# 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): July 10, 2013

# AXOGEN, INC.

(Exact name of registrant as specified in its charter)

0-16159

(Commission

File Number

Minnesota (State or other jurisdiction of incorporation)

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

41-1301878 (IRS Employer Identification No.)

32615 (Zip Cope)

Registrant's telephone number, including area code

(386) 462-6800

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

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the 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 July 11, 2013, AxoGen, Inc. (the "Company") issued a press release announcing its financial results for the quarter ended June 30, 2013. 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.Description99.1AxoGen, Inc. press release, dated July 11, 2013.

#### 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: July 11, 2013

By: /s/ Gregory G. Freitag

Gregory G. Freitag Chief Financial Officer Exhibit No.Description99.1AxoGen, Inc. press release, dated July 11, 2013.



#### AxoGen, Inc. Reports Second Quarter 2013 Financial Results

Regenerative medicine company announces record quarter for peripheral nerve repair products

#### AxoGen Second Quarter 2013 Highlights:

- Revenues increased 42.2% from 2Q 2012 to \$2.86 million
- Gross profit increased 47.6% from 2Q 2012 to \$2.23 million
- Gross profit margin at 77.9%, up 2.8% from 2Q 2012
- Operating Loss increased 38.2% from 2Q 2012 to \$2.19 million
- Received CE Mark and Health Canada Approval for AxoGuard® Nerve Protector and AxoGuard® Nerve Connector

ALACHUA, FL – July 11, 2013 – AxoGen, Inc. (OTCQB: AXGN), a leading regenerative medicine company focused on the commercialization of proprietary products and technologies for peripheral nerve reconstruction and regeneration, announced financial results for the second quarter ended June 30, 2013.

Karen Zaderej, Chief Executive Officer of AxoGen, said, "The Company achieved another quarter of record revenue driven by solid execution by our sales and marketing team. We also made excellent progress with our initiatives to expand adoption of our full suite of nerve repair products. This included European and Canadian regulatory approval for our AxoGuard® Nerve Protector and AxoGuard® Nerve Connector products. AxoGen continues to demonstrate that we are well positioned to capture the significant opportunity to provide off-the-shelf treatment options for patients with peripheral nerve injuries, which, we believe, will translate into continued sales growth and positive financial results."

#### Revenue

Revenues for the second quarter 2013 were \$2.86 million, up 42.2% compared to \$2.01 million in the second quarter 2012, driven by an increase in the number of facilities utilizing the Company's products and increased penetration of existing accounts.

#### **Gross Profit**

Gross profit for the second quarter 2013 was \$2.23 million, up 47.6% compared to \$1.51 million in the second quarter 2012. Gross profit margin for the second quarter 2013 was 77.9%, up 2.8% compared to 75.1% in the second quarter 2012. The year-over-year improvement in gross profit and gross margin was primarily attributable to revenue growth and a product price increase implemented during the first quarter 2013, respectively.

#### **Operating Expenses**

Total operating expenses in the second quarter 2013 were \$4.42 million, up 42.8% compared to \$3.10 million in the second quarter 2012. As a percentage of revenues, operating expenses were up 0.73% in the second quarter 2013 as compared to the same period in 2012.

Second quarter 2013 sales and marketing expense was \$2.53 million, up 60.0% compared to \$1.58 million in the second quarter 2012. The increase was primarily attributable to increased commissions due to higher sales and the expansion of the Company's marketing efforts and direct sales force.

Second quarter 2013 general and administrative expense was \$1.40 million, up 21.8% compared to \$1.15 million in the second quarter 2012. The increase was primarily attributable to increased salary expense and benefits, travel, and public company expenses.

Second quarter 2013 research and development expense was \$0.50 million, up 35.7% compared to \$0.37 million in the second quarter 2012. The increase was primarily attributable to costs associated with the Company's investment in clinical studies that support the use and regulatory position of the Company's products.

#### Loss from Operations and Net Loss

Operating loss in the second quarter 2013 was \$2.20 million, compared to \$1.59 million in the second quarter 2012. Net loss in the second quarter 2013 was \$3.45 million, or (\$0.31) per share, compared to net loss of \$1.03 million, or (\$0.09) per share, in the second quarter 2012.

#### **Balance Sheet**

As of June 30, 2013, the Company had \$8.69 million in cash and cash equivalents and approximately \$23.38 million in long-term note payable – revenue interest purchase agreement. AxoGen had working capital of approximately \$12.22 million and a current ratio of 8.7 at June 30, 2013, compared to working capital of \$16.82 million and a current ratio of 12.4 at December 31, 2012.

#### **Conference Call**

AxoGen, Inc. management will provide a review of the second quarter 2013 financial results in conjunction with its Annual Shareholders' Meeting on Thursday, August 1, 2013, beginning at 1:00 pm ET. Participants can join an interactive broadcast of the Annual Shareholders' Meeting via the Internet link, <u>www.virtualshareholdermeeting.com/axogen</u>.

Following the live Annual Shareholders' Meeting, a replay will be available on the Investors section of the Company's website, <u>http://www.axogeninc.com/investors.html</u>.

#### About AxoGen, Inc.

AxoGen (AXGN) is a leading regenerative medicine company dedicated to advancing the science and commercialization of peripheral nerve repair solutions. The Company's innovative approach to regenerative medicine has resulted in first-in-class products that we believe 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 for bridging severed nerves without the comorbidities associated with a second surgical site, AxoGuard® Nerve Connector, a porcine submucosa ExtraCellular Matrix ("ECM") coaptation aid for tensionless repair of severed nerves, and AxoGuard® Nerve Protector, a porcine submucosa ECM product used to wrap and protect injured peripheral nerves and reinforce the nerve reconstruction while preventing soft tissue attachments.

AxoGuard® Nerve Connector and AxoGuard® Nerve Protector are manufactured in the United States by Cook Biotech Incorporated, West Lafayette, Indiana, and are distributed exclusively by AxoGen. AxoGen is the parent of its wholly owned operating subsidiary, AxoGen Corporation. AxoGen's principal executive office and operations are located in Alachua, FL. To receive email alerts directly from AxoGen, please click here <u>www.axogeninc.com/emailalerts.html</u>.

#### **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", "continue", "may", "should", "will" 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 commercialization and marketing efforts for its portfolio of peripheral nerve repair products, Avance® Nerve Graft, AxoGuard® Nerve Connector and AxoGuard® Nerve Protector, product development, financial performance, sales growth, product adoption, market awareness of our products, data validation and the intent to list on a national securities exchange. The 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.

#### **Contact:**

AxoGen, Inc. Greg Freitag, Chief Financial Officer 386-462-6856 <u>InvestorRelations@AxoGenInc.com</u> <u>www.axogeninc.com</u>

## AxoGen, Inc. Condensed Consolidated Balance Sheets

	June 30.	December 31,
	2013	2012
	(unaudited)	
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	<u>\$ 1,587,938</u>	<u>\$ 1,479,752</u>
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:	111,399	111,226
Common stock, \$.01 par value; 50,000,000 shares authorized; 11,139,939 and 11,122,573 shares issued and outstanding	,	,
Additional paid-in capital	55,333,916	54,908,226
Accumulated deficit	(64,744,200)	(57,848,893)
Total shareholders' equity	(9,298,885)	(2,829,441)
	\$ 15,672,745	\$ 20,230,563

## AxoGen, Inc. 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)
Net loss available to common shareholders	\$(3,457,799)	<u>\$(1,029,719</u> )	<u>\$(6,895,309</u> )	\$(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)

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

	Six Mont	hs Ended
	June 30, 2013	June 30, 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
Stock-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 (used by) provided by 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