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 4, 2025

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 December 4, 2025, Denali Therapeutics Inc. ("Denali" or the "Company") entered into a synthetic royalty funding agreement (the "Royalty Agreement") with Royalty Pharma plc ("Royalty Pharma"). Pursuant to the Royalty Agreement, Royalty Pharma has agreed to provide up to $275 million in funding to the Company in exchange for a 9.25% royalty on future net sales of tividenofusp alfa, Denali's investigational TransportVehicle™-enabled enzyme replacement therapy for the treatment of mucopolysaccharidosis type II (Hunter syndrome).

The transaction is subject to various closing conditions, including Denali achieving U.S. Food and Drug and Administration (FDA) accelerated approval of tividenofusp alfa on or before June 30, 2026. At the closing, Royalty Pharma will make an initial payment of $200 million. Denali will receive an additional payment of $75 million upon approval of tividenofusp alfa by the European Medicines Agency (EMA) on or before December 31, 2029.

In exchange for these payments, Royalty Pharma will be entitled to receive a 9.25% royalty on worldwide net sales of tividenofusp alfa. The royalty payments to Royalty Pharma will cease upon reaching a multiple of 3.0x, or 2.5x if achieved by the first quarter of 2039. Denali will retain all worldwide development and commercialization rights to tividenofusp alfa.

Tividenofusp alfa is currently under review by the FDA with a Prescription Drug User Fee Act (PDUFA) target action date of April 5, 2026.

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

Forward-Looking Statements

Certain statements made in this report are forward looking, such as those relating to: plans, timelines and expectations related to tividenofusp alfa and Denali's TransportVehicle platform; expectations regarding the collaboration with Royalty Pharma, including financial aspects of the royalty financing agreement; the potential benefits and results of the royalty financing agreement; expectations regarding achieving accelerated approval from the FDA; plans to conduct development and commercialization activities; and other information relating to the transaction between Royalty Pharma and Denali. Actual results are subject to risks and uncertainties and may differ materially from those projected or implied in these forward-looking statements as a result of these risks and uncertainties, including but not limited to: the risk that the transaction may not close in a timely manner or at all; risks related to obtaining the requisite regulatory approvals; the risk of the occurrence of any event, change or other circumstance that could give rise to the termination of the agreement; and other risks, including those described in Denali's Annual Report on Form 10-K and Quarterly Report filed on Form 10-Q filed with the SEC on February 27, 2025, and November 6, 2025, respectively, and Denali's future reports to be filed with the SEC. 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.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Denali Therapeutics 2025 Royalty Funding Agreement (December 4, 2025)
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: December 4, 2025

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

Denali Therapeutics and Royalty Pharma Announce $275 Million Royalty Funding Agreement

SOUTH SAN FRANCISCO, Calif. and NEW YORK, N.Y. — December 4, 2025 — Denali Therapeutics Inc. (Nasdaq: DNLI) and Royalty Pharma plc (Nasdaq: RPRX) today announced a $275 million synthetic royalty funding agreement based on future net sales of tividenofusp alfa.

Tividenofusp alfa is Denali's lead investigational TransportVehicle™-enabled enzyme replacement therapy for the treatment of mucopolysaccharidosis type II (MPS II, or Hunter syndrome). A Biologics License Application (BLA) for accelerated approval of tividenofusp alfa is under review by the U.S. Food and Drug Administration (FDA) with a Prescription Drug User Fee Act (PDUFA) target date of April 5, 2026.

"We are pleased to partner with Royalty Pharma, whose investment recognizes the value and potential of tividenofusp alfa for the Hunter community and supports our ability more broadly to realize the promise of the TransportVehicle platform," said Ryan Watts, Ph.D., Chief Executive Officer of Denali Therapeutics. "With these additional funds, we are well positioned to advance our development programs as we prepare for the launch of tividenofusp alfa, unlocking broad opportunities across serious diseases."

"We are delighted to partner with Denali and acquire a royalty on tividenofusp alfa, an innovative therapy that addresses a significant unmet need in the cognitive and physical manifestations of Hunter syndrome," said Pablo Legorreta, Chief Executive Officer and Chairman of the Board of Royalty Pharma. "Denali's technology platform delivers therapeutics across the blood-brain barrier and is a promising new approach to brain diseases. We are thrilled to establish a relationship with Denali and believe tividenofusp alfa is a potential practice-changing therapy that could transform the lives of patients with Hunter syndrome."

Transaction Terms

The transaction is subject to various closing conditions, including Denali achieving U.S. FDA accelerated approval of tividenofusp alfa. At the closing, Royalty Pharma will make an initial payment of $200 million and Royalty Pharma will be obligated to make an additional payment of $75 million upon achieving European Medicines Agency (EMA) approval of tividenofusp alfa by December 31, 2029. In exchange, Royalty Pharma will receive a 9.25% royalty on worldwide net sales of tividenofusp alfa from Denali. The royalty payments to Royalty Pharma will cease upon reaching a multiple of 3.0x, or 2.5x if achieved by the first quarter of 2039.

Advisors

Gibson Dunn acted as legal advisor to Denali. Goodwin Procter and Maiwald acted as legal advisors to Royalty Pharma.

About Denali Therapeutics

Denali Therapeutics Inc. is a biotechnology company pioneering a new class of biotherapeutics designed to cross the blood-brain barrier using its proprietary TransportVehicle™ platform. With 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 the lives of people living with neurodegenerative, lysosomal storage and other serious diseases. For more information, please visit www.denalitherapeutics.com.

About Royalty Pharma

Founded in 1996, Royalty Pharma is the largest buyer of biopharmaceutical royalties and a leading funder of innovation across the biopharmaceutical industry, collaborating with innovators from academic institutions, research hospitals and non-profits through small and mid-cap biotechnology companies to leading global pharmaceutical companies. Royalty Pharma has assembled a portfolio of royalties which entitles it to payments based directly on the top-line sales of many of the industry's leading therapies. Royalty Pharma funds innovation in the biopharmaceutical industry both directly and indirectly – directly when it partners with companies to co-fund late-stage clinical trials and new product launches in exchange for future royalties, and indirectly when it acquires existing royalties from the original innovators. Royalty Pharma's current portfolio includes royalties on more than 35 commercial products, including Vertex's Trikafta and Alyftrek, GSK's Trelegy, Roche's Evrysdi, Johnson & Johnson's Tremfya, Biogen's Tysabri and Spinraza, Servier's Voranigo, AbbVie and Johnson & Johnson's Imbruvica, Astellas and Pfizer's Xtandi, Pfizer's Nurtec ODT, and Gilead's Trodelvy, and 18 development-stage product candidates.

Denali Therapeutics 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, plans, timelines and expectations related to tividenofusp alfa and Denali's TransportVehicle platform; expectations regarding the collaboration with Royalty Pharma, including financial aspects of the royalty financing agreement; the potential benefits and results of the royalty financing agreement; expectations regarding achieving accelerated approval from the FDA; and plans to conduct development and commercialization activities.

Actual results are subject to risks and uncertainties and may differ materially from those indicated by these forward-looking statements as a result of these risks and uncertainties, including but not limited to: the risk of the occurrence of any event, change or other circumstance that could give rise to the termination of the agreement with Royalty Pharma; the impact of adverse economic conditions, tariffs, and inflation on Denali's business and operations; Denali's transition to a late-stage clinical drug development company; Denali's and its partners' ability to complete the development and, if approved, commercialization of its product candidates; Denali's reliance on third parties for the manufacture and supply of its product candidates; Denali's dependence on successful development of its blood-brain barrier platform technology; Denali's and its partners' ability to conduct or complete clinical trials on expected timelines; the risk of significant adverse events, toxicities, or other undesirable side effects; the uncertainty that product candidates will receive regulatory approval necessary to be commercialized; 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; implementation 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; general economic and market conditions; and other risks and uncertainties, including those described in Denali's most recent Annual Report on Form 10-K and most recent Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on February 27, 2025 and November 6, 2025, and Denali's future reports to be filed with the SEC. The forward-looking statements in this press release are based on information available to Denali as of the date hereof. Denali disclaims any obligation to update any forward-looking statements, except as required by law.

Royalty Pharma Forward-Looking Statements

The information set forth herein does not purport to be complete or to contain all of the information you may desire. Statements contained herein are made as of the date of this document unless stated otherwise, and neither the delivery of this document at any time, nor any sale of securities, shall under any circumstances create an implication that the information contained herein is correct as of any time after such date or that information will be updated or revised to reflect information that subsequently becomes available or changes occurring after the date hereof. This document contains statements that constitute "forward-looking statements" as that term is defined in the United States Private Securities Litigation Reform Act of 1995, including statements that express the company's opinions, expectations, beliefs, plans, objectives, assumptions or projections regarding future events or future results, in contrast with statements that reflect historical facts. Examples include discussion of Royalty Pharma's strategies, financing plans, growth opportunities, market growth, and plans for capital deployment. In some cases, you can identify such forward-looking statements by terminology such as "may," "might," "will," "should," "expects," "plans," "anticipates," "believes," "estimates," "target," "forecast," "guidance," "goal," "predicts," "project," "potential" or "continue," the negative of these terms or similar expressions. Forward-looking statements are based on management's current beliefs and assumptions and on information currently available to the company. However, these forward-looking statements are not a guarantee of Royalty Pharma's performance, and you should not place undue reliance on such statements. Forward-looking statements are subject to many risks, uncertainties and other variable circumstances, and other factors. Such risks and uncertainties may cause the statements to be inaccurate and readers are cautioned not to place undue reliance on such statements. Many of these risks are outside of Royalty Pharma's control and could cause its actual results to differ materially from those it thought would occur. The forward-looking statements included in this document are made only as of the date hereof. Royalty Pharma does not undertake, and specifically declines, any obligation to update any such statements or to publicly announce the results of any revisions to any such statements to reflect future events or developments, except as required by law. For further information, please reference Royalty Pharma's reports and documents filed with the U.S. Securities and Exchange Commission ("SEC") by visiting EDGAR on the SEC's website at www.sec.gov.

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