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):
January 3, 2018

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)	(IRS 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 report)

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 (see General Instruction A.2. below):

☐ 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.

Takeda Option and Collaboration Agreement

On January 3, 2018, Denali Therapeutics Inc., ("Denali" or "we"), entered into an option and collaboration agreement ("Collaboration Agreement") with Takeda Pharmaceutical Company Limited ("Takeda"), pursuant to which we granted Takeda an option in respect of three (3) of our programs to develop and commercialize, jointly with us, certain biologic products that are enabled by our blood-brain barrier delivery technology and intended for the treatment of neurodegenerative disorders. The three programs are Denali's ATV:BACE1/Tau and ATV: TREM2 programs, as well as a third identified, but yet undisclosed discovery stage program. The Collaboration Agreement will become effective when the requirements of the Hart–Scott–Rodino Antitrust Improvements Act of 1976 have been satisfied (the "Effective Date").

When the Collaboration Agreement becomes effective, Takeda is obligated to pay us $155 million, consisting of an upfront cash payment of $40 million, a milestone payment of $5 million and a further payment of $110 million to purchase approximately 4.21 million shares of Denali's common stock at a price of approximately $26.10 per share, as described further below.

Research Phase and Takeda's Option

Under the Collaboration Agreement and unless we otherwise agree jointly with Takeda, we will be responsible, at our cost, for conducting activities relating to pre-IND development of biologic products directed to the three identified targets and enabled by our blood-brain barrier delivery technology targeting transferrin receptor during the applicable option period. The option period continues for each target until the first biologic product directed to the relevant target is IND-ready or about five (5) years after selection of the target, whichever is earlier.

For a limited period of time, subject to further limitations and the mutual agreement of the parties, ATV:TREM2 and the undisclosed target can each be replaced one time. If the parties cannot agree on a proposed target, the rejecting party will be restricted, subject to certain exceptions and only for a specified period of time, from conducting additional activities related to any antibody or other protein-based therapeutic product directed to the proposed replacement target outside the collaboration.

Takeda is obligated to pay us up to an aggregate of $25 million with respect to each program under the Collaboration Agreement directed to a target and based upon the achievement of certain pre-clinical milestone events, up to $75 million in total; $5 million of this amount will be due when the Collaboration Agreement becomes effective.

Collaboration Activities Following Takeda's Option Exercise

If Takeda exercises its option with respect to a particular target and collaboration program (i.e., the biologic products directed to the target for which Takeda has exercised its option), then Takeda will have the right to develop and commercialize, jointly with us, a specified number of biologic products enabled by our blood-brain barrier delivery technology that were developed during the option period and which are directed to the relevant target, and we will grant to Takeda a co-exclusive license under the intellectual property we control related to those biologic products.

Takeda is obligated to pay us a $5 million option fee for each target for which Takeda exercises its option, up to $15 million in total.

In addition, Takeda will be obligated to pay us up to an aggregate of $707.5 million upon achievement of certain clinical and regulatory milestone events if Takeda exercises its option for all three (3) collaboration programs. As well, Takeda will be obligated to pay us up to $75 million per biologic product upon achievement of a certain sales-based milestone, or an aggregate of $225 million if one biologic product from each program achieves the milestone.

After Takeda exercises its option for a particular target, Denali and Takeda will share equally the development and commercialization costs, and, if applicable, the profits, for each collaboration program. However, for each collaboration program, we may elect not to continue sharing development and commercialization costs, or Takeda may elect to terminate our cost-profit sharing rights and obligations if, following notice from Takeda and a cure period, we fail to satisfy our cost sharing obligations with respect to the relevant collaboration program. After such an election by us or termination by Takeda becomes effective, we will no longer be obligated to share in the development and commercialization costs for the relevant collaboration program, and we will not share in any profits from that collaboration program. Instead we will be entitled to

receive tiered royalties. The royalty rates will be in the low- to mid-teen percentages on net sales, or low- to high-teen percentages on net sales if Denali has met a certain co-funding threshold at the time of our election to opt out of co-development or Takeda's termination of our cost-profit sharing rights and obligations, and, in each case, these royalty rates will be subject to certain reductions specified in the Collaboration Agreement. Takeda will pay these royalties to us for each biologic product included in the relevant collaboration program, on a country-by-country basis, until the latest of (i) the expiration of certain patents covering the relevant biologic product, (ii) the expiration of all regulatory exclusivity for that biologic product, and (iii) an agreed period of time after the first commercial sale of that biologic product in the applicable country, unless biosimilar competition in excess of a significant level specified in the Collaboration Agreement occurs earlier, in which case Takeda's royalty obligations in the applicable country would terminate.

For each collaboration program for which we are sharing costs and profits with Takeda, we will lead the conduct of clinical activities for each indication up to the first Phase 2 trial with a clinical outcomes-based efficacy endpoints, and Takeda will lead the conduct of all subsequent clinical activities for that indication. For each collaboration program for which we are sharing costs and profits with Takeda, Denali and Takeda will jointly commercialize biologic products included in the relevant collaboration program in the United States and China. Unless we have opted out of cost-sharing for two collaboration programs, Denali has the right to lead commercialization activities in the United States for one collaboration program and Takeda will lead commercialization activities in the United States for all collaboration programs for which we do not lead commercialization activities. Further, Takeda will lead commercialization activities in China and will solely conduct commercialization activities in all other countries. Denali has the right to lead all manufacturing activities for all collaboration programs for which the parties are sharing costs and profits.

Exclusivity

During the option period for a particular target and, if the applicable option is exercised by Takeda (unless the Collaboration Agreement is terminated earlier), until expiration of an agreed period of time after the first regulatory approval in the United States or Europe of a biologic product within the applicable collaboration program, neither party may conduct clinical or commercial activities involving antibodies or protein-based therapeutic products directed to the same target (or in the case of a bi-specific program, the same combination of targets) that have an intended therapeutic effect in diseases and conditions of the central nervous system (including lysosomal storage diseases), except to the extent permitted under the Collaboration Agreement.

Termination

Each party may terminate the Collaboration Agreement in its entirety, or with respect to a particular collaboration program, as applicable, if the other party remains in material breach of the Collaboration Agreement following a cure period to remedy the material breach. Takeda may terminate the Collaboration Agreement in its entirety or with respect to any particular collaboration program, for convenience and after giving a specified amount of prior notice to us, but Takeda may not do so for a certain period of time after the Effective Date of the Collaboration Agreement. Takeda may also terminate the Collaboration Agreement with respect to any collaboration program if the joint steering committee established under the Collaboration Agreement unanimously agrees that a material safety event has occurred with respect to the applicable collaboration program. We may terminate the Collaboration Agreement with respect to a particular collaboration program if Takeda fails to conduct material development and commercial activities for a specified period of time with respect to a collaboration program, unless Takeda cures such failure within a certain period of time. We and Takeda may each terminate the Collaboration Agreement in its entirety if the other party is declared insolvent or in similar financial distress or if, subject to a specified cure period, the other party challenges any patents licensed to it under the Collaboration Agreement.

Following any termination of the Collaboration Agreement with respect to a particular collaboration program or the Collaboration Agreement in its entirety, our rights to each terminated collaboration program will revert to us, Takeda will grant us a license to intellectual property owned by Takeda with respect to such collaboration program (which could be subject to certain royalty payments that would be negotiated at the time of such a termination) and, unless the termination was by Takeda on the basis of a material safety event, Takeda will conduct certain development, manufacturing and commercialization wind-down activities.

Common Stock Purchase Agreement

Pursuant to the terms of the Collaboration Agreement, Denali entered into a common stock purchase agreement (the "Purchase Agreement") with Takeda on January 3, 2018, pursuant to which we agreed to issue and sell, and Takeda has agreed to purchase, 4,214,559 shares of Denali's common stock (the "Shares") for an aggregate purchase price of $110 million pursuant to the terms and conditions thereof. We expect to close the sale of the Shares within ten business days following the Effective Date of the Collaboration Agreement.

Pursuant to the terms of a standstill and stock restriction agreement (the "Standstill Agreement") to be entered into between Takeda and Denali at the closing of the sale of the Shares, Takeda will agree to certain transfer and standstill restrictions, including a restriction on acquiring more than 10% of Denali's capital stock, for a specified period of time following the closing of the sale of the Shares, or earlier upon a change of control of Denali or, with respect to the transfer restrictions, termination of the Collaboration Agreement. In addition, Takeda will be entitled to certain registration rights with respect to the Shares following termination of the transfer restrictions if the Shares cannot be resold without restriction pursuant to Rule 144 promulgated under the Securities Act of 1933, as amended (the "Securities Act").

The foregoing descriptions of the Collaboration Agreement, Purchase Agreement and Standstill Agreement (together, the "Agreements") do not purport to be complete and are qualified in their entirety by reference to the full text of such Agreements, which Denali intends to file with the Securities and Exchange Commission as exhibits to its Annual Report on Form 10-K for the fiscal year ended December 31, 2017. Denali also intends to seek confidential treatment of certain terms of the Collaboration Agreement at such time.

Item 3.02 Unregistered Sales of Equity Securities.

The information set forth above in Item 1.01 of this Current Report on Form 8-K under the heading "Common Stock Purchase Agreement" is hereby incorporated by reference into this Item 3.02.

Upon the closing of the sale of Shares pursuant to the above-referenced Purchase Agreement, Takeda will purchase the Shares in a private placement in reliance on Section 4(a)(2) of the Securities Act. Denali relied upon these exemptions from registration based in part on representations made by Takeda in the Purchase Agreement. Takeda will acquire the Shares for investment only and not with a view to or for sale in connection with any distribution thereof, and appropriate legends will be affixed to the Shares.

Item 7.01 Regulation FD Disclosure.

Press Release

On January 5, 2018, Denali issued a press release announcing the collaboration with Takeda. 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 or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Website as Channel of Distribution

Denali's website is located at www.denalitherapeutics.com. Denali uses its website as a channel of distribution of important company information. Important information, including news or announcements regarding our financial performance, investor events and press releases, is posted on and accessible from Denali's website. We intend to use Denali's website as a means of disclosing material non-public information and for complying with our disclosure obligations under Regulation FD.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press Release, dated January 5, 2018.

SIGNATURES

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.

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

Date: January 5, 2018

Exhibit 99.1

Takeda and Denali Therapeutics Collaborate to Develop and Commercialize Therapies for Neurodegenerative Diseases

Collaboration includes three named programs for the treatment of Alzheimer's disease and other neurodegenerative diseases, utilizing Denali's Antibody Transport Vehicle (ATV) technology to enhance blood-brain barrier (BBB) penetration.

Osaka, Japan and South San Francisco, CA, January 5, 2018 – Takeda Pharmaceutical Company Limited (TSE: 4502) and Denali Therapeutics (NASDAQ: DNLI) today announced that they have entered into a strategic option and collaboration agreement to develop and commercialize up to three specified therapeutic product candidates for neurodegenerative diseases. Each program is directed to a genetically validated target for neurodegenerative disorders, including Alzheimer's disease and other indications, and incorporates Denali's ATV platform for increased exposure of biotherapeutic products in the brain.

"This partnership further exemplifies Takeda's continued commitment to developing genetically validated therapies for neurodegenerative diseases through an enhanced portfolio comprised of new modalities," said Emiliangelo Ratti, Head of the Neuroscience Therapy Area at Takeda. "We are excited to partner with the Denali team, whose innovative technology is uniquely poised to deliver the next generation of antibody therapeutics for patients."

"We are impressed with Takeda's commitment to developing treatments for difficult to treat neurodegenerative diseases and look forward to partnering with them to bring medicines to patients," said Denali CEO Ryan Watts, Ph.D. "Takeda has a great track record of partnering with biotech firms in addition to unique development expertise and a strong global commercial presence."

Terms of Collaboration

Under the terms of the agreement, Takeda will make an initial payment to Denali of $150 million through a combination of cash upfront payments and the purchase of Denali equity. In addition, Denali is eligible to receive development and commercial milestone payments, including $90 million in preclinical milestones and opt-in payments.

Denali will be responsible for all development activities and costs prior to IND filing for each of the three programs. Takeda has the option to co-develop and co-commercialize each of the three programs. If Takeda exercises the option, the parties will then jointly conduct clinical development and share all costs equally. Denali will lead early clinical development activities and Takeda will lead late stage clinical development activities. Takeda and Denali will jointly commercialize products in the United States and China, and Takeda will have exclusive commercialization rights in all other markets. The parties will share global profits equally. The agreement will become effective when the requirements of the Hart–Scott–Rodino Antitrust Improvements Act of 1976 have been satisfied.

About Takeda Pharmaceutical Company

Takeda Pharmaceutical Company Limited (TSE: 4502) is a global, research and development-driven pharmaceutical company committed to bringing better health and a brighter future to patients by translating science into life-changing medicines. Takeda focuses its R&D efforts on oncology, gastroenterology and neuroscience therapeutic areas plus vaccines. Takeda conducts R&D both internally and with partners to stay at the leading edge of innovation. New innovative products, especially in oncology and gastroenterology, as well as Takeda's presence in emerging markets, are currently fueling the growth of Takeda. Approximately 30,000 Takeda employees are committed to improving quality of life for patients, working with Takeda's partners in health care in more than 70 countries. For more information, visit https://www.takeda.com/newsroom/.

Additional information about Takeda is available through its corporate website, www.takeda.com, and additional information about Takeda Oncology, the brand for the global oncology business unit of Takeda Pharmaceutical Company Limited, is available through its website, www.takedaoncology.com.

About Denali Therapeutics

Denali is a biopharmaceutical company developing a broad portfolio of therapeutic candidates for neurodegenerative diseases. 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, the potential benefits of the collaboration; plans to conduct clinical development activities and commercialize products; the expectation as to when the agreement will become effective; and other information relating to the transaction between Takeda and Denali. 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 that the agreement may not become effective 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 (including without limitation the failure to timely obtain requisite regulatory approvals); risks related to the effect of the announcement of the transaction on Denali's business relationships, operating results and business generally; and other risks, including those described in Denali's Prospectus filed with the SEC on December 8, 2017. The forward-looking statements in this press release are based on information available to Denali as of the date hereof. Denali and Takeda disclaim any obligation to update any forward-looking statements, except as required by law.

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