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): September 1, 2021

AXOGEN, INC.
(Exact Name of Registrant as Specified in Charter)

Minnesota	001-36046	41-1301878
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(I.R.S. 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)

N/A
(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

☐ 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 each 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.

On September 1, 2021, Axogen, Inc. (the "Company") issued a press release regarding its RECON clinical study. The press release is attached hereto as Exhibit 99.1.

The information in Item 7.01 of this Current Report on Form8-K, as well as Exhibit 99.1 attached hereto, shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), nor shall it be deemed incorporated by reference in any filing under the Securities Act, or the Exchange Act, except as shall be expressly set forth by specific reference in such a filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description of Exhibit
99.1	Axogen, Inc. Press Release, dated September 1, 2021.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURES

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: September 1, 2021

By: /s/ Bradley L. Ottinger
Bradley L. Ottinger
General Counsel and Chief Compliance Officer

Exhibit 99.1

Axogen RECON(SM) Clinical Study
Completes Subject Follow-up

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

ALACHUA, Fla. and TAMPA, Fla., Sept. 01, 2021 (GLOBE NEWSWIRE) — 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 Clinical Study supporting its Biologics License Application (BLA) for Avance Nerve Graft has completed follow-up of study subjects.

RECON reached its enrollment target of 220 subjects in July 2020. The study remains on schedule with a top line study data read-out expected in the second quarter of 2022, followed by filing of the BLA submission in 2023. RECON compares Avance Nerve Graft to manufactured conduits in digital nerve injuries with a primary endpoint of recovery of static two-point discrimination, a measure of sensation, and secondary endpoints for quality of life and subject satisfaction. The BLA will transition Avance Nerve Graft from a human tissue product to a biological product.

"We are pleased to have reached this milestone and thank the study investigators and research teams for their dedication and commitment to this landmark study," commented Karen Zaderej, chairman, CEO, and president of Axogen. "The RECON study is designed to provide Level 1 clinical data for our BLA, and will provide additional evidence for surgeons in their clinical decision making for the repair of peripheral nerve injuries."

About the RECON Clinical Study

RECON is a multicenter, prospective, randomized, subject, and evaluator blinded comparative clinical study of nerve cuffs (manufactured conduits) and Avance Nerve Graft evaluating recovery outcomes for the repair of nerve discontinuities. The phase 3 pivotal study is designed to test for non-inferiority between the static two-point discrimination outcomes for Avance Nerve Graft and manufactured conduit. The study design also allows for a sequential test for superiority of Avance Nerve Graft, following the non-inferiority analysis.

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.

A 2010 written agreement between the FDA and Axogen allows the company to continue marketing Avance as a Human Cells, Tissues and Cellular and Tissue Based Product (HCT/P) while taking the necessary steps to file a Biologics License Application (BLA).

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; and 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. The Axogen portfolio of products is available in the United States, Canada, the United Kingdom, South Korea, and several other European and international countries.

Contact:
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Source: Axogen, Inc.