
**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 8, 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,)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class:	Trading Symbol	Name of each exchange on which registered:
Common Stock, \$0.01 par value	AXGN	The Nasdaq Stock Market

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 8, 2019, Axogen, Inc. (“Axogen”) issued a press release announcing its financial results for the quarter and three months ended March 31, 2019. 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 May 8, 2019.</u>

SIGNATURE

Pursuant to the requirements of the Exchange Act, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

AXOGEN, INC.

Date: May 8, 2019

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



Axogen, Inc. Reports 2019 First Quarter Financial Results

First Quarter Revenue of \$23.3 million, representing 35% growth versus first quarter 2018

ALACHUA, FL – May 8, 2019 – 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 first quarter ended March 31, 2019.

First Quarter 2019 Financial Results and Recent Business Highlights

- Revenue of \$23.3 million, an increase of 35% compared to first quarter 2018 revenue of \$17.3 million
- Gross margin of 84.0% compared to 84.3% in the first quarter of 2018
- Net loss for the quarter was \$9.5 million, or \$0.24 per share, compared to net loss of \$5.6 million, or \$0.16 per share in the first quarter of 2018
- Adjusted net loss for the first quarter of 2019 was \$6.0 million, or \$0.15 per share, compared with adjusted net loss of \$3.9 million, or \$0.11 per share, in the first quarter of 2018
- Adjusted EBITDA loss of \$6.5 million compared to Adjusted EBITDA loss of \$3.1 million in the first quarter of 2018
- Completed planned blinded interim analysis for its RECON[®] Study, with 50 additional patients to be enrolled by the summer of 2020
- Increased the number of members who may serve on our Board of Directors to nine and appointed two new Board members: Quentin S. Blackford, executive vice president and chief financial officer of Dexcom, and Alan M. Levine, chairman, president, and chief executive officer of Ballard Health

“We are pleased with our start to the year, and the progress we’ve made strengthening and expanding our commercial capabilities,” said Karen Zaderej, chairman, chief executive officer, and president of Axogen. “We continue to make investments across our broader capabilities, including additional clinical and product development programs.”

Additional First Quarter and Recent Operational Highlights

- Increased active accounts in the first quarter to 731, up 21% from 604 a year ago
- Ended the quarter with 93 direct sales representatives and 18 independent agencies
- Conducted three national education courses in the first quarter, including one Fellows program, and expect to conduct 25 programs in total during 2019
- Increased the number of clinical publications related to the Axogen surgical portfolio to a total of 91
- Ended the quarter with \$113.8 million in cash, cash equivalents, and investments compared to \$122.6 million at the end of the fourth quarter of 2018. The decrease of \$8.8 million in the quarter includes \$3.8 million for payment of the 2018 all-employee annual performance bonuses, awards and related costs

“We are seeing growing surgeon awareness of our clinical data that we believe will continue to drive adoption in our core trauma market,” noted Zaderej. “We are also pleased with continued surgeon response to our oral and maxillofacial application, forward momentum in our breast reconstruction neurotization market development, and early progress in our development work in the surgical treatment of pain. I am confident we are building strong capabilities to drive long-term, sustainable growth across an expanding set of nerve repair applications.”

2019 Financial Guidance

The Company continues to expect 2019 revenue will be between \$109 million and \$114 million. Management reiterates its expectation for gross margin to remain above 80%. Additionally, the Company expects 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.
CONDENSED CONSOLIDATED BALANCE SHEETS
(unaudited)
(in thousands except share and per share amounts)

	March 31, 2019	December 31, 2018
Assets		
Current assets:		
Cash and cash equivalents	\$ 23,522	\$ 24,294
Restricted cash	6,000	6,000
Investments	84,323	92,311
Accounts receivable, net	15,193	15,321
Inventory	13,120	11,982
Prepaid expenses and other	3,471	1,045
Total current assets	145,629	150,953
Property and equipment, net	9,158	8,039
Operating lease right-of-use assets	4,437	—
Finance lease right-of-use assets	104	—
Intangible assets	1,164	1,181
Total assets	\$ 160,492	\$ 160,173
Liabilities and Shareholders' Equity		
Current liabilities:		
Accounts payable and accrued expenses	\$ 15,107	\$ 12,998
Current maturities of long-term obligations	1,361	28
Contract liabilities, current	24	18
Total current liabilities	16,492	13,044
Long-term obligations, net of current maturities and deferred financing fees	3,223	35
Other long-term liabilities	—	70
Contract liabilities	34	42
Total liabilities	19,749	13,191
Shareholders' equity:		
Common stock, \$.01 par value per share; 50,000,000 shares authorized; 39,128,843 and 38,900,875 shares issued and outstanding	391	389
Additional paid-in capital	300,582	297,319
Accumulated deficit	(160,230)	(150,726)
Total shareholders' equity	140,743	146,982
Total liabilities and shareholders' equity	\$ 160,492	\$ 160,173

AXOGEN, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
Three Months ended March 31, 2019 and 2018
(unaudited)
(in thousands except share and per share amounts)

	Three Months Ended	
	March 31, 2019	March 31, 2018
Revenues	\$ 23,285	\$ 17,260
Cost of goods sold	3,714	2,712
Gross profit	19,571	14,548
Costs and expenses:		
Sales and marketing	16,434	12,469
Research and development	4,139	2,058
General and administrative	9,201	5,012
Total costs and expenses	29,774	19,539
Loss from operations	(10,203)	(4,991)
Other income (expense):		
Investment income	716	-
Interest expense	(14)	(586)
Interest expense - deferred financing costs	—	(61)
Other expense	(3)	(1)
Total other income (expense)	699	(648)
Net loss	\$ (9,504)	\$ (5,639)
Weighted Average Common Shares outstanding – basic and diluted	38,933,984	34,521,122
Loss Per Common share – basic and diluted	\$ (0.24)	\$ (0.16)
Adjusted Net Loss	(6,004)	(3,910)
Adjusted Net Loss Per Common Share - basic and diluted	\$ (0.15)	\$ (0.11)

AXOGEN, INC.
RECONCILIATION OF GAAP FINANCIAL MEASURES TO NON-GAAP FINANCIAL MEASURES
Three Months ended March 31, 2019 and 2018
(unaudited)
(in thousands except share and per share amounts)

	Three Months Ended	
	March 31, 2019	March 31, 2018
Net loss	\$ (9,504)	\$ (5,639)
Depreciation and amortization expense	251	260
Investment income	(716)	—
Interest expense	14	586
EBITDA - non GAAP	<u>\$ (9,955)</u>	<u>\$ (4,793)</u>
Non Cash Stock Compensation Expense	2,315	1,729
Litigation and related costs	1,185	—
Adjusted EBITDA - non GAAP	<u>\$ (6,455)</u>	<u>\$ (3,064)</u>
Net loss	\$ (9,504)	\$ (5,639)
Non Cash Stock Compensation Expense	2,315	1,729
Litigation and related costs	1,185	—
Adjusted Net Loss - non GAAP	<u>\$ (6,004)</u>	<u>\$ (3,910)</u>
Weighted Average Common Shares outstanding – basic and diluted	<u>38,933,984</u>	<u>34,521,122</u>
Adjusted Net Loss Per Common Share - basic and diluted	<u>\$ (0.15)</u>	<u>\$ (0.11)</u>

AXOGEN, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CHANGES IN SHAREHOLDERS' EQUITY
Three Months ended March 31, 2019 and 2018
(unaudited)
(in thousands except share and per share amounts)

	Common Stock	Additional Paid- in Capital	Accumulated Deficit	Total Shareholders' Equity
Balance at December 31, 2017	\$ 344	\$ 153,167	\$ (128,329)	\$ 25,182
Net Loss	—	—	(5,639)	(5,639)
Stock-based compensation	—	1,729	—	1,729
Exercise of stock options	3	416	—	419
Balance at March 31, 2018	\$ 347	\$ 155,312	\$ (133,968)	\$ 21,691
Balance at December 31, 2018	\$ 389	\$ 297,319	\$ (150,726)	\$ 146,982
Net Loss	—	—	(9,504)	(9,504)
Stock-based compensation	—	2,315	—	2,315
Exercise of stock options	2	948	—	950
Balance at March 31, 2019	\$ 391	\$ 300,582	\$ (160,230)	\$ 140,743

AXOGEN, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
Three Months ended March 31, 2019 and 2018
(unaudited)
(in thousands except share and per share amounts)

	Three Months Ended	
	March 31, 2019	March 31, 2018
Cash flows from operating activities:		
Net loss	\$ (9,504)	\$ (5,639)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	211	180
Amortization of right-of-use assets	437	—
Amortization of intangible assets	26	20
Amortization of deferred financing costs	—	61
Provision for bad debt	16	57
Inventory write-downs	444	354
Unrealized (gains) losses on short term investments	(294)	—
Share-based compensation	2,315	1,729
Change in assets and liabilities:		
Accounts receivable	112	(759)
Inventory	(1,582)	(1,091)
Prepaid expenses and other	(1,783)	(502)
Accounts payable and accrued expenses	1,161	(241)
Cash paid for Operating Leases	(423)	—
Cash paid for interest portion of Finance Leases	(1)	—
Contract and other liabilities	(2)	(13)
Net cash used in operating activities	(8,867)	(5,844)
Cash flows from investing activities:		
Purchase of property and equipment	(478)	(360)
Sale of investments	57,171	—
Purchase of investments	(48,914)	—
Acquisition of intangible assets	(9)	(141)
Net cash provided by / (used for) investing activities	7,770	(501)
Cash flows from financing activities:		
Borrowing on revolving loan	—	16,146
Payments on revolving loan	—	(16,163)
Repayments of long term debt	—	(3)
Cash paid for debt portion of Finance Leases	(7)	—
Proceeds from exercise of stock options and warrants	332	419
Net cash provided by financing activities	325	399
Net decrease in cash, cash equivalents, and restricted cash	(772)	(5,947)
Cash, cash equivalents, and restricted cash, beginning of period	30,294	36,507
Cash, cash equivalents, and restricted cash, end of period	\$ 29,522	\$ 30,560
Supplemental disclosures of cash flow activity:		
Cash paid for interest	\$ 14	\$ 577
Supplemental disclosure of non-cash investing and financing activities		
Payments of fixed assets in accounts payable and accrued expenses	\$ 946	\$ —
Proceeds from stock option exercise in Other Receivables	\$ 618	\$ —