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 6, 2024

AXOGEN, INC.

(Exact Name of Registrant as Specified in Charter)

Minnesota	**001-36046**	**41-1301878**
(State or Other Jurisdiction of Incorporation or Organization)	(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 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 6, 2024, Axogen Inc., (the "Company") issued a press release announcing it has completed the rolling submission process for its Biologics License Application (BLA) to the U.S. Food and Drug Administration (FDA) for its Avance Nerve Graft®. A copy of this press release is filed as Exhibit 99.1 to this Current Report on Form 8-K and incorporated herein by reference.

The information in this Item 7.01 is being furnished and shall not be deemed to be "filed" for purposes of Section 18 of the Exchange Act or otherwise subject to the liabilities of that section and shall not be deemed incorporated by reference into any filing under the Securities Act or Exchange Act, except as shall be expressly set forth by specific reference in such filing.

Item 9.01. Financial Statements and Exhibits

(d) Exhibits

Exhibit No.	Description
99.1	Axogen Inc. Press Release, dated September 6, 2024
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.

Dated: September 6, 2024

By: /s/ Marc Began

Marc Began

Executive Vice President, General Counsel and Chief Compliance Officer

Axogen Completes Submission of Biologics License Application to U.S. Food and Drug Administration for Avance Nerve Graft®

ALACHUA, FL and TAMPA, FL, September 6, 2024 (GLOBE NEWSWIRE) -- Axogen, Inc. (NASDAQ: AXGN), a global leader in developing and marketing innovative surgical solutions for peripheral nerve injuries, announced that it has completed the rolling submission process for its Biologics License Application (BLA) to the U.S. Food and Drug Administration (FDA) for Avance Nerve Graft®.

“I am proud of the significant progress our team has made towards the regulatory transition of Avance from a tissue to a biologic,” said Michael Dale, CEO and Director of Axogen, Inc. “We will continue to collaborate closely with the FDA as they review our application.”

The Company anticipates the FDA will notify the company regarding whether the submission is accepted for review and confirm the procedural review timeline (either standard or priority) within approximately the next 60 days. Avance Nerve Graft previously received Regenerative Medicine Advanced Therapy (RMAT) designation from the FDA. The RMAT designation, under the 21st Century Cures Act, aims to streamline the development of regenerative medicine therapies intended for the treatment of serious diseases and life-threatening conditions. The Company has requested priority review status for this BLA which, if granted, could reduce the review timeline from the standard 10-month to a priority 6-month review timeline from the date the submission is accepted by FDA. Based on this process, we believe we are on track for FDA determination of approvability between April and September of next year.

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 used across various applications and surgical specialties, including traumatic injuries, oral and maxillofacial surgery, breast reconstruction, and the surgical treatment of pain. These applications encompass both scheduled and emergent procedures. Specifically, scheduled procedures are often pursued by patients seeking relief from conditions caused by a nerve defect or previous surgical interventions. Such procedures include providing sensation for women undergoing breast reconstruction following a mastectomy, nerve reconstruction after the surgical removal of painful neuromas, and oral and maxillofacial procedures, as well as nerve decompression. Conversely, emergent procedures typically arise from injuries that initially present in an emergency room, with specialists intervening either immediately or within a few days following the initial injury. This

broad range of applications underscores Axogen's vital role in addressing diverse patient needs in peripheral nerve repair.

Axogen's platform for peripheral nerve repair features a comprehensive portfolio of products, including Avance® Nerve Graft, a biologically active 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 HA+ Nerve Protector™, a porcine submucosa ECM base layer coated with a proprietary hyaluronate-alginate gel, a next-generation technology designed to enhance nerve gliding and provide short- and long-term protection for peripheral nerve injuries; Avive+ Soft Tissue Matrix ™, a multi-layer amniotic membrane allograft used to protect and separate tissues in the surgical bed during the critical phase of tissue repair; 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 markets.

For more information, visit www.axogeninc.com

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. Forward-looking statements include, without limitation, the Company's expectations that the FDA will accept its BLA submission, and that the FDA will ultimately approve the BLA for Avance Nerve Graft, as well as the Company's estimated review and regulatory action timelines. Actual results or events could differ materially from those described in any forward-looking statements as a result of various factors, including, without limitation, global supply chain issues, hospital staffing issues, product development, product potential, clinical outcomes, regulatory process and approvals, financial performance, sales growth, surgeon and product adoption, market awareness of our products, data validation, our visibility at and sponsorship of conferences and educational events, global business disruption caused by Russia's invasion of Ukraine and related sanctions, recent geopolitical conflicts in the Middle East, potential disruptions due to management transitions, as well as those risk factors described under Part I, Item 1A, "Risk Factors," of our Annual Report on Form 10-K for the most recently ended fiscal year. 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.

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