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): January 15, 2019

AXOGEN, INC.

(Exact name of registrant as specified in its charter)

Minnesota	**001-36046**	**41-1301878**
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

13631 Progress Boulevard, Suite 400, Alachua, Florida	**32615**
(Address of Principal Executive Offices)	(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))

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 8.01 Other Events

On January 15, 2019, AxoGen, Inc. (the "Company") issued a press release announcing information regarding the Company's RECON® study which supports its Biologic License Application Submission for Avance ® Nerve Graft. A copy of the press release is furnished as Exhibit 99.1 to this Current Report.

Item 9.01. Financial Statements and Exhibits

(d) Exhibits

Exhibit No.	Description
99.1	AxoGen, Inc. Press Release, dated January 15, 2019.

EXHIBIT INDEX

Exhibit No.	Description
99.1	AxoGen, Inc. Press Release, dated January 15, 2019.

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

AXOGEN, INC.

Date: January 15, 2019

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

Exhibit 99.1

AxoGen Announces RECON® Study Update

Study Supports Company's Planned Biologic License Application (BLA) for Avance® Nerve Graft

ALACHUA, FL – January 15, 2019 – AxoGen, Inc. (NASDAQ: AXGN), a global leader in developing and marketing innovative surgical solutions for damage or discontinuity to peripheral nerves, today announced that the RECON® Study supporting its Biologic License Application (BLA) Submission for Avance® Nerve Graft has reached its current enrollment milestone of 170 subjects.

RECON® is AxoGen's phase three pivotal study comparing Avance® Nerve Graft to manufactured conduits. The study requires a one year follow up period for all subjects and is designed to assess return of sensation in digital nerve injuries, quality of life outcomes, and subject satisfaction. The FDA-approved statistical analysis plan was designed with an interim blinded analysis to provide a safeguard for the assumptions used in the design of the protocol. It is possible to increase the study sample size to maintain the original power of the study in the event the pooled variance of the standard deviation, a key statistical assumption in the power analysis, is not consistent with the original assumptions. This interim analysis is designed to protect the validity and integrity of the study. AxoGen has submitted the interim analysis to the FDA for review with the intention of obtaining agreement on next steps, which could include continuing study enrollment. The Company will provide further updates upon completion of the review, the timing of which is uncertain based upon near-term funding issues faced by the FDA.

"We are pleased to have achieved this important enrollment milestone, which we could not have reached without the dedication and commitment of each of the participating study teams," said Karen Zaderej, chairman, CEO, and president of AxoGen. "We have been working diligently to transition our nerve graft from classification as a 361 HCT/P tissue product to a biologic product. The RECON® study is a critical step in this transition process."

In September 2018 the FDA granted a Regenerative Medicine Advance Therapy (RMAT) designation for Avance® Nerve Graft. A regenerative medicine therapy is eligible for the designation if it is intended to treat, modify, reverse or cure a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the product has the potential to address unmet medical needs for such a disease or condition. The RMAT designation provides access to a streamlined approval process for regenerative medicine technologies and ensures continued informal meetings with the FDA in support of the BLA for Avance® Nerve Graft.

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 discontinuity 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; and Avive® Soft Tissue Membrane, a minimally processed human umbilical cord membrane that may be used as a resorbable soft tissue covering to separate tissue layers and modulate inflammation in the surgical bed. Along with these core surgical products, AxoGen also offers AcroVal® Neurosensory & Motor Testing System and AxoTouch® Two-Point Discriminator. These evaluation and measurement tools assist health care professionals in detecting changes in sensation, assessing return of sensory, grip, and pinch function, evaluating effective treatment interventions, and providing feedback to patients on peripheral nerve function. 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,” 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 assessment on our internal control over financial reporting, our growth, our 2018 and 2019 guidance, product development, product potential, financial performance, sales growth, product adoption, market awareness of our products, data validation, our visibility at and sponsorship of conferences and educational events. The forward-looking statements are subject to risks and uncertainties, which may cause results to differ materially from those set forth in the statements. Forward-looking statements in this release should be evaluated together with the many uncertainties that affect AxoGen's business and its market, particularly those discussed in the risk factors and cautionary statements in AxoGen's filings with the Securities and Exchange Commission. Forward-looking statements are not guarantees 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 law, AxoGen assumes no responsibility to update any forward-looking statements, whether as a result of new information, future events, or otherwise.

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