# 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 June 30, 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)

13859 Progress Blvd., Suite 100, Alachua, FL (Address of principal executive offices)

> <u>386-462-6800</u> (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  $\boxtimes$  NO  $\square$ 

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 ( $\S232.405$  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  $\boxtimes$  NO  $\square$ 

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  $\Box$ Non-Accelerated filer  $\Box$  (Do not check if a smaller reporting company) Accelerated filer □ 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 August 13, 2012, the registrant had 11,104,037 shares of common stock outstanding.

41-1301878 (I.R.S. Employer Identification No.)

> 32615 (Zip Code)

# Part I — Financial Information

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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 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.

# PART 1 — FINANCIAL INFORMATION

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

# AxoGen, Inc. Condensed Consolidated Balance Sheets

	June 30, 2012 (unaudited)	December 31, 2011
Assets		
Current assets:		
Cash and cash equivalents	\$ 4,638,793	\$ 8,190,781
Accounts receivable	862,228	797,654
Inventory	2,467,787	1,760,540
Prepaid expenses and other	240,678	133,500
Total current assets	8,209,486	10,882,475
Property and equipment, net	176,995	247,824
Goodwill	169,987	169,987
Intangible assets	884,935	899,480
Deferred Financing Costs	266,550	295,276
Other assets	129,702	
	\$ 9,837,655	\$ 12,495,042
Liabilities and Stockholders' Equity (Deficit)		
Current liabilities:		
Accounts payable and accrued expenses	\$ 1,704,033	\$ 1,585,100
Current portion of long-term debt	1,402,226	434,734
Total current liabilities	3,106,259	2,019,834
Long-term debt	3,460,751	4,403,737
Total liabilities	6,567,010	6,423,571
Commitments and contingencies		
Stockholders' equity:		
Common stock, \$.01 par value; 50,000,000 shares authorized; 11,104,037 and 11,062,188 shares issued and outstanding	111,040	110,622
Additional paid-in capital	54,729,584	54,391,784
Accumulated deficit	(51,569,979)	(48,430,935)
Total stockholders' equity	3,270,645	6,071,471
	\$ 9,837,655	\$ 12,495,042

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See notes to condensed consolidated financial statements.

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

	Three Months Ended		Six Months Ended	
	June 30, 2012	June 30, 2011	June 30, 2012	June 30, 2011
Revenues	\$ 2,012,513	\$ 1,225,495	\$ 3,665,943	\$ 2,347,056
Cost of goods sold	501,917	424,303	941,075	763,080
Gross profit	1,510,596	801,192	2,724,868	1,583,976
Costs and expenses:				
Sales and marketing	1,581,875	948,026	3,210,483	1,805,002
Research and development	367,363	101,117	663,494	206,708
General and administrative	1,148,161	1,203,271	2,378,769	1,925,436
Total costs and expenses	3,097,399	2,252,414	6,252,746	3,937,146
Loss from operations	(1,586,803)	(1,451,222)	(3,527,878)	(2,353,170)
Other income (expense):				
Interest expense	(125,218)	(405,690)	(250,343)	(636,250)
Interest expense — deferred financing costs	(59,983)		(94,934)	(1,031,406)
Change in fair value of warrant liability	—	181,765	—	62,305
Other income (expense)	5,851	(2,643)	(2,323)	(10,543)
Total other income (expense)	(179,350)	(226,568)	(347,600)	(1,615,894)
Loss before income taxes	(1,766,153)	(1,677,790)	(3,875,478)	(3,969,064)
Income tax benefit	736,434		736,434	
Net loss	\$(1,029,719)	\$(1,677,790)	\$(3,139,044)	\$(3,969,064)
Preferred stock dividends (assumes all paid)		322,739		698,518
Net loss available to common shareholders	(1,029,719)	(2,000,529)	(3,139,044)	(4,667,582)
Weighted Average Common Shares outstanding — basic and diluted	11,084,620	1,214,514	11,073,480	1,210,082
Loss Per Common share — basic and diluted	\$ (0.09)	<u>\$ (1.65</u> )	\$ (0.28)	<u>\$ (3.86</u> )

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

Net cash used for investing activities(80,166)(25,550)Cash flows from financing activities:-3,000,000Debt issuance of long-term debt-3,000,000Debt issuance costs(16,701)(82,346)Proceeds from exercise of stock options9,2151,149Payment of fractional shares from Merger(59)-Net cash (used by) provided by financing activities(7,545)2,918,803Net increase (decrease) in cash and cash equivalents(3,551,988)430,717Cash and cash equivalents, beginning of year8,190,7811,799,048Cash and cash equivalents, end of period4,638,7932,229,765Supplemental disclosures of cash flow activity: Cash paid for interest\$ 276,718\$ 397,623		Six Mont	Six Months Ended	
Cash flows from operating activities:       \$(3,139,044)       \$(3,969,064)         Adjustments to reconcile net loss to net cash used for operating activities:       101,869       147,162         Amortization of intangible assets       63,671       22,707         Amortization of deferred financing costs       45,427       1.031,406         Amortization of debt discount       24,506       11,435         Stock-based compensation       329,062       60,000         Change in fair value of warrant liability				
Net loss         \$(3,139,044)         \$(3,969,064)           Adjustments to reconcile net loss to net cash used for operating activities:         101,869         147,162           Depreciation         101,869         147,162           Amortization of intangible assets         63,671         22,707           Amortization of deferred financing costs         45,427         1,031,406           Amortization of debt discount         24,506         11,435           Stock-based compensation         329,062         60,000           Change in fair value of warrant liability:	Cash flama from an anoting a stinition	2012	2011	
Adjustments to reconcile net loss to net cash used for operating activities:       101,869       147,162         Depreciation       101,869       147,162         Amortization of intangible assets       63,671       22,707         Amortization of deferred financing costs       45,427       1,031,406         Amortization of debt discount       24,506       11,435         Stock-based compensation       329,062       60,000         Change in fair value of warrant liability		¢(2,120,044)	¢(2,0,0,0,0,0,0)	
Depreciation         101,869         147,162           Amortization of intangible assets         63,671         22,707           Amortization of deferred financing costs         44,5427         1,031,406           Amortization of debt discount         24,506         11,435           Stock-based compensation         329,062         60,000           Change in fair value of warrant liability         —         (62,305)           Change in sests and liabilities:         —         (64,574)         (208,478)           Accounts receivable         (64,574)         (208,478)         (96,236)           Accounts payable and accrued expenses		\$(3,139,044)	\$(3,969,064)	
Amortization of intangible assets       63,671       22,707         Amortization of deferred financing costs       45,427       1,031,406         Amortization of debt discount       24,506       11,435         Stock-based compensation       329,062       60,000         Change in assets and liabilities:		101.860	147 160	
Amortization of deferred financing costs       45,427       1,031,406         Amortization of debt discount       24,506       11,435         Stock-based compensation       329,062       60,000         Change in fair value of warrant liability        (62,305)         Change in assets and liabilities:       (208,478)         Accounts receivable       (64,574)       (208,478)         Accounts receivable       (64,574)       (208,478)         Accounts receivable       (31,040)          Accounts payable and accrued expenses       (18,933)       _655,348         Net cash used for operating activities:       (24,62,536)       (25,550)         Cash flows from investing activities:       (49,126)       _(25,550)         Cash flows from financing activities:       (80,166)       (25,550)         Cash flows from financing activities:        3,000,000         Proceeds from sisuance of long-term debt        3,000,000         Debt issuance costs       (16,701)       (82,346)         Proceeds from sisuance of long-term debt       (59)          Proceeds from sisuance of long-term debt       (7,545)       2,918,803         Net increase (decrease) in cash and cash equivalents       (3,551,988)       430,717				
Amortization of debt discount       24,506       11,435         Stock-based compensation       329,062       60,000         Change in fair value of warrant liability       —       (62,305)         Change in assets and liabilities:       (64,574)       (208,478)         Accounts receivable       (64,574)       (208,478)         Inventory       (707,247)       (54,511)         Prepaid expenses and other       (236,880)       (96,236)         Accounts payable and accrued expenses       118,933       655,348         Net cash used for operating activities:       (31,040)       —         Purchase of property and equipment       (31,040)       —         Acquisition of intangible assets       (49,126)       (25,550)         Net cash used for investing activities:       —       3,000,000         Debt issuance costs       (16,701)       (82,346)         Proceeds from issuance of long-term debt       —       3,000,000         Debt issuance costs       (16,701)       (82,346)         Proceeds from exercise of stock options       9,215       1,149         Payment of fractional shares from Merger       _       _         Net cash (used by) provided by financing activities       _       _         Cash and cash equivalen			,	
Stock-based compensation         329,062         60,000           Change in fair value of warrant liability         —         (62,305)           Change in assets and liabilities:         (707,247)         (54,511)           Accounts receivable         (64,574)         (208,478)           Inventory         (707,247)         (54,511)           Prepaid expenses and other         (236,880)         (96,236)           Accounts payable and accrued expenses         [118,933]         655,348           Net cash used for operating activities:         (31,040)         —           Purchase of property and equipment         (31,040)         —           Acquisition of intangible assets         (49,126)         (25,550)           Cash flows from financing activities:         —         3,000,000           Debt sugance collog-term debt         —         3,000,000           Debt sisuance collog-term debt         —         3,000,000           Proceeds from issuance of long-term debt         _         (59)				
Change in fair value of warrant liability       —       (62,305)         Change in assets and liabilities:       (64,574)       (208,478)         Accounts receivable       (64,574)       (208,478)         Inventory       (707,247)       (54,511)         Prepaid expenses and other       (236,880)       (96,236)         Accounts payable and accrued expenses       118,933       655,348         Net cash used for operating activities       (3,464,277)       (2,462,536)         Cash flows from investing activities:       (49,126)       (25,550)         Net cash used for investing activities       (80,166)       (25,550)         Net cash used for investing activities:       (80,166)       (25,550)         Net cash used for mextring activities       (16,701)       (82,346)         Proceeds from issuance of long-term debt       —       3,000,000         Debt issuance of stock options       9,215       1,149         Payment of fractional shares from Merger       (59)       —         Net ash (used by) provided by financing activities       (7,54,5)       2,918,803         Net increase (decrease) in cash and cash equivalents       (3,551,988)       430,717         Cash and cash equivalents, beginning of year       \$,1790,048       1,790,048         Cash and c				
Change in assets and liabilities:Accounts receivable(64,574)(208,478)Inventory(707,247)(54,511)Prepaid expenses and other(236,880)(96,236)Accounts payable and accrued expenses118,933655,348Net cash used for operating activities(34,64,277)(2,462,536)Purchase of property and equipment(31,040)Acquisition of intangible assets(49,126)(25,550)Net cash used for investing activities:(80,166)(25,550)Purchase of property and equipment(31,040)Acquisition of intangible assets(16,701)(82,346)Cash flows from financing activities:(16,701)(82,346)Proceeds from issuance of long-term debt3,000,000Debt issuance costs(16,701)(82,346)Proceeds from exercise of stock options9,2151,149Payment of fractional shares from Merger(59)Net cash (used by) provided by financing activities(3,551,988)430,717Cash and cash equivalents(3,551,988)430,717Cash and cash equivalents, beginning of year8,190,7811,799,048Cash paid for interest\$ 276,718\$ 397,623Supplemental disclosure of non-cash investing and financing activities:-\$ 200,602Accretion of dividends of Series B preferred stock\$ -\$ 4,98,07		329,002		
Accounts receivable       (64,574)       (208,478)         Inventory       (707,247)       (54,511)         Prepaid expenses and other       (236,880)       (96,236)         Accounts payable and accrued expenses       118,933       655,348         Net cash used for operating activities:       (3464,277)       (2,462,536)         Purchase of property and equipment       (31,040)       -         Acquisition of intangible assets       (49,126)       (25,550)         Net cash used for investing activities:       (80,166)       (25,550)         Cash flows from financing activities:       (16,701)       (82,346)         Proceeds from issuance of long-term debt       -       3,000,000         Debt issuance costs       (16,701)       (82,346)         Proceeds from exercise of stock options       9,215       1,149         Payment of fractional shares from Merger       (59)       -         Net cash (used by) provided by financing activities       (7,545)       2,918,803         Net increase (decrease) in cash and cash equivalents       (3,551,988)       430,717         Cash and cash equivalents, beginning of year       8,190,781       1,799,048         Cash and cash equivalents, end of period       4,638,793       2,229,765         Supplemental disclosures			(02,505)	
Inventory(707,247)(54,511)Prepaid expenses and other(236,880)(96,236)Accounts payable and accrued expenses118,933655,348Net cash used for operating activities(3,464,277)(2,462,536)Cash flows from investing activities:(31,040)-Purchase of property and equipment(31,040)-Acquisition of intangible assets(49,126)(25,550)Net cash used for investing activities:(80,166)(25,550)Net cash used for investing activities:(80,166)(25,550)Proceeds from issuance of long-term debt-3,000,000Debt issuance costs(16,701)(82,346)Proceeds from exercise of stock options9,2151,149Payment of fractional shares from Merger(59)-Net cash (used by) provided by financing activities(3,551,988)430,717Cash and cash equivalents, beginning of year8,190,7811,799,048Cash and cash equivalents, end of period4,638,7932,229,765Supplemental disclosures of cash flow activity: Cash paid for interest\$ 276,718\$ 397,623Supplemental disclosure of non-cash investing and financing activities: Accretion of dividends of Series B preferred stock\$ -\$ 200,602Accretion of dividends of Series C preferred stock\$ -349,807		(64 574)	(208.478)	
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Proceeds from issuance of long-term debt—3,000,000Debt issuance costs(16,701)(82,346)Proceeds from exercise of stock options9,2151,149Payment of fractional shares from Merger(59)—Net cash (used by) provided by financing activities(7,545)2,918,803Net increase (decrease) in cash and cash equivalents(3,551,988)430,717Cash and cash equivalents, beginning of year8,190,7811,799,048Cash and cash equivalents, end of period4,638,7932,229,765Supplemental disclosures of cash flow activity: Cash paid for interest\$ 276,718\$ 397,623Supplemental disclosure of non-cash investing and financing activities: Accretion of dividends of Series B preferred stock\$ —\$ 200,602Accretion of dividends of Series C preferred stock\$ —\$ 200,602Accretion of dividends of Series C preferred stock—349,807	Cash flows from financing activities:			
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Payment of fractional shares from Merger(59)Net cash (used by) provided by financing activities(7,545)2,918,803Net increase (decrease) in cash and cash equivalents(3,551,988)430,717Cash and cash equivalents, beginning of year8,190,7811,799,048Cash and cash equivalents, end of period4,638,7932,229,765Supplemental disclosures of cash flow activity: Cash paid for interest\$ 276,718\$ 397,623Supplemental disclosure of non-cash investing and financing activities: Accretion of dividends of Series B preferred stock\$		(16,701)	(82,346)	
Net cash (used by) provided by financing activities(7,545)2,918,803Net increase (decrease) in cash and cash equivalents(3,551,988)430,717Cash and cash equivalents, beginning of year8,190,7811,799,048Cash and cash equivalents, end of period4,638,7932,229,765Supplemental disclosures of cash flow activity: Cash paid for interest\$ 276,718\$ 397,623Supplemental disclosure of non-cash investing and financing activities: Accretion of dividends of Series B preferred stock\$ —\$ 200,602 349,807	Proceeds from exercise of stock options	9,215	1,149	
Net increase (decrease) in cash and cash equivalents(3,551,988)430,717Cash and cash equivalents, beginning of year8,190,7811,799,048Cash and cash equivalents, end of period4,638,7932,229,765Supplemental disclosures of cash flow activity: Cash paid for interest\$ 276,718\$ 397,623Supplemental disclosure of non-cash investing and financing activities: Accretion of dividends of Series B preferred stock\$ — \$ 200,602 \$ 349,807	Payment of fractional shares from Merger	(59)		
Net increase (decrease) in cash and cash equivalents(3,551,988)430,717Cash and cash equivalents, beginning of year8,190,7811,799,048Cash and cash equivalents, end of period4,638,7932,229,765Supplemental disclosures of cash flow activity: Cash paid for interest\$ 276,718\$ 397,623Supplemental disclosure of non-cash investing and financing activities: Accretion of dividends of Series B preferred stock\$ —\$ 200,602Accretion of dividends of Series C preferred stock\$ —\$ 349,807	Net cash (used by) provided by financing activities	(7,545)	2,918,803	
Cash and cash equivalents, end of period       4,638,793       2,229,765         Supplemental disclosures of cash flow activity:       397,623         Cash paid for interest       \$ 276,718       \$ 397,623         Supplemental disclosure of non-cash investing and financing activities:	Net increase (decrease) in cash and cash equivalents	(3,551,988)		
Cash and cash equivalents, end of period       4,638,793       2,229,765         Supplemental disclosures of cash flow activity:       397,623         Cash paid for interest       \$ 276,718       \$ 397,623         Supplemental disclosure of non-cash investing and financing activities:	Cash and cash equivalents, beginning of year	8,190,781	1,799,048	
Cash paid for interest\$ 276,718\$ 397,623Supplemental disclosure of non-cash investing and financing activities: Accretion of dividends of Series B preferred stock\$\$ 200,602Accretion of dividends of Series C preferred stock349,807	Cash and cash equivalents, end of period	4,638,793	2,229,765	
Supplemental disclosure of non-cash investing and financing activities:       Accretion of dividends of Series B preferred stock       \$ — \$ 200,602         Accretion of dividends of Series C preferred stock       — 349,807	Supplemental disclosures of cash flow activity:			
Accretion of dividends of Series B preferred stock\$—\$200,602Accretion of dividends of Series C preferred stock—349,807	Cash paid for interest	\$ 276,718	\$ 397,623	
Accretion of dividends of Series C preferred stock — 349,807	Supplemental disclosure of non-cash investing and financing activities:			
Accretion of dividends of Series C preferred stock — 349,807		\$ —	\$ 200,602	

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 June 30, 2012 and December 31, 2011 and for the three month and six month periods ended June 30, 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 patented and patent pending technologies which are used in its portfolio of products. This product portfolio includes Avance® Nerve Graft, a commercially available allograft nerve for bridging nerve discontinuities (a gap created when the nerve is severed) of 5mm to 70mm in length, Avance® Nerve Graft is sterilized and processed using a patented cleaning process that preserves the inherent and relevent structural characteristics of the tissue allowing regenerating axons to grow through the scaffold to the motor or sensory organ.

AxoGen's portfolio also includes AxoGuard<sup>®</sup> Nerve Connector, a coaptation aid allowing for close approximation of severed nerves, and AxoGuard<sup>®</sup> Nerve Protector, a bioscaffold used to reinforce a cooptation site, wrap a partially severed nerve or isolate and protect nerve tissue.

### 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 June 30, 2012 and December 31, 2011, 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, nerve grafts, Avance<sup>®</sup> Nerve Graft, AxoGuard<sup>®</sup> Nerve Connector, AxoGuard<sup>®</sup> Nerve Protector, and supplies that are valued at the lower of cost (first-in, first-out) or market and consist of the following:

	June 30, 2012	December 31, 2011
	(unaudited)	
Finished goods	\$1,714,190	\$1,374,817
Work in process	164,765	145,300
Raw materials	588,832	240,423
	\$2,467,787	\$1,760,540

Inventories was net of reserve of \$282,393 and \$433,706 at June 30, 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 six months ended June 30:

Six months ended June 30,	2012	2011
Expected term (in years)	4.0	4.0
Expected volatility	118.11%	83.42%
Risk free rate	0.63%	1.49%
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 six months ended June 30, 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 July 2012, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) 2012-02, Intangibles-Goodwill and Other (Topic 350): Testing Indefinite-Lived Intangible Assets for Impairment. This ASU permits an entity the option to first assess qualitative factors to determine whether it is more-likely-than-not that an indefinite-lived intangible asset is impaired. The results of the qualitative assessment would be used as a basis in determining whether it is necessary to perform the two-step quantitative impairment test. If the qualitative assessment supports the conclusion that it is more-likely-than-not that the fair value of the asset exceeds its carrying amount, the entity would not need to perform the two-step quantitative impairment test. The objective of this update is to reduce the cost and complexity of performing impairment tests for indefinite-lived intangible assets other than goodwill, and to improve consistency in impairment testing among long-lived asset categories. This ASU is effective for annual and interim impairment tests performed for fiscal years beginning after September 15, 2012. Early adoption is permitted, including for annual and interim impairment tests performed prior to the issuance of the final ASU, if an entity's financial statements for the most recent annual or interim period have not yet been issued. The Company has not early-adopted this ASU and does not believe adoption will have a material effect on its financial condition and 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 and six months ended June 30, 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.

	Three Months Ended June 30, 2011	Six Months Ended June 30, 2011
Revenues	\$ 1,244,606	\$ 2,391,174
Net Loss	(2,276,914)	(3,460,036)
Basic and diluted net loss per common share	10,949,530	10,947,542
Weighted average shares — basic and diluted	(0.21)	(0.32)

# 5. Intangible Assets

The Company's intangible assets consist of the following:

	June 30, 2012 (unaudited)	December 31, 2011
License agreements	\$ 948,358	\$ 899,231
Patents	291,907	291,907
Less: accumulated amortization	(355,330)	(291,658)
Intangible assets, net	\$ 884,935	\$ 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 was approximately \$35,000 and \$12,000 for the three months and \$64,000 and \$23,000 for the six months ended June 30, 2012 and 2011 respectively. As of June 30, 2012, future amortization of license agreements is expected to be approximately \$68,000 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") 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 \$ 45,000 and \$33,000 for the three months and approximately \$82,000 and \$56,000 for the six months ended June 30, 2012 and 2011, 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 (the "Emory Agreement"). The Company does not believe that this termination will have any material adverse effect on the Company's operations.

# 6. Long-Term Debt

Long-term debt consists of the following:

	June 30, 2012 (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	(137,023)	(161,529)
Less current portion	(1,402,226)	(434,734)
Long-term portion	\$ 3,460,751	\$4,403,737

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 Loan and Security Agreement was subsequently amended on May 14, and August 14, 2012 (the Loan and Security Agreement, as amended, 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, as defined in the agreement, or maintain a cash balance not less than 80% of the loan principal amount. The Company currently does not expect that it will meet its Net Invoiced Revenue requirement as of the September 1, 2012 compliance date, and there is no assurance that it will meet it thereafter in the future. The Company continues to maintain its required cash balance.

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 \$12,269 and \$24,507 for the three months and six months ended June 30, 2012, respectively. 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 \$22,714 and \$45,427 for the three months and six months ended June 30, 2012, respectively.

The Company currently has sufficient capital to maintain its compliance with the MidCap Loan Agreement cash covenant for approximately three months. 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, royalty contracts or from other sources. The sale of additional equity may result in dilution to AxoGen's shareholders. To the extent that the Company enters into additional financing transactions, the Company may use the proceeds from such financing transactions to repay the MidCap Loan and for general corporate purposes. There is no assurance that AxoGen will be able to secure additional 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 certain regulatory activities or reducing headcount.

#### 7. Stockholders' Equity

In June 2012, the Company issued 7,500 shares of its common stock to an individual as compensation for investor relations services. The aggregate value of the shares issued, determined based on market value of the Company's common stock, was \$21,375 and was reported as an operating expenses in the Company's consolidated statements of operations.

# 8. Stock Options

The Company granted 221,076 shares of stock options for the six months ended June 30, 2012. Stock-based compensation expense was \$149,826 and \$30,000 for the three months and \$307,686 and \$60,000 for the six months ended June 30, 2012 and 2011, respectively. Total future stock compensation expense related to nonvested awards is expected to be approximately \$2,016,000 at June 30, 2012.

Subsequent to June 2012, the Company granted stock options for an additional 15,000 shares to employees.

#### 9. Income Taxes

Income tax benefit of approximately \$736,000 for the three months and six months ended June 30, 2012 was the result of the Company's ability to utilize net operating losses and franchise tax adjustments which resulted in tax refunds. Approximately \$563,000 of the tax refund has been received and \$173,000 is to be received and included in prepaid expenses and other.

#### 10. Subsequent Event

On August 14, 2012, the Company entered into a two year Interim Revenue Interest Purchase Agreement (the "Interim Royalty Contract") with PDL BioPharma, Inc. ("PDL"), pursuant to which PDL paid the Company \$1,750,000 in exchange for the purchase of specified "Acquired Revenues," from the Company in an amount equal to the following: (i) during the period from August 1, 2012 to December 31, 2012, 3% of the Company's Net Revenues per month, and (ii) during the period from January 1, 2013 to August 31, 2014, the greater of 5% of the Company's Net Revenues or \$112,257 per month. The Company shall repurchase the Acquired Revenues and terminate the Interim Royalty Contract at any time, in the event the Company (i) receives equity or debt financing in an aggregate amount greater than \$5,000,000 from an investor(s) other than PDL, or (ii) experiences a change in control (as defined in the Interim Royalty Contract). Upon repurchase of the Acquired Revenues in such circumstances, the Company is required to pay PDL the outstanding balance under the Interim Royalty Contract as of the payment date, any accrued but unpaid Acquired Revenues through the payment date, and a \$150,000 fee.

In addition, on August 14, 2012, the Company and MidCap entered into an amendment to the MidCap Loan, under which (i) the lenders to the MidCap Loan consented to the Company's entry into the Interim Royalty Contract, and (ii) the parties agreed that PDL's rights in the Acquired Revenues under the Interim Royalty Contract are subordinated to the MidCap Loan.

# 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. The Company has developed and licensed patented and patent pending technologies, which are used in its portfolio of products. This portfolio includes Avance® Nerve Graft, a commercially available allograft nerve for bridging nerve discontinuities (a gap created when the nerve is severed), of 5mm to 70mm in length. Avance® Nerve Graft is sterilized and processed using a patented cleaning process that preserves the inherent and relevant structural characteristics of the tissue allowing regenerating axons to grow through the scaffold to the motor or sensory organs.

Axogen's portfolio also includes AxoGuard<sup>®</sup> Nerve Connector, a coaptation aid allowing for close approximation of severed nerves, and AxoGuard<sup>®</sup> Nerve Protector, a bioscaffold used to reinforce a coaptation site, wrap a partially severed nerve or protect nerve tissue.

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 second quarter of 2012 compared to the second 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 and Six Months Ended June 30, 2012 and 2011

# Revenues

Revenues for the three months ended June 30, 2012 increased 64.3% to approximately \$2,013,000 as compared to approximately \$1,225,000 for the three months ended June 30, 2011. Additionally, revenues for the six months ended June 30, 2012 increased 56.2% to approximately \$3,666,000 as compared to approximately \$2,347,000 for the six months ended June 30, 2011. These increases were principally due to increased sales penetration into key accounts and establishing new accounts as a result of expanding the Company's sales and marketing efforts.

# Gross Profit

Gross profit for the three months ended June 30, 2012 increased 88.6% to approximately \$1,511,000 as compared to approximately \$801,000 for the three months ended June 30, 2011, primarily attributable to the increased revenues and reduced processing, travel and temporary labor costs related to manufacturing, in 2012. 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 second quarter of 2012. Product sales mix also has an effect on gross profit As a result, gross margin also improved to 75.1% for the three months ended June 30, 2012 as compared to 65.4% for the same period in 2011.

Gross profit for the six months ended June 30, 2012 increased 72.0% to approximately \$2,725,000 as compared to approximately \$1,584,000 for the six months ended June 30, 2011, primarily attributable to the increased revenues and reduced processing, travel and temporary labor costs related to manufacturing, in 2012. 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 six months of 2012. Product sales mix also has an effect on gross profit As a result, gross margin also improved to 74.3% for the six months ended June 30, 2012 as compared to 67.5% for the same period in 2011.



#### Costs and Expenses

Total cost and expenses increased 37.5% to approximately \$3,097,000 for the three months ended June 30, 2012 as compared to approximately \$2,252,000 for the three months ended June 30, 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 153.8% for the three months ended June 30, 2011. This decrease in total costs and expenses as a percentage of revenue is primarily a result of the Company's increase in revenues outpacing the increase in sales and marketing costs during the second quarter of 2012.

Total cost and expenses increased 58.8% to approximately \$6,253,000 for the six months ended June 30, 2012 as compared to approximately \$3,937,000 for the six months ended June 30, 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. Additionally, these increases were 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 170.6% for the six months ended June 30, 2012 compared to 167.7% for the six months ended June 30, 2011. This increase in total costs and expenses as a percentage of revenue was primarily a result of the Company's sales and marketing costs increasing faster than revenue while we expanded our sales force and marketing activities during the first six months of 2012.

Sales and marketing expenses increased 66.9% to approximately \$1,582,000 for the three months ended June 30, 2012 as compared to approximately \$948,000 for the three months ended June 30, 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 78.6% for the three months ended June 30, 2012 compared to 77.4% for the three months ended June 30, 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.

Sales and marketing expenses increased 77.8% to approximately \$3,210,000 for the six months ended June 30, 2012 as compared to approximately \$1,805,000 for the six months ended June 30, 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 87.6% for the six months ended June 30, 2012 compared to 76.9% for the six months ended June 30, 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 decreased 4.6% to approximately \$1,148,000 for the three months ended June 30, 2012 as compared to approximately \$1,203,000 for the three months ended June 30, 2011. As a percentage of revenues, general and administrative expenses were 57.0% for the three months ended June 30, 2012 compared to 98. 2% for the three months ended June 30, 2011. These decreases were principally a result of a decrease in legal and consulting services as the company experienced higher costs in 2011 associated with the Merger, partially offset by an increase in payroll and benefits and expenses associated with being a public company.

General and administrative expenses increased 23.6% to approximately \$2,379,000 for the six months ended June 30, 2012 as compared to approximately \$1,925,000 for the six months ended June 30, 2011. This increase was principally a result of an increase in payroll and benefits as the company hired additional personnel to support its growth demand offset by a decrease in legal and consulting charges as the costs associated with the Merger did not recur in 2012. As a percentage of revenues, general and administrative expenses were 64.9% for the six months ended June 30, 2011. This decrease was principally a result of a decrease in legal and consulting services as the Company experienced higher costs in 2011 associated with its financing activity and the Merger, partially offset by an increase in payroll and benefits and expenses associated with being a public company.

Research and development expenses increased 263.4% to approximately \$367,000 in the three months ended June 30, 2012 as compared to approximately \$101,000 for the three months ended June 30, 2011. Research and development expenses increased 220.3% to approximately \$663,000 in the six months ended June 30, 2012 as compared to approximately \$207,000 for the six months ended June 30, 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 69.2% to approximately \$125,000 for the three months ended June 30, 2012 compared to approximately \$406,000 for the three months ended June 30, 2011. Interest expense decreased 60.7% to approximately \$250,000 for the six months ended June 30, 2012 compared to approximately \$636,000 for the six months ended June 30, 2011. These decreases were primarily due to the interest accrued that was related to the 2010 Convertible Debt (see Note 7 to the audited Consolidated Financial Statements included in Axogen's Annual Report on Form 10-K for the year ended December 31, 2011) 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 increased to approximately \$60,000 for the three months ended June 30, 2012, as compared to \$0 for the three months ended June 30, 2011. This increase was the result of the amortization of the financing fees associated with the current debt exceeding the prior year's amortization as the previous debt had fully matured. However, Interest expense — deferred financing costs decreased to approximately \$95,000 for the six months ended June 30, 2012, as compared to approximately \$1,031,000 for the six months ended June 30, 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, there were no gain in fair value of warrant liability for the three month and six month periods ended June 30, 2012, respectively, as compared to approximately \$182,000 and \$62,000 for the three month and six month periods ended June 30, 2011, respectively.

#### **Income Taxes**

Income tax benefit of approximately \$736,000 for the three months and six months ended June 30, 2012 was the result of the Company's ability to utilize net operating losses and franchise tax adjustments which resulted in tax refunds. Approximately \$563,000 of the tax refund has been received and \$173,000 is to be received and included in prepaid expenses and other. The Company does not believe there are any additional tax refund opportunities currently available.

The company had no income tax expense or income tax benefit for each of the three months and six months ended June 30, 2011 due to incurrence of net operating losses.

#### Effect of Inflation

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

#### 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 Loan and Security Agreement was subsequently amended on May 14 and August 14, 2012 (the Loan and Security Agreement, as amended, (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, as defined in the agreement, or maintain a cash balance not less than 80% of the loan principal amount. The company currently does not expect that it will meet its Net Invoiced Revenue requirement as of the September 1, 2012 compliance date, but continues to maintain its required cash balance, there can be no assurance as to the Company's ability to comply with the MidCap loan covenants.

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 June 30, 2012 or 2011.

# **Cash Flow Information**

AxoGen had working capital of approximately \$4,930,000 and a current ratio of 2.59 at June 30, 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 June 30, 2012 as compared to December 31, 2011 was primarily due to the use of working capital for operations in excess of revenues. AxoGen's future capital requirements depend on a number of factors, including, without limitation, revenue increases consistent with its business plan, 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 or maintain a cash balance not less than 80% of the loan principal amount. Currently, the Company does not expect that it will meet the portion of the covenant as to Net Invoiced Revenue as of the September 1, 2012 compliance date and there can be no assurance that it will meet it thereafter in the future. The Company remains in compliance with the covenants because it has a cash balance not less than 80% of the loan principal amount.

On August 14, 2012, the Company entered into a two year Interim Revenue Interest Purchase Agreement (the "Interim Royalty Contract") with PDL BioPharma, Inc. ("PDL"), pursuant to which PDL paid the Company \$1,750,000 in exchange for the purchase of specified "Acquired Revenues," from the Company in an amount equal to the following: (i) during the period from August 1, 2012 to December 31, 2012, 3% of the Company's Net Revenue, per month, and (ii) during the period from January 1, 2013 to August 31, 2014, the greater of 5% of the Company's Net Revenue, or \$112,257 per month. The Company shall repurchase the Acquired Revenues and terminate the Interim Royalty Contract at any time, in the event the Company (i) receives equity or debt financing in an aggregate amount greater than \$5,000,000 from an investor(s) other than PDL, or (ii) experiences a change in control (as defined in the Interim Royalty Contract). Upon repurchase of the Acquired Revenues in such circumstances, the Company is required to pay PDL the outstanding balance under the Interim Royalty Contract as of the payment date, any accrued but unpaid Acquired Revenues through the payment date, and a \$150,000 fee.

In addition, on August 14, 2012, the Company and MidCap entered into an amendment to the MidCap Loan, under which (i) the lenders to the MidCap Loan consented to the Company's entry into the Interim Royalty Contract, and (ii) the parties agreed that PDL's rights in the Acquired Revenues under the Interim Royalty Contract are subordinated to the MidCap Loan.

The Company currently has sufficient capital to maintain its compliance with the MidCap Loan Agreement cash covenant for approximately three months. 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, royalty contracts or from other sources. The sale of additional equity may result in dilution to AxoGen's shareholders. To the extent that the Company enters into additional financing transactions, the Company may use the proceeds from such financing transactions to repay the MidCap Loan and for general corporate purposes. There is no assurance that AxoGen will be able to secure additional 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 certain regulatory activities or reducing headcount.

During the six months ended June 30, 2012, the Company had a net decrease in cash and cash equivalents of approximately \$3,552,000 as compared to a net increase of cash and cash equivalents of approximately \$431,000 in the six months ended June 30, 2011. The Company's principal sources and uses of funds are explained below:

# Cash used in operating activities

The Company used approximately \$3,464,000 of cash for operating activities in the six months ended June 30, 2012, as compared to using approximately \$2,463,000 of cash for operating activities in the six months ended June 30, 2011. This increase in cash used in operating activities is primarily attributed to the net loss generated in the six months ended June 30, 2012, along with an increase in our accounts receivable and inventory.

# Cash used for investing activities

Investing activities for the six months ended June 30, 2012 used approximately \$80,000 of cash as compared to using approximately \$26,000 of cash in the six months ended June 30, 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 six months ended June 30, 2012 used approximately \$8,000 of cash as compared to providing approximately \$2,919,000 of cash in the six months ended June 30, 2011. This use as compared to cash provided in 2011 was the result of the Company incurring debt issuance cost of \$16,701 in 2012, partially offset by funds received for stock option exercises. In 2011, the Company received proceeds from the issuance of long-term debt of \$3.0 million.

# **Off-Balance Sheet Arrangements**

AxoGen does not have any off-balance sheet arrangements.

# **RECENT ACCOUNTING PRONOUNCEMENTS**

In July 2012, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) 2012-02, Intangibles-Goodwill and Other (Topic 350): Testing Indefinite-Lived Intangible Assets for Impairment. This ASU permits an entity the option to first assess qualitative factors to determine whether it is more-likely-than-not that an indefinite-lived intangible asset is impaired. The results of the qualitative assessment would be used as a basis in determining whether it is necessary to perform the two-step quantitative impairment test. If the qualitative assessment supports the conclusion that it is more-likely-than-not that the fair value of the asset exceeds its carrying amount, the

entity would not need to perform the two-step quantitative impairment test. The objective of this update is to reduce the cost and complexity of performing impairment tests for indefinite-lived intangible assets other than goodwill, and to improve consistency in impairment testing among long-lived asset categories. This ASU is effective for annual and interim impairment tests performed for fiscal years beginning after September 15, 2012. Early adoption is permitted, including for annual and interim impairment tests performed prior to the issuance of the final ASU, if an entity's financial statements for the most recent annual or interim period have not yet been issued. The Company has not early-adopted this ASU and does not believe adoption will have a material effect on its financial condition and 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 June 30, 2012 and concluded that our disclosure controls and procedures were effective

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

During the quarter ended 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 June 30, 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

On June 29, 2012, the Company issued 7,500 shares of its common stock to an individual who is an accredited investor (as defined in Rule 501(a) of Regulation D promulgated under the Securities Act of 1933, as amended (the "Securities Act")) as compensation for investor relations services this individual rendered to the Company. The aggregate value of the shares issued, determined based on market value of the Company's common stock was \$21,375 and was reported as an operating expense in the Company's consolidated statements of operations.

The above-described transaction was exempt from the registration requirements of the Securities Act pursuant to Section 4(2) thereof or Regulation D promulgated thereunder, as a transaction not involving a public offering. With respect to the transaction listed above, no general solicitation was made by either the Registrant or any person acting on its behalf; the securities sold are subject to transfer restrictions; and the certificate representing the securities contain an appropriate legend stating that such securities have not been registered under the Securities Act and may not be offered or sold other than pursuant to an effective registration statement under the Securities Act or an applicable exemption from the registration requirements thereof.

# ITEM 3 — DEFAULTS UPON SENIOR SECURITIES

None.

# ITEM 4 — MINE SAFETY DISCLOSURES

Not Applicable.

# **ITEM 5 — OTHER INFORMATION**

On August 14, 2012, the Company entered into a two year Interim Revenue Interest Purchase Agreement (the "Interim Royalty Contract") with PDL BioPharma, Inc. ("PDL"), pursuant to which PDL paid the Company \$1,750,000 in exchange for the purchase of specified "Acquired Revenues," from the Company in an amount equal to the following: (i) during the period from August 1, 2012 to December 31, 2012, 3% of the Company's Net Revenues per month, and (ii) during the period from January 1, 2013 to August 31, 2014, the greater of 5% of the Company's Net Revenues or \$112,257 per month. The Company shall repurchase the Acquired Revenues and terminate the Interim Royalty Contract at any time, in the event the Company (i) receives equity or debt financing in an aggregate amount greater than \$5,000,000 from an investor(s) other than PDL, or (ii) experiences a change in control (as defined in the Interim Royalty Contract). Upon repurchase of the Acquired Revenues in such circumstances, the Company is required to pay PDL the outstanding balance under the Interim Royalty Contract as of the payment date, any accrued but unpaid Acquired Revenues through the payment date, and a \$150,000 fee.

In addition, on August 14, 2012, the Company and MidCap entered into an amendment to the MidCap Loan, under which (i) the lenders to the MidCap Loan consented to the Company's entry into the Interim Royalty Contract, and (ii) the parties agreed that PDL's rights in the Acquired Revenues under the Interim Royalty Contract are subordinated to the MidCap Loan.

# ITEM 6 – EXHIBITS

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

†† Furnished herewith.

# SIGNATURES

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

AXOGEN, INC.

Dated August 14, 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)

# EXHIBIT INDEX

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101.LAB††	XBRL Extension Labels Linkbase.
101.PRE††	XBRL Taxonomy Extension Presentation Linkbase Document.

# 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: August 14, 2012

/s/ Karen Zaderej

Karen Zaderej Chief Executive Officer

# **EXHIBIT 31.2**

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

I, Gregory G. Freitag, certify that:

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

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

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

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

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

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

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

Date: August 14, 2012

<u>/s/ Gregory G. Freitag</u> Gregory G. Freitag Chief Financial Officer

# EXHIBIT 32.1

# 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: August 14, 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)