Denali Therapeutics Reports Fourth Quarter and Full Year 2025 Financial Results and Business Highlights

February 26, 2026

- Tividenofusp alfa (DNL310; ETV:IDS) launch readiness established ahead of April 5, 2026 Prescription Drug User Fee Act (PDUFA) target action date for Hunter syndrome
- DNL126 (ETV:SGSH) Phase 1/2 preliminary data presented at 2026 WORLD*Symposium*™, supporting plans to pursue an accelerated approval path in Sanfilippo syndrome type A
- Start-up activities underway for DNL628 (OTV:MAPT) Phase 1b study for Alzheimer's disease and DNL952 (ETV:GAA) Phase 1 study for late-onset Pompe disease
- TransportVehicle™ platform and clinical pipeline progressing across lysosomal storage disorders and neurodegenerative diseases

SOUTH SAN FRANCISCO, Calif., Feb. 26, 2026 (GLOBE NEWSWIRE) -- Denali Therapeutics Inc. (Nasdaq: DNLI) today reported financial results for the fourth quarter and full year ended December 31, 2025, and provided business highlights.

“In 2025, we made meaningful progress toward delivering urgently needed treatment options for people living with neurodegenerative diseases and lysosomal storage disorders, building on the strong scientific foundation that defines Denali,” said Ryan Watts, Ph.D., Chief Executive Officer of Denali Therapeutics. “We established commercial readiness for the anticipated launch of tividenofusp alfa for individuals and families affected by Hunter syndrome and continued advancing our TransportVehicle platform across serious neurologic and systemic diseases that impact millions worldwide.

"In 2026, we are focused on launching tividenofusp alfa and transforming life for individuals living with other serious diseases. Data presented at WORLD*Symposium* support our plans to pursue an accelerated approval path for DNL126 in Sanfilippo syndrome type A. We are also initiating clinical studies of DNL628 (OTV:MAPT) in Alzheimer’s disease and DNL952 (ETV:GAA) in late-onset Pompe disease. Over the next three years, we expect to advance four to six additional programs into the clinic, guided by our commitment to the patients we serve.”

Fourth Quarter 2025 and Recent Program Updates

CLINICAL PROGRAMS

Tividenofusp alfa (DNL310; ETV:IDS) for Hunter syndrome (mucopolysaccharidosis type II [MPS II])

Denali has established commercial launch readiness in anticipation of a regulatory decision on the Biologics License Application (BLA) for tividenofusp alfa under the U.S. Food and Drug Administration (FDA) accelerated approval pathway with a Prescription Drug User Fee Act (PDUFA) target action date of April 5, 2026. Results from the open-label Phase 1/2 clinical trial of tividenofusp alfa were published in the January 1, 2026 issue of *The New England Journal of Medicine*. The ongoing global Phase 2/3 COMPASS study is expected to generate confirmatory evidence and support global regulatory submissions; enrollment in Cohort A (neuronopathic participants) was completed in December 2025.

DNL126 (ETV:SGSH) for Sanfilippo syndrome type A (MPS IIIA)

In February 2026, Denali presented preliminary Phase 1/2 data at WORLD*Symposium* demonstrating treatment with DNL126 resulted in substantial reductions in disease biomarkers in cerebrospinal fluid (CSF heparan sulfate and GM3) and the periphery (urinary heparan sulfate) with a safety profile generally consistent with established enzyme replacement therapies. These preliminary data support an accelerated approval path in Sanfilippo syndrome type A. Planning for a global Phase 3 confirmatory study is ongoing.

TAK-594/DNL593 (PTV:PGRN) for *GRN*-related frontotemporal dementia (FTD-*GRN*)

TAK-594/DNL593 is an intravenously administered progranulin replacement therapy utilizing Denali’s Protein TransportVehicle ™(PTV) technology to deliver progranulin across the blood-brain barrier (BBB) and into the brain for individuals with FTD-*GRN*. Enrollment in the ongoing Phase 1/2 study is complete with a total of 40 participants with FTD-*GRN* enrolled. Initial FTD-*GRN* patient data are expected in 2026. The program is being developed in collaboration with Takeda.

DNL952 (ETV:GAA) for Pompe disease

DNL952 is enabled by Denali’s Enzyme TransportVehicle ™(ETV) and designed to enhance delivery of the missing enzyme, GAA, into muscle tissues and across the BBB into the brain. In January 2026, Denali announced that the FDA had lifted the clinical hold on the Investigational New Drug (IND) application for DNL952. Phase 1 study start-up activities are underway.

DNL628 (OTV:MAPT) for Alzheimer's disease

DNL628 is enabled by Denali's Oligonucleotide TransportVehicle ™(OTV) and is designed to cross the BBB and reduce the tau protein by targeting the MAPT gene that encodes for tau. In January 2026, Denali announced that the Clinical Trial Application (CTA) for the Phase 1b study of DNL628 had been approved and study start-up activities are underway.

BIIB122/DNL151 (small molecule LRRK2 inhibitor) for Parkinson's disease

A clinical data readout of the global Phase 2b LUMA study of BIIB122 for early-stage Parkinson's disease is expected in mid-2026. Denali's Phase 2a BEACON study in LRRK2-associated Parkinson's disease remains ongoing. The LRRK2 program is being developed in collaboration with Biogen.

SAR443122/DNL758 (eclitasertib; small molecule RIPK1 inhibitor) for ulcerative colitis

The Phase 2 study of eclitasertib in participants with moderate to severe ulcerative colitis is expected to have results in the first half of 2026. The program is being developed by Sanofi.

IND-ENABLING STAGE PROGRAMS

Denali has multiple additional programs in the IND-enabling stage including DNL921 (ATV:Abeta) for Alzheimer's disease; DNL111 (ETV:GCase) for Parkinson's disease and Gaucher disease; DNL622 (ETV:IDUA) for MPS I; and DNL422 (OTV:SNCA) for Parkinson's disease.

Corporate Updates

In December, Denali announced two funding events. The first was a $275.0 million synthetic royalty funding agreement with Royalty Pharma plc based on future net sales of tividenofusp alfa. The second was a successful public offering of common stock and pre-funded warrants totaling approximately $200.0 million in net proceeds.

Participation in Upcoming Investor Conferences

- TD Cowen 46th Annual Healthcare Conference, March 2-4, 2026, Boston
- UBS Biotech Summit Miami - Catalyst for Change, March 8-10, 2026, Miami
- Leerink Global Healthcare Conference, March 8-11, 2026, Miami
- Jefferies 2026 Biotech on the Beach Summit, March 10-11, 2026, Miami

Fourth Quarter and Full Year 2025 Financial Results

Net losses were $128.5 million and $512.5 million for the quarter and year ended December 31, 2025, respectively, compared to net losses of $114.8 million and $422.8 million for the quarter and year ended December 31, 2024, respectively.

Total research and development expenses were $97.9 million and $418.8 million for the quarter and year ended December 31, 2025, respectively, compared to $99.8 million and $396.4 million for the quarter and year ended December 31, 2024, respectively. The increase of approximately $22.4 million for the year ended December 31, 2025, compared to the comparative period in the prior year was primarily attributable to higher external research and development costs related to multiple preclinical and clinical TransportVehicle programs, as well as increased personnel and other operating expenses associated with our large molecule manufacturing facility in Salt Lake City, Utah. These increases were partially offset by lower external expenses related to small molecule programs, which also contributed to the $1.9 million decrease in research and development expenses for the quarter ended December 31, 2025, compared to the same period in the prior year.

General and administrative expenses were $39.5 million and $136.6 million for the quarter and year ended December 31, 2025, respectively, compared to $30.1 million and $105.4 million for the quarter and year ended December 31, 2024, respectively. The increases of $9.4 million and $31.1 million for the quarter and year ended December 31, 2025, compared to the comparative period in the prior year were primarily driven by headcount increases and other activities associated with preparing for the potential commercial launch for tividenofusp alfa.

Cash, cash equivalents and marketable securities were approximately $966.2 million as of December 31, 2025.

About Denali Therapeutics

Denali Therapeutics Inc. is a biotechnology company pioneering a new class of biotherapeutics designed to cross the blood-brain barrier using its proprietary TransportVehicle™ platform. With a clinically validated delivery platform and a growing portfolio of therapeutic candidates across all stages of development, Denali is advancing toward its goal of delivering effective medicines to transform the lives of people living with neurodegenerative diseases, lysosomal storage disorders and other serious diseases. For more 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

expectations for Denali's TransportVehicle™ (TV) platform and its therapeutics and commercial potential; statements regarding Denali's business strategy and business plans, including expected key milestones for Denali's therapeutic portfolio in 2026 and beyond and Denali's ability to execute on its commercial strategies; plans, timelines and expectations related to Denali's Enzyme TransportVehicle™ (ETV) franchise and its therapeutic and commercial potential; plans, timelines and expectations relating to tividenofusp alfa (DNL310), including the timing, likelihood and scope of regulatory approvals and commercial launch, the therapeutic potential of tividenofusp alfa, and the likelihood of the Phase 2/3 COMPASS data to support confirmatory evidence for global regulatory submissions and approval; plans, timelines and expectations related to DNL126, including the timing and availability of data from the Phase 1/2 study, the therapeutic potential of DNL126, the likelihood and pathway of regulatory approval, and the plans to initiate a Phase 3 study; plans and expectations regarding DNL593 and the timing and availability of data from the ongoing Phase 1/2 study; plans and expectations regarding DNL628, including the planned Phase 1b study; plans and expectations regarding DNL952, including the Phase 1 study and the program's therapeutic potential; plans, timelines and expectations regarding DNL151, including the ongoing Phase 2a BEACON study, and timing and expectations for availability of data from the Phase 2b LUMA study; expectations regarding DNL758 and the timing and availability of data from the Phase 2 study; the timing and occurrence of potential milestone payments, including from Royalty Pharma plc; Denali's future operating expenses and anticipated cash runway; plans regarding participation in upcoming investor conferences; and statements by Denali's Chief Executive Officer. All drugs currently being developed by Denali are investigational and have not received regulatory approval for any indication. 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 impact of adverse economic conditions, tariffs and inflation on Denali's business and operations; 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 other collaborators; 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 commercialize products; 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 and hedge against financial risk in the current environment; and other risks and uncertainties, including those described in Denali's most recent Annual Report and Quarterly Reports on Forms 10-K and 10-Q filed with the Securities and Exchange Commission (SEC) on February 27, 2025 and November 6, 2025, and Denali's future reports to be filed with the SEC. Denali does not undertake any obligation to update or revise any forward-looking statements, to conform these statements to actual results or to make changes in Denali's expectations, 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 December 31,		Twelve Months Ended December 31,	
	2025	**2024**	**2025**	**2024**
Operating expenses:				
Research and development	$ 97,905	$ 99,787	$ 418,778	$ 396,440
General and administration	39,460	30,059	136,564	105,438
Total operating expenses	137,365	129,846	555,342	501,878
Gain from divestiture of small molecule programs	—	—	—	14,537
Loss from operations	(137,365)	(129,846)	(555,342)	(487,341)
Interest and other income, net	8,918	15,161	42,904	64,636
Loss before income taxes	(128,447)	(114,685)	(512,438)	(422,705)
Income tax expense	(102)	(68)	(102)	(68)
Net loss	$ (128,549)	$ (114,753)	$ (512,540)	$ (422,773)
Net loss per share, basic and diluted	$ (0.73)	$ (0.67)	$ (2.97)	$ (2.57)
Weighted average number of shares outstanding, basic and diluted	175,458,962	170,086,146	172,649,097	164,473,772

Denali Therapeutics Inc.
Condensed Consolidated Balance Sheets

(Unaudited)
(In thousands)

	December 31, 2025	December 31, 2024
Assets		
Current assets:		
Cash and cash equivalents	$ 205,326	$ 174,960
Short-term marketable securities	662,553	657,371
Prepaid expenses and other current assets	32,779	32,105
Total current assets	900,658	864,436
Long-term marketable securities	98,322	359,373
Property and equipment, net	52,402	55,236
Finance lease right-of-use asset	48,531	47,533
Operating lease right-of-use asset	19,002	22,861
Other non-current assets	25,939	24,741
Total assets	$ 1,144,854	$ 1,374,180
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 3,330	$ 11,137
Accrued expenses and other current liabilities	95,021	91,071
Total current liabilities	98,351	102,208
Operating lease liability, less current portion	27,210	36,673
Finance lease liability, less current portion	5,532	5,615
Total liabilities	131,093	144,496
Total stockholders' equity	1,013,761	1,229,684
Total liabilities and stockholders' equity	$ 1,144,854	$ 1,374,180

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