
**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**
WASHINGTON, DC 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of report (Date of earliest event reported): **March 2, 2016**

Catabasis Pharmaceuticals, Inc.
(Exact Name of Registrant as Specified in Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-37467
(Commission
File Number)

26-3687168
(IRS Employer
Identification No.)

One Kendall Square
Bldg. 1400E, Suite B14202
Cambridge, Massachusetts
(Address of Principal Executive Offices)

02139
(Zip Code)

Registrant's telephone number, including area code: **(617) 349-1971**

(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
 - Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
 - Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
 - Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))
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Item 2.02. Results of Operations and Financial Condition.

On March 2, 2016, Catabasis Pharmaceuticals, Inc. announced its financial results for the fiscal quarter and year ended December 31, 2015. The full text of the press release issued in connection with the announcement is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information contained in Item 2.02 in this Current Report on Form 8-K, including Exhibit 99.1, shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

The Exhibits to this Current Report on Form 8-K are listed in the Exhibit Index attached hereto.

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

CATABASIS PHARMACEUTICALS, INC.

Date: March 2, 2016

By: /s/ Ian C. Sanderson
Ian C. Sanderson
Chief Financial Officer

EXHIBIT INDEX

Exhibit No.	Description
99.1	Press Release issued by Catabasis Pharmaceuticals, Inc., dated March 2, 2016.

**FOR IMMEDIATE RELEASE****Catabasis Pharmaceuticals Reports Fourth Quarter and Full Year 2015 Financial Results and Recent Corporate Developments**

— *CAT-1004: Positive Top-Line MoveDMDSM Part A Results in Duchenne Muscular Dystrophy* —

— *CAT-2054: Phase 2a Trial in Hypercholesterolemia Progressing On Schedule* —

CAMBRIDGE, MA, March 2, 2016 — Catabasis Pharmaceuticals, Inc. (NASDAQ:CATB), a clinical-stage biopharmaceutical company, today announced financial results for the fourth quarter ended December 31, 2015 and full year 2015 and corporate highlights.

“Catabasis continues to advance our clinical-stage programs,” commented Jill C. Milne, Ph.D., chief executive officer of Catabasis. “We recently announced positive top-line results from Part A of our MoveDMD trial of CAT-1004, which we believe has the potential to be a disease-modifying therapy in patients with Duchenne muscular dystrophy (DMD), regardless of the underlying mutation. Based on these positive results, we are preparing to launch Part B of the MoveDMD trial during the first half of the year, subject to regulatory approval of our proposed protocol. The Phase 2a trial of CAT-2054 in hypercholesterolemia is substantially enrolled. Additionally, we have generated promising pre-clinical results with the CAT-2000 series in non-alcoholic steatohepatitis (NASH). We expect 2016 will be a pivotal year for Catabasis. We anticipate Phase 2 data for CAT-1004 in DMD late this year and Phase 2a data for CAT-2054 in hypercholesterolemia in Q3.”

Recent and Upcoming Corporate Highlights**CAT-1004: Positive Top-Line MoveDMD Part A Results in DMD**

- In January 2016, we reported positive top-line results for the dose-ranging portion (Part A) of the MoveDMD trial of CAT-1004. MoveDMD is a Phase 1 / 2 trial of CAT-1004 for boys aged 4-7 with DMD, regardless of the underlying mutation. In MoveDMD Part A, all three doses of CAT-1004 were generally well tolerated with no safety signals observed. Pharmacokinetic results demonstrated CAT-1004 average plasma exposure levels consistent with those previously observed in adults at which inhibition of NF-κB was observed and in animal models in which disease modification was observed.
 - Subject to regulatory approval of our proposed protocol, we expect to initiate the 12-week efficacy portion of the MoveDMD trial (Part B) in the first half of 2016 and to
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report top-line results in late 2016, contingent on patient enrollment.

- The Parent Project Muscular Dystrophy and the Muscular Dystrophy Association are providing funding to support participant travel for the MoveDMD trial.

CAT-2054: Phase 2a Trial in Hypercholesterolemia Progressing On Schedule

- In December 2015, we initiated patient dosing for the 4-week Phase 2a trial of CAT-2054 in addition to atorvastatin in hypercholesterolemia. Enrollment in this trial is substantially complete and we expect to report top-line results in Q3 2016.
- Results of recent pre-clinical studies for the CAT-2000 series support the potential development of CAT-2054 for NASH. We expect to present these pre-clinical data at a scientific conference later this year.

CAT-4001 in Friedreich's Ataxia and ALS: Conducting IND-Enabling Activities

- In 2016, we plan to continue pre-clinical evaluation of CAT-4001 in animal models of Friedreich's ataxia and Amyotrophic Lateral Sclerosis (ALS) and to conduct IND-enabling activities. If we are successful in these activities, we intend to advance CAT-4001 into a Phase 1 clinical trial in 2017.
- The Friedreich's Ataxia Research Alliance awarded us the Kyle Bryant Translational Research Award to evaluate CAT-4001 as a potential treatment for Friedreich's ataxia.

SMART Linker Scientific Article Publication

- Our internally-developed SMART linker drug discovery platform, which underlies each of our candidates, was featured in the February 11, 2016 issue of the *Journal of Medicinal Chemistry*.

Fourth Quarter and Full Year 2015 Financial Results

Cash Position: At December 31, 2015, Catabasis had cash and cash equivalents of \$62.8 million, compared to \$72.7 million as of September 30, 2015 and \$14.7 million as of December 31, 2014. Net cash used in operating activities for the three months ended December 31, 2015 was \$8.7 million, compared to \$5.9 million for the three months ended December 31, 2014. Net cash used in operating activities for the full year 2015 was \$29.8 million, net of financings, compared to \$20.4 million for the full year 2014.

R&D Expenses: Research and development expenses were \$6.7 million for the three months ended December 31, 2015, compared to \$4.3 million for the three months ended December 31, 2014, and \$23.0 million for the full year 2015, compared to \$15.7 million for the full year 2014. The increases in research and development expenses for the 2015 periods relative to the 2014 periods were primarily attributable to increased direct program costs related to the initiation of the CAT-1004 MoveDMD trial in 2015 and expansion of our research, development and clinical teams.

G&A Expenses: General and administrative expenses were \$2.7 million for the three months

ended December 31, 2015, compared to \$1.6 million for the three months ended December 31, 2014, and \$8.6 million for the full year 2015, compared to \$6.0 million for the full year 2014. The increases in general and administrative expenses for the 2015 periods relative to the 2014 periods were primarily due to increased G&A headcount and increased consulting and professional expenses.

Operating Loss: Loss from operations was \$9.3 million for the three months ended December 31, 2015, compared to \$5.9 million for the three months ended December 31, 2014, and \$31.7 million for the full year 2015, compared to \$21.7 million for the full year 2014.

Net Loss: Net loss was \$9.6 million, or \$0.63 per share, for the three months ended December 31, 2015, compared to a net loss of \$6.0 million for the three months ended December 31, 2014. Net loss for the full year 2015 was \$32.6 million, compared to \$21.9 million for the full year 2014.

Conference Call and Webcast

Catabasis will host a conference call and webcast at 4:30pm ET today to provide an update on corporate developments and to discuss fourth quarter and full year 2015 financial results and recent corporate developments.

Participant Toll-Free Dial-In Number: (877) 259-0810

Participant International Dial-In Number: (916) 582-3604

Pass Code: 50133621

Please specify to the operator that you would like to join the “Catabasis Fourth Quarter and Full Year 2015 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 conference call will also be available to be replayed for two weeks following the call at (855) 859-2056 for domestic callers and (404) 537-3406 for international callers, both with the Pass Code 50133621. The webcast will be archived for 90 days.

About CAT-1004

CAT-1004 is an oral small molecule that has the potential to be a disease-modifying therapy for all patients affected by Duchenne muscular dystrophy (DMD or Duchenne), regardless of the underlying mutation. CAT-1004 inhibits NF- κ B, a protein that is activated in Duchenne and drives inflammation and fibrosis, muscle degeneration and suppresses muscle regeneration. In animal models of DMD, CAT-1004 inhibited NF- κ B, reduced muscle degeneration and improved muscle regeneration and function, and beneficial effects were observed in skeletal, diaphragm and cardiac muscle. The FDA has granted orphan drug, fast track and rare pediatric disease

designations and the European Commission has granted orphan medicinal product designation to CAT-1004 for the treatment of DMD. We have previously reported safety, tolerability and reduction in NF-kB activity in Phase I trials in adults. We are currently conducting the MoveDMDSM trial of CAT-1004 in 4-7 year-old boys affected by Duchenne. From Part A of the MoveDMD trial, we have reported that all three doses of CT-1004 tested were generally well tolerated with no safety signals observed. Pharmacokinetic results demonstrated CAT-1004 average plasma exposure levels consistent with those previously observed in adults at which inhibition of NF-kB was observed.

About CAT-2054

CAT-2054 is an oral small molecule with a novel mechanism of action targeting Sterol Regulatory Element-Binding Protein (SREBP) being developed for serious lipid disorders such as hypercholesterolemia. By inhibiting SREBP, a master regulator of lipid metabolism in the body, CAT-2054 has the potential to significantly reduce LDL-C; it may also have beneficial effects on other metabolic parameters such as triglycerides, glucose and liver fat. This profile may differentiate CAT-2054 from currently approved therapies for hypercholesterolemia and others in development. Catabasis is developing CAT-2054 to be used on top of statins in patients who cannot reach their LDL-C goal with statins alone. We are currently conducting a Phase 2a trial of CAT-2054 in addition to high intensity statin therapy in patients with hypercholesterolemia, and have previously reported positive top-line Phase 1 data. We are also conducting research studies to support the potential of CAT-2054 in non-alcoholic steatohepatitis (NASH).

About Catabasis

At Catabasis Pharmaceuticals, our mission is to bring hope and life-changing therapies to patients and their families. We have product candidates in both rare diseases and serious lipid disorders. Our SMART (Safely Metabolized And Rationally Targeted) linker drug discovery platform enables us to engineer molecules that simultaneously modulate multiple targets in a disease. We are applying our SMART linker platform to build an internal pipeline of product candidates for rare diseases and plan to pursue partnerships to develop additional product candidates. For more information on the Company's drug discovery platform and 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 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; availability and timing of results from preclinical studies and clinical trials; 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 three months ended September 30, 2015, 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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Corporate and Media Contact

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

	<u>Three Months Ended December 31,</u>		<u>Year Ended December 31,</u>	
	<u>2015</u>	<u>2014</u>	<u>2015</u>	<u>2014</u>
Operating expenses:				
Research and development	\$ 6,670	\$ 4,325	\$ 23,030	\$ 15,686
General and administrative	2,663	1,552	8,629	5,995
Total operating expenses	<u>9,333</u>	<u>5,877</u>	<u>31,659</u>	<u>21,681</u>
Loss from operations	(9,333)	(5,877)	(31,659)	(21,681)
Other (expense) income:				
Other (expense) income, net	(5)	—	7	3
Interest expense	(268)	(149)	(978)	(206)
Total other income (expense)	<u>(273)</u>	<u>(149)</u>	<u>(971)</u>	<u>(203)</u>
Net loss and comprehensive loss	<u>\$ (9,606)</u>	<u>\$ (6,026)</u>	<u>\$ (32,630)</u>	<u>\$ (21,884)</u>
Net loss per share - basic and diluted	<u>\$ (0.63)</u>	<u>\$ (13.19)</u>	<u>\$ (4.06)</u>	<u>\$ (51.56)</u>
Weighted-average common shares outstanding used in net loss per share - basic and diluted	<u>15,298,810</u>	<u>456,690</u>	<u>8,041,948</u>	<u>424,477</u>

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

	As of December 31,	
	2015	2014
Assets		
Current assets:		
Cash and cash equivalents	\$ 62,780	\$ 14,668
Prepaid expenses and other current assets	804	354
Total current assets	63,584	15,022
Property and equipment, net	504	288
Other assets	135	654
Total assets	<u>\$ 64,223</u>	<u>\$ 15,964</u>
Liabilities, convertible preferred stock, and stockholders' equity (deficit)		
Current liabilities:		
Accounts payable	\$ 1,328	\$ 1,132
Accrued expenses	3,278	2,793
Current portion of notes payable, net of discount	3,205	309
Total current liabilities	7,811	4,234
Deferred rent, net of current portion	26	67
Notes payable, net of current portion and discount	5,742	4,439
Other liability	151	23
Warrant liability	—	108
Total liabilities	13,730	8,871
Convertible preferred stock:		
Series A convertible preferred stock	—	47,898
Series B convertible preferred stock	—	32,248
Total stockholders' equity (deficit)	50,493	(73,053)
Total liabilities, convertible preferred stock and stockholders' equity (deficit)	<u>\$ 64,223</u>	<u>\$ 15,964</u>