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):
August 7, 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 2.02 Results of Operations and Financial Condition.

On August 7, 2020, Denali Therapeutics Inc. (the "Company") issued a press release announcing its financial results for the second quarter ended June 30, 2020. The full text of the press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

All of the information furnished in this Item 2.02 and Item 9.01 (including Exhibit 99.1) shall not be deemed to be “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and shall not be incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, except as shall be expressly set forth by specific reference in such a filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

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

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

Denali Therapeutics Reports Second Quarter 2020 Financial Results and Business Highlights

SOUTH SAN FRANCISCO – August 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 reported financial results for the second quarter ended June 30, 2020 and provided business highlights.

“We are thrilled with the strong progress across our pipeline, the continued productivity across the company despite the current situation imposed by the COVID-19 pandemic, and a new collaboration with Biogen on our LRRK2 program for Parkinson’s disease patients and certain TV-enabled programs,” said Ryan Watts, Ph.D., CEO. “I am particularly excited that our first therapeutic candidate leveraging our proprietary blood-brain barrier crossing TV technology platform has entered clinical studies in patients. We believe the TV platform could transform the treatment of neurological disease.”

Second Quarter 2020 and Recent Business Highlights

- **Entered into a Collaboration Agreement with Biogen on LRRK2 program for Parkinson’s disease and certain transport vehicle ("TV") platform-enabled programs for neurodegenerative diseases** - In August 2020, Denali entered into a binding agreement with Biogen to co-develop and co-commercialize Denali’s small molecule inhibitors of leucine-rich repeat kinase 2 ("LRRK2") for Parkinson’s disease. Biogen will also receive rights to opt into two programs and a right of first negotiation for two additional programs, in each case for neurodegenerative diseases leveraging Denali’s TV technology platform to cross the BBB.

  Under the terms of the agreement, Biogen will make an upfront payment to Denali of $560 million and make a $465 million equity investment in Denali from the purchase of 13.3 million newly issued shares of Denali common stock at approximately $34.94 per share, representing 11.2 percent of Denali’s pro-forma outstanding stock. 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. In the LRRK2 collaboration, Biogen and Denali will share responsibility and costs for global development (60 percent Biogen; 40 percent Denali), and will share responsibility and costs as well as profits and losses for commercialization in the U.S. (50 percent Biogen; 50 percent Denali) and China (60 percent Biogen; 40 percent Denali). Outside the U.S. and China, Biogen will be responsible for commercialization and pay Denali tiered royalties. The transaction is expected to close after satisfaction of requirements under applicable antitrust laws and other customary closing conditions, and with respect to the collaboration, execution of a definitive collaboration agreement.

- **Selected DNL151 to advance into late stage clinical studies in Parkinson’s disease patients** - In August 2020, Denali announced that DNL151 has been selected to progress into late stage clinical studies in Parkinson’s disease patients with a kinase activating mutation in LRRK2 and in sporadic Parkinson’s disease patients. Patient enrollment is expected to commence in 2021.

- **Commenced dosing of DNL310 in Hunter syndrome patients** - In August 2020, Denali commenced dosing of its ETV:IDS biotherapeutic (DNL310) enabled by its TV platform technology in a Phase 1/2 Hunter syndrome clinical study. DNL310 is an intravenously administered recombinant form of the iduronate 2-sulfatase (“IDS”) enzyme engineered to cross the BBB using Denali’s TV technology. It is intended to treat overall clinical manifestations of Hunter syndrome, including cognitive and behavioral function, which are not adequately addressed by current standard of care.

- **Publication of two scientific papers describing blood-brain barrier transport vehicle delivery technology** - In May 2020, Denali announced the publication of two new papers describing its BBB delivery technology in *Science Translational Medicine*. The first paper describes the invention of Denali's TV technology and demonstrates its ability to successfully deliver therapeutic antibodies to the brain at levels sufficient for robust effects. The second paper focuses on the application of the TV technology for lysosomal storage disease by delivering enzymes across the BBB resulting in the normalization of biomarkers in a disease model of Hunter syndrome.

- **RIPK1 CNS program update** - In June 2020, together with partner Sanofi, Denali announced results from Phase 1b clinical studies with small molecule RIPK1 inhibitor DNL747 in Alzheimer's disease and ALS. Denali and Sanofi have paused DNL747 and switched to DNL788, with plans to initiate a clinical study around year-end 2020.

- **RIPK1 peripheral program update** - In July 2020, Denali announced that partner Sanofi has commenced dosing of DNL758, a peripherally-restricted small molecule inhibitor of RIPK1, in a Phase 1b clinical study in hospitalized adult patients with severe COVID-19 lung disease. Prior to this, Sanofi successfully completed the Phase 1 healthy volunteer study with DNL758, which appears well tolerated at doses tested. Further clinical studies in multiple indications are being planned by Sanofi.

- **Leadership promotion** - In June 2020, Denali appointed Joe Lewcock, Ph.D. as Chief Scientific Officer. Dr. Lewcock had previously served as Senior Vice President of Biology Discovery.

- **COVID-19 response update** - To address risks posed by the COVID-19 pandemic, Denali has implemented policies that enable some of its employees to work remotely. For all on-site personnel, Denali has implemented several safety protocols, including regular, mandatory COVID-19 testing procedures and compliance measures for social distancing and use of personal protective equipment. After initial COVID-19 pandemic shutdown restrictions were put in place in March 2020, Denali experienced a pause in patient recruitment in several clinical trials. Recruitment has since resumed for all affected clinical trials.

Second Quarter 2020 Financial Results

For the three months ended June 30, 2020, Denali reported a net loss of $58.8 million compared with a net loss of $58.3 million for the three months ended June 30, 2019.

Collaboration revenue was $5.8 million for the three months ended June 30, 2020, compared to $4.2 million for the three months ended June 30, 2019. The increase of $1.6 million in collaboration revenue was primarily due to a $4.8 million increase in revenue recognized under the Takeda Collaboration Agreement, partially offset by a $3.2 million decrease in revenue recognized under the Sanofi Collaboration Agreement.

Total research and development expenses were $53.2 million for the three months ended June 30, 2020, compared to $51.9 million for the three months ended June 30, 2019. The increase of approximately $1.3 million was primarily due to an increase in personnel-related expenses, including stock-based compensation, attributable to an increase in Denali's research and development headcount and new equity award grants. Additionally, there were increases in external expenses related to progression of Denali's portfolio, including the ETV:IDS and EIF2B programs due to the progress of these programs in the clinic. These increases were partially offset by decreases in the LRRK2 platform associated expenses, reflecting completion of the DNL201 clinical activities and slowdown of DNL151 clinical activities in the three months ended June 30, 2020 as a result of COVID-19, and certain other TV platform and other research and development expenses.

General and administrative expenses were $14.0 million for the three months ended June 30, 2020 compared to $15.1 million for the three months ended June 30, 2019. The decrease of approximately $1.1 million was primarily attributable to a decrease in personnel-related expenses, including stock-based compensation, primarily driven by lower stock-based compensation expense related to certain performance and market-based awards, partially offset by increases in professional services costs.

Cash, cash equivalents, and marketable securities were $556.8 million as of June 30, 2020.

About Denali Therapeutics

Denali Therapeutics is a biopharmaceutical company developing a broad portfolio of product candidates engineered to cross the blood-brain barrier 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, statements regarding Denali's progress and business plans; expectations regarding the proposed transaction with Biogen, including all financial aspects of the collaboration and equity investment; the potential benefits and results of the proposed transaction with Biogen; the anticipated completion of the Biogen transaction; plans to conduct clinical development activities and commercialize products; LRRK2 inhibitors as modifying therapy for Parkinson's disease; plans, timelines and expectations related to DNL151, DNL310 and Denali's TV technology; plans, timelines and expectations related to DNL747, DNL788 and DNL758 of both Denali and Sanofi; and statements made by Denali's Chief Executive Officer.

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: any and all risks to Denali's business and operations caused directly or indirectly by the evolving COVID-19 pandemic; the risks that the proposed transaction with Biogen may not be completed in a timely manner or at all; the possibility that certain closing conditions to the proposed transaction will not be satisfied, including the finalization of a definitive collaboration agreement; risks related to obtaining the requisite regulatory approvals, including those required under antitrust laws; risk of the occurrence of any event, change or other circumstance that could give rise to the termination of Denali's agreements with Biogen or any of Denali's other collaboration agreements (including without limitation the failure to timely obtain requisite regulatory approvals); risks related to the effect of the announcement of the Biogen 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 its ongoing and future 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 blood-brain barrier platform technology and product candidates currently in its core program; Denali's and it's partners' ability to conduct or complete clinical trials on expected timelines; the risk that preclinical profiles of Denali's product candidates, such as DNL151, DNL310, DNL788 and DNL758, may not translate in clinical trials; 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; 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 blood-brain barrier platform technology; and other risks, 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.

Denali Therapeutics Inc.
Condensed Consolidated Statements of Operations
(Unaudited)
(In thousands, except share and per share amounts)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	**2019**	**2020**	**2019**
Collaboration revenue:				
Collaboration revenue from customers	$ 5,811	$ 4,098	$ 9,363	$ 8,209
Other collaboration revenue	36	99	88	193
Total collaboration revenue	5,847	4,197	9,451	8,402
Operating expenses:				
Research and development	53,152	51,884	104,168	89,287
General and administrative	13,972	15,076	26,527	24,386
Total operating expenses	67,124	66,960	130,695	113,673
Loss from operations	(61,277)	(62,763)	(121,244)	(105,271)
Interest and other income, net	2,598	4,113	5,667	7,629
Loss before income taxes	(58,679)	(58,650)	(115,577)	(97,642)
Income tax benefit (provision)	(79)	313	56	313
Net loss	$ (58,758)	$ (58,337)	$ (115,521)	$ (97,329)
Net loss per share, basic and diluted	$ (0.56)	$ (0.61)	$ (1.11)	$ (1.02)
Weighted average number of shares outstanding, basic and diluted	105,717,912	95,495,497	104,068,815	95,241,412

Denali Therapeutics Inc.
Condensed Consolidated Balance Sheets
(Unaudited)
(In thousands)

	June 30, 2020	December 31, 2019
Assets		
Current assets:		
Cash and cash equivalents	$ 137,184	$ 79,449
Short-term marketable securities	412,397	335,907
Prepaid expenses and other current assets	9,828	14,675
Total current assets	559,409	430,031
Long-term marketable securities	7,229	39,886
Property and equipment, net	43,622	46,732
Operating lease right-of-use asset	33,312	33,923
Other non-current assets	3,765	2,659
Total assets	$ 647,337	$ 553,231
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 1,866	$ 2,590
Accrued compensation	5,531	8,739
Accrued clinical costs	4,179	5,042
Other accruals and other current liabilities	8,424	6,569
Operating lease liability, current	4,330	3,665
Contract liabilities	34,134	18,739
Total current liabilities	58,464	45,344
Contract liabilities, less current portion	19,715	43,753
Operating lease liability, less current portion	66,612	68,865
Other non-current liabilities	379	379
Total liabilities	145,170	158,341
Total stockholders' equity	502,167	394,890
Total liabilities and stockholders' equity	$ 647,337	$ 553,231

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