

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 6, 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 May 6, 2020, Axogen, Inc. (the “Company”) issued a press release announcing its first quarter 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 May 6, 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: May 6, 2020

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



Axogen, Inc. Reports First Quarter 2020 Financial Results

ALACHUA, FL – May 6, 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 first quarter ended March 31, 2020.

First Quarter 2020 Financial Results and Business Highlights

- Net revenue was \$24.3 million during the quarter, an increase of 4% compared to first quarter 2019 revenue of \$23.3 million.
- Gross margin was 80.1% for the quarter, compared to 84.0% in the first quarter of 2019.
- Net loss was \$8.2 million for the quarter, or \$0.21 per share, compared to a net loss of \$9.5 million, or \$0.24 per share, in the first quarter of 2019.
- Adjusted net loss was \$7.6 million for the quarter, or \$0.19 per share, compared with adjusted net loss of \$6.0 million, or \$0.15 per share, in the first quarter of 2019.
- Adjusted EBITDA loss was \$7.6 million for the quarter, compared to an adjusted EBITDA loss of \$6.5 million in the first quarter of 2019.
- The balance of cash, cash equivalents, and investments on March 31, 2020 was \$89.0 million, compared to a balance of \$102.5 million on December 31, 2019.

“Our first quarter results were negatively impacted in the month of March as our customers reallocated resources to prepare for and treat COVID-19 patients, and as shelter-in-place orders reduced the incidence of traumatic injuries,” commented Karen Zaderej, chairman, CEO, and president of Axogen, Inc. “We have taken a number of steps to protect our employees and customers and have adapted our business to enable continued support of all of our key stakeholders through this pandemic. We believe the long-term fundamentals of our business remain intact, and we are well-positioned to drive continued growth in the future.”

Additional Operational and Business Highlights

- Ended the first quarter with 109 direct sales representatives, which is consistent with 2019 year-end, and up from 93 at the end of Q1 2019.
 - Active accounts in the first quarter were 825, an increase of 13% compared to 731 in the first quarter a year ago.
 - Revenue from the direct sales channel represented approximately 90% of total revenue in the first quarter, compared to approximately 85% in the first quarter of 2019.
 - Ended the quarter with 119 peer-reviewed clinical publications featuring Axogen’s nerve repair product portfolio.
 - Results from the largest RANGER® Registry data set to date were published in the journal *Microsurgery*. This comprehensive publication reported quantitative outcomes from 475 repairs of nerve injuries, including sensory, mixed and motor nerves throughout the body, showing an overall 82% meaningful recovery rate in gaps up to 70mm. These results are
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consistent with prior data for Avance® Nerve Graft, comparable to historical literature for nerve autograft, and exceed that of conduits.

- On April 1, 2020, the Company disclosed that although RECON® study enrollment was nearing completion, the study's enrollment may not be completed by the end of June 2020 as previously projected due to clinical study sites reallocating resources toward COVID-19 treatment. The Company does not believe that this will negatively impact the study or the enforcement discretion provided by the U.S. Food and Drug Administration.

Update on Small Business Administration Loan

On April 23, 2020, Axogen announced that it had received a Small Business Administration (SBA) loan under the Paycheck Protection Program (PPP) in the amount of \$7.8 million. The loan was obtained pursuant to the original guidance of the SBA to preserve positions in the Company by providing necessary economic relief during this period of reduced surgical volumes because of the negative business effects of COVID-19. The Company believes that it correctly applied for the loan, meets the initial intent of the PPP program to preserve jobs, and that it complied with the representations provided in the loan documents. However, subsequent to obtaining the loan, the United States Treasury Department issued guidance that the Company believes contradicts the original intent and language of the PPP, providing that public companies are unlikely to be able to meet the standards for receiving the loan. As a result of this change, the Company repaid the loan on May 5, 2020. Because the Company returned the loan, it may take additional cost reduction measures based upon the recovery of surgical volumes and explore other non-dilutive financing alternatives.

Dismissal of Class Action Lawsuit

On April 21, 2020, the United States District Court for the Middle District of Florida (the "Court") dismissed a class action complaint filed January 9, 2019, without prejudice, finding Neil Einhorn (the "Plaintiff") failed to state a claim upon which relief could be granted. The Plaintiff has 60 days to file an amended complaint or the action will be dismissed with prejudice.

Cost Mitigation Initiative

On April 23, 2020, the Company announced the implementation of a cost mitigation initiative to offset the COVID-19-related impact on revenue by deferring and reducing certain expenses and capital expenditures. More specifically, the Company:

- Implemented a plan reducing executive cash compensation and board fees by 20%, and reducing cash compensation for all other exempt employees by 10% to 15%;
 - Completed an employee layoff of approximately 10% of its workforce and implemented a hiring freeze;
 - Temporarily suspended recovery and processing of tissue in order to utilize existing inventory, and preserve PPE;
 - Deferred completion of its new biologics processing center in Dayton, Ohio by up to one year, which defers approximately \$25 million of expected 2020 capital expenditures to 2021, and extended its current production facility License and Services agreement with Community Tissue Services (CTS) by one year; and
 - Reduced certain discretionary spending, including travel, conference participation, surgeon education (as a result of surgeon travel restrictions), certain clinical trials and selected projects across the organization.
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2020 Financial Guidance

On April 1, 2020, the Company disclosed that it was suspending its 2020 annual financial guidance as previously provided on February 24, 2020 due to factors associated with COVID-19. At this date, the Company cannot predict the extent or duration of the impact of the COVID-19 pandemic on its financial results, but believes the current environment will negatively impact its revenues for the second quarter of 2020 and potentially longer.

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 related to the expected impact of COVID-19 on our business, statements regarding our growth, 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)

	March 31, 2020	December 31, 2019
Assets		
Current assets:		
Cash and cash equivalents	\$ 35,894	\$ 35,724
Restricted Cash	6,000	6,000
Investments	47,145	60,786
Accounts receivable	13,020	16,944
Inventory	14,563	13,861
Prepaid expenses and other	3,730	1,706
Total current assets	120,352	135,021
Property and equipment, net	20,063	14,887
Operating lease right-of-use assets	2,788	3,133
Finance lease right-of-use assets	82	87
Intangible assets	1,598	1,515
Total assets	\$ 144,883	\$ 154,643
 Liabilities and Shareholders' Equity		
Current liabilities:		
Accounts payable and accrued expenses	\$ 17,689	\$ 19,130
Current maturities of long term obligations	1,785	1,736
Contract liabilities, current	14	14
Total current liabilities	19,488	20,880
Long-term obligations, net of current maturities	1,189	1,595
Contract liabilities	12	15
Total liabilities	20,689	22,490
Shareholders' equity:		
Common stock, \$.01 par value; 100,000,000 shares authorized; 39,738,767 and 39,589,755 shares issued and outstanding	397	396
Additional paid-in capital	311,850	311,618
Accumulated deficit	(188,053)	(179,861)
Total shareholders' equity	124,194	132,153
Total liabilities and shareholders' equity	\$ 144,883	\$ 154,643

AXOGEN, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
Three Months ended March 31, 2020 and 2019
(unaudited)

	Three Months Ended	
	Mar 31, 2020	Mar 31, 2019
Revenues	\$ 24,261	\$ 23,285
Cost of goods sold	4,816	3,714
Gross profit	19,445	19,571
Costs and expenses:		
Sales and marketing	17,838	16,434
Research and development	4,614	4,139
General and administrative	5,502	9,201
Total costs and expenses	27,954	29,774
Loss from operations	(8,509)	(10,203)
Other income (expense):		
Interest income	311	716
Interest expense	(31)	(14)
Other income (expense)	37	(3)
Total other expense	317	699
Net loss	\$ (8,192)	\$ (9,504)
Weighted average common shares outstanding – basic and diluted	39,698	38,934
Loss per common share – basic and diluted	\$ (0.21)	\$ (0.24)
 Adjusted net loss - non GAAP	 (7,636)	 (6,004)
Adjusted net loss per common share - basic and diluted	\$ (0.19)	\$ (0.15)

AXOGEN, INC.
RECONCILIATION OF GAAP FINANCIAL MEASURES TO NON-GAAP FINANCIAL MEASURES
Three Months ended March 31, 2020 and 2019
(unaudited)

	Three Months Ended	
	Mar 31, 2020	Mar 31, 2019
Net loss	\$ (8,192)	\$ (9,504)
Depreciation and amortization expense	343	251
Investment income	(311)	(716)
Income tax	(10)	—
Interest expense	31	14
EBITDA - non GAAP	\$ (8,139)	\$ (9,955)
Non cash stock compensation expense	556	2,315
Litigation and related costs	—	1,185
Adjusted EBITDA - non GAAP	\$ (7,583)	\$ (6,455)
Net loss	\$ (8,192)	\$ (9,504)
Non cash stock compensation expense	556	2,315
Litigation and related costs	—	1,185
Loss on extinguishment of debt	—	—
Adjusted Net Loss - non GAAP	\$ (7,636)	\$ (6,004)
Weighted average common shares outstanding – basic and diluted	39,698	38,934
Adjusted net loss per common share - basic and diluted	\$ (0.19)	\$ (0.15)

AXOGEN, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CHANGES IN SHAREHOLDERS' EQUITY
Three Months Ended March 31, 2020 and 2019
(unaudited)

	Common Stock	Additional Paid-in Capital	Accumulated Deficit	Total Shareholders' Equity
For the Three Months Ended March 31, 2020:				
Balance at December 31, 2019	\$ 396	\$ 311,618	\$ (179,861)	\$ 132,153
Net Loss	-	-	(8,192)	(8,192)
Issuance of restricted/performance service awards	1	(1)	-	-
Stock-based compensation	-	556	-	556
Shares surrendered by employees to pay taxes	-	(639)	-	(639)
Exercise of stock options and employee stock purchase plan	-	316	-	316
Balance at March 31, 2020	\$ 397	\$ 311,850	\$ (188,053)	\$ 124,194
For the Three Months Ended March 31, 2019:				
Balance at December 30, 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 and employee stock purchase plan	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, 2020 and 2019
(unaudited)

	Fiscal Year	
	Mar 31, 2020	Mar 31, 2019
Cash flows from operating activities:		
Net loss	\$ (8,192)	\$ (9,504)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	307	211
Amortization of right-of-use assets	470	437
Amortization of intangible assets	36	26
Provision for bad debt	22	16
Provision for inventory write down	924	444
Change in investment gains and losses	(49)	(294)
Share-based compensation	556	2,315
Change in assets and liabilities:		
Accounts receivable	3,903	112
Inventory	(1,626)	(1,582)
Prepaid expenses and other	(2,024)	(1,783)
Accounts payable and accrued expenses	(1,904)	1,161
Operating Lease Obligations	(472)	(423)
Cash paid for interest portion of Finance Leases	-	(1)
Contract and other liabilities	(3)	(2)
Net cash used in operating activities	(8,052)	(8,867)
Cash flows from investing activities:		
Purchase of short-term investments	(11,760)	(48,914)
Purchase of property and equipment	(5,021)	(478)
Sale/Maturities of short-term investments	25,450	57,171
Cash payments for intangible assets	(119)	(9)
Net cash provided by/ (used for) investing activities	8,550	7,770
Cash flows from financing activities:		
Payments for repurchase of common stock for employee tax withholding	(639)	—
Cash paid for debt portion of finance leases	(5)	(7)
Proceeds from exercise of stock options and warrants	316	332
Net cash provided by financing activities	(328)	325
Net increase in cash, cash equivalents and restricted cash	170	(772)
Cash, cash equivalents and restricted cash , beginning of year	41,724	30,294
Cash, cash equivalents and restricted cash , end of period	\$ 41,894	\$ 29,522
Supplemental disclosures of cash flow activity:		
Cash paid for interest	\$ 11	\$ 14
Supplemental disclosure of non-cash investing and financing activities		
Acquisition of fixed assets in accounts payable and accrued expenses	\$ 3,674	\$ 946
Right-of-use asset and operating lease liability	\$ 120	\$ 618