# 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):**

**May 5, 2022**

# 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 May 5, 2022, Denali Therapeutics Inc. (the "Company") issued a press release announcing its financial results for the first quarter ended March 31, 2022. 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 May 5, 2022. |
| 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: May 5, 2022

By: /s/ Alexander O. Schuth
Alexander O. Schuth, M.D.
Chief Operating and Financial Officer

# Denali Therapeutics Reports First Quarter 2022 Financial Results and Business Highlights

**SOUTH SAN FRANCISCO – May 5, 2022 –** 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 first quarter ended March 31, 2022, and provided business highlights.

“Recent achievements highlight the broad potential of our BBB-crossing Transport Vehicle (TV) platform and the transition of our therapeutic portfolio to late-stage development,” said Ryan Watts, Ph.D., Denali’s Chief Executive Officer. “In collaboration with Takeda, we initiated a first-in-human study with our second TV-enabled program, DNL593 (PTV:PGRN) for FTD-GRN, while our flagship TV-enabled program, DNL310 (ETV:IDS) for MPS II (Hunter syndrome), remains on track to begin a potentially registrational Phase 2/3 study in the first half of the year. These programs demonstrate the potential for TV-enabled brain delivery of enzymes and proteins, and we continue to advance other TV modalities towards the clinic, including antibodies and oligonucleotides. We are also pleased with progress in our ALS portfolio, including Sanofi’s initiation of a Phase 2 study with our RIPK1 inhibitor SAR443820 (DNL788), and we look forward to Biogen’s initiation of late-stage studies with our LRRK2 inhibitor BIIB122 (DNL151) for Parkinson’s disease.”

**Key First Quarter and Recent Program Updates**

**SAR443820/DNL788 (CNS-penetrant RIPK1 inhibitor): ALS**

- Announced that Denali collaborator Sanofi began dosing with SAR443820 in the HIMALAYA Phase 2 study expected to enroll approximately 260 participants with ALS.
- Denali will receive a $40 million milestone payment from Sanofi related to initiation of the Phase 2 study.

**DNL593 (PTV:PGRN): FTD-GRN**

- Announced that dosing began in a Phase 1/2 clinical study of DNL593 (PTV:PGRN) for the potential treatment of frontotemporal dementia (FTD) caused by mutations in the granulin gene (*GRN*).
- Pending initial clinical data from the Phase 1 healthy volunteer portion of the clinical study, Denali expects to begin dosing individuals with FTD-GRN in the second half of 2022.

**DNL310 (ETV:IDS): Hunter syndrome**

- Presented interim, longer-term data in 20 patients with MPS II (Hunter syndrome) from the Phase 1/2 clinical trial of DNL310 demonstrating sustained normalization of CSF heparan sulfate, consistent with durable CNS activity, with up to one year of intravenous dosing with DNL310.
- DNL310 remained generally well tolerated with a safety profile consistent with standard-of-care enzyme replacement therapy.

**DNL919 (ATV:TREM2): Alzheimer's disease**

- Received a formal clinical hold letter from the U.S. Food and Drug Administration (FDA) on the Investigational New Drug application for DNL919, which Denali is moving forward to address.
- Denali expects a delay of at least three months to the DNL919 program plans to begin dosing in a first-in-human clinical trial of DNL919 and intends to provide an update in the second half of 2022 once a clear path forward is established.

**Recent Corporate Highlights**

- Announced the expansion of the role of Alexander Schuth from Chief Operating Officer to Chief Operating and Financial Officer and the transition of Steve Krognes from his former role as Chief Financial Officer to Denali's Board of Directors, effective May 1, 2022.

**Participation in Upcoming Investor Conferences**

- Jefferies Global Healthcare Conference, June 8 - 10
- Goldman Sachs 43rd Annual Global Healthcare Conference, June 13 - 16

**First Quarter 2022 Financial Results**

For the three months ended March 31, 2022, Denali reported a net loss of $65.2 million compared to a net loss of $70.0 million for the three months ended March 31, 2021.

Collaboration revenue was $42.1 million for the three months ended March 31, 2022, compared to $7.9 million for the three months ended March 31, 2021. The increase in collaboration revenue of $34.2 million was primarily due to an increase in revenue from the Company's collaborations with Takeda and Biogen of $32.9 million and $1.3 million, respectively. Takeda revenue for the three months ended March 31, 2022 is composed of $27.9 million recognized due to the performance obligation satisfaction associated with termination of the Tau program, and $12.0 million related to the milestone earned for approval of the CTA for TAK-594/DNL593 (PTV:PGRN).

Total research and development expenses were $86.1 million for the three months ended March 31, 2022, compared to $60.2 million for the three months ended March 31, 2021. The increase of approximately $25.9 million was primarily attributable to an increase in ETV:IDS program costs due to progress in the clinic in 2022, and personnel-related expenses, including stock-based compensation, driven primarily by higher headcount and equity award grants. Additionally, there were increases in external expenses related to progression of the rest of Denali's portfolio, including the development of the PTV and TV platform reflecting the progress in the PTV:PGRN and ATV:TREM2 programs, as well as the Company's continued overall investment in developing a robust pipeline. These increases to expenses were partially offset by a decrease in external expenses related to the LRRK2 program primarily due to the transition of clinical activities to Biogen.

General and administrative expenses were $22.5 million for the three months ended March 31, 2022, compared to $18.9 million for the three months ended March 31, 2021. The increase of approximately $3.6 million was primarily attributable to an increase in personnel-related expenses, including stock-based compensation, driven primarily by higher headcount and equity award grants. Additionally, there were increases in other general costs such as insurance, software subscriptions, travel and facilities related expenses. These increases were partially offset by a decrease in legal and other professional services expenses due to accounting and tax fees incurred in 2021 associated with the assessment of the Biogen collaboration agreement.

Cash, cash equivalents, and marketable securities were approximately $1.2 billion as of March 31, 2022.

**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, business plans, business strategy, product candidates, planned preclinical studies and clinical trials and expected milestones; plans to conduct clinical development activities across various programs; plans, timelines and expectations related to Denali's Transport Vehicle (TV) platform, including its Enzyme Transport Vehicle (ETV), Antibody Transport Vehicle (ATV), and Protein Transport Vehicle (PTV) technologies; plans for advancing new TV programs into the clinic for the potential treatment of FTD-GRN and Alzheimer's disease; expectations regarding DNL151 for the treatment of Parkinson's disease in collaboration with Biogen; plans, timelines and expectations regarding DNL310, including advancement into a potentially registrational Phase 2/3 study; plans, timelines and expectations regarding DNL919 for the treatment of Alzheimer's disease, including with respect to the DNL919 program delay related to the FDA's clinical hold letter; plans, timelines and expectations regarding DNL788 of both Denali and Sanofi, including with respect to dosing and expected enrollment for a Phase 2 trial in ALS and Denali's expected milestone payment from Sanofi; plans, timelines and expectations regarding DNL593, including Phase 1/2 trial dosing and initial clinical data from the Phase 1 portion of such trial; Denali's priorities, regulatory approvals, timing and likelihood of success and expectations regarding collaborations; 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 ongoing 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, Takeda, Biogen or any of Denali's other collaboration agreements; Denali's transition to a late stage clinical drug development company; Denali's and its collaborators' ability to complete the development and, if approved, commercialization of its product candidates; Denali's and its collaborators' 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 its programs and product candidates; Denali's and its collaborators' ability to conduct or complete clinical trials on expected timelines; the risk that preclinical profiles of Denali's product candidates may not translate in clinical trials; the potential for clinical trials to differ from preclinical, early clinical, preliminary or expected results; the risk of significant adverse events, toxicities or other undesirable side effects; 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 attract, motivate and retain qualified managerial, scientific and medical personnel; developments relating to Denali's competitors and its industry, including competing product candidates and therapies; 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; Denali's ability to obtain additional capital to finance its operations, as needed; Denali's ability to accurately forecast future financial results in the current environment; general economic and market conditions; and other risks and uncertainties, including those described in Denali's most recent Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission (SEC) on May 5, 2022 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 March 31, | |
|---|---|---|
| | **2022** | **2021** |
| Collaboration revenue: | | |
| Collaboration revenue from customers[1] | $ 42,141 | $ 7,922 |
| Other collaboration revenue | — | 1 |
| Total collaboration revenue | 42,141 | 7,923 |
| Operating expenses: | | |
| Research and development[2] | 86,098 | 60,207 |
| General and administrative | 22,541 | 18,936 |
| Total operating expenses | 108,639 | 79,143 |
| Loss from operations | (66,498) | (71,220) |
| Interest and other income, net | 1,278 | 1,179 |
| Net loss | $ (65,220) | $ (70,041) |
| Net loss per share, basic and diluted | $ (0.53) | $ (0.58) |
| Weighted average number of shares outstanding, basic and diluted | 122,673,935 | 120,884,665 |

(1) Includes related party collaboration revenue from a customer of $2.2 million and $0.9 million for the three months ended March 31, 2022 and 2021, respectively.
(2) Includes expense for cost sharing payments to a related party of $2.7 million, for the three months ended March 31, 2022, and an offset to expense from related party cost sharing reimbursements of $2.5 million for the three months ended March 31, 2021

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

| | March 31, 2022 | December 31, 2021 |
|---|---|---|
| **Assets** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 104,953 | $ 293,477 |
| Short-term marketable securities | 852,569 | 571,930 |
| Cost sharing reimbursements due from related party | — | 1,226 |
| Prepaid expenses and other current assets | 30,914 | 30,601 |
| Total current assets | 988,436 | 897,234 |
| Long-term marketable securities | 250,268 | 425,449 |
| Property and equipment, net | 37,679 | 38,865 |
| Operating lease right-of-use asset | 30,263 | 30,743 |
| Other non-current assets | 14,212 | 11,871 |
| Total assets | $ 1,320,858 | $ 1,404,162 |
| **Liabilities and stockholders' equity** | | |
| Current liabilities: | | |
| Accounts payable | $ 3,358 | $ 4,779 |
| Cost sharing payments due to related party | 2,713 | — |
| Accrued compensation | 5,844 | 19,013 |
| Accrued clinical and other research & development costs | 19,283 | 15,887 |
| Accrued manufacturing costs | 11,366 | 9,955 |
| Other accrued costs and current liabilities | 2,390 | 2,857 |
| Operating lease liability, current | 5,659 | 5,453 |
| Related party contract liability, current | 290,627 | 292,386 |
| Contract liabilities, current | — | 27,915 |
| Total current liabilities | 341,240 | 378,245 |
| Related party contract liability, less current portion | 828 | 1,295 |
| Contract liabilities, less current portion | 3,398 | 3,398 |
| Operating lease liability, less current portion | 57,086 | 58,554 |
| Other non-current liabilities | 379 | 379 |
| Total liabilities | 402,931 | 441,871 |
| Total stockholders' equity | 917,927 | 962,291 |
| Total liabilities and stockholders' equity | $ 1,320,858 | $ 1,404,162 |

**Investor Relations Contact:**

Laura Hansen, Ph.D.
Vice President, Investor Relations
(650) 452-2747
**hansen@dnli.com**

**Media Contacts:**

Lizzie Hyland
(646) 495-2706
**lizzie.hyland@fgh.com**

**or**

Morgan Warners
(202) 295-0124
**morgan.warners@fgh.com**