
**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):

February 27, 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 February 27, 2020, Denali Therapeutics Inc. (the "**Company**") issued a press release announcing its financial results for the fourth quarter and year ended December 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 February 27, 2020.

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: February 27, 2020

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



Denali Therapeutics Reports Full Year 2019 Financial Results and Business Highlights

SOUTH SAN FRANCISCO – February 27, 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 fourth quarter and full year ended December 31, 2019, and provided business highlights.

“2019 was an extraordinary year for Denali with significant progress across our portfolio in programs targeting Alzheimer’s, ALS and Hunter syndrome, as well as completing our first patient trial for a LRRK2 inhibitor in Parkinson’s disease,” said Ryan Watts, Ph.D., CEO. “We look forward to building on this momentum in 2020 with key milestones expected for multiple programs, including advancing our LRRK2 program into late stage clinical testing, and establishing clinical biomarker proof-of-concept with our first large molecule program, ETV:IDS (DNL310) in Hunter syndrome, enabled by our blood-brain barrier delivery Transport Vehicle platform.”

Recent Business Highlights

- **Biomarker proof of concept for LRRK2 inhibitor program (DNL201 and DNL151)** - In January 2020, Denali presented positive results from a Phase 1b study with DNL201 in patients with Parkinson’s disease and from a Phase 1 study with DNL151 in healthy volunteers. Both clinical trials showed dose-dependent target engagement, improvement in biomarkers of lysosomal function and demonstrated safety profiles supporting progression to further development in upcoming Phase 2/3 studies.
- **First-in-human dosing of EIF2B activator program (DNL343)** - In February 2020, Denali commenced dosing of its small molecule activator of EIF2B, DNL343, in healthy volunteers. DNL343 is a brain penetrant small molecule EIF2B activator designed to resolve cellular integrated stress response and restore protein translation and RNA metabolism in ALS, Frontotemporal Dementia and other neurodegenerative diseases.
- **IND accepted for DNL310 for Hunter syndrome** - In January 2020, the IND for DNL310 was accepted and Denali plans to initiate a Phase 1/2 study for DNL310 in Hunter syndrome patients in the first half of 2020. DNL310 is an intravenously administered recombinant form of the iduronate 2-sulfatase (“IDS”) enzyme engineered to cross the BBB using Denali’s proprietary Transport Vehicle (“TV”) technology. It is intended to treat overall clinical manifestations of Hunter syndrome, including cognitive and behavioral function, which are not addressed by the current standard of care.
- **Pipeline update** - In January 2020, Denali disclosed two additional biotherapeutic programs in its portfolio, which are engineered to cross the BBB using Denali’s proprietary TV technology.
 - DNL593 (PTV:Progranulin (“PGRN”)) is an intravenously administered recombinant form of PGRN intended to restore normal levels of PGRN in the brain without interfering with normal PGRN processing. PGRN is genetically linked to Frontotemporal Dementia and other neurodegenerative diseases.
 - ETV:N-sulphoglucosamine sulphohydrolase (“SGSH”), is an intravenously administered recombinant form of the enzyme SGSH, which is defective in patients with San Filippo syndrome. ETV:SGSH is intended to treat overall clinical manifestations of San Filippo syndrome, including cognitive and behavioral function.
- **Balance sheet strengthened** - In January 2020, Denali raised net proceeds of approximately \$194.1 million through a public offering of its common stock.

Fourth Quarter and Full Year 2019 Financial Results

For the quarter ended December 31, 2019, Denali reported a net loss of \$54.0 million compared with net income of \$77.5 million for the quarter ended December 31, 2018. For the year ended December 31, 2019, net loss was \$197.6 million, compared with a net loss for the year ended December 31, 2018 of \$36.2 million.

Collaboration revenue was \$4.7 million and \$26.7 million for the quarter and year ended December 31, 2019, respectively compared to \$125.7 million and \$129.2 million for the quarter and year ended December 31, 2018. The decreases in revenue of \$121.0 million and \$102.5 million for the quarter and year ended December 31, 2019, respectively, compared to the same periods in 2018 was primarily due to a decrease of \$102.7 million of revenue recognized under our Sanofi Collaboration Agreement in 2019.

Total research and development expenses were \$51.6 million and \$193.4 million for the quarter and year ended December 31, 2019, respectively compared to \$39.9 million and \$143.2 million for the quarter and year ended December 31, 2018, respectively. The increases of approximately \$11.6 million and \$50.2 million in total research and development expenses for the quarter and year ended December 31, 2019, respectively, were primarily attributable to an increase in external expenses related to progression of our portfolio, in particular our LRRK2 and ETV:IDS 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 BBB platform external expense, the majority of which related to expenses incurred in 2018 associated with the acquisition of F-star Gamma Limited, and the nomination of two additional Fcab targets under the F-star Collaboration Agreement, both of which occurred in May 2018.

General and administrative expenses were \$10.9 million and \$46.5 million for the quarter and year ended December 31, 2019, respectively compared to \$11.0 million and \$32.3 million for the quarter and year ended December 31, 2018, respectively. The increase of approximately \$14.1 million year over year was primarily attributable to an increase in personnel-related expenses, including stock-based compensation, driven primarily by higher headcount, additional equity award grants and certain performance and market-based awards, as well as higher rent expense associated with the new headquarters lease.

Cash, cash equivalents, and marketable securities were \$455.2 million as of December 31, 2019.

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 Therapeutics 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 Therapeutics 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 plan to initiate a Phase 1/2 study for DNL310 in Hunter syndrome patients in the first half of 2020; Denali's expectations regarding key milestones in 2020 including advancing its LRRK2 program into late stage clinical testing and establishing clinical biomarker proof-of-concept with its first large molecule program, ETV:IDS (DNL310) in Hunter syndrome, enabled by its blood-brain barrier delivery Transport Vehicle platform; 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; 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 blood-brain barrier 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,	
	2019	2018	2019	2018
Collaboration revenue	\$ 4,672	\$ 125,676	\$ 26,678	\$ 129,160
Operating expenses:				
Research and development	51,551	39,909	193,382	143,183
General and administrative	10,879	11,045	46,480	32,349
Total operating expenses	62,430	50,954	239,862	175,532
Income (loss) from operations	(57,758)	74,722	(213,184)	(46,372)
Interest and other income, net	3,808	2,811	15,219	10,132
Income (loss) before income taxes	(53,950)	77,533	(197,965)	(36,240)
Income tax benefit (provision)	(75)	—	351	—
Net income (loss)	\$ (54,025)	\$ 77,533	\$ (197,614)	\$ (36,240)
Net income (loss) per share, basic	\$ (0.56)	\$ 0.82	\$ (2.07)	\$ (0.39)
Net income (loss) per share, diluted	\$ (0.56)	\$ 0.79	\$ (2.07)	\$ (0.39)
Weighted average number of shares outstanding, basic	96,078,950	94,299,096	95,608,208	92,621,991
Weighted average number of shares outstanding, diluted	96,078,950	97,746,224	95,608,208	92,621,991

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

	December 31, 2019	December 31, 2018
Assets		
Current assets:		
Cash and cash equivalents	\$ 79,449	\$ 77,123
Short-term marketable securities	335,907	387,174
Prepaid expenses and other current assets	14,675	16,539
Total current assets	430,031	480,836
Long-term marketable securities	39,886	147,881
Property and equipment, net	46,732	25,162
Operating lease right-of-use asset	33,923	—
Other non-current assets	2,659	8,105
Total assets	<u>\$ 553,231</u>	<u>\$ 661,984</u>
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 2,590	\$ 1,891
Accrued expenses and other current liabilities	24,015	19,468
Contract liabilities	18,739	11,427
Total current liabilities	45,344	32,786
Contract liabilities, less current portion	43,753	57,350
Operating lease liability, less current portion	68,865	—
Deferred rent, less current portion	—	24,532
Other non-current liabilities	379	471
Total liabilities	158,341	115,139
Total stockholders' equity	394,890	546,845
Total liabilities and stockholders' equity	<u>\$ 553,231</u>	<u>\$ 661,984</u>

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