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): July 22, 2020

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)

(386) 462-6800
Registrant's telephone number, including area code

(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 8.01 Other Events.

On July 22, 2020, 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.

The information furnished pursuant to Item 8.01 of this Current Report, including Exhibit 99.1 hereto, shall not be considered "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, 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

99.1	Press Release of the Company dated July 22, 2020.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document and contained in Exhibit 101)

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.

Dated: July 22, 2020

AXOGEN, INC.

By: /s/ Bradley L. Ottinger, Esq.
Name: Bradley L. Ottinger, Esq.
Title: General Counsel

Axogen RECON*SM* Clinical Study Completes Target Enrollment of 220 Subjects

RECON is a pivotal study supporting the Company's
Biologics License Application (BLA) for Avance® Nerve Graft

ALACHUA, FL – July 22, 2020 – Axogen, Inc. (NASDAQ: AXGN), a global leader in developing and marketing innovative surgical solutions for damage or transection to peripheral nerves, today announced that its phase 3 pivotal RECON Clinical Study supporting its Biologics License Application (BLA) submission for Avance Nerve Graft has reached its enrollment target of 220 subjects. RECON compares Avance Nerve Graft to manufactured conduits in digital nerve injuries with a primary endpoint of return of sensation and secondary endpoints for quality of life and patient satisfaction.

"We are pleased to have reached this important milestone and appreciate the dedication and commitment of each of the participating study teams," commented Karen Zaderej, chairman, CEO, and president of Axogen. "Completing enrollment for the RECON Study is a critical step in transitioning our Avance Nerve Graft from classification as a section 361 HCT/P tissue product to a section 351 biological product."

The RECON Clinical Study protocol requires a one-year follow-up assessment with an additional three month visit window. With the final subject enrolled in July of 2020, the last patient is expected to complete the study no later than October of 2021. The company anticipates it will provide a preliminary report of trial data in the second quarter of 2022 and expects to file the BLA in 2023.

About the RECON Clinical Study
Comparison of Processed Nerve Allograft and Collagen Nerve Cuffs for Peripheral Nerve Repair (RECON) is a multicenter, prospective, randomized, subject, and evaluator blinded comparative clinical study of nerve cuffs and Avance Nerve Graft evaluating recovery outcomes for the repair of nerve discontinuities. The study is designed to test for non-inferiority between the static two-point discrimination outcomes for Avance Nerve Graft and nerve cuffs.

About Avance Nerve Graft
Avance Nerve Graft is a biologically active off-the-shelf processed human nerve allograft for bridging severed peripheral nerves without the comorbidities associated with a second surgical

site. Avance provides structural guidance for regenerating axons, and revascularizes and remodels into the patient's own tissue. It is available in a variety of lengths and diameters.

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. 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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