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):
November 5, 2020

Denali Therapeutics Inc.

(Exact name of registrant as specified in its charter)

Delaware	001-38311	46-3872213
(State or other jurisdiction of incorporation)	(Commission File Number)	(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 November 5, 2020, Denali Therapeutics Inc. (the "Company") issued a press release announcing its financial results for the third quarter ended September 30, 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 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release dated November 5, 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: November 5, 2020

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

Denali Therapeutics Reports Third Quarter 2020 Financial Results and Business Highlights

SOUTH SAN FRANCISCO – November 5, 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 third quarter ended September 30, 2020 and provided business highlights.

“We have continued our approach of advancing a broad therapeutic portfolio by making parallel investments in multiple programs and forging strategic partnerships. We are particularly excited about our collaboration with Biogen and working together on late-stage clinical development plans for DNL151, our lead investigational small molecule inhibitor of LRRK2 for the treatment of Parkinson’s disease,” said Ryan Watts, Ph.D., Denali’s chief executive officer. “In addition, we have made significant progress across multiple programs enabled by our Transport Vehicle (TV) technology platform, including our lead Enzyme Transport Vehicle: iduronate 2-sulfatase (ETV:IDS) program, which is evaluating DNL310 in a Phase 1/2 trial in patients with Hunter syndrome (MPS II). Preclinical data from additional select TV-enabled programs were highlighted at our recent virtual R&D Day, showing potential applications in other lysosomal storage disorders, Alzheimer’s disease, and HER2-positive central nervous system metastases. Of note, our new collaboration with Secarna Pharmaceuticals expands our capabilities in developing TV-enabled antisense oligonucleotides (ASOs). This progress, despite the ongoing challenges of a global pandemic, is made possible by the grit and unity that our employees consistently bring forth in working towards defeating degeneration for patients.”

Third Quarter 2020 and Recent Business Highlights

- **Commenced Biogen collaboration:** In August 2020, Denali and Biogen announced a collaboration to co-develop and co-commercialize Denali’s small molecule inhibitors of leucine-rich repeat kinase 2 (LRRK2) for Parkinson’s disease. Biogen also received rights to opt into two programs and a right of first negotiation for two additional programs, in each case for certain neurodegenerative diseases leveraging Denali’s TV technology platform to cross the BBB. In September 2020, Biogen made a $465.0 million equity investment in Denali. In October 2020 the companies executed definitive agreements under which Denali received an aggregate of $560.0 million in upfront payments. Denali may be eligible to receive up to $1.125 billion in potential milestone payments plus profit sharing and royalties for the LRRK2 program.

- **Completed patient enrollment in Cohort A for ETV:IDS (DNL310) Phase 1/2 in Hunter syndrome:** During Q3 2020, Denali completed the planned enrollment of patients in Cohort A in the Phase 1/2 clinical trial of DNL310 and is on track to announce early safety and biomarker data from the trial by year end 2020.

- **Potential of TV-enabled biotherapeutics portfolio highlighted at R&D Day:** In October 2020, Denali hosted a virtual R&D Day to share insights and key developments across the company’s broad biotherapeutics portfolio enabled by its TV technology platform including new preclinical data from Enzyme TV (ETV), Protein TV (PTV), Antibody TV (ATV) and Oligonucleotide TV (OTV) programs. A replay of the webcast can be found here. A PDF of the R&D Day presentation can be found here. Both the webcast replay and presentation PDF are also accessible on the Events page of the Investor Relations section on the company’s website

- **Entered collaboration with Secarna Pharmaceuticals for antisense therapies**: In October 2020, Denali entered into a research and option agreement with Secarna Pharmaceuticals GmbH & Co. KG, a leader in ASO technology, to develop novel ASO therapeutics that can be delivered to the brain after intravenous dosing using Denali’s Oligonucleotide TV technology.

- **Investigational New Drug (IND) application for DNL788 (SAR443820) submitted by Sanofi:** In October 2020, Denali reported that its partner Sanofi submitted an IND application for DNL788, a potent, selective brain-penetrant small molecule inhibitor of RIPK1 intended to treat patients with Alzheimer's disease, amyotrophic lateral sclerosis (ALS), multiple sclerosis (MS) and potentially other indications. First-in-human dosing in a healthy volunteer study is planned to begin in late 2020 or early 2021.

- **DNL758 (SAR443122) clinical development advanced by Sanofi:** In October, Denali reported its partner Sanofi completed enrollment in a Phase 1b clinical trial of DNL758, a peripherally-restricted small molecule inhibitor of RIPK1, in a Phase 1b clinical trial in hospitalized adult patients with severe COVID-19 lung disease. Separately, Sanofi plans to initiate a Phase 2 clinical trial of DNL758 in cutaneous lupus in early 2021.

- **Strong financial position:** Cash, cash equivalents, and marketable securities were $981.5 million as of September 30, 2020. The company's pro forma cash balance was $1.5 billion considering addition of the $560 million upfront payment received in October.

Participation in Upcoming Investor Conferences

Members of Denali's management will participate in the following upcoming investor conferences:

- **Stifel 2020 Virtual Healthcare Conference**: fireside chat with Ryan Watts, Ph.D., chief executive officer, beginning at 1:20 p.m. Eastern Time on Monday, November 16, 2020

- **Jefferies Virtual London Healthcare Conference**: presentation by Alex Schuth, M.D., chief operating officer, beginning at 6:10 p.m. Greenwich Mean Time / 1:10 p.m. Eastern Time on Wednesday, November 18, 2020

- **Wolfe Virtual Healthcare Conference 2020:** Denali's management team will participate in meetings on Thursday, November 19, 2020

- **Evercore ISI HealthCONx Conference:** fireside chat with Ryan Watts, Ph.D., chief executive officer, and Carole Ho, M.D., chief medical officer, beginning at 3:55 p.m. Eastern Time on Tuesday, December 1, 2020

Third Quarter 2020 Financial Results

For the three months ended September 30, 2020, Denali reported a net loss of $58.2 million compared with a net loss of $46.3 million for the three months ended September 30, 2019.

Collaboration revenue was $9.4 million for the three months ended September 30, 2020, compared to $13.6 million for the three months ended September 30, 2019. The decrease of $4.2 million in collaboration revenue was primarily due to a $12.4 million decrease in revenue recognized under the Sanofi Collaboration Agreement driven by a $10.0 million milestone recognized in the three months ended September 30, 2019 related to the peripheral program, and the winding down of revenue for retained activities as activities are transferred to Sanofi. The decrease was partially offset by a $8.2 million increase in revenue recognized under the Takeda Collaboration Agreement driven by increased costs in the programs partnered with Takeda.

Total research and development expenses were $53.7 million for the three months ended September 30, 2020, compared to $52.5 million for the three months ended September 30, 2019. The increase of approximately $1.2 million was primarily due to an increase in personnel-related expenses, including stock-based compensation, attributable to an increase in Denali's research and development headcount and new equity award grants. Additionally, there were increases in external expenses related to progression of Denali's portfolio, including the EIF2B program due to the progress of this program in the clinic. These increases were partially offset by decreases in other external research and development expenses, primarily attributable to a decrease in DNL747 costs after completion of the Phase 1b trials, completion of DNL201 clinical activities, significant CMC activity for the ETV:IDS program in 2019 and other unallocated research and development expenses attributable to decreased lab consumables costs and reductions in associated expenses related to COVID-19.

General and administrative expenses were $15.8 million for the three months ended September 30, 2020 compared to $11.2 million for the three months ended September 30, 2019. The increase of approximately $4.6 million was primarily attributable to an increase in personnel-related expenses, including stock-based compensation, primarily driven by higher stock-based compensation expense related to new equity award grants, and an increase in professional services costs associated with the execution of the Biogen collaboration agreements.

Cash, cash equivalents, and marketable securities were $981.5 million as of September 30, 2020. The company's pro forma cash balance was $1.5 billion considering addition of the $560 million upfront payment received in October.

About Denali Therapeutics

Denali Therapeutics is a biopharmaceutical company developing a broad portfolio of product candidates engineered to cross the blood-brain barrier (BBB) 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 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 payments, profit sharing and royalties under the collaboration with Biogen; the potential benefits and results of the collaboration with Biogen; development plans under, and potential benefits and results of, the collaboration with Secarna Pharmaceuticals; plans to conduct clinical development activities and commercialize products; LRRK2 inhibitors as modifying therapy for Parkinson's disease; plans, timelines and expectations related to DNL151, DNL310 and Denali's TV technology; plans, timelines and expectations related to DNL788 and DNL758 of both Denali and Sanofi; 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: any and all risks to Denali's business and operations caused directly or indirectly by the evolving COVID-19 pandemic; risk of the occurrence of any event, change or other circumstance that could give rise to the termination of Denali's agreements with Sanofi, Biogen, Secarna Pharmaceuticals or any of Denali's other collaboration agreements; Denali's early stages of clinical drug development; Denali's and its partners' ability to complete the development and, if approved, commercialization of its product candidates; Denali's and its partners' ability to enroll patients in its ongoing and future clinical trials; Denali's reliance on third parties for the manufacture and supply of its product candidates for clinical trials; Denali's dependence on successful development of its blood-brain barrier platform technology and product candidates currently in its core program; Denali's and it's partners' ability to conduct or complete clinical trials on expected timelines; the risk that preclinical profiles of Denali's product candidates, such as DNL151, DNL310, DNL788 and DNL758, may not translate in clinical trials; the potential for clinical trials of DNL151, DNL310, DNL788 and DNL758 or clinical trials of any other product candidates to differ from preclinical, preliminary or expected results; 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 September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Collaboration revenue:				
Collaboration revenue from customers	$ 9,388	$ 13,508	$ 18,751	$ 21,717
Other collaboration revenue	5	96	93	289
Total collaboration revenue	9,393	13,604	18,844	22,006
Operating expenses:				
Research and development	53,704	52,544	157,872	141,831
General and administrative	15,805	11,215	42,332	35,601
Total operating expenses	69,509	63,759	200,204	177,432
Loss from operations	(60,116)	(50,155)	(181,360)	(155,426)
Interest and other income, net	1,944	3,782	7,611	11,411
Loss before income taxes	(58,172)	(46,373)	(173,749)	(144,015)
Income tax benefit (provision)	(56)	113	—	426
Net loss	$ (58,228)	$ (46,260)	$ (173,749)	$ (143,589)
Net loss per share, basic and diluted	$ (0.54)	$ (0.48)	$ (1.65)	$ (1.50)
Weighted average number of shares outstanding, basic and diluted	107,490,702	95,859,048	105,217,770	95,449,570

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

	September 30, 2020	December 31, 2019
Assets		
Current assets:		
Cash and cash equivalents	$ 351,047	$ 79,449
Short-term marketable securities	610,154	335,907
Prepaid expenses and other current assets	9,665	14,675
Total current assets	970,866	430,031
Long-term marketable securities	20,341	39,886
Property and equipment, net	42,265	46,732
Operating lease right-of-use asset	32,976	33,923
Other non-current assets	3,858	2,659
Total assets	$ 1,070,306	$ 553,231
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 2,806	$ 2,590
Accrued compensation	9,010	8,739
Accrued clinical costs	4,689	5,042
Other accruals and other current liabilities	11,531	6,569
Operating lease liability, current	4,508	3,665
Related party contract liability	44,854	—
Other contract liabilities	28,015	18,739
Total current liabilities	105,413	45,344
Contract liabilities, less current portion	16,557	43,753
Operating lease liability, less current portion	65,407	68,865
Other non-current liabilities	379	379
Total liabilities	187,756	158,341
Total stockholders' equity	882,550	394,890
Total liabilities and stockholders' equity	$ 1,070,306	$ 553,231

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