
**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):
February 14, 2022**

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) 866-8548
(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.

As previously announced, Denali Therapeutics Inc. (“Denali”) was informed on January 12, 2022, via e-mail communication from the U.S. Food and Drug Administration (FDA) that the DNL919 (ATV:TREM2) Investigational New Drug (IND) application to begin clinical testing was placed on clinical hold. Denali has now received a formal clinical hold letter and is moving forward to address the FDA’s observations related to the preclinical toxicology assessment and to provide the information requested to initiate clinical studies, including proposed changes to the clinical trial protocol, the informed consent form, and the investigator brochure. Denali intends to provide an update once a clear path forward has been established.

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 regarding the submission of certain requested information to the FDA, proposed changes to the clinical trial protocol for DNL919 (ATV:TREM2), Denali’s expectations regarding the effects of the issues raised in the clinical hold letter and Denali’s intention to provide an update on the status of the clinical hold. 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, delays in reaching a consensus with regulatory agencies on trial designs, 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 26, 2021, and November 4, 2021, 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: February 14, 2022

By: /s/ Steve E. Krognas
Steve E. Krognas
Chief Financial Officer and Treasurer