
**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 7, 2020

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

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 May 7, 2020, Denali Therapeutics Inc. (the "Company") issued a press release announcing its financial results for the first quarter ended March 31, 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 8.01 Other Events.

The Company filed its amended and restated certificate of incorporation on December 12, 2017 (the "Certificate of Incorporation") with the Secretary of State of the State of Delaware. Article XI of the Certificate of Incorporation provides in part, that, unless the Company consents in writing to the selection of an alternative forum, the federal district courts of the United States of America shall be the exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act of 1933, as amended (such provision, a "Federal Forum Provision").

On December 19, 2018, the Delaware Court of Chancery issued a decision in *Matthew Sciabacucchi v. Matthew B. Salzberg et al.*, C.A. No. 2017-0931-JTL (Del. Ch.), finding that provisions such as the Federal Forum Provision are invalid under Delaware law. Following this decision, the Company issued an 8-K stating that it did not intend to enforce the Federal Forum Provision in its Certificate of Incorporation unless and until such time that the Court of Chancery, or the Delaware Supreme Court, determines that such a provision is valid under Delaware law.

On March 18, 2020, the Delaware Supreme Court issued its decision in *Salzburg et al. v. Matthew Sciabacucchi*, No. 346, 2019 (Del.), which reversed the Delaware Court of Chancery's decision. The Delaware Supreme Court found that provisions such as the Federal Forum Provision are facially valid under Delaware law. In light of this decision finally resolving the facial validity of such provisions, the Company intends to enforce the Federal Forum Provision in its Certificate of Incorporation.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release dated May 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: May 7, 2020

By: /s/ Steve E. Krognes

Steve E. Krognes

Chief Financial Officer and Treasurer



Denali Therapeutics Reports First Quarter 2020 Financial Results and Provides COVID-19 Response Update

SOUTH SAN FRANCISCO – May 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 first quarter ended March 31, 2020 and provided an update on the Company's response to COVID-19.

"Our commitment to defeat degeneration for our patients remains undeterred and we are working tirelessly toward our goals, with key data and decisions on track for mid-year 2020, despite the challenging external environment imposed by the pandemic," said Ryan Watts, Ph.D., CEO. "We are also looking forward to DNL310 clinical biomarker data in Hunter syndrome in late 2020, with the goal of validating our Transport Vehicle platform technology for brain uptake of biotherapeutics."

Denali provided a business update in response to the COVID-19 pandemic on April 2, 2020. There has been no significant change to the status of the Company's clinical trials since. Denali is continuously assessing and adapting its working practices and business operations to ensure compliance with official guidance and orders related to the pandemic. Furthermore, the Company is working proactively with its partners and other stakeholders in an effort to mitigate and minimize any negative impact to its research, clinical trials or other business operations.

First Quarter 2020 Financial Results

For the three months ended March 31, 2020, Denali reported a net loss of \$56.8 million compared with a net loss of \$39.0 million for the three months ended March 31, 2019.

Collaboration revenue was \$3.6 million for the three months ended March 31, 2020, compared to \$4.2 million for the three months ended March 31, 2019. The decrease of \$0.6 million in collaboration revenue was primarily due to a \$2.9 million decrease in revenue from the collaboration with Sanofi, driven by lower revenue for retained activities as activities are transferred to Sanofi, partially offset by a \$2.3 million increase in revenue from the collaboration with Takeda, driven by increased costs incurred in the programs partnered with Takeda.

Total research and development expenses were \$51.0 million for the three months ended March 31, 2020, compared to \$37.4 million for the three months ended March 31, 2019. The increase of approximately \$13.6 million was primarily due to an increase in external expenses related to progression of Denali's portfolio, in particular the LRRK2 and EIF2B programs. In addition, there was an increase in personnel-related expenses, including stock-based compensation, driven primarily by higher headcount and additional equity award grants. Other increases include external research and development expenses to support pipeline growth as well as higher rent expense associated with the new headquarters lease. These increases were partially offset by a decrease in external expenses for Denali's RIPK1 program, as well as its TV platform and other program external expenses.

General and administrative expenses were \$12.6 million for the three months ended March 31, 2020 compared to \$9.3 million for the three months ended March 31, 2019. The increase of approximately \$3.3 million was primarily attributable to an increase in personnel-related expenses, including stock-based compensation, driven primarily by higher headcount and additional equity award grants.

Cash, cash equivalents, and marketable securities were \$596.9 million as of March 31, 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 <http://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 response to COVID-19, including status of clinical trials as well as efforts to mitigate any negative impact on the Company's research, clinical trials and other business operations; status of pipeline, including the clinical trial for DNL310 in Hunter syndrome patients; 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 business and operations, including its clinical trials, caused directly or indirectly by the evolving COVID-19 pandemic; whether Denali's efforts to mitigate and minimize any negative impact to its research, clinical programs and other business operations will be effective or sufficient; Denali's early stages of clinical drug development; Denali's ability to complete the development and, if approved, commercialization of its product candidates; Denali's ability to enroll patients in its ongoing and future clinical trials; Denali's reliance on third parties for the manufacture and supply its product candidates for clinical trials; 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; 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; developments relating to Denali's competitors and its industry, including competing product candidates and therapies; 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; Denali's ability to obtain additional capital to finance its operations, as needed; Denali's ability to accurately forecast future financial results in the current environment; general economic and market conditions; and other risks and uncertainties, 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 March 31,	
	2020	2019
Collaboration revenue:		
Collaboration revenue from customers	\$ 3,552	\$ 4,111
Other collaboration revenue	52	94
Total collaboration revenue	\$ 3,604	\$ 4,205
Operating expenses:		
Research and development	51,016	37,403
General and administrative	12,555	9,310
Total operating expenses	63,571	46,713
Loss from operations	(59,967)	(42,508)
Interest and other income, net	3,069	3,516
Loss before income taxes	(56,898)	(38,992)
Income tax benefit	135	—
Net loss	\$ (56,763)	\$ (38,992)
Net loss per share, basic and diluted	\$ (0.55)	\$ (0.41)
Weighted average number of shares outstanding, basic and diluted	102,419,718	94,984,503

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

	March 31, 2020	December 31, 2019
Assets		
Current assets:		
Cash and cash equivalents	\$ 207,537	\$ 79,449
Short-term marketable securities	379,713	335,907
Prepaid expenses and other current assets	17,535	14,675
Total current assets	604,785	430,031
Long-term marketable securities	9,684	39,886
Property and equipment, net	45,452	46,732
Operating lease right-of-use asset	33,626	33,923
Other non-current assets	2,318	2,659
Total assets	<u>\$ 695,865</u>	<u>\$ 553,231</u>
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 2,316	\$ 2,590
Accrued compensation	3,910	8,739
Accrued clinical costs	5,349	5,042
Other accruals and other current liabilities	7,265	6,569
Operating lease liability, current	4,121	3,665
Contract liabilities	24,674	18,739
Total current liabilities	47,635	45,344
Contract liabilities, less current portion	34,747	43,753
Operating lease liability, less current portion	67,793	68,865
Other non-current liabilities	379	379
Total liabilities	150,554	158,341
Total stockholders' equity	545,311	394,890
Total liabilities and stockholders' equity	<u>\$ 695,865</u>	<u>\$ 553,231</u>

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