
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 28, 2018

AXOGEN, INC.

(Exact name of registrant as specified in its charter)

Minnesota (State or other jurisdiction of incorporation)	001-36046 (Commission File Number)	41-1301878 (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))

Indicate by check mark whether the registrant is an emerging growth company as defined in as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 2.02 Results of Operations and Financial Condition

On February 28, 2018, AxoGen, Inc. (“AxoGen”) issued a press release announcing its financial results for the quarter and year ended December 31, 2017. 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 February 28, 2018.

EXHIBIT INDEX

<u>Exhibit No.</u>	<u>Description</u>
99.1	AxoGen, Inc. press release, dated February 28, 2018.

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 28, 2018

By: /s/ Gregory G. Freitag

Gregory G. Freitag
General Counsel & Senior VP of
Business Development



AxoGen, Inc. Reports
2017 Fourth Quarter and Full Year Financial Results

*Record Q4 Revenue of \$17.0 million, representing 49% growth over prior year
 Record Full year 2017 Revenue of \$60.4 million, representing 47% growth over prior year*

ALACHUA, FL – February 28, 2018 – AxoGen, Inc. (NASDAQ: AXGN), a global leader in developing and marketing innovative surgical solutions for peripheral nerves, today reported financial results and business highlights for the fourth quarter and full year ended December 31, 2017.

Fourth Quarter 2017 Financial Results and Recent Business Highlights

- Revenue of \$17.0 million, up 49% compared to \$11.4 million in the fourth quarter of 2016
- Gross margin of 84.6% compared to 84.0% in the fourth quarter of 2016
- Adjusted EBITDA loss of \$531,000 compared to adjusted EBITDA loss of \$2.2 million in Q4 2016
- Announced expanded application in Breast Reconstruction Neurotization
- Adjusted net loss for the fourth quarter of 2017 was \$2.5 million, or \$0.07 per share, compared with adjusted net loss of \$3.2 million, or \$0.10 per share, in the fourth quarter of 2016
- Raised \$15.6 million in net proceeds through a public offering of common stock on November 20

“We are pleased to report another successful quarter and a solid finish to 2017,” said Karen Zaderej, president and CEO of AxoGen. “These results reflect the strength of our growing platform for nerve repair where we see continued momentum in our core trauma, nerve protection and oral and maxillofacial markets. We enter 2018 with an expanding sales force that will allow us to continue growth in our core markets while also supporting our newest application in breast reconstruction neurotization.”

Additional Fourth Quarter and Recent Operational Highlights

- Increased active accounts in the fourth quarter to 591, up 31% from 452 a year ago
- Ended the quarter with 60 direct sales representatives and 20 independent distributors
- Conducted four national education programs in the fourth quarter
- Increased the number of clinical presentations related to our surgical portfolio by three to a total of 21 for the year
- Announced FDA clearance for AxoGuard ® Nerve Cap and will begin a clinical study evaluating its application in the surgical management of pain
- Began training surgeons on the ReSensation™ technique for breast reconstruction neurotization
- Ended the quarter with \$36.5 million in cash compared to \$22 million at the end of the Q3 2017. The \$14.5 million net increase in cash was the result of the company’s \$15.6 million equity raise in November, partially offset by net use of cash in Q4 of \$1.1 million
- Ended the quarter with \$25 million of total bank debt, equivalent to the end of Q3 2017

Full Year 2017 Summary Financial Results and Business Highlights

- 2017 Revenue of \$60.4 million, an increase of 47% compared to \$41.1 million for the prior year
 - Gross margin of 84.6% compared to 84.3% in 2016
-

- Adjusted EBITDA loss of \$3.8 million compared to adjusted EBITDA loss of \$6.3 million in 2016
- Increased total addressable market across all current applications to \$2.2 billion. The increase is a result of expanded use in oral and maxillofacial surgery and the addition of breast reconstruction neurotization.
- Total clinical publications increased by nine to 53, including important data in the areas of mixed and motor, and long gap nerve repair, as well as oral and maxillofacial surgery
- Completed 15 national education programs in 2017 and expect to conduct 18 programs in 2018
- Expanded leadership team with the appointment of Jon Gingrich as Chief Commercial Officer
- Named Employee Engagement Best Practices Award Winner by DecisionWise International

“We continue to produce record revenues and are pleased with 2017 results that demonstrate our ability to consistently and successfully execute our strategy,” said Zaderej. “Our efforts to increase market awareness, provide quality surgeon education programs, expand our commercial presence and effectiveness, and further develop clinical data are helping surgeons develop confidence in the adoption of the AxoGen platform for nerve repair.”

2018 Financial Guidance

Management expects that 2018 revenue will grow at least 40% over 2017 revenue and gross margins will remain above 80%.

Upcoming Investor Events

Members of the AxoGen senior management team will participate at the following upcoming conferences:

- Canaccord Genuity Musculoskeletal Conference in New Orleans on March 6
- 30th Annual ROTH Conference in Dana Point, CA on March 13

Conference Call

The Company will host a conference call and webcast for the investment community today at 4:30 p.m. 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 can 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 the leading company focused specifically on the science, development and commercialization of technologies for peripheral nerve regeneration and repair. We are passionate about helping to restore peripheral nerve function and quality of life to patients with physical damage or discontinuity to peripheral nerves by providing innovative, clinically proven and economically effective repair solutions for surgeons and health care providers. Peripheral nerves provide the pathways for both motor and sensory signals throughout the body. Every day, people suffer traumatic injuries or undergo surgical procedures that impact the function of their peripheral nerves. Physical damage to a peripheral nerve, or the inability to properly reconnect peripheral nerves, can result in the loss of muscle or organ function, the loss of sensory feeling, or the initiation of pain.

AxoGen's platform for peripheral nerve repair features a comprehensive portfolio of products, including Avance® Nerve Graft, an off-the-shelf processed human nerve allograft for bridging severed peripheral 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 peripheral nerves, AxoGuard® Nerve Protector, a porcine submucosa ECM product used to wrap and protect damaged peripheral nerves and reinforce the nerve reconstruction while preventing soft tissue attachments, and Avive® Soft Tissue Membrane, a minimally processed human umbilical cord membrane that may be used as a resorbable soft tissue covering to separate tissue layers and modulate inflammation in the surgical bed. Along

with these core surgical products, AxoGen also offers AcroVal® Neurosensory & Motor Testing System and AxoTouch® Two-Point Discriminator. These evaluation and measurement tools assist health care professionals in detecting changes in sensation, assessing return of sensory, grip, and pinch function, evaluating effective treatment interventions, and providing feedback to patients on peripheral nerve function. The AxoGen portfolio of products is available in the United States, Canada, the United Kingdom, and several other 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,” and 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 assessment on our internal control over financial reporting, our growth, our 2018 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.

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AXOGEN, INC.

CONSOLIDATED BALANCE SHEETS

	December 31, 2017	December 31, 2016
Assets		
Current assets:		
Cash and cash equivalents	\$ 36,506,624	\$ 30,014,405
Accounts receivable, net	11,064,720	8,052,203
Inventory	7,315,942	5,458,840
Prepaid expenses and other	853,381	511,804
Total current assets	<u>55,740,667</u>	<u>44,037,252</u>
Property and equipment, net	2,197,039	1,494,247
Intangible assets	<u>936,992</u>	<u>828,979</u>
	<u>\$ 58,874,698</u>	<u>\$ 46,360,478</u>
Liabilities and Shareholders' Equity		
Current liabilities:		
Borrowings under revolving loan agreement	\$ 4,000,000	\$ 4,025,023
Accounts payable and accrued expenses	8,952,061	7,002,165
Current maturities of long term obligations	735,017	20,899
Deferred revenue, current	31,668	33,282
Total current liabilities	<u>13,718,746</u>	<u>11,081,369</u>
Long Term Obligations, net of current maturities and deferred financing fees	19,905,286	20,265,745
Deferred revenue	<u>68,631</u>	<u>92,215</u>
Total liabilities	<u>33,692,663</u>	<u>31,439,329</u>
Shareholders' equity:		
Common stock, \$.01 par value; 50,000,000 shares authorized; 34,350,329 and 33,008,865 shares issued and outstanding	343,503	330,088
Additional paid-in capital	153,167,817	132,474,884
Accumulated deficit	<u>(128,329,285)</u>	<u>(117,883,823)</u>
Total shareholders' equity	<u>25,182,035</u>	<u>14,921,149</u>
	<u>\$ 58,874,698</u>	<u>\$ 46,360,478</u>

AXOGEN, INC.

CONSONLIDATED STATEMENTS OF OPERATIONS

Three Months and Years ended December 31, 2017 and 2016

	Three Months Ended		Years Ended	
	December 31, 2017	December 31, 2016	December 31, 2017	December 31, 2016
Revenues	\$ 16,971,005	\$ 11,408,672	\$ 60,426,395	\$ 41,107,538
Cost of goods sold	2,614,458	1,829,804	9,311,585	6,467,250
Gross profit	14,356,547	9,578,868	51,114,810	34,640,288
Costs and expenses:				
Sales and marketing	10,120,605	8,349,206	37,635,871	28,425,503
Research and development	1,971,569	1,178,502	6,699,120	4,212,023
General and administrative	4,071,349	2,770,561	14,731,105	10,132,624
Total costs and expenses	16,163,523	12,298,269	59,066,096	42,770,150
Loss from operations	(1,806,976)	(2,719,401)	(7,951,286)	(8,129,862)
Other income (expense):				
Interest expense	(576,971)	(2,130,694)	(2,216,845)	(5,386,268)
Interest expense—deferred financing costs	(109,846)	(780,135)	(246,557)	(875,389)
Other income (expense)	(5,386)	3,246	(30,774)	(19,625)
Total other income (expense)	(692,203)	(2,907,583)	(2,494,176)	(6,281,282)
Net loss	\$ (2,499,179)	\$ (5,626,984)	\$ (10,445,462)	\$ (14,411,144)
Weighted Average Common Shares outstanding – basic and diluted	33,845,684	32,567,893	33,322,767	30,702,164
Loss Per Common share - basic and diluted	\$ (0.07)	\$ (0.17)	\$ (0.31)	\$ (0.47)
Adjusted net loss	\$ (2,499,179)	\$ (3,176,379)	\$ (10,445,462)	\$ (11,960,539)
Adjusted net loss per Common shaee	\$ (0.07)	\$ (0.10)	\$ (0.31)	\$ (0.39)

AXOGEN, INC.

RECONCILIATION OF GAAP FINANCIAL MEASURES TO NON-GAAP FINANCIAL MEASURES

Three Months and Years ended December 31, 2017 and 2016

	Three Months Ended		Years Ended	
	December 31, 2017	December 31, 2016	December 31, 2017	December 31, 2016
Net loss	\$ (2,499,179)	\$ (5,626,984)	\$ (10,445,462)	\$ (14,411,144)
Depreciation and amortization expense	140,772	98,484	487,611	361,617
Amortization expense of intangible assets	18,534	26,821	78,993	74,871
Income Taxes	5,347	—	29,321	21,426
Interest expense	576,971	2,130,694	2,216,845	5,386,268
Interest expense - deferred financing costs	109,846	780,135	246,557	875,389
EBITDA - non GAAP	\$ (1,647,709)	\$ (2,590,850)	\$ (7,386,135)	\$ (7,691,573)
Non Cash Stock Compensation Expense	1,116,926	343,913	3,608,918	1,390,277
Adjusted EBITDA - non GAAP	\$ (530,783)	\$ (2,246,937)	\$ (3,777,217)	\$ (6,301,296)

AXOGEN, INC.

RECONCILIATION OF NET LOSS TO ADJUSTED NET LOSS

Three Months and Years ended December 31, 2017 and 2016

	Three Months Ended		Years Ended	
	December 31, 2017	December 31, 2016	December 31, 2017	December 31, 2016
Net loss	\$ (2,499,179)	\$ (5,626,984)	\$ (10,445,462)	\$ (14,411,144)
Prepayment fees net of accrued interest	—	1,700,131	—	1,700,131
Write off of deferred financing fees	—	750,474	—	750,474
Adjusted Net Loss	\$ (2,499,179)	\$ (3,176,379)	\$ (10,445,462)	\$ (11,960,539)
Adjusted net loss per Common share	\$ (0.07)	\$ (0.10)	\$ (0.31)	\$ (0.39)

AXOGEN, INC.

CONSOLIDATED STATEMENTS OF CASHFLOWS

Years ended December 31, 2017 and 2016

	2017	2016
Cash flows from operating activities:		
Net loss	\$ (10,445,462)	\$ (14,411,144)
Adjustments to reconcile net loss to net cash used for operating activities:		
Depreciation	487,611	361,617
Amortization of intangible assets	78,993	74,871
Amortization of deferred financing costs	246,557	124,915
Write off of deferred financing costs	—	750,474
Provision for bad debts	223,323	79,593
Stock-based compensation	3,608,918	1,390,277
Interest added to note	—	1,924,279
Change in assets and liabilities:		
Accounts receivable	(3,235,840)	(3,348,807)
Inventory	(1,857,102)	(1,524,880)
Prepaid expenses and other	(341,577)	(86,879)
Accounts payable and accrued expenses	1,926,664	3,411,507
Deferred liabilities	70,316	17,582
Net cash used for operating activities	(9,237,599)	(11,236,595)
Cash flows from investing activities:		
Purchase of property and equipment	(1,105,212)	(931,634)
Acquisition of intangible assets	(187,006)	(225,768)
Net cash used for investing activities	(1,292,218)	(1,157,402)
Cash flows from financing activities:		
Proceeds from issuance of common stock	15,662,905	18,668,092
Borrowing on revolving loan	57,599,165	6,684,894
Payments on revolving loan	(57,624,188)	(6,684,894)
Repayments of long term debt	(20,899)	(2,446,676)
Debt issuance costs	(29,472)	(800,847)
Proceeds from exercise of stock options	1,434,525	1,078,333
Net cash provided by financing activities	17,022,036	16,498,902
Net increase in cash and cash equivalents	6,492,219	4,104,905
Cash and cash equivalents, beginning of year	30,014,405	25,909,500
Cash and cash equivalents, end of period	\$ 36,506,624	\$ 30,014,405
Supplemental disclosures of cash flow activity:		
Cash paid for interest	\$ 2,198,286	\$ 5,769,372
Supplemental disclosure of non-cash investing and financing activities:		
Payments of fixed assets in accounts payable	\$ 55,385	\$ 32,153
Payments of long term debt with proceeds from term loan of \$21,000,000 and revolver loan of \$4,000,000	\$ —	\$ 25,000,000
Capital lease additions	\$ 61,959	\$ —