
**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 16, 2018

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.)

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 March 19, 2018, Denali Therapeutics Inc. (the “Company”) issued a press release announcing its financial results for the fourth quarter and full year ended December 31, 2017. 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 March 16, 2018, Mr. Peter Klein was appointed to the Company’s Board of Directors (the “Board”) and to the Audit Committee of the Board (the “Audit Committee”), for which he will serve as chair. Mr. Klein will serve as a Class II director, with a term expiring at the Company’s 2019 annual meeting of stockholders.

Mr. Klein, 55, served as Chief Financial Officer of William Morris Endeavor Entertainment, LLC (“WME”), a marketing firm, from January 2014 to June 2014. Prior to joining WME, Mr. Klein spent over 11 years at Microsoft Corporation, including serving as Chief Financial Officer from November 2009 until May 2013. Mr. Klein currently serves on the boards of directors of F5 Networks Inc., a software company, and Apptio, Inc., a software company. Mr. Klein holds a B.A. in history from Yale University and an M.B.A. from the University of Washington.

In accordance with Company policy, Mr. Klein will receive annual cash compensation of \$40,000 for his services as a member of the Board and an additional \$15,000 per year for service as chair of the Audit Committee, each payable quarterly in arrears on a pro-rata basis, and on March 16, 2018, Mr. Klein was automatically granted an option to purchase common stock with a grant date value of \$600,000, which shall vest 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 he remains a service provider through the applicable vesting date.

Mr. Klein 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.

Mr. Klein 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 Mr. Klein and any other persons pursuant to which Mr. Klein was elected as a director. In addition, Mr. Klein 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 March 19, 2018, the Company issued a press release announcing Mr. Klein’s appointment as a director. The press release is attached hereto as Exhibit 99.1.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release, dated March 19, 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: March 19, 2018

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



Denali Therapeutics Announces First-In-Human Dosing Of Its RIPK1 Inhibitor Clinical Program And The Appointment Of Peter Klein To Board Of Directors; Reports Fourth Quarter And Full Year 2017 Financial Results And Business Highlights

March 19, 2018

SOUTH SAN FRANCISCO – March 19, 2018 – Denali Therapeutics Inc. (NASDAQ: DNLI), a biopharmaceutical company developing a broad portfolio of therapeutic candidates for neurodegenerative diseases, today announced that it has commenced dosing of its small molecule inhibitor of RIPK1 in a Phase 1 clinical trial in healthy volunteers and achieved proof of concept of its large molecule blood-brain barrier delivery platform technology in nonhuman primates. In addition, the Company reported financial results for the fourth quarter and full year ended December 31, 2017 and appointed Peter Klein to the Board of Directors.

“The recent clinical progress with our RIPK1 inhibitor and LRRK2 inhibitor programs, along with achieving proof of concept for our blood-brain barrier delivery platform for biologics in nonhuman primates, 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 about initiating our collaboration with Takeda, which has allowed us to expand efforts on our blood-brain barrier delivery technology platform.”

Fourth Quarter 2017 and Recent Corporate Highlights

- **Achieved first-in-human dosing in Phase 1 clinical trial of RIPK1 inhibitor program** - In March 2018, Denali commenced dosing of its small molecule inhibitor of RIPK1, DNL747, in healthy volunteers in the Netherlands. DNL747 is a potent, selective and brain-penetrant small molecule inhibitor of RIPK1 in development for Alzheimer’s disease and ALS.
- **Advanced and expanded LRRK2 inhibitor program** - In December 2017, Denali announced that it had achieved robust target engagement in humans with DNL201, a LRRK2 inhibitor, in a Phase 1 clinical trial, and that the FDA removed the partial clinical hold on DNL201. This Phase 1 clinical trial in healthy volunteers for DNL201 is continuing. Denali also announced that it commenced dosing of its second LRRK2 inhibitor, DNL151, in a Phase 1 clinical trial in healthy volunteers in the Netherlands. DNL201 and DNL151 are both potent, selective and brain-penetrant small molecule inhibitors of LRRK2 in development for Parkinson’s disease.
- **Achieved proof of concept of the blood-brain barrier delivery platform technology in nonhuman primates** - In January 2018, Denali completed a 28-day study demonstrating sustained brain activity of its proprietary Antibody Transport Vehicle (ATV) technology, as measured by reduction of cerebral spinal fluid amyloid beta in cynomolgus monkeys after dosing of an anti-BACE1 antibody that is enabled by Denali’s proprietary ATV technology, compared to a standard anti-BACE1 antibody. These data are consistent with initial 7-day study data previously disclosed and establish preclinical proof of concept for future human studies.

-
- **Entered into Option and Collaboration Agreement with Takeda** - In January 2018, Denali entered into an Option and Collaboration Agreement with Takeda pursuant to which Denali granted Takeda an option in respect of three named Denali programs to develop and commercialize, jointly with Denali, certain biologic products that are enabled by Denali's blood-brain barrier delivery platform technology and intended for the treatment of neurodegenerative disorders. Denali received \$155.0 million of cash associated with this transaction in February 2018, including \$110.0 million for Takeda's purchase of 4,214,559 shares of Denali's common stock.
 - **Appointed Peter Klein to the Board of Directors** - On March 16, 2018, Peter Klein joined the Board of Directors as an independent director. Mr. Klein has 25 years of experience as a senior finance executive. He served as Chief Financial Officer of Microsoft Corporation from November 2009 until May 2013 and spent over 11 years at Microsoft. Most recently, he served as Chief Financial Officer of WME, a global leader in sports and entertainment marketing, from January 2014 until June 2014. Mr. Klein holds a B.A. from Yale University and an M.B.A from University of Washington. He currently serves on the board of directors of two publicly traded companies: Aptio Inc. and F5 Networks, Inc.
 - **Raised net proceeds of \$294.2 million during the fourth quarter of 2017 through the sale of convertible preferred stock and a subsequent initial public offering and listing on the Nasdaq Global Select Market;**

Fourth Quarter and Full Year 2017 Financial Results

For the fourth quarter of 2017, Denali reported a net loss of \$22.9 million, compared with a net loss for the fourth quarter of 2016 of \$19.4 million. For the year ended December 31, 2017, net loss was \$88.2 million, compared with a net loss for the same period in 2016 of \$86.7 million.

Total operating expenses for the fourth quarter of 2017 were \$23.5 million compared with \$19.8 million for the same period in 2016 including non-cash stock-based compensation of \$1.5 million and \$0.7 million in the fourth quarter of 2017 and 2016, respectively. Total operating expenses for the year ended December 31, 2017 were \$90.1 million compared with \$87.4 million for the same period in 2016, including non-cash stock-based compensation of \$4.4 million and \$3.0 million in 2017 and 2016, respectively. The increase in total operating expenses is due to the increase in research, development, and general and administrative costs as Denali's pipeline expanded and advanced.

Cash, cash equivalents, and marketable securities were \$467.0 million as of December 31, 2017.

About Denali Therapeutics

Denali is a biopharmaceutical company developing a broad portfolio of therapeutic candidates for neurodegenerative diseases. Denali is based in South San Francisco. For additional information, please visit www.denalitherapeutics.com.

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; clinical trial plans, timelines and expectations, including regarding proof of concept for future human studies; Denali's expectations regarding collaborations; and statements made by Denali's CEO. 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 stage of clinical drug development; Denali's ability to complete the development of, and if approved, commercialization of its product candidates; Denali's dependence on successful development of its BBB platform technology and product candidates currently in its core program; Denali's ability to conduct or complete clinical trials on expected timelines; the uncertainty that any of Denali's 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 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, the final prospectus related to Denali's initial public offering filed with the SEC on December 8, 2017, 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.
Unaudited Consolidated Statements of Operations
(In thousands, except per share amounts)

	Three Months Ended December 31,		Year Ended December 31,	
	2017	2016	2017	2016
Operating expenses:				
Research and development	\$ 18,471	\$ 16,730	\$ 74,460	\$ 75,702
General and administrative	5,069	3,046	15,680	11,731
Total operating expenses	<u>23,540</u>	<u>19,776</u>	<u>90,140</u>	<u>87,433</u>
Loss from operations	(23,540)	(19,776)	(90,140)	(87,433)
Interest income (expense), net	653	422	1,955	781
Net loss	<u>\$ (22,887)</u>	<u>\$ (19,354)</u>	<u>\$ (88,185)</u>	<u>\$ (86,652)</u>
Net loss per share, basic and diluted	<u>\$ (0.74)</u>	<u>\$ (2.41)</u>	<u>\$ (5.89)</u>	<u>\$ (13.49)</u>
Weighted average number of shares outstanding, basic and diluted ¹	<u>30,743,977</u>	<u>8,022,066</u>	<u>14,964,144</u>	<u>6,424,720</u>

¹ Share numbers have been adjusted, as appropriate, for the 4-for-1 reverse stock split that occurred on November 28, 2017. The increase in the weighted average number of common shares outstanding from 2016 to 2017 is primarily due to the conversion of preferred stock into common stock, and issuance of additional shares of common stock, both of which occurred at the time of our initial public offering in December 2017.

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

	December 31,	
	2017	2016
Assets		
Current assets:		
Cash and cash equivalents	\$218,375	\$ 39,853
Short-term marketable securities	187,851	138,478
Prepaid expenses and other current assets	3,381	3,624
Total current assets	<u>409,607</u>	<u>181,955</u>
Long-term marketable securities	60,750	72,580
Property and equipment, net	14,923	15,262
Other non-current assets	1,441	1,270
Total assets	<u>\$486,721</u>	<u>\$271,067</u>
Liabilities, convertible preferred stock and stockholders' equity (deficit)		
Current liabilities:		
Accounts payable	\$ 2,716	\$ 1,963
Accrued liabilities	5,364	3,850
Accrued compensation	5,166	2,592
Deferred rent	855	538
Other current liabilities	63	163
Total current liabilities	<u>14,164</u>	<u>9,106</u>
Deferred rent	6,294	7,045
Other non-current liabilities	467	397
Total liabilities	<u>20,925</u>	<u>16,548</u>
Convertible preferred stock	—	348,673
Total stockholders' equity (deficit)	<u>465,796</u>	<u>(94,154)</u>
Total liabilities, convertible preferred stock and stockholders' equity (deficit)	<u>\$486,721</u>	<u>\$271,067</u>