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): December 3, 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 December 3, 2025, Axogen, Inc. ("Axogen" or the "Company") issued a press release announcing that the U.S. Food and Drug Administration (the "FDA") has approved the Company's Biologics License Application for Avance® (acellular nerve allograft-arwx).

A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated into this Item 7.01 by reference.

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.

Item 8.01 Other Events

On December 3, 2025, the Company announced it received FDA approval of its Biologics License Application for Avance® (acellular nerve allograft-arwx). Continued approval for these indications depends on verification and description of clinical benefit in confirmatory studies.

The indications for sensory nerve discontinuities >25 mm and for mixed and motor nerve discontinuities were approved under FDA's Accelerated Approval pathway based on the effect on static two-point discrimination in sensory nerve gaps ≤25 mm, which provided empirical evidence to reasonably predict clinical benefit given similarities in pathophysiology and anticipated therapeutic effects. Continued approval for these indications depends on verification and description of clinical benefit in confirmatory studies.

Commercial availability of the licensed Avance® product is expected early in the second quarter of 2026. In the meantime, Avance® remains available under the current tissue framework.

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 commercial availability of the licensed Avance® (acellular nerve allograft-arwx) product.

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 December 3, 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: December 3, 2025

By: /s/ Marc Began

Marc Began

Executive Vice President, General Counsel and Chief Compliance Officer

Axogen Announces FDA Approval of Biologics License Application for AVANCE® (acellular nerve allograft–arwx)

ALACHUA, FL and TAMPA, FL – December 3, 2025 – Axogen, Inc. (NASDAQ: AXGN), a global leader in developing and marketing innovative surgical technologies for the restoration of peripheral nerve function, today announced that the U.S. Food and Drug Administration (the "FDA") has approved the Biologics License Application ("BLA") for AVANCE® (acellular nerve allograft-arwx).

Avance is an acellular nerve scaffold for the treatment of adult and pediatric patients aged 1 month or older with sensory, mixed, and motor peripheral nerve discontinuities.

The indications for sensory nerve discontinuities >25mm and for mixed and motor nerve discontinuities were approved under FDA's Accelerated Approval pathway based on the effect on static two-point discrimination in sensory nerve gaps ≤25mm, which provided empirical evidence to reasonably predict clinical benefit given similarities in pathophysiology and anticipated therapeutic effects. Continued approval for these indications depends on verification and description of clinical benefit in confirmatory studies.

"All stakeholders in Axogen's mission to restore health and improve quality of life by making restoration of peripheral nerve function an expected standard of care should take great pride in today's approval," said Michael Dale, Axogen's Chief Executive Officer. "This approval represents a meaningful shift from our historical classification as a human tissue product and brings the product in line with FDA's classification of Avance as a biologic. This milestone clarifies and strengthens our regulatory footing and confirms approval for use of Avance as an acceptable therapeutic option for treating peripheral nerve discontinuities in all of Axogen's present nerve repair use cases. The approved BLA and successful transition of Avance to a biologic regulatory framework should give all stakeholders the assurance that Avance has been rigorously evaluated and determined to be safe, pure, and potent for its intended use, and that its benefits outweigh its known or potential risks. We want to thank FDA and the surgical community for the tremendous work and collaboration over more than a decade to make this therapy available to patients."

Commercial availability of the licensed Avance product is expected early in the second quarter of 2026. In the meantime, Avance remains available under the current tissue framework.

About Avance

Indications

AVANCE® is an acellular nerve scaffold indicated for the treatment of adult and pediatric patients aged one month and older with:

- Sensory nerve discontinuity (≤25mm)
- Sensory nerve discontinuity (>25mm); Approved under accelerated approval based on static two-point discrimination (s2PD) at 12 months in sensory nerve gaps ≤25 mm, which reasonably predicts clinical benefit. Continued approval is contingent upon confirmatory clinical trial results.

- Mixed and motor nerve discontinuity; Approved under accelerated approval based on s2PD outcomes in sensory nerves; continued approval is contingent upon confirmatory clinical trial results.

Important Safety Information

Warnings and Precautions

- Procedural Complications: Monitor for procedural complications, including pain, hyperesthesia, infection, implant site swelling, adhesions, hypertrophic scar formation, impaired motor or sensory function, bleeding, and neuroma formation, and manage accordingly.
- Transmission of Infectious Diseases: Because AVANCE is made from human donor tissue, it may carry a risk of transmitting infectious agents, e.g., viruses, the variant Creutzfeldt-Jakob disease (vCJD) agent, and theoretically, the Creutzfeldt-Jakob disease (CJD) agent.

Adverse Reactions

The most common adverse reactions (≥2%) were procedural pain (4%) and hyperesthesia (3%).

See full prescribing information for complete warnings, precautions, and risk information. Full Prescribing Information is available at www.avancenervegraft.com or by calling 1-888-296-4631.

About Axogen

Axogen (NASDAQ: AXGN) is focused on the science, development and commercialization of technologies for peripheral nerve repair. With a mission to make nerve repair the expected standard of care, Axogen advances the field through research, education, and collaboration with surgeons and healthcare providers across a global network.

Axogen's product portfolio includes Avance® (acellular nerve allograft-arwx), Axoguard Nerve Connector®, Axoguard Nerve Protector®, Axoguard HA+ Nerve Protector™, Axoguard Nerve Cap®, and Avive+ Soft Tissue Matrix™. The Axogen portfolio of products is available in the United States, Canada, Germany, the United Kingdom, Spain and several other countries. 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," "priorities," "objectives," "targets," "intends," "plan(s)," "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, but are not limited to, statements regarding the commercial availability of AVANCE in early 2026 and future confirmatory clinical trials required under accelerated approval, as well as statements related to Axogen's ability to continue to serve all clinical nerve repair use cases. Actual results or events could differ materially from those described in any forward-looking statements as a result of various factors, including, without limitation, potential disruptions from global supply chain issues, inflation, hospital staffing challenges, product development timelines, regulatory processes, financial performance, surgeon and product adoption rates, market awareness of our products, and other risks described in our filings with the SEC. 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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