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 6, 2019

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 x

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. x

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 6, 2019, Denali Therapeutics Inc. (the "***Company***") issued a press release announcing its financial results for the second quarter ended June 30, 2019. 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 6, 2019.

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 6, 2019

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

Denali Therapeutics Reports Second Quarter 2019 Financial Results and Business Highlights

SOUTH SAN FRANCISCO – August 6, 2019 – Denali Therapeutics Inc. (NASDAQ: DNLI), a biopharmaceutical company developing a broad portfolio of product candidates for neurodegenerative diseases, today reported financial results for the second quarter ended June 30, 2019, and provided business highlights.

“With one more program entering clinical testing, steady patient recruitment into our ongoing clinical trials in Alzheimer’s, Parkinson’s and ALS as well as encouraging data in many of our discovery and IND-enabling programs, we continue to make progress towards our goal of defeating degeneration,” said Ryan Watts, Ph.D., CEO.

Second Quarter 2019 and Recent Business Highlights

- **Achieved First Clinical Milestone for Peripheral RIPK1 Inhibitor Under the Sanofi Collaboration Agreement** - In July 2019, Sanofi commenced dosing in healthy volunteers of the partnered small molecule inhibitor of RIPK1, DNL758. This triggered a milestone payment of $10.0 million, which Denali expects to receive in August 2019.

- **Presented progress of EIF2B program DNL343** - In June 2019, the progress of DNL343, a therapeutic candidate designed to inhibit the formation of stress granules by activating EIF2B, was presented. Stress granule formation is present in many neurodegenerative diseases, including ALS and Frontotemporal Dementia (FTD). Denali plans to commence dosing in a Phase 1 clinical study in healthy volunteers for this program in the first half of 2020.

- **Announced Orphan Drug and Rare Pediatric Disease Designation for DNL310 and expansion of portfolio of brain penetrant enzyme replacement therapy (ERT) programs** - In June 2019, Denali announced that the FDA granted Orphan Drug Designation and Rare Pediatric Disease Designation for its DNL310 program, which Denali is developing for patients with Hunter Syndrome. Based on pre-clinical proof of concept with DNL310, Denali has initiated two additional ERT programs that are enabled by its enzyme transport vehicle technology. A Phase 1/2 patient study of DNL310 in Hunter Syndrome is planned for mid 2020.

Second Quarter 2019 Financial Results

For the three months ended June 30, 2019, Denali reported a net loss of $58.3 million compared with a net loss of $54.7 million for the three months ended June 30, 2018.

Collaboration revenue was $4.2 million for the three months ended June 30, 2019, compared with collaboration revenue of $1.6 million for the three months ended June 30, 2018. The increase was due to $3.5 million of revenue recognized under the Sanofi Collaboration Agreement in the three months ended June 30, 2019, partially offset by a decrease in revenue recognized under the Takeda Collaboration Agreement.

Total research and development expenses were $51.9 million for the three months ended June 30, 2019 compared to $52.1 million for the three months ended June 30, 2018. The decrease in total research and development expenses of $0.3 million was primarily attributable to expenses associated with the nomination of two additional Fcab targets under the F-star Collaboration Agreement, and the acquisition of F-star Gamma Limited in the three months ended June 30, 2018. The decrease was largely offset by increases in external expenses related to the Company's portfolio and platform technology, and personnel-related expenses, including non-cash stock-based compensation, driven primarily by higher headcount and stock-based compensation expense associated with new equity award grants and certain performance and market-based awards. There were also increases in external research and development expenses supporting a growing pipeline, and increased facilities-related expenses primarily due to rent expense.

General and administrative expenses were $15.1 million for the three months ended June 30, 2019, compared to $6.9 million for the three months ended June 30, 2018. The increase in total general and administrative expenses of $8.2 million was primarily attributable to an increase in personnel-related expenses, including non-cash stock-based compensation, driven primarily by higher headcount and stock-based compensation expense associated with new equity award grants and certain performance and market-based awards. Additionally, there were increases in legal and professional services expenses required to support Denali's growing operations, and facilities-related expenses primarily due to rent expense.

Cash, cash equivalents, and marketable securities were $534.4 million as of June 30, 2019.

About Denali Therapeutics

Denali is a biopharmaceutical company developing a broad portfolio of product 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.

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; Denali's expected receipt of a clinical milestone payment from Sanofi; Denali's plans for, and the timing of commencing, dosing in a Phase 1 clinical study of DNL343 in healthy volunteers and a Phase 1/2 patient study of DNL310 in Hunter Syndrome; 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: Denali's early stages of clinical drug development; Denali's ability to complete the development and, if approved, commercialization of its product candidates; the risk of the occurrence of any event, change or other circumstance that could give rise to the termination of Denali's collaboration agreements; Denali's dependence on successful development of its BBB 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 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 BBB platform technology; and other risks, including those described in Denali's Annual Report on Form 10-K filed with the SEC on March 12, 2019, Denali's Quarterly Report on From 10-Q filed with the SEC on August 6, 2019, 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,	
	2019	**2018**	**2019**	**2018**
Collaboration revenue	$ 4,197	$ 1,648	$ 8,402	$ 2,289
Operating expenses:				
Research and development	51,884	52,134	89,287	72,953
General and administrative	15,076	6,896	24,386	12,466
Total operating expenses	66,960	59,030	113,673	85,419
Loss from operations	(62,763)	(57,382)	(105,271)	(83,130)
Interest and other income, net	4,113	2,658	7,629	4,728
Income tax benefit	313	—	313	—
Net loss	$ (58,337)	$ (54,724)	$ (97,329)	$ (78,402)
Net loss per share, basic and diluted	$ (0.61)	$ (0.59)	$ (1.02)	$ (0.86)
Weighted average number of shares outstanding, basic and diluted	95,495,497	92,899,524	95,241,412	91,239,274

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

	June 30, 2019	December 31, 2018
Assets		
Current assets:		
Cash and cash equivalents	$ 62,936	$ 77,123
Short-term marketable securities	415,667	387,174
Prepaid expenses and other current assets	17,378	16,539
Total current assets	495,981	480,836
Long-term marketable securities	55,832	147,881
Property and equipment, net	47,195	25,162
Operating lease right-of-use asset	34,647	—
Other non-current assets	3,949	8,105
Total assets	$ 637,604	$ 661,984
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 3,931	$ 1,891
Accrued liabilities	13,793	8,520
Accrued compensation	4,092	9,952
Contract liabilities	22,598	11,427
Other current liabilities	2,135	996
Total current liabilities	46,549	32,786
Contract liabilities, less current portion	44,563	57,350
Operating lease liability, less current portion	70,911	—
Deferred rent, less current portion	—	24,532
Other non-current liabilities	408	471
Total liabilities	162,431	115,139
Total stockholders' equity	475,173	546,845
Total liabilities and stockholders’ equity	$ 637,604	$ 661,984