
**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):
May 30, 2018

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.)

151 Oyster Point Blvd., 2nd Floor
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.

Item 1.01 Entry into a Material Definitive Agreement.

In August 2016, Denali Therapeutics Inc. (“Denali” or the “Company”) entered into a license and collaboration agreement with F-star Gamma Limited, a private limited liability company incorporated under the laws of England and Wales (“F-star Gamma”), f-star Biotechnologische Forschungs-und Entwicklungsges m.b.H and F-star Biotechnology Limited (the “Collaboration Agreement”). In connection with the entry into the Collaboration Agreement, the Company also purchased an option, referred to as the buy-out option, to acquire all of the outstanding shares of F-star Gamma pursuant to a pre-negotiated buy-out option agreement.

On May 30, 2018, the Company exercised such buy-out option and entered into a Share Purchase Agreement (the “Purchase Agreement”) with the shareholders of F-star Gamma and Shareholder Representative Services LLC, pursuant to which the Company acquired all of the outstanding shares of F-star Gamma (the “Acquisition”).

As a result of the Acquisition, F-star Gamma has become a wholly owned subsidiary of the Company and the Company plans to change the entity’s name to Denali BBB Holding Limited. In addition, the Company became a direct licensee of certain intellectual property of F-star Biotechnology Limited (by way of the Company’s assumption of F-star Gamma’s license agreement with F-star Biotechnology Limited, dated August 24, 2016, (the “F-star Gamma License”). The Company is obligated to make initial exercise payments under the buy-out option agreement and the F-star Gamma License of, in the aggregate, \$18.0 million, less the estimated net liabilities of F-star Gamma, which is approximately \$0.2 million. In addition, the Company is required under the buy-out option agreement and the F-star Gamma License to make future contingent payments up to a maximum amount of \$447.0 million in the aggregate upon the achievement of certain defined preclinical, clinical, regulatory and commercial milestones. The amount of the contingent payments varies based on whether F-star delivers an Fcab™ (constant Fc-domains with antigen-binding activity) that meets pre-defined criteria and whether the Fcab has been identified solely by the Company or solely by F-star or jointly by the Company and F-star.

In addition, Denali has expanded certain rights under the existing Collaboration Agreement and has exercised its right to nominate two additional blood-brain barrier (“BBB”) transporter Fcab targets. The Company is obligated to make a one-time payment for these expanded rights under the existing Collaboration Agreement of, in the aggregate, \$6.0 million.

Under the Collaboration Agreement, f-star Biotechnologische Forschungs-und Entwicklungsges m.b.H and F-star Biotechnology Limited will continue to be prohibited from developing, commercializing and manufacturing any antibody or other molecule that incorporates any Fcab directed to any of the three BBB transporter Fcab targets nominated by the Company, or any such Fcab as a standalone product, and from authorizing any third party to take any such action.

The foregoing summary does not purport to be complete and is qualified in its entirety by reference to the Collaboration Agreement and related buy-out option agreement, which were previously filed with the Securities and Exchange Commission as Exhibit 10.11 to the Company’s Registration Statement on Form S-1, as well as the Purchase Agreement and the F-star Gamma License, which will be filed as exhibits to the Company’s Quarterly Report on Form 10-Q for the period ending June 30, 2018. Denali also intends to seek confidential treatment of certain terms of the Purchase Agreement and the F-star Gamma License at such time.

Item 2.01 Completion of Acquisition or Disposition of Assets.

The information set forth above in Item 1.01 of this Current Report on Form 8-K is hereby incorporated by reference into this Item 2.01.

Item 7.01 Regulation FD Disclosure.

On May 30, 2018, Denali issued a press release announcing the Acquisition. A copy of the press release is attached hereto as Exhibit 99.1 and incorporated herein by reference. The information in the press release shall not be deemed “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 other filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release dated May 30, 2018.

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: May 30, 2018

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



Denali Therapeutics Announces Early Exercise of Its Option to Acquire F-star Gamma

May 30, 2018

SOUTH SAN FRANCISCO, May 30, 2018 (GLOBE NEWSWIRE) — Denali Therapeutics Inc. (NASDAQ: DNLI), a biopharmaceutical company developing a broad portfolio of therapeutic candidates for neurodegenerative diseases, today announced that it has exercised its option to acquire all outstanding shares in F-star Gamma pursuant to the Option Agreement dated August 24, 2016 and expanded its collaboration with F-star on Denali's biologics Transport Vehicle ("TV") blood-brain barrier ("BBB") platform technology.

Denali entered into a License and Collaboration Agreement with F-star in August 2016 to support the development of and provide rights to intellectual property for Denali's proprietary TV platform technology to deliver therapeutics across the BBB. Based on compelling preclinical proof of concept data for the TV platform technology and substantive progress with Denali's lead program enabled by this technology, Denali has decided to exercise its option to acquire F-star Gamma, a private limited liability company incorporated under the laws of England and Wales. F-star Gamma holds certain intellectual property rights to F-star's Modular Antibody Technology™ which has been used to generate Fcabs against a transporter in the BBB. In addition, Denali has expanded certain rights under the existing License and Collaboration Agreement and has exercised its right to nominate two additional BBB transporter Fcab™ (constant Fc-domains with antigen-binding activity) targets.

"Our decision to exercise the option to buy F-star Gamma reflects the progress in our collaboration with F-star and the generation of preclinical data showing that our proprietary TV platform technology may enable us to deliver biologics across the BBB and into the brain. Specifically, recent data demonstrated robust and sustained peripheral and brain activity for our ETV:IDS program for Hunter Syndrome and hence preclinical proof of concept. Furthermore, the expanded collaboration allows us to deepen and broaden our research efforts supporting our TV platform technology," said Ryan Watts, Ph.D., CEO of Denali Therapeutics.

"With the growing number of patients affected by neurological disorders, there is an urgent need to efficiently deliver medicines into the brain. Denali's approach is well positioned to tackle this challenge and we firmly believe that its TV platform technology, enabled by F-star's Modular Antibody Technology has the potential to create a new class of disruptive CNS-targeting biological therapeutics," said John Haurum, CEO of F-star.

The total consideration for the option exercise and expanded collaboration amounts to \$24 million, plus any net cash held by F-star Gamma at closing of the transaction. In addition, Denali may make future contingent payments up to a maximum of \$447 million upon the achievement of defined preclinical, clinical, regulatory and commercial milestones. There are no royalty payments on net sales from future products. Through the acquisition of F-star Gamma, Denali obtains exclusive rights to discover, develop and commercialize an unlimited number of therapeutic products enabled by F-star's intellectual property and utilizing any of the three BBB transporter Fcab targets nominated by Denali.

About Denali Therapeutics

Denali is a biopharmaceutical company developing a broad portfolio of therapeutic candidates for neurodegenerative diseases. Denali pursues new treatments by rigorously assessing genetically validated targets, engineering delivery across the blood-brain barrier and guiding development with biomarker monitoring to demonstrate target engagement and select patients. Denali is based in South San Francisco. For additional 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 Denali's progress, expectations and business plans; expectations regarding, and potential benefits of, the F-star collaboration and the acquisition of F-star Gamma; and statements made by Denali's CEO and F-star's CEO. 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, risks related to: Denali's early stages of clinical drug development; Denali's ability to complete the development of, and if approved, commercialization of its product candidates; Denali's dependence on successful development of its TV platform technology and product candidates currently in its core program; Denali's ability to conduct or complete clinical trials on expected timelines; the uncertainty that any of Denali's 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; Denali's ability to obtain, maintain, or protect intellectual property rights related to its product candidates and TV platform technology; implementation of Denali's strategic plans for its business, product candidates and TV platform technology; and other risks, including those described in Denali's Annual Report on Form 10-K filed with the SEC on March 19, 2018, Denali's Quarterly Report on Form 10-Q filed with the SEC on May 11, 2018 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.