
**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): February 29, 2016

AXOGEN, INC.

(Exact name of registrant as specified in its charter)

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

13631 Progress Boulevard, Suite 400,
Alachua, Florida

(Address of Principal Executive Offices)

32615

(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 February 29, 2016, AxoGen, Inc. (“the Company”) issued a press release announcing its financial results for the quarter and twelve months ended December 31, 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 5.02 Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers; Compensatory Arrangements of Certain Officers

On February 29, 2016, the Company announced that Peter Mariani will become the Company’s Chief Financial Officer, effective March 1, 2016.

In connection with his employment and appointment as the Company’s Chief Financial Officer, Mr. Mariani entered into an Executive Employment Agreement with AxoGen Corporation, a wholly owned subsidiary of the Company (“AC”), dated as of February 25, 2016 (the “Mariani Employment Agreement”). Under the Mariani Employment Agreement, Mr. Mariani’s employment is at-will. In the event Mr. Mariani is terminated without “Substantial Cause” (as defined below) either prior to a “Change of Control” (as defined below) or within 180 days following a Change in Control he is entitled to a severance payment consisting of: (a) twelve months of base salary; and (b) an amount equal to any bonuses paid to Mr. Mariani during the twelve month period prior to termination of employment, or, if termination of employment occurs prior to December 31, 2016, Mr. Mariani will receive a pro-rated amount of expected bonus for 2016. Mr. Mariani is also entitled to such severance if he leaves AxoGen for “Good Reason” (as defined below) within 180 days following a Change of Control. Upon a Change in Control, any stock options held by Mr. Mariani shall automatically accelerate and become fully exercisable in the event that within twelve months following the Change of Control he is terminated without cause or leaves for Good Reason, and so long as the Company or AC are subject to federal COBRA, and Mr. Mariani timely elects continuation coverage under COBRA, the Company or AC shall pay the premiums for twelve months or until Mr. Mariani obtains new employment with comparable health care coverage, whichever is shorter.

For purposes of the Mariani employment agreement, Change of Control means the occurrence of any of the following events: (i) any person who holds less than 20% of the combined voting power of the securities of AC or the Company, becomes the beneficial owner, directly or indirectly, of securities of AC or the Company, representing 50% or more of the combined voting power of the securities of AC or the Company then outstanding; (ii) during any period of 24 consecutive months, individuals who at the beginning of such period constitute all members of the Company’s Board of Directors cease, for any reason, to constitute at least a majority of the Company’s Board of Directors, unless the election of each director who was not a director at the beginning of the period was either nominated for election by, or was approved by a vote of, at least two-thirds of the directors then still in office who were directors at the beginning of the period; (iii) AC or the Company consolidates or merges with another company and AC or the Company is not the continuing or surviving corporation, provided, however, that any consolidation or merger whereby the Company continues as the majority holder of AC securities or a merger or consolidation of AC and the Company will not constitute a Change in Control; (iv) shares of AC’s or the Company’s common stock are converted into cash,

securities, or other property (other than by a merger set forth in (iii) above) in which the holders of the AC's or the Company's common stock immediately prior to the merger have the same proportionate ownership of common shares of the surviving corporation as immediately after the merger; (v) AC or the Company sells, leases, exchanges, or otherwise transfers all or substantially all of its assets (in one transaction or in a series of related transactions) *provided, however*, that any such transaction related to AC where the Company continues as the majority holder of AC common stock or the Company is the sole other party to the transaction will not constitute a Change in Control; or (vi) the holders of shares of AC's or the Company's common stock approve a plan or proposal for the liquidation or dissolution of AC or the Company

For purposes of the Mariani Employment Agreement, Substantial Cause means: (a) the commission by Mr. Mariani of any act of fraud, theft, or embezzlement; (b) any material breach by Mr. Mariani of the Mariani Employment Agreement, provided that AC shall have first delivered to Mr. Mariani written notice of the alleged breach, specifying the exact nature of the breach in detail, and provided, further, that Mr. Mariani shall have failed to cure or substantially mitigate such breach within ten days after receiving such written notice; (c) commission or conviction of any felony, or of any misdemeanor involving moral turpitude, or entry of a plea of guilty or nolo contendere to any felony or misdemeanor; (d) material failure to adhere to AC's or the Company corporate codes, policies or procedures which have been adopted in good faith for a valid business purpose as in effect from time to time; or (e) failure to meet reasonable performance standards as determined by AC or the Company.

For purposes of the Mariani Employment Agreement Good Reason means Mr. Mariani's resignation from employment upon or within 90 days following a Change in Control if AC or the Company is not the surviving entity, provided that Substantial Cause for termination of Mr. Mariani's employment does not exist at the time of such resignation and the resignation is the result of the occurrence of any one or more of the following: (a) the assignment of any duties inconsistent in any respect with Mr. Mariani's position (including status, offices, titles, and reporting requirements), authorities, duties, or other responsibilities as in effect immediately prior to a Change of Control or any other action by AC or the Company which results in a diminishment in such position, authority, duties, or responsibilities, other than an insubstantial and inadvertent action which is remedied by AC or the Company; (b) a reduction by AC in Mr. Mariani's base salary; or (c) the failure by AC to (a) continue in effect any material compensation or benefit plan, program, policy or practice in which Mr. Mariani was participating at the time of the Change of Control of AC or the Company or (b) provide Mr. Mariani with compensation and benefits at least equal (in terms of benefit levels and/or reward opportunities) to those provided for under each employee benefit plan, program, policy and practice as in effect immediately prior to the Change in Control (or as in effect following the Change in Control of AC or the Company), if greater.

Mr. Mariani will receive a base salary of \$320,000 (to be reviewed on an annual basis), be eligible to participate in AxoGen's current bonus program and receive benefits afforded to other executive officers. Mr. Mariani will receive a one-time signing bonus of \$15,000 upon the first AC payroll period following the effectiveness of Mr. Mariani's employment. He will be granted incentive stock options for 205,000 shares of the Company's Common Stock on March 1, 2016, such options having a seven year term, at an exercise price equal to the fair market value of the Company's common stock based on the closing price of the Company common stock on the option grant date and pursuant to the terms of the Company's form of incentive stock options. Such options will vest as to 25% of the shares after one year and 12.5% every six months thereafter until fully vested.

Mr. Peter Mariani, age 52, brings more than 25 years of experience as a financial executive in private and public companies. He previously served as Chief Financial Officer of Lensar, Inc, a privately held laser refractive cataract surgery company, from July 2014 through January 2016, which was sold in December

2015. From June 2011 to June 2014 he served as Chief Financial Officer of Hansen Medical, a publicly traded medical device company developing robotic solutions for intravascular procedures. From 2007 through 2010 he served as Chief Financial Officer for two privately held companies: Harlan Laboratories (2007 – 2009); and BMW Constructors (2009 – 2010). From 1994 through 2006 Mr. Mariani served in various senior financial roles with Guidant Corporation, a publicly traded leader in the development and sale of medical devices for the treatment of cardiovascular disease. Mr. Mariani began his career with Guidant as Director of Corporate Financial Reporting where he supported the initial public offering of Guidant and ultimately served as Vice President, Controller and Chief Accounting Officer. Mr. Mariani's experience at Guidant included two years as Director of Financial Reporting, Guidant Vascular Intervention in Santa Clara, California, and four years in Tokyo, Japan, mostly as Vice President Finance and Administration where he helped to facilitate the conversion and scale of the Japan business from a distributor network to a direct sales and marketing organization. Following the 2006 sale of Guidant to Boston Scientific Corporation, Mr. Mariani co-lead the initial integration of the two companies. From 1987 to 1994 Mr. Mariani worked with Ernst and Young, LLP, where he served a diverse client base as a Certified Public Accountant (CPA). Mr. Mariani received a Bachelor of Science Degree in Accounting from Indiana University.

Mr. Mariani does not have any family relationship with any director or executive officer, or a person nominated to be a director or executive officer of the Company or AC. Mr. Mariani has not engaged in any transactions with the Company or AC that are required to be disclosed under Item 404(a) of Regulation S-K, nor have any such transactions been proposed.

Upon the effectiveness of Mr. Mariani's appointment on March 1, 2016, Gregory G. Freitag will no longer serve as the Company's Chief Financial Officer. Mr. Freitag will continue to serve as a member of the Company's Board of Directors and as General Counsel and Senior Vice President of Business Development of the Company.

Item 9.01. Financial Statements and Exhibits

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	AxoGen, Inc. press release, dated February 29, 2016.

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: February 29, 2016

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

EXHIBIT INDEX

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



AxoGen Inc. Reports Record Revenue Results

- Record Annual Revenue of \$27.33 Million and Fourth Quarter Revenue of \$7.81 Million

- 2016 Outlook Provided

ALACHUA, FL – February 29, 2016 – AxoGen, Inc. (NASDAQ: AXGN), a leader in developing and marketing innovative surgical solutions for peripheral nerve injuries, today reported record 2015 revenue of \$27.33 million and fourth quarter revenue of \$7.81 million. For both the full year and fourth quarter, the Company's revenue increased approximately 63% as compared to the prior corresponding period. In addition, management introduced revenue and gross margin guidance for 2016 that anticipates continued strong growth.

"Our fourth quarter and full year performance reflects the successful execution of our growth strategies and continued adoption of our product portfolio," commented Karen Zaderej, President and Chief Executive Officer. "As more surgeons become aware of and evaluate the clinical and economic benefits of Avance® Nerve Graft, AxoGuard® Nerve Connector and AxoGuard® Nerve Protector, they are adopting our product portfolio to achieve better treatment outcomes for their patients. As we enter 2016, we are financially stronger than we were a year ago and our surgeon education forums continue to drive surgeon acceptance. Our strength and momentum, combined with a larger and more knowledgeable sales force, gives us confidence we can continue to significantly grow our top line during 2016. As a result, our plan for the coming year is for revenue to approach \$39 million."

2015 Fourth Quarter Financial Results

For the fourth quarter ended December 31, 2015, revenue totaled \$7.81 million, a 63% increase when compared to \$4.79 million reported in the same quarter last year. The Company generated a gross margin of 81.9% compared to 80.0% in the fourth quarter of 2014.

Operating expenses for the quarter totaled \$9.0 million compared to \$6.5 million for the fourth quarter of 2014, reflecting the increased investment in sales and marketing to raise awareness of AxoGen's product portfolio and expand its sales footprint. Operating loss was comparable between the quarters at \$2.7 million. Net loss was \$3.6 million, or \$0.12 per share, compared to a net loss of \$6.5 million, or \$0.35 per share for the fourth quarter of 2014. In the year-ago fourth quarter,

the net loss included one-time interest expenses and the write off of non-cash deferred financing charges totaling \$2.5 million that were related to the retirement of the PDL Royalty Contract.

2015 Full Year Financial Results

For the full year ended December 31, 2015, revenue totaled \$27.33 million, a 63% increase when compared to \$16.82 million reported in 2014. Gross margin for the full year expanded to 82.3% compared to 79.5% for the full year ended December 31, 2014. Operating expenses were \$31.7 million compared to \$23.2 million for the 2014 full year. The increased operating expenses primarily reflect management's continued investment in sales and marketing to raise awareness of AxoGen's product portfolio and expand its sales footprint, as well, to a lesser extent, increased activity related to initiating the RECON clinical trial, product development and increased compensation and general expenses of operating a larger organization. As a percentage of revenue, total cost and expenses decreased 21.6% from 2014 to 2015. For the full year ended December 31, 2015, the net loss was \$13.4 million, or \$0.51 per share compared to a net loss of \$17.7 million, or \$0.99 per share for the full year ended December 31, 2014.

As of December 31, 2015, cash and cash equivalents totaled \$25.9 million. The weighted common average shares for the fourth quarter were 29.9 million, an increase from 18.6 million shares for the fourth quarter of the prior year due to a common stock offering in the first and third quarters of 2015.

2016 Guidance

The Company is forecasting full year 2016 revenue to approach \$39 million and gross margin for the year in the high 70% range.

Conference Call

The Company will host a conference call and webcast for the investment community 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/q4-2015>.

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.

.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 2016 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.

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EVC Group

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AXOGEN, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
Three Months ended December 31, 2015 and 2014
(unaudited)

	2015	2014
Revenues	\$ 7,808,848	\$ 4,793,614
Cost of goods sold	1,415,258	956,884
Gross profit	6,393,590	3,836,730
Costs and expenses:		
Sales and marketing	5,831,972	3,867,199
Research and development	893,720	983,723
General and administrative	2,319,808	1,694,809
Total costs and expenses	9,045,500	6,545,731
Loss from operations	(2,651,910)	(2,709,001)
Other expense:		
Interest expense	(927,840)	(2,762,652)
Interest expense – deferred financing costs	(31,537)	(941,875)
Other expense	(207)	8,035
Total other expense	(959,583)	(3,696,492)
Net loss	\$ (3,611,494)	\$ (6,405,493)
Weighted Average Common Shares outstanding – basic and diluted	29,926,001	18,565,577
Loss Per Common share – basic and diluted	\$ (0.12)	\$ (0.35)

AXOGEN, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
Years ended December 31, 2015 and 2014

	2015	2014
Revenues	\$ 27,331,092	\$ 16,817,403
Cost of goods sold	4,848,396	3,442,183
Gross profit	22,482,696	13,375,220
Costs and expenses:		
Sales and marketing	20,089,369	13,193,795
Research and development	3,237,171	3,033,325
General and administrative	8,422,866	6,948,890
Total costs and expenses	31,749,406	23,176,010
Loss from operations	(9,266,710)	(9,800,790)
Other expense:		
Interest expense	(3,988,619)	(6,812,315)
Interest expense – deferred financing costs	(127,912)	(1,100,520)
Other income (expense)	26,816	3,149
Total other income (expense)	(4,089,715)	(7,909,686)
Net Loss	(13,356,425)	(17,710,476)
Weighted Average Common Shares outstanding – basic and diluted	26,075,670	17,721,742
Loss Per Common share – basic and diluted	\$ (0.51)	\$ (0.99)

AXOGEN, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
December 31, 2015 and 2014

	December 31, 2015	December 31, 2014
Assets		
Current assets:		
Cash and cash equivalents	\$ 25,909,500	\$ 8,215,791
Accounts receivable	4,782,989	2,872,308
Inventory	3,933,960	3,213,620
Prepaid expenses and other	424,925	109,369
Total current assets	35,051,374	14,411,088
Property and equipment, net	970,870	619,028
Intangible assets	678,082	577,174
Deferred financing costs	845,727	793,499
	\$ 37,546,053	\$ 16,400,789
Liabilities and Shareholders' Equity (Deficit)		
Current liabilities:		
Accounts payable and accrued expenses	\$ 3,695,127	\$ 2,431,194
Current deferred revenue	14,118	14,118
Total current liabilities	3,709,245	2,445,312
Note Payable	25,547,420	25,085,777
Long Term Deferred Revenue	93,797	115,380
Total liabilities	29,350,462	27,646,469
Shareholders' equity (deficit):		
Common stock, \$.01 par value; 50,000,000 shares authorized; 29,984,591 and 19,488,814 shares issued and outstanding	299,846	194,888
Additional paid-in capital	111,368,424	78,675,686
Accumulated deficit	(103,472,679)	(90,116,254)
Total shareholders' equity (deficit)	8,195,591	(11,245,680)
	\$ 37,546,053	\$ 16,400,789

AXOGEN, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
Years ended December 31, 2015 and 2014

	<u>2015</u>	<u>2014</u>
Cash flows from operating activities:		
Net loss	\$(13,356,425)	\$(17,710,476)
Adjustments to reconcile net loss to net cash used for operating activities:		
Depreciation	203,140	153,670
Amortization of intangible assets	45,828	45,224
Amortization of deferred financing costs	127,913	199,328
Write off of deferred financing costs	—	901,192
Provision for bad debt	125,371	35,478
Stock-based compensation	1,316,509	956,449
Stock grants	—	60,125
Interest added to note payable	461,643	5,022,082
Change in assets and liabilities:		
Accounts receivable	(2,036,052)	(1,014,087)
Inventory	(720,340)	184,818
Prepaid expenses and other	(315,556)	187,350
Accounts payable and accrued expenses	1,117,733	498,290
Deferred revenue	(21,583)	29,498
Net cash used for operating activities	<u>(13,051,819)</u>	<u>(10,451,059)</u>
Cash flows from investing activities:		
Purchase of property and equipment	(408,782)	(542,045)
Acquisition of intangible assets	(146,736)	(52,002)
Net cash used for investing activities	<u>(555,518)</u>	<u>(594,047)</u>
Cash flows from financing activities:		
Proceeds from issuance of common stock	30,968,386	1,625,748
Repayments of long-term debt	—	(1,750,000)
Debt issuance costs	(180,139)	(820,441)
Proceeds from exercise of stock options	512,799	135,840
Net cash provided by (used in) financing activities	<u>31,301,046</u>	<u>(808,853)</u>
Net increase (decrease) in cash and cash equivalents	17,693,709	(11,853,959)
Cash and cash equivalents, beginning of year	<u>8,215,791</u>	<u>20,069,750</u>
Cash and cash equivalents, end of period	<u>\$ 25,909,500</u>	<u>\$ 8,215,791</u>
Supplemental disclosures of cash flow activity:		
Cash paid for interest	\$ 3,525,978	\$ 3,912,463
Supplemental disclosure of non-cash investing and financing activities:		
Payments of fixed assets in accounts payable	\$ 168,775	\$ 22,575
Payments of long term debt with proceeds from note payable of \$25,000,000 and issuance of shares of \$3,550,000	—	28,550,000