UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 8-K

Current Report

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): November 7, 2012

AXOGEN, INC.

(Exact name of registrant as specified in its charter)

0-16159 Minnesota (State or other jurisdiction (Commission of incorporation) File Number Identification No.)

> 13859 Progress Boulevard, Suite 100, Alachua, Florida (Address of Principal Executive Offices)

32615 (Zip Cope)

41-1301878

(IRS Employer

Registrant's telephone number, including area code

(386) 462-6800

(Former name or former address if changed since last report,)

ck the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of following provisions:
Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Item 2.02 Results of Operations and Financial Condition

On November 7, 2012, AxoGen, Inc. (the "Company") issued a press release announcing its financial results for the quarter ended September 30, 2012. A copy of the press release is furnished as Exhibit 99.1 to this Current Report.

The information furnished pursuant to Item 2.02 of this Current Report, including Exhibit 99.1 hereto, shall not be considered "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liability of such section, nor shall it be incorporated by reference into future filings by the Company under the Securities Act of 1933, as amended, or under the Exchange Act, unless the Company expressly sets forth in such future filing that such information is to be considered "filed" or incorporated by reference therein.

Item 9.01. Financial Statements and Exhibits

(d) Exhibits

Exhibit No. Description

99.1 AxoGen, Inc. press release, dated November 7, 2012.

SIGNATURE

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 hereunto duly authorized.

AXOGEN, INC.

Date: November 9, 2012 By: <u>/s/ Gregory G. Freitag</u>

Gregory G. Freitag Chief Financial Officer

EXHIBIT INDEX

Description

Exhibit No. 99.1 AxoGen, Inc. press release, dated November 7, 2012.



AxoGen, Inc. Announces Third Quarter 2012 Financial Results

Third Quarter 2012 Highlights

- Revenues increased 74% to \$1.98 million from \$1.14 million reported third quarter 2011
- Gross profit increased to \$1.44 million from \$10,000 reported third quarter 2011
- Gross profit margins improved to 73% compared to 0.9% for the same period in 2011 and remained strong for the nine months ended September 30, 2012 at 74%.
- \$20.8 million in proceeds from financing with PDL BioPharma, Inc. closed post third quarter

November 7, 2012: ALACHUA, FL- AxoGen, Inc. (OTCBB: AXGN), a leading regenerative medicine company dedicated to advancing the science and commercialization of peripheral nerve repair solutions, today announced revenues for the third quarter ended September 30, 2012 of \$1.98 million, a 74% increase over revenues of \$1.14 million in the third quarter 2011.

"Compared to last year, we delivered solid top-line growth during the quarter despite cash constraints and the distraction of raising capital," commented Karen Zaderej, Chief Executive Officer of AxoGen. "In addition, to remain in compliance with covenants imposed by our former lender, we carefully managed cash and chose to defer certain sales force growth and marketing activities."

Ms. Zaderej continued, "As a result of the recent financing with PDL, we paid off all bank debt and eliminated the restrictive lender requirements. This will allow us the flexibility to develop and expand our sales force and invest in significant marketing efforts."

Revenues

Revenues for the period were \$1.98 million, a 74% increase, compared to \$1.14 million for the same period in 2011. These results were due to expansion of sales and marketing efforts versus third quarter 2011 and focused on the development of new accounts as well as penetration into key accounts.

Revenues decreased 1.5% compared to second quarter 2012 revenues of \$2.01 million. This is the second year in which the third quarter has been relatively flat compared to the second quarter. While this may suggest seasonality in peripheral nerve surgery, it is important to note that in both of these quarters there were material corporate transactions that may have distracted operations. In addition, during the period, the Company made personnel changes in certain sales territories, but did not increase the size of its direct sales force.

Gross Profit

Gross profit for the period increased to \$1.44 million from the reported third quarter 2011 results of \$10,000. The favorable result reflects increased revenues and lower manufacturing costs in 2012 and excludes an inventory write-off of \$0.83 million which occurred during the third quarter 2011.

The gross profit margin for the period increased to 73% compared to 0.9% for the same quarter last year.

Sales and Marketing Expenses

During the period sales and marketing expenses increased to \$1.70 million from \$1.11 million reported during the same period last year. The increase was the result of the Company's increased support for its sales force and an increase in the number of direct sales persons. As of October 31, 2012, the Company had 17 direct and 24 independent sales representatives and distributors.

Research and Development Expenses

Research and development expenses increased to \$0.39 million during the quarter, compared to \$0.23 million reported during the same period last year. Substantially all of the research and development expenses relate to expenditures for clinical activity.

General and Administrative Expenses

General and administrative expenses increased to \$1.39 million for the period, compared to \$1.30 million reported in the same quarter last year. These expenses were principally an increase in payroll and benefits as the Company hired additional personnel to support its sales growth.

Loss From Operations and Net Loss

The Company reported loss from operations for third quarter of 2012 of \$2.04 million, compared to the reported loss from operations of \$2.63 million during the same period in 2011.

The net loss for the period decreased to \$2.24 million, or \$0.20 per common share, from a net loss of \$3.11 million, or \$2.60 per common share, reported during the third quarter of 2011.

Financial Liquidity

At September 30, 2012, the Company had \$4.4 million in cash and cash equivalents, with approximately \$6.6 million in debt outstanding.

On October 5, 2012, the Company entered into a Revenue Interests Purchase Agreement with PDL BioPharma Inc., under which the Company received \$20.8 million in cash. Certain proceeds of which were used to repay existing debt and expenses related to the transaction.

As of November 1, 2012, the Company had \$15.8 million in cash and equivalents and no bank debt outstanding.

Earnings Call Information

As previously announced, AxoGen, Inc. management will review third quarter 2012 financials during a conference call scheduled for November 8, 2012 at 11:00 AM Eastern Time. The conference call information is as follows:

Conference dial-in: 877-709-8150
International dial-in: 201-689-8354
Webcast: www.axogeninc.com/investors.html

A webcast replay of the conference call will be available under the "Investor" tab on the Company's website, www.axogeninc.com.

About AxoGen, Inc.

AxoGen (OTCBB: AXGN) is a leading regenerative medicine company dedicated to advancing the science and commercialization of peripheral nerve repair solutions. AxoGen's products offer a full suite of surgical nerve reconstruction solutions including Avance® Nerve Graft, the only commercially available processed nerve allograft for bridging severed nerves, AxoGuard® Nerve Connector, a coaptation aid allowing for close approximation of severed nerves, and AxoGuard® Nerve Protector, a bioscaffold used to reinforce a coaptation site, wrap a partially severed nerve or isolate and protect nerve tissue. For more information, visit our website at www.axogeninc.com.

AxoGen is the parent of its wholly owned operating subsidiary, AxoGen Corporation. AxoGen's principal executive office and operations are located in Alachua, FL.

Cautionary Statements Concerning Forward-Looking Statements

This Press Release contains "forward-looking" statements as defined in the Private Securities Litigation Reform Act of 1995. 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 or financial 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 release should be evaluated together with the many uncertainties that affect AxoGen's business and its market, particularly those discussed in the risk factors and cautionary statements in AxoGen'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 AxoGen assumes no responsibility to update any forward-looking statements, whether as a result of new information, future events or otherwise.

AxoGen, Inc.

Condensed Consolidated Balance Sheets

	September 30, 2012	December 31, 2011
Assets		
Current assets:		
Cash and cash equivalents	\$ 4,445,099	\$ 8,190,781
Accounts receivable	925,544	797,654
Inventory	2,722,670	1,760,540
Prepaid expenses and other	89,835	133,500
Total current assets	8,183,148	10,882,475
Property and equipment, net	139,362	247,824
Goodwill	169,987	169,987
Intangible assets	736,772	899,480
Deferred Financing Costs	345,611	295,276
Other assets	118,891	
Total Assets	\$ 9,693,771	\$ 12,495,042
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable and accrued expenses	\$ 1,863,494	\$ 1,585,100
Current portion of long-term debt	1,885,972	434,734
Total current liabilities	3,749,466	2,019,834
Long-term debt	4,739,305	4,403,737
Total liabilities	8,488,771	6,423,571
Commitments and contingencies		
Stockholders' equity:	111,046	110,622
Common stock, \$.01 par value; 50,000,000 shares authorized; 11,104,596 and 11,062,188 shares issued and outstanding	,	,
Additional paid-in capital	54,900,742	54,391,784
Accumulated deficit	(53,806,788)	(48,430,935
Total stockholders' equity	1,205,000	6,071,471
Total liabilities and stockholders' equity	\$ 9,693,771	\$ 12,495,042

AxoGen, Inc. Consolidated Statements of Operations (unaudited)

	Three Mon	ths Ended
	September 30, 2012	September 30, 2011
Revenues	\$ 1,980,849	\$ 1,140,768
Cost of goods sold	542,235	1,130,332
Gross profit	1,438,614	10,436
Costs and expenses:		
Sales and marketing	1,697,317	1,106,942
Research and development	390,395	229,709
General and administrative	1,393,890	1,300,219
Total costs and expenses	3,481,602	2,636,870
Loss from operations	(2,042,988)	(2,626,434)
Other income (expense):		
Interest expense	(145,426)	(318,110)
Interest expense—deferred financing costs	(60,013)	(169,007)
Change in fair value of warrant liability	_	_
Other income (expense)	11,618	381
Total other (expense)	(193,821)	(486,736)
Loss before income taxes	(2,236,809)	(3,113,170)
Income tax benefit	_ <u></u>	
Net loss \$ (2,2		\$(3,113,170)
Preferred stock dividends (assumes all paid)	_ <u></u>	329,832
Net loss available to common shareholders	(2,236,809)	(3,443,002)
Weighted Average Common Shares outstanding - basic and diluted	11,104,353	1,324,967
Loss Per Common share—basic and diluted	\$ (0.20)	\$ (2.60)

AxoGen, Inc.

Consolidated Statements of Cash Flows

(unaudited)

	Nine Mon	Nine Months Ended	
	September 30, 2012	September 30, 2011	
Cash flows from operating activities:			
Net loss	\$(5,375,853)	\$ (7,082,234	
Adjustments to reconcile net loss to net cash used for operating activities:			
Depreciation	145,891	214,919	
Amortization of intangible assets	295,002	36,265	
Amortization of deferred financing costs	68,141	1,200,413	
Amortization of debt discount	36,806	11,436	
Stock-based compensation	478,701	97,499	
Change in fair value of warrant liability	_	(62,305	
Interest added to note payable	_	55,562	
Change in assets and liabilities:			
Accounts receivable	(127,890)	(109,409	
Inventory	(962,130)	240,446	
Prepaid expenses and other	(75,228)	(66,276	
Accounts payable and accrued expenses	278,394	572,833	
Net cash used for operating activities	(5,288,166)	(4,890,851	
Cash flows from investing activities:	· · · · · · · · · · · · · · · · · · ·	, ,	
Purchase of property and equipment	(37,429)	(7,858	
Acquisition of intangible assets	(82,294)	(45,454	
Cash acquired with Merger		7,201,638	
Net cash (used for) provided by investing activities	(119,723)	7,148,326	
Cash flows from financing activities:	` , , ,	, ,	
Proceeds from issuance of long-term debt	1,750,000	10,500,000	
Proceeds from issuance of common stock	<u> </u>	1,000,000	
Repayments of long-term debt	<u> </u>	(4,732,857	
Debt issuance costs	(118,476)	(301,778	
Proceeds from exercise of stock options	30,741	3,649	

Payment of fractional shares from Merger	(58)	
Net cash provided by financing activities	1,662,207	6,469,014
Net increase (decrease) in cash and cash equivalents	(3,745,682)	8,726,489
Cash and cash equivalents, beginning of year	8,190,781	1,799,048
Cash and cash equivalents, end of period	\$ 4,445,099	\$10,525,537
Supplemental disclosures of cash flow activity:		
Cash paid for interest	\$ 447,144	\$ 611,501
Supplemental disclosure of non-cash investing and financing activities:		
Conversion of preferred stock convertible debt and accrued interest into common stock	\$ —	\$21,497,955
Accretion of dividends of Series B preferred stock	_	292,330
Accretion of dividends of Series C preferred stock	_	515,577
Accretion of dividends of Series D preferred stock	_	220,444
Preferred stock dividend payable forfeited with the Merger	_	7,076,729
Warrant Liability forfeited with the Merger	_	2,607,510
Debt discount related to warrants issued with debt	_	173,736
Net assets acquired on Merger	_	11,847,916
Note and accrued interest retired with the Merger	_	4,555,562
Reclassification from common stock to additional paid in capital for change in par value		11.639

Contacts

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