

**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):

July 27, 2026

Denali Therapeutics Inc.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation)

001-38311
(Commission
File Number)

46-3872213
(I.R.S. Employer
Identification No.)

161 Oyster Point Blvd.
South San Francisco, California 94080
(Address of principal executive offices, including zip code)

(650) 866-8547
(Registrant's telephone number, including area code)

Not Applicable
(Former name or former address, if changed since last reports)

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:

- ☐ 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	Name of each exchange on which registered
Common Stock, par value \$0.01 per share	DNLI	Nasdaq Global Select 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 2.01 Completion of Acquisition or Disposition of Assets.

On July 27, 2026, Denali Therapeutics Inc. (the “Company”) completed the previously disclosed sale (the “Sale”) of its Rare Pediatric Disease Priority Review Voucher (the “PRV”) to a large pharmaceutical company. The Company received the PRV when AVLAYAHTM (tividenofusp alfa) was approved by the U.S. Food and Drug Administration for the treatment of Hunter syndrome (mucopolysaccharidosis type II; MPS II) in March 2026. The Sale was completed pursuant to the terms of an asset purchase agreement, dated June 12, 2026 (the “PRV Transfer Agreement”). Pursuant to the PRV Transfer Agreement, the Company received gross proceeds of \$195.0 million from the buyer upon the closing of the Sale.

The foregoing description of the PRV Transfer Agreement does not purport to be complete and is qualified in its entirety by the full text of the PRV Transfer Agreement, which will be filed as an exhibit to a subsequent filing with the Securities and Exchange Commission.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
104	Cover Page Interactive Data File (formatted as Inline XBRL)

SIGNATURE

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.

DENALI THERAPEUTICS INC.

Date: July 27, 2025

By: /s/ Alexander O. Schuth
Alexander O. Schuth, M.D.
Chief Operating and Financial Officer