

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 1, 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 7.01 Regulation FD Disclosure

Suspension of Guidance

The impact of the coronavirus (“COVID-19”) pandemic continues to develop across the United States healthcare system. The immediate impact has caused United States hospitals to: 1) reallocate their medical teams and resources to prepare for increased COVID-19 patients; 2) defer or limit elective and non-emergency procedures; and 3) restrict hospital access to non-essential personnel, including sales and clinical representatives not directly required for a specific procedure. Accordingly, Axogen, Inc. (the “Company”) has advised all field-based teams to enter hospitals or clinics only at the request of a surgeon or hospital staff and to complete all tasks occurring in hospitals or clinics in a manner that minimizes human interaction and maintains social distancing. Additionally, the Company believes that the incidence of traumatic injuries is likely being reduced by “shelter-in-place” orders that have been issued across the United States.

Although the Company’s sales team continues to support customers and their patients, these limitations on travel and access, and procedures, as well as others caused by the evolving COVID-19 pandemic and macroeconomic environment, will negatively impact the Company’s financial results. Accordingly, management is suspending its 2020 financial guidance as provided on February 24, 2020. Additionally, although the RECON® study’s patient enrollment is near completion, enrollment may not be completed by the end of June 2020 as previously provided, however, any such enrollment delay would not negatively impact the trial or the enforcement discretion provided by the U.S. Food and Drug Administration. The Company will provide additional information during its next earnings call, scheduled for May 6, 2020.

The Company’s goal is straightforward: to keep employees and customers safe while continuing to provide needed nerve repair products and services to hospitals and their patients. The Company believes that the long-term fundamentals of its business remain intact. Additionally, the Company believes that its balance sheet is strong and that its business model is sufficiently flexible to respond to lower sales with cost reductions in order to maintain liquidity for an extended period of time.

The information furnished pursuant to Item 7.01 of this Current Report on Form 8-K 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.

Cautionary Statements Concerning Forward-Looking Statements

This Current Report 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 current report 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.

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 1, 2020

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