
**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 2, 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.)

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

Registrant's telephone number, including area code

<u>(386) 462-6800</u>	
(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 2, 2016, AxoGen, Inc. (“AxoGen”) issued a press release announcing its financial results for the quarter and nine months ended September 30, 2016. 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 2, 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: November 2, 2016

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

EXHIBIT INDEX

Exhibit No.	Description
99.1	AxoGen, Inc. press release, dated November 2, 2016.



AxoGen, Inc. Reports Financial Results for Third Quarter 2016

Record revenues of \$11.2 million, continued growth in accounts, and increased presence of nerve repair at key medical meetings

ALACHUA, FL – November 2, 2016 AxoGen, Inc. (NASDAQ: AXGN), a global leader in innovative surgical solutions for peripheral nerve injuries, today announced financial results for the third quarter ended September 30, 2016 and provided a business update.

Third Quarter 2016 Financial and Recent Business Highlights

- Third quarter revenue of \$11.2 million up 37% compared to 2015 revenue of \$8.2 million
- Year-to-date revenue of \$29.7 million up 52% compared to 2015 of \$19.5 million
- Gross margin of 84.9% compared to 2015 gross margin of 82.7%
- Improved EBITDA loss of \$1.1 million compared to 2015 EBITDA loss of \$1.8 million
- Increasing awareness of nerve injury and repair seen in multiple conference presentations at the Annual American Society for Surgery of the Hand Meeting and American Association of Oral and Maxillofacial Surgeons
- Appointed former Covidien executive Amy Wendell to the Board of Directors
- Raised \$18.6 million in net proceeds through a public offering of common stock on October 13th
- Refinanced \$25.0 million debt facility on October 25th which will reduce annual interest costs by at least \$1.5 million

“We are pleased with another successful quarter including record revenues of \$11.2 million, continued growth in active and new accounts, and a significantly improved balance sheet” commented Karen Zaderej, President and Chief Executive Officer. “With a large presence at two recent medical meetings, it’s particularly pleasing to see surgeons becoming more familiar with the role of our portfolio of products for peripheral nerve repair. Our recent equity raise and the refinancing of our debt provide us with a solid capital structure as we continue to drive awareness and growth in this emerging nerve repair market.”

Additional Operational and Financial Highlights

- Increased active accounts in the third quarter to 414 up 40% from 296 a year ago
 - Ended the quarter with 45 direct sales representatives as compared to 38 a year ago; 23 independent agencies, consistent with prior year
 - Conducted 11 national education courses year to date and will complete two more for a
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- total of 13 courses by the end of this calendar year
- Ended the quarter with \$16.0 million in cash and \$25.0 million in debt
- Use of cash in the quarter was \$2.3 million
- Seven peer reviewed publications year to date on the AxoGen nerve repair portfolio
- After giving effect for the recent equity raise and debt refinancing, as of September 30, 2016, pro forma cash was approximately \$31.7 million and pro forma bank debt was approximately \$25.0 million

2016 Financial Guidance

Management maintains its full year 2016 revenue guidance of over \$40 million and full year 2016 gross margin guidance to exceed 80%.

Introducing 2017 Financial Guidance

Management expects 2017 annual revenue will grow at least 40% over 2016 revenue and gross margins will remain above 80%.

Upcoming Events

The Company will be conducting its first Analyst and Investor Event on Monday November 21st in New York City. This event will include a review of clinical data and best practices in the repair of peripheral nerves from surgeons that use the AxoGen portfolio of products and a business review from Company management. Those interested in attending this event can register by sending an email to AxoGenEvents@TroutGroup.com.

Conference Call

The Company will host a conference call and webcast for the investment community today 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 listening to the conference call live via the Internet may do so by visiting the Investors page of the company's website at www.axogeninc.com and clicking on the webcast link on the Investors home page.

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

About AxoGen

AxoGen (AXGN) is a global leader in innovative surgical solutions for peripheral nerve injuries. AxoGen's portfolio of products 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. Along with these core surgical products, AxoGen also offers AxoTouch™ Two-Point Discriminator and AcroVal™ Neurosensory & Motor Testing System. These evaluation and measurement tools assist healthcare professionals in detecting changes in sensation, assessing return of sensory, grip and pinch function, evaluating effective treatment interventions, and providing feedback to patients on nerve function. The

AxoGen portfolio of products is available in the United States, Canada, the United Kingdom and several European and international countries.

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.

About Non-GAAP Financial Measures

To supplement our consolidated financial statements, we use the non-GAAP financial measure of EBITDA, which measures earnings before interest, income taxes, depreciation and amortization.

We use this non-GAAP financial measure for financial and operational decision-making and as a means to evaluate period-to-period comparisons. We believe that this non-GAAP financial measure provides meaningful supplemental information regarding our performance and liquidity and that both management and investors benefit from referring this non-GAAP financial measure in assessing our performance and when planning, forecasting, and analyzing future periods. We believe this non-GAAP financial measure is useful to investors because (1) it allows for greater transparency with respect to key metrics used by management in its financial and operational decision-making and (2) it is used by our institutional investors and the analyst community to help them analyze the performance of our business.

Contacts:

AxoGen, Inc.

Peter J. Mariani, Chief Financial Officer

InvestorRelations@AxoGenInc.com

The Trout Group – Investor Relations

Brian Korb

646.378.2923

bkorb@troutgroup.com

AXOGEN, INC
CONDENSED CONSOLIDATED BALANCE SHEETS

	September 30, 2016 (unaudited)	December 31, 2015
Assets		
Current assets:		
Cash and cash equivalents	\$ 16,003,245	\$ 25,909,500
Accounts receivable	7,004,756	4,782,989
Inventory	4,970,819	3,933,960
Prepaid expenses and other	685,711	424,925
Total current assets	<u>28,664,531</u>	<u>35,051,374</u>
Property and equipment, net	1,320,711	970,870
Intangible assets	787,523	678,082
	<u>\$ 30,772,765</u>	<u>\$ 36,700,326</u>
Liabilities and Shareholders' Equity		
Current liabilities:		
Accounts payable and accrued expenses	\$ 4,559,394	\$ 3,695,127
Current deferred revenue	36,032	14,118
Total current liabilities	<u>4,595,426</u>	<u>3,709,245</u>
Note Payable - Revenue Interest Purchase Agreement	24,996,070	24,701,693
Long Term Deferred Revenue	<u>77,610</u>	<u>93,797</u>
Total liabilities	<u>29,669,106</u>	<u>28,504,735</u>
Shareholders' equity:		
Common stock, \$.01 par value; 50,000,000 shares authorized; 30,209,036 and 29,984,591 shares issued and outstanding	302,090	299,846
Additional paid-in capital	113,058,408	111,368,424
Accumulated deficit	<u>(112,256,839)</u>	<u>(103,472,679)</u>
Total shareholders' equity	<u>1,103,659</u>	<u>8,195,591</u>
	<u>\$ 30,772,765</u>	<u>\$ 36,700,326</u>

AXOGEN, INC
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
Three and Nine Months ended September 30, 2016 and 2015
(unaudited)

	Three Months Ended		Nine Months Ended	
	September 30, 2016	September 30, 2015	September 30, 2016	September 30, 2015
Revenues	\$ 11,205,224	\$ 8,153,675	\$ 29,698,866	\$ 19,522,244
Cost of goods sold	1,697,443	1,410,416	4,637,446	3,433,138
Gross profit	9,507,781	6,743,259	25,061,420	16,089,106
Costs and expenses:				
Sales and marketing	7,090,059	5,512,613	20,076,297	14,257,397
Research and development	1,118,358	936,015	3,033,521	2,343,450
General and administrative	2,481,051	2,212,457	7,362,063	6,103,058
Total costs and expenses	10,689,468	8,661,085	30,471,881	22,703,905
Loss from operations	(1,181,687)	(1,917,826)	(5,410,461)	(6,614,799)
Other income (expense):				
Interest expense	(1,089,134)	(1,042,258)	(3,255,574)	(3,060,779)
Interest expense — deferred financing costs	(31,748)	(31,419)	(95,254)	(96,375)
Other income (expense)	(2,804)	12,645	(22,871)	27,021
Total other income (expense)	(1,123,686)	(1,061,032)	(3,373,699)	(3,130,133)
Net Loss	\$ (2,305,373)	\$ (2,978,858)	\$ (8,784,160)	\$ (9,744,932)
Weighted Average Common Shares outstanding — basic and diluted	30,152,279	26,841,060	30,075,715	24,778,123
Loss Per Common share — basic and diluted	\$ (0.08)	\$ (0.11)	\$ (0.29)	\$ (0.39)

AXOGEN, INC
RECONCILIATION OF GAAP FINANCIAL MEASURES TO NON-GAAP
FINANCIAL MEASURES
Three and Nine Months ended September 30, 2016 and 2015
(unaudited)

	Three Months Ended		Nine Months Ended	
	September 30, 2016	September 30, 2015	September 30, 2016	September 30, 2015
Net loss	\$(2,305,373)	\$(2,978,858)	\$(8,784,160)	\$(9,744,932)
Depreciation and amortization expense	95,543	54,428	263,133	142,038
Amortization expense of intangible assets	16,017	11,299	48,050	34,009
Interest expense	1,089,134	1,042,258	3,255,574	3,060,779
Interest expense - deferred financing costs	31,748	31,419	95,254	96,375
EBITDA - non GAAP	\$(1,072,931)	\$(1,839,454)	\$(5,122,149)	\$(6,411,731)

AXOGEN, INC
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
Nine Months ended September 30, 2016 and 2015
(unaudited)

	2016	2015
Cash flows from operating activities:		
Net loss	\$ (8,784,160)	\$ (9,744,932)
Adjustments to reconcile net loss to net cash used for operating activities:		
Depreciation	263,133	142,038
Amortization of intangible assets	48,050	34,009
Amortization of deferred financing costs	95,253	96,375
Provision for bad debts	80,934	—
Stock-based compensation	1,046,364	1,031,218
Interest added to note	199,124	451,590
Change in assets and liabilities:		
Accounts receivable	(2,302,701)	(1,770,494)
Inventory	(1,036,859)	(488,135)
Prepaid expenses and other	(260,786)	(180,862)
Accounts payable and accrued expenses	864,267	1,655,114
Deferred Revenue	5,727	(16,187)
Net cash used for operating activities	(9,781,654)	(8,790,266)
Cash flows from investing activities:		
Purchase of property and equipment	(612,974)	(353,093)
Acquisition of intangible assets	(157,491)	(92,184)
Net cash used for investing activities	(770,465)	(445,277)
Cash flows from financing activities:		
Proceeds from issuance of common stock	—	30,970,735
Debt issuance costs	—	(180,142)
Proceeds from exercise of stock options	645,864	164,626
Net cash provided by financing activities	645,864	30,955,219
Net increase (decrease) in cash and cash equivalents	(9,906,255)	21,719,676
Cash and cash equivalents, beginning of year	25,909,500	8,215,791
Cash and cash equivalents, end of period	\$16,003,245	\$29,935,467
Supplemental disclosures of cash flow activity:		
Cash paid for interest	\$ 3,031,528	\$ 1,949,381