Denali Therapeutics Reports Third Quarter 2019 Financial Results and Business Highlights

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SOUTH SAN FRANCISCO, Calif., Nov. 06, 2019 (GLOBE NEWSWIRE) -- 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, 2019, and provided business highlights.

“Our clinical and preclinical programs continue to progress and we plan to submit an IND or CTA for two programs by year-end 2019. One of these programs, ETV:IDS, will be our first biotherapeutic engineered to cross the blood-brain barrier using our Transport Vehicle platform. We are also particularly excited about our LRRK2 program and the potential to make a difference for patients suffering from Parkinson's disease,” said Ryan Watts, Ph.D., CEO.

Third Quarter 2019 and Recent Business Highlights

- **First patient dosed in DNL151 Phase 1b clinical trial** - In September 2019, Denali announced initiation of dosing in a Phase 1b clinical study of LRRK2 inhibitor DNL151 in patients with Parkinson's disease, and the launch of its Engage Parkinson's website.

- **RIPK1 program update** - The DNL747 Phase 1b trials in Alzheimer's disease and ALS continue to progress, enrollment of an ALS open label extension in the Netherlands has commenced, and sites for the Phase 1b ALS study have been expanded into the United States. Denali intends, together with its partner Sanofi, to evaluate the full data set from the ongoing clinical and preclinical studies to inform decisions on further clinical testing for the RIPK1 program. The timing of such decisions is delayed to mid-2020.

- **First patient enrolled in Hunter Syndrome patient biomarker study** - In October 2019, Denali enrolled the first patient in a biomarker study for the ETV:IDS program in Hunter Syndrome. This non-interventional study is expected to yield critical biomarker and clinical data in patients to inform future clinical studies with DNL310 (ETV:IDS) and facilitate patient recruitment into these studies. DNL310 is a CNS-penetrant, intravenous enzyme replacement therapy that utilizes our Transport Vehicle platform technology to increase penetration across the blood-brain barrier.

- **Leadership promotions** - In November 2019, Zach Sweeney was promoted to Chief Scientific Officer, and Cindy Dunkle was promoted to Chief People Officer. Both Zach and Cindy joined Denali in 2015.

Third Quarter 2019 Financial Results

For the three months ended September 30, 2019, Denali reported a net loss of $46.3 million compared with a net loss of $35.4 million for the three months ended September 30, 2018.

Collaboration revenue was $13.6 million for the three months ended September 30, 2019, compared with collaboration revenue of $1.2 million for the three months ended September 30, 2018. The $12.4 million increase was due to $12.5 million of revenue recognized under the Sanofi Collaboration Agreement in the three months ended September 30, 2019, which included a $10 million milestone earned upon Sanofi's commencement of a DNL758 Phase 1 clinical trial in healthy volunteers, partially offset by a decrease in revenue recognized under the Takeda Collaboration Agreement.

Total research and development expenses were $52.5 million for the three months ended September 30, 2019 compared to $30.3 million for the three months ended September 30, 2018. The $22.2 million increase in total research and development expenses was primarily attributable to an increase in external expenses related to the LRRK2 and ETV:IDS programs among other programs in the Company's portfolio. In addition, there was an increase in personnel-related expenses, including stock-based compensation, driven primarily by higher headcount and stock-based awards. Other increases include external research and development expenses to support pipeline growth as well as higher rent expense associated with the new headquarters lease.

General and administrative expenses were $11.2 million for the three months ended September 30, 2019, compared to $8.8 million for the three months ended September 30, 2018. The $2.4 million increase in total general and administrative expenses was primarily attributable to an increase in personnel-related expenses, including stock-based compensation, driven primarily by higher headcount and stock-based awards as well as higher rent expense associated with the new headquarters lease.

Cash, cash equivalents, and marketable securities were $502.9 million as of September 30, 2019.

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, statements regarding Denali's progress and business plans; the expected timing to submit an IND or CTA for two of Denali's programs; Denali's expectations regarding its ETV:IDS and LRRK2 programs, including the non-interventional biomarker study for the ETV:IDS program in Hunter Syndrome; Denali's intentions and plans regarding the RIPK1 program; 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: Denali's early stages of clinical drug development; Denali's ability to complete the development and, if approved, commercialization of its product candidates; the risk of the occurrence of any event, change or other circumstance that could give rise to the termination of Denali's collaboration agreements; Denali's dependence on successful development of its blood-brain barrier 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 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 blood-brain barrier platform technology; and other risks, including those described in Denali's Annual Report on Form 10-K filed with the SEC on March 12, 2019, Denali's Quarterly Report on From 10-Q filed with the SEC on November 6, 2019, 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,	
	2019	**2018**	**2019**	**2018**
Collaboration revenue	$ 13,604	$ 1,195	$ 22,006	$ 3,484
Operating expenses:				
Research and development	52,544	30,321	141,831	103,274
General and administrative	11,215	8,838	35,601	21,304
Total operating expenses	63,759	39,159	177,432	124,578
Loss from operations	(50,155)	(37,964)	(155,426)	(121,094)
Interest and other income, net	3,782	2,593	11,411	7,321
Loss before income taxes	(46,373)	(35,371)	(144,015)	(113,773)
Income tax benefit	113	—	426	—
Net loss	$ (46,260)	$ (35,371)	$ (143,589)	$ (113,773)
Net loss per share, basic and diluted	$ (0.48)	$ (0.38)	$ (1.50)	$ (1.24)
Weighted average number of shares outstanding, basic and diluted	95,859,048	93,665,231	95,449,570	92,056,812

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

	September 30, 2019	December 31, 2018
Assets		
Current assets:		
Cash and cash equivalents	$ 82,673	$ 77,123

Short-term marketable securities	396,717	387,174
Prepaid expenses and other current assets	14,987	16,539
Total current assets	494,377	480,836
Long-term marketable securities	23,534	147,881
Property and equipment, net	47,481	25,162
Operating lease right-of-use asset	34,344	—
Other non-current assets	3,242	8,105
Total assets	$ 602,978	$ 661,984
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 2,022	$ 1,891
Accrued liabilities	15,467	8,520
Accrued compensation	7,528	9,952
Contract liabilities	18,185	11,427
Other current liabilities	3,483	996
Total current liabilities	46,685	32,786
Contract liabilities, less current portion	47,795	57,350
Operating lease liability, less current portion	69,915	—
Deferred rent, less current portion	—	24,532
Other non-current liabilities	386	471
Total liabilities	164,781	115,139
Total stockholders' equity	438,197	546,845
Total liabilities and stockholders’ equity	$ 602,978	$ 661,984

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