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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 March 31, 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: 0-16159

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 April 29, 2014 the registrant had 17,466,091 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

	March 31, 2014	December 31,

	(unaudited)	2013
Assets		
Current assets:		
Cash and cash equivalents	$ 16,807,753	$ 20,069,750
Accounts receivable, net of allowance for doubtful accounts of approximately $54,000 and $59,000, respectively	1,965,157	1,893,699
Inventory	3,466,099	3,398,438
Prepaid expenses and other	195,489	296,719
Total current assets	22,434,498	25,658,606
Property and equipment, net	543,227	381,689
Intangible assets	567,787	570,396
Deferred financing costs	1,022,363	1,073,579
	$ 24,567,875	$ 27,684,270
Liabilities and Shareholders' Equity (Deficit)		
Current liabilities:		
Accounts payable and accrued expenses	$ 1,908,743	$ 2,083,942
Current Deferred Revenue	14,118	14,118
Total current liabilities	1,922,861	2,098,060
Note Payable — Revenue Interest Purchase Agreement	26,255,540	25,363,695
Long Term Deferred Revenue	82,311	85,882
Total liabilities	28,260,712	27,547,637
Commitments and contingencies		
Shareholders' equity (deficit):		
Common stock, $.01 par value; 50,000,000 shares authorized; 17,445,968 and 17,339,561 shares issued and outstanding	174,459	173,395
Additional paid-in capital	72,778,043	72,369,016
Accumulated deficit	(76,645,339)	(72,405,778)
Total shareholders' equity (deficit)	(3,692,837)	136,633
	$ 24,567,875	$ 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	
	March 31, 2014	March 31, 2013
Revenues	$ 3,138,256	$ 2,142,932
Cost of goods sold	701,300	560,243
Gross profit	2,436,956	1,582,689
Costs and expenses:		
Sales and marketing	2,720,707	1,893,541
Research and development	812,615	406,943
General and administrative	1,894,776	1,605,759
Total costs and expenses	5,428,098	3,906,243
Loss from operations	(2,991,142)	(2,323,554)
Other expense:		
Interest expense	(1,191,317)	(1,067,621)
Interest expense — deferred financing costs	(51,216)	(44,216)
Other income (expense)	(5,889)	(2,117)
Total other expense	(1,248,422)	(1,113,954)
Net loss	(4,239,564)	(3,437,508)
Net loss available to common shareholders	$ (4,239,564)	$ (3,437,508)
Weighted Average Common Shares outstanding — basic and diluted	17,383,786	11,124,633
Loss Per Common share — basic and diluted	$ (0.24)	$ (0.31)

See notes to condensed consolidated financial statements.

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

	Three Months Ended March 31,	
	2014	2013
Cash flows from operating activities:		
Net loss	$ (4,239,564)	$ (3,437,508)
Adjustments to reconcile net loss to net cash used for operating activities:		
Depreciation	33,944	23,140
Amortization of intangible assets	10,955	14,687
Amortization of deferred financing costs	51,216	44,216
Share-based compensation	257,542	259,912
Stock grants	60,125	—
Interest added to note	891,845	858,151
Change in assets and liabilities:		
Accounts receivable	(71,458)	(129,049)
Inventory	(67,661)	(269,144)
Prepaid expenses and other	101,230	45,223
Accounts payable and accrued expenses	(175,196)	(60,814)
Deferred revenue	(3,571)	—
Net cash used for operating activities	(3,150,593)	(2,651,186)
Cash flows from investing activities:		
Purchase of property and equipment	(195,482)	(26,007)
Acquisition of intangible assets	(8,346)	(31,415)
Net cash used for investing activities	(203,828)	(57,422)
Cash flows from financing activities:		
Proceeds from exercise of stock options	92,424	1,654
Net cash provided by financing activities	92,424	1,654
Net decrease in cash and cash equivalents	(3,261,997)	(2,706,954)
Cash and cash equivalents, beginning of year	20,069,750	13,907,401
Cash and cash equivalents, end of period	$ 16,807,753	$ 11,200,447
Supplemental disclosures of cash flow activity:		
Cash paid for interest	$ 303,919	$ 172,527

See notes to condensed consolidated financial statements.

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 March 31, 2014 and December 31, 2013 and for the three month periods ended March 31, 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 European 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 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.

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.

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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 $54,000 and $59,000 at March 31, 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:

	March 31, 2014 (unaudited)	December 31, 2013
Finished goods	$ 2,215,469	$ 2,131,336
Work in process	222,760	235,966
Raw materials	1,027,870	1,031,136
	$ 3,466,099	$ 3,398,438

Inventories were net of reserve of approximately $300,000 and $383,000 at March 31, 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 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.

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

Share-Based Compensation

Stock-based compensation cost related to stock options granted under the AC 2002 Stock Option Plan 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 three months ended March 31:

Three months ended March 31,	2014	2013
Expected term (in years)	4.0	4.0
Expected volatility	81.26%	84.90%
Risk free rate	1.12%	0.56%
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 three months ended March 31, 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 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.

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Recent Accounting Pronouncements

The Company's management has reviewed and considered all 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. Property and Equipment

Property and equipment consist of the following:

	March 31, 2014 (unaudited)	December 31, 2013
Furniture and equipment	$ 877,742	$ 893,973
Leasehold improvements	90,260	53,864
Processing equipment	1,190,704	1,015,388
Less: accumulated depreciation and amortization	(1,615,479)	(1,581,536)
Property and equipment	$ 543,227	$ 381,689

5. Intangible Assets

The Company's intangible assets consist of the following:

	March 31, 2014 (unaudited)	December 31, 2013
License agreements	$ 821,231	$ 816,300
Patents	65,968	62,553
Less: accumulated amortization	(319,412)	(308,457)
Intangible assets, net	$ 567,787	$ 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 $62,553 were pending patent costs and were not amortizable. Amortization expense for the three months ended March 31, 2014 and 2013 was approximately $11,000 and $15,000, respectively. As of March 31, 2014, future amortization of license agreements is expected to be $37,000 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

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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 sublicensee 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 $60,668 and $47,031 during the three months ended March 31, 2014 and 2013, respectively, and are included in sales and marketing expense on the accompanying condensed consolidated statements of operations.

6. Accounts Payable and Accrued Expenses

Accounts payable and accrued expenses includes $148,438 and $203,380 for accrued payroll at March 31, 2014 and December 31, 2013, respectively, and $395,002 and $417,825 for accrued commissions at March 31, 2014 and December 31, 2013, respectively.

7. Notes Payable

Notes Payable consists of the following:

	March 31, 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.	$ 26,255,540	$ 25,363,695
Long-term Notes Payable	$ 26,255,540	$ 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 thereunder. The Royalty Contract has a term of eight years. Under the Royalty Contract, PDL is to receive royalty payments based on a royalty rate 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.

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

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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.

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.

8. Stock Options

The Company granted 226,000 shares of stock options pursuant to its 2010 Stock Incentive Plan for the three months ended March 31, 2014. Stock-based compensation expense was $257,542 and $259,912 for the three months ended March 31, 2014 and 2013, respectively. Total future stock compensation expense related to nonvested awards is expected to be approximately $1,610,000 at March 31, 2014.

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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") after the Merger (as defined below), and AC before the Merger.

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 European 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 first quarter 2014 compared to 2013 primarily as a result of sales to new accounts and increased product usage by 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 Months Ended March 31, 2014 and 2013

Revenues

Revenues for the three months ended March 31, 2014 increased 46.4% to approximately $3,138,000 as compared to approximately $2,143,000 for the three months ended March 31, 2013. This increase was primarily a result of sales to new accounts and increased product usage by existing accounts. In addition, AxoGen recognized $62,000 of grant revenue in the first quarter of 2014 as compared to no such revenue in first quarter 2013.

Gross Profit

Gross profit for the three months ended March 31, 2014 increased 53.9% to approximately $2,437,000 as compared to approximately $1,583,000 for the three months ended March 31, 2013. Such increase in aggregate dollars was primarily attributable to the increased revenues in the first quarter of 2014, with additional contributions by the factors also affecting gross margin. Gross margin improved to 77.7% for the three months ended March 31, 2014 as compared to 73.9% for the same period in 2013 as a result of manufacturing efficiencies, a price increase in March 2014 and change in product mix.

Costs and Expenses

Total cost and expenses increased 38.9% to approximately $5,428,000 for the three months ended March 31, 2014 as compared to approximately $3,906,000 for the three months ended March 31, 2013. These increases were primarily due to increasing sales and marketing activities and increases in salaries 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. As a percentage of revenues, total operating expenses were 172.9% for the three months ended March 31, 2014 as compared to

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182.3% for the three months ended March 31, 2013. Such lower total costs and expenses as a percentage of revenue were primarily a result of the Company's revenue increase outpacing increases in costs and expenses.

Sales and marketing expenses increased 43.6% to approximately $2,721,000 for the three months ended March 31, 2014 as compared to approximately $1,894,000 for the three months ended March 31, 2013. This increase was primarily due to expansion of the direct sales force, increased support for both its direct sales force and independent distributors, sales training and surgeon education. As a percentage of revenues, sales and marketing expenses were 86.7% for the three months ended March 31, 2014 compared to 88.4% for the three months ended March 31, 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 17.9% to approximately $1,895,000 for the three months ended March 31, 2014 as compared to approximately $1,606,000 for the three months ended March 31, 2013. The increase was primarily a result of increased payroll and benefits, public company related expenditures and increased rent and utilities for the Company's new corporate headquarters and distribution facility, offset by a reduction in travel expenses. As a percentage of revenues, general and administrative expenses were 60.3% for the three months ended March 31, 2014 as compared to 74.9% for the three months ended March 31, 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 99.7% to approximately $813,000 in the three months ended March 31, 2014 as compared to approximately $407,000 for the three months ended March 31, 2013. Development includes AxoGen's product development, clinical efforts substantially focused on its biological license application ("BLA") for the Avance® Nerve Graft and surgeon education. A substantial portion of the increase in research and development expenses from 2013 to 2014 related to expenditures for such clinical activity. AxoGen has also increased activity related to education of surgeons as to surgical techniques and AxoGen's products in support of its sales function, which activity contributed to a portion of the 2014 expense increase. 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. This AxoGen product pipeline development also contributed to a portion of the research and development expense increase in 2014, with grant revenue offseting a portion of this activity.

Other Income and Expenses

Interest expense increased 11.5% to approximately $1,191,000 for the three months ended March 31, 2014 as compared to approximately $1,068,000 for the three months ended March 31, 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 $892,000 and $858,000 for the three months ended March 31, 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 $892,000 and $858,000 non-cash expense, the remaining $299,000 and $210,000 in interest expense for the three months ended March 31, 2014 and 2013, respectively, is related to cash paid for interest on the note payable.

Interest expense—deferred financing costs increased 15.9% to approximately $51,000 for the three months ended March 31, 2014 as compared to approximately $44,000 for the three months ended March 31, 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 ended March 31, 2014 and 2013 due to incurrence of net operating loss in each of these periods.

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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 high single digit royalty rate 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 March 31, 2014.

Cash Flow Information

AxoGen had working capital of approximately $20.51 million and a current ratio of 11.67 at March 31, 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 March 31, 2014 as compared to December 31, 2013 was primarily due to the use of working capital for operations in excess of revenues.

AxoGen's future capital requirements depend on a number of factors, including, without limitation, revenue increases consistent with its business plan, and the corresponding royalty payments of approximately $1.3 to $2.5 million per quarter, starting in October 2014, due to PDL and pursuant to AxoGen's licensing agreements in connection with Avance® Nerve Graft, cost of products and acquisition and/or development of new products. In particular, if revenue does not increase by fourth quarter 2014 to a level whereby the 9.95% royalty owed to PDL on AxoGen's gross revenues exceeds the PDL minimum royalty payments at such time of approximately $1.3 million, and such differential continues, or grows larger as the PDL minimum royalty payments increase, AxoGen would face increasing capital needs. Such capital needs could be substantial depending on the extent to which AxoGen is unable to increase revenue. 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, cost of products and acquisition and/or development of new products pursuant to the PDL transaction.

AxoGen continually evaluates its capital needs and takes action as it deems appropriate to maximize its flexibility to address these needs. As a result, although it has no current operating capital requirements, if such need arose it would 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 as the PDL transaction matures 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 three months ended March 31, 2014, the Company had a net decrease in cash and cash equivalents of approximately $3,262,000 as compared to a net decrease of cash and cash equivalents of approximately $2,707,000 in the three months ended March 31, 2013. The Company's principal sources and uses of funds are explained below:

Cash used in operating activities

The Company used approximately $3,151,000 of cash for operating activities in the three months ended March 31, 2014, as compared to using approximately $2,651,000 of cash for operating activities in the three months ended March 31, 2013. This increase in cash used in operating activities is primarily attributed to the net loss generated in the three months ended March 31, 2014, along with an increase in our accounts receivable and inventory and a decrease in accounts payable and accrued expenses.

Cash used for investing activities

Investing activities for the three months ended March 31, 2014 used approximately $204,000 of cash as compared to using approximately $57,000 of cash in the three months ended March 31, 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.

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Cash provided by financing activities

Financing activities in the three months ended March 31, 2014 provided approximately $92,000 of cash as compared to providing approximately $1,700 of cash in the three months ended March 31, 2013. The increase was due to proceeds received from the exercise of stock options.

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 March 31, 2014 and concluded that our disclosure controls and procedures were effective.

Changes in Internal Controls Over Financial Reporting

During the quarter ended March 31, 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.

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UNITED STATES
PART II —OTHER INFORMATION

ITEM 1 — Legal Proceedings

The Company is not a party to any material litigation as of March 31, 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).
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.

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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 April 30, 2014

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

/s/ Gregory G. Freitag
Gregory G. Freitag
Chief Financial Officer
(Principal Financial and Accounting Officer)

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EXHIBIT INDEX

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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.

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: April 30, 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, Gregory G. Freitag, 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: April 30, 2014

/s/ Gregory G. Freitag
Gregory G. Freitag
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 Gregory G. Freitag, 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: April 30, 2014

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

/s/ Gregory G. Freitag
Gregory G. Freitag
Chief Financial Officer
(Principal Financial Officer)