Catabasis Pharmaceuticals Reports Second Quarter 2021 Financial Results and Provides a Corporate Update

August 9, 2021

BOSTON--(BUSINESS WIRE)--Aug. 9, 2021-- Catabasis Pharmaceuticals, Inc. (NASDAQ:CATB), a biopharmaceutical company, today reported financial results for the second quarter ended June 30, 2021 and provided a corporate update.

“We are focused on advancing the development of our lead program, QLS-215, as a differentiated and potentially the most patient-friendly treatment option for the chronic treatment of patients with hereditary angioedema to prevent attacks,” said Jill C. Milne, Ph.D., Chief Executive Officer of Catabasis. “We anticipate that our first clinical trial with QLS-215 could demonstrate clinical proof of concept of its differentiated profile and long antibody half-life. Initial results from this trial are anticipated by the end of 2022.”

QLS-215 for the Treatment of Hereditary Angioedema (HAE)

- The vision for the lead program, QLS-215, is to develop a monoclonal antibody inhibitor of plasma kallikrein for HAE with dosing once every three months or longer and sustained inhibitory blood levels. QLS-215 has the potential to be the most patient-friendly chronic treatment option, based on the data generated to date and the existing HAE treatment landscape.
- HAE is a rare genetic disorder characterized by severe, recurrent, unpredictable, painful and sometimes life-threatening swelling in the face, limbs, abdomen and airway. Targeted plasma kallikrein inhibition can prevent HAE attacks by suppressing the pathway that generates bradykinin and causes excessive swelling.
- QLS-215 is a humanized monoclonal antibody targeting plasma kallikrein that has demonstrated potent inhibition of plasma kallikrein as well as a long plasma half-life in non-human primates.
- Recent discussions with physicians and patients confirm the need for effective treatments that reduce HAE attacks as well as reduce the burden of treatment.
- Catabasis expects to file an Investigational New Drug application for QLS-215 in mid-2022 and plans to initiate a Phase 1 clinical trial with initial results anticipated by year end 2022. Catabasis expects that the results of this trial, if positive, could provide clinical proof of concept for the activity and plasma half-life improvements for QLS-215.

Capital Structure

- Stockholders of the Company approved the conversion of the Company’s non-voting Series X Preferred Stock at the 2021 Annual Meeting held on June 2, 2021. As a result, each share of Series X Preferred Stock converted automatically into 1,000 shares of Catabasis common stock, subject to certain beneficial ownership limitations. 53,532 shares of Series X Preferred Stock have converted and, as of August 9, 2021, approximately 76.9 million shares of common stock are outstanding. 32,545 shares of Series X Preferred Stock remain unconverted as a result of beneficial ownership limitations, which shares are convertible into approximately 32.5 million shares of common stock. After giving effect to the conversion of these shares on a pro forma basis, approximately 109.5 million shares of common stock would have been outstanding as of August 9, 2021.
- Catabasis will effect a reverse stock split of its shares of common stock at a ratio of 1-for-6, effective as of August 19, 2021, with trading of Catabasis’ common stock on the Nasdaq Capital Market to begin on a split-adjusted basis at market open on August 20, 2021. The common stock will continue to trade on the Nasdaq Capital Market under the ticker symbol “CATB,” although a new CUSIP number (14875P 305) has been assigned.
- Catabasis’s stockholders approved the reverse stock split at the 2021 Annual Meeting and granted Catabasis’s board of directors the authority to effect a reverse stock split.
- As a result of the reverse stock split, every 6 shares of Catabasis’s pre-reverse split common stock will be combined and reclassified into one share of common stock. No fractional shares will be issued in connection with the reverse stock split, and if the stock split results in any stockholders owning a fractional share, then such stockholders will receive a cash payment in lieu of such fractional share. The reverse stock split will not modify any rights of Catabasis’s common stock. The reverse stock split will proportionately reduce the number of shares of common stock issuable upon the conversion of Catabasis’s outstanding shares of Series X Preferred Stock and upon the exercise of its outstanding stock options and warrants, and with a proportionate increase in the exercise prices of such stock options and warrants. Catabasis has chosen its transfer agent, American Stock Transfer & Trust Company, LLC, to act as exchange agent for the reverse stock split. Stockholders owning shares via a bank, broker or other nominee will have their positions automatically adjusted to reflect the reverse stock split and will not be required to take further action in connection with the reverse stock split, subject to brokers’ particular processes. For those stockholders holding physical stock certificates, the exchange agent will send instructions for exchanging those certificates for shares held in book-entry form representing the post-split number of

shares.

- The par value of the Company's common stock will remain unchanged at $0.001 per share after the reverse stock split. The reverse stock split will not change the authorized number of shares of the Company's common stock. The reverse stock split will affect all stockholders uniformly and will not alter any stockholder's percentage interest in the Company's equity, except to the extent that the reverse stock split results in some stockholders owning a fractional share as described above.
- The reverse stock split will reduce the number of shares of common stock issued and outstanding from approximately 76.9 million to approximately 12.8 million and the number of shares of common stock issuable upon conversion of the Company's outstanding shares of Series X Preferred Stock from approximately 32.5 million to approximately 5.4 million.

Second Quarter 2021 Financial Results

Cash Position: As of June 30, 2021, Catabasis had cash, cash equivalents and short-term investments of $139.5 million, compared to $146.9 million as of March 31, 2021. The Company expects that it has sufficient cash to fund its current operating plan through 2023. Net cash used in operating activities for the three months ended June 30, 2021, was $7.4 million, compared to $7.5 million for the three months ended June 30, 2020.

R&D Expenses: Research and development expenses were $3.5 million for the three months ended June 30, 2021, compared to $6.8 million for the three months ended June 30, 2020.

G&A Expenses: General and administrative expenses were $4.0 million for the three months ended June 30, 2021, compared to $2.8 million for the three months ended June 30, 2020.

Operating Loss: Loss from operations was $7.5 million for the three months ended June 30, 2021, compared to $9.6 million for the three months ended June 30, 2020.

Net Loss: Net loss was $7.5 million for the three months ended June 30, 2021, compared to a net loss of $9.5 million for the three months ended June 30, 2020.

Net Loss Per Share Basic and Diluted: Net loss per share basic and diluted was $0.89 for the three months ended June 30, 2021, compared to a net loss basic and diluted of $0.53 per share for the three months ended June 30, 2020.

About Catabasis

At Catabasis Pharmaceuticals, our mission is to bring hope with life-changing therapies to patients and families affected by rare and niche diseases. Our lead program, QLS-215, is a monoclonal antibody inhibitor of plasma kallikrein in preclinical development for the treatment of hereditary angioedema.

Forward Looking Statements

This press release contains forward-looking statements within the meaning of applicable securities laws and regulations including, but not limited to, statements regarding: the Company's projected cash runway; expectations regarding the timing for the filing of an IND and commencement of a Phase 1 clinical trial for QLS-215, the timing and nature of the initial results from such trial; the potential attributes and differentiated profile of QLS-215; and the need for effective treatments for HAE. The use of words such as, but not limited to, "anticipate," "believe," "continue," "could," "estimate," "expect," "intend," "may," "might," "plan," "potential," "predict," "project," "should," "target," "will," or "would" and similar words expressions are intended to identify forward-looking statements. Forward-looking statements are neither historical facts nor assurances of future performance. Instead, they are based on the Company's current beliefs, expectations and assumptions regarding the future of its business, future plans and strategies, future financial performance, results of pre-clinical and clinical results of the Company's product candidates and other future conditions. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including risks and uncertainties: related to the Company's ability to recognize the anticipated benefits of the Quellis acquisition; the outcome of any legal proceedings that may be instituted against the Company or Quellis following the announcement of the Quellis acquisition and related transactions; changes in applicable laws or regulations; the possibility that the Company may be adversely affected by other economic, business, and/or competitive factors, including the COVID-19 pandemic; risks inherent in pharmaceutical research and development, such as: adverse results in our drug discovery, preclinical and clinical development activities, the risk that the results of pre-clinical studies may not be replicated in clinical studies, the Company's ability to enroll patients in our clinical trials, and the risk that any of the Company's clinical trials may not commence, continue or be completed on time, or at all; decisions made by, or feedback received from, the U.S. FDA and other regulatory authorities, investigational review boards at clinical trial sites and other review bodies with respect to QLS-215 and any future product candidates; the Company's ability to manufacture sufficient quantities of drug substance and drug product on a cost-effective and timely basis; the Company's ability to obtain, maintain and enforce intellectual property rights for QLS-215 and any other future product candidates; competition; the Company's ability to manage its cash usage and the possibility of unexpected cash expenditures; the Company's ability to obtain necessary financing to conduct its planned activities and to manage unplanned cash requirements; general economic and market conditions; as well as the risks and uncertainties set forth under the caption "Risk Factors" in the Company's most recent Annual Report on Form 10-K filed with the SEC, as well as discussions of potential risks, uncertainties, and other important factors in the Company's subsequent filings with the SEC. New risks and uncertainties may emerge from time to time, and it is not possible to predict all risks and uncertainties. The Company may not actually achieve the forecasts or expectations disclosed in our forward-looking statements, and investors and potential investors should not place undue reliance on the Company's forward-looking statements. Neither the Company, nor its affiliates, advisors or representatives, undertake any obligation to publicly update or revise any forward-looking statement, whether as result of new information, future events or otherwise, except as required by law. These forward-looking statements should not be relied upon as representing the Company's views as of any date subsequent to the date hereof.

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,	
	2021	2020	2021	2020
Operating expenses:				
Research and development	$ 3,478	$ 6,750	$ 6,071	$ 12,039
General and administrative	4,008	2,803	6,881	5,555
Acquired in-process research and development	-	-	164,617	-
Total operating expenses	7,486	9,553	177,569	17,594
Loss from operations	(7,486)	(9,553)	(177,569)	(17,594)
Other income (expense):				
Interest and investment income	40	60	53	227
Other expense, net	(20)	(15)	(34)	(93)
Total other income, net	20	45	19	134
Net loss	(7,466)	(9,508)	(177,550)	(17,460)
Dividend on convertible preferred stock related to beneficial conversion feature and issuance costs	(24,437)	-	(24,437)	-
Net loss attributable to common shareholders	$ (31,903)	$ (9,508)	$ (201,987)	$ (17,460)
Net loss per share - basic and diluted	$ (0.89)	$ (0.53)	$ (6.93)	$ (1.03)
Weighted-average common shares outstanding used in net loss per share - basic and diluted	35,880,580	17,967,495	29,167,672	16,933,079

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

	June 30, 2021	December 31, 2020
Assets		
Cash and cash equivalents	$139,520	$ 24,930
Short-term investments	-	20,000
Right-of-use asset	717	966
Other current and long-term assets	708	1,560
Total assets	140,945	47,456
Liabilities and stockholders' equity		
Current portion of operating lease liabilities	655	649
Long-term portion of operating lease liabilities	58	397
Other current and long-term liabilities	3,333	5,741
Total liabilities	4,046	6,787
Total stockholders' equity	$136,899	$ 40,669

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

	Six Months Ended June 30,	
	2021	2020
Net cash used in operating activities	$ (16,116)	$ (14,455)
Net cash provided by investing activities	26,445	24,310
Net cash provided by financing activities	104,261	31,889
Net increase in cash, cash equivalents and restricted cash	$ 114,590	$ 41,744

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