
**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 5, 2015

AXOGEN, INC.

(Exact name of registrant as specified in its charter)

Minnesota	001-36046	41-1301878
(State or other jurisdiction of incorporation)	(Commission File Number	(IRS Employer Identification No.)

13631 Progress Boulevard, Suite 400, Alachua, Florida	32615
(Address of Principal Executive Offices)	(Zip Code)

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))
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Item 2.02 Results of Operations and Financial Condition

On November 5, 2015, AxoGen, Inc. (“AxoGen”) issued a press release announcing its financial results for the quarter and nine months ended September 30, 2015. 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

<u>Exhibit No.</u>	<u>Description</u>
99.1	AxoGen, Inc. press release, dated November 5, 2015.

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 5, 2015

By: /s/ Gregory G. Freitag
Gregory G. Freitag
Chief Financial Officer, General Counsel &
Senior VP of Business Development

EXHIBIT INDEX

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AxoGen Inc. Third Quarter Revenue Exceeds \$8 Million

- Revenue Increased 74.5%; Gross Profit Margin of 82.7%; AXGN Raises 2015 Guidance

ALACHUA, FL – November 5, 2015 – AxoGen, Inc. (NASDAQ: AXGN), a leader in developing and marketing innovative surgical solutions for peripheral nerve injuries, reported record revenue of \$8.15 million in the third quarter. The record quarterly result represents the first time in the Company’s history that quarterly revenue surpassed \$8 million. In addition, management raised revenue guidance for the full year to reflect the strong year-to-date growth.

2015 Third Quarter Financial Results

For the third quarter ended September 30, 2015, revenue totaled \$8.15 million, a 74.5% increase when compared to \$4.67 million reported in the same quarter last year. The Company reported gross margin of 82.7% compared to 80.8% in the third quarter of 2014.

Operating expenses for the quarter increased 55.3% to \$8.7 million, compared to \$5.6 million for the third quarter of 2014. The increase in operating expense was in line with the Company’s expectations as management continues to invest in sales and marketing to raise awareness of AxoGen’s product portfolio and expand the sales footprint. Operating loss was \$1.9 million compared to \$1.8 million for the same quarter last year. Net loss was \$3.0 million, or \$0.11 per share, compared to a net loss of \$3.2 million, or \$0.19 per share for the third quarter of 2014. The weighted common average shares for the third quarter of 2015 were approximately 26.8 million shares, an increase from 17.5 million shares for the third quarter of the prior year due to a common stock offering in the first and third quarters of 2015.

“Successful execution of our growth strategy is driving the strong third quarter and nine month revenue performance and enabling us to increase our revenue guidance for 2015,” said Karen Zaderej, President & Chief Executive Officer. “Professional education forums, the expansion of our sales team, and increased adoption by surgeons continues to grow sales and customer interest in AxoGen’s portfolio of products for peripheral nerve injuries.

We remain focused on helping surgeons improve nerve repair algorithms and outcomes. We are developing additional revenue opportunities that capitalize on our market presence, including expansion into new geographies and building a pipeline of new products that will broaden our ability to be a peripheral nerve repair solution provider. Our first product from this effort is the AcroVal™ Neurosensory & Motor Testing System which is the result of our collaboration with Dr. A. Lee Dellon, M.D. This system is designed to

measure a patient's functional outcomes following nerve injuries and will be launched in the first quarter of next year," concluded Ms. Zaderej.

Third Quarter Highlights

- Year to date held seven "Best Practices in Nerve Repair" surgeon education forums, providing over 180 surgeons in attendance with a comprehensive review of nerve repair techniques. The Company has found that as surgeons return to their practice and use these new techniques, the revenue from their usage increases by over 80%.
- Attended and participated in the 2015 American Association of Oral and Maxillofacial Surgeons (AAOMS) 97th Annual Meeting. Exhibited portfolio of peripheral nerve repair products for the treatment of trigeminal nerve injuries.
- Presented data from the RANGER[®] Registry at the 70th Annual Meeting of the American Society for Surgery of the Hand (ASSH). During the best clinical papers feature of the conference, Dr. Gregory Buncke, Director of The Buncke Clinic in San Francisco, presented "Evaluating Nerve Repair Outcomes in Upper Extremity Nerve Injuries Utilizing Processed Nerve Allografts, Tube Conduits, and Nerve Autograft".
- In addition, in late August the Company completed a funding with Essex Woodlands which provides AxoGen with the resources necessary to continue to execute its growth strategies as well as drive the Company towards positive cash flow. Guido Neels, an Operating Partner with Essex Woodlands joined AxoGen's Board of Directors as its eighth member. Mr. Neels brings to the AxoGen Board more than 40 years of experience developing international healthcare businesses.

2015 Nine Month Financial Results

For the nine months ended September 30, 2015, revenue totaled \$19.5 million, a 62.5% increase when compared to \$12.0 million reported in the first nine months of 2014. Gross margin for the first nine months of 2015 was 82.4% compared to 79.3% for the comparable nine month period in 2014. Operating expenses for the nine month period ended September 30, 2015 were \$22.7 million compared to \$16.6 million for the first nine months of 2014. The increased operating expenses reflect management's continued investment in sales and marketing to raise awareness of AxoGen's product portfolio and expand its sales footprint, as well as increased activity related to initiating the RECON clinical trial, and product development. For the nine months ended September 30, 2015, the net loss was \$9.7 million, or \$0.39 per share compared to a net loss of \$11.2 million, or \$0.64 per share for the nine months ended September 30, 2014.

As of September 30, 2015, cash and cash equivalents totaled \$29.9 million. Total common shares outstanding were 29,844,503 as of September 30, 2015.

2015 Guidance

Based on the strong growth in the first nine months of 2015 and continued sales momentum in the third quarter, AxoGen is raising its revenue guidance and now expects 2015 full year revenue to be greater than \$26.5 million with annual gross margins in the high 70% range.

Conference Call

The Company will host a conference call and webcast for the investment community following the release at 4:30 PM ET. Investors interested in participating by phone are invited to call toll free at 1.877.407.0993 or use the direct dial-in number 1.201.689.8795. Those interested in joining via the webcast, should visit <http://axogeninc.equisolvewebcast.com/q3-2015>

Following the conference call, a replay will be available on the Company's website at www.AxoGenInc.com, under 'Investors.'

About AxoGen, Inc.

AxoGen (NASDAQ: AXGN) is a leading medical technology company dedicated to peripheral nerve repair. AxoGen's portfolio of regenerative medicine products is available in the United States, Canada and several other countries and includes Avance® Nerve Graft, an off-the-shelf processed human 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.

Avance® Nerve Graft is processed in the United States by AxoGen. AxoGuard® Nerve Connector and AxoGuard® Nerve Protector are manufactured in the United States by Cook Biotech Incorporated, and are distributed worldwide exclusively by AxoGen. AxoGen maintains its corporate offices in Alachua, Florida and is the parent of its wholly owned operating subsidiary, AxoGen Corporation.

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 our growth, our 2015 guidance, product development, product potential, financial performance, sales growth, product adoption, market awareness of our products, data validation, our visibility at and sponsorship of conferences and educational events. 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, except as required by law, AxoGen assumes no responsibility to update any forward-looking statements, whether as a result of new information, future events or otherwise.

Source: AxoGen, Inc.

Contact:

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Summary Financial Information

AxoGen, Inc.

Condensed Consolidated Statements of Operations

(unaudited)

	Three Months Ended		Nine Months Ended	
	September 30, 2015	September 30, 2014	September 30, 2015	September 30, 2014
Revenues	\$ 8,153,675	\$ 4,671,340	\$19,522,244	\$ 12,023,789
Cost of goods sold	1,410,416	896,178	3,433,138	2,485,299
Gross profit	6,743,259	3,775,162	16,089,106	9,538,490
Costs and expenses:				
Sales and marketing	5,512,613	3,250,977	14,257,397	9,326,596
Research and development	936,015	681,230	2,343,450	2,049,603
General and administrative	2,212,457	1,645,859	6,103,058	5,254,082
Total costs and expenses	8,661,085	5,578,066	22,703,905	16,630,281
Loss from operations	(1,917,826)	(1,802,904)	(6,614,799)	(7,091,791)
Other income (expense):				
Interest expense	(1,042,258)	(1,380,470)	(3,060,779)	(3,963,885)
Interest expense—deferred financing costs	(31,419)	(55,217)	(96,375)	(158,648)
Other income (expense)	12,645	417	27,021	(4,886)
Total other income (expense)	(1,061,032)	(1,435,270)	(3,130,133)	(4,127,419)
Net loss	<u>\$(2,978,858)</u>	<u>\$(3,238,174)</u>	<u>\$(9,744,932)</u>	<u>\$(11,219,210)</u>
Weighted Average Common Shares outstanding – basic and diluted	26,841,060	17,466,097	24,778,123	17,437,373
Loss Per Common share - basic and diluted	<u>\$ (0.11)</u>	<u>\$ (0.19)</u>	<u>\$ (0.39)</u>	<u>\$ (0.64)</u>

AxoGen, Inc.

Condensed Consolidated Balance Sheets

	<u>September 30,</u> <u>2015</u>	<u>December 31,</u> <u>2014</u>
	<u>(unaudited)</u>	
Assets		
Current assets:		
Cash and cash equivalents	\$ 29,935,467	\$ 8,215,791
Accounts receivable	4,642,802	2,872,308
Inventory	3,701,755	3,213,620
Prepaid expenses and other	290,231	109,369
Total current assets	<u>38,570,255</u>	<u>14,411,088</u>
Property and equipment, net	830,083	619,028
Intangible assets	635,349	577,174
Deferred Financing Costs	877,265	793,499
	<u>\$ 40,912,952</u>	<u>\$ 16,400,789</u>
Liabilities and Shareholders' Equity (Deficit)		
Current liabilities:		
Accounts payable and accrued expenses	\$ 4,086,307	\$ 2,431,194
Current deferred revenue	14,118	14,118
Total current liabilities	<u>4,100,425</u>	<u>2,445,312</u>
Note Payable - Revenue Interest Purchase Agreement	25,537,367	25,085,777
Long Term Deferred Revenue	99,193	115,380
Total liabilities	<u>29,736,985</u>	<u>27,646,469</u>
Commitments and contingencies	—	—
Shareholders' equity:		
Common stock, \$.01 par value; 50,000,000 shares authorized; 29,844,503 and 19,488,814 shares issued and outstanding	298,445	194,888
Additional paid-in capital	110,738,708	78,675,686
Accumulated deficit	<u>(99,861,186)</u>	<u>(90,116,254)</u>
Total shareholders' equity	<u>11,175,967</u>	<u>(11,245,680)</u>
	<u>\$ 40,912,952</u>	<u>\$ 16,400,789</u>

AxoGen, Inc.

Condensed Consolidated Statements of Cash Flows

(unaudited)

	Nine Months Ended	
	September 30, 2015	September 30, 2014
Cash flows from operating activities:		
Net loss	\$(9,744,932)	\$(11,219,210)
Adjustments to reconcile net loss to net cash used for operating activities:		
Depreciation	142,038	111,390
Amortization of intangible assets	34,009	33,468
Amortization of deferred financing costs	96,375	158,648
Stock-based compensation	1,031,218	701,697
Stock grants	—	60,125
Interest added to note	451,590	2,810,182
Change in assets and liabilities:		
Accounts receivable	(1,770,494)	(849,342)
Inventory	(488,135)	52,323
Prepaid expenses and other	(180,862)	195,796
Accounts payable and accrued expenses	1,655,114	(63,848)
Deferred revenue	(16,187)	(10,714)
Net cash used for operating activities	(8,790,266)	(8,019,485)
Cash flows from investing activities:		
Purchase of property and equipment	(353,093)	(342,875)
Acquisition of intangible assets	(92,184)	(39,454)
Net cash used for investing activities	(445,277)	(382,329)
Cash flows from financing activities:		
Proceeds from exercise of stock options	164,626	134,672
Proceeds from issuance of common stock	30,970,735	—
Debt issuance costs	(180,142)	—
Net cash provided by financing activities	30,955,219	134,672
Net increase / (decrease) in cash and cash equivalents	21,719,676	(8,267,142)
Cash and cash equivalents, beginning of year	8,215,791	20,069,750
Cash and cash equivalents, end of period	\$29,935,467	\$ 11,802,608
Supplemental disclosures of cash flow activity:		
Cash paid for interest	\$ 1,949,381	\$ 1,154,738