

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 24, 2020

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))

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

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 24, 2020, Axogen, Inc. (the “Company”) issued a press release announcing its fourth quarter and full year 2019 revenue. A copy of the press release is furnished as Exhibit 99.1.

The information furnished pursuant to Item 2.02 of this Current Report on Form 8-K, including Exhibit 99.1 hereto, shall not be deemed “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 (the “Securities Act”), 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 February 24, 2020.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURES

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: February 24, 2020

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



Axogen, Inc. Reports Fourth Quarter and Full-Year 2019 Financial Results

ALACHUA, FL – February 24, 2020 – 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 fourth quarter and full year ended December 31, 2019.

Fourth Quarter 2019 Financial Results and Business Highlights

- Net sales were \$28.1 million during the quarter, an increase of 20% compared to fourth quarter 2018 revenue of \$23.4 million.
- Gross margin was 82.7% for the quarter, compared to 84.4% in the fourth quarter of 2018.
- Net loss for the quarter was \$7.0 million, or \$0.18 per share, compared to a net loss of \$5.2 million, or \$0.13 per share, in the fourth quarter of 2018.
- Adjusted net loss was \$ 4.0 million for the quarter, or \$0.10 per share, compared with adjusted net loss of \$3.6 million, or \$0.09 per share, in the fourth quarter of 2018.
- Adjusted EBITDA loss was \$4.2 million for the quarter, compared to an adjusted EBITDA loss of \$4.0 million in the fourth quarter of 2018.
- The balance of cash, cash equivalents, and investments, on December 31, 2019 was \$102.5 million, compared to a balance of \$106.1 million on September 30, 2019.
- Revenue from the direct sales channel represented approximately 90% of total revenue in the fourth quarter, compared to approximately 85% in the fourth quarter of 2018.
- Active accounts in the fourth quarter were 797, an increase of 12%, compared to 712 in the fourth quarter a year ago.

“I am pleased with our fourth quarter and full-year performance. We delivered solid revenue growth and continued to make progress rebalancing and refocusing our commercial operation toward our largest market opportunity, extremity trauma,” commented Karen Zaderej, chairman, CEO, and president of Axogen, Inc. “I am confident that we have the right commercial strategy in place to drive strong surgeon adoption of our technology as we continue to develop the nerve repair market.”

Full-Year 2019 Financial Results and Business Highlights

- Full-year 2019 revenue was \$106.7 million, an increase of 27% compared to 2018 revenue of \$83.9 million.
 - Gross margin was 83.7% for the full year, compared to 84.6% in 2018.
 - Net loss for the full year was \$29.1 million, or \$0.74 per share, compared to \$22.4 million, or \$0.60 per share, in 2018.
 - Adjusted net loss was \$16.4 million for the full year, or \$0.42 per share, compared to \$12.6 million, or \$0.34 per share, in 2018.
 - Adjusted EBITDA loss was \$17.7 million for the full year, compared to an adjusted EBITDA loss of \$12.1 million in 2018.
 - Ended the year with 109 direct sales representatives, compared to 85 at the end of 2018.
 - RECON® Study enrollment progressed well in the second half of 2019 and we now believe the study enrollment will be completed by the end of June 2020. We anticipate the data report-out for RECON will occur in Q3 of 2022.
 - Ended the year with 112 peer-reviewed clinical publications featuring Axogen’s nerve repair product portfolio.
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2020 Financial Guidance

Management reiterates that 2020 revenue will be in the range of \$124 million to \$128 million and expects that the number of direct sales representatives will increase to between approximately 126 and 131. Additionally, management expects gross margin to remain above 80% and that operating margin will see moderate improvement year over year.

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. Axogen employees 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; Axoguard[®] Nerve Cap, a porcine submucosa ECM product used to protect a peripheral nerve end and separate the nerve from the surrounding environment to reduce the development of symptomatic or painful neuroma; and Avive[®] 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, South Korea, 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 2020 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, 2019, 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

AXOGEN, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(unaudited)

	December 31, 2019	December 31, 2018
Assets		
Current assets:		
Cash and cash equivalents	\$ 35,724	\$ 24,294
Restricted Cash	6,000	6,000
Investments	60,786	92,311
Accounts receivable, net	16,944	15,321
Inventory	13,861	11,982
Prepaid expenses and other	1,706	1,045
Total current assets	135,021	150,953
Property and equipment, net	14,887	8,039
Operating lease right-of-use assets	3,133	—
Finance lease right-of-use assets	87	—
Intangible assets	1,515	1,181
Total assets	\$ 154,643	\$ 160,173
Liabilities and Shareholders' Equity		
Current liabilities:		
Accounts payable and accrued expenses	\$ 19,130	\$ 12,998
Current maturities of long term obligations	1,736	28
Contract liabilities, current	14	18
Total current liabilities	20,880	13,044
Long-term obligations, net of current maturities and deferred financing fees	1,595	35
Other long-term liabilities	—	70
Contract liabilities	15	42
Total liabilities	22,490	13,191
Shareholders' equity:		
Common stock, \$.01 par value; 100,000,000 shares authorized; 39,589,755 and 38,900,875 shares issued and outstanding	396	389
Additional paid-in capital	311,618	297,319
Accumulated deficit	(179,861)	(150,726)
Total shareholders' equity	132,153	146,982
Total liabilities and shareholders' equity	\$ 154,643	\$ 160,173

AXOGEN, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
Three and Twelve Months ended December 31, 2019 and 2018
(unaudited)

	Three Months Ended		Fiscal Year Ended	
	Dec 31, 2019	Dec 31, 2018	Dec 31, 2019	Dec 31, 2018
Revenues	\$ 28,162	\$ 23,433	\$ 106,712	\$ 83,937
Cost of goods sold	4,881	3,640	17,349	12,923
Gross profit	23,281	19,793	89,363	71,014
Costs and expenses:				
Sales and marketing	18,804	15,462	71,950	56,617
Research and development	4,912	3,807	17,514	11,773
General and administrative	6,984	6,373	31,305	23,124
Total costs and expenses	30,700	25,642	120,769	91,514
Loss from operations	(7,419)	(5,849)	(31,406)	(20,500)
Other income (expense):				
Interest income	439	641	2,364	1,525
Interest expense	(8)	(3)	(40)	(1,127)
Interest expense – deferred financing costs	—	—	—	(81)
Loss on extinguishment of debt	—	—	—	(2,186)
Other expense	(50)	(13)	(53)	(28)
Total other expense	381	625	2,271	(1,897)
Net loss	\$ (7,038)	\$ (5,224)	\$ (29,135)	\$ (22,397)
Weighted average common shares outstanding – basic and diluted	39,485	38,745	39,235	37,127
Loss per common share – basic and diluted	\$ (0.18)	\$ (0.13)	\$ (0.74)	\$ (0.60)
Adjusted net loss - non GAAP	(3,978)	(3,599)	(16,364)	(12,605)
Adjusted net loss per common share - basic and diluted	\$ (0.10)	\$ (0.09)	\$ (0.42)	\$ (0.34)

AXOGEN, INC.
RECONCILIATION OF GAAP FINANCIAL MEASURES TO NON-GAAP FINANCIAL MEASURES
Three and Twelve Months ended December 31, 2019 and 2018
(unaudited)

	Three Months Ended		Fiscal Year Ended	
	Dec 31, 2019	Dec 31, 2018	Dec 31, 2019	Dec 31, 2018
Net loss	\$ (7,038)	\$ (5,224)	\$ (29,135)	\$ (22,397)
Depreciation and amortization expense	299	217	1,056	851
Investment income	(439)	(641)	(2,364)	(1,525)
Income tax	(52)	—	(67)	13
Interest expense	8	—	40	3,391
EBITDA - non GAAP	\$ (7,222)	\$ (5,648)	\$ (30,470)	\$ (19,667)
Non cash stock compensation expense	2,920	1,625	10,304	7,606
Litigation and related costs	140	—	2,467	—
Adjusted EBITDA - non GAAP	\$ (4,162)	\$ (4,023)	\$ (17,699)	\$ (12,061)
Net loss	\$ (7,038)	\$ (5,224)	\$ (29,135)	\$ (22,397)
Non cash stock compensation expense	2,920	1,625	10,304	7,606
Litigation and related costs	140	—	2,467	—
Loss on extinguishment of debt	—	—	—	2,186
Adjusted Net Loss - non GAAP	\$ (3,978)	\$ (3,599)	\$ (16,364)	\$ (12,605)
Weighted average common shares outstanding – basic and diluted	39,485	38,745	39,235	37,127
Adjusted net loss per common share - basic and diluted	\$ (0.10)	\$ (0.09)	\$ (0.42)	\$ (0.34)

AXOGEN, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CHANGES IN SHAREHOLDERS' EQUITY
Fiscal Year Ended December 31, 2019 and 2018
(unaudited)

	Common Stock	Additional Paid-in Capital	Deficit Accumulated	Total Shareholders' Equity
For the Three Months Ended December 31, 2019:				
Balance at September 30, 2019	\$ 395	\$ 307,839	\$ (172,823)	\$ 135,411
Net Loss	—	—	(7,038)	(7,038)
Stock-based compensation	—	2,919	—	2,919
Exercise of stock options and employee stock purchase plan	1	860	—	861
Balance at December 31, 2019	<u>\$ 396</u>	<u>\$ 311,618</u>	<u>\$ (179,861)</u>	<u>\$ 132,153</u>
For the Fiscal Year Ended December 31, 2019:				
Balance at December 31, 2018	\$ 389	\$ 297,319	\$ (150,726)	\$ 146,982
Net Loss	—	—	(29,135)	(29,135)
Stock-based compensation	—	10,304	—	10,304
Exercise of stock options and employee stock purchase plan	7	3,995	—	4,002
Balance at December 31, 2019	<u>\$ 396</u>	<u>\$ 311,618</u>	<u>\$ (179,861)</u>	<u>\$ 132,153</u>
For the Three Months Ended December 31, 2018:				
Balance at September 30, 2018	\$ 387	\$ 294,589	\$ (145,497)	\$ 149,479
Net Loss	—	—	(5,224)	(5,224)
Issuance of common stock	—	—	—	—
Stock-based compensation	—	1,625	—	1,625
Exercise of stock options and employee stock purchase plan	2	1,105	—	1,107
Balance at December 31, 2018	<u>\$ 389</u>	<u>\$ 297,319</u>	<u>\$ (150,721)</u>	<u>\$ 146,987</u>
For the Fiscal Year Ended December 31, 2018:				
Balance at December 31, 2017	\$ 343	\$ 153,168	\$ (128,329)	\$ 25,182
Net Loss	—	—	(22,397)	(22,397)
Issuance of common stock	35	132,672	—	132,707
Stock-based compensation	—	7,606	—	7,606
Exercise of stock options and employee stock purchase plan	11	3,873	—	3,884
Balance at December 31, 2018	<u>\$ 389</u>	<u>\$ 297,319</u>	<u>\$ (150,726)</u>	<u>\$ 146,982</u>

AXOGEN, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
Fiscal Year Ended December 31, 2019 and 2018
(unaudited)

	Fiscal Year	
	December 31, 2019	December 31, 2018
Cash flows from operating activities:		
Net loss	\$ (29,135)	\$ (22,397)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	933	774
Amortization of right-of-use assets	1,821	—
Amortization of intangible assets	123	77
Write-down of trademark	104	—
Amortization of deferred financing costs	—	81
Loss on extinguishment of debt	—	2,186
Loss on disposal of property, plant and equipment	—	1
Provision for bad debt	514	852
Provision for inventory write down	1,887	1,343
Change in investment gains and losses	(972)	(721)
Share-based compensation	10,304	7,606
Change in assets and liabilities:		
Accounts receivable	(2,136)	(5,108)
Inventory	(3,767)	(6,009)
Prepaid expenses and other	(661)	(192)
Accounts payable and accrued expenses	2,920	3,711
Operating Lease Obligations	(1,773)	—
Cash paid for interest portion of Finance Leases	(4)	—
Contract and other liabilities	(30)	(66)
Net cash used in operating activities	(19,872)	(17,862)
Cash flows from investing activities:		
Purchase of short-term investments	(4,664)	(6,282)
Purchase of property and equipment	(121,074)	(114,736)
Sale/Maturities of short-term investments	153,571	23,146
Cash payments for intangible assets	(562)	(321)
Net cash provided by/ (used for) investing activities	27,271	(98,193)
Cash flows from financing activities:		
Proceeds from the issuance of common stock	—	132,964
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	—	(22,513)
Cash paid for debt portion of finance leases	29	—
Proceeds from exercise of stock options and warrants	4,002	3,884
Net cash provided by financing activities	4,031	109,842
Net increase in cash, cash equivalents and restricted cash	11,430	(6,213)
Cash, cash equivalents and restricted cash, beginning of year	30,294	36,507
Cash, cash equivalents and restricted cash, end of period	\$ 41,724	\$ 30,294
Supplemental disclosures of cash flow activity:		
Cash paid for interest	34	1,325
Supplemental disclosure of non-cash investing and financing activities		
Acquisition of fixed assets in accounts payable and accrued expenses	3,212	335
Right-of-use asset and operating lease liability	26	—