
**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): August 2, 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 August 2, 2017, AxoGen, Inc. (“AxoGen”) issued a press release announcing its financial results for the quarter and six months ended June 30, 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 August 2, 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: August 2, 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 August 2, 2017.



AxoGen, Inc. Reports 2017 Second Quarter Financial Results

Record Q2 Revenue of \$15.2 million, representing 46% growth over prior year

ALACHUA, FL – August 2, 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 second quarter ended June 30, 2017.

Second Quarter 2017 Financial Results and Recent Business Highlights

- Revenue of \$15.2 million, up 46% compared to \$10.4 million in the second quarter of 2016
- Gross margin of 85.0% compared to 85.2% in the second quarter of 2016
- Net loss for the second quarter of 2017 is \$2.1 million, or \$0.06 per share, compared with a net loss of \$2.8 million, or \$0.09 per share, in the second quarter of 2016
- Adjusted EBITDA loss of \$593,000 compared to Adjusted EBITDA loss of \$932,000 in Q2 2016
- Increased our addressable market opportunity to \$2 billion to include expanded use in oral and maxillofacial (OMF) procedures, including nerve repair during mandible reconstruction due to benign tumor resections
- Appointed Jon Gingrich as Chief Commercial Officer. He brings extensive medical device experience with Hologic and Boston Scientific and will oversee the development and execution of the company's sales and marketing strategies

"Our continued growth reflects our focus on execution," said Karen Zaderej, President and Chief Executive Officer. "We are building the peripheral nerve repair market and increasing confidence in our portfolio of products, as illustrated by OMF surgeons' expanding use of our products in nerve repair during mandible reconstruction."

Additional Second Quarter and Recent Operational Highlights

- Increased active accounts in the second quarter to 510, up 36% from 374 in Q2 2016
 - Ended the quarter with 51 direct sales reps and 52 year-to-date, as well as 20 independent distributors
 - Conducted three national education symposia in the second quarter, and eight year-to-date; these surgeon led symposia highlight recent data and emerging best practices in peripheral nerve repair
 - Increased the number of presentations of our surgical portfolio to a total of 18 year to date
 - Built peer reviewed clinical publications for our surgical portfolio to a total of 52. Three of these recent publications focused on the use of AxoGen products in nerve repair during mandible reconstruction
 - Continued market development activities in potential expansion applications, including breast reconstruction neurotization and neuropathic pain associated with lower limb total joint replacement
-

- Increased global awareness of our product portfolio by exhibiting and conducting surgeon-lead educational programs at professional society meetings in Europe and Asia
- Ended the quarter with \$23.9 million in cash compared to \$25.9 million at the end of Q1 2017. Net cash burn in Q2 was \$2.0 million
- Ended the quarter with \$25 million of total bank debt, unchanged from the end of Q1 2017

“We’re pleased with our results through the first half of 2017,” added Zaderej. “We continue to increase our capabilities across the company, and will continue to develop new nerve repair applications and expand our portfolio of products where we believe we can bring meaningful solutions to current clinical challenges.”

2017 Financial Guidance

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

Upcoming Events

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

- Wedbush PacGrow Healthcare Conference in New York City on August 15
- American Society for Surgery of the Hand Annual Meeting in San Francisco on September 7-9
- Dougherty & Co Investor Conference in Minneapolis on September 19
- Cantor Fitzgerald Healthcare Conference in New York City on September 25
- American Association of Oral and Maxillofacial Surgeons Scientific Sessions in San Francisco on October 9-14

The Company is also announcing that it will be conducting its second analyst and investor day on Monday, November 20 in New York City. This event will provide an additional opportunity to educate the investment community about the Company, as well as a more detailed review of our current market and expansion opportunities.

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.

About Non-GAAP Financial Measures

To supplement our consolidated financial statements, we use the non-GAAP financial measures of EBITDA, which measures earnings before interest, income taxes, depreciation and amortization, and Adjusted EBITDA which further excludes non-cash stock compensation expense. These non-GAAP measures are not based on any comprehensive set of accounting rules or principles and should not be considered a substitute for, or superior to, financial measures calculated in accordance with GAAP, and may be different from non-GAAP measures used by other companies. In addition, these non-GAAP measures should be read in conjunction with our financial statements prepared in accordance with GAAP. The reconciliations of AxoGen's GAAP financial measures to the corresponding non-GAAP measures should be carefully evaluated.

We use these non-GAAP financial measures for financial and operational decision-making and as a means to evaluate period-to-period comparisons. We believe that these non-GAAP financial measures provide

meaningful supplemental information regarding our performance and liquidity and that both management and investors benefit from referring these non-GAAP financial measures in assessing our performance and when planning, forecasting, and analyzing future periods. We believe these non-GAAP financial measures are useful to investors because (1) they allow for greater transparency with respect to key metrics used by management in its financial and operational decision-making and (2) they are used by our institutional investors and the analyst community to help them analyze the performance of our business.

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AXOGEN, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS

	June 30, 2017 (unaudited)	December 31, 2016
Assets		
Current assets:		
Cash and cash equivalents	\$ 23,870,200	\$ 30,014,405
Accounts receivable, net	9,422,467	8,052,203
Inventory	6,304,097	5,458,840
Prepaid expenses and other	585,090	511,804
Total current assets	40,181,854	44,037,252
Property and equipment, net	1,643,257	1,494,247
Intangible assets	940,594	828,979
	\$ 42,765,705	\$ 46,360,478
Liabilities and Shareholders' Equity (Deficit)		
Current liabilities:		
Borrowings under revolving loan agreement	\$ 3,829,765	\$ 4,025,023
Accounts payable and accrued expenses	7,057,831	7,002,165
Current maturities of long term obligations	24,947	20,899
Deferred revenue, current	39,399	33,282
Total current liabilities	10,951,942	11,081,369
Long Term Obligations, net of current maturities and deferred financing fees	20,314,254	20,265,745
Deferred lease	109,332	--
Deferred revenue	81,423	92,215
Total liabilities	31,456,951	31,439,329
Shareholders' equity (deficit):		
Common stock, \$.01 par value; 50,000,000 shares authorized; 33,184,710 and 33,008,865 shares issued and outstanding	331,847	330,088
Additional paid-in capital	134,682,934	132,474,884
Accumulated deficit	(123,706,027)	(117,883,823)
Total shareholders' equity	11,308,754	14,921,149
	\$ 42,765,705	\$ 46,360,478

AXOGEN, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
Three and Six Months ended June 30, 2017 and 2016

	Three Months Ended		Six Months Ended	
	June 30, 2017	June 30, 2016	June 30, 2017	June 30, 2016
Revenues	\$15,168,064	\$10,381,883	\$27,409,137	\$18,493,642
Cost of goods sold	2,277,201	1,534,412	4,192,849	2,940,003
Gross profit	12,890,863	8,847,471	23,216,288	15,553,639
Costs and expenses:				
Sales and marketing	9,438,288	6,780,363	18,048,770	12,986,238
Research and development	1,521,123	936,823	2,932,259	1,915,163
General and administrative	3,377,105	2,736,255	6,881,144	4,881,012
Total costs and expenses	14,336,516	10,453,441	27,862,173	19,782,413
Loss from operations	(1,445,653)	(1,605,970)	(4,645,885)	(4,228,774)
Other expense:				
Interest expense	(554,384)	(1,163,413)	(1,061,933)	(2,166,440)
Interest expense – deferred financing costs	(46,110)	(32,696)	(90,601)	(63,506)
Other expense	(14,032)	(617)	(23,785)	(20,067)
Total other expense	(614,526)	(1,196,726)	(1,176,319)	(2,250,013)
Net loss	<u>\$ (2,060,179)</u>	<u>\$ (2,802,696)</u>	<u>\$ (5,822,204)</u>	<u>\$ (6,478,787)</u>
Weighted Average Common Shares outstanding – basic and diluted	33,124,139	30,079,960	33,075,555	30,037,013
Loss Per Common share – basic and diluted	<u>\$ (0.06)</u>	<u>\$ (0.09)</u>	<u>\$ (0.18)</u>	<u>\$ (0.22)</u>

AXOGEN, INC.
RECONCILIATION OF GAAP FINANCIAL MEASURES TO NON-GAAP FINANCIAL MEASURES
Three and Six Months ended June 30, 2017 and 2016

	Three Months Ended		Six Months Ended	
	June 30, 2017	June 30, 2016	June 30, 2017	June 30, 2016
Net loss	<u>\$ (2,060,179)</u>	<u>\$ (2,802,696)</u>	<u>\$ (5,822,204)</u>	<u>\$ (6,478,787)</u>
Depreciation and amortization expense	109,517	88,734	217,876	167,590
Amortization expense of intangible assets	18,517	16,017	41,706	32,033
Income Taxes	14,173	--	23,974	21,427
Interest expense	554,384	1,163,413	1,061,933	2,166,440
Interest expense - deferred financing costs	46,110	32,696	90,601	63,506
EBITDA - non GAAP	<u>\$ (1,317,478)</u>	<u>\$ (1,501,836)</u>	<u>\$ (4,386,114)</u>	<u>\$ (4,027,791)</u>
Non Cash Stock Compensation Expense	724,377	569,834	1,572,966	752,789
Adjusted EBITDA - non GAAP	<u>\$ (593,101)</u>	<u>\$ (932,002)</u>	<u>\$ (2,813,148)</u>	<u>\$ (3,275,002)</u>

AXOGEN, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
Six Months ended June 30, 2017 and 2016

	2017	2016
Cash flows from operating activities:		
Net loss	\$ (5,822,204)	\$(6,478,787)
Adjustments to reconcile net loss to net cash used for operating activities:		
Depreciation	217,876	167,590
Amortization of intangible assets	41,706	32,033
Amortization of deferred financing costs	90,601	63,506
Provision for bad debt	99,834	48,600
Share-based compensation	1,572,966	752,789
Interest added to note payable	--	187,002
Change in assets and liabilities:		
Accounts receivable	(1,470,098)	(1,337,732)
Inventory	(845,257)	(852,362)
Prepaid expenses and other	(73,286)	(190,586)
Accounts payable and accrued expenses	55,666	198,707
Deferred liabilities	104,657	3,684
Net cash used for operating activities	(6,027,539)	(7,405,556)
Cash flows from investing activities:		
Purchase of property and equipment	(366,886)	(456,910)
Acquisition of intangible assets	(153,321)	(97,341)
Net cash used for investing activities	(520,207)	(554,251)
Cash flows from financing activities:		
Borrowing on revolving loan	26,119,539	--
Payments on revolving loan	(26,314,797)	--
Repayments of long term debt	(8,572)	--
Debt issuance costs	(29,472)	--
Proceeds from exercise of stock options	636,843	323,510
Net cash provided by financing activities	403,541	323,510
Net decrease in cash and cash equivalents	(6,144,205)	(7,636,297)
Cash and cash equivalents, beginning of year	30,014,405	25,909,500
Cash and cash equivalents, end of period	\$ 23,870,200	\$18,273,203
Supplemental disclosures of cash flow activity:		
Cash paid for interest	\$ 1,058,599	\$ 1,964,256