



## **Catabasis Pharmaceuticals Reports Third Quarter 2019 Financial Results and Reviews Business Progress**

*-- Edasalonexent Global Phase 3 PolarisDMD Trial in Duchenne Muscular Dystrophy Fully Enrolled with Top-Line Results Expected in Q4 2020 --*

*-- Conference Call and Webcast Today at 8:30am ET --*

**BOSTON, Mass., November 7, 2019** – [Catabasis Pharmaceuticals, Inc.](#) (NASDAQ:CATB), a clinical-stage biopharmaceutical company, today reported financial results for the third quarter ended September 30, 2019 and reviewed recent business progress.

“We have made significant clinical progress with our lead program edasalonexent, a potential foundational therapy for the treatment of Duchenne muscular dystrophy. We are excited that enrollment is complete and target enrollment was exceeded for our Phase 3 PolarisDMD trial of edasalonexent. We very much appreciate the strong interest from physicians and the Duchenne community that propelled trial enrollment. We look forward to reporting top-line results in the fourth quarter of next year,” said Jill C. Milne, Ph.D., Chief Executive Officer of Catabasis. “In preparation for the potential commercialization of edasalonexent, we strengthened our executive team with the addition of Andrew Komjathy as Chief Commercial Officer.”

### **Recent and Upcoming Corporate Highlights**

- Phase 3 PolarisDMD of edasalonexent in Duchenne muscular dystrophy (DMD)
  - Trial enrollment is complete and has exceeded the enrollment target with 131 boys enrolled. Patients are enrolled across all 8 countries where the trial is active.
  - Top-line results from the Phase 3 PolarisDMD trial are expected in Q4 of 2020, and the trial is intended to support an application for commercial registration of edasalonexent in 2021.
- Clinical findings supporting edasalonexent as a potential foundational therapy for the treatment of DMD from the Phase 2 MoveDMD trial and open-label extension were presented at the 24<sup>th</sup> International Annual Congress of the World Muscle Society by Dr. Richard Finkel, M.D., Chief, Division of Neurology, Department of Pediatrics at Nemours Children’s Health System, and Principal Investigator for the MoveDMD and Phase 3 PolarisDMD trials of edasalonexent in DMD. Edasalonexent slowed disease progression compared to the off-treatment control period and was well tolerated through 60 cumulative years of patient exposure in boys affected by DMD.
- Catabasis named Andrew A. Komjathy as its Chief Commercial Officer, adding deep rare disease commercial experience to the executive team.

- Catabasis and the Jain Foundation announced a preclinical research collaboration to study edasalonexent in Dysferlinopathy, which includes Limb-girdle muscular dystrophy type 2B and Miyoshi myopathy. Edasalonexent has the potential to benefit patients with other diseases beyond DMD, such as Dysferlinopathy.

### **Third Quarter 2019 Financial Results**

**Cash Position:** As of September 30, 2019, Catabasis had cash, cash equivalents and short-term investments of \$40.6 million, compared to \$46.1 million as of June 30, 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 September 30, 2019 was \$6.5 million, compared to \$5.8 million for the three months ended September 30, 2018.

**R&D Expenses:** Research and development expenses were \$4.7 million for the three months ended September 30, 2019, compared to \$3.9 million for the three months ended September 30, 2018.

**G&A Expenses:** General and administrative expenses were \$2.0 million for the three months ended September 30, 2019, compared to \$2.1 million for the three months ended September 30, 2018.

**Operating Loss:** Loss from operations was \$6.7 million for the three months ended September 30, 2019, compared to \$6.0 million for the three months ended September 30, 2018.

**Net Loss:** Net loss was \$6.5 million, or \$0.56 per share, for the three months ended September 30, 2019, compared to a net loss of \$5.7 million, or \$0.80 per share, for the three months ended September 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 third 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 Third 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](http://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. Our ongoing global Phase 3 PolarisDMD trial is evaluating 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](http://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 Phase 3 development for the treatment of Duchenne muscular dystrophy. For more information on edasalonexent and our Phase 3 PolarisDMD trial, please visit [www.catabasis.com](http://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 and the open-label extension trial GalaxyDMD, including the anticipated timing for 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 September 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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**Catabasis Pharmaceuticals, Inc.**  
**Consolidated Statements of Operations**  
(In thousands, except share and per share data)  
*(Unaudited)*

	<u>Three Months Ended September 30,</u>		<u>Nine Months Ended September 30,</u>	
	<u>2019</u>	<u>2018</u>	<u>2019</u>	<u>2018</u>
<b>Operating expenses:</b>				
Research and development	4,697	3,897	14,054	13,383
General and administrative	1,985	2,111	6,287	6,900
Total operating expenses	<u>6,682</u>	<u>6,008</u>	<u>20,341</u>	<u>20,283</u>
Loss from operations	(6,682)	(6,008)	(20,341)	(20,283)
<b>Other income (expense):</b>				
Interest expense	-	(10)	-	(100)
Interest and investment income	214	177	697	252
Other (expense) income, net	(46)	162	(39)	321
Total other income, net	<u>168</u>	<u>329</u>	<u>658</u>	<u>473</u>
Net loss	<u>\$ (6,514)</u>	<u>\$ (5,679)</u>	<u>\$ (19,683)</u>	<u>\$ (19,810)</u>
Net loss per share - basic and diluted	<u>\$ (0.56)</u>	<u>\$ (0.80)</u>	<u>\$ (1.80)</u>	<u>\$ (4.54)</u>
Weighted-average common shares outstanding used in net loss per share - basic and diluted	<u>11,624,232</u>	<u>7,103,842</u>	<u>10,945,765</u>	<u>4,360,395</u>

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

	<u>September 30,</u>	<u>December 31,</u>
	<u>2019</u>	<u>2018</u>
<b>Assets</b>		
Cash and cash equivalents	\$ 17,765	\$ 15,294
Short-term investments	22,850	22,276
Right-of-use asset	965	-
Other current and long-term assets	<u>2,254</u>	<u>1,599</u>
Total assets	43,834	39,169
<b>Liabilities and stockholders' equity</b>		
Current portion of operating lease liabilities	929	-
Other current and long-term liabilities	<u>4,632</u>	<u>4,227</u>
Total liabilities	5,561	4,227
Total stockholders' equity	\$ 38,273	\$ 34,942

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

	<b>Nine Months Ended September 30,</b>	
	<b>2019</b>	<b>2018</b>
Net cash used in operating activities	\$ (18,799)	\$ (18,196)
Net cash used in investing activities	(578)	(22,999)
Net cash provided by financing activities	21,848	44,702
Net increase in cash, cash equivalents and restricted cash	<u>\$ 2,471</u>	<u>\$ 3,507</u>