Table of Contents

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2013

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: 1-36046

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.)**
13859 Progress Blvd., Suite 100, 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 October 30, 2013 the registrant had 17,339,271 shares of common stock outstanding.

Table of Contents

Table of Contents

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, capital resources or, operating performance and anticipated leasing of a new facility in Alachua, Florida and another new facility in Burleson, Texas. 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.

Table of Contents

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, 2013 (unaudited)	December 31, 2012
Assets		
Current assets:		
Cash and cash equivalents	$ 22,586,450	$ 13,907,401
Accounts receivable	1,740,216	1,050,089
Inventory	3,460,064	3,151,109
Prepaid expenses and other	177,435	187,256
Total current assets	27,964,165	18,295,855
Property and equipment, net	114,229	108,534
Intangible assets	579,817	573,731
Deferred financing costs	1,105,795	1,252,443
	$ 29,764,006	$ 20,230,563
Liabilities and Shareholders' Equity (Deficit)		
Current liabilities:		
Accounts payable and accrued expenses	$ 1,317,121	$ 1,479,752
Total current liabilities	1,317,121	1,479,752
Note Payable – Revenue Interest Purchase Agreement	24,332,525	21,580,252
Total liabilities	25,649,646	23,060,004
Commitments and contingencies		
Shareholders' equity (deficit):		
Common stock, $.01 par value; 50,000,000 shares authorized; 17,339,271 and 11,122,573 shares issued and outstanding	173,393	111,226
Additional paid-in capital	72,237,945	54,908,226
Accumulated deficit	(68,296,978)	(57,848,893)
Total shareholders' equity (deficit)	4,114,360	(2,829,441)
	$ 29,764,006	$ 20,230,563

See notes to condensed consolidated financial statements.

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

	Three Months Ended		Nine Months Ended	
	September 30, 2013	September 30, 2012	September 30, 2013	September 30, 2012
Revenues	$ 2,957,462	$ 1,980,849	$ 7,962,683	$ 5,646,792
Cost of goods sold	650,212	542,235	1,843,748	1,483,310
Gross profit	2,307,250	1,438,614	6,118,935	4,163,482
Costs and expenses:				
Sales and marketing	2,757,241	1,697,317	7,177,170	4,907,800
Research and development	593,643	390,395	1,498,904	1,053,889
General and administrative	1,233,360	1,393,890	4,237,738	3,772,659
Total costs and expenses	4,584,244	3,481,602	12,913,812	9,734,348
Loss from operations	(2,276,994)	(2,042,988)	(6,794,877)	(5,570,866)
Other income (expense):				
Interest expense	(1,214,603)	(145,426)	(3,505,869)	(395,769)
Interest expense—deferred financing costs	(61,216)	(60,013)	(146,648)	(154,947)
Other income (expense)	32	11,618	(696)	9,295
Total other income (expense)	(1,275,787)	(193,821)	(3,653,213)	(541,421)
Loss before income taxes	(3,552,781)	(2,236,809)	(10,448,090)	(6,112,287)
Income tax benefit	—	—	—	736,434
Net loss	$ (3,552,781)	$ (2,236,809)	$ (10,448,090)	$ (5,375,853)
Weighted Average Common Shares outstanding – basic and diluted	14,320,113	11,104,353	12,205,863	11,083,740
Loss Per Common share—basic and diluted	$ (0.25)	$ (0.20)	$ (0.86)	$ (0.49)

See notes to condensed consolidated financial statements.

Table of Contents

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

	Nine Months Ended September 30,	
	2013	2012
Cash flows from operating activities:		
Net loss	$(10,448,090)	$(5,375,853)
Adjustments to reconcile net loss to net cash used for operating activities:		
Depreciation	60,869	145,891
Amortization of intangible assets	44,176	245,002
Amortization of deferred financing costs	146,648	68,141
Amortization of debt discount	—	36,806
Share-based compensation	534,673	478,701
Interest added to note	2,752,273	—
Change in assets and liabilities:		
Accounts receivable	(690,127)	(127,890)
Inventory	(308,955)	(962,130)
Prepaid expenses and other	9,821	(75,228)
Accounts payable and accrued expenses	(162,631)	278,394
Net cash used for operating activities	(8,061,343)	(5,288,166)
Cash flows from investing activities:		
Purchase of property and equipment	(66,564)	(37,429)
Acquisition of intangible assets	(50,262)	(82,294)
Net cash used for investing activities	(116,826)	(119,723)
Cash flows from financing activities:		
Proceeds from issuance of long-term debt	—	1,750,000
Proceeds from issuance of common stock	16,784,203	—
Debt issuance costs	—	(118,476)
Proceeds from exercise of stock options	73,015	30,741
Payment of fractional shares from Merger	—	(58)
Net cash provided by financing activities	16,857,218	1,662,207
Net increase (decrease) in cash and cash equivalents	8,679,049	(3,745,682)
Cash and cash equivalents, beginning of year	13,907,401	8,190,781
Cash and cash equivalents, end of period	$ 22,586,450	$ 4,445,099
Supplemental disclosures of cash flow activity:		
Cash paid for interest	$ 749,857	$ 447,144

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 September 30, 2013 and December 31, 2012 and for the three and nine month periods ended September 30, 2013 and 2012. 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, 2012, which are included in the Annual Report on Form 10-K for the year ended December 31, 2012. 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 regenerative medicine company dedicated to advancing the science and commercialization of peripheral nerve repair solutions. Peripheral nerves provide the pathways for both motor and sensory signals throughout the body and their damage can result in the loss of muscle function and/or feeling. In order to improve the options available for the surgical repair and regeneration of peripheral nerves, the Company has developed and licensed, patented and patent pending technologies. The Company's innovative approach to regenerative medicine has resulted in first-in-class products that the Company believes will define their product categories. AxoGen's products offer a full suite of surgical nerve repair solutions including Avance® Nerve Graft, the only off-the-shelf commercially available processed nerve allograft, human nerve tissue obtained from a donor, for bridging severed nerves without the comorbidities of an autograft second surgical site, such as loss of feeling where the nerve was removed and potential pain at the donor site. The Company's AxoGuard® line of products are derived from pig tissue and are natural scaffolds of the body called ExtraCellular Matrix, or ECM. AxoGuard® Nerve Connector is used to facilitate the tensionless repair of severed nerves, and AxoGuard® Nerve Protector is used to wrap and protect injured peripheral nerves and reinforce the nerve reconstruction while preventing soft tissue attachments.

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. 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.

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. As of September 30, 2013 and December 31, 2012, there were no amounts deemed uncollectible and there was no allowance for doubtful accounts recorded.

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, 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, 2013 (unaudited)	December 31, 2012
Finished goods	$ 2,398,038	$2,143,176
Work in process	192,260	145,156
Raw materials	869,766	862,777
	$ 3,460,064	$3,151,109

Inventories were net of reserve of approximately $416,000 and $538,000 at September 30, 2013 and December 31, 2012, 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.

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, 2009 through 2012; currently there are no examinations in process.

Share-Based Compensation

AxoGen's 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 October 1, 2011, and based on the Company's common stock for periods subsequent to that date. 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 during the periods reflected herein 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,	2013	2012
Expected term (in years)	4.0	4.0
Expected volatility	83.27%	118.00%
Risk free rate	0.71%	0.60%
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, 2013 and 2012 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.

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. Intangible Assets

The Company's intangible assets consist of the following:

	September 30, 2013 (unaudited)	December 31, 2012
License agreements	$ 805,717	$ 772,230
Patents	70,776	63,429
Less: accumulated amortization	(296,676)	(261,928)
Intangible assets, net	$ 579,817	$ 573,731

License agreements are being amortized over periods ranging from 17-20 years. Patent costs are being amortized over three years. Pending patent costs are not amortizable. Amortization expense was approximately $15,000 and $36,000 for the three months and was approximately $44,000 and $100,000 for the nine months ended September 30, 2013 and 2012, respectively. As of September 30, 2013, future amortization of license agreements is expected to be approximately $14,000 for the remainder of fiscal 2013, $55,000 for 2014, $46,000 each year 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 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 approximately $64,000 and $43,000 for the three months and were $169,000 and $125,000 for the nine months ended September 30, 2013 and 2012, respectively, and are included in sales and marketing expense on the accompanying condensed consolidated statements of operations.

In July 2012, the Company terminated its license agreement with Emory University. Such license agreement did not relate to any technology or intellectual property used in any of the Company's current products.

Table of Contents

5. Notes Payable

Notes Payable consists of the following:

	September 30, 2013 (unaudited)	December 31, 2012
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.	$24,332,525	$21,580,252
Long-term Notes Payable	$24,332,525	$21,580,252

Notes 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 specified royalties of 9.95% on 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. 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 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 and currently 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. Payments made to PDL consist of interest and principal. Based on current calculations of the repayments, using actual payments to date, an estimate of future revenue streams and an estimated effective rate of 20% (calculated using the put rate in the agreement), principal payments are scheduled to begin in February 2015. All payments made prior to this date are interest only payments.

Put Option

Under the Royalty Contract, on October 5, 2016, or in the event of the occurrence of a material adverse event, the Company's transfer of revenue interest or substantially all of its 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," provided that within 60 days of PDL's receipt of AxoGen's notice that such an event has occurred, PDL provides AoxGen with a written notice of its election to exercise the put option. 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") until the Company's next Annual Meeting of Shareholders (the "Annual Meeting"). The Company shall include such nomination in AxoGen's proxy statement for such Annual Meeting, 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.

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 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.

6. Stock Options

The Company granted 65,500 shares of stock options pursuant to its 2010 Stock Incentive Plan for the three months ended September 30, 2013. The Company granted 231,500 shares of stock options pursuant to its 2010 Stock Incentive Plan for the nine months ended September 30, 2013. Stock-based compensation expense was $142,200 and $171,017 for the three months ended September 30, 2013 and 2012, respectively and $534,673 and $478,701 for the nine months ended September 30, 2013 and 2012, respectively. Total future stock compensation expense related to nonvested awards is expected to be approximately $1,354,000 at September 30, 2013.

7. Income Taxes

Income tax benefit of $0 and approximately $736,000 for the three months and nine months ended September 30, 2013 and 2012, respectively, was the result of the Company's ability to utilize net operating losses and franchise tax adjustments which resulted in tax refunds in 2012. The entire amount of the tax refund was received in 2012.

8. 2013 Equity Offering

On August 14, 2013, the Company completed an underwritten offering of 6,000,000 shares of its common stock at a price to the public of $3.00 per share. The Company granted the underwriters a 30-day option to purchase up to an aggregate of 900,000 additional shares of Company common stock at the public offering price, less the underwriting discount, to cover over-allotments, if any. On September 11, 2013, the underwriters exercised their option to purchase an additional 184,332 shares. The Company received net proceeds of approximately $16.7 million, after deducting approximately $1.8 million in underwriting discounts and commissions and offering expenses payable by the Company, and including the underwriters' over-allotment option. The Company intends to use the net proceeds from the offering to continue product commercialization and marketing efforts for its portfolio of peripheral nerve repair products; to further develop its product pipeline; and for general working capital purposes.

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

AxoGen is a leading regenerative medicine company dedicated to advancing the science and commercialization of peripheral nerve repair solutions. Peripheral nerves provide the pathways for both motor and sensory signals throughout the body and their damage can result in the loss of muscle function and feeling. AxoGen's innovative approach to regenerative medicine has resulted in first-in-class products that it believes will define their product categories. AxoGen's products offer a full suite of surgical nerve repair solutions including Avance® Nerve Graft, the only off-the-shelf commercially available processed nerve allograft, human nerve tissue obtained from a donor, for bridging severed nerves without the comorbidities of an autograft second surgical site, such as loss of feeling where the nerve was removed and potential pain at the donor site. The Company's AxoGuard® line of products are derived from pig tissue and are natural scaffolds of the body called an ExtraCellular Matrix, or ECM. AxoGuard® Nerve Connector is used to facilitate the tensionless repair of severed nerves, and AxoGuard® Nerve Protector is 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 the third quarter of 2013 compared to the third quarter of 2012 primarily as a result of sales to new accounts and increased product usage by existing accounts. AxoGen has continued to broaden its sales and marketing focus which is expected to have a positive contribution to its revenue growth in the long term. In the near term revenue growth lags behind the expense increases for market development such as hiring and training of new sales representatives and surgeon education programs.

The Company anticipates to lease two new facilities to accommodate its growth and to allow for same-day shipment of orders from regions in western U.S. time zones. The Company anticipates moving to a new lease facility in Alachua, Florida in December of 2013 that will provide an additional 6,929 square feet. The cost of such move is anticipated to be approximately $225,000. The Company also anticipates moving into lease space in Burleson, Texas in November or December of 2013 that will minimize time zone difference and allow same-day shipping to regions in western U.S. time zones. The Company also expects to move raw material storage from the facility of its current contractor to the Burleson Facility. The cost of such move is anticipated to be approximately $500,000, with certain anticipated economic incentives from the City of Burleson offsetting a portion of such costs. The Burleson facility will allow the Company to eliminate the use of certain space in Alachua it currently uses to conduct such activity and monthly storage costs for raw material and certain record storage.

Results of Operations

Comparison of the Three and Nine Months Ended September 30, 2013 and 2012

Revenues

Revenues for the three months ended September 30, 2013 increased 49.3% to approximately $2,957,000 as compared to approximately $1,981,000 for the three months ended September 30, 2012. Additionally, revenues for the nine months ended September 30, 2013 increased 41.0% to approximately $7,963,000 as compared to approximately $5,647,000 for the six months ended September 30, 2012. This increase was primarily a result of sales to new accounts and increased product usage by existing accounts. Each new customer in a defined

period has the potential to become an established customer with repeat orders and increased account penetration. As such, revenue growth occurs from both new customers who purchase for the first time in a period and increased purchasing from established customers. Each new period of measurement is thus benefited from the additional new customers added in the prior period.

Gross Profit

Gross profit for the three months ended September 30, 2013 increased 60.3% to approximately $2,307,000 as compared to approximately $1,439,000 for the three months ended September 30, 2012. This increase is primarily attributable to the increased revenues in the third quarter of 2013, manufacturing efficiencies and a product price increase instituted in March 2013, partially offset by an increase in the inventory reserve. As a result, gross margin also improved to 78.0% for the three months ended September 30, 2013 as compared to 72.6% for the same period in 2012.

Gross profit for the nine months ended September 30, 2013 increased 47.0% to approximately $6,119,000 as compared to approximately $4,163,000 for the nine months ended September 30, 2012, primarily attributable to the increased revenues, manufacturing efficiencies and a product price increase instituted in March 2013, partially offset by an increase in the inventory reserve. As a result, gross margin also improved to 76.9% for the nine months ended September 30, 2013 as compared to 73.7% for the same period in 2012. Product sales mix also has an effect on gross profit changes between periods.

Costs and Expenses

Total cost and expenses increased 31.6% to approximately $4,584,000 for the three months ended September 30, 2013 as compared to approximately $3,482,000 for the three months ended September 30, 2012. These increases were primarily due to increasing sales and marketing activities, which includes increased commissions as a result of increased sales. To a lesser extent, these increases were also attributable to expenses associated with being a public company and research and development costs associated with the Company's clinical efforts. As a percentage of revenues, total operating expenses were 155.0% for the three months ended September 30, 2013 as compared to 175.8% for the three months ended September 30, 2012. This decrease in total costs and expenses as a percentage of revenue were primarily a result of the Company's revenue increase outpacing costs and expenses increase.

Total cost and expenses increased 32.7% to approximately $12,914,000 for the nine months ended September 30, 2013 as compared to approximately $9,734,000 for the nine months ended September 30, 2012. These increases were primarily due to increasing sales and marketing activities, which includes increased commissions as a result of increased sales. To a lesser extent, these increases were also attributable to expenses associated with being a public company and research and development costs associated with the Company's clinical efforts. As a percentage of revenues, total operating expenses were 162.2% for the nine months ended September 30, 2013 as compared to 172.4% for the nine months ended September 30, 2012. Such lower total costs and expenses as a percentage of revenue were primarily a result of the Company's revenue increase outpacing costs and expenses increase.

Sales and marketing expenses increased 62.5% to approximately $2,757,000 for the three months ended September 30, 2013 as compared to approximately $1,697,000 for the three months ended September 30, 2012. This increase was primarily due to increased commissions attributable to higher sales and the expansion of the Company's direct sales force and marketing efforts. Increased marketing efforts included expansion of surgeon education, including training events and materials, and public relations. As a percentage of revenues, sales and marketing expenses were 93.2% for the three months ended September 30, 2013 compared to 85.7% for the three months ended September 30, 2012. Such higher sales and marketing expenses as a percentage of revenue were a result of the costs and expenses increase outpacing the revenue increase, primarily due to the fact that the direct sales force personnel require time to become effective in their territory and provide a positive financial contribution.

Sales and marketing expenses increased 46.2% to approximately $7,177,000 for the nine months ended September 30, 2013 as compared to approximately $4,908,000 for the nine months ended September 30, 2012. This increase was primarily due to increased commissions attributable to higher sales and the expansion of the Company's direct sales force and marketing efforts. Increased marketing efforts included expansion of surgeon education, including training events and product materials, and public relations. As a percentage of revenues, sales and marketing expenses were 90.1% for the nine months ended September 30, 2013 compared to 86.9% for the nine months ended September 30, 2012. Such higher sales and marketing expenses as a percentage of revenue were a result of the costs and expenses increase outpacing the revenue increase, primarily due to the fact that the direct sales force personnel require time to become effective in their territory and provide a positive financial contribution.

General and administrative expenses decreased 11.5% to approximately $1,233,000 for the three months ended September 30, 2013 as compared to approximately $1,394,000 for the three months ended September 30, 2012. The decrease was primarily the result of a non-recurring expense related to a license agreement, which expense was incurred in the third quarter of 2012, reduced depreciation and amortization expenses and lower professional fees based upon the timing of such services. Such decreases were offset by increases in expenses associated with being a public company and those related to travel. As a percentage of revenues, general and administrative expenses were 41.7% for the three months ended September 30, 2013 as compared to 70.4% for the three months ended September 30, 2012. Such lower general and administrative expenses as a percentage of revenue were a result of the Company being able to limit increases in such expenses while sales continue to increase.

General and administrative expenses increased 12.3% to approximately $4,238,000 for the nine months ended September 30, 2013 as compared to approximately $3,773,000 for the nine months ended September 30, 2012. Such increase was the result of increased expenses related to being a public company and travel, offset by a non-recurring expense related to a license agreement, which expense was incurred in the third quarter of 2012, and reduced depreciation and amortization expenses. As a percentage of revenues, general and administrative expenses were 53.2% for the nine months ended September 30, 2013 as compared to 66.8% the nine months ended September 30, 2012. This decrease in total costs and expenses as a percentage of revenue were primarily a result of the Company's revenue increase outpacing costs and expenses increase.

Research and development expenses increased approximately 52.3% to approximately $594,000 in the three months ended September 30, 2013 as compared to approximately $390,000 for the three months ended September 30, 2012. Research and development expenses increased 42.2% to approximately $1,499,000 in the nine months ended September 30, 2013 as compared to approximately $1,054,000 for the nine months ended September 30, 2012. Because AxoGen's products are developed for sale in their current use, it conducts limited direct research and product development, but intends to pursue new products and new applications for existing products in the future that may result in increased spending. Research and development includes AxoGen's clinical efforts and substantially all of the increase in research and development expenses from 2012 to 2013 related to expenditures for such clinical activity, including increase in personnel and associated expenses.

Other Income and Expenses

Interest expense increased 737.9% to approximately $1,215,000 for the three months ended September 30, 2013 as compared to approximately $145,000 for the three months ended September 30, 2012. Interest expense increased 785.4% to approximately $3,506,000 for the nine months ended September 30, 2013 compared to approximately $396,000 for the nine months ended September 30, 2012. This increase was primarily due to the interest accrued related to PDL. As a result of the accounting treatment for the PDL transaction, interest expense for the three months ended September 30, 2013 included approximately $923,000 of non-cash expense and for the nine months ended September 30, 2013 included approximately $2,756,000 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. The $923,000 and $2,756,000 of non-cash expense was derived from taking the total amount of imputed interest for the three months and nine months ended September 30, 2013, respectively, on the PDL agreement less the actual cash payment made to PDL in the quarter. Other than the $923,000 and $2,756,000 non-cash expense, the remaining $292,000 and $750,000 in interest expense for the three months and nine months ended September 30, 2013, respectively, is related to cash paid for interest on the note payable. The $396,000 interest expense for the nine months ended September 30, 2012 was cash paid for interest on previous debt.

Interest expense—deferred financing costs increased 1.7% to approximately $61,000 for the three months ended September 30, 2013 as compared to approximately $60,000 for the three months ended September 30, 2012. Interest expense—deferred financing costs decreased 5.2% to approximately $147,000 for the nine months ended September 30, 2013 as compared to approximately $155,000 for the nine months ended September 30, 2012. This decrease is primarily due to lower deferred financing cost amortization associated with the PDL agreement when compared to the previous bank debt.

Income Taxes

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

However, the Company did have an income tax benefit of approximately $736,000 for the nine months ended September 30, 2012 which was the result of the Company's ability to utilize net operating losses and franchise tax adjustments which resulted in tax refunds. The entire amount of the tax refund has been received. The Company does not believe there are any additional tax refund opportunities currently available.

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 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 currently paid weekly based on a 9.95% royalty rate of certain of the Company's Net Revenues (the "Assigned Interests"), subject to certain guaranteed quarterly payment amounts of approximately $1.3 to $2.5 million per quarter that commence in the quarter ending December 31, 2014. 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. The royalty payment is based on only that portion of Company Net Revenue that is 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"), which at this time represents all of the Company's Net Revenue with the exception of shipping and handling fees which represent less than 2.3% of total revenues. Future revenue, if any, from other products or services will not be subject to the PDL royalty payment. Further, on October 5, 2016, or in the event of the occurrence of a material adverse event, the Company's transfer of revenue interest or substantially all of its interest in the products or 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 20% internal rate of return to PDL on the Funded Amount, taking into consideration payments made to PDL by AxoGen, and (ii) any Delinquent Assigned Interests Payment AxoGen owed to PDL. Although we have no knowledge of PDL's intent to exercise the Put, based on actual payments to date, projected future revenues and the required minimum payments, we currently believe the Put Rate is the best estimate of the effective interest rate of the Royalty Contract. Finally, in the event of a Change of Control, AxoGen 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 the sum of (i) an amount that, when paid to PDL, would generate an internal rate of return to PDL of thirty-two and one half percent (32.5%) on all payments made by PDL pursuant to the Royalty Contract as of the date of the Change of Control Payment, taking into account the amount and timing of all payments made by AxoGen to PDL (and retained by PDL) prior to and as of the date of payment of the Change of Control Payment, plus (ii) any Delinquent Assigned Interests Payment owed. 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, 2013. Under the Royalty Contract, the Company sold to PDL the Acquired Revenues and PDL is to receive for eight years the Assigned Interests, i.e., a royalty payment based on a 9.95% royalty rate of the Company's Net Revenues, subject to certain agreed upon minimum payments of approximately $1.3 to $2.5 million per quarter, and was provided the Put and receives certain payments in the event of a Change of Control. The total consideration PDL paid to the Company was $20,800,000, 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 under the Royalty contract, which was concurrent with its execution, the Interim Royalty Contract was terminated. Proceeds from the PDL Royalty Contract transaction where used to fully repay the MidCap Loan and extinguish AxoGen's obligations thereunder. There are no financial covenants or other restrictions on the use of capital by AxoGen as a result of the Royalty Contract. In the event that the Company is unable to generate revenue in excess of its PDL Assigned Interests payments and other expenses, or PDL were to exercise the Put at a time when the Company did not have sufficient capital to pay the Put Price, AxoGen would need to raise additional capital. There is no assurance that if AxoGen is required to secure funding it can do so on terms acceptable to it, or at all, and its liquidity would be severely compromised.

Cash Flow Information

AxoGen had working capital of approximately $26.66 million and a current ratio of 21.24 at September 30, 2013, compared to working capital of $16.82 million and a current ratio of 12.36 at December 31, 2012. The increase in working capital and the current ratio at September 30, 2013 as compared to December 31, 2012 was primarily due to the Company on August 14, 2013 completing an underwritten offering of 6,000,000 shares of its common stock at a price to the public of $3.00 per share. The Company granted the underwriters a 30-day option to purchase up to an aggregate of 900,000 additional shares of Company common stock at the public offering price, less the underwriting discount, to cover over-allotments, if any. On September 11, 2013, the underwriters exercised their option to purchase an additional 184,332 shares. The Company received net proceeds of approximately $16.7 million, after deducting approximately $1.8 million in underwriting discounts and commissions and offering expenses payable by the Company, and including the underwriters' over-allotment option. The Company intends to use the net proceeds from the offering to continue product commercialization and marketing efforts for its portfolio of peripheral nerve repair products; to further develop its product pipeline; and for general working capital purposes. 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 the corresponding royalty payments of approximately $1.3 to $2.5 million per quarter 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.

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 may 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 nine months ended September 30, 2013, the

Company had a net increase in cash and cash equivalents of approximately $8,679,000 as compared to a net decrease of cash and cash equivalents of approximately $3,746,000 in the nine months ended September 30, 2012. The Company's principal sources and uses of funds are explained below:

Cash used in operating activities

The Company used approximately $8,061,000 of cash for operating activities in the nine months ended September 30, 2013, as compared to using approximately $5,288,000 of cash for operating activities in the nine months ended September 30, 2012. This increase in cash used in operating activities is primarily attributed to the net loss generated in the nine months ended September 30, 2013, net of significant non-cash interest added to the note payable, along with an increase in our accounts receivable and inventory.

Cash used for investing activities

Investing activities for the nine months ended September 30, 2013 used approximately $117,000 of cash as compared to using approximately $120,000 of cash in the nine months ended September 30, 2012. This use is principally attributable to the purchase of certain fixed and intangible assets.

Cash provided by financing activities

Financing activities through the sale of Company Common Stock in the nine months ended September 30, 2013 provided approximately $16,857,000 of cash as compared to providing approximately $1,662,000 of cash in the nine months ended September 30, 2012. The Company did not incur any debt issuance costs in 2013.

Anticipated Cash usage for facilities

The Company anticipates to lease two new facilities to accommodate its growth and to allow for same-day shipment of orders from regions in western U.S. time zones. The Company anticipates moving to a new lease facility in Alachua, Florida in December of 2013 that will provide an additional 6,929 square feet. The cost of such move is anticipated to be approximately $225,000. The Company also anticipates moving into lease space in Burleson, Texas in November or December of 2013 that will minimize time zone difference and allow same-day shipping to regions in western U.S. time zones. The Company also expects to move raw material storage from the facility of its current contractor to the Burleson Facility. The cost of such move is anticipated to be approximately $500,000, with certain anticipated economic incentives from the City of Burleson offsetting a portion of such costs. The Burleson facility will allow the Company to eliminate the use of certain space in Alachua it currently uses to conduct such activity and monthly storage costs for raw material and certain record storage.

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, 2013 and concluded that our disclosure controls and procedures were effective.

Changes in Internal Controls Over Financial Reporting

During the quarter ended September 30, 2013, there were no changes in the Company's internal control over financial reporting (as defined in Rule 13a-15(f) and 15d–15(f) under the Exchange Act) that have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

PART II — OTHER INFORMATION

ITEM 1 — Legal Proceedings

The Company is not a party to any material litigation as of September 30, 2013.

ITEM 1A — RISK FACTORS

The Company's business involves a number of risks and uncertainties, some of which are beyond its control. 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 for the year ended December 31, 2012, as updated in "Item 1A – Risk Factors" in the Company's Quarterly Report on Form 10-Q for the Quarter ended June 30, 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.

Table of Contents

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).
10.6.4	Amendment dated July 26, 2013 to Revenue Interests Purchase Agreement, dated, dated as of October 5, 2012, by and between AxoGen, Inc. and PDL BioPharma, Inc. (Incorporated by reference to the Company's Amendment No. 3 to Registration Statement on Form S-1 (registration No. 333-188597) filed with the Securities and Exchange Commission on July 30, 2013)
31.1†	Certification of Principal Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2†	Certification of Principal 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.

Table of Contents

SIGNATURES

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

AXOGEN, INC.

Dated October 30, 2013

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

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

Table of Contents

EXHIBIT INDEX

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).
10.6.4	Amendment dated July 26, 2013 to Revenue Interests Purchase Agreement, dated, dated as of October 5, 2012, by and between AxoGen, Inc. and PDL BioPharma, Inc. (Incorporated by reference to the Company's Amendment No. 3 to Registration Statement on Form S-1 (registration No. 333-188597) filed with the Securities and Exchange Commission on July 30, 2013)
31.1†	Certification of Principal Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2†	Certification of Principal 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.

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: October 30, 2013

/s/ Karen Zaderej
Karen Zaderej
Chief Executive Officer
(Principal 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: October 30, 2013

/s/ Gregory G. Freitag
Gregory G. Freitag
Chief Financial Officer
(Principal 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: October 30, 2013

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

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