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

FORM 10-Q

(Mark One)

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

For the quarterly period ended June 30, 2013

or

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

For the transition period from _____ to _____

Commission file number: 0-16159

AxoGen, Inc.

(Exact name of registrant as specified in its charter)

Minnesota	**41-1301878**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
13859 Progress Blvd., Suite 100, Alachua, FL	**32615**
(Address of principal executive offices)	**(Zip Code)**

386-462-6800
(Registrant's telephone number, including area code)

Not Applicable
(Former name, former address and former fiscal year, if changed since last report)

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

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

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

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

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

As of August 14, 2013 the registrant had 17,139,939 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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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, 2013 (unaudited)	December 31, 2012
Assets		
Current assets:		
Cash and cash equivalents	$ 8,692,683	$ 13,907,401
Accounts receivable	1,415,524	1,050,089
Inventory	3,575,779	3,151,109
Prepaid expenses and other	127,326	187,256
Total current assets	13,811,312	18,295,855
Property and equipment, net	111,036	108,534
Intangible assets	583,386	573,731
Deferred financing costs	1,167,011	1,252,443
	$ 15,672,745	$ 20,230,563
Liabilities and Shareholders' Equity (Deficit)		
Current liabilities:		
Accounts payable and accrued expenses	$ 1,587,938	$ 1,479,752
Total current liabilities	1,587,938	1,479,752
Note Payable – Revenue Interest Purchase Agreement	23,383,692	21,580,252
Total liabilities	24,971,630	23,060,004
Commitments and contingencies		
Shareholders' equity (deficit):		
Common stock, $.01 par value; 50,000,000 shares authorized; 11,139,939 and 11,122,573 shares issued and outstanding	111,399	111,226
Additional paid-in capital	55,333,916	54,908,226
Accumulated deficit	(64,744,200)	(57,848,893)
Total shareholders' equity (deficit)	(9,298,885)	(2,829,441)
	$ 15,672,745	$ 20,230,563

See notes to condensed consolidated financial statements.

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AxoGen, Inc.

Condensed Consolidated Statements of Operations

(unaudited)

	Three Months Ended		Six Months Ended	
	June 30, 2013	June 30, 2012	June 30, 2013	June 30, 2012
Revenues	$ 2,862,289	$ 2,012,513	$ 5,005,221	$ 3,665,943
Cost of goods sold	633,293	501,917	1,193,536	941,075
Gross profit	2,228,996	1,510,596	3,811,685	2,724,868
Costs and expenses:				
Sales and marketing	2,526,388	1,581,875	4,419,929	3,210,483
Research and development	498,318	367,363	905,261	663,494
General and administrative	1,398,619	1,148,161	3,004,378	2,378,769
Total costs and expenses	4,423,325	3,097,399	8,329,568	6,252,746
Loss from operations	(2,194,329)	(1,586,803)	(4,517,883)	(3,527,878)
Other income (expense):				
Interest expense	(1,223,645)	(125,218)	(2,291,266)	(250,343)
Interest expense—deferred financing costs	(41,215)	(59,983)	(85,432)	(94,934)
Other income (expense)	1,390	5,851	(728)	(2,323)
Total other income (expense)	(1,263,470)	(179,350)	(2,377,426)	(347,600)
Loss before income taxes	(3,457,799)	(1,766,153)	(6,895,309)	(3,875,478)
Income tax benefit	—	736,434	—	736,434
Net loss	$ (3,457,799)	$ (1,029,719)	$ (6,895,309)	$ (3,139,044)
Weighted Average Common Shares outstanding—basic and diluted	11,137,729	11,084,620	11,131,217	11,073,480
Loss Per Common share—basic and diluted	$ (0.31)	$ (0.09)	$ (0.62)	$ (0.28)

See notes to condensed consolidated financial statements.

AxoGen, Inc.

Condensed Consolidated Statements of Cash Flows

(unaudited)

	Six Months Ended June 30,	
	2013	2012
Cash flows from operating activities:		
Net loss	$ (6,895,309)	$(3,139,044)
Adjustments to reconcile net loss to net cash used for operating activities:		
Depreciation	42,813	101,869
Amortization of intangible assets	29,405	63,671
Amortization of deferred financing costs	85,432	45,427
Amortization of debt discount	—	24,506
Share-based compensation	392,473	329,062
Interest added to note	1,803,439	—
Change in assets and liabilities:		
Accounts receivable	(365,435)	(64,574)
Inventory	(424,670)	(707,247)
Prepaid expenses and other	59,930	(236,880)
Accounts payable and accrued expenses	108,186	118,933
Net cash used for operating activities	(5,163,736)	(3,464,277)
Cash flows from investing activities:		
Purchase of property and equipment	(45,315)	(31,040)
Acquisition of intangible assets	(39,060)	(49,126)
Net cash used for investing activities	(84,375)	(80,166)
Cash flows from financing activities:		
Debt issuance costs	—	(16,701)
Proceeds from exercise of stock options	33,393	9,215
Payment of fractional shares from Merger	—	(59)
Net cash provided by (used for) financing activities	33,393	(7,545)
Net decrease in cash and cash equivalents	(5,214,718)	(3,551,988)
Cash and cash equivalents, beginning of year	13,907,401	8,190,781
Cash and cash equivalents, end of period	$ 8,692,683	$ 4,638,793
Supplemental disclosures of cash flow activity:		
Cash paid for interest	$ 458,394	$ 276,718

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, 2013 and December 31, 2012 and for the three and six month periods ended June 30, 2013 and 2012. The Company's condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America and should be read in conjunction with the audited financial statements of the Company for the year ended December 31, 2012, which are included in the Annual Report on Form 10-K for the year ended December 31, 2012. The interim condensed consolidated financial statements are unaudited and in the opinion of management, reflect all adjustments necessary for a fair presentation of results for the periods presented. Results for interim periods are not necessarily indicative of results for the full year. All significant intercompany accounts and transactions have been eliminated in consolidation

2. Organization and Business

Business Summary

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

3. Summary of Significant Accounting Policies

Revenue Recognition

Revenue is recognized when persuasive evidence of an arrangement exists, the price is fixed and determinable, delivery has occurred and there is a reasonable assurance of collection of the sales proceeds. Revenues for manufactured products and products sold under a distribution agreement are recognized when the product is 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 product into a contracted distribution location. At such time, this product cannot be sold to any other customer. Fees charged to customers for shipping are recognized as revenues when products are shipped to the customer 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, 2013 and December 31, 2012, there were no amounts deemed uncollectible and there was no allowance for doubtful accounts recorded.

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

Inventories

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

	June 30, 2013 (unaudited)	December 31, 2012
Finished goods	$2,405,237	$2,143,176
Work in process	198,030	145,156
Raw materials	972,512	862,777
	$3,575,779	$3,151,109

Inventories were net of reserve of approximately $334,000 and $538,000 at June 30, 2013 and December 31, 2012, respectively.

Income Taxes

The Company has not recorded current income tax expense due to the generation of net operating losses. Deferred income taxes are accounted for using the balance sheet approach which requires recognition of deferred tax assets and liabilities for the expected future consequences of temporary differences between the financial reporting basis and the tax basis of assets and liabilities. A valuation allowance is provided when it is more likely than not that a deferred tax asset will not be realized. A full valuation allowance has been established on the deferred tax asset as it is more likely than not that future tax benefit will not be realized. In addition, future utilization of the available net operating loss carryforward may be limited under Internal Revenue Code Section 382 as a result of changes in ownership.

The Company identifies and evaluates uncertain tax positions, if any, and recognizes the impact of uncertain tax positions for which there is a less than more-likely-than-not probability of the position being upheld when reviewed by the relevant taxing authority. Such positions are deemed to be unrecognized tax benefits and a corresponding liability is established on the balance sheet. The Company has not recognized a liability for uncertain tax positions. If there were an unrecognized tax benefit, the Company would recognize interest accrued related to unrecognized tax benefits in interest expense and penalties in operating expenses. The Company's remaining open tax years subject to examination by the Internal Revenue Service include the years ended December 31, 2009 through 2012; currently there are no examinations in process.

Share-Based Compensation

AxoGen's 2010 Stock Incentive Plan is measured at grant date, based on the fair value of the award, and is recognized as an expense over the employee's requisite service period. The Company estimates the fair value of each option award issued under the Plan on the date of grant using a Black-Scholes-Merton option pricing model that uses the assumptions noted in the table below. The Company estimates the volatility of its common stock at the date of grant based on the volatility of comparable peer companies which are publicly traded for the

periods prior to October 1, 2011, and based on the Company's common stock for periods subsequent to that date. The Company determines the expected life based on historical experience with similar awards, giving consideration to the contractual terms, vesting schedules and post-vesting forfeitures. The Company uses the risk-free interest rate on the implied yield currently available on U.S. Treasury issues with an equivalent remaining term approximately equal to the expected life of the award. The Company has never paid any cash dividends on its common stock during the periods reflected herein and does not anticipate paying any cash dividends in the foreseeable future. The Company used the following weighted-average assumptions for options granted during the six months ended June 30:

Six months ended June 30,	2013	2012
Expected term (in years)	4.0	4.0
Expected volatility	84.10%	118.11%
Risk free rate	0.60%	0.63%
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, 2013 and 2012 as they were deemed insignificant.

Use of Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

Recent Accounting Pronouncements

The Company's management has reviewed and considered all recent accounting pronouncements and believe there are none that could potentially have a material impact on the Company's consolidated financial condition, results of operations, or disclosures.

4. Intangible Assets

The Company's intangible assets consist of the following:

	June 30, 2013 (unaudited)	December 31, 2012
License agreements	$ 805,225	$ 772,230
Patents	63,208	63,429
Less: accumulated amortization	(285,047)	(261,928)
Intangible assets, net	$ 583,386	$ 573,731

License agreements are being amortized over periods ranging from 17-20 years. Patent costs are being amortized over three years. Pending patent costs are not amortizable. Amortization expense was approximately $15,000 and $35,000 for the three months and was approximately $29,000 and $64,000 for the six months ended June 30, 2013 and 2012, respectively. As of June 30, 2013, future amortization of license agreements is expected to be approximately $29,000 for the remainder of fiscal 2013, $55,000 for 2014, $46,000 each year for 2015 through 2018.

License Agreements

The Company has entered into multiple license agreements (the "License Agreements") with the University of Florida Research Foundation ("UFRF") and University of Texas at Austin ("UTA"). Under the terms of the License Agreements, the Company acquired exclusive worldwide licenses for underlying technology used in repairing and regenerating nerves. The licensed technologies include the rights to issued patents and patents pending in the United States and international markets. The effective term of the License Agreements extends through the term of the related patents and the agreements may be terminated by the Company with 60 days prior written notice. Additionally, in the event of default, licensors may terminate an agreement if the Company fails to cure a breach after written notice. The License Agreements contain the key terms listed below:

- AxoGen pays royalty fees ranging from 1% to 3% under the License Agreements based on net sales of licensed products. One of the agreements also contains a minimum royalty of $12,500 per quarter, which may include a credit in future quarters in the same calendar year for the amount the minimum royalty exceeds the royalty fees. Also, when AxoGen pays royalties to more than one licensor for sales of the same product, a royalty stack cap applies, capping total royalties at 3.75%;
- If AxoGen sublicenses technologies covered by the License Agreements to third parties, AxoGen would pay a percentage of sublicense fees received from the third party to the licensor. Currently, AxoGen does not sublicense any technologies covered by License Agreements. The Company is not considered a sub-licensee under the License Agreements and does not owe any sublicensee fees for its own use of the technologies;
- AxoGen reimburses the licensors for certain legal expenses incurred for patent prosecution and defense of the technologies covered by the License Agreements; and
- Currently, under one of the License Agreements, AxoGen would owe a $15,000 milestone fee upon receiving a Phase II Small Business Innovation Research or Phase II Small Business Technology Transfer grant involving the licensed technology. The Company has not received either grant and does not owe such a milestone fee. Other milestone fees are due if AxoGen develops certain pharmaceutical or medical device products under the License Agreements. No such products are currently under development.

Royalty fees were approximately $58,000 and $45,000 for the three months and were $105,000 and $82,000 for the six months ended June 30, 2013 and 2012, respectively, and are included in sales and marketing expense on the accompanying condensed consolidated statements of operations.

5. Notes Payable

Notes Payable consists of the following:

	June 30, 2013 (unaudited)	December 31, 2012
Revenue Interest Purchase Agreement with PDL BioPharma, Inc. ("PDL") for aggregate of $20,800,000 with amounts payable monthly at 9.95% of Net Revenues through September 2014; and the greater of (i) 9.95% of product revenue or (ii) specific quarterly amounts varying from approximately $1.3 million to $2.5 million per quarter through September 2020. The minimum annual payment amounts are as follows: 2014—$1,250,805, 2015—$6,781,440, 2016—$9,232,642, 2017 and 2018—$9,000,000, 2019—$9,063,000 and 2020—$6,939,000.	$ 23,383,692	$ 21,580,252
Long-term Notes Payable	$ 23,383,692	$ 21,580,252

Notes Payable

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

The Company records interest using its best estimate of the effective interest rate and currently is accruing interest using the specified internal rate of return of the put option of 20%. From time to time, the Company will reevaluate the expected cash flows and may adjust the effective interest rate. Determining the effective interest rate requires judgment and is based on significant assumptions related to estimates of the amounts and timing of future revenue streams. Payments made to PDL consist of interest and principal. Based on current calculations of the repayments, using actual payments to date, an estimate of future revenue streams and an estimated effective rate of 20% (calculated using the put rate in the agreement), principal payments are scheduled to begin in April 2015. All payments made prior to this date are interest only payments.

Put Option

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

Change of Control; Call Option

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

Board Designee

Under the Royalty Contract, during the term of the Royalty Contract PDL is entitled to designate, and AxoGen shall appoint an individual designated by PDL, who shall serve on the Board of Directors of the Company (the "Board") until the Company's 2013 Annual Meeting of Shareholders (the "2013 Annual Meeting"). For the 2013 Annual Meeting and each annual meeting thereafter during the term of the Royalty Contract, the Board shall nominate and recommend the PDL designee as a director nominee to serve on the Board until the next annual meeting and shall include such nomination in AxoGen's proxy statement for the 2013 Annual Meeting and each annual meeting thereafter, provided that the election of the PDL designee is subject to shareholders' approval. Should at any time there become a vacancy on the Board as a result of (i) the resignation, death or removal of the PDL designee or (ii) such PDL designee failing to obtain the requisite approval of the Company's shareholders at any annual or special meeting of the Company's shareholders and where no other individual is elected to such vacancy, PDL shall have the right to designate an individual to fill such vacancy, and AxoGen shall take such actions necessary to appoint, such individual to the Board.

Preemptive Rights

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

Restriction on Dividends

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

Guarantee and Collateral Agreement

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

6. Stock Options

The Company granted 193,000 shares of stock options pursuant to its 2010 Stock Incentive Plan for the six months ended June 30, 2013. Stock-based compensation expense was $132,561 and $149,826 for the three months ended June 30, 2013 and 2012, respectively and $392,473 and $307,686 for the six months ended June 30, 2013 and 2012, respectively. Total future stock compensation expense related to nonvested awards is expected to be approximately $1,401,000 at June 30, 2013.

7. Income Taxes

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

8. Subsequent Event

On August 14, 2013, the Company completed an underwritten offering of 6,000,000 shares of its common stock at a price to the public of $3.00 per share. The Company received net proceeds of approximately $16.2 million, after deducting underwriting discounts and commissions and estimated offering expenses payable by the Company, and excluding the underwriters' over-allotment option. The Company has granted the underwriters a 30-day option to purchase up to an aggregate of 900,000 additional shares of Company common stock at the public offering price, less the underwriting discount, to cover over-allotments, if any. The Company will use the net proceeds from the offering to continue product commercialization and marketing efforts for its portfolio of peripheral nerve repair products; to further develop its product pipeline; and for general working capital purposes.

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

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

OVERVIEW

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

Revenue from the distribution of these products is the main contributor to AxoGen's total reported sales and has been the key component of its growth to date. AxoGen revenues increased in the second quarter of 2013 compared to the second quarter of 2012 primarily as a result of sales to new accounts and increased product usage by existing accounts. AxoGen has continued to broaden its sales and marketing focus which is expected to have a positive contribution to its revenue growth in the long term, even though in the near term revenue growth may lag behind this near term expense increase.

Results of Operations

Comparison of the Three and Six Months Ended June 30, 2013 and 2012

Revenues

Revenues for the three months ended June 30, 2013 increased 42.2% to approximately $2,862,000 as compared to approximately $2,013,000 for the three months ended June 30, 2012. Additionally, revenues for the six months ended June 30, 2013 increased 36.5% to approximately $5,005,000 as compared to approximately $3,666,000 for the six months ended June 30, 2012. This increase was primarily a result of sales to new accounts and increased product usage by existing accounts. For the three months ended June 30, 2013, new AxoGen customers in that quarter represented approximately $293,000 of total revenue for such quarter or approximately 10%. For the six months ended June 30, 2013, new AxoGen customers in that period represented approximately $441,000 of total revenue or approximately 9%. Each new customer in a defined period has the potential to become an established customer that increases its purchasing. As such, revenue growth occurs from both new customers who purchase for the first time in a period and increased purchasing from established customers. Each new period of measurement is thus benefited from the additional new customers added in the prior period.

Gross Profit

Gross profit for the three months ended June 30, 2013 increased 47.5% to approximately $2,229,000 as compared to approximately $1,511,000 for the three months ended June 30, 2012, primarily attributable to the increased revenues in the second quarter of 2013, manufacturing efficiencies and a product price increase instituted in March 2013 which contributed approximately $238,000 or approximately 8.3%, partially offset by an increase in the inventory reserve. As a result, gross margin also improved to 77.9% for the three months ended June 30, 2013 as compared to 75.1% for the same period in 2012.

Gross profit for the six months ended June 30, 2013 increased 39.9% to approximately $3,812,000 as compared to approximately $2,725,000 for the six months ended June 30, 2012, primarily attributable to the increased revenues, manufacturing efficiencies and a product price increase instituted in March 2013 which contributed approximately $207,000 or approximately 4.1%, partially offset by an increase in the inventory reserve. Product sales mix also has an effect on gross profit. As a result, gross margin also improved to 76.2% for the six months ended June 30, 2013 as compared to 74.3% for the same period in 2012.

Costs and Expenses

Total cost and expenses increased 42.8% to approximately $4,423,000 for the three months ended June 30, 2013 as compared to approximately $3,097,000 for the three months ended June 30, 2012. These increases were primarily due to increasing sales and marketing activities and increases in salaries as AxoGen hired additional personnel to meet its current and expected growth. To a lesser extent, these increases were also attributable to expenses associated with being a public company and research and development costs associated with the Company's preparation for its clinical trial. As a percentage of revenues, total operating expenses were 154.5% for the three months ended June 30, 2013 as compared to 153.8% for the three months ended June 30, 2012. This increase in total costs and expenses as a percentage of revenue were primarily a result of the Company's increased sales and marketing costs which outpaced the increase in revenues.

Total cost and expenses increased 33.2% to approximately $8,330,000 for the six months ended June 30, 2013 as compared to approximately $6,253,000 for the six months ended June 30, 2012. These increases were primarily due to increasing sales and marketing activities and increases in salaries as AxoGen hired additional personnel to meet its current and expected growth. To a lesser extent, these increases were also attributable to expenses associated with being a public company and research and development costs associated with the Company's preparation for its clinical trial. As a percentage of revenues, total operating expenses were 166.4% for the six months ended June 30, 2013 as compared to 170.6% for the six months ended June 30, 2012. Such lower total costs and expenses as a percentage of revenue were primarily a result of the Company's revenue increase outpacing costs and expenses increase.

Sales and marketing expenses increased 59.7% to approximately $2,526,000 for the three months ended June 30, 2013 as compared to approximately $1,582,000 for the three months ended June 30, 2012. This increase was primarily due to increased commissions attributable to higher sales and the expansion of the Company's marketing efforts and direct sales force. Direct sales force personnel require time to become effective in the territory and new sales personnel hired during the first and second quarters of 2013 are not expected to contribute significantly to revenue in the third quarter of this year. As a percentage of revenues, sales and marketing expenses were 88.3% for the three months ended June 30, 2013 compared to 78.6% for the three months ended June 30, 2012. Such higher sales and marketing expenses as a percentage of revenue were a result of the costs and expenses increase outpacing the revenue increase.

Sales and marketing expenses increased 37.7% to approximately $4,420,000 for the six months ended June 30, 2013 as compared to approximately $3,210,000 for the six months ended June 30, 2012. 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 88.3% for the six months ended June 30, 2013 compared to 87.6% for the six months ended June 30, 2012. Such higher sales and marketing expenses as a percentage of revenue were a result of the costs and expenses increase slightly outpacing the revenue increase.

General and administrative expenses increased 21.9% to approximately $1,399,000 for the three months ended June 30, 2013 as compared to approximately $1,148,000 for the three months ended June 30, 2012. As a percentage of revenues, general and administrative expenses were 48.9% for the three months ended June 30, 2013 as compared to 57.1% for the three months ended June 30, 2012. The increase was a result of increased payroll and benefits, public company related expenditures, travel and other general expenses.

General and administrative expenses increased 26.3% to approximately $3,004,000 for the six months ended June 30, 2013 as compared to approximately $2,379,000 for the six months ended June 30, 2012. As a percentage of revenues, general and administrative expenses were 60.0% for the six months ended June 30, 2013 as compared to 64.9% the six months ended June 30, 2012. The increase was a result of increased payroll and benefits, public company related expenditures, travel and other general expenses.

Research and development expenses increased approximately 35.7% to approximately $498,000 in the three months ended June 30, 2013 as compared to approximately $367,000 for the three months ended June 30, 2012. Research and development expenses increased 36.5% to approximately $905,000 in the six months ended June 30, 2013 as compared to approximately $663,000 for the six months ended June 30, 2012. Development includes AxoGen's clinical efforts and substantially all of the increase in research and

development expenses from 2012 to 2013 related to expenditures for such clinical activity. 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 increased 879.2% to approximately $1,224,000 for the three months ended June 30, 2013 as compared to approximately $125,000 for the three months ended June 30, 2012. Interest expense increased 816.4% to approximately $2,291,000 for the six months ended June 30, 2013 compared to approximately $250,000 for the six months ended June 30, 2012. This increase was primarily due to the interest accrued related to PDL. As a result of the accounting treatment for the PDL transaction, interest expense for the three months ended June 30, 2013 included approximately $938,000 of non-cash expense and for the six months ended June 30, 2013 included approximately $1,833,000 of non-cash expense, that is expected to be paid in the future based upon the terms of the PDL transaction and increases in AxoGen revenues. The $938,000 and $$1,833,000 of non-cash expense was derived from taking the total amount of imputed interest for the three months and six months ended June 30, 2013, respectively on the PDL agreement less the actual cash payment made to PDL in the quarter. Other than the $938,000 and $1,833,000 non-cash expense, the remaining $285,000 and $458,000 in interest expense for the three months and six months ended June 30, 2013, respectively, is related to cash paid for interest on the note payable. The $250,000 interest expense for the six months ended June 30, 2012 was cash paid for interest on the previous debt.

Interest expense—deferred financing costs decreased 31.6% to approximately $41,000 for the three months ended June 30, 2013 as compared to approximately $60,000 for the three months ended June 30, 2012. Interest expense—deferred financing costs decreased 10.5% to approximately $85,000 for the six months ended June 30, 2013 as compared to approximately $95,000 for the six months ended June 30, 2012. This decrease is primarily due to lower deferred financing cost amortization associated with the PDL agreement when compared to the previous bank debt.

Income Taxes

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

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

Effect of Inflation

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

Liquidity and Capital Resources

Note Payable

On October 5, 2012, AxoGen entered into the Royalty Contract with PDL. Proceeds from the PDL transaction were used to fully repay the MidCap Loan, as defined below, and extinguish AxoGen's long-term debt obligations thereunder. The Royalty Contract has a term of eight years. Under the Royalty Contract, PDL is to receive royalty payments currently paid weekly based on a 9.95% royalty rate of certain of the Company's Net Revenues (the "Assigned Interests"), subject to certain guaranteed quarterly payment amounts of approximately $1.3 to $2.5 million per quarter that commence in the quarter ending December 31, 2014. The minimum annual payment amounts are as follows: 2014-$1,250,805, 2015-$6,781,440, 2016-$9,232,642, 2017 and 2018-$9,000,000, 2019-$9,063,000 and 2020-$6,939,000. The royalty payment is based on only that portion of Company Net Revenue that is generated by the sale, distribution or other use of the Company's products Avance® Nerve Graft, AxoGuard® Nerve Protector and AxoGuard® Nerve Connector (the "Acquired Revenues"), which at this time represents all of the Company's Net Revenue with the exception of shipping and handling fees which represent less than 2.3% of total revenues. Future revenue, if any, from other products or services will not be subject to the PDL royalty payment. Further, on October 5, 2016, or in the event of the occurrence of a material adverse event, the Company's transfer of revenue interest or substantially all of its interest in the products or bankruptcy or material breach of the Royalty Contract, PDL may require Axo Gen to repurchase the Assigned Interests at the Put Price. The Put Price is equal to the sum of (i) an amount that, when paid to PDL, would generate a 20% internal rate of return to PDL on the Funded Amount, taking into consideration payments made to PDL by AxoGen, and (ii) any Delinquent Assigned Interests Payment AxoGen owned to PDL. Although we have no knowledge of PDL's intent to exercise the Put, based on actual payments to date, projected future revenues and the required minimum payments, we currently believe the Put Rate is the best estimate of the effective interest rate of the Royalty Contract. Finally, in the event of a Change of Control, AxoGen must repurchase the Assigned Interests from PDL for a repurchase price equal to the Change of Control Price on or prior to the third business day after the occurrence of the Change of Control. The Change of Control Price is the sum of (i) an amount that, when paid to PDL, would generate an internal rate of return to PDL of thirty-two and one half percent (32.5%) on all payments made by PDL pursuant to the Royalty Contract as of the date of the Change of Control Payment, taking into account the amount and timing of all payments made by AxoGen to PDL (and retained by PDL) prior to and as of the date of payment of Change of Control Payment, plus (ii) any Delinquent Assigned Interests Payment owed. The total consideration PDL paid to the Company was $20,800,00 (the "Funded Amount"), including $19,050,000 PDL paid to the Company on October 5, 2012, and $1,1750,000 PDL paid to the Company on August 14, 2012 pursuant to the Interim Royalty Contract. Upon the closing of PDL's purchase of the specified royalties described above, which was concurrent with the execution of the Royalty Contract, the Interim Royalty Contract was terminated. There are no financial covenants or other restrictions on the use of capital by AxoGen as a result of the Royalty Contract, however, PDL has a first perfected security interest in the Assigned Interests.

The Company had no material commitments for capital expenditures at June 30, 2013. Under the Royalty Contract, the Company sold to PDL the Acquired Revenues and PDL is to receive for eight years the Assigned Interests, i.e., a royalty payment based on a 9.95% royalty rate of the Company's Net Revenues, subject to certain agreed upon minimum payments of approximately $1.3 to $2.5 million per quarter, and was provided the Put and receives certain payments in the event of a Change of Control. The total consideration PDL paid to the Company was $20,800,000, including $19,050,000 PDL paid to the Company on October 5, 2012, and $1,750,000 PDL paid to the Company on August 14, 2012, pursuant to the Interim Royalty Contract. Upon the closing of PDL's purchase of the specified royalties under the Royalty contract, which was concurrent with its execution, the Interim Royalty Contract was terminated. Proceeds from the PDL Royalty Contract transaction where used to fully repay the MidCap Loan and extinguish AxoGen's obligations thereunder. There are no financial covenants or other restrictions on the use of capital by AxoGen as a result of the Royalty Contract, however, PDL has a first perfected security interest in the Assigned Interests. In the event that the Company is unable to generate revenue in excess of its PDL Assigned Interests payments and other expenses, or PDL were to exercise the Put at a time when the Company did not have sufficient capital to pay the Put Price, AxoGen would need to raise additional capital. There is no assurance that if AxoGen is required to secure funding it can do so on terms acceptable to it, or at all, and its liquidity would be severely compromised.

Cash Flow Information

AxoGen had working capital of approximately $12.22 million and a current ratio of 8.70 at June 30, 2013, compared to working capital of $16.82 million and a current ratio of 12.36 at December 31, 2012. The decrease in working capital and the current ratio at June 30, 2013 as compared to December 31, 2012 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 for at least the next 12 months.

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

On August 14, 2013, AxoGen completed an underwritten offering of 6,000,000 shares of its common stock at a price to the public of $3.00 per share. AxoGen received net proceeds of approximately $16.2 million, after deducting underwriting discounts and commissions and estimated offering expenses payable by AxoGen, and excluding the underwriters' over-allotment option. AxoGen has granted the underwriters a 30-day option to purchase up to an aggregate of 900,000 additional shares of AxoGen common stock at the public offering price, less the underwriting discount, to cover over-allotments, if any. AxoGen will use the net proceeds from the offering to continue product commercialization and marketing efforts for its portfolio of peripheral nerve repair products; to further develop its product pipeline; and for general working capital purposes.

If AxoGen needs additional capital in the future, it may raise additional funds through public or private equity offerings, debt financings or from other sources. The sale of additional equity may result in dilution to AxoGen's shareholders. There is no assurance that AxoGen will be able to secure funding on terms acceptable to it, or at all. The increasing need for capital as the PDL transaction matures could also make it more difficult to obtain funding through either equity or debt. Should additional capital not become available to AxoGen as needed, AxoGen may be required to take certain action, such as, slowing sales and marketing expansion, delaying regulatory approvals or reducing headcount. During the six months ended June 30, 2013, the Company had a net decrease in cash and cash equivalents of approximately $5,215,000 as compared to a net decrease of cash and cash equivalents of approximately $3,552,000 in the six months ended June 30, 2012. The Company's principal sources and uses of funds are explained below:

Cash used in operating activities

The Company used approximately $5,164,000 of cash for operating activities in the six months ended June 30, 2013, as compared to using approximately $3,464,000 of cash for operating activities in the six months ended June 30, 2012. This increase in cash used in operating activities is primarily attributed to the net loss generated in the six months ended June 30, 2013, net of significant non-cash interest added to note, along with an increase in our accounts receivable and inventory.

Cash used for investing activities

Investing activities for the six months ended June 30, 2013 used approximately $84,000 of cash as compared to using approximately $80,000 of cash in the six months ended June 30, 2012. 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, 2013 provided $33,393 of cash as compared to using $7,545 of cash in the six months ended June 30, 2012. The Company did not incur any debt issuance costs in 2013.

Off-Balance Sheet Arrangements

AxoGen does not have any off-balance sheet arrangements.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Not Applicable.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

The Company maintains "disclosure controls and procedures" as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, (the "Exchange Act"), that are designed to ensure that information required to be disclosed by us in reports we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission's rules and forms, and that such information is accumulated and communicated to our management, including our principal executive officer and principal financial officer, and Board of Directors, as appropriate, to allow timely decisions regarding required disclosure. In designing and evaluating our disclosure controls and procedures, management recognizes that disclosure controls and procedures, no matter how well conceived and operated, can provide only reasonable assurance of achieving the desired objectives, and we necessarily are required to apply our judgment in evaluating the cost-benefit relationship of possible disclosure controls and procedures.

Our management, including our principal executive officer and principal financial officer, evaluated the effectiveness of the design and operation of our disclosure controls and procedures as of June 30, 2013 and concluded that our disclosure controls and procedures were effective.

Changes in Internal Controls Over Financial Reporting

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

PART II – OTHER INFORMATION

ITEM 1 – Legal Proceedings

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

ITEM 1A – RISK FACTORS

AxoGen's business involves a number of risks, some of which are beyond its control. The risk and uncertainties described below are not the only ones AxoGen faces. Set forth below is a discussion of the risks and uncertainties that management believes to be material to AxoGen.

Risk Related To Company

AxoGen has not experienced positive cash flow from its operations, and the ability to achieve positive cash flow from operations will depend on increasing sales of its products, which may not be achievable.

AxoGen has historically operated with negative cash flow from its operations. As of March 31, 2013, AxoGen had an accumulated deficit of approximately $61.0 million. If AxoGen product sales do not increase as anticipated, then it will continue to experience negative cash flows and adverse operating conditions. AxoGen's continuing capital needs and other factors could cause the Company 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.

AxoGen's revenue growth depends on its ability to expand its sales force and develop new customers, and there can be no assurance that these efforts will result in significant increase in sales.

AxoGen is in the process of investing in its sales channel composed of a combination of its direct sales force and independent distributors to allow it to reach new customers. There can be no assurance that these efforts will be successful in expanding AxoGen's product sales. AxoGen currently sells products directly through its employees and indirectly through distributor relationships. AxoGen is engaged in a major initiative to build and further expand sales and marketing capabilities. The incurrence of these expenses impacts AxoGen's operating results, and there can be no assurance of their effectiveness. If AxoGen is unable to develop its sales force and new customers, or increase sales to existing customers, it may not be able to grow revenue or maintain its current level of revenue generation.

AxoGen's revenue depends solely on three products.

All of AxoGen's revenue is currently derived from only three products, the Avance® Nerve Graft, AxoGuard® Nerve Protector and AxoGuard® Nerve Connector, for the treatment of peripheral nerve damage. Its ability to generate revenue is dependent on the success of these products. Accordingly, any disruption in AxoGen's ability to generate revenue from the sale of these products will have a material adverse impact on its business, results of operations, financial condition and growth prospects. In addition, AxoGen's expenditures for research and development are minimal and funding to develop, or increase efforts to find collaboration or licensing opportunities to obtain, additional products will be necessary.

The AxoGuard® products are only available through an exclusive distribution agreement with Cook Biotech. Such contract is for an initial seven year term and following such initial term, the agreement automatically renews for an additional seven (7) year period provided that the parties agree to meet at least ninety (90) days before the end of such initial term to review whether the purchase price of the products obtained from Cook Biotech need to be adjusted and reasonably agree to such adjustment in writing, where such agreement shall not be unreasonably withheld. However, there are conditions for continuation of the agreement, including payment terms and minimum purchase requirements, that if breached could result in an earlier termination of the agreement; except that through mutual agreement the parties have not established such minimums and to date have not enforce such minimum purchase provision. Additionally, in the event that AxoGen and Cook Biotech were to fail to reach an agreement as to minimum purchase quantities, Cook Biotech could terminate the agreement if it was deemed that AxoGen had failed to generate commercially reasonable sales of AxoGuard as measured by sales similar to a competitive product at the same stage in its commercial launch as verified by a mutually acceptable third-party. Although there are products that AxoGen believes it could develop or obtain that would replace the AxoGuard® products, the loss of the ability to sell the AxoGuard products could have a material adverse effect on AxoGen's business until other replacement products are available.

AxoGen's success will be dependent on continued acceptance of its products by the medical community.

Continued market acceptance of AxoGen's products will depend on its ability to demonstrate that its products are an attractive alternative to existing nerve reconstruction treatment options. Its ability to do so will depend on surgeons' evaluations of clinical safety, efficacy, ease of use, reliability, and cost-effectiveness of AxoGen's nerve repair products. For example, although AxoGen's Avance® Nerve Graft follows stringent safety standards, including sterilization by gamma irradiation, AxoGen believes that a small portion of the medical community has lingering concerns over the risk of disease transmission through the use of allografts in general. Furthermore, AxoGen believes that even if its products receive general acceptance within the medical community, acceptance and clinical recommendations by influential surgeons will be important to the commercial success of AxoGen's products.

Negative publicity concerning methods of donating human tissue and screening of donated tissue, in the industry in which AxoGen operates, may reduce demand for its Avance Nerve Graft product and negatively impact the supply of available donor tissue.

AxoGen is highly dependent on its ability to recover cadaveric nerves from tissue donors for its Avance® Nerve Graft product. The availability of acceptable donors is relatively limited, and this availability is impacted by regulatory changes, general public opinion of the donation process and AxoGen's reputation for its handling of the donation process. Media reports or other negative publicity concerning both improper methods of tissue recovery from donors and disease transmission from donated cadaver tissue (allografts) including bones, tendon, etc. may limit widespread acceptance of AxoGen's Avance® Nerve Graft. Unfavorable reports of improper or illegal tissue recovery practices, both in the U.S. and internationally, as well as incidents of improperly processed tissue leading to transmission of disease, may broadly affect the rate of future tissue donation and market acceptance of allograft technologies. Potential patients may not be able to distinguish AxoGen products, technologies, and tissue recovery and processing procedures from others engaged in tissue recovery. In addition, unfavorable reports could make families of potential donors from whom AxoGen is required to obtain consent before processing tissue reluctant to agree to donate tissue to for-profit tissue processors. Any disruption in the supply could have negative consequences for AxoGen's revenue, operating results and continued operations.

AxoGen is highly dependent on the continued availability of its facilities and could be harmed if the facilities are unavailable for any prolonged period of time.

Any failure in the physical infrastructure of AxoGen's facilities, including the facility it leases from LifeNet Health, could lead to significant costs and disruptions that could reduce its revenues and harm its business reputation and financial results. Any natural or man-made event that impacts AxoGen's ability to utilize its facilities could have a significant impact on its operating results, reputation and ability to continue operations. This includes termination of the LifeNet Health facility lease which can occur upon six months' notice from either party. Although AxoGen believes it can find and make operational a new facility in less than six months, the regulatory process for approval of facilities is time-consuming and unpredictable. AxoGen's ability to rebuild or find acceptable lease facilities would take a considerable amount of time and expense and could cause a significant disruption in service to its customers. Although AxoGen has business interruption insurance which would, in instances other than lease termination, cover certain costs, it may not cover all costs nor help to regain AxoGen's standing in the market.

AxoGen must maintain high quality manufacturing and processing.

AxoGen's Avance® Nerve Graft is processed through its Avance® Process which requires careful calibration and precise, high-quality processing and manufacturing. Achieving precision and quality control requires skill and diligence by its personnel. If it fails to achieve and maintain these high quality controls, processing and manufacturing standards, including avoidance of manufacturing errors, defects or

product failures, AxoGen could experience recalls or withdrawals of its product, delays in delivery, cost overruns or other problems that would adversely affect its business. AxoGen cannot completely eliminate the risk of errors, defects or failures. In addition, AxoGen may experience difficulties in scaling-up manufacturing of its Avance® product, including problems related to yields, quality control and assurance, tissue availability, adequacy of control policies and procedures, and lack of skilled personnel. If AxoGen is unable to process and produce its allografts on a timely basis, at acceptable quality and costs, and in sufficient quantities, or if it experiences unanticipated technological problems or delays in production, its business would be adversely affected.

AxoGen relies on third-party suppliers, some of which are currently the only source for the respective components or materials they supply to it.

Most of the raw materials used in the Avance® Process for the production of Avance® Nerve Graft are available from more than one supplier. However, one of the chemicals AxoGen uses in the manufacture of Avance® Nerve Graft is no longer provided by the original single source provider. AxoGen has inventory of such chemical which it believes provides more than one year of production. AxoGen is currently evaluating a new supplier of the chemical. In addition, some of the test results, packaging and reagents/chemicals AxoGen uses in its manufacturing process are also obtained from single suppliers. We do not have written contracts with any of our single source suppliers, and at any time they could stop supplying our orders. FDA approval of a new supplier may be required if these materials become unavailable from AxoGen's current suppliers. Although there may be other suppliers that have equivalent materials that would be available to AxoGen, FDA approval of any alternate suppliers if required could take several months or years to obtain, if able to be obtained at all. Any delay, interruption or cessation of production by AxoGen's third-party suppliers of important materials, or any delay in qualifying new materials, if necessary, would prevent or delay AxoGen's ability to manufacture products. In addition, an uncorrected impurity, a supplier's variation in a raw material or testing, either unknown to AxoGen or incompatible with its manufacturing process, or any other problem with AxoGen's materials, testing or components, would prevent or delay its ability to manufacture products. These delays may limit AxoGen's ability to meet demand for its products and delay its clinical trial, which would have a material adverse impact on its business, results of operations and financial condition.

AxoGen relies on third parties to perform many necessary services for the commercialization of Avance® Nerve Graft, including services related to the recovery, distribution, storage and transportation.

AxoGen relies upon third parties for certain recovery, distribution, and transportation services. In accordance with product specifications, these third parties ship Avance® Nerve Graft in specially validated shipping containers at frozen temperatures. If any of the third parties that AxoGen relies upon in its recovery, distribution, storage or transportation process fail to comply with applicable laws and regulations, fail to meet expected deadlines, or otherwise do not carry out their contractual duties to AxoGen, or encounter physical damage or natural disaster at their facilities, AxoGen's ability to deliver product to meet commercial demand may be significantly impaired.

AxoGen is dependent on its relationships with distributors to generate revenue.

AxoGen derives material revenues through its relationships with distributors. If such distributor relationships were terminated for any reason, it could materially and adversely affect AxoGen's ability to generate revenues and profits. AxoGen intends to obtain the assistance of additional distributors to continue its sales growth. It may not be able to find additional distributors who will agree to market and distribute its products on commercially reasonable terms, if at all. If it is unable to establish new distribution relationships or renew current distribution agreements on commercially acceptable terms, operating results could suffer.

Loss of key members of management, who it needs to succeed, could adversely affect its business.

AxoGen's future success depends on the continued efforts of the members of its senior management team. Competition for experienced management personnel in the healthcare industry is intense. If one or more of AxoGen's senior executives or other key personnel are unable or unwilling to continue in their present positions, or if AxoGen is unable to attract and retain high quality senior executives or key personnel in the future, its business may be adversely affected.

AxoGen's operating results will be harmed if it is unable to effectively manage and sustain its future growth.

There can be no assurance that AxoGen will be able to manage its future growth efficiently or profitably. Its business is unproven on a large scale and actual revenue and operating margins, or revenue and margin growth, may be less than expected. If AxoGen is unable to scale its production capabilities efficiently, it may fail to achieve expected operating margins, which would have a material and adverse effect on its operating results. Growth may also stress AxoGen's ability to adequately manage its operations, quality of products, safety and regulatory compliance. If growth significantly decreases AxoGen's cash reserves, it may be required to obtain additional financing, which may increase indebtedness or result in dilution to shareholders. Further, there can be no assurance that AxoGen would be able to obtain additional financing on acceptable terms if all at.

There may be significant fluctuations in AxoGen's operating results.

Significant quarterly fluctuations in AxoGen's results of operations may be caused by, among other factors, its volume of revenues, seasonal changes in nerve repair activity, timing of sales force expansion and general economic conditions. There can be no assurance that the level of revenues and profits, if any, achieved by AxoGen in any particular fiscal period, will not be significantly lower than in other comparable fiscal periods. AxoGen's expense levels are based, in part, on its expectations as to future revenues. As a result, if future revenues are below expectations, net income or loss may be disproportionately affected by a reduction in revenues, as any corresponding reduction in expenses may not be proportionate to the reduction in revenues.

AxoGen's revenues depend upon prompt and adequate reimbursement from public and private insurers and national health systems.

Political, economic and regulatory influences are subjecting the healthcare industry in the U.S. to fundamental change. The ability of hospitals to pay fees for AxoGen's products depends in part on the extent to which reimbursement for the costs of such materials and related treatments will continue to be available from governmental health administration authorities, private health coverage insurers and other organizations. Major third-party payers of hospital services and hospital outpatient services, including Medicare, Medicaid and private healthcare insurers, annually revise their payment methodologies, which can result in stricter standards for reimbursement of hospital charges for certain medical procedures or the elimination of reimbursement. Further, Medicare, Medicaid and private healthcare insurer cutbacks could create downward price pressure on AxoGen's products.

AxoGen may be subject to future product liability litigation that could be expensive and its insurance coverage may not be adequate.

Although AxoGen is not currently subject to any product liability proceedings, and it has no reserves for product liability disbursements, it may incur material liabilities relating to product liability claims in the future, including product liability claims arising out of the usage of AxoGen products. AxoGen currently carries product liability insurance in an amount consistent with industry averages, however, its insurance coverage and any reserves it may maintain in the future for product related liabilities may not be adequate and AxoGen's business could suffer material adverse consequences.

Technological change could reduce demand for AxoGen's products.

The medical technology industry is intensely competitive. AxoGen competes with both U.S. and international companies that engage in the development and production of medical technologies and processes including:

- biotechnology, orthopedic, pharmaceutical, biomaterial, chemical and other companies;
- academic and scientific institutions; and
- public and private research organizations.

AxoGen products compete with autograft and hollow-tube conduits, as well as with alternative medical procedures. For the foreseeable future, AxoGen believes a significant number of surgeons will continue to choose to perform autograft procedures when feasible, despite the necessity of performing a second operation and its drawbacks. In addition, many members of the medical community will continue to prefer the use of hollow-tube conduits due in part to their familiarity with these products and the procedures required for their use. Also, steady improvements have been made in synthetic human tissue substitutes, which could compete with AxoGen's products. Unlike allografts, synthetic tissue technologies are not dependent on the availability of human or animal tissue. Although AxoGen's growth strategy contemplates the introduction of new technologies, the development of these technologies is a complex and uncertain process, requiring a high level of innovation, as well as the ability to accurately predict future technology and market trends. AxoGen may not be able to respond effectively to technological changes and emerging industry standards, or to successfully identify, develop or support new technologies or enhancements to existing products in a timely and cost effective manner, if at all. Finally, there can be no assurance that in the future AxoGen's competitors will not develop products that have superior performance or are less expensive relative to its products rendering them obsolete or noncompetitive.

AxoGen may be unsuccessful in commercializing its products outside the U.S.

To date, AxoGen has focused its commercialization efforts in the U.S., except for minor revenues from the Avance® Nerve Graft in the United Kingdom, the Netherlands, Switzerland, Italy, Austria and Canada. It intends to expand sales beyond these countries outside the U.S. and will need to comply with applicable foreign regulatory requirements, including obtaining the requisite approvals to do so. Additionally, AxoGen will need to either enter into distribution agreements with third parties or develop a direct sales force in these foreign markets. If it does not obtain adequate levels of reimbursement from third-party payers outside of the U.S., it may be unable to develop and grow its product sales internationally. Outside of the U.S., reimbursement systems vary significantly by country. Many foreign markets have government-managed healthcare systems that govern reimbursement for medical devices and procedures. Additionally, some foreign reimbursement systems provide for limited payments in a given period and therefore result in extended payment periods. If AxoGen is unable to successfully commercialize its products internationally, its long term growth prospects may be limited.

If AxoGen does not manage tissue and tissue donation in an effective and efficient manner, it could adversely affect its business.

Many factors affect the supply, quantity and timing of donor medical releases, such as effectiveness of donor screening (currently performed by donor recovery groups), the effective recovery of tissue, the timely receipt, recording and review of required medical documentation, and employee loss and turnover in AxoGen's and its contractor's recovery department. AxoGen can provide no assurance that tissue recovery or donor medical releases will occur at levels that will maximize processing efficiency and minimize AxoGen's cost per allograft processed.

If AxoGen does not manage product inventory in an effective and efficient manner, it could adversely affect profitability.

Many factors affect the efficient use and planning of product inventory, such as effectiveness of predicting demand, effectiveness of preparing manufacturing to meet demand, efficiently meeting product mix and product demand requirements and product expiration. AxoGen may be unable to manage its inventory efficiently, keep inventory within expected budget goals, keep its work-in-process inventory on hand or manage it efficiently, or keep sufficient product on hand to meet demand, and AxoGen can provide no assurance that it can keep inventory costs within its target levels. Failing to do so may require AxoGen to raise additional cash resources or may harm long term growth prospects.

AxoGen is a party to a Royalty Contract which requires it to pay royalty fees that could materially adversely affect its financial position.

On October 5, 2012, AxoGen entered into a Royalty Contract with PDL, pursuant to which AxoGen sold to PDL the right to receive specified royalties on AxoGen's Net Revenues generated by the sale, distribution or other use of AxoGen's products Avance® Nerve Graft, AxoGuard® Nerve Protector and AxoGuard® Nerve Connector (the Assigned Interests as defined in the Royalty Contract). The Royalty Contract has a term of eight years. Under the Royalty Contract, PDL is to receive royalty payments, currently paid weekly, based on a 9.95% royalty rate of AxoGen's Net Revenues, subject to certain agreed upon minimum guaranteed quarterly payment amounts of approximately $1.3 to $2.5 million per quarter that commence in the quarter ending December 31, 2014. The minimum annual payment amounts are as follows: 2014—$1,250,805, 2015—$6,781,440, 2016—$9,232,642, 2017 and 2018—$9,000,000, 2019—$9,063,000 and 2020—$6,939,000. Further, on October 5, 2016, or in the event of the occurrence of a material adverse event, our transfer of revenue interest or substantially all of our interest in the products or AxoGen's bankruptcy or material breach of the Royalty Contract, PDL may require AxoGen to repurchase the Assigned Interests (the "Put") at the Put Price (as defined in the Royalty Contract). The Put Price is equal to the sum of (i) an amount that, when paid to PDL, would generate a 20% internal rate of return to PDL (the "Put Rate") on the Funded Amount, taking into consideration payments made to PDL by AxoGen, and (ii) any "Delinquent Assigned Interests Payment" (as defined in the Royalty Contract) AxoGen owed to PDL. For purposes of estimating the effective interest rate of the Royalty Contract, we considered that the effective rate of 20% (currently the Put Rate) is currently slightly higher than the implicit rate of return and, as a result, we assume for accounting purposes that PDL will exercise its put option in order to receive the higher rate of return. However we have no actual knowledge or other indications of PDL's intent to do so.

During 2012, AxoGen's monthly expenses exceeded its revenues and thus it operated at a cash loss. Royalty payments to PDL are owed without consideration to any negative affect it has on AxoGen's cash or loss position. In addition, minimum payments under the Royalty Contract start in October 2014 and if AxoGen is required to pay an amount greater than the royalty fee, AxoGen would have an even greater cash burden. Finally, there is no assurance that AxoGen will have sufficient capital to pay the Put Price if it was exercised. If AxoGen does not have sufficient cash to pay PDL, AxoGen would need to raise additional capital. The sale of additional equity to further finance the company may result in dilution to AxoGen's shareholders. There is no assurance that if AxoGen is required to secure funding it can do so on terms acceptable to it, or at all. The increasing need for capital as the PDL transaction matures could also make it more difficult to obtain funding through either equity or debt. See "Notes to Consolidated Financial Statements – Footnote 7 Long-Term Debt/Note Payable."

PDL Royalty Contract has Change of Control provision that could have material impact on price received by AxoGen shareholders in the event of a Change of Control.

In the event of a "Change of Control" (as defined in the Royalty Contract), AxoGen must repurchase the Assigned Interests from PDL for a repurchase price equal to the "Change of Control Price" on or prior to the third business day after the occurrence of the Change of Control. The Change of Control Price is the sum of (i) an amount that, when paid to PDL, would generate an internal rate of return to PDL of thirty-two and one half percent (32.5%) on all payments made by PDL pursuant to the Royalty Contract as of the date of the Change of Control Payment (as defined in the Royalty Contract), taking into account the amount and timing of all payments made by AxoGen to PDL (and retained by PDL) prior to and as of the date of payment of the Change of Control Payment, plus (ii) any Delinquent Assigned Interests Payment owed. For purposes of example only, the Change of Control payment at March 31, 2013 would have been $23,439,186. Payment of the Change of Control Price could materially reduce the consideration to be received by AxoGen shareholders if the Change of Control event was in conjunction with the acquisition of the Company.

AxoGen incurs costs as a result of operating as a public company, and its management is required to devote substantial time to compliance initiatives.

As a public company, AxoGen incurs legal, accounting and other expenses to comply with relevant securities laws and regulations, including, without limitation, the requirement of establishment and maintenance of effective disclosure and financial controls and corporate governance practices. AxoGen's management devotes substantial time and financial resources to these compliance initiatives. In addition, since August 9, 2013, AxoGen common shares have been traded on the NASDAQ Capital Market, and AxoGen expects to incur additional costs to comply with rules and regulations of the NASDAQ Capital Market. Failure to comply with public company requirements and rules of the NASDAQ Capital Market could have a material adverse effect on AxoGen's business.

Our Business and Stock Price May Be Adversely Affected if Our Internal Controls Are Not Effective.

Section 404 of the Sarbanes-Oxley Act of 2002 requires companies to conduct a comprehensive evaluation of their internal control over financial reporting. To comply with this statute, each year we are required to document and test our internal control over financial reporting and our management is required to assess and issue a report concerning our internal control over financial reporting.

In our annual report for the period ended December 31, 2011, we reported a material weakness in our internal control over financial reporting, which related to an instance in which the accounting for a contract was inappropriately treated as an expense as opposed to a prepaid asset. Specifically, an effective control was not operating to ensure that accounting for the contract was completely and accurately recorded during the 4th quarter of 2011. This control deficiency could have resulted in misstatement of net loss that would not have been prevented or detected. Accordingly, we determined that this control deficiency constituted a material weakness. During the first quarter of 2012, in response to the conclusion reached by our Chief Executive and Chief Financial Officers that, as of December 31, 2011, our disclosure controls and procedures were not effective, we implemented a control procedure whereby all significant contracts will be reviewed by the Chief Financial Officer, and at the end of each quarter, the Chief Financial Officer will then review the accounting with the Company's corporate controller prior to the recording of all such contracts. Based on its most recent evaluation, management concluded that internal control over financial reporting was effective as of December 31, 2012.

Although we believe we took appropriate actions to remediate the control deficiencies we identified and to strengthen our internal control over financial reporting, we cannot assure you that we will not discover other material weaknesses in the future or that no material weakness will result from any difficulties, errors, delays or disruptions while we implement and transition to new internal systems. The existence of one or more material weaknesses could result in errors in our financial statements, and substantial costs and resources may be required to rectify these or other internal control deficiencies. If we cannot produce reliable financial reports, investors could lose confidence in our reported financial information, the market price of our common stock could decline significantly, we may be unable to obtain additional financing to operate and expand our business, and our business and financial condition could be harmed.

Risks Related to the Regulatory Environment in which AxoGen Operates

AxoGen's business is subject to continuing regulatory compliance by the FDA and other authorities which is costly and could result in negative effects on its business.

AxoGen is subject to extensive regulation. Its products are subject to regulation by the FDA in the U.S., the Center for Medicare Services of the U.S. Department of Health and Human Services and other federal governmental agencies and, in some jurisdictions, by state and foreign governmental authorities. The FDA regulates the development, clinical testing, marketing, distribution, manufacturing, labeling, and promotion of biological products, such as that of AxoGen's Avance® Nerve Graft product. The FDA also regulates medical devices, such as the AxoGuard® products. The FDA requires the approval of a

biological product, such as the Avance® Nerve Graft product, through a biological license application, or BLA, prior to marketing. Although the Avance® Nerve Graft product has not yet been approved by FDA through a BLA, FDA is permitting the product to be sold pursuant to a transition plan while AxoGen performs clinical testing and prepares a BLA submission for the Avance® Nerve Graft. See "Business — Government Regulations — U.S. Government Regulation Review." The FDA also regulates medical devices and requires that certain medical devices, such as the AxoGuard® products, be cleared through the 510(k) premarket notification process prior to marketing. The FDA's premarket review process for new and modified existing devices that precedes product marketing can be time consuming and expensive. Some of the future products and enhancements to such products that AxoGen expects to develop and market may require marketing clearance or approval from the FDA. There can be no assurance, however, that clearance or approval will be granted with respect to any of AxoGen's products or enhancements or that FDA review will not involve delays that would adversely affect AxoGen's ability to market such products or enhancements. In addition, there can be no assurance that AxoGen products, including the Avance® Nerve Graft, or enhancements will not be subject to a lengthy and expensive approval process with the FDA.

It is possible that if regulatory clearances or approvals to market a product are obtained from the FDA, the clearances or approvals may contain limitations on the indicated uses of such product and other uses may be prohibited. Product approvals by the FDA can also be withdrawn due to failure to comply with regulatory standards or the occurrence of unforeseen problems following initial approval. Also, the FDA could limit or prevent the distribution of AxoGen products and has the power to require the recall of such products. FDA regulations depend heavily on administrative interpretation, and there can be no assurance that future interpretations made by the FDA or other regulatory bodies will not adversely affect AxoGen's operations. AxoGen, and its facilities, may be inspected by the FDA from time to time to determine whether it is in compliance with various regulations relating to specification, development, documentation, validation, testing, quality control, and product labeling. A determination that AxoGen is in violation of such regulations could lead to imposition of civil penalties, including fines, product recalls or product seizures and, in certain cases, criminal sanctions.

The use, misuse or off-label use of AxoGen's products may harm its reputation or the image of its products in the marketplace, or result in injuries that lead to product liability suits, which could be costly to AxoGen's business or result in FDA sanctions if the company is deemed to have engaged in off-label promotion. AxoGen is seeking a biologics license through the BLA process for specific uses of Avance® Nerve Graft under specific circumstances. Its promotional materials and training methods must comply with FDA requirements and other applicable laws and regulations, including the prohibition against off-label promotion. AxoGen's promotion of the AxoGuard® products, which are regulated as medical devices, also must comply with FDA's requirements and must only use labeling that is consistent with the specific indication(s) for use included in FDA's substantial equivalence order that results in marketing the devices. The FDA does not restrict or regulate a physician's use of a medical product within the practice of medicine, and AxoGen cannot prevent a physician from using its products for an off-label use. However, the Federal Food, Drug, and Cosmetic Act, referred to herein as the FD&C Act, and the FDA's regulations restrict the kind of promotional communications that may be made about AxoGen's products and if the FDA determines that AxoGen's promotional or training materials constitute the unlawful promotion of an off-label use, it could request that AxoGen modify its training or promotional materials and/or subject the Company to regulatory or enforcement actions, including the issuance of an untitled letter, a warning letter, civil money penalties, or criminal fines and penalties. Other federal, state or foreign governmental authorities might also take action if they consider AxoGen promotion or training materials to constitute promotion of an uncleared or unapproved use, which could result in significant fines or penalties under other statutory authorities, such as laws prohibiting false claims for reimbursement, or exclusion from participation in federal health programs. In that event, AxoGen's reputation could be damaged and the use of its products in the marketplace could be impaired.

In addition, there may be increased risk of injury if physicians or others attempt to use AxoGen products off-label. Furthermore, the use of AxoGen's product for indications other than those for which its products have been approved, cleared or licensed by the FDA may not effectively treat the conditions not referenced in product indications, which could harm AxoGen's reputation in the marketplace among physicians and patients. Physicians may also misuse AxoGen's product or use improper techniques if they are not adequately trained in the particular use, potentially leading to injury and an increased risk of product liability. Product liability claims are expensive to defend and could divert management's attention from its primary business and result in substantial damage awards against AxoGen. Any of these events could harm AxoGen's business, results of operations and financial condition.

AxoGen's Avance® Nerve Graft product is currently allowed to be sold pursuant to a transition plan with the FDA and a change in position by the FDA regarding its use of enforcement discretion to permit the sale of Avance would have a material adverse effect on AxoGen.

The FDA considers the AxoGen's Avance® Nerve Graft product to be a biological product, subject to BLA approval requirements. Although the Avance® Nerve Graft product has not yet been approved by FDA through a BLA, AxoGen's Avance® Nerve Graft product is currently sold under the controls applicable to a HCT/P pursuant to section 361 of the Public Health Service Act and 21 CFR Part 1271 of FDA's regulations, in accordance with a transition plan with the FDA in which the agency will monitor AxoGen's compliance with 21 CFR Part 1271. See "Business — Government Regulations — U.S. Government Regulation Review." AxoGen has continued to communicate with FDA's CBER since the acceptance of the transition plan on clinical trial design and Chemistry, Manufacturing, and Controls ("CMC") for the Avance® Nerve Graft. AxoGen can commercially distribute the Avance® Nerve Graft subject to the controls HCT/Ps until FDA makes a final determination on an Avance® Nerve Graft BLA submission, assuming AxoGen remains in compliance with the transition plan. In the event that the FDA becomes dissatisfied with AxoGen's progress or actions with respect to the transition plan or FDA otherwise changes its position regarding its use of enforcement discretion to permit AxoGen to provide the Avance® Nerve Graft product in accordance with the transition plan, AxoGen would no longer be able to sell the Avance® Nerve Graft product, which would have a material adverse effect on AxoGen's operations and financial viability. In addition, if AxoGen does not meet the conditions for the transition plan, fails to comply with applicable regulatory requirements or fails to comply with the ongoing requirements of the premarket submission to transition to a biological product, the FDA could deny approval of the premarket application, or impose civil penalties, including fines, product seizures, injunctions or product recalls and, in certain cases, criminal sanctions.

AxoGen's AxoGuard products are subject to FDA and other regulatory requirements.

AxoGen's AxoGuard® product line is regulated as a medical device under the FD&C Act and subject to premarket notification and clearance requirements under section 510(k) of the FD&C Act, 21 CFR Part 820 (Quality System Regulation) and other FDA regulations. AxoGen distributes for Cook Biotech Incorporated the AxoGuard® product line and Cook Biotech is responsible for the regulatory compliance of the AxoGuard® product line. Cook Biotech has obtained a 510(k) premarket clearance from the FDA for porcine small intestine submucosa for the repair of peripheral nerve discontinuities where gap closure can be achieved by flexion of the extremity. If AxoGen or Cook Biotech Incorporated fails to comply with applicable regulatory requirements the FDA could deny or withdraw 510(k) clearance for the AxoGuard® products, or impose civil penalties, including fines, product seizures or product recalls and, in certain cases, criminal sanctions.

Defective AxoGen product could lead to recall or other negative business conditions.

If AxoGen's products are defective or otherwise pose safety risks, the FDA could require their recall, or AxoGen may initiate a voluntary recall of its products. The FDA may require recall of a marketed medical device product, such as the AxoGuard® products, in the event that it determines that due to material deficiencies or defects that use of the medical device product would pose a reasonable probability of serious adverse health consequences or death. However, FDA does not have authority to require most

device recalls because they do not rise to this level of health significance. FDA may request, but not require, the recall of a biological product, such as the Avance® Nerve Graft. However, if a company does not comply with an FDA request for a recall, FDA can pursue other enforcement actions, such as product seizure. In addition, manufacturers may, on their own initiative, recall a product to remove or correct a deficiency or to remedy a violation of the Federal Food, Drug, and Cosmetic Act that may pose a risk to health. A government-mandated, government-requested or voluntary recall could occur as a result of an unacceptable risk to health, reports of safety issues, failures, manufacturing errors, design or labeling defects or other deficiencies and issues. Recalls and other field corrections for any of AxoGen's products would divert managerial and financial resources and have an adverse effect on its business, results of operations and financial condition. A recall could harm AxoGen's reputation with customers and negatively affect its sales. AxoGen may initiate recalls involving some of its products in the future that it determines do not require notification of the FDA. If the FDA were to disagree with AxoGen's determinations, it could request that it report those actions as recalls, and take regulatory or enforcement action against AxoGen or the product.

If AxoGen's products cause or contribute to a death, a serious injury or any adverse reaction involving a communicable disease related to its products, or malfunction in certain ways, it will be subject to reporting regulations, which can result in voluntary corrective actions or agency enforcement actions. See "Business — Regulation — Education Grants, U.S. Anti-kickback, False Claims and Other Healthcare Fraud and Abuse Laws — Pervasive and Continuing Regulation." If AxoGen fails to report these events to the FDA within the required timeframes, or at all, the FDA could take regulatory or enforcement action against AxoGen. Any adverse event involving AxoGen's products could result in future voluntary corrective actions, such as recalls or customer notifications, or agency action, such as inspection, mandatory recall or other enforcement action. Any corrective action, whether voluntary or involuntary, as well as AxoGen defending itself in a lawsuit, would require the dedication of time and capital, distract management from operating its business, and may harm AxoGen's reputation, business, results of operations and financial condition.

AxoGen's manufacturing operations must comply with FDA and other governmental requirements.

AxoGen's manufacturing operations require it to comply with the FDA's and other governmental authorities' laws and regulations regarding the manufacture and production of medical products, which is costly and could subject AxoGen to enforcement action. See Business — Government Regulations — Education Grants, U.S. Anti-kickback, False Claims and Other Healthcare Fraud and Abuse Laws — Pervasive and Continuing Regulation. Any of these actions could impair AxoGen's ability to produce its products in a cost-effective and timely manner in order to meet customer demands. AxoGen may also be required to bear other costs or take other actions that may have an adverse impact on its future sales and its ability to generate profits. Furthermore, AxoGen key material suppliers, licensors and or other contractors may not continue to be in compliance with all applicable regulatory requirements, which could result in AxoGen's failure to produce its products on a timely basis and in the required quantities, if at all.

Sales of AxoGen products outside the U.S. are subject to foreign regulatory requirements that vary from country to country. In the European Union (the "E.U."), regulations, if applicable, differ from one E.U. member state to the next. Because of the absence of a harmonized regulatory framework and the proposed regulation for advanced therapy medicinal products in the E.U., as well as for other countries, the approval process for human derived cell or tissue based medical products may be extensive, lengthy, expensive and unpredictable. AxoGen products will be subject to E.U. member states' regulations that govern the donation, procurement, testing, coding, traceability, processing, preservation, storage, and distribution of human tissues and cells and cellular or tissue-based products. In addition, some E.U. member states have their own tissue banking regulations. The inability to meet foreign regulatory requirements could materially affect AxoGen's future growth and compliance with such requirements could place a significant financial burden on AxoGen.

Clinical trials can be long, expensive and ultimately uncertain which could jeopardize AxoGen's ability to obtain regulatory approval and continue to market its Avance® Nerve Graft product.

AxoGen is required to perform a clinical trial for its Avance® Nerve Graft pursuant to requirements of the FDA to obtain approval of a BLA for the product. This trial is expensive, is expected to take several years to execute, and is subject to factors within and outside of AxoGen's control. The outcome of this trial is uncertain.

AxoGen has continued to communicate with the FDA regarding clinical trial design, preclinical studies and CMC for the Avance® Nerve Graft, and will have significant work to continue to meet the requirements asked of AxoGen by the FDA for each of these components to begin its clinical study and receive approval of its BLA approval. If AxoGen is unable to agree with FDA, or unable to meet the standards required of it by the FDA, regarding preclinical studies, clinical studies and CMC, the approval of AxoGen's BLA may be impossible, delayed and/or may add significant costs to the ongoing production of Avance® Nerve Graft.

The results of non-clinical studies do not necessarily predict future clinical trial results, and predecessor clinical trial results may not be repeated in subsequent clinical trials. Additionally, the FDA may disagree with AxoGen's interpretation of the data from its non-clinical studies and clinical trials and may require it to pursue additional non-clinical studies or clinical trials, or not approve AxoGen's BLA or future supplements, which could further delay the BLA for the Avance® Nerve Graft of AxoGen's products. If AxoGen is unable to demonstrate the safety and efficacy of its product through its clinical trials, it will be unable to obtain regulatory approval to market the Avance® Nerve Graft and will not be able to continue to sell it.

AxoGen will rely on third parties to conduct its clinical trial and they may not perform as contractually required or expected.

AxoGen will rely on third parties, such as contract research organizations ("CROs"), medical institutions, clinical investigators and contract laboratories to conduct its clinical trial and certain nonclinical studies. AxoGen and its CROs are required to comply with all applicable regulations governing clinical research, including good clinical practice, or GCP. The FDA enforces these regulations through periodic inspections of trial sponsors, principal investigators, CROs and trial sites. If AxoGen or its CROs fail to comply with applicable FDA regulations, the data generated in its clinical trials may be deemed unreliable and the FDA may require AxoGen to perform additional clinical trials before approving its applications. AxoGen cannot be certain that, upon inspection, the FDA and similar foreign regulatory authorities will determine that AxoGen's clinical trial complies or complied with clinical trial regulations, including GCP. In addition, AxoGen's clinical trial must be conducted with product produced under applicable current Good Manufacturing Practice, or GMP, regulations. Failure to comply with the clinical trial regulations may require AxoGen to repeat clinical trials, which would delay the regulatory approval process. If these third parties do not successfully carry out their contractual duties or regulatory obligations or meet expected deadlines, if these third parties need to be replaced, or if the quality or accuracy of the data they obtain is compromised due to the failure to adhere to AxoGen's clinical protocols or regulatory requirements or for other reasons, AxoGen's non-clinical development activities or clinical trials may be extended, delayed, suspended or terminated, and it would not be able to obtain regulatory approval for, its products on a timely basis, if at all, and its business, results of operations, financial condition and growth prospects would be adversely affected. Furthermore, AxoGen's third-party clinical trial investigators may be delayed in conducting its clinical trials for reasons outside of their control.

U.S. governmental regulation could restrict the use of AxoGen's Avance® Nerve Graft product, restrict AxoGen's procurement of tissue or increase costs.

In addition to the FDA requirements for biological products, the Avance® Nerve Graft will continue to be subject to various requirements for human tissue under 21 CFR Part 1271 controls. Human tissues intended for transplantation have been regulated by the FDA since 1993. In May 2005, three new

comprehensive regulations went into effect that address manufacturing activities associated with HCT/P. The first requires that companies that produce and distribute HCT/Ps register with the FDA. The second provides criteria that must be met for donors to be eligible to donate tissues and is referred to as the "Donor Eligibility" rule. The third rule governs the processing and distribution of the tissues and is often referred to as the Current Good Tissue Practices rule. The Current Good Tissue Practices rule covers all stages of allograft processing, from procurement of tissue to distribution of final allografts. Together, they are designed to ensure that sound, high quality practices are followed to reduce the risk of tissue contamination and of communicable disease transmission to recipients. These regulations increased regulatory scrutiny within the industry in which AxoGen operates and have led to increased enforcement action, which affects the conduct of its business. See "Business — Government Regulations." These regulations can also increase the cost of tissue recovery activities. Additionally, the Avance® Nerve Graft is subjected to certain state and local regulations, as well as compliance to the standards of the tissue bank industry's accrediting organization, the American Association of Tissue Banks ("AATB").

The procurement and transplantation of allograft nerve tissue is also subject to federal law pursuant to the National Organ Transplant Act ("NOTA"), a criminal statute which prohibits the purchase and sale of human organs used in human transplantation, including nerve and related tissue, for "valuable consideration." NOTA only permits reasonable payments associated with the removal, transportation, processing, preservation, quality control, implantation and storage of human nerve tissue. AxoGen makes payments to certain of its clients and tissue banks for their services related to recovering allograft nerve tissue on its behalf. If NOTA is interpreted or enforced in a manner which prevents AxoGen from receiving payment for services it renders, or which prevents it from paying tissue banks or certain of its clients for the services they render for AxoGen, its business could be materially and adversely affected.

AxoGen has engaged, through its marketing employees, independent sales agents and sales representatives, in ongoing efforts designed to educate the medical community as to the benefits of AxoGen products, and AxoGen intends to continue its educational activities. Although AxoGen believes that NOTA permits payments in connection with these educational efforts as reasonable payments associated with the processing, transportation and implantation of AxoGen products, payments in connection with such education efforts are not exempt from NOTA's restrictions and AxoGen's inability to make such payments in connection with its education efforts may prevent it from paying AxoGen sales representatives for their education efforts and could adversely affect AxoGen's business and prospects. No federal agency or court has determined whether NOTA is, or will be, applicable to every allograft nerve tissue-based material which AxoGen's processing technologies may generate. Assuming that NOTA applies to AxoGen's processing of allograft nerve tissue, AxoGen believes that it complies with NOTA, but there can be no assurance that more restrictive interpretations of, or amendments to, NOTA will not be adopted in the future, which would call into question one or more aspects of AxoGen's method of operations.

Other regulatory entities include state agencies with statutes covering tissue banking. Regulations issued by Florida, New York, California and Maryland, among others, will be particularly relevant to AxoGen's business. Most states do not currently have tissue banking regulations. However, incidents of allograft related infections in the industry may stimulate the development of regulation in other states. It is possible that others may make allegations against AxoGen or against donor recovery groups or tissue banks about non-compliance with applicable FDA regulations or other relevant statutes or regulations. Allegations like these could cause regulators or other authorities to take investigative or other action, or could cause negative publicity for AxoGen's business and the industry in which it operates.

Healthcare policy changes may have a material adverse effect on AxoGen.

In March 2010, President Obama signed into law the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, which substantially changes the way healthcare is financed by both governmental and private insurers, and encourages improvements in the quality of healthcare items and services. This Act significantly impacts the biotechnology and medical device industries and could have a material adverse impact on numerous aspects of AxoGen's business.

This Act includes, among other things, the following measures:

- a 2.3% excise tax on any entity that manufactures or imports medical devices offered for sale in the U.S., with limited exceptions, beginning in 2013, referred to as the Device Tax;
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities and conduct comparative clinical effectiveness research;
- new reporting and disclosure requirements on healthcare manufacturers for any "transfer of value" made or distributed to physicians and teaching hospitals, as well as reporting of certain physician ownership interests, with the first of such reports due March 31, 2014 for calendar year 2013 ("Sunshine Act");
- payment system reforms including a national pilot program on payment bundling to encourage hospitals, physicians and other providers to improve the coordination, quality and efficiency of certain healthcare services through bundled payment models which began January 2013;
- an independent payment advisory board that will submit recommendations to reduce Medicare spending if projected Medicare spending exceeds a specified growth rate; and
- a new abbreviated pathway for the licensure of biologic products that are demonstrated to be biosimilar or interchangeable with a licensed biologic product.

Because the Avance® Nerve Graft is a biological product and is not a medical device it is not subject to the Device Tax. Cook Biotech is the manufacturer of the AxoGuard® products and AxoGen is the distributor. As such, Cook Biotech is responsible for payment of the Device Tax on the transfer price of the AxoGuard® products from Cook Biotech to AxoGen and AxoGen has no further Device Tax obligations with respect to its resale. Although AxoGen currently has no Device Tax obligations, there can be no assurance that changes in regulations will not subject it to such obligations in the future.

There are also a number of states (such as Vermont, Massachusetts, Minnesota) with their own Sunshine Acts that implement the reporting and disclosure requirements on healthcare manufacturers for any "transfer of value" made or distributed to physicians and teaching hospitals, as well as reporting of certain physician ownership interests.

In the future, there may continue to be additional proposals relating to the reform of the U.S. healthcare system. Certain of these proposals could limit the prices AxoGen is able to charge for its products or the amounts of reimbursement available for its products and could also limit the acceptance and availability of its products. The adoption of some or all of these proposals could have a material adverse effect on AxoGen's business, results of operations and financial condition.

Additionally, initiatives sponsored by government agencies, legislative bodies and the private sector to limit the growth of healthcare costs, including price regulation and competitive pricing, are ongoing in markets where AxoGen does business. AxoGen could experience an adverse impact on operating results due to increased pricing pressure in the U.S. and in other markets. Governments, hospitals and other third-party payors could reduce the amount of approved reimbursement for AxoGen's products or deny coverage altogether. Reductions in reimbursement levels or coverage or other cost-containment measures could unfavorably affect AxoGen's future operating results.

Risks Related to AxoGen's Intellectual Property

Failure to protect AxoGen's Intellectual Property rights could result in costly and time consuming litigation and its loss of any potential competitive advantage.

AxoGen's success will depend, to a large extent, on its ability to successfully obtain and maintain patents, prevent misappropriation or infringement of intellectual property, or IP, maintain trade secret protection, and conduct operations without violating or infringing on the IP rights of third parties. See "Business — Intellectual Property." There can be no assurance that AxoGen's patented and patent pending

technologies will provide it with a competitive advantage, that AxoGen will be able to develop or acquire additional technology that is patentable, or that third parties will not develop and offer technologies which are similar to AxoGen's. Moreover, AxoGen can provide no assurance that confidentiality agreements with its employees, consultants and other parties, trade secrecy agreements or similar agreements intended to protect unpatented technology will provide the intended protection. IP litigation is extremely expensive and time-consuming, and it is often difficult, if not impossible, to predict the outcome of such litigation. A failure by AxoGen to protect its IP could have a materially adverse effect on its business and operating results and its ability to successfully compete in its industry.

Future protection for AxoGen's proprietary rights is uncertain which may impact its ability to successfully compete in its industry.

The degree of future protection for AxoGen's proprietary rights is uncertain. AxoGen cannot ensure that:

- it, or its licensors, were the first to make the inventions covered by each of AxoGen's patents;
- it, or its licensors, were the first to file patent applications for these inventions;
- others will not independently develop similar or alternative technologies or duplicate any of AxoGen's technologies;
- any of AxoGen's pending patent applications will result in issued patents;
- any of AxoGen's issued patents or those of its licensors will be valid and enforceable;
- any patents issued to AxoGen or its collaborators will provide any competitive advantages or will not be challenged by third parties;
- it will develop additional proprietary technologies that are patentable;
- the patents of others will not have a material adverse effect on its business rights; or
- the measures AxoGen relies on to protect its IP underlying their products may not be adequate to prevent third parties from using its technology, all of which could harm its ability to compete in the market.

AxoGen's success depends on its ability to avoid infringing on the intellectual property rights of third parties which could expose it to litigation or commercially unfavorable licensing arrangements.

AxoGen's commercial success depends in part on its ability and the ability of its collaborators and licensors to avoid infringing patents and proprietary rights of third parties. Third parties may accuse AxoGen or collaborators and licensors of employing their proprietary technology in AxoGen products, or in the materials or processes used to research or develop AxoGen products, without authorization. Any legal action against AxoGen collaborators, licensors or it claiming damages and/or seeking to stop AxoGen's commercial activities relating to the affected products, materials and processes could, in addition to subjecting AxoGen to potential liability for damages, require it or its collaborators and licensors to obtain a license to continue to utilize the affected materials or processes or to manufacture or market the affected products. AxoGen cannot predict whether AxoGen or its collaborators and licensors would prevail in any of these actions or whether any license required under any of these patents would be made available on commercially reasonable terms, if at all. If AxoGen were unable to obtain such a license, it and its collaborators and licensors may be unable to continue to utilize the affected materials or processes, or manufacture or market the affected products, or AxoGen may be obligated by a court to pay substantial royalties and/or other damages to the patent holder. Even if AxoGen were able to obtain such a license, the terms of such a license could substantially reduce the commercial value of the affected product or products and impair AxoGen's prospects for profitability. Accordingly, AxoGen cannot predict whether, or to what extent, the commercial value of the affected product or products, or AxoGen's prospects for profitability may be harmed as a result of any of the liabilities discussed above. Furthermore, infringement and other IP claims, with or without merit, can be expensive and time-consuming to litigate and can divert management's attention from its core business. AxoGen and its licensors may be unable to obtain and enforce IP rights to adequately protect its products and related IP.

The patent protection for our products may expire before we are able to maximize their commercial value which may subject us to increased competition and reduce or eliminate our opportunity to generate product revenue.

The patents for our commercialized products and products in development have varying expiration dates and, when these patents expire, we may be subject to increased competition and we may not be able to recover our development costs. For example, the two U.S. patents covering the formulations used in our AxoGuard® product line, which are held by Cook Biotech, are scheduled to expire in August and September 2016. Although we expect that Cook Biotech is using best efforts to take any action possible to extend the life of these patents, there can be no assurance that any action is possible or action taken will be successful. If these patents expire while we have the right to distribute and market the AxoGuard® products, it could adversely affect our ability to successfully execute our business strategy to maximize the value of AxoGuard® products and could likely negatively impact our future financial condition and results of operations.

Others may claim an ownership interest in AxoGen IP which could expose it to litigation and have a significant adverse effect on its prospects.

A third party may claim an ownership interest in one or more of AxoGen's patents or other IP. A third party could bring legal actions against AxoGen claiming it infringes their patents or proprietary rights, and seek monetary damages and/or enjoin clinical testing, manufacturing and marketing of the affected product or products. While AxoGen believes it owns the right, title and interest in the patents for which it or its licensors have applied and AxoGen's other IP (including that which is licensed from third parties), and is presently unaware of any claims or assertions by third-parties with respect to AxoGen's patents or IP, it cannot guarantee that a third-party will not assert a claim or an interest in any of such patents or IP. If AxoGen becomes involved in any litigation, it could consume a substantial portion of AxoGen's resources, and cause a significant diversion of effort by AxoGen's technical and management personnel regardless of the outcome of the litigation. If any of these actions were successful, in addition to any potential liability for damages, AxoGen could be required to obtain a license to continue to manufacture or market the affected product, in which case AxoGen may be required to pay substantial royalties or grant cross-licenses to AxoGen's patents. AxoGen cannot, however, assure you that any such license will be available on acceptable terms, if at all. Ultimately, AxoGen could be prevented from commercializing a product, or be forced to cease some aspect of its business operations as a result of claims of patent infringement or violation of other IP rights, which could have a material and adverse effect on AxoGen's business, financial condition, and results of operations. Further, the outcome of IP litigation is subject to uncertainties that cannot be adequately quantified in advance, including the demeanor and credibility of witnesses and the identity of the adverse party. This is especially true in IP cases that may turn on the testimony of experts as to technical facts upon which experts may reasonably disagree.

AxoGen depends on maintenance of exclusive licenses.

AxoGen depends fundamentally on keeping and satisfying the terms of exclusive licenses of its nerve repair technologies from the University of Florida Research Foundation (the "UFRF") and the University of Texas at Austin ("UT")where the original technologies are purported to be invented. Though AxoGen makes an effort to follow these agreements strictly, a disagreement between AxoGen and either party could have negative impacts on its ability to operate its business effectively. In addition, AxoGen could learn that the technologies it has licensed from UFRF and UT do not perform as purported, are not efficacious, or are not the property of UFRF or UT, or some similar problem with the license, any of which would have an immediate and negative impact on AxoGen's business.

Risk Related to Common Shares

The price of AxoGen's common shares could be highly volatile due to a number of factors, which could lead to losses by investors and costly securities litigation.

Until August 9, 2013 when trading began on the NASDAQ Capital Market, our common shares traded on the OTCQB Marketplace in limited volumes. The trading price of our common shares experienced substantial volatility while trading on the OTCQB Marketplace and could continue to be highly volatile while trading on the NASDAQ Capital Market in response to a number of factors including, without limitation, the following:

- limited daily trading volume resulting in the lack of a liquid market;
- fluctuations in price and volume due to investor speculation and other factors that may not be tied to the financial performance of AxoGen;
- performance by AxoGen in the execution of its business plan;
- financial viability; actual or anticipated variations in our operating results;
- announcements of developments by us or our competitors;
- market conditions in our industry;
- announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures or capital commitments;
- adoption of new accounting standards affecting our industry;
- additions or departures of key personnel;
- introduction of new products by us or our competitors;
- sales of our common shares or other securities in the open market;
- regulatory developments in both the United States and foreign countries;
- performance of products sold and advertised by licensees in the marketplace;
- economic and other external factors;
- period-to-period fluctuations in financial results; and
- other events or factors, many of which are beyond our control.

The stock market is subject to significant price and volume fluctuations. In the past, and several recent situations, following periods of volatility in the market price of a company's securities, securities class action litigation has been initiated against such company. Litigation initiated against us, whether or not successful, could result in substantial costs and diversion of our management's attention and resources, which could harm our business and financial condition.

While our common shares have been traded on the NASDAQ Capital Market since August 9, 2013, if our common share price is below $4 per share and we fail to meet certain minimum financial metrics, our common shares will be considered a "penny stock" and will not qualify for exemption from the "penny stock" restrictions, which may make it more difficult for you to sell your shares.

Since August 9, 2013, our common shares have been traded on the NASDAQ Capital Market, which generally provides a safe harbor from "penny stock" classification. However, because we initially listed pursuant to NASDAQ Rule 5505(a)(1)(B), if our share price continues to be below $4 per share, and if we fail to meet certain financial metrics, then our common shares will be considered a "penny stock" by the SEC and subject to rules adopted by the SEC regulating broker-dealer practices in connection with transactions in "penny stocks." For any transaction involving a penny stock, unless exempt, these rules require delivery, prior to any transaction in a penny stock, of a disclosure schedule relating to the penny stock market. Disclosure is also required to be made about current quotations for the securities and commissions payable to both the broker-dealer and the registered representative. Finally, broker-dealers must send monthly statements to purchasers of penny stocks disclosing recent price information for the penny stock held in the account and information on the limited market in penny stocks. As a result of our common shares being subject to the rules on penny stocks, the liquidity of our common shares may be adversely affected.

We do not anticipate paying any cash dividends in the foreseeable future.

The continued operation and expansion of our business will require substantial funding. In additional, the PDL Royalty Contract places certain restrictions on our ability to pay dividends. Accordingly, we do not anticipate that we will pay any cash dividends on our common shares for the foreseeable future. Any determination to pay dividends in the future will be at the discretion of our board of directors and will depend upon results of operations, financial condition, contractual restrictions, restrictions imposed by applicable law and other factors our board of directors deems relevant. Accordingly, if you hold our common shares, realization of a gain on your investment will depend on the appreciation of the price of our common shares, which may never occur. Investors seeking cash dividends in the foreseeable future should not purchase our common shares.

Anti-takeover provisions in Minnesota law may deter acquisition bids for us that you might consider favorable.

We are governed by the provisions of Sections 302A.671, 302A.673 and 302A.675 of the Minnesota Business Corporation Act (the "MBCA"). These provisions may discourage a negotiated acquisition or unsolicited takeover of us and deprive our shareholders of an opportunity to sell their shares at a premium over the market price.

In general, Section 302A.671 of the MBCA provides that a corporation's shares acquired in a control share acquisition have no voting rights unless voting rights are approved in a prescribed manner. A "control share acquisition" is a direct or indirect acquisition of beneficial ownership of shares that would, when added to all other shares beneficially owned by the acquiring person, entitle the acquiring person to have voting power of 20% or more in the election of directors.

In general, Section 302A.673 of the MBCA prohibits a public Minnesota corporation from engaging in a business combination with an interested shareholder for a period of four years after the date of the transaction in which the person became an interested shareholder, unless the business combination is approved in a prescribed manner. The term "business combination" includes mergers, asset sales and other transactions resulting in a financial benefit to the interested shareholder. An "interested shareholder" is a person who is the beneficial owner, directly or indirectly, of 10% or more of a corporation's voting stock, or who is an affiliate or associate of the corporation, and who, at any time within four years before the date in question, was the beneficial owner, directly or indirectly, of 10% or more of the corporation's voting stock. Section 302A.673 does not apply if a committee of our Board of Directors consisting of all of its disinterested directors (excluding current and former officers) approves the proposed transaction or the interested shareholder's acquisition of shares before the interested shareholder becomes an interested shareholder.

If a tender offer is made for our common shares, Section 302A.675 of the MBCA precludes the offer or from acquiring additional shares of stock (including in acquisitions pursuant to mergers, consolidations or statutory share exchanges) within two years following the completion of the tender offer, unless shareholders selling their shares in the later acquisition are given the opportunity to sell their shares on terms that are substantially the same as those contained in the earlier tender offer. Section 302A.675 does not apply if a committee of our Board of Directors consisting of all of its disinterested directors (excluding its current and former officers) approves the proposed acquisition before any shares are acquired pursuant to the earlier tender offer.

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

None.

ITEM 3 – DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4 MINE SAFETY DISCLOSURES

Not Applicable.

ITEM 5 – OTHER INFORMATION

None.

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ITEM 6 – EXHIBITS

Exhibit Number	Description
3.1	Amended and Restated Articles of Incorporation of AxoGen, Inc. (incorporated by reference to Appendix B to the Proxy Statement/Prospectus included as part of LecTec Corporation's Amendment No. 2 to Registration Statement on Form S-4 filed on August 29, 2011)
3.2	AxoGen, Inc. Amended and Restated Bylaws (incorporated by reference to Appendix C to the Proxy Statement/Prospectus included as part of LecTec Corporation's Amendment No. 2 to Registration Statement on Form S-4 filed on August 29, 2011).
**10.6.1	Revenue Interests Purchase Agreement, dated as of October 5, 2012, by and between AxoGen, Inc. and PDL BioPharma, Inc. (Incorporated by reference to the Company's Amendment No. 1 to the Annual Report on Form 10-K for the year ended December 31, 2012).
**10.6.2	Guarantee and Collateral Agreement, dated as of October 5, 2012, by and between AxoGen, Inc. and AxoGen Corporation and PDL BioPharma, Inc. (Incorporated by reference to the Company's Amendment No. 1 to the Annual Report on Form 10-K for the year ended December 31, 2012).
10.6.4	Amendment dated July 26, 2013 to Revenue Interests Purchase Agreement, dated as of October 5, 2012, by and between AxoGen, Inc. and PDL BioPharma, Inc. (Incorporated by reference to the Company's Amendment No. 3 to Registration Statement on Form S-1 (Registration No. 333-188597) filed with the Securities and Exchange Commission on July 30, 2013)
31.1†	Certification of Principal Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2†	Certification of Principal Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32†	Certification Pursuant to 18 U.S.C. §1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS††	XBRL Instance Document.
101.SCH††	XBRL Taxonomy Extension Schema Document.
101.CAL††	XBRL Taxonomy Extension Calculation Linkbase Document.
101.DEF††	XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB††	XBRL Extension Labels Linkbase.
101.PRE††	XBRL Taxonomy Extension Presentation Linkbase Document.

** 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 August 14, 2013

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

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

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† Filed herewith.
†† Furnished herewith.

Exhibit 31.1

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

I, Karen Zaderej, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: August 14, 2013

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

Exhibit 31.2

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

I, Gregory G. Freitag, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: August 14, 2013

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

Exhibit 32

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

In connection with the Quarterly Report on Form 10-Q (the "Report") of AxoGen, Inc. (the "Company"), Karen Zaderej, Chief Executive Officer of the Company and Gregory G. Freitag, Chief Financial Officer of the Company, each certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, to the best of her/his knowledge that:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: August 14, 2013

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

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