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):
October 4, 2020

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 1.01 Entry into a Material Definitive Agreement.

Denali Therapeutics Inc. ("Denali") entered into a Definitive LRRK2 Collaboration and License Agreement ("LRRK2 Agreement") with Biogen, Inc.'s subsidiaries, Biogen MA, Inc. ("BIMA") and Biogen International GmbH ("BIG") (BIMA and BIG, collectively, "Biogen") on October 4, 2020 and a Right of First Negotiation, Option and License Agreement (the "ROFN and Option Agreement") on October 6, 2020. The material terms of the LRRK2 Agreement and the ROFN and Option Agreement are consistent with, and supersede, the Provisional Collaboration and License Agreement between Denali and Biogen dated August 5, 2020 (the "Provisional Agreement"), the terms of which were disclosed in Denali's Current Report on Form 8-K filed with the Securities and Exchange Commission on August 6, 2020.

Upfront Payment

Under the LRRK2 Agreement and the ROFN and Option Agreement, Biogen is obligated to pay Denali an aggregate of $560 million in upfront payments. In addition, a separate stock purchase agreement between Denali and BIMA was signed on August 5, 2020 and closed on September 22, 2020, under which BIMA purchased 13,310,243 shares of Denali's common stock (the "Shares") for an aggregate purchase price of approximately $465.0 million.

LRRK2 Agreement

Under the LRRK2 Agreement, Denali granted to Biogen a co-exclusive license under Denali's intellectual property related to small molecule inhibitors of leucine-rich repeat kinase 2 ("LRRK2"), and Denali and Biogen will co-develop such inhibitors worldwide for Parkinson's disease and will co-commercialize products containing such inhibitors in the United States and China, with shared responsibility for worldwide development costs, as well as sharing of profits and losses in the United States and China.

The material terms of the LRRK2 Agreement are consistent with the Provisional Agreement, including without limitation the maximum aggregate milestone payments and royalty payments that Biogen is obligated to pay to Denali, and the cost-profit sharing arrangement between Denali and Biogen, as disclosed in Denali's Current Report on Form 8-K filed with the Securities and Exchange Commission on August 6, 2020.

ROFN and Option Agreement

Under the ROFN and Option Agreement, Denali granted to Biogen an exclusive option to license two preclinical programs leveraging Denali's transport vehicle ("TV") technology platform, one of which programs is for products directed to amyloid beta and the other for an undisclosed target, as well as a right of first negotiation with respect to two of Denali's TV-enabled therapeutics programs in the field of Alzheimer's disease, Parkinson's disease, amyotrophic lateral sclerosis and multiple sclerosis (excluding all small molecule, gene therapy and oligonucleotide programs) should Denali decide to seek a collaboration for such programs.

With respect to the options granted by Denali to Biogen, Biogen is obligated to pay to Denali an aggregate of up to $270 million in option exercise and development milestone payments and an aggregate of up to $615 million in commercial milestone payments, following the achievement of certain prespecified milestone events and if Biogen exercises both of its options. Furthermore, Biogen is obligated to pay to Denali royalties in the mid-single digit to mid-teens percentages, depending on the program for which Biogen exercises its option and upon the achievement of certain sales thresholds.

In addition, if Biogen exercises its right of first negotiation with respect to an eligible Denali program, the parties are obligated to negotiate in good faith for a specified period of time regarding the financial and other terms of an agreement pursuant to which Biogen would obtain rights to such program.

The foregoing descriptions of the LRRK2 Agreement and the ROFN and Option Agreement do not purport to be complete and are qualified in their entirety by reference to the full text of the LRRK2 Agreement and the ROFN and Option Agreement, as applicable, both of which Denali intends to file as an exhibit to a subsequent filing with the Securities and Exchange Commission.

Item 7.01 Regulation FD Disclosure.

On October 7, 2020, Denali issued a press release announcing the signing of the LRRK2 Agreement and the ROFN and Option Agreement and the closing of the related common stock purchase agreement. A copy of the press release is attached hereto as Exhibit 99.1 and incorporated herein by reference.

The information furnished in this Item 7.01 and Item 9.01 (including Exhibits 99.1) 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 or the Exchange Act, except as shall be expressly set forth by specific reference in such a filing.

Item 8.01 Other Events.

On September 22, 2020, Denali closed the previously announced sale of 13,310,243 Shares to Biogen for an aggregate purchase price of approximately $465.0 million. The Shares were issued pursuant to a stock purchase agreement between Denali and BIMA dated August 5, 2020, as previously disclosed in the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on August 6, 2020.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release dated October 7, 2020.
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: October 7, 2020

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

Denali Therapeutics Announces Closing of Collaboration and Share Purchase Agreements with Biogen

SOUTH SAN FRANCISCO, Calif., Oct 7, 2020 — Denali Therapeutics Inc. (NASDAQ: DNLI), a biopharmaceutical company developing a broad portfolio of product candidates engineered to cross the blood-brain barrier (BBB) for neurodegenerative diseases, today announced the signing of a Definitive LRRK2 Collaboration and License Agreement and a Right of First Negotiation, Option and License Agreement with Biogen, in connection with its previously announced binding provisional collaboration and license agreement for neurodegenerative diseases with Biogen, and the closing of the related common stock purchase agreement.

In connection with the signing of the agreements with Biogen, Denali will receive a $560 million upfront payment. In addition, on September 22, 2020, in a private placement transaction, Biogen made an equity investment of $465 million in Denali through the purchase of 13,310,243 newly issued shares of Denali common stock at approximately $34.94 per share in connection with its previously announced stock purchase agreement.

Under the terms of the Definitive LRRK2 Collaboration and License Agreement, the companies will co-develop Denali's small molecule inhibitors of leucine-rich repeat kinase 2 (LRRK2) for Parkinson's disease, and will co-commercialize Denali's LRRK2 products in the United States and China, with shared responsibility for worldwide development costs(60 percent Biogen; 40 percent Denali), as well as profits and losses for commercialization in the United States (50 percent Biogen; 50 percent Denali) and China (60 percent Biogen; 40 percent Denali). Outside the United States and China, Biogen will be responsible for commercialization and will pay Denali tiered royalties. Should the LRRK2 program achieve certain development and commercial milestones, Denali will be eligible to receive up to $1.125 billion in potential milestone payments.

Mutations in LRRK2 can cause Parkinson's disease. LRRK2 is a regulator of lysosomal function, which is impaired in Parkinson's disease and may contribute to neurodegeneration. As previously announced, Denali's small molecule inhibitor of LRRK2, DNL151, has been selected to progress into late-stage clinical studies, which are expected to commence in 2021.

Under the terms of the Right of First Negotiation, Option and License Agreement with Biogen, Biogen has exclusive option rights to two programs for neurodegenerative diseases using Denali's BBB-crossing transport vehicle (TV) technology platform, including for amyloid beta, plus right of first negotiation for two additional unnamed TV platform programs should Denali decide to seek a collaboration for such programs. These rights are limited to certain modalities and indications and are also exercisable during a limited time period. Denali's proprietary TV technology is designed to effectively deliver large therapeutic molecules such as antibodies, enzymes, proteins and oligonucleotides across the BBB after intravenous administration.

The closing of the common stock purchase agreement and the definitive collaboration agreements were subject to the satisfaction of customary closing conditions, including the expiration of the waiting period under the Hart-Scott-Rodino (HSR) Antitrust Improvements Act of 1976. Additional details regarding the financial terms can be found in Denali's Form 8-K filed with the Securities and Exchange Commission on October 7, 2020.

About Denali's LRRK2 DNL151 Program

DNL151 is a small molecule inhibitor of LRRK2 invented at Denali which has completed dosing of 162 healthy volunteers in an ongoing Phase 1 clinical study and completed dosing in 25 Parkinson's patients in a Phase 1b clinical study. Denali is currently completing further dose escalation cohorts in an expanded Phase 1 and an additional cohort in the Phase 1b study to define the full therapeutic window of the molecule. Based on the clinical data to date that has been generated in Europe, DNL151 appears to have an acceptable safety and tolerability profile and has met desired target engagement goals. An Investigational New Drug application for DNL151 was cleared by the U.S. Food and Drug Administration in July 2020 and enables expansion of Denali clinical trials for DNL151 globally.

About Denali Therapeutics

Denali Therapeutics is a biopharmaceutical company developing a broad portfolio of product candidates engineered to cross the blood-brain barrier (BBB) for neurodegenerative diseases. Denali pursues new treatments by rigorously assessing genetically validated targets, engineering delivery across the BBB and guiding development through biomarkers that demonstrate target and pathway engagement. Denali is based in South San Francisco. For additional information, please visit www.denalitherapeutics.com.

Cautionary Note Regarding 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 DNL151 and other LRRK2 inhibitor molecules, Denali's TV technology platform and TV programs; LRRK2 inhibitors as modifying therapy for Parkinson's disease; the ability of the TV technology to effectively deliver large therapeutic molecules across the BBB; expectations regarding the collaboration with Biogen, including financial aspects of the collaboration; the potential benefits and results of the transaction with Biogen; expectations regarding the commencement of clinical trials; expectations regarding ongoing clinical trials; 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: any and all risks to Denali's business and operations caused directly or indirectly by the evolving COVID-19 pandemic; the risk of the occurrence of any event, change or other circumstance that could give rise to the termination of the agreements with Biogen; risks related to the effect of the announcement of the transaction on Denali's business relationships, operating results, stock price and business generally; Denali's early stages of clinical drug development; Denali's and its partners' ability to complete the development and, if approved, commercialization of its product candidates; Denali's and its partners' ability to enroll patients in clinical trials; Denali's reliance on third parties for the manufacture and supply of its product candidates for clinical trials; Denali's dependence on successful development of its BBB platform technology and whether the platform technology effectively delivers large therapeutic molecules across the BBB; Denali's and its partners' ability to conduct or complete clinical trials on expected timelines; the risk that preclinical profiles and results of early clinical trials of Denali's product candidates, such as DNL151, may not translate in later clinical trials; the risk that DNL151 and Denali's other LRRK2 inhibitors may not sufficiently modify Parkinson's disease; the uncertainty that product candidates will receive regulatory approval necessary to be commercialized; Denali's ability to continue to create 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; implementation of Denali's strategic plans for its business, product candidates and BBB 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, most recent Quarterly Report on Form 10-Q 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.

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