
**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 1, 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 November 1, 2017, AxoGen, Inc. (“AxoGen”) issued a press release announcing its financial results for the quarter and nine months ended September 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 November 1, 2017.

EXHIBIT INDEX

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99.1	<u>AxoGen, Inc. press release, dated November 1, 2017.</u>

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 1, 2017

By: /s/ Gregory G. Freitag

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



AxoGen, Inc. Reports 2017 Third Quarter Financial Results

Record Q3 Revenue of \$16.0 million, representing 43% growth over prior year

ALACHUA, FL – November 1, 2017 – AxoGen, Inc. (NASDAQ: AXGN), a global leader in developing and marketing innovative surgical solutions for the repair of peripheral nerve damage, today reported financial results and business highlights for the third quarter ended September 30, 2017.

Third Quarter 2017 Financial Results and Recent Business Highlights

- Revenue of \$16.0 million, up 43% compared to \$11.2 million in the third quarter of 2016
- Gross margin of 84.4% compared to 84.9% in the third quarter of 2016
- Net loss for the third quarter of 2017 is \$2.1 million, or \$0.06 per share, compared with a net loss of \$2.3 million, or \$0.08 per share, in the third quarter of 2016
- Adjusted EBITDA loss of \$433,000 compared to Adjusted EBITDA loss of \$779,000 in Q3 2016

“We are pleased with another successful quarter, including record revenue of 16.0 million,” said Karen Zaderej, President and Chief Executive Officer. “It is gratifying to see surgeons expanding use of our product portfolio in oral and maxillofacial procedures. In addition, we see increased adoption by hand surgeons in response to data in mixed and motor nerve repair, as well as long gap nerve repair.”

Additional Third Quarter and Recent Operational Highlights

- Increased active accounts in the third quarter to 563, up 36% from 414 in Q3 2016
 - Ended the quarter with 53 direct sales reps and 20 independent distributors
 - A RANGER® Registry data subset presented at the American Society for Surgery of the Hand (ASSH) annual meeting demonstrated favorable results for the Avance® Nerve Graft in mixed, motor, and long gap nerve repairs when compared to historical autograft outcomes
 - Surgeon demonstrations at the American Association of Oral and Maxillofacial Surgeons (AAOMS) meeting increased OMF surgeon awareness of AxoGen's comprehensive platform for nerve repair, including solutions to address nerve damage in the jaw resulting from either surgical injuries or reconstruction following benign tumor removal or similar
-

procedures. Recent clinical data show that repair of these injuries with the AxoGen portfolio can provide meaningful recovery in 87 to 94 percent of these patients

- Conducted four national education symposia in the third quarter, and 12 year-to-date; these surgeon lead symposia highlight recent data and emerging best practices in peripheral nerve repair
- Increased the number of clinical presentations related to our surgical portfolio by three to a total of 21 year-to-date
- Added one peer reviewed clinical publication for our surgical portfolio for a total of 53
- Continued market development activities in potential expansion applications, including breast reconstruction neurotization and neuropathic pain associated with lower limb total joint replacement
- Ended the quarter with \$22.0 million in cash, a reduction of \$1.8 million from the end of Q2 2017.
- Ended the quarter with \$25 million of total bank debt, unchanged from the end of Q2 2017

“We are encouraged by the increasing number of peripheral nerve repair data presentations at scientific meetings, added Zaderej. “The clinical evidence supporting meaningful recovery associated with our Avance® Nerve Graft is compelling. This data, along with the library of evidence on the full AxoGen portfolio, help build awareness and surgeon confidence in our platform for nerve repair.”

2017 Financial Guidance

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

Introducing 2018 Financial Guidance

Management expects that 2018 revenue will grow at least 40% over 2017 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:

- Second Annual AxoGen Analyst and Investor Day in New York City on November 20
- 29th Annual Piper Jaffray Healthcare Conference in New York City on November 28
- Guggenheim 5th Annual Healthcare Conference in Boston on December 13
- The Trout Group Annual 1-on-1 Management Access Event in San Francisco, January 9–11, 2018 (to request a meeting, please contact axogenevents@troutgroup.com).
- 2018 Combined Meeting of the American Association for Hand Surgery, American Society for Peripheral Nerve, and American Society of Reconstructive Microsurgery in Phoenix, January 10-16, 2018

The Company will host its second annual **Analyst and Investor Day** on Monday, November 20 in New York City. Join AxoGen executives and surgeon thought leaders for a discussion of the company's comprehensive platform for nerve repair and the emerging nerve repair market. Those interested in attending the event can RSVP at axogenevents@troutgroup.com.

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 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 platform for nerve repair features a comprehensive portfolio of products, including 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 and 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.

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

	September 30, 2017 (unaudited)	December 31, 2016
Assets		
Current assets:		
Cash and cash equivalents	\$ 22,041,097	\$ 30,014,405
Accounts receivable, net	10,200,560	8,052,203
Inventory	6,698,943	5,458,840
Prepaid expenses and other	571,912	511,804
Total current assets	39,512,512	44,037,252
Property and equipment, net	1,763,840	1,494,247
Intangible assets	951,473	828,979
	\$ 42,227,825	\$ 46,360,478
Liabilities and Shareholders' Equity (Deficit)		
Current liabilities:		
Borrowings under revolving loan agreement	\$ 4,000,000	\$ 4,025,023
Accounts payable and accrued expenses	7,072,530	7,002,165
Current maturities of long term obligations	21,596	20,899
Deferred revenue, current	43,576	33,282
Total current liabilities	11,137,702	11,081,369
Long Term Obligations, net of current maturities and deferred financing fees	20,356,698	20,265,745
Deferred lease	105,261	—
Deferred revenue	76,027	92,215
Total liabilities	31,675,688	31,439,329
Shareholders' equity (deficit):		
Common stock, \$.01 par value; 50,000,000 shares authorized; 33,393,804 and 33,008,865 shares issued and outstanding	333,938	330,088
Additional paid-in capital	136,048,305	132,474,884
Accumulated deficit	(125,830,106)	(117,883,823)
Total shareholders' equity	10,552,137	14,921,149
	\$ 42,227,825	\$ 46,360,478

AXOGEN, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
Three and Nine Months ended September 30, 2017 and 2016
(unaudited)

	Three Months Ended		Nine Months Ended	
	September 30, 2017	September 30, 2016	September 30, 2017	September 30, 2016
Revenues	\$ 16,046,253	\$ 11,205,224	\$ 43,455,390	\$ 29,698,866
Cost of goods sold	2,504,278	1,697,443	6,697,127	4,637,446
Gross profit	13,541,975	9,507,781	36,758,263	25,061,420
Costs and expenses:				
Sales and marketing	9,466,496	7,090,059	27,515,266	20,076,297
Research and development	1,795,292	1,118,358	4,727,551	3,033,521
General and administrative	3,778,612	2,481,051	10,659,756	7,362,063
Total costs and expenses	15,040,400	10,689,468	42,902,573	30,471,881
Loss from operations	(1,498,425)	(1,181,687)	(6,144,310)	(5,410,461)
Other expense:				
Interest expense	(577,941)	(1,089,134)	(1,639,874)	(3,255,574)
Interest expense – deferred financing costs	(46,110)	(31,748)	(136,711)	(95,254)
Other expense	(1,603)	(2,804)	(25,388)	(22,871)
Total other expense	(625,654)	(1,123,686)	(1,801,973)	(3,373,699)
Net loss	\$ (2,124,079)	\$ (2,305,373)	\$ (7,946,283)	\$ (8,784,160)
Weighted Average Common Shares outstanding – basic and diluted	33,286,211	30,152,279	33,146,546	30,075,715
Loss Per Common share – basic and diluted	\$ (0.06)	\$ (0.08)	\$ (0.24)	\$ (0.29)

AXOGEN, INC.
RECONCILIATION OF GAAP FINANCIAL MEASURES TO NON-GAAP FINANCIAL MEASURES
Three and Nine Months ended September 30, 2017 and 2016
(unaudited)

	Three Months Ended		Nine Months Ended	
	September 30, 2017	September 30, 2016	September 30, 2017	September 30, 2016
Net loss	\$ (2,124,079)	\$ (2,305,373)	\$ (7,946,283)	\$ (8,784,160)
Depreciation and amortization expense	128,963	95,543	346,839	263,133
Amortization expense of intangible assets	18,753	16,017	60,459	48,050
Income Taxes	—	—	23,974	21,427
Interest expense	577,941	1,089,134	1,639,874	3,255,574
Interest expense - deferred financing costs	46,110	31,748	136,711	95,254
EBITDA - non GAAP	\$ (1,352,312)	\$ (1,072,931)	\$ (5,738,426)	\$ (5,100,722)
Non Cash Stock Compensation Expense	919,026	293,575	2,491,992	1,046,364
Adjusted EBITDA - non GAAP	\$ (433,286)	\$ (779,356)	\$ (3,246,434)	\$ (4,054,358)

AXOGEN, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
Nine Months ended September 30, 2017 and 2016
(unaudited)

	2017	2016
Cash flows from operating activities:		
Net loss	\$ (7,946,283)	\$ (8,784,160)
Adjustments to reconcile net loss to net cash used for operating activities:		
Depreciation	346,839	263,133
Amortization of intangible assets	60,459	48,050
Amortization of deferred financing costs	136,711	95,253
Provision for bad debt	83,733	80,934
Share-based compensation	2,491,992	1,046,364
Interest added to note payable	—	199,124
Change in assets and liabilities:		
Accounts receivable	(2,232,090)	(2,302,701)
Inventory	(1,240,103)	(1,036,859)
Prepaid expenses and other	(60,108)	(260,786)
Accounts payable and accrued expenses	70,365	864,267
Deferred liabilities	99,367	5,727
Net cash used for operating activities	(8,189,118)	(9,781,654)
Cash flows from investing activities:		
Purchase of property and equipment	(616,432)	(612,974)
Acquisition of intangible assets	(182,953)	(157,491)
Net cash used for investing activities	(799,385)	(770,465)
Cash flows from financing activities:		
Borrowing on revolving loan	41,553,210	—
Payments on revolving loan	(41,578,233)	—
Repayments of long term debt	(15,589)	—
Debt issuance costs	(29,472)	—
Proceeds from exercise of stock options	1,085,279	645,864
Net cash provided by financing activities	1,015,195	645,864
Net decrease in cash and cash equivalents	(7,973,308)	(9,906,255)
Cash and cash equivalents, beginning of year	30,014,405	25,909,500
Cash and cash equivalents, end of period	\$ 22,041,097	\$ 16,003,245
Supplemental disclosures of cash flow activity:		
Cash paid for interest	\$ 1,631,795	\$ 3,031,528