



Denali Therapeutics Reports First Quarter 2022 Financial Results and Business Highlights

May 5, 2022

SOUTH SAN FRANCISCO, Calif., May 05, 2022 (GLOBE NEWSWIRE) -- Denali Therapeutics Inc. (Nasdaq: DNL), 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 Kroghes 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	<u>\$ (65,220)</u>	<u>\$ (70,041)</u>
Net loss per share, basic and diluted	<u>\$ (0.53)</u>	<u>\$ (0.58)</u>
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	<u>988,436</u>	<u>897,234</u>
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	<u>\$ 1,320,858</u>	<u>\$ 1,404,162</u>
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	<u>341,240</u>	<u>378,245</u>
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	<u>402,931</u>	<u>441,871</u>
Total stockholders' equity	<u>917,927</u>	<u>962,291</u>
Total liabilities and stockholders' equity	<u>\$ 1,320,858</u>	<u>\$ 1,404,162</u>

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