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 6, 2018

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.)

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 November 8, 2018, Denali Therapeutics Inc. (the "***Company***") issued a press release announcing its financial results for the third quarter ended September 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 5.02 Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers; Compensatory Arrangements of Certain Officers.

On November 6, 2018, Jennifer Cook was appointed to the Company's Board of Directors (the "***Board***") and to the Corporate Governance and Nominating Committee of the Board (the "***Nominating Committee***"). Ms. Cook will serve as a Class III director, with a term expiring at the Company's 2020 annual meeting of the stockholders.

Jennifer Cook is the Chief Executive Officer of GRAIL. Previously, she was at Roche Pharmaceuticals and Genentech, where she has held a number of senior management positions, covering the full lifecycle of product development and commercialization. From 2013 to 2016 she was Head of Region Europe for Roche Pharmaceuticals, where she was responsible for the commercial success of Roche's pharmaceutical products in Europe and leading more than 5,500 employees across the 28 countries of the region. Other key positions during her 25-year tenure at Roche and Genentech included leading Global Clinical Operations, US and Global Product Portfolio Management, a Commercial Business Unit in the US, and Market Development. Ms. Cook started her career in research and development at Genentech. In 2016, Ms. Cook was recognized for her contributions to the healthcare industry and inspirational leadership when she was named Woman of the Year by the Healthcare Businesswomen's Association. Ms. Cook holds a BA in Human Biology and an MS in Biology from Stanford University, as well as an MBA from the Haas School of Business at University of California, Berkeley.

In accordance with Company policy, Ms. Cook will receive annual cash compensation of $40,000 for her services as a member of the Board and an additional $4,000 per year for service as a member of the Nominating Committee, each payable quarterly in arrears on a pro-rata basis, and on November 6, 2018, Ms. Cook was automatically granted an option to purchase common stock with a grant date value of $600,000, which vests as to 25% of the shares on the one year anniversary of the grant date and as to 1/48th of the shares on each monthly anniversary of the grant date thereafter, provided that she remains a service provider through the applicable vesting date.

Ms. Cook will be eligible for equity awards on the same terms as other continuing non-employee members of the Board. Currently, Company policy provides that on the date of each annual meeting of stockholders, each non-employee director who has been a director for six months or more on the date of the annual meeting will automatically be granted an option to purchase common stock having a grant date value equal to $350,000. Each annual option award will vest fully on the earlier of the one year anniversary of the grant date or the day prior to the next annual meeting of stockholders held after the grant date, in each case provided that such director remains a service provider through the applicable vesting date.

Ms. Cook also executed the Company's standard form of indemnification agreement, a copy of which has been filed as Exhibit 10.1 to the Company's Amendment No. 2 to Registration Statement on Form S-1 (File No. 333-221522) filed with the Securities and Exchange Commission on December 7, 2017.

There is no arrangement or understanding between Ms. Cook and any other persons pursuant to which Ms. Cook was elected as a director. In addition, Ms. Cook is not a party to any transaction, or series of transactions, required to be disclosed pursuant to Item 404(a) of Regulation S-K.

On November 8, 2018, the Company issued a press release announcing Ms. Cook's appointment as a director. The press release is attached hereto as Exhibit 99.1.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release dated November 8, 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: November 8, 2018

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

Exhibit 99.1

Denali Therapeutics Reports Third Quarter 2018 Financial Results and Business Highlights and Announces the Appointment of Jennifer Cook to Board of Directors

SOUTH SAN FRANCISCO – November 8, 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 third quarter ended September 30, 2018, provided business highlights and announced the appointment of Jennifer Cook to the Board of Directors.

“The recent clinical progress with our LRRK2 inhibitor and RIPK1 inhibitor programs are important milestones towards our goal of developing medicines for patients suffering from neurodegenerative diseases,” said Ryan Watts, Ph.D., CEO. “Furthermore, we are very excited to partner with Sanofi and expand our RIPK1 program into new indications.”

Third Quarter 2018 and Recent Business Highlights

- **Presented Phase 1 data and commenced recruitment for Phase 1b clinical trial for DNL201** – On October 25, 2018 detailed preclinical and clinical data from the DNL201 Phase 1 clinical trial in healthy volunteers were presented at the Michael J. Fox Foundation Parkinson's Disease Therapeutic Conference. The results met all endpoints and support testing DNL201 in patients. Patient recruitment has commenced for the DNL201 Phase 1b clinical trial in Parkinson’s disease patients with and without the LRRK2 mutation, with the first patient expected to be dosed in late 2018.

- **Completed dosing in DNL747 Phase 1 clinical trial** – In October 2018, dosing was completed in the DNL747 Phase 1 clinical trial in healthy volunteers. The data from this trial will be presented at the Denali 2018 R&D Day on December 10, 2018.

- **Entered into a broad RIPK1 Collaboration Agreement with Sanofi** – On October 29, 2018, Denali entered into a Collaboration and License Agreement with Genzyme Corporation, a wholly owned subsidiary of Sanofi S.A., to develop and commercialize therapeutic products to treat neurological and systemic inflammatory diseases by targeting RIPK1. Denali will receive an upfront fee of $125 million and 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. The transaction is expected to close in the coming months in accordance with customary regulatory approvals.

- **Appointed Jennifer Cook to the Board of Directors** – On November 6, 2018 Jennifer Cook joined the Board of Directors as an independent director. Ms. Cook is the Chief Executive Officer of GRAIL. Previously, she was at Roche Pharmaceuticals and Genentech, where she held a number of senior management positions during a 25-year tenure, covering the full lifecycle of product development and commercialization. Ms. Cook holds a BA in Human Biology and an MS in Biology from Stanford University, as well as an MBA from the Haas School of Business at University of California, Berkeley.

Third Quarter 2018 Financial Results

For the three months ended September 30, 2018, Denali reported a net loss of $35.4 million compared with a net loss of $21.8 million for the three months ended September 30, 2017.

Collaboration revenue was $1.2 million for the three months ended September 30, 2018, with no collaboration revenue recognized for the three months ended September 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 $30.3 million for the three months ended September 30, 2018, including non-cash stock-based compensation of $2.9 million, compared to $18.5 million for the three months ended September 30, 2017, including non-cash stock-based compensation of $0.7 million. The increase in total research and development expenses of $11.8 million 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 the Company's initial public offering. Further, there was an increase in other external research and development expenses, reflecting Denali's growing and maturing pipeline, increased LRRK2 program expenses due to increased costs associated with Phase 1 clinical trials in healthy volunteers with DNL201 and DNL151, and an increase in other research and development expenses primarily due to rent expense associated with the new headquarters lease and an increase in lab consumable expenses.

General and administrative expenses were $8.8 million for the three months ended September 30, 2018, including non-cash stock-based compensation of $2.6 million, compared to $3.8 million for the three months ended September 30, 2017, including non-cash stock-based compensation of $0.4 million. The increase in total general and administrative expenses of $5.0 million 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 the Company's initial public offering, and an increase in legal and professional service expenses required to support Denali's ongoing operations as a public company.

Cash, cash equivalents, and marketable securities were $517.1 million as of September 30, 2018, compared to $467.0 million as of December 31, 2017. The increase of $50.1 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, partially 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.

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, the potential benefits of the collaboration with Sanofi; the expectation as to when such transaction will close; expectations regarding clinical development activities; 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 that the Sanofi transaction may not close in a timely manner or at all; risks related to obtaining the requisite regulatory approvals; the risk of the occurrence of any event, change or other circumstance that could give rise to the termination of the collaboration agreement (including without limitation the failure to timely obtain requisite regulatory approvals); risks related to the effect of the announcement of the transaction 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 Annual Report on Form 10-K filed with the SEC on March 19, 2018, Denali’s Quarterly Report on Form 10-Q filed with the SEC on November 8, 2018 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,	
	2018	2017	2018	2017
Collaboration revenue	$ 1,195	$ —	$ 3,484	$ —
Operating expenses:				
Research and development	30,321	18,515	103,274	55,989
General and administrative	8,838	3,773	21,304	10,611
Total operating expenses	39,159	22,288	124,578	66,600
Loss from operations	(37,964)	(22,288)	(121,094)	(66,600)
Interest and other income, net	2,593	444	7,321	1,302
Net loss	$ (35,371)	$ (21,844)	$ (113,773)	$ (65,298)
Net loss per share, basic and diluted	$ (0.38)	$ (2.14)	$ (1.24)	$ (6.77)
Weighted average number of shares outstanding, basic and diluted	93,665,231	10,231,036	92,056,812	9,643,686

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

	September 30, 2018	December 31, 2017
Assets		
Current assets:		
Cash and cash equivalents	$ 43,651	$ 218,375
Short-term marketable securities	331,307	187,851
Prepaid expenses and other current assets	8,445	3,381
Total current assets	383,403	409,607
Long-term marketable securities	142,173	60,750
Property and equipment, net	16,245	14,923
Other non-current assets	2,654	1,441
Total assets	$ 544,475	$ 486,721
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 3,354	$ 2,716
Accrued liabilities	7,393	5,364
Accrued compensation	4,847	5,166
Contract liability	12,658	—
Deferred rent	3,227	855
Other current liabilities	138	63
Total current liabilities	31,617	14,164
Contract liability, less current portion	44,452	—
Deferred rent, less current portion	7,103	6,294
Other non-current liabilities	124	467
Total liabilities	83,296	20,925
Total stockholders' equity	461,179	465,796
Total liabilities and stockholders' equity	$ 544,475	$ 486,721