
**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 8, 2019

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.)

**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 May 8, 2019, Denali Therapeutics Inc. (the “**Company**”) issued a press release announcing its financial results for the first quarter ended March 31, 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 May 8, 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: May 8, 2019

By: /s/ Steve E. Krogn

Steve E. Krogn

Chief Financial Officer



Denali Therapeutics Reports First Quarter 2019 Financial Results

SOUTH SAN FRANCISCO – May 8, 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 first quarter ended March 31, 2019.

First Quarter 2019 Financial Results

For the three months ended March 31, 2019, Denali reported a net loss of \$39.0 million compared with a net loss of \$23.7 million for the three months ended March 31, 2018.

Collaboration revenue was \$4.2 million for the three months ended March 31, 2019, compared with collaboration revenue of \$0.6 million for the three months ended March 31, 2018. The increase was due to \$3.5 million of revenue recognized under the Sanofi Collaboration Agreement in the three months ended March 31, 2019.

Total research and development expenses were \$37.4 million for the three months ended March 31, 2019, including non-cash stock-based compensation of \$4.0 million, compared to \$20.8 million for the three months ended March 31, 2018, including non-cash stock-based compensation of \$1.7 million. The increase in total research and development expenses of \$16.6 million was primarily attributable to increases in personnel-related expenses, including non-cash stock-based compensation, driven primarily by higher headcount and new option grants. Further, there were increases in external research and development expenses, reflecting both the progress of Denali's most advanced programs and increased investment in growing and developing its pipeline, and facilities-related expenses primarily due to rent expense.

General and administrative expenses were \$9.3 million for the three months ended March 31, 2019, including non-cash stock-based compensation of \$2.9 million, compared to \$5.6 million for the three months ended March 31, 2018, including non-cash stock-based compensation of \$1.2 million. The increase in total general and administrative expenses of \$3.7 million was primarily attributable to an increase in personnel-related expenses, including non-cash stock-based compensation, driven primarily by higher headcount and new option grants. Further, there were increases in legal and professional services expenses required to support Denali's ongoing operations as a public company, and facilities-related expenses primarily due to rent expense.

Cash, cash equivalents, and marketable securities were \$583.0 million as of March 31, 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.

Denali Therapeutics Inc.
Condensed Consolidated Statements of Operations
(Unaudited)

(In thousands, except share and per share amounts)

	Three Months Ended March 31,	
	2019	2018
Collaboration revenue	\$ 4,205	\$ 641
Operating expenses:		
Research and development	37,403	20,819
General and administrative	9,310	5,570
Total operating expenses	46,713	26,389
Loss from operations	(42,508)	(25,748)
Interest and other income, net	3,516	2,070
Net loss	\$ (38,992)	\$ (23,678)
Net loss per share, basic and diluted	\$ (0.41)	\$ (0.26)
Weighted average number of shares outstanding, basic and diluted	94,984,503	89,560,576

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

	March 31, 2019	December 31, 2018
Assets		
Current assets:		
Cash and cash equivalents	\$ 39,661	\$ 77,123
Short-term marketable securities	445,820	387,174
Prepaid expenses and other current assets	14,052	16,539
Total current assets	499,533	480,836
Long-term marketable securities	97,554	147,881
Property and equipment, net	36,955	25,162
Operating lease right-of-use asset	34,407	—
Other non-current assets	8,147	8,105
Total assets	<u>\$ 676,596</u>	<u>\$ 661,984</u>
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 3,662	\$ 1,891
Accrued liabilities	12,114	8,520
Accrued compensation	3,213	9,952
Contract liabilities	23,148	11,427
Other current liabilities	1,107	996
Total current liabilities	43,244	32,786
Contract liabilities, less current portion	44,852	57,350
Operating lease liability, less current portion	71,412	—
Deferred rent, less current portion	—	24,532
Other non-current liabilities	440	471
Total liabilities	159,948	115,139
Total stockholders' equity	516,648	546,845
Total liabilities and stockholders' equity	<u>\$ 676,596</u>	<u>\$ 661,984</u>