
**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 9, 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 2.02 Results of Operations and Financial Condition.

On August 9, 2018, Denali Therapeutics Inc. (the "**Company**") issued a press release announcing its financial results for the second quarter ended June 30, 2018. 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

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release dated August 9, 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: August 9, 2018

By: /s/ Steve E. Krognes

Steve E. Krognes

Chief Financial Officer



Denali Therapeutics Reports Second Quarter 2018 Financial Results

SOUTH SAN FRANCISCO – August 9, 2018 – 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, 2018.

Second Quarter 2018 Financial Results

For the three months ended June 30, 2018, Denali reported a net loss of \$54.7 million compared with a net loss of \$22.1 million for the three months ended June 30, 2017.

Collaboration revenue was \$1.6 million for the three months ended June 30, 2018, with no collaboration revenue recognized for the three months ended June 30, 2017. The increase was due to revenue recognized under the Option and Collaboration Agreement with Takeda Pharmaceutical Company Limited, which was entered into in January 2018.

Total research and development expenses were \$52.1 million for the three months ended June 30, 2018, including non-cash stock-based compensation of \$2.6 million, compared to \$19.0 million for the three months ended June 30, 2017, including non-cash stock-based compensation \$0.7 million. The increase in total research and development expenses of \$33.1 million was primarily attributable to a \$26.7 million increase in BBB platform external expenses, the majority of which related to expense associated with the acquisition of F-star Gamma Limited and the nomination of two additional Fcab targets under the F-star Collaboration Agreement. Additionally, there was an increase in personnel related expenses including stock-based compensation driven by increased headcount and options granted at higher valuations subsequent to the IPO, as well as an increase in lab consumable costs and facilities related expenses.

General and administrative expenses were \$6.9 million for the three months ended June 30, 2018, including non-cash stock-based compensation of \$2.1 million, compared to \$3.6 million for the three months ended June 30, 2017, including non-cash stock-based compensation of \$0.4 million. The increase in total general and administrative expenses of \$3.3 million was primarily attributable to an increase in personnel related expenses, including stock-based compensation, and an increase in legal and professional service expenses. The increases were primarily attributable to an increase in general and administrative headcount and options granted at higher valuations subsequent to the IPO, as well as the increased professional services required to support Denali's ongoing operations as a public company.

Cash, cash equivalents, and marketable securities were \$551.3 million as of June 30, 2018, compared to \$467.0 million as of December 31, 2017. The increase of \$84.3 million was primarily attributable to \$155.0 million in cash received related to the Option and the Collaboration Agreement and Stock Purchase Agreement with Takeda, both entered into in January 2018, offset by operating and investing cash payments.

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 June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
Collaboration revenue	\$ 1,648	\$ —	\$ 2,289	\$ —
Operating expenses:				
Research and development	52,134	19,004	72,953	37,474
General and administrative	6,896	3,564	12,466	6,838
Total operating expenses	59,030	22,568	85,419	44,312
Loss from operations	(57,382)	(22,568)	(83,130)	(44,312)
Interest and other income, net	2,658	434	4,728	858
Net loss	\$ (54,724)	\$ (22,134)	\$ (78,402)	\$ (43,454)
Net loss per share, basic and diluted	\$ (0.59)	\$ (2.29)	\$ (0.86)	\$ (4.65)
Weighted average number of shares outstanding, basic and diluted	92,899,524	9,670,449	91,239,274	9,346,051

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

	<u>June 30, 2018</u>	<u>December 31, 2017</u>
Assets		
Current assets:		
Cash and cash equivalents	\$ 33,088	\$ 218,375
Short-term marketable securities	339,503	187,851
Prepaid expenses and other current assets	4,827	3,381
Total current assets	<u>377,418</u>	<u>409,607</u>
Long-term marketable securities	178,703	60,750
Property and equipment, net	13,323	14,923
Other non-current assets	2,611	1,441
Total assets	<u>\$ 572,055</u>	<u>\$ 486,721</u>
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 9,176	\$ 2,716
Accrued liabilities	5,537	5,364
Accrued compensation	2,751	5,166
Contract liability	8,715	—
Deferred rent	4,782	855
Other current liabilities	47	63
Total current liabilities	<u>31,008</u>	<u>14,164</u>
Contract liability, less current portion	49,590	—
Deferred rent, less current portion	1,029	6,294
Other non-current liabilities	156	467
Total liabilities	<u>81,783</u>	<u>20,925</u>
Total stockholders' equity	490,272	465,796
Total liabilities and stockholders' equity	<u>\$ 572,055</u>	<u>\$ 486,721</u>