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): August 22, 2025

AXOGEN, INC.

(Exact Name of Registrant as Specified in Charter)

Minnesota (State or Other Jurisdiction of	Incorporation or Organization) **001-36046** (Commission File Number)	**41-1301878** (I.R.S. Employer Identification No.)
13631 Progress Boulevard, Suite 400 Alachua, Florida (Address of principal executive offices)		**32615** (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 August 22, 2025, Axogen, Inc. (the "Company") received a communication from the U.S. Food and Drug Administration (the "FDA") stating that the Company's recent submission of facility and manufacturing information, provided in response to an FDA information request, constitutes a Major Amendment to the Company's Biologics License Application ("BLA") for Avance® Nerve Graft. The FDA indicated that the submission contained a substantial amount of new manufacturing or facility information not previously submitted to or reviewed by the Agency.

As a result, the FDA has extended the Prescription Drug User Fee Act ("PDUFA") goal date for the BLA to December 5, 2025, representing the three-month extension from the previous goal date contemplated by FDA guidelines following a major amendment.

The FDA also informed the Company that it now anticipates providing feedback on product labeling in November 2025.

The information in this Item 7.01, including Exhibit 99.1, is being furnished and shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (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 of 1933, as amended, or Exchange Act, except as shall be expressly set forth by specific reference in such filing.

Forward-Looking Statements

This Current Report on Form 8-K, including the exhibit furnished herewith, contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements include statements regarding the potential approval and timing of FDA review of Avance® Nerve Graft and anticipated labeling feedback.

Forward-looking statements are based on current expectations and involve risks and uncertainties. Actual results may differ materially from those expressed or implied due to factors such as the timing and outcome of regulatory review, potential delays, requests for additional information by the FDA, and other risks identified in Axogen' s filings with the SEC.

Axogen undertakes no obligation to update or revise any forward-looking statements, whether as a result of new information, future events, or otherwise, except as required by law.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits

Exhibit No.	Description
99.1	Axogen Inc. Press Release, dated August 25, 2025
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURES

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

AXOGEN, INC.

Dated: August 25, 2025

By: /s/ Marc Began

Marc Began

Executive Vice President, General Counsel and Chief Compliance Officer

Axogen, Inc. Provides Update on FDA Review Timeline for Avance® Nerve Graft

FDA PDUFA Goal Date Extended by Three Months

ALACHUA, FL and TAMPA, FL – August 25, 2025 – Axogen, Inc. (NASDAQ: AXGN), a global leader in developing and marketing innovative surgical solutions for the restoration of peripheral nerve function, today announced that the U.S. Food and Drug Administration (the "FDA") has extended the Prescription Drug User Fee Act ("PDUFA") goal date for its Biologics License Application ("BLA") for Avance® Nerve Graft by three months to December 5, 2025.

On August 22, 2025, the Company received a communication from the FDA indicating that the information submitted by the Company in response to an FDA information request, which included substantial new manufacturing and facility data not previously reviewed by the Agency, was deemed a Major Amendment to its BLA. Under FDA guidelines, this designation allows for additional time to review the submission. As a result, the FDA has extended the PDUFA goal date to December 5, 2025.

The FDA also informed the Company that it now anticipates providing feedback on product labeling in November 2025, consistent with PDUFA review procedures.

"We appreciate the FDA's thorough review and look forward to continuing our engagement with the agency to complete the transition of Avance Nerve Graft from a tissue product to a BLA-approved biologic," said Michael Dale, Axogen's Chief Executive Officer.

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 providing the opportunity to restore nerve function and quality of life for patients with peripheral nerve injuries by providing innovative, clinically proven and economically effective repair solutions for surgeons and healthcare 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 product portfolio includes 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 (pig) 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 minimizing 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; 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 Matrix™, a multi-layer amniotic membrane allograft used to protect and separate tissues in the surgical bed during the critical phase of tissue

healing. The Axogen portfolio of products is available in the United States, Canada, Germany, the United Kingdom, Spain, South Korea and several other countries. For more information, visit www.axogeninc.com.

Cautionary Statements Concerning Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, including statements regarding the potential approval, timing of regulatory review and labeling feedback for Avance Nerve Graft. Words such as “anticipate,” “expect,” “plan,” “intend,” “may,” “will,” “could,” “should,” “potential,” and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words.

Readers are cautioned not to place undue reliance on these forward-looking statements. Forward-looking statements are based on current expectations and assumptions and are subject to risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statements. These risks and uncertainties include, but are not limited to, the timing and outcome of FDA review, potential requests for additional data or information, the possibility of delays, and other risks described in the “Risk Factors” section of Axogen’s filings with the Securities and Exchange Commission (SEC).

Axogen undertakes no obligation to update any forward-looking statements contained in this press release as a result of new information, future events, or otherwise, except as required by law.