
**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): May 4, 2017

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 May 4, 2017, AxoGen, Inc. (“AxoGen”) issued a press release announcing its financial results for the quarter and three months ended March 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

<u>Exhibit No.</u>	<u>Description</u>
99.1	AxoGen, Inc. press release, dated May 4, 2017.

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: May 4, 2017

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 May 4, 2017.



AxoGen, Inc. Reports 2017 First Quarter Financial Results

Record Q1 Revenue of \$12.2 million, representing 51% growth over prior year

ALACHUA, FL — May 4, 2017 — AxoGen, Inc. (NASDAQ: AXGN), a global leader in developing and marketing innovative surgical solutions for peripheral nerve injuries, today reported financial results and business highlights for the first quarter ended March 31, 2017.

First Quarter 2017 Financial Results and Recent Business Highlights

- Revenue of \$12.2 million, up 51% compared to \$8.1 million in the first quarter of 2016
- Gross margin of 84.4% compared to 82.7% in the first quarter of 2016
- Net loss for the first quarter of 2017 is \$3.8 million, or \$0.11 per share, compared with a net loss of \$3.7 million, or \$0.12 per share, in the first quarter of 2016
- Adjusted EBITDA loss of \$2.2 million compared to Adjusted EBITDA loss of \$2.3 million in Q1 2016

"We are pleased to complete another successful quarter, with record revenues of \$12.2 million and growth of 51 percent," stated Karen Zaderej, President and Chief Executive Officer. "We are successfully executing against our strategic initiatives and driving awareness and growth in the emerging peripheral nerve repair market."

Additional First Quarter and Recent Operational Highlights

- Increased active accounts in the first quarter to 465, up 37% from 340 in Q1 2016
- We ended the quarter with 49 direct sales reps and have 50 as of today's call; we also have 20 independent distributors
- Conducted three national education courses in the first quarter, and four year-to-date
- Increased the number of peer reviewed clinical publications for our surgical portfolio by six to a total of 50 year to date
- Conducted a second clinical advisory panel with leading reconstructive breast surgeons - the panel reviewed patient, surgeon, and health care stakeholder perspectives and needs, as well as how the AxoGen portfolio of products may help surgeons overcome current clinical challenges related to restoring breast sensation for women who choose autologous reconstruction following a mastectomy
- Ended the quarter with \$25.9 million in cash compared to \$30 million at the end of 2016. Net cash burn in Q1 was \$4.1 million and includes \$1.2 million payment of the 2016 all-employee annual performance bonus
- Ended the quarter with \$25 million of total bank debt, compared to \$25 million at the end of 2016

"We continue to focus on surgeon education and growing the body of clinical evidence for our nerve repair solutions," added Zaderej. "As a result we are building awareness of peripheral

nerve repair and expanding usage of our products with innovator and early adopter surgeons, while also working to develop the middle adopter market."

2017 Financial Guidance

Management reiterates 2017 annual revenue will grow at least 40% over 2016 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 and events:

- Jefferies Global Healthcare Conference in New York City on June 6
- JMP Securities Conference in New York City on June 21-22

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 a global leader in innovative surgical solutions for peripheral nerve injuries. AxoGen is the only company focused specifically on the science, development and commercialization of technologies for peripheral nerve regeneration and repair. We are passionate about restoring nerve function and quality of life to patients with peripheral nerve injuries 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. Damage to a peripheral nerve can result in the loss of muscle or organ function, the loss of sensory feeling, or the initiation of pain.

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, 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, 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 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 2017 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.
CONDENSED CONSOLIDATED BALANCE SHEETS

	March 31, 2017 (unaudited)	December 31, 2016
Assets		
Current assets:		
Cash and cash equivalents	\$ 25,913,765	\$ 30,014,405
Accounts receivable, net	8,383,925	8,052,203
Inventory	5,850,730	5,458,840
Prepaid expenses and other	749,437	511,804
Total current assets	40,897,857	44,037,252
Property and equipment, net	1,484,279	1,494,247
Intangible assets	890,688	828,979
	\$ 43,272,824	\$ 46,360,478
Liabilities and Shareholders' Equity (Deficit)		
Current liabilities:		
Borrowings under revolving loan agreement	\$ 3,976,320	\$ 4,025,023
Accounts payable and accrued expenses	6,660,267	7,002,165
Current maturities of long term obligations	22,913	20,899
Deferred revenue, current	35,250	33,282
Total current liabilities	10,694,750	11,081,369
Long Term Obligations, net of current maturities and deferred financing fees	20,276,634	20,265,745
Deferred lease	89,888	—
Deferred revenue	86,818	92,215
Total liabilities	31,148,090	31,439,329
Shareholders' equity (deficit):		
Common stock, \$.01 par value; 50,000,000 shares authorized; 33,063,960 and 33,008,865 shares issued and outstanding	330,639	330,088
Additional paid-in capital	133,439,943	132,474,884
Accumulated deficit	(121,645,848)	(117,883,823)
Total shareholders' equity	12,124,734	14,921,149
	\$ 43,272,824	\$ 46,360,478

AXOGEN, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(unaudited)

	Three Months ended March 31,	
	2017	2016
Revenues	\$ 12,241,073	\$ 8,111,759
Cost of goods sold	1,915,648	1,405,591
Gross profit	10,325,425	6,706,168
Costs and expenses:		
Sales and marketing	8,610,482	6,205,875
Research and development	1,411,136	978,340
General and administrative	3,504,039	2,144,757
Total costs and expenses	13,525,657	9,328,972
Loss from operations	(3,200,232)	(2,622,804)
Other expense:		
Interest expense	(507,549)	(1,003,027)
Interest expense — deferred financing costs	(44,491)	(30,810)
Other expense	(9,753)	(19,450)
Total other expense	(561,793)	(1,053,287)
Net loss	\$ (3,762,025)	\$ (3,676,091)
Weighted Average Common Shares outstanding — basic and diluted	33,026,433	29,994,066
Loss Per Common share — basic and diluted	\$ (0.11)	\$ (0.12)

AXOGEN, INC.
RECONCILIATION OF GAAP FINANCIAL MEASURES TO NON-GAAP FINANCIAL
MEASURES
(unaudited)

	Three Months ended March	
	2017	2016
Net loss	<u>\$(3,762,025)</u>	<u>\$(3,676,091)</u>
Depreciation and amortization expense	108,359	78,856
Amortization expense of intangible assets	23,189	16,016
Income Taxes	9,801	21,427
Interest expense	507,549	1,003,027
Interest expense — deferred financing costs	44,491	30,810
EBITDA — non GAAP	<u>\$(3,068,636)</u>	<u>\$(2,525,955)</u>
Non Cash Stock Compensation Expense	848,589	182,955
Adjusted EBITDA — non GAAP	<u>\$(2,220,047)</u>	<u>\$(2,343,000)</u>

AXOGEN, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(unaudited)

	<u>Three Months ended March 31.</u>	
	<u>2017</u>	<u>2016</u>
Cash flows from operating activities:		
Net loss	\$ (3,762,025)	\$ (3,676,091)
Adjustments to reconcile net loss to net cash used for operating activities:		
Depreciation	108,359	78,856
Amortization of intangible assets	23,189	16,016
Amortization of deferred financing costs	44,491	30,810
Provision for bad debt	34,747	80,651
Share-based compensation	848,589	182,955
Interest added to note payable	—	71,950
Change in assets and liabilities:		
Accounts receivable	(366,469)	(588,243)
Inventory	(391,890)	(581,980)
Prepaid expenses and other	(237,633)	(274,114)
Accounts payable and accrued expenses	(341,899)	55,479
Deferred revenue	86,459	(5,396)
Net cash used for operating activities	<u>(3,954,082)</u>	<u>(4,609,107)</u>
Cash flows from investing activities:		
Purchase of property and equipment	(98,391)	(402,927)
Acquisition of intangible assets	(84,898)	(85,416)
Net cash used for investing activities	<u>(183,289)</u>	<u>(488,343)</u>
Cash flows from financing activities:		
Borrowing on revolving loan	11,247,114	—
Payments on revolving loan	(11,295,817)	—
Repayments of long term debt	(5,158)	—
Debt issuance costs	(26,429)	—
Proceeds from exercise of stock options	117,021	136,702
Net cash provided by financing activities	<u>36,731</u>	<u>136,702</u>
Net increase (decrease) in cash and cash equivalents	(4,100,640)	(4,960,748)
Cash and cash equivalents, beginning of year	30,014,405	25,909,500
Cash and cash equivalents, end of period	<u>\$ 25,913,765</u>	<u>\$20,948,752</u>
Supplemental disclosures of cash flow activity:		
Cash paid for interest	\$ 505,020	\$ 900,410

AXOGEN, INC.
RECONCILIATION OF GAAP FINANCIAL MEASURES TO NON-GAAP FINANCIAL
MEASURES
(unaudited)

	Quarter Ended March 31, 2016	Quarter Ended June 30, 2016	Quarter Ended September 30, 2016	Quarter Ended December 31, 2016	Year Ended December 31, 2016	Quarter Ended March 31, 2017
Net loss	<u>\$ (3,676,091)</u>	<u>\$ (2,802,696)</u>	<u>\$ (2,305,373)</u>	<u>\$ (5,626,984)</u>	<u>\$ (14,411,144)</u>	<u>\$ (3,762,025)</u>
Depreciation and amortization expense	78,856	88,734	95,543	98,484	361,617	108,359
Amortization expense of intangible assets	16,016	16,017	16,017	26,821	74,871	23,189
Income Taxes	21,427	—	—	—	—	9,801
Interest expense	1,003,027	1,163,413	1,089,134	2,130,694	5,386,268	507,549
Interest expense — deferred financing costs	30,810	32,696	31,748	780,135	875,389	44,491
EBITDA — non GAAP	<u>\$ (2,525,955)</u>	<u>\$ (1,501,836)</u>	<u>\$ (1,072,931)</u>	<u>\$ (2,590,850)</u>	<u>\$ (7,712,999)</u>	<u>\$ (3,068,636)</u>
Non Cash Stock Compensation Expense	182,955	569,834	293,575	343,913	1,390,277	848,589
Adjusted EBITDA — non GAAP	<u>\$ (2,343,000)</u>	<u>\$ (932,002)</u>	<u>\$ (779,356)</u>	<u>\$ (2,246,937)</u>	<u>\$ (6,322,722)</u>	<u>\$ (2,220,047)</u>