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

November 13, 2018

-- Edasalonexent Phase 3 PolarisDMD Trial in Duchenne Muscular Dystrophy Underway and Starting Enrollment --

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Nov. 13, 2018-- Catabasis Pharmaceuticals, Inc. (NASDAQ:CATB), a clinical-stage biopharmaceutical company, today reported financial results for the third quarter ended September 30, 2018, and reviewed recent business progress.

"We have made great advancements across our edasalonexent program over the last quarter. Clinical trial sites for our Phase 3 PolarisDMD trial are now open for enrollment and we are receiving tremendous interest and positive feedback from families and physicians, reflecting the high level of unmet need in Duchenne and enthusiasm for edasalonexent," said Jill C. Milne, Ph.D., Chief Executive Officer of Catabasis. "We presented new data showing preserved muscle function and stabilized disease progression following 72 weeks of edasalonexent treatment compared to control. We also presented data that could potentially contribute to establishing MRI as an endpoint for clinical outcome in Duchenne. We are excited to advance our understanding of the potential cardiac benefits of edasalonexent through a preclinical collaboration with Dr. Mammen from UT Southwestern who treats patients with Duchenne and Becker muscular dystrophies. Together, these advancements support the potential value of edasalonexent and get us closer to our goal of making edasalonexent available to all those affected by Duchenne with the hope of enabling patients to maintain their functional abilities longer."

Recent and Upcoming Corporate Highlights

- Multiple sites open for enrollment for the Phase 3 PolarisDMD clinical trial evaluating edasalonexent in boys affected by Duchenne muscular dystrophy (DMD)
    - The Phase 3 PolarisDMD trial is a one-year, randomized, double-blind, placebo-controlled trial. Catabasis plans to enroll approximately 125 patients ages 4 to 7 (up to 8th birthday) regardless of mutation type who have not been on steroids for at least 6 months.
    - Top-line results from the Phase 3 PolarisDMD trial are expected in the second quarter of 2020, and the trial is intended to support an application for commercial registration of edasalonexent.

- New MoveDMD Phase 2 trial and open-label extension data through 72 weeks of edasalonexent treatment
    - Preserved muscle function and sustained disease-modifying effects in all assessments of physical function in boys with DMD was seen through 72 weeks of edasalonexent treatment compared to the off-treatment control period. Data were presented at the International Congress of the World Muscle Society in October 2018.
    - Significant decreases in muscle enzymes through 72 weeks were also seen in boys treated with edasalonexent, supporting the durability of edasalonexent treatment effects and positive effects on muscle integrity.
    - Significantly decreased heart rate towards age-normative values was observed and supports the potential beneficial cardiac effects of edasalonexent. Boys with DMD in this age range typically have elevated heart rates, which is the first cardiac manifestation in boys with DMD. Cardiomyopathy is the leading cause of mortality in DMD.
    - Edasalonexent continued to be well tolerated with no safety signals observed in the trial. Boys treated with edasalonexent continued to follow age-appropriate growth curves with age-appropriate increases in weight and height.
    - Catabasis expects to present additional clinical data from the MoveDMD trial with edasalonexent in 2019.
- New magnetic resonance imaging (MRI) data support MRI T2 as a potential marker of clinical outcome in DMD
    - Data from ImagingDMD, the largest natural history database of MRI measurements in more than 150 boys with DMD, show a strong correlation of lower leg composite MRI T2 with clinically relevant functional abilities and DMD disease progression.
    - These results highlight the clinical importance of the significant improvement observed in the Catabasis Phase 2 MoveDMD trial and open-label extension following 12, 24, 36 and 48 weeks of edasalonexent treatment for lower leg MRI T2 compared to the off-treatment control period.
    - ImagingDMD and MoveDMD data were presented at the International Congress of the World Muscle Society in

October 2018.

- Preclinical collaboration with University of Texas Southwestern (UT Southwestern) to explore the potential benefits of edasalonexent on cardiac function in Duchenne and Becker muscular dystrophies
    - The collaboration is with Pradeep Mammen, M.D., founder and Medical Director of the Neuromuscular Cardiomyopathy Clinic at the UT Southwestern Medical Center and Co-Director of the Nation Institute of Health Sponsored UT Southwestern Senator Paul D. Wellstone Muscular Dystrophy Cooperative Research Center.

Third Quarter 2018 Financial Results

Cash Position: As of September 30, 2018, Catabasis had cash, cash equivalents and short-term investments of $43.2 million, compared to $49.9 million as of June 30, 2018. Based on the Company's current operating plan, Catabasis believes it has sufficient cash to fund operations into the second quarter of 2020. Net cash used in operating activities for the three months ended September 30, 2018 was $5.8 million, compared to $7.4 million for the three months ended September 30, 2017. Net cash used in operating activities for the nine months ended September 30, 2018 was $18.2 million, compared to $21.2 million for the nine months ended September 30, 2017.

Debt: All principal and interest due under the credit facility Catabasis established in 2014 had been paid as of September 30, 2018. There are no further payments due under the credit facility.

R&D Expenses: Research and development expenses were $3.9 million for the three months ended September 30, 2018, compared to $4.8 million for the three months ended September 30, 2017 and $13.4 million for the nine months ended September 30, 2018, compared to $14.7 million for the nine months ended September 30, 2017. The decrease in research and development expenses was primarily attributable to a decrease in post-restructuring employee compensation and other non-program costs.

G&A Expenses: General and administrative expenses were $2.1 million for the three months ended September 30, 2018, compared to $2.4 million for the three months ended September 30, 2017, and $6.9 million for the nine months ended September 30, 2018 compared to $7.2 million for the nine months ended September 30, 2017.

Operating Loss: Loss from operations was $6.0 million for the three months ended September 30, 2018, compared to $7.0 million for the three months ended September 30, 2017 and $20.3 million for the nine months ended September 30, 2018, compared to $21.6 million for the nine months ended September 30, 2017.

Net Loss: Net loss was $5.7 million, or $0.08 per share, for the three months ended September 30, 2018, compared to a net loss of $7.0 million, or $0.31 per share, for the three months ended September 30, 2017. Net loss for the nine months ended September 30, 2018 was $19.8 million, compared to $21.9 million for the nine months ended September 30, 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 third quarter 2018 financial results.

Participant Toll-Free Dial-In Number:	(877) 388-2733
Participant International Dial-In Number:	(541) 797-2984
Pass Code:	5269109

Please specify to the operator that you would like to join the "Catabasis Third 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 new standard of care for all patients affected by DMD, regardless of their underlying mutation. Edasalonexent inhibits NF-kB, which is a key link between loss of dystrophin and disease progression in DMD. NF-kB has a fundamental role in skeletal and cardiac muscle disease in DMD. We are currently enrolling our global Phase 3 PolarisDMD trial to evaluate the efficacy and safety of edasalonexent for registration purposes. In our MoveDMD Phase 2 trial and open-label extension, we observed that edasalonexent preserved muscle function and substantially slowed disease progression compared to rates of change in a control period, and significantly improved biomarkers of muscle health and inflammation. Edasalonexent continues to be dosed in the open-label extension of the MoveDMD trial. 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, 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 lead program is edasalonexent, an NF-kB inhibitor in development for the treatment of Duchenne muscular dystrophy. Our global Phase 3 PolarisDMD trial is currently enrolling boys affected by Duchenne. For more information on edasalonexent and our Phase 3 PolarisDMD trial, please visit www.catabasis.com or www.twitter.com/catabasispharma.

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 global Phase 3 PolarisDMD trial in DMD to evaluate the efficacy and safety of edasalonexent for registration purposes, the Company's plans to report top-line results from this trial in the second quarter of 2020, and the Company's expectation that its current operating plan provides for cash to fund operations into the second quarter of 2020, 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; 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 quarter ended September 30, 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.

Catabasis Pharmaceuticals, Inc.
Condensed Consolidated Statements of Operations
(In thousands, except share and per share data)
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	**2017**	**2018**	**2017**
Revenue	$ -	$ 250	$ -	$ 250
Operating expenses:				
Research and development	3,897	4,776	13,383	14,693
General and administrative	2,111	2,426	6,900	7,189
Total operating expenses	6,008	7,202	20,283	21,882
Loss from operations	(6,008)	(6,952)	(20,283)	(21,632)
Other income (expense):				
Interest expense	(10)	(105)	(100)	(381)
Interest and investment income	177	45	252	128
Other income (loss), net	162	(5)	321	18
Total other income (expense), net	329	(65)	473	(235)
Net loss	$ (5,679)	$ (7,017)	$ (19,810)	$ (21,867)
Net loss per share - basic and diluted	$ (0.08)	$ (0.31)	$ (0.45)	$ (1.03)
Weighted-average common shares outstanding used in net loss per share - basic and diluted	71,038,419	22,563,174	43,603,950	21,163,591

Catabasis Pharmaceuticals, Inc.
Condensed Consolidated Balance Sheets
(In thousands)
(Unaudited)

	September 30, 2018	**December 31, 2017**
Assets		
Cash and cash equivalents	$ 19,876	$ 16,369
Short-term investments	23,363	-
Total assets	44,699	17,897
Liabilities and stockholders’ equity		
Current portion of notes payable, net of discount	-	2,479
Total liabilities	4,180	6,105
Total stockholders’ equity	$ 40,519	$ 11,792

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

	Nine Months Ended September 30,	
	2018	**2017**
Net cash used in operating activities	$ (18,197)	$ (21,199)
Net cash (used in) provided by investing activities	(22,999)	14,883
Net cash provided by financing activities	44,703	4,433
Net increase in cash and cash equivalents	$ 3,507	$ (1,883)

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Source: Catabasis Pharmaceuticals, Inc.

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