

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): April 23, 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.)
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13631 Progress Boulevard, Suite 400, Alachua, Florida (Address of Principal Executive Offices)	32615 (Zip Code)
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Registrant's telephone number, including area code

(386) 462-6800 (Former name or former address if changed since last report,)
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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 April 23, 2020, Axogen, Inc. (the “Company”) issued a press release announcing its estimated first quarter 2020 revenue, as well as certain cost mitigation initiatives the Company is taking in response to the COVID-19 global pandemic (as more fully described in Item 8.01 of this Current Report on Form 8-K). 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 5.02 Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers; Compensatory Arrangements of Certain Officers.

In response to the COVID-19 global pandemic, the Board of Directors (the “Board”) of the Company, supported by the Company’s executive officers, has approved a 20% reduction in salary for each of the following executive officers commencing April 26, 2020 for the remainder of 2020: Karen Zaderej, Peter Mariani, Eric Sandberg, Maria Martinez, Angelo Scopelianos, Isabelle Billet, Erick DeVinney, Mike Donovan, Dr. Ivica Ducic, Greg Freitag and Mark Friedman. Additionally, as of April 26, 2020, the Board approved a 20% reduction in cash retainers for Board and Board Committee membership, chairmanships of Board Committees, and acting as Lead Director, for the remainder of 2020.

Item 8.01 Other Events.

On April 23, 2020, the Company issued a press release detailing certain proactive steps the Company is taking in response to the COVID-19 global pandemic, including: (1) a reduction in cash compensation as of April 26, 2020 for all employees of 10% to 15%, depending on their position; (2) a reduction in salaries and retainers as provided in Item 5.02 of this Current Report; (3) completing an employee layoff of approximately 10% of its workforce; (4) implementing a hiring freeze with very limited exceptions; (5) temporarily suspending recovery and processing of tissue for certain of its products in order to utilize existing inventory; (6) deferring completion and validation of the Company’s new biologics processing center in Dayton, Ohio by up to one year; (7) entering into a Sixth Amendment to the License and Services Agreement (the “Agreement”) with Community Blood Center (d/b/a Community Tissue Services) to extend the termination date to December 31, 2022, which allows the Company to continue its manufacturing pursuant to the Agreement through such date; and (8) reducing certain discretionary spending including travel, conference participation, surgeon education (as a result of surgeon travel restrictions) and selected projects across the organization.

In addition, the press release provided that the Company applied for a Small Business Administration (“SBA”) loan under the Paycheck Protection Program. The Company has received an SBA Loan Number and completed documents for a loan of approximately \$7.8 million dollars. The loan will preserve key positions in the Company supporting ongoing operations by providing necessary economic relief during this period of reduced surgical volumes.

Finally, on January 9, 2019, Plaintiff Neil Einhorn (“Plaintiff”), on behalf of himself and others similarly situated, filed a putative class action complaint alleging violations of the federal securities laws against the Company, certain of its directors and officers, and the Company’s underwriters (collectively, “Defendants”). Plaintiff claimed that Defendants made false or misleading statements when the Company provided its opinion as to the size of the total addressable market (“TAM”) for its products. On July 22, 2019, Defendants filed a motion to dismiss. On April 21, 2020, the United States District Court for the Middle District of Florida dismissed the complaint without prejudice, finding 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.

A copy of the press release is furnished as Exhibit 99.1 to this Current Report.

The information furnished pursuant to Item 8.01 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 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, 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 April 23, 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: April 23, 2020

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



**Axogen, Inc. Reports Preliminary Revenue for the First Quarter 2020,
Provides Business Update in Response to COVID-19 Pandemic, and
Announces Dismissal of Class Action Lawsuit**

ALACHUA, FL – April 23, 2020 –Axogen, Inc. (NASDAQ: AXGN), a global leader in developing and marketing innovative surgical solutions for peripheral nerve injuries, today announced preliminary first quarter 2020 revenue, provided a business update on its actions in response to the COVID-19 pandemic, and announced the dismissal of its class-action lawsuit.

First quarter 2020 net revenue is estimated to be approximately \$24.3 million, an increase of approximately 4% over the first quarter 2019. Although revenue exiting February was trending toward the Company's annual guidance, hospital reallocation of resources toward the COVID-19 pandemic, along with deferrals and restrictions placed on elective procedures, had a material negative impact on revenue in March. Additionally, management believes that demand for the Company's products has been temporarily reduced as nationwide shelter-in-place orders have lowered the incidence of traumatic injuries.

In response to the current restrictions in hospital and community activity, as well as the anticipated reduction of revenue caused by these factors, the Company has implemented a cost mitigation initiative designed to defer and reduce certain expenses and capital expenditures during this time. More specifically, the Company has:

- Implemented a plan reducing executive cash compensation and board fees by 20%, and reducing cash compensation for all other 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;
- 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), and selected projects across the organization.

Additionally, the Company announced today approval for a Small Business Administration loan under the Paycheck Protection Program in the amount of \$7.8 million. The loan will preserve key positions in the Company by providing necessary economic relief during this period of reduced surgical volumes.

“Our first priority in response to the COVID-19 pandemic is the health and safety of those we serve, including healthcare teams and patients, as well as our employees, communities, and suppliers. Our team has adapted to this environment, and we will continue to provide full support to our hospitals and their patients as surgical volumes recover,” commented Karen Zaderej, chairman, CEO, and president of Axogen, Inc. “We believe the long-term fundamentals of our business remain intact, and we are taking steps to defer and reduce our spending while maintaining the ability to respond to our customers’ needs and drive future revenue growth.

2020 Financial Guidance

On April 1, 2020, the Company suspended its 2020 annual financial guidance as previously provided on February 24, 2020, due to uncertainty associated with COVID-19. At this date, management cannot predict the extent or duration of the impact of the COVID-19 pandemic on its financial results but believes the current environment will continue to negatively impact its revenue in the second quarter of 2020 and potentially beyond.

The Company will provide final financial results for the quarter, along with commentary and additional information related to the impact of COVID-19, during its upcoming Q1 2020 earnings call on May 6, 2020, at 4:30 pm ET. More information about the conference call is available on the Company’s website at <https://ir.axogeninc.com/>.

Update on Class Action Lawsuit

On April 21, 2020, the United States District Court for the Middle District of Florida (Court) dismissed a putative class action complaint filed January 9, 2019, against the Company, certain of its directors and officers, and Company underwriters alleging violations of the federal securities laws. The Court dismissed the complaint without prejudice, finding 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.

Commenting on the court’s finding, Zaderej stated, “We are extremely pleased that the Court found in our favor, dismissing the Class Action, which we have spent considerable time and resources defending, and allowing us to move forward without this distraction.”

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.

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