

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 6, 2019

**AXOGEN, INC.**

(Exact name of registrant as specified in its charter)

<b>Minnesota</b> (State or other jurisdiction of incorporation)	<b>001-36046</b> (Commission File Number)	<b>41-1301878</b> (IRS Employer Identification No.)
<b>13631 Progress Boulevard, Suite 400, Alachua, Florida</b> (Address of Principal Executive Offices)		<b>32615</b> (Zip Code)
Registrant's telephone number, including area code		
<b>(386) 462-6800</b> (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.

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

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

**Item 2.02 Results of Operations and Financial Condition**

On November 6, 2019, Axogen, Inc. (the “Company”) issued a press release announcing its financial results for the third quarter and nine months ended September 30, 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	<a href="#">Axogen, Inc. Press Release, dated November 6, 2019.</a>
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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**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: November 6, 2019

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

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## Axogen, Inc. Reports 2019 Third Quarter Financial Results

**ALACHUA, FL – November 6, 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 third quarter ended September 30, 2019.

### Third Quarter 2019 Financial Results:

- Net sales were \$28.6 million during the quarter, an increase of 26.1% compared to third quarter 2018 revenue of \$22.7 million.
- Gross margin was 84.2% for the quarter, compared to 84.7% in the third quarter of 2018.
- Net loss for the quarter was \$5.6 million, or \$0.14 per share, compared to net loss of \$4.1 million, or \$0.11 per share in the third quarter of 2018.
- Adjusted net loss was \$2.6 million for the quarter, or \$0.07 per share, compared with adjusted net loss of \$1.9 million, or \$0.05 per share, in the third quarter of 2018.
- Adjusted EBITDA loss was \$3.0 million for the quarter, compared to adjusted EBITDA loss of \$2.4 million in the third quarter of 2018.
- Ended the quarter with \$106.1 million in cash, cash equivalents, and investments, compared to \$109.1 million at the end of the second quarter of 2019.

“We delivered solid financial results during the quarter, and I am pleased with the progress we are making to improve our commercial operations,” commented Karen Zaderej, chairman, CEO, and president. “We are rebalancing our efforts toward our largest market opportunity, extremity trauma, which represents the most efficient and effective path to sustainable long-term growth. We will continue to invest in the breast reconstruction neurotization and oral and maxillofacial markets and expect to expand these efforts as these nascent markets continue to develop. Additionally, we are slowing the rate of sales force expansion to enable further productivity gains across our existing commercial footprint. We are encouraged with the early results of these initiatives and will continue to evaluate and build upon them throughout the remainder of the year and into 2020.”

### Additional Third Quarter 2019 Operational and Clinical Updates:

- Increased active accounts in the third quarter to 791, up 16% from 679 a year ago.
  - Ended the quarter with 105 direct sales representatives and 19 independent agencies.
  - Conducted four national education programs in the third quarter, including one OMF specialty program, and expect to conduct 25 programs in total during 2019.
  - Added five peer reviewed clinical publications to our surgical portfolio for a total of 105.
  - Increased the number of presentations at clinical and scientific conferences related to our surgical portfolio by 14, for a total of 44 year-to-date.
  - The following updates were provided by clinical investigators at the 2019 American Society for Surgery of the Hand (ASSH) meeting:
    - o Updated data from the RANGER® registry, including 511 upper extremity nerve repairs, demonstrate a consistent meaningful recovery rate for Avance® Nerve Graft of 84%
    - o Findings from the MATCH<sup>SM</sup> study show Avance Nerve Graft had statistically significant improvements as compared to synthetic conduits in three essential areas: the rate of recovery,
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the overall degree of recovery, and in average recovery of static two-point discrimination, a key sensory measure in the hand

### **2019 Financial Guidance**

The Company continues to expect 2019 revenue will be between \$106 million and \$110 million. Management reiterates its expectation for gross margin to remain above 80%. Additionally, the Company now expects to have between 105 and 110 direct sales representatives by year-end, compared to its previous estimate of at least 115.

### **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](http://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](http://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<sup>®</sup> 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<sup>®</sup> Nerve Connector, a porcine submucosa extracellular matrix (ECM) coaptation aid for tensionless repair of severed peripheral nerves; Axoguard<sup>®</sup> 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<sup>®</sup> Soft Tissue Membrane, a processed human umbilical cord intended for surgical use as a resorbable soft tissue barrier. 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,

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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 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.  
**Peter J. Mariani, Chief Financial Officer**  
pmariani@axogeninc.com  
InvestorRelations@AxogenInc.com

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**AXOGEN, INC.**  
**CONDENSED CONSOLIDATED BALANCE SHEETS**  
(unaudited)

	September 30, 2019	December 31, 2018
<b>Assets</b>		
<b>Current assets:</b>		
Cash and cash equivalents	\$ 24,555	\$ 24,294
Restricted Cash	6,000	6,000
Short-term investments	75,511	92,311
Accounts receivable, net	15,451	15,321
Inventory	13,682	11,982
Prepaid expenses and other	2,144	1,045
<b>Total current assets</b>	<b>137,343</b>	<b>150,953</b>
<b>Property and equipment, net</b>	<b>11,673</b>	<b>8,039</b>
<b>Operating lease right-of-use assets</b>	<b>3,595</b>	<b>—</b>
<b>Finance lease right-of-use assets</b>	<b>93</b>	<b>—</b>
<b>Intangible assets</b>	<b>1,488</b>	<b>1,181</b>
<b>Total assets</b>	<b>\$ 154,192</b>	<b>\$ 160,173</b>
<b>Liabilities and Shareholders' Equity</b>		
<b>Current liabilities:</b>		
Accounts payable and accrued expenses	\$ 14,970	\$ 12,998
Current maturities of long term obligations	1,773	28
Contract liabilities, current	14	18
<b>Total current liabilities</b>	<b>16,757</b>	<b>13,044</b>
<b>Long-term obligations, net of current maturities and deferred financing fees</b>	<b>2,002</b>	<b>35</b>
<b>Other long-term liabilities</b>	<b>-</b>	<b>70</b>
<b>Contract liabilities</b>	<b>22</b>	<b>42</b>
<b>Total liabilities</b>	<b>18,781</b>	<b>13,191</b>
<b>Shareholders' equity:</b>		
Common stock, \$.01 par value; 100,000,000 shares authorized; 39,461,318 and 38,900,875 shares issued and outstanding	395	389
Additional paid-in capital	307,839	297,319
Accumulated deficit	(172,823)	(150,726)
<b>Total shareholders' equity</b>	<b>135,411</b>	<b>146,982</b>
<b>Total liabilities and shareholders' equity</b>	<b>\$ 154,192</b>	<b>\$ 160,173</b>

**AXOGEN, INC.**  
**CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS**  
**Three and Nine Months ended September 30, 2019 and 2018**  
**(unaudited)**

	Three Months Ended		Nine Months Ended	
	September 30, 2019	September 30, 2018	September 30, 2019	September 30, 2018
<b>Revenues</b>	\$ 28,564	\$ 22,660	\$ 78,550	\$ 60,504
<b>Cost of goods sold</b>	4,510	3,464	12,468	9,282
<b>Gross profit</b>	24,054	19,196	66,082	51,222
<b>Costs and expenses:</b>				
Sales and marketing	18,245	14,653	53,146	41,149
Research and development	4,181	3,307	12,602	7,967
General and administrative	7,740	6,071	24,321	16,751
<b>Total costs and expenses</b>	30,166	24,031	90,069	65,867
<b>Loss from operations</b>	(6,112)	(4,835)	(23,987)	(14,645)
<b>Other income (expense):</b>				
Interest income	555	727	1,925	884
Interest expense	(7)	6	(32)	(1,124)
Interest expense – deferred financing costs	—	—	—	(81)
Loss on extinguishment of debt	—	—	—	(2,186)
Other expense	(7)	—	(3)	(16)
<b>Total other expense</b>	541	733	1,890	(2,523)
<b>Net loss</b>	\$ (5,571)	\$ (4,102)	\$ (22,097)	\$ (17,168)
Weighted average common shares outstanding – basic and diluted	39,340	38,505	39,151	36,582
Loss per common share – basic and diluted	\$ (0.14)	\$ (0.11)	\$ (0.56)	\$ (0.47)
<b>Adjusted net loss - non GAAP</b>	(2,644)	(1,891)	(12,386)	(9,001)
Adjusted net loss per common share - basic and diluted	\$ (0.07)	\$ (0.05)	\$ (0.32)	\$ (0.25)

**AXOGEN, INC.**  
**RECONCILIATION OF GAAP FINANCIAL MEASURES TO NON-GAAP FINANCIAL MEASURES**  
**Three and Nine Months ended September 30, 2019 and 2018**  
**(unaudited)**

	Three Months Ended		Nine Months Ended	
	September 30, 2019	September 30, 2018	September 30, 2019	September 30, 2018
<b>Net loss</b>	\$ (5,571)	\$ (4,102)	\$ (22,097)	\$ (17,168)
Depreciation and amortization expense	244	219	757	634
Investment income	(555)	(727)	(1,925)	(884)
Income tax	(3)	—	(15)	13
Interest expense	7	(6)	32	3,391
<b>EBITDA - non GAAP</b>	<b>\$ (5,878)</b>	<b>\$ (4,616)</b>	<b>\$ (23,248)</b>	<b>\$ (14,014)</b>
Non cash stock compensation expense	\$ 2,395	\$ 2,211	\$ 7,384	\$ 5,981
Litigation and related costs	532	—	2,327	—
<b>Adjusted EBITDA - non GAAP</b>	<b>\$ (2,951)</b>	<b>\$ (2,405)</b>	<b>\$ (13,537)</b>	<b>\$ (8,033)</b>
<b>Net loss</b>	\$ (5,571)	\$ (4,102)	\$ (22,097)	\$ (17,168)
Non cash stock compensation expense	2,395	2,211	7,384	5,981
Litigation and related costs	532	—	2,327	—
Loss on extinguishment of debt	—	—	—	2,186
<b>Adjusted Net Loss - non GAAP</b>	<b>\$ (2,644)</b>	<b>\$ (1,891)</b>	<b>\$ (12,386)</b>	<b>\$ (9,001)</b>
Weighted average common shares outstanding – basic and diluted	39,340	38,505	39,151	36,582
Adjusted net loss per common share - basic and diluted	\$ (0.07)	\$ (0.05)	\$ (0.32)	\$ (0.25)

**AXOGEN, INC.**  
**CONDENSED CONSOLIDATED STATEMENTS OF CHANGES IN SHAREHOLDERS' EQUITY**  
**Nine Months Ended September 30, 2019 and 2018**  
**(unaudited)**

	Common Stock	Additional Paid-in Capital	Accumulated Deficit	Total Shareholders' Equity
<b>For the Three Months Ended September 30, 2019:</b>				
<b>Balance at June 30, 2019</b>	\$ 393	\$ 304,819	\$ (167,252)	\$ 137,960
Net loss	—	—	(5,571)	(5,571)
Issuance of common stock	—	—	—	—
Stock-based compensation	—	2,397	—	2,397
Exercise of stock options and employee stock purchase plan	2	623	—	625
<b>Balance at September 30, 2019</b>	<u>\$ 395</u>	<u>\$ 307,839</u>	<u>\$ (172,823)</u>	<u>\$ 135,411</u>
<b>For the Nine Months Ended September 30, 2019:</b>				
<b>Balance at December 31, 2018</b>	\$ 389	\$ 297,319	\$ (150,726)	\$ 146,982
Net loss	—	—	(22,097)	(22,097)
Stock-based compensation	—	7,384	—	7,384
Exercise of stock options and employee stock purchase plan	6	3,136	—	3,142
<b>Balance at September 30, 2019</b>	<u>\$ 395</u>	<u>\$ 307,839</u>	<u>\$ (172,823)</u>	<u>\$ 135,411</u>
<b>For the Three Months Ended September 30, 2018:</b>				
<b>Balance at June 30, 2018</b>	\$ 383	\$ 291,515	\$ (141,395)	\$ 150,503
Net loss	—	—	(4,102)	(4,102)
Issuance of common stock	—	—	—	—
Stock-based compensation	—	2,211	—	2,211
Exercise of stock options and employee stock purchase plan	4	863	—	867
<b>Balance at September 30, 2018</b>	<u>\$ 387</u>	<u>\$ 294,589</u>	<u>\$ (145,497)</u>	<u>\$ 149,479</u>
<b>For the Nine Months Ended September 30, 2018:</b>				
<b>Balance at December 31, 2018</b>	\$ 343	\$ 153,169	\$ (128,329)	\$ 25,183
Net loss	—	—	(17,168)	(17,168)
Issuance of common stock	35	132,670	—	132,705
Stock-based compensation	—	5,981	—	5,981
Exercise of stock options and employee stock purchase plan	9	2,769	—	2,778
<b>Balance at September 30, 2018</b>	<u>\$ 387</u>	<u>\$ 294,589</u>	<u>\$ (145,497)</u>	<u>\$ 149,479</u>

**AXOGEN, INC.**  
**CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS**  
**Nine Months ended September 30, 2019 and 2018**  
**(unaudited)**

	Nine Months Ended	
	Sept 30, 2019	Sept 30, 2018
<b>Cash flows from operating activities:</b>		
Net loss	\$ (22,097)	\$ (17,168)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	631	575
Amortization of right-of-use assets	1,352	—
Amortization of intangible assets	89	59
Amortization of deferred financing costs	—	81
Loss on extinguishment of debt	—	2,186
Provision for bad debt	(150)	298
Provision for inventory write down	(44)	877
Change in investment gains and losses	(957)	(375)
Share-based compensation	7,384	5,981
Change in assets and liabilities:		
Accounts receivable	20	(3,223)
Inventory	(1,657)	(4,510)
Prepaid expenses and other	(1,099)	(624)
Accounts payable and accrued expenses	1,288	3,005
Operating Lease Obligations	(1,276)	—
Cash paid for interest portion of Finance Leases	(3)	—
Contract and other liabilities	(23)	(48)
<b>Net cash used in operating activities</b>	<b>(16,542)</b>	<b>(12,886)</b>
<b>Cash flows from investing activities:</b>		
Purchase of short-term investments	(104,314)	(103,865)
Purchase of property and equipment	(3,676)	(6,052)
Sale/Maturities of short-term investments	122,071	3,500
Cash payments for intangible assets	(396)	(320)
<b>Net cash provided by/ (used for) investing activities</b>	<b>13,685</b>	<b>(106,737)</b>
<b>Cash flows from financing activities:</b>		
Proceeds from the issuance of common stock	—	132,963
Cash paid for equity offering	—	(257)
Borrowing on revolving loan	—	26,253
Payments on revolving loan and prepayment penalties	—	(30,489)
Repayments of long term debt and prepayment penalties	—	(22,503)
Cash paid for debt portion of finance leases	(24)	—
Proceeds from exercise of stock options and warrants	3,142	2,778
<b>Net cash provided by financing activities</b>	<b>3,118</b>	<b>108,745</b>
Net increase in cash, cash equivalents and restricted cash	261	(10,878)
<b>Cash, cash equivalents and restricted cash, beginning of year</b>	<b>30,294</b>	<b>36,507</b>
<b>Cash, cash equivalents and restricted cash, end of period</b>	<b>\$ 30,555</b>	<b>\$ 25,629</b>
<b>Supplemental disclosures of cash flow activity:</b>		
Cash paid for interest	31	1,322
<b>Supplemental disclosure of non-cash investing and financing activities</b>		
Acquisition of fixed assets in accounts payable and accrued expenses	684	—
Right-of-use asset and operating lease liability	26	—