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):

June 12, 2026

Denali Therapeutics Inc.

(Exact name of registrant as specified in its charter)

Delaware	001-38311	46-3872213
(State or other jurisdiction of incorporation)	(Commission File Number)	(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 (s)	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 1.01 Entry into a Material Definitive Agreement

On June 12, 2026, Denali Therapeutics Inc. (the "Company") entered into an asset purchase agreement (the "PRV Transfer Agreement"), pursuant to which the Company agreed to sell its Rare Pediatric Disease Priority Review Voucher ("PRV"). The Company was awarded the voucher under a U.S. Food and Drug Administration ("FDA") program intended to encourage the development of certain rare pediatric disease product applications. The Company received the PRV when AVLAYAHTM (tividenofusp alfa) was approved by the FDA for the treatment of Hunter syndrome (mucopolysaccharidosis type II; MPS II) in March 2026. Pursuant to the PRV Transfer Agreement, the buyer agreed to pay the Company $195 million, payable in cash, upon the closing of the sale.

The PRV Transfer Agreement contains customary representations, warranties, covenants, and indemnification provisions subject to certain limitations. The transaction remains subject to customary closing conditions, including the expiration or termination of the applicable waiting period under the Hart-Scott-Rodino Antitrust Improvements Act of 1976.

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 (SEC).

Item 7.01 Regulation FD Disclosure

On June 18, 2026, the Company issued a press release announcing the matters disclosed in this report. A copy of the press release is attached as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

The information in this Item 7.01 and Exhibit 99.1 attached hereto shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that section, nor shall they be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, except as expressly set forth by specific reference in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release dated June 18, 2026
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: June 18, 2026

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

Denali Therapeutics Enters Agreement to Sell Rare Pediatric Disease Priority Review Voucher for $195 Million

- *Proceeds from transaction to support advancement of Denali's broad TransportVehicle™-enabled clinical portfolio for lysosomal storage disorders and neurodegenerative diseases*
- *Denali was awarded Priority Review Voucher following FDA approval of AVLAYAH™, the first FDA-approved biologic specifically designed to cross blood-brain barrier*

SOUTH SAN FRANCISCO, Calif., – June 18, 2026 – Denali Therapeutics Inc. (Nasdaq: DNLI) today announced it has entered into a definitive agreement to sell its Rare Pediatric Disease Priority Review Voucher (PRV) for gross proceeds of $195 million. The U.S. Food and Drug Administration (FDA) awarded the PRV to Denali following accelerated approval of the enzyme replacement therapy AVLAYAH™ (tividenofusp alfa-eknm) for the treatment of Hunter syndrome (mucopolysaccharidosis type II; MPS II) in March 2026. AVLAYAH is the first FDA-approved medicine in an emerging class of biotherapeutics designed to cross the blood-brain barrier via transferrin receptor (TfR)-mediated transport.

"The Priority Review Voucher program is an important and effective mechanism to support the development of medicines for rare pediatric diseases. Monetizing this PRV strengthens our financial flexibility at a pivotal moment as we build on the momentum created by the FDA approval of AVLAYAH, the first FDA-approved biotherapeutic designed to reach the whole body, including the brain," said Alexander Schuth, M.D., Chief Operating and Financial Officer of Denali Therapeutics. "The proceeds will fuel the advancement and acceleration of our broad clinical pipeline, including additional Enzyme TransportVehicle programs for lysosomal storage disorders and Oligonucleotide and Antibody TransportVehicle programs targeting Alzheimer's and other neurodegenerative diseases."

Denali's clinical-stage portfolio includes DNL126 (ETV:SGSH) for Sanfilippo syndrome type A (MPS IIIA), DNL593 (PTV:PGRN) for *GRN*-related frontotemporal dementia, DNL952 (ETV:GAA) for Pompe disease and DNL628 (OTV:MAPT) for Alzheimer's disease. Denali also has multiple programs in the Investigational New Drug (IND)-enabling stage, including DNL921 (ATV:Abeta) for Alzheimer's disease, DNL111 (ETV:GCase) for Parkinson's disease and Gaucher disease, DNL622 (ETV:IDUA) for Hurler syndrome (MPS I) and DNL422 (OTV:SNCA) for Parkinson's disease.

The PRV transaction is subject to customary closing conditions, including expiration of the applicable waiting period under the Hart-Scott Rodino Antitrust Improvements Act.

About the Denali TransportVehicle™ Platform

The blood-brain barrier (BBB) is essential in maintaining the brain's microenvironment and protecting it from harmful substances and pathogens circulating in the bloodstream. Historically, the BBB has posed significant challenges to drug development for central nervous system diseases by preventing most drugs from reaching the brain in therapeutically relevant concentrations. Denali's TransportVehicle™ (TV) platform is a proprietary technology designed to effectively deliver large therapeutic molecules such as antibodies, enzymes and oligonucleotides throughout the whole body, including the brain, by crossing the BBB after intravenous administration. The TV platform is based on engineered Fc domains that bind to specific natural transport receptors, such as transferrin receptor and CD98 heavy chain amino acid transporter, which are expressed at the BBB and deliver the TV and its therapeutic cargo to the brain through receptor-mediated transcytosis. In animal models, antibodies and enzymes engineered with the TV platform demonstrate more than 10- to 30-fold greater brain exposure than similar antibodies and enzymes without this technology. Oligonucleotides engineered with the TV platform demonstrate more than a 1,000-fold greater brain exposure in primates than systemically delivered oligonucleotides without this technology. Improved exposure and broad distribution in the brain may increase therapeutic efficacy by enabling widespread achievement of therapeutically relevant concentrations of product candidates. The TV platform has been clinically validated, with AVLAYAH™ (tividenofusp alfa-eknm) as the first FDA-approved medicine leveraging transferrin receptor to cross the BBB.

About Denali Therapeutics

Denali Therapeutics Inc. is a biotechnology company pioneering a new class of biotherapeutics designed to cross the blood-brain barrier (BBB) using its proprietary TransportVehicle™ platform. With the first FDA-approved biologic specifically designed to cross the BBB, a clinically validated delivery platform and a growing portfolio of therapeutic candidates across all stages of development, Denali is advancing toward its goal of delivering effective medicines to transform life for people with neurodegenerative diseases, lysosomal storage disorders and other serious diseases. For more information, please visit www.denalitherapeutics.com.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements expressed or implied in this press release include, but are not limited to, statements regarding the timeline and likelihood of satisfying closing conditions for, and consummating the sale of, the Priority Review Voucher ("PRV"); expected use of proceeds from the sale of the PRV and the anticipated impact on Denali's cash runway; plans, timelines and expectations related to Denali's Enzyme TransportVehicle™ (ETV) franchise and its therapeutic and commercial potential; plans, timelines and expectations related to AVLAYAH™ (tividenofusp alfa-eknm); and statements by Denali's Chief Operating and Financial Officer. Actual results may differ materially from those expressed or implied by these forward-looking statements due to a variety of risks and uncertainties. These include, but are not limited to, uncertainties related to the FDA's policies and accelerated approval program; risks arising from adverse economic conditions and their impact on Denali's business and operations; the possibility of events or changes that could lead to the termination of Denali's collaboration agreements; challenges associated with Denali's transition to a commercial company; the ability of Denali and its collaborators to complete the development and, if approved, the commercialization of product candidates; difficulties in patient enrollment for ongoing and future clinical trials; whether the current ongoing trials have been powered sufficiently to demonstrate approvability to regulatory agencies; reliance on third-party manufacturers and suppliers for clinical trial materials; dependence on the successful development of Denali's blood-brain barrier platform technology and related programs; potential delays or failures in meeting expected clinical trial timelines; the risk that promising preclinical profiles may not be replicated in clinical settings; discrepancies between preclinical, early-stage or preliminary clinical results and outcomes from later-stage trials; the occurrence of significant adverse events or other undesirable side effects; the uncertainty surrounding regulatory approvals required for commercialization in the U.S., Europe or other international jurisdictions; Denali's ability to advance a pipeline of product candidates or develop commercially successful products; developments relating to Denali's competitors and its industry, including competing product candidates and therapies; Denali's ability to obtain, maintain or protect intellectual property rights related to its product candidates; the implementation and success of Denali's strategic plans for its business, product candidates and blood-brain barrier platform technology; Denali's ability to obtain additional capital to finance its operations, as needed; Denali's ability to accurately forecast future financial results in the current environment; and other risks and uncertainties, including those described in Denali's most recent Annual and Quarterly Reports on Forms 10-K and 10-Q filed with the Securities and Exchange Commission (SEC) on February 26, 2026 and May 7, 2026, respectively, and Denali's future reports to be filed with the SEC. Except for AVLAYAH, Denali's product candidates are investigational, and their safety and efficacy profiles have not yet been established. Denali does not undertake any obligation to update or revise any forward-looking statements, to conform these statements to actual results or to make changes in Denali's expectations, except as required by law.

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