Johnston, Jr.
Chief Financial Officer
(Principal Financial and Accounting Officer)

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EXHIBIT INDEX

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†† Furnished herewith.

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Exhibit 10.4.3

Pursuant to 17 CFR 240.24b-2, confidential information has been omitted in places marked "*" and has been filed separately with the Securities and Exchange Commission pursuant to a Confidential Treatment Application filed with the Commission.**

FOURTH AMENDMENT TO AMENDED AND RESTATED NERVE TISSUE PROCESSING AGREEMENT

THIS FOURTH AMENDMENT ("Fourth Amendment") to the Amended and Restated Nerve Tissue Processing Agreement dated February 27, 2008 as amended from time to time (the "Agreement"), is effective upon last signature hereto by and between LifeNet Health ("LIFENET Health") and AxoGen Corporation ("AXOGEN").

WHEREAS, the parties desire to amend the Agreement under the terms and subject to the conditions set forth below;

In consideration of the mutual promises contained herein, the parties agree to the following:

1. The parties agree that Appendix B to the Agreement is hereby deleted in its entirety and replaced with the attached Appendix B.

IN WITNESS, WHEREOF, the parties execute this Fourth Amendment as of the date of the last party signing hereto:

AXOGEN CORPORATION	LIFENET HEALTH
By: /s/ Lee R. Johnston, Jr.	By: /s/ Gordon Berustresser
Name: Lee R. Johnston, Jr.	Name: Gordon Berustresser
Its: Chief Financial Officer	Its: Chief Financial Officer
Date: 9/8/2014	Date: 8/29/2014

AxoGen

APPENDIX B — Revised
FEE SCHEDULE

1) AXOGEN shall pay LIFENET HEALTH a $**[***]** fee per week for processing in Suite 114;

2) LIFENET HEALTH shall bill AXOGEN at the rate of $**[***]** per each batch debrided at LIFENET HEALTH; and

3) LIFENET HEALTH shall bill AXOGEN at the rate of $**[***]** per each [***] at LIFENET HEALTH.

OTHER TERMS:

- There shall be no Minimum Batches/Year and no Maximum Batches/Year;
- Pricing reflected in this Exhibit B shall be increased by 3% on January 1, 2015. The fees for use of Suite 114 may be adjusted thereafter annually beginning January 1, 2016 as mutually agreed upon by the parties, provided, however, that any such adjustment shall not exceed the annual change in the CPI-U of the Bureau of Labor Statistics of the U.S. Department of Labor. AXOGEN will have the right to use Suite 114 of the Ward Court facility for up to three shifts per normal business day.
- Parties may periodically review usage and space needs.
- AXOGEN is to employ processors and assume supervisory and oversight responsibilities for processors who process for AXOGEN in the LIFENET HEALTH facility. LIFENET HEALTH will provide support as described in the Quality Plan.
- In conjunction with LIFENET HEALTH's need for the use of Suite 118, AXOGEN equipment currently situated in Suite 118 (the "Equipment") will be stored in such area in 3417 Chandler Creek Road, Virginia Beach, Virginia 23453 ("Location") as designated by LIFENET HEALTH. Any additional equipment relocated to this location must be pre-approved by LIFENET HEALTH. Any cost or expense associated with equipment being removed from this Location, shall be the sole responsibility of AXOGEN. AxoGen will be responsible for the cost of moving the Equipment from Suite 118 to the particular area in the Location designated by LIFENET HEALTH. After the move of the Equipment, LIFENET HEALTH will have complete control and access to Suite 118. Upon 90 days' notice from AXOGEN to LIFENET HEALTH, LIFENET HEALTH will make reasonable efforts to provide AXOGEN with space to meet AXOGEN's forecasted needs, provided, however, such space shall be reasonably equivalent as to functionality as Suite 118. AXOGEN would pay for the cost of moving and calibrating the Equipment so it may be operated in the same manner as is available currently. Rates for such comparable space will be equivalent to the

rates paid by AXOGEN for Suite 114 (or such other space that replaced Suite 114) as of such time.

- AXOGEN agrees to maintain adequate property insurance coverage on all property and/or equipment it stores in 3417 Chandler Creek Road, Virginia Beach, Virginia 23453 to cover the cost of any damage to or replacement of such property and/ or equipment and, upon request, shall submit a Certificate of Insurance to LIFENET HEALTH. Any cost of insurance or deductible shall be the sole responsibility of AXOGEN.

EXHIBIT 31.1

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

I, Karen Zaderej, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: November 13, 2014

/s/ Karen Zaderej
Karen Zaderej
Chief Executive Officer

EXHIBIT 31.2

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

I, Lee R. Johnston, Jr., certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: November 13, 2014

/s/ Lee R. Johnston, Jr.
Lee R. Johnston, Jr.
Chief Financial Officer

EXHIBIT 32

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

In connection with the Quarterly Report on Form 10-Q (the "Report") of AxoGen, Inc. (the "Company"), Karen Zaderej, Chief Executive Officer of the Company and Lee R. Johnston, Jr., 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 13, 2014

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

/s/ Lee R. Johnston, Jr.
Lee R. Johnston, Jr.
Chief Financial Officer
(Principal Financial Officer)