



Catabasis Pharmaceuticals Reports Second Quarter 2019 Financial Results and Reviews Business Progress

-- Edasalonexent Global Phase 3 PolarisDMD Trial in Duchenne Muscular Dystrophy Is Enrolling Rapidly --

-- Recent Data Supports Potential for Bone Preservation with Edasalonexent in DMD --

CAMBRIDGE, Mass., August 8, 2019 – [Catabasis Pharmaceuticals, Inc.](#) (NASDAQ:CATB), a clinical-stage biopharmaceutical company, today reported financial results for the second quarter ended June 30, 2019 and reviewed recent business progress.

“Thanks to the enthusiasm from the Duchenne community and support from our clinical trial sites, all of our 40 trial sites are open and our Phase 3 PolarisDMD clinical trial is rapidly enrolling patients,” said Jill C. Milne, Ph.D., Chief Executive Officer of Catabasis. “We continue to generate important insights into the full potential of edasalonexent. Recent preclinical data showing preservation of bone health with 6 months of edasalonexent treatment compared to control support our belief that edasalonexent has the potential to become a foundational treatment for Duchenne and benefit skeletal muscle function as well as cardiac and bone health in patients. The ability to impact multiple aspects of health affected by Duchenne is important to patients, caregivers and physicians, and we look forward to generating additional data on these potential benefits in our Phase 3 study.”

Recent and Upcoming Corporate Highlights

- An update on the Phase 3 PolarisDMD clinical trial as well as an overview of the edasalonexent development program for the treatment of Duchenne muscular dystrophy (DMD) was presented in July at the Parent Project Muscular Dystrophy 25th Annual Conference. Current status of the Phase 3 trial:
 - All 40 clinical trial sites across 8 countries have opened for enrollment.
 - Clinical trial sites globally are enrolling rapidly. There is limited remaining space in the United States, Canada and Australia and sites in the United Kingdom, Ireland, Sweden, Germany and Israel are at capacity and no longer accepting additional patients.
 - Final patients are being scheduled and the remaining screening visits are expected to be completed in September.
 - Top-line results from the Phase 3 PolarisDMD trial are expected in the second half of 2020, and the trial is intended to support an application for commercial registration of edasalonexent in early 2021.

- The GalaxyDMD open-label extension trial is underway and has enrolled remaining participating boys from the MoveDMD open-label extension and their eligible siblings. Boys who complete the PolarisDMD trial as well as their eligible siblings will also have the opportunity to participate in the GalaxyDMD trial.
- Preclinical data demonstrated that edasalonexent preserved bone health in contrast to negative bone effects produced with corticosteroids following 6 months of treatment in the *mdx* mouse model of DMD. The data were presented in June at the Symposium on Muscle-Bone Interaction in Duchenne Muscular Dystrophy. Preserved bone health is important to those affected by DMD as many patients experience long bone and/or vertebral fractures before the age of 13.
- Catabasis' Board of Directors was strengthened by the appointment of Hugh M. Cole, who has extensive business development and commercial strategy experience.

Second Quarter 2019 Financial Results

Cash Position: As of June 30, 2019, Catabasis had cash, cash equivalents and short-term investments of \$46.1 million, compared to \$51.7 million as of March 31, 2019. Based on the Company's current operating plan, Catabasis expects that it has sufficient cash to fund operations beyond top-line Phase 3 results and through 2020. Net cash used in operating activities for the three months ended June 30, 2019 was \$5.7 million, compared to \$5.6 million for the three months ended June 30, 2018.

R&D Expenses: Research and development expenses were \$5.2 million for the three months ended June 30, 2019, compared to \$4.2 million for the three months ended June 30, 2018.

G&A Expenses: General and administrative expenses were \$2.2 million for the three months ended June 30, 2019, compared to \$2.4 million for the three months ended June 30, 2018.

Operating Loss: Loss from operations was \$7.3 million for the three months ended June 30, 2019, compared to \$6.6 million for the three months ended June 30, 2018.

Net Loss: Net loss was \$7.1 million, or \$0.62 per share, for the three months ended June 30, 2019, compared to a net loss of \$6.5 million, or \$1.98 per share, for the three months ended June 30, 2018.

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 second quarter 2019 financial results.

Participant Toll-Free Dial-In Number: (877) 388-2733
Participant International Dial-In Number: (541) 797-2984
Pass Code: 4740699

Please specify to the operator that you would like to join the “Catabasis Second Quarter 2019 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 designed to inhibit NF-kB that is being developed as a potential foundational therapy for all patients affected by DMD, regardless of their underlying mutation. In DMD the loss of dystrophin leads to chronic activation of NF-kB, which is a key driver of skeletal and cardiac muscle disease progression. We are currently enrolling our global Phase 3 PolarisDMD trial to evaluate the efficacy and safety of edasalonexent for registration purposes. Edasalonexent is also being dosed in the open-label extension trial GalaxyDMD. 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. 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.

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, including the anticipated timing for completion of enrollment and top-line results, the potential timing for the filing of an NDA, the Company’s cash expectations, the Company’s planned transition to a commercial-stage organization 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 Annual Report on Form 10-Q for the year ended June 30, 2019, 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.

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Investor and Media Contact

Andrea Matthews

Catabasis Pharmaceuticals, Inc.

T: (617) 349-1971

amatthews@catabasis.com

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
Operating expenses:				
Research and development	5,160	4,239	9,357	9,486
General and administrative	2,165	2,397	4,302	4,789
Total operating expenses	<u>7,325</u>	<u>6,636</u>	<u>13,659</u>	<u>14,275</u>
Loss from operations	(7,325)	(6,636)	(13,659)	(14,275)
Other income (expense):				
Interest expense	-	(33)	-	(90)
Interest and investment income	257	43	483	75
Other (expense) income, net	(63)	147	7	159
Total other income, net	<u>194</u>	<u>157</u>	<u>490</u>	<u>144</u>
Net loss	<u>\$ (7,131)</u>	<u>\$ (6,479)</u>	<u>\$ (13,169)</u>	<u>\$ (14,131)</u>
Net loss per share - basic and diluted	<u>\$ (0.62)</u>	<u>\$ (1.98)</u>	<u>\$ (1.24)</u>	<u>\$ (4.76)</u>
Weighted-average common shares outstanding used in net loss per share - basic and diluted	<u>11,505,542</u>	<u>3,272,877</u>	<u>10,600,909</u>	<u>2,965,936</u>

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

	June 30,	December 31,
	2019	2018
Assets		
Cash and cash equivalents	\$ 9,615	\$ 15,294
Short-term investments	36,496	22,276
Right-of-use asset	1,274	-
Other current and long-term assets	<u>1,144</u>	<u>1,599</u>
Total assets	48,529	39,169
Liabilities and stockholders' equity		
Current portion of operating lease liabilities	1,266	-
Other current and long-term liabilities	<u>3,902</u>	<u>4,227</u>
Total liabilities	5,168	4,227
Total stockholders' equity	\$ 43,361	\$ 34,942

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

	Six Months Ended June 30,	
	2019	2018
Net cash used in operating activities	\$ (12,325)	\$ (12,421)
Net cash (used in) provided by investing activities	(14,229)	8
Net cash provided by financing activities	20,875	45,975
Net (decrease) increase in cash, cash equivalents and restricted cash	\$ (5,679)	\$ 33,562