
**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):

March 12, 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

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 March 12, 2019, Denali Therapeutics Inc. (the "**Company**") issued a press release announcing its financial results for the fourth quarter and year ended December 31, 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 March 12, 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: March 12, 2019

By: /s/ Steve E. Krognas

Steve E. Krognas

Chief Financial Officer



Denali Therapeutics Reports Full Year 2018 Financial Results and Business Highlights

SOUTH SAN FRANCISCO – March 12, 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 fourth quarter and full year ended December 31, 2018 and provided business highlights.

"We have made significant progress toward our long-term goal of defeating neurodegenerative diseases. We successfully completed Phase 1 healthy volunteer clinical trials for our LRRK2 inhibitor and RIPK1 inhibitor programs, initiated clinical studies in patients with Parkinson's disease, ALS and Alzheimer's disease, and further validated our blood-brain barrier delivery technology," said Ryan Watts, Ph.D., CEO. "Furthermore, we are excited about our strategic partnerships with Takeda and Sanofi which allow us to broaden our portfolio and expand into new programs and indications."

Fourth Quarter 2018 and Recent Business Highlights

- **First Patient dosed in Three Phase 1b Studies** - In December 2018, we announced the first patient dosed in our Phase 1b Study of DNL201 in Parkinson's disease patients with and without a genetic LRRK2 mutation; in January and February 2019, in collaboration with our partner Sanofi, we announced the first patient dosed in two Phase 1b studies of DNL747 in ALS and Alzheimer's patients, respectively.
- **Entered into a broad RIPK1 Collaboration Agreement with Sanofi** – In October 2018, Denali entered into a Collaboration and License Agreement with Genzyme Corporation, a wholly owned subsidiary of Sanofi S.A., ("Sanofi") to develop and commercialize therapeutic products to treat neurological and systemic inflammatory diseases by targeting RIPK1. Denali received an upfront fee of \$125 million in November 2018 and is eligible to receive contingent milestone payments that could exceed \$1 billion. For products intended to treat neurological diseases, Denali and Sanofi will share development costs and commercial profits and losses in the United States and China, while Denali will receive a royalty from Sanofi for other territories. For products intended to treat systemic inflammatory diseases, Sanofi will pay all development costs and Denali will receive a royalty worldwide.
- **Achieved First Milestone for the Second and Third Programs Under the Takeda Collaboration Agreement** - In October and December 2018, the first preclinical milestone was met for the second and third program partnered with Takeda, respectively, upon which Takeda paid Denali a milestone payment of \$5 million for each program.

Fourth Quarter and Full Year 2018 Financial Results

For the fourth quarter of 2018, Denali reported a net income of \$77.5 million compared with a net loss for the fourth quarter December 31, 2017 of \$22.9 million. For the year ended December 31, 2018, net loss was \$36.2 million, compared with a net loss for the year ended December 31, 2017 of \$88.2 million.

Collaboration revenue was \$125.7 million and \$129.2 million for the fourth quarter and year ended December 31, 2018, respectively, with no collaboration revenue recognized for both the fourth quarter and year ended December 31, 2017. The increase in revenue in both the fourth quarter and year ended December 31, 2018 compared to the same periods in 2017, was due to revenue recognized under the Option and Collaboration Agreement with Takeda Pharmaceutical Company Limited, which we entered into in January 2018 and amended in February 2019, and the Collaboration and License Agreement with Sanofi, which we entered into in October 2018.

Total research and development expenses were \$39.9 million for the fourth quarter of 2018, including non-cash stock-based compensation of \$2.9 million, compared to \$18.5 million for the fourth quarter of 2017, including non-cash stock-based compensation of \$0.7 million. Total research and development expenses were \$143.2 million for the year ended December 31, 2018, including non-cash stock-based compensation of \$10.1 million, compared to \$74.5 million for the year ended December 31, 2017, including non-cash stock-based compensation of \$2.9 million. The increase in total research and development expenses of \$21.4 million and \$68.7 million for the fourth quarter and year ended December 31, 2018, respectively compared to the same periods in 2017, was primarily attributable to an increase in personnel-related expenses, including non-cash stock-based compensation, driven primarily by higher headcount and new options granted at higher exercise prices subsequent to Denali's initial public offering. Further, there was an increase in external research and development expenses reflecting the progress of Denali's most advanced programs in the clinic, the growing and maturing pipeline, and an increase in other research and development expenses primarily due to rent expense associated with the headquarters lease amendment to relocate and expand our headquarters and an increase in lab consumable expenses.

General and administrative expenses were \$11.0 million for the fourth quarter of 2018, including non-cash stock-based compensation of \$2.7 million, compared to \$5.1 million for the fourth quarter of 2017, including non-cash stock-based compensation of \$0.4 million. General and administrative expenses were \$32.3 million for the year ended December 31, 2018, including non-cash stock-based compensation of \$8.7 million, compared to \$15.7 million for the year ended December 31, 2017, including non-cash stock-based compensation of \$1.6 million. The increase in total general and administrative expenses of \$6.0 million and \$16.7 million for both the fourth quarter and year ended December 31, 2018, respectively, compared to the same periods in 2017, was primarily attributable to an increase in personnel-related expenses, including non-cash stock-based compensation, driven primarily by higher headcount and new options granted at higher exercise prices subsequent to Denali's initial public offering, an increase in legal and professional service expenses required to support Denali's ongoing operations as a public company, and an increase in rent expense associated with the headquarters lease amendment.

Cash, cash equivalents, and marketable securities were \$612.2 million as of December 31, 2018.

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; the potential benefits of the collaborations with Sanofi and Takeda; plans for Sanofi and Denali to collaborate on global clinical development; 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: the risk of the occurrence of any event, change or other circumstance that could give rise to the termination of the Sanofi or Takeda collaboration agreements; risks related to the effect of the announcement of the transactions on Denali's business relationships, operating results and business generally; 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 conduct or complete clinical trials on expected timelines; implementation of Denali's strategic plans for its business, product candidates and BBB 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 December 31,		Twelve Months Ended December 31,	
	2018	2017	2018	2017
Collaboration revenue	\$ 125,676	\$ —	\$ 129,160	\$ —
Operating expenses:				
Research and development	39,909	18,471	143,183	74,460
General and administrative	11,045	5,069	32,349	15,680
Total operating expenses	50,954	23,540	175,532	90,140
Profit (loss) from operations	74,722	(23,540)	(46,372)	(90,140)
Interest and other income, net	2,811	653	10,132	1,955
Net income (loss)	\$ 77,533	\$ (22,887)	\$ (36,240)	\$ (88,185)
Net income (loss) per share, basic	\$ 0.82	\$ (0.74)	\$ (0.39)	\$ (5.89)
Net income (loss) per share, diluted	\$ 0.79	\$ (0.74)	\$ (0.39)	\$ (5.89)
Weighted average number of shares outstanding, basic	94,299,096	30,743,980	92,621,991	14,964,144
Weighted average number of shares outstanding, diluted	97,746,224	30,743,980	92,621,991	14,964,144

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

	December 31, 2018	December 31, 2017
Assets		
Current assets:		
Cash and cash equivalents	\$ 77,123	\$ 218,375
Short-term marketable securities	387,174	187,851
Prepaid expenses and other current assets	16,539	3,381
Total current assets	480,836	409,607
Long-term marketable securities	147,881	60,750
Property and equipment, net	25,162	14,923
Other non-current assets	8,105	1,441
Total assets	\$ 661,984	\$ 486,721
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 1,891	\$ 2,716
Accrued liabilities	8,520	5,364
Accrued compensation	9,952	5,166
Contract liability	11,427	—
Deferred rent	616	855
Other current liabilities	380	63
Total current liabilities	32,786	14,164
Contract liability, less current portion	57,350	—
Deferred rent, less current portion	24,532	6,294
Other non-current liabilities	471	467
Total liabilities	115,139	20,925
Total stockholders' equity	546,845	465,796
Total liabilities and stockholders' equity	\$ 661,984	\$ 486,721