

Catabasis Pharmaceuticals Reports First Quarter 2018 Financial Results and Reviews Business Progress

May 10, 2018

- -- MoveDMD® Trial Data Through One Year of Treatment Reinforce Edasalonexent Potential as Disease-Modifying Therapy for Duchenne Muscular Dystrophy --
- -- 2018 Priorities Focused on Advancing Edasalonexent and Improving the Lives of Boys Affected by Duchenne Muscular Dystrophy --

CAMBRIDGE, Mass.--(BUSINESS WIRE)--May 10, 2018-- Catabasis Pharmaceuticals, Inc. (NASDAQ:CATB), a clinical-stage biopharmaceutical company, today reported financial results for the first quarter ended March 31, 2018, and reviewed recent business progress.

"We are pleased to see additional positive clinical data from our MoveDMD trial early in 2018 that continue to demonstrate the potential of edasalonexent as a disease-modifying therapy for all patients affected by Duchenne, regardless of mutation. As evidenced by sustained improvements in all assessments of physical function and in biomarkers of muscle health and inflammation, edasalonexent has slowed the progression of Duchenne in the MoveDMD trial," said Jill C. Milne, Ph.D., Chief Executive Officer of Catabasis. "We believe that these effects ultimately will translate to boys with Duchenne maintaining functional abilities longer."

Recent and Upcoming Corporate Highlights

- Edasalonexent significantly slowed Duchenne muscular dystrophy (DMD) disease progression as measured by MRI through one year of treatment, as reported at the American Academy of Neurology 70th Annual Meeting in April 2018. Statistically significant improvements in MRI T2 rate of change through 48 weeks of oral 100 mg/kg of edasalonexent treatment compared to control were observed in the MoveDMD trial. The rate of fat fraction accumulation slowed in both the soleus and vastus lateralis through 48 weeks of edasalonexent treatment compared to the off-treatment control period. There was a greater reduction in the rate of fat fraction accumulation in boys on edasalonexent treatment than in a population of boys in a separate ImagingDMD natural history study who were largely on steroids. Edasalonexent continued to be well tolerated with no safety signals observed throughout the trial.
- Height and weight through 60 weeks of edasalonexent treatment was on track with standard growth curves for unaffected boys, as presented at the 2018 Muscular Dystrophy Association (MDA) Clinical Conference in March 2018. This profile is favorably differentiated from the typical profile associated with the corticosteroid standard of care in DMD, which includes weight gain and curtailed growth.
- Heart rate data from boys treated with edasalonexent decreased toward age-normative values through 48 weeks of treatment, as reported at the MDA Clinical Conference in March 2018. In the 4-7 year old age range, boys typically have resting tachycardia, a heart rate that exceeds the normal resting rate, which is the first cardiac manifestation in DMD. Cardiac failure is a leading cause of mortality in DMD.
- Observations from an ImagingDMD natural history study, as presented at the MDA Clinical Conference in March 2018, were generally consistent with the absolute functional abilities as well as declines in abilities experienced by boys in the off-treatment control period of the Catabasis MoveDMD trial. We believe that these data provide important corroboration that the MoveDMD off-treatment control period observations are characteristic of the expected natural history and provide added confidence in the slowing of disease progression treatment effects observed with edasalonexent.
- Preservation of muscle function and substantially slowed DMD disease progression through more than a year of edasalonexent treatment, as reported at the XVI International Conference on Duchenne and Becker Muscular Dystrophy in February 2018. Consistent improvements in all assessments of muscle function (North Star Ambulatory Assessment, time to stand, 4-stair climb and 10-meter walk/run) were observed following 48 and 60 weeks of edasalonexent treatment compared to the rates of change in the off-treatment control period. Statistically significant improvements in multiple non-effort based biomarkers of muscle health and inflammation (muscle enzymes and C-reactive protein) were observed compared to baseline.
- Company resources have been aligned to focus on its lead program edasalonexent for the treatment of DMD. Catabasis is
 preparing for a global Phase 3 trial to evaluate the safety and efficacy of edasalonexent for registration purposes.

First Quarter 2018 Financial Results

Cash Position: As of March 31, 2018, Catabasis had cash and cash equivalents of \$17.0 million, compared to \$16.4 million as of December 31, 2017. Based on the Company's current operating plan, Catabasis believes that it has sufficient cash to fund operations through December 2018. To advance edasalonexent in the Phase 3 trial, Catabasis expects to seek additional funds through equity or debt financings and/or through partnering or licensing transactions. Net cash used in operating activities for the three months ended March 31, 2018 was \$6.8 million, compared to \$8.1 million for the three months ended March 31, 2017.

R&D Expenses: Research and development expenses were \$5.2 million for the three months ended March 31, 2018, compared to \$5.4 million for the three months ended March 31, 2017.

G&A Expenses: General and administrative expenses remained consistent at \$2.4 million for the three months ended March 31, 2018 and for the three months ended March 31, 2017.

Operating Loss: Loss from operations was \$7.6 million for the three months ended March 31, 2018, compared to \$7.8 million for the three months ended March 31, 2017.

Net Loss: Net loss was \$7.7 million, or \$0.29 per share, for the three months ended March 31, 2018, compared to a net loss of \$7.9 million, or \$0.41 per share, for the three months ended March 31, 2017.

Conference Call and Webcast

Catabasis will host a conference call and webcast at 8:30am ET today to provide an update on corporate developments and to discuss first quarter 2018 financial results.

Participant Toll-Free Dial-In Number: (877) 388-2733
Participant International Dial-In Number: (541) 797-2984
Pass Code: 2192025

Please specify to the operator that you would like to join the "Catabasis First Quarter 2018 Results Call."

Interested parties may access a live audio webcast of the conference call via the investor section of the Catabasis website, www.catabasis.com.

Please connect to the Catabasis website several minutes prior to the start of the broadcast to ensure adequate time for any software download that may be necessary. The webcast will be archived for 90 days.

About Edasalonexent (CAT-1004)

Edasalonexent (CAT-1004) is an investigational oral small molecule that is being developed as a potential disease-modifying therapy for all patients affected by DMD, regardless of their underlying mutation. Edasalonexent inhibits NF-kB, a protein that is activated in DMD and drives inflammation and fibrosis, muscle degeneration and suppresses muscle regeneration. Edasalonexent continues to be dosed in the open-label extension of the MoveDMD Phase 2 clinical trial and Catabasis is preparing for a single global Phase 3 trial to evaluate the efficacy and safety of edasalonexent for registration purposes, dependent on raising capital. The FDA has granted orphan drug, fast track and rare pediatric disease designations and the European Commission has granted orphan medicinal product designation to edasalonexent for the treatment of DMD. For a summary of clinical results reported to date, please visit www.catabasis.com.

About Catabasis

At Catabasis Pharmaceuticals, our mission is to bring hope and life-changing therapies to patients and their families. Our SMART (Safely Metabolized And Rationally Targeted) Linker drug discovery platform enables us to engineer molecules that simultaneously modulate multiple targets in a disease. Our lead program in development is edasalonexent for the treatment of Duchenne muscular dystrophy. For more information on edasalonexent and our pipeline of drug candidates, please visit www.catabasis.com.

Forward Looking Statements

Any statements in this press release about future expectations, plans and prospects for the Company, including statements about future clinical trial plans including, among other things, statements about the Company's plans to commence a single global Phase 3 trial in DMD to evaluate the efficacy and safety of edasalonexent for registration purposes, and the Company's expectation that based on its current operating plan it has sufficient cash to fund operations through December 2018, and other statements containing the words "believes," "anticipates," "plans," "expects," "may" and similar expressions, constitute forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including: uncertainties inherent in the initiation and completion of preclinical studies and clinical trials and clinical development of the Company's product candidates; whether interim results from a clinical trial will be predictive of the final results of the trial or the results of future trials; expectations for regulatory approvals to conduct trials or to market products; the Company's ability to obtain financing on acceptable terms and in a timely manner to fund the Company's planned Phase 3 trial of edasalonexent in DMD for registration purposes; availability of funding sufficient for the Company's foreseeable and unforeseeable operating expenses and capital expenditure requirements; other matters that could affect the availability or commercial potential of the Company's product candidates; and general economic and market conditions and other factors discussed in the "Risk Factors" section of the Company's Quarterly Report on Form 10-Q for the guarter ended March 31, 2018, which is on file with the Securities and Exchange Commission, and in other filings that the Company may make with the Securities and Exchange Commission in the future. In addition, the forward-looking statements included in this press release represent the Company's views as of the date of this press release. The Company anticipates that subsequent events and developments will cause the Company's views to change. However, while the Company may elect to update these forward-looking statements at some point in the future, the Company specifically disclaims any obligation to do so. These forward-looking statements should not be relied upon as representing the Company's views as of any date subsequent to the date of this release.

	Three Months Ended March 31,	
	2018	2017
Operating expenses:		
Research and development	5,247	5,398
General and administrative	2,392	2,363
Total operating expenses	7,639	7,761
Loss from operations	(7,639)	(7,761)
Other (expense) income:		
Interest expense	(57)	(149)
Interest and investment income	32	39
Other income (expense), net	12	(5)
Total other expense, net	(13)	(115)
Net loss	\$ (7,652)	\$ (7,876)
Net loss per share - basic and diluted	\$ (0.29)	\$ (0.41)
Weighted-average common shares outstanding used in net loss per share - basic and diluted	26,555,840	19,093,273

Catabasis Pharmaceuticals, Inc. Condensed Consolidated Balance Sheets

(In thousands) (Unaudited)

	March 31, 2018	December 31, 2017
Assets		
Cash and cash equivalents	\$ 17,030	\$ 16,369
Total assets	18,290	17,897
Liabilities and stockholders' equity		
Current portion of notes payable, net of discount	1,657	2,479
Total liabilities	5,359	6,105
Total stockholders' equity	\$ 12,931	\$ 11,792

Catabasis Pharmaceuticals, Inc. Condensed Consolidated Statements of Cash Flows (In thousands)

(In thousands (Unaudited)

	Three Months Ended March 31,				
	2018		2	2017	
Net cash used in operating activities	\$	(6,819)	\$	(8,105)	
Net cash provided by investing activities		-		14,901	
Net cash provided by financing activities		7,480		1,403	
Net increase in cash and cash equivalents	\$	661	\$	8,199	

View source version on businesswire.com: https://www.businesswire.com/news/home/20180510005248/en/

Source: Catabasis Pharmaceuticals, Inc.

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