

**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): November 20, 2024

Neurogene Inc.

(Exact name of registrant as specified in its charter)

Delaware **001-36327** **98-0542593**
(State or other jurisdiction of incorporation or organization) **(Commission File Number)** **(I.R.S. Employer Identification No.)**

**535 W 24th Street, 5th Floor
New York, NY 10011**

(Address of principal executive offices, including zip code)

Registrant's telephone number, including area code: (877) 237-5020

N/A

(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 (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, \$0.000001 par value | NGNE | The Nasdaq Global 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.

The participant in Neurogene's ongoing Phase 1/2 clinical trial for Rett syndrome who was dosed on November 5 with 3E15 vg of NGN-401 and was previously reported to be in critical condition, has died following complications from a rare and life-threatening hyperinflammatory syndrome associated with systemic exposure to high doses of adeno-associated virus (AAV).

The FDA allowed Neurogene to proceed with the Phase 1/2 trial using the 1E15 vg dose for both the pediatric and adolescent/adult cohorts. Neurogene will also incorporate the 1E15 vg dose in its future registrational trial design planning.

The information in this Item 7.01 is being furnished and shall not be deemed "filed" for the 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, nor shall it be deemed incorporated by reference into any filing under the Exchange Act or the Securities Act of 1933, as amended, except as expressly set forth by specific reference to such filing.

SIGNATURE

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 thereunto duly authorized.

Date: November 21, 2024

NEUROGENE INC.

By: /s/ Christine Mikail

Name: Christine Mikail

Title: President, Chief Financial Officer