
**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 26, 2019

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 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 26, 2019, Axogen, Inc. (the “Company”) issued a press release announcing its fourth quarter and full year 2018 revenue. 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	<u>Axogen, Inc. Press Release, dated February 26, 2019 .</u>

EXHIBIT INDEX

<u>Exhibit No.</u>	<u>Description</u>
99.1	<u>Axogen, Inc. Press Release, dated February 26, 2019.</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: February 26, 2019

By: /s/ Gregory G. Freitag
Gregory G. Freitag
General Counsel



Axogen, Inc. Reports 2018 Fourth Quarter and Full Year 2018 Financial Results

*Fourth Quarter Revenue of \$23.4 million, representing 38% growth over prior year
Full year 2018 Revenue of \$83.9 million, representing 39% growth over prior year*

ALACHUA, FL – February 26, 2018 – Axogen, Inc. (NASDAQ: AXGN), a global leader in developing and marketing innovative surgical solutions for damage or transection to peripheral nerves, today reported financial results and business highlights for the fourth quarter and full year ended December 31, 2018.

Fourth Quarter 2018 Financial Results and Recent Business Highlights

- Revenue of \$23.4 million, up 38% compared to fourth quarter 2017 revenue of \$17.0 million
- Gross margin of 84.5% compared to 84.6% in the fourth quarter of 2017
- Net loss for the quarter was \$5.2 million, or \$0.13 per share, compared to net loss of \$2.5 million, or \$0.07 per share in the fourth quarter of 2017
- Adjusted net loss for the fourth quarter of 2018 was \$3.6 million, or \$0.09 per share, compared with adjusted net loss of \$1.4 million, or \$0.04 per share, in the fourth quarter of 2017
- Adjusted EBITDA loss of \$4.0M compared to Adjusted EBITDA loss of \$531,000 in the fourth quarter of 2017
- Appointed Eric Sandberg to Chief Commercial Officer, and Chris Crisman to Vice President, U.S. Sales
- Achieved the current enrollment target of 170 subjects in the RECON study in support of the Company's BLA application for Avance® Nerve Graft and initiated the planned blinded interim analysis

“We continue to see momentum in our core trauma, oral and maxillofacial, and breast reconstruction neurotization markets,” said Karen Zaderej, chairman, chief executive officer, and president of Axogen. “Looking ahead, we believe the investments made in 2018, including our strengthened and expanded commercial capabilities, will allow us to drive sharper and more consistent execution. I am confident in our ability to deliver another successful year as we continue to grow our core markets and develop expansion markets.”

Regarding the RECON study, as required by the statistical analysis plan and agreed to by the FDA and Axogen, a blinded independent statistical analysis was conducted to determine if greater study enrollment is appropriate. The interim analysis looks only at the pooled standard

deviation of the first 80 enrolled subjects and does not include an interim look at outcomes. Axogen is working with the FDA to review the interim analysis findings and obtain agreement on the next phase of the study.

Additional Fourth Quarter and Recent Operational Highlights

- Increased active accounts in the fourth quarter to 712, up 20% from 591 a year ago
- Ended the quarter with 85 direct sales representatives and 17 independent distributors
- Conducted six national education courses in the fourth quarter
- Increased the number of clinical publications related to the Axogen surgical portfolio to a total of 77
- Ended the quarter with \$122.6 million in cash, cash equivalents, and investments compared to \$126.4 million at the end of the third quarter of 2018

Full Year 2018 Summary Financial Results and Business Highlights

- 2018 revenue of \$83.9 million, an increase of 39% compared to \$60.4 million for the prior year
- Gross margin of 84.6%, consistent with gross margin in 2017
- Net loss of \$22.4 million, or \$0.60 per share, compared to net loss of \$10.4 million, or \$0.31 per share in 2017
- Adjusted net loss \$12.6 million, or \$0.34 per share, compared with adjusted net loss of \$6.8 million, or \$0.21 per share in 2017
- Adjusted EBITDA loss of \$12.1 million compared to adjusted EBITDA loss of \$3.8 million in 2017
- Updated total addressable market estimate for current applications to \$2.7 billion
- Announced market development and clinical initiatives for a new application, the surgical treatment of chronic neuropathic pain
- Granted Regenerative Medicine Advanced Therapy (RMAT) designation by U.S. Food and Drug Administration in support of the biologic license application (BLA) for Avance® Nerve Graft
- Completed 18 national education programs in 2018 and expect to conduct 25 programs in 2019
- Expanded leadership team, increasing capabilities for long term sustainable growth
- Initiated plans to secure long term capacity needs for production, office, and lab space
- Raised \$132.7 million in net proceeds through a public offering of common stock on May 9, 2018
- Repaid in full outstanding debt of \$25.0 million with MidCap Financial on May 22, 2018

Updating 2019 Financial Guidance and Disclosure

Going forward, the Company will be providing revenue guidance as a dollar range. The Company now expects 2019 revenue will be between \$109 million and \$114 million. Management reiterates its expectation for gross margin to remain above 80%. Additionally, we expect to have at least 115 direct sales representatives by year-end.

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 transection 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, a biologically active 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," "goals," 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 growth, our 2019 guidance, product development, product potential, financial performance, sales growth, product adoption, market awareness of our products, data validation, our assessment of our internal controls over financial reporting, our visibility at and sponsorship of conferences and educational events. The forward-looking statements are and will be subject to risks and uncertainties, which may cause actual results to differ materially from those expressed or implied in such forward-looking statements. Forward-looking statements contained in this press release should be evaluated together with the many uncertainties that affect our business and our market, particularly those discussed under Part I, Item 1A., "Risk Factors," of our Annual Report on Form 10-K for the fiscal year ended December 31, 2018, as well as other risks and cautionary statements set forth in our filings with the U.S. Securities and Exchange Commission. Forward-looking statements are not a guarantee 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 applicable law, we assume no responsibility to publicly update or revise any forward-looking statements, whether as a result of new information, future events, changed circumstances, 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. We also use the non-GAAP financial measures of Adjusted Net Loss and Adjusted Net Loss Per Common Share - basic and diluted which excludes non-cash stock compensation expense and loss on extinguishment of debt from Net Loss and Net Loss Per Common Share - basic and diluted, respectively. 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 to 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.

Contact:

Axogen, Inc.

Kaila Krum, Vice President, Investor Relations and Corporate Development

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InvestorRelations@AxogenInc.com

AXOGEN, INC.
CONSOLIDATED BALANCE SHEETS
(In Thousands, Except Share Amounts)

	<u>December 31,</u> <u>2018</u>	<u>December 31,</u> <u>2017</u>
Assets		
Current assets:		
Cash and cash equivalents	\$ 24,294	\$ 36,507
Restricted cash	6,000	—
Investments	92,311	—
Accounts receivable, net	15,321	11,065
Inventory	11,982	7,316
Prepaid expenses and other	1,045	853
Total current assets	<u>150,953</u>	<u>55,741</u>
Property and equipment, net	8,039	2,197
Intangible assets	1,181	937
	<u>\$ 160,173</u>	<u>\$ 58,875</u>
 Liabilities and Shareholders' Equity		
Current liabilities:		
Borrowings under revolving loan agreement	\$ —	\$ 4,000
Accounts payable and accrued expenses	12,998	8,952
Current maturities of long term obligations	28	735
Contract liabilities, current	18	32
Total current liabilities	<u>13,044</u>	<u>13,719</u>
Long Term Obligations, net of current maturities and deferred financing fees	35	19,810
Other long-term liabilities	70	95
Contract liabilities	42	69
Total liabilities	<u>13,191</u>	<u>33,693</u>
Shareholders' equity:		
Common stock, \$.01 par value; 100,000,000 shares authorized; 38,900,875 and 34,350,329 shares issued and outstanding	389	343
Additional paid-in capital	297,319	153,168
Accumulated deficit	(150,726)	(128,329)
Total shareholders' equity	<u>146,982</u>	<u>25,182</u>
Total liabilities and shareholders' equity	<u>\$ 160,173</u>	<u>\$ 58,875</u>

AXOGEN, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS
Three Months and Years ended December 31, 2018 and 2017
(In Thousands, Except per Share Amounts)

	Three Months Ended		Years Ended	
	December 31, 2018	December 31, 2017	December 31, 2018	December 31, 2017
Revenues	\$ 23,433	\$ 16,971	\$ 83,937	\$ 60,426
Cost of goods sold	3,640	2,614	12,923	9,311
Gross profit	19,793	14,357	71,014	51,115
Costs and expenses:				
Sales and marketing	15,462	10,121	56,617	37,636
Research and development	3,807	1,972	11,773	6,699
General and administrative	6,373	4,071	23,124	14,731
Total costs and expenses	25,642	16,164	91,514	59,066
Loss from operations	(5,849)	(1,807)	(20,500)	(7,951)
Other income (expense):				
Investment income	641	—	1,525	—
Interest expense	(3)	(577)	(1,127)	(2,217)
Interest expense—deferred financing costs	—	(110)	(81)	(246)
Loss on extinguishment of debt	—	—	(2,186)	—
Other income (expense)	(13)	(5)	(28)	(31)
Total other income (expense)	625	(692)	(1,897)	(2,494)
Net loss	\$ (5,224)	\$ (2,499)	\$ (22,397)	\$ (10,445)
Weighted Average Common Shares outstanding – basic and diluted	38,745	33,846	37,127	33,323
Loss Per Common share - basic and diluted	\$ (0.13)	\$ (0.07)	\$ (0.60)	\$ (0.31)
Adjusted net loss	\$ (3,599)	\$ (1,382)	\$ (12,605)	\$ (6,836)
Adjusted loss per Common share - basic and diluted	\$ (0.09)	\$ (0.04)	\$ (0.34)	\$ (0.21)

AXOGEN, INC.
RECONCILIATION OF GAAP FINANCIAL MEASURES TO NON-GAAP FINANCIAL MEASURES
Three Months and Years ended December 31, 2018 and 2017
(In Thousands, Except per Share Amounts)

	Three Months Ended		Years Ended	
	December 31, 2018	December 31, 2017	December 31, 2018	December 31, 2017
Net loss	\$ (5,224)	\$ (2,499)	\$ (22,397)	\$ (10,445)
Depreciation and amortization expense	199	141	774	488
Amortization expense of intangible assets	18	18	77	79
Income taxes	—	5	13	29
Investment income	(641)	—	(1,525)	—
Interest expense	—	577	2,637	2,217
Interest expense - deferred financing costs	—	110	754	246
EBITDA - non GAAP	\$ (5,648)	\$ (1,648)	\$ (19,667)	\$ (7,386)
Non Cash Stock Compensation Expense	1,625	1,117	7,606	3,609
Adjusted EBITDA - non GAAP	\$ (4,023)	\$ (531)	\$ (12,061)	\$ (3,777)
Net loss	\$ (5,224)	\$ (2,499)	\$ (22,397)	\$ (10,445)
Loss on extinguishment of debt	—	—	2,186	—
Non cash stock compensation expense	1,625	1,117	7,606	3,609
Adjusted Net Loss - non GAAP	\$ (3,599)	\$ (1,382)	\$ (12,605)	\$ (6,836)
Weighted Average Common Shares outstanding – basic and diluted	38,745	33,846	37,127	33,323
Adjusted net loss per Common share - basic and diluted	\$ (0.09)	\$ (0.04)	\$ (0.34)	\$ (0.21)

AXOGEN, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS
Years ended December 31, 2018 and 2017
(In Thousands)

	<u>2018</u>	<u>2017</u>
Cash flows from operating activities:		
Net loss	\$ (22,397)	\$ (10,445)
Adjustments to reconcile net loss to net cash used for operating activities:		
Depreciation	774	488
Amortization of intangible assets	77	79
Amortization of deferred financing costs	81	246
Loss on disposal of equipment	1	—
Loss on extinguishment of debt	2,186	—
Provision for bad debts	852	223
Provision for inventory write down	1,343	1,438
Changes in investment gains and losses	(721)	—
Share-based compensation	7,606	3,609
Change in assets and liabilities:		
Accounts receivable	(5,108)	(3,236)
Inventory	(6,009)	(3,295)
Prepaid expenses and other	(192)	(342)
Accounts payable and accrued expenses	3,711	1,927
Contract and other liabilities	(66)	70
Net cash used for operating activities	<u>(17,862)</u>	<u>(9,238)</u>
Cash flows from investing activities:		
Purchase of property and equipment	(6,282)	(1,105)
Purchase of investments	(114,736)	—
Sale of investments	23,146	—
Acquisition of intangible assets	(321)	(187)
Net cash used for investing activities	<u>(98,193)</u>	<u>(1,292)</u>
Cash flows from financing activities:		
Proceeds from issuance of common stock	132,964	15,891
Cash paid for equity offering	(257)	(228)
Borrowing on revolving loan	26,253	57,599
Payments on revolving loan	(30,489)	(57,624)
Repayments of long-term debt	(22,513)	(21)
Debt issuance costs	—	(29)
Proceeds from exercise of stock options	3,884	1,434
Net cash provided by financing activities	<u>109,842</u>	<u>17,022</u>
Net (decrease) increase in cash, cash equivalents and restricted cash	(6,213)	6,492
Cash, cash equivalents, and restricted cash beginning of year	<u>36,507</u>	<u>30,015</u>
Cash, cash equivalents, and restricted cash end of year	<u>\$ 30,294</u>	<u>\$ 36,507</u>
Supplemental disclosures of cash flow activity:		
Cash paid for interest	\$ 1,325	\$ 2,198
Supplemental disclosure of non-cash investing and financing activities:		
Payments of fixed assets in accounts payable and accrued expenses	\$ 335	\$ 55
Capital lease additions	\$ —	\$ 62