

**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, 2012

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

(State or other jurisdiction of
incorporation or organization)

41-1301878

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

13859 Progress Blvd., Suite 100, Alachua, FL

(Address of principal executive offices)

32615

(Zip Code)

386-462-6800

(Registrant's telephone number, including area code)

Not Applicable

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

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

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, 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 May 15, 2012 the registrant had 11,062,421 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, 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.

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Condensed Consolidated Balance Sheets

	March 31, 2012 (unaudited)	December 31, 2011
Assets		
Current assets:		
Cash and cash equivalents	\$ 5,641,947	\$ 8,190,781
Accounts receivable	893,983	797,654
Inventory	2,126,336	1,760,540
Prepaid expenses and other	142,257	133,500
Total current assets	8,804,523	10,882,475
Property and equipment, net	221,446	247,824
Goodwill	169,987	169,987
Intangible assets	911,297	899,480
Deferred financing costs	272,563	295,276
Other assets	97,276	
	<u>\$ 10,477,092</u>	<u>\$ 12,495,042</u>
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable and accrued expenses	\$ 1,506,373	\$ 1,585,100
Current portion of long-term debt	918,480	434,734
Total current liabilities	2,424,853	2,019,834
Long-term debt	3,932,229	4,403,737
Total liabilities	6,357,082	6,423,571
Commitments and contingencies		
Stockholders' equity:		
Common stock, \$.01 par value; 50,000,000 shares authorized; 11,062,421 and 11,062,188 shares issued and outstanding	110,624	110,622
Additional paid-in capital	54,549,646	54,391,784
Accumulated deficit	(50,540,260)	(48,430,935)
Total stockholders' equity	4,120,010	6,071,471
	<u>\$ 10,477,092</u>	<u>\$ 12,495,042</u>

See notes to condensed consolidated financial statements.

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AxoGen, Inc.
Consolidated Statements of Operations
(unaudited)

	Three Months Ended	
	March 31, 2012	March 31, 2011
Revenues	\$ 1,653,430	\$ 1,121,561
Cost of goods sold	439,158	338,777
Gross profit	1,214,272	782,784
Costs and expenses:		
Sales and marketing	1,628,608	856,976
Research and development	296,131	105,591
General and administrative	1,230,608	722,165
Total costs and expenses	3,155,347	1,684,732
Loss from operations	(1,941,075)	(901,948)
Other income (expense):		
Interest expense	(125,125)	(202,799)
Interest expense—deferred financing costs	(34,951)	(1,059,167)
Change in fair value of warrant liability	—	(119,460)
Other income (expense)	(8,174)	(7,900)
Total other income (expense)	(168,250)	(1,389,326)
Net loss	(2,109,325)	(2,291,274)
Preferred Stock dividends (assumes all paid)	—	375,779
Net loss available to common shareholders	\$ (2,109,325)	\$ (2,667,053)
Weighted Average Common Shares outstanding—basic and diluted	11,062,339	1,205,600
Loss Per Common share—basic and diluted	\$ (0.19)	\$ (2.21)

See notes to condensed consolidated financial statements.

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

	Three Months Ended March 31,	
	2012	2011
Cash flows from operating activities:		
Net loss	\$(2,109,325)	\$(2,291,274)
Adjustments to reconcile net loss to net cash used for operating activities:		
Depreciation	55,691	75,129
Amortization of intangible assets	29,419	10,676
Amortization of deferred financing costs	22,713	1,059,167
Amortization of debt discount	12,238	8,578
Stock-based compensation	157,860	30,000
Change in fair value of warrant liability	—	119,460
Change in assets and liabilities:		
Accounts receivable	(96,329)	(85,251)
Inventory	(365,796)	30,429
Prepaid expenses and other	(106,033)	32,973
Accounts payable and accrued expenses	(78,727)	(146,867)
Net cash used for operating activities	<u>(2,478,289)</u>	<u>(1,156,980)</u>
Cash flows from investing activities:		
Purchase of property and equipment	(29,313)	—
Acquisition of intangible assets	(41,236)	(17,981)
Net cash used for investing activities	<u>(70,549)</u>	<u>(17,981)</u>
Cash flows from financing activities:		
Debt issuance costs	—	(37,346)
Proceeds from exercise of stock options	63	—
Payment of fractional shares from Merger	(59)	—
Net cash provided by (used for) financing activities	<u>4</u>	<u>(37,346)</u>
Net decrease in cash and cash equivalents	<u>(2,548,834)</u>	<u>(1,212,307)</u>
Cash and cash equivalents, beginning of year	<u>8,190,781</u>	<u>1,799,048</u>
Cash and cash equivalents, end of period	\$ 5,641,947	\$ 586,741
Supplemental disclosures of cash flow activity:		
Cash paid for interest	\$ 125,125	\$ 184,051
Supplemental disclosure of non-cash investing and financing activities:		
Accretion of dividends of Series B preferred stock	\$ —	\$ 110,849
Accretion of dividends of Series C preferred stock	—	187,601
Accretion of dividends of Series D preferred stock	—	77,329

See notes to condensed consolidated financial statements.

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

1. Basis of Presentation

The accompanying condensed consolidated financial statements include the accounts of AxoGen, Inc. (the “Company” or “AxoGen”) and its wholly owned subsidiary AxoGen Corporation (“AC”) as of March 31, 2012 and December 31, 2011 and for the three month periods ended March 31, 2012 and 2011. 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, 2011, which are included in the Annual Report on Form 10-K for the year ended December 31, 2011. 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. In October 2011, the Company moved its corporate headquarter facilities (principal executive office) from Texarkana, Texas to 13859 Progress Blvd., Suite 100, Alachua, Florida 32615.

2. Organization and Business

Business Summary

The Company is a regenerative medicine company with a portfolio of proprietary products and technologies for peripheral nerve reconstruction and regeneration. Peripheral nerves provide the pathways for both motor and sensory signals throughout the body and their damage can result in the loss of function and feeling. In order to improve surgical reconstruction and regeneration of peripheral nerves, the Company has developed and licensed technologies which are used in its products. Its product portfolio includes Avance® Nerve Graft, which the Company believes is the only commercially available allograft nerve for bridging nerve discontinuities (a gap created when the nerve is severed), AxoGuard® Nerve Connector, a coaptation aid allowing for close approximation of severed nerves, and AxoGuard® Nerve Protector that protects nerves during the body’s healing process after surgery.

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 products are recognized when products are delivered to the customer, at which time title passes to the customer. Once a product is delivered, the Company has no further performance obligations. Delivery is defined as delivery to a customer location or segregation of a product into a contracted distribution location. At such time, this product cannot be sold to any other customer. Fees charged to customers for storage and shipping of products are recognized as revenues when products are shipped to the customer 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 March 31, 2012 and December 31, 2011, there were no amounts deemed uncollectible and there was no allowance for doubtful accounts recorded.

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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, 2012 (unaudited)	December 31, 2011
Finished goods	\$1,632,036	\$1,374,817
Work in process	109,612	145,300
Raw materials	384,688	240,423
	<u>\$2,126,336</u>	<u>\$1,760,540</u>

Inventories was net of reserve of \$366,871 and \$433,706 at March 31, 2012 and December 31, 2011, 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.

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, 2008 through 2011.

Stock-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. 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,	2012	2011
Expected term (in years)	4.0	4.0
Expected volatility	118.17%	83.42%
Risk free rate	0.62%	1.58%
Expected dividends	0.0%	0.0%

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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, 2012 and 2011 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

In September 2011, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) No. 2011-08, Intangibles — Goodwill and Other (Topic 350)—Testing Goodwill for Impairment.” ASU 2011-8 is intended to simplify the testing of goodwill for impairment by permitting an entity to first assess qualitative factors to determine whether it is more likely than not that the fair value of a reporting unit is less than its carrying amount as a basis for determining whether it is necessary to perform the two-step goodwill impairment test described in Topic 350. ASU 2011-8 will become effective for fiscal years beginning after December 15, 2011, with early adoption permitted in limited circumstances. The Company is assessing the impact of ASU 2011-08 on its goodwill impairment test but do not expect an impact on its financial condition or results of operations.

4. Merger

On September 30, 2011, LecTec Corporation completed its business combination with AC pursuant to the terms of the Merger Agreement.

The following table sets forth the unaudited pro forma results of the Company for the three months ended March 31, 2011, as if the Merger had taken place on the first day of the period presented. These combined results are not necessarily indicative of the results that may have been achieved had the companies always been combined.

Revenues	\$ 1,146,568
Net Loss	(1,522,556)
Basic and diluted net loss per common share	\$ (0.14)
Weighted average shares – basic and diluted	10,945,531

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5. Intangible Assets

The Company's intangible assets consist of the following:

	March 31, 2012 (unaudited)	December 31, 2011
License agreements	\$ 940,467	\$ 899,231
Patents	291,907	291,907
Less: accumulated amortization	(321,077)	(291,658)
Intangible assets, net	\$ 911,297	\$ 899,480

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 for the three months ended March 31, 2012 and 2011 was approximately \$29,000 and \$11,000, respectively. As of March 31, 2012, future amortization of license agreements is expected to be approximately \$103,000 for the remainder of fiscal 2012, \$137,000 for 2013, \$115,000 for 2014 and \$50,000 each year for 2015 through 2017.

License Agreements

The Company has entered into multiple license agreements (the "License Agreements") with the University of Florida Research Foundation ("UFRF"), University of Texas at Austin ("UTA") and Emory University ("Emory"). 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%;
- Under one of the agreements, if AxoGen does not achieve certain regulatory milestones, which AxoGen has not achieved, AxoGen would owe an annual license maintenance fee starting on August 31, 2012 of \$120,000, escalating to \$240,000 on August 31, 2013 and August 31, 2014;
- 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.

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Regarding the license agreement with Emory, a series of milestone payments are listed within the agreement. Particularly, the agreement includes a schedule of license maintenance fees to be paid in the event that no regulatory-related milestone payments have been paid by certain anniversary dates of the agreement, of which none has yet been met. AxoGen renegotiated the License Agreement with Emory prior to any license maintenance fees coming due, but will continue to owe certain fees in the future or risk the loss of such license.

Royalty fees were approximately \$37,265 and \$23,285 during the three months ended March 31, 2012 and 2011, respectively, and are included in sales and marketing expense on the accompanying condensed consolidated statements of operations.

6. Long-Term Debt

Long-term debt consists of the following:

	March 31, 2011 (unaudited)	December 31, 2011
Loan and Security Agreement with financial institutions for aggregate of \$5,000,000 with 9.9% interest payable monthly through September 2012; principal and interest payable monthly for the 30 months thereafter maturing on April 1, 2015, collateralized by all the assets of the Company and subject to certain financial covenant restrictions including minimum revenue or cash requirements	\$5,000,000	\$5,000,000
Less unamortized debt discount	(149,291)	(161,529)
Less current portion	(918,480)	(434,734)
Long-term portion	<u>\$3,932,229</u>	<u>\$4,403,737</u>

Future principal payments on long-term debt are \$483,871 for 2012, \$1,935,484 for each of 2013 and 2014, and \$645,161 for 2015.

Loan and Security Agreements and Warrants

On September 30, 2011, the Company entered into the Loan and Security Agreement with MidCap Financial SBIC, LP (“MidCap”), as administrative agent, and the Lenders listed on Schedule 1 thereto (the “MidCap Loan”). The credit facility under the MidCap loan has a principal amount of \$5.0 million and a term of 42 months, and is subject to prepayment penalties. Under the MidCap Loan, AxoGen is required to make interest only payments for the first 12 months, and payments of both interest and straight line amortization of principal for the remaining 30 months. The interest rate is 9.9% per annum, and interest is computed on the basis of a 360-day year and the actual number of days elapsed during which such interest accrues.

The agreement contains customary affirmative and negative covenants, including, without limitation, (i) covenants requiring AxoGen to comply with applicable laws, provide to MidCap copies of AxoGen’s financial statements, maintain appropriate levels of insurance, protect, defend and maintain the validity and enforceability of AxoGen’s material intellectual property, (ii) covenants restricting AxoGen’s ability to dispose of all or any part of its assets (subject to certain exceptions), engage in other lines of business, change its senior management, enter into merger or consolidation transactions, incur or assume additional indebtedness, or incur liens on its assets, and (iii) covenants requiring the Company to meet certain minimum Net Invoiced Revenue, which were revised in May 2012, as defined in the agreement, or maintain a cash balance not less than 80% of the loan principal amount.

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The MidCap Loan is secured by all of AxoGen's assets. The lenders also received a ten-year warrant to purchase 89,686 shares of AxoGen's common stock at \$2.23 per share. The fair value of the warrant was \$173,736 and was recorded as debt discount and is being amortized through interest expense-deferred financing costs using the effective interest method over the term of the debt. Amortization of debt discount was \$12,238 for the three months ended March 31, 2012. The Company also recorded \$317,990 in deferred financing costs which is being amortized over the term of the loan. Amortization of the deferred financing cost was \$22,713 for the three months ended March 31, 2012.

7. Stock Options

The Company granted 201,826 shares of stock options for the three months ended March 31, 2012. Stock-based compensation expense was \$157,860 and \$30,000 for the three months ended March 31, 2012 and 2011, respectively. Total future stock compensation expense related to nonvested awards is expected to be approximately \$2,161,000 at March 31, 2012.

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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

On September 30, 2011, LecTec Corporation (“LecTec”) completed its business combination with AC in accordance with the terms of an Agreement and Plan of Merger, dated as of May 31, 2011, by and among LecTec, Nerve Merger Sub Corp., a subsidiary of LecTec (“Merger Sub”), and AC, which the parties amended on September 30, 2011 and August 9, 2011 (as amended, the “Merger Agreement”). Pursuant to the Merger Agreement, Merger Sub merged with and into AC, with AC continuing after the merger as the surviving corporation and a wholly owned subsidiary of LecTec (the “Merger”). Immediately following the Merger, LecTec changed its name to AxoGen, Inc.

AxoGen is a regenerative medicine company with a portfolio of proprietary products and technologies for peripheral nerve reconstruction and regeneration. Peripheral nerves provide the pathways for both motor and sensory signals throughout the body and their damage can result in the loss of function and feeling. In order to improve surgical reconstruction and regeneration of peripheral nerves, AxoGen has developed and licensed technologies, which are used in its products. Its product portfolio includes Avance® Nerve Graft, which AxoGen believes is the only commercially available allograft nerve for bridging nerve discontinuities (a gap created when the nerve is severed), AxoGuard® Nerve Connector, a coaptation aid allowing for close approximation of severed nerves, and AxoGuard® Nerve Protector, an implant that protects nerves during the body’s healing process after surgery.

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 first quarter of 2012 compared to the first quarter of 2011, as a result of increased penetration into key accounts and establishing new accounts through both its direct sales force and independent distributors. 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, even though in the near term revenue growth lags behind expense increase.

Results of Operations

Comparison of the Three Months Ended March 31, 2012 and 2011

Revenues

Revenues for the three months ended March 31, 2012 increased 47.3% to approximately \$1,653,000 as compared to approximately \$1,122,000 for the three months ended March 31, 2011. This increase was principally due to increased sales penetration into key accounts and establishing new accounts as a result of expanding the Company’s direct sales force.

Gross Profit

Gross profit for the three months ended March 31, 2012 increased 55.0% to approximately \$1,214,000 as compared to approximately \$783,000 for the three months ended March 31, 2011, primarily attributable to the increased revenues in 2012 and reduced processing, travel and temporary labor costs. In addition, in January 2011, the Company resumed the manufacturing of Avance® Nerve Graft and incurred certain additional manufacturing start-up expenses, which did not recur in the first quarter of 2012. As a result, gross margin also improved to 73.4% for the three months ended March 31, 2012 as compared to 69.8% for the same period in 2011.

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Costs and Expenses

Total cost and expenses increased 87.2% to approximately \$3,155,000 for the three months ended March 31, 2012 as compared to approximately \$1,685,000 for the three months ended March 31, 2011. These increases were primarily due to increasing sales and marketing activities and increases in salaries as AxoGen hired additional personnel to meet its growth demand. 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 preparation for its clinical trial. As a percentage of revenues, total operating expenses were 190.9% for the three months ended March 31, 2012 compared to 150.2% for the three months ended March 31, 2011. Such higher total costs and expenses as a percentage of revenue were primarily a result of the Company's sales and marketing costs increasing faster than revenue while we expand our sales force and marketing activities.

Sales and marketing expenses increased 90.1% to approximately \$1,629,000 for the three months ended March 31, 2012 as compared to approximately \$857,000 for the three months ended March 31, 2011. This increase was primarily due to expansion of the direct sales force and increased support for both its direct sales force and independent distributors. As a percentage of revenues, sales and marketing expenses were 98.5% for the three months ended March 31, 2012 compared to 76.4% for the three months ended March 31, 2011. Such higher sales and marketing expenses as a percentage of revenue were a result of the additional expenses associated with the expansion of the direct sales force.

General and administrative expenses increased 70.5% to approximately \$1,231,000 for the three months ended March 31, 2012 as compared to approximately \$722,000 for the three months ended March 31, 2011. As a percentage of revenues, general and administrative expenses were 74.5% for the three months ended March 31, 2012 compared to 64.3% the three months ended March 31, 2011. These increases were principally a result of an increase in payroll and benefits and expenses associated with being a public company.

Research and development expenses increased approximately 179.2% to approximately \$296,000 in the three months ended March 31, 2012 as compared to approximately \$106,000 for the three months ended March 31, 2011. Development includes AxoGen's clinical efforts and substantially all of the increase in research and development expenses from 2011 to 2012 related to expenditures for such clinical activity. 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.

Other Income and Expenses

Interest expense decreased 38.4% to approximately \$125,000 for the three months ended March 31, 2012 as compared to approximately \$203,000 for the three months ended March 31, 2011. This decrease was primarily due to the interest accrued related to the 2010 Convertible Debt (see Note 7 to the Consolidated Financial Statements included in Form 10-K) and the increase in the stated interest rate during 2011 pursuant to the amendment to AxoGen's Loan and Security Agreement originally entered into in April 2008.

Interest expense—deferred financing costs decreased 96.7% to approximately \$35,000 for the three months ended March 31, 2012 as compared to approximately \$1,059,000 for the three months ended March 31, 2011. This decrease is primarily due to certain deferred financing costs associated with warrants issued as consideration for several amendments executed during 2010 related to the Loan and Security agreement originally entered into in April 2008 becoming fully amortized by March 31, 2011. The warrants were forfeited upon completion of the Merger on September 30, 2011.

Also due to forfeiture of the warrants, gain in fair value of warrant liability was \$0 for the three months ended March 31, 2012 as compared to approximately \$119,000 for the three months ended March 31, 2011.

Income Taxes

The Company had no income tax expenses or income tax benefit for each of the three months ended March 31, 2012 and 2011 due to incurrence of net operating loss in each of these years.

Effect of Inflation

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

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Liquidity and Capital Resources

Long-Term Debt

On September 30, 2011, the Company, entered into the Loan and Security Agreement with MidCap Financial SBIC, LP (“MidCap”), as administrative agent, and the Lenders listed on Schedule 1 thereto (the “MidCap Loan”). The MidCap Loan has a principal amount of \$5.0 million and a term of 42 months, and is subject to prepayment penalties. Under this agreement, AxoGen is required to make interest only payments for the first 12 months, and payments of both interest and straight line amortization of principal for the remaining 30 months. The interest rate is 9.9% per annum, and interest is computed on the basis of a 360-day year and the actual number of days elapsed during which such interest accrues.

The MidCap Loan contains customary affirmative and negative covenants, including, without limitation, (i) covenants requiring AxoGen to comply with applicable laws, provide to MidCap copies of AxoGen’s financial statements, maintain appropriate levels of insurance and protect, defend and maintain the validity and enforceability of AxoGen’s material intellectual property, (ii) covenants restricting AxoGen’s ability to dispose of all or any part of its assets (subject to certain exceptions), engage in other lines of business, changes in its senior management, enter into merger or consolidation transactions, incur or assume additional indebtedness, or incur liens on its assets, and (iii) covenants requiring the Company to meet certain minimum Net Invoiced Revenue, which were revised in May 2012, as defined in the agreement, or maintain a cash balance not less than 80% of the loan principal amount.

The MidCap Loan is secured by all of AxoGen’s assets. The Lenders also received a ten-year warrant to purchase 89,686 shares of AxoGen’s common stock at \$2.23 per share.

The Company had no material commitments for capital expenditures at March 31, 2012 or 2011.

Cash Flow Information

AxoGen had working capital of approximately \$6,380,000 and a current ratio of 3.63 at March 31, 2012, compared to working capital of \$8,863,000 and a current ratio of 5.39 at December 31, 2011. The decrease in working capital and the current ratio at March 31, 2012 as compared to December 31, 2011 was primarily due to the use of working capital for operations in excess of revenues. The Company believes it has sufficient cash resources to meet its liquidity requirements beyond the fiscal year. 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. As described in — “Long-Term Debt” above, AxoGen must also comply with the covenants in the MidCap Loan agreement to meet certain minimum Net Invoiced Revenue, which were revised in May 2012, as defined in the agreement, or maintain a cash balance not less than 80% of the loan principal amount.

As a result of AxoGen’s continuing capital needs and other factors, it is considering to 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. 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, 2012, the Company had a net decrease in cash and cash equivalents of approximately \$2,549,000 as compared to a net decrease of cash and cash equivalents of approximately \$1,212,000 in the three months ended March 31, 2011. The Company’s principal sources and uses of funds are explained below:

Cash used in operating activities

The Company used approximately \$2,478,000 of cash for operating activities in the three months ended March 31, 2012, as compared to using approximately \$1,157,000 of cash for operating activities in the three months ended March 31, 2011. This increase in cash used in operating activities is primarily attributed to the net loss generated in the three months ended March 31, 2012, along with an increase in our accounts receivable and inventory.

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Cash used for investing activities

Investing activities for the three months ended March 31, 2012 used approximately \$71,000 of cash as compared to using \$18,000 of cash in the three months ended March 31, 2011. This increase in use is principally attributable to the purchase of certain fixed and intangible assets.

Cash provided by financing activities

Financing activities in the three months ended March 31, 2012 provided \$0 of cash as compared to using approximately \$37,000 of cash in the three months ended March 31, 2011. The Company did not incur any debt issuance cost in 2012.

Off-Balance Sheet Arrangements

AxoGen does not have any off-balance sheet arrangements.

RECENT ACCOUNTING PRONOUNCEMENTS

In September 2011, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) No. 2011-08, Intangibles—Goodwill and Other (Topic 350)—Testing Goodwill for Impairment.” ASU 2011-8 is intended to simplify the testing of goodwill for impairment by permitting an entity to first assess qualitative factors to determine whether it is more likely than not that the fair value of a reporting unit is less than its carrying amount as a basis for determining whether it is necessary to perform the two-step goodwill impairment test described in Topic 350. ASU 2011-8 will become effective for fiscal years beginning after December 15, 2011, with early adoption permitted in limited circumstances. The Company is assessing the impact of ASU 2011-08 on its goodwill impairment test but do not expect an impact on its financial condition or results of operations.

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, 2012 and concluded that our disclosure controls and procedures were effective.

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Changes in Internal Controls Over Financial Reporting

During the quarter ended the March 31, 2012, in response to the conclusion reached by our Chief Executive and Chief Financial Officers that we did not maintain effective internal control over financial reporting as of December 31, 2011 based on criteria issued by the Committee of Sponsoring Organizations of the Treadway Commission, and that our disclosure controls and procedures were not effective as of December 31, 2011, as reported in “Item 9A. Controls and Procedures” in our Annual Report on Form 10-K for the year ended December 31, 2011, we have implemented a control procedure whereby all significant contracts will be reviewed by the Chief Financial Officer at the end of each quarter and the Chief Financial Officer will then review the accounting with the Company’s corporate controller prior to the recording of all such contracts.

PART II – OTHER INFORMATION

ITEM 1 – Legal Proceedings

The Company is not a party to any material litigation as of March 31, 2012.

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 for the year ended December 31, 2011. 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

<u>Exhibit Number</u>	<u>Description</u>
3.1	Amended and Restated Articles of Incorporation of AxoGen, Inc. (incorporated by reference to Appendix B to the Proxy Statement/Prospectus included as part of LecTec Corporation's Amendment No. 2 to Registration Statement on Form S-4 filed on August 29, 2011)
3.2	AxoGen, Inc. Amended and Restated Bylaws (incorporated by reference to Appendix C to the Proxy Statement/Prospectus included as part of LecTec Corporation's Amendment No. 2 to Registration Statement on Form S-4 filed on August 29, 2011).
10.4.3*	Third Amendment dated March 12, 2012 to Amended and Restated Nerve Tissue Processing Agreement, dated as of February 27, 2008, by and between AxoGen Corporation and LifeNet Health (incorporated by reference to Exhibit 10.4.3 to the Company's Annual Report on Form 10-K for the year ended on December 31, 2011, filed on March 15, 2012).
10.5.2	Amendment dated March 14, 2012 to Distribution Agreement, dated as of August 27, 2008, by and between AxoGen, Inc. and Cook Biotech Incorporated (incorporated by reference to Exhibit 10.5.2 to the Company's Annual Report on Form 10-K for the year ended on December 31, 2011, filed on March 15, 2012).
10.22	Executive Employment Agreement, effective as of February 27, 2012, by and between AxoGen, Inc. and Jill Schiaparelli (incorporated by reference to Exhibit 10.22 to the Company's Annual Report on Form 10-K for the year ended on December 31, 2011, filed on March 15, 2012).
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.

* Confidential treatment has been granted for portions of this Exhibit pursuant to Rule 24b-2 under the Securities Exchange Act of 1934 as amended. The confidential portions have been deleted and filed separately with the United States Securities and Exchange Commission.

† 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 May 15, 2012

/s/ Karen Zaderej

Karen Zaderej
Chief Executive Officer
(Principal Executive Officer)

/s/ Gregory G. Freitag

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

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* Confidential treatment has been granted for portions of this Exhibit pursuant to Rule 24b-2 under the Securities Exchange Act of 1934 as amended. The confidential portions have been deleted and filed separately with the United States Securities and Exchange Commission.

EXHIBIT 31.01

**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: May 15, 2012

/s/ Karen Zaderej
Karen Zaderej
Chief Executive Officer

EXHIBIT 31.02

**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: May 15, 2012

/s/ Gregory G. Freitag

Gregory G. Freitag
Chief Financial Officer

EXHIBIT 32.01

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: May 15, 2012

/s/ Karen Zaderej

Karen Zaderej
Chief Executive Officer
(Principal Executive Officer)

/s/ Gregory G. Freitag

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