# 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 4, 2022**

# 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) 866-8548**
**(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))

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. ☐

| 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 |

**Item 7.01 Regulation FD Disclosure.**

Denali Therapeutics Inc. (“Denali”) has received clearance of its Clinical Trial Application (“CTA”) to begin a Phase 1 clinical study of DNL919 (ATV:TREM2) in healthy volunteers. Denali expects to initiate the Phase 1 single ascending dose study in the Netherlands in the third quarter of 2022. Denali has not yet submitted a response to the previously announced clinical hold placed on the Investigational New Drug (“IND”) application for DNL919 by the U.S. Food and Drug Administration (“FDA”). Denali continues to engage with the FDA and regulatory authorities in Europe to define the path forward for the DNL919 clinical program, including plans to advance into a Phase 1b study in patients with Alzheimer’s disease.

The information furnished in this Item 7.01 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, nor shall it be deemed incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such a filing.

***Forward-Looking Statements***

Certain of the statements made in this report are forward looking, such as those, among others, relating to Denali’s plans and timelines for a Phase 1 single ascending dose clinical study of DNL919 (ATV:TREM2) in healthy volunteers in the Netherlands, Denali’s continued engagement with the FDA and regulatory authorities to define the path forward for the DNL919 clinical program, and plans to advance DNL919 into a Phase 1b study in patients with Alzheimer's disease. Actual results or developments may differ materially from those projected or implied in these forward-looking statements. Factors that may cause such a difference include risks and uncertainties related to new or additional information received from the FDA or regulatory authorities in Europe, delays in reaching a consensus with regulatory agencies on trial designs, Denali’s ability to enroll patients in its clinical trials, and delays in Denali’s clinical trials for its programs, including DNL919 (ATV:TREM2). More information about the risks and uncertainties faced by Denali may be found in Denali’s Annual and Quarterly Reports filed on Forms 10-K and 10-Q filed with the Securities and Exchange Commission (the “SEC”) on February 28, 2022, and May 5, 2022, 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.

**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 5, 2022

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