CATABASIS PHARMACEUTICALS INC Form 8-K October 04, 2017

UNITED STATES SECURITIES AND EXCHANGE COMMISSION

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): October 4, 2017

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 (<i>see</i> General Instruction A.2. below): |
|--|
| o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425) |
| o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12) |
| o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b)) |
| o Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c)) |
| Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter). |
| Emerging growth company X |
| If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. X |
| |

Item 8.01. Other Events.

On October 4, 2017, Catabasis Pharmaceuticals, Inc. (the Company) issued a press release and made publicly available a slide presentation announcing data from the open-label extension of the Company s MoveDMD clinical trial. The press release and the slide presentation are filed as Exhibits 99.1 and 99.2, respectively, to this Current Report on Form 8-K, and the information contained therein is incorporated herein by reference.

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 below.

Cautionary Note Regarding Forward-Looking Statements

This Current Report on Form 8-K, including the press release and the slide presentation filed as Exhibits 99.1 and 99.2, respectively, contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. All statements, other than statements of historical facts, contained in this Current Report on Form 8-K, including statements regarding the Company s plans to commence a single global Phase 3 trial in Duchenne muscular dystrophy, or DMD, in the first half of 2018 to evaluate the efficacy and safety of edasalonexent for registration purposes, the Company s plans to report top-line results from this trial in 2020 and the Company s plans to continue to evaluate data from the open-label extension of the Company s MoveDMD clinical trial of edasalonexent for the treatment of DMD, are forward-looking plan, statements. The words anticipate, believe, continue, could, estimate, expect, intend, may, project. and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. The Company may not actually achieve the plans, intentions or expectations disclosed in these forward-looking statements, and you should not place undue reliance on these forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in these forward-looking statements as a result of important risks and uncertainties, including uncertainties inherent in the initiation and completion of preclinical studies and clinical trials and clinical development of the Company s product candidates, including the final trial design of the Company s planned Phase 3 clinical trial in DMD; availability and timing of results from preclinical studies and clinical trials, including the availability of top-line results from the Company s planned Phase 3 clinical trial in DMD in 2020; 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, including the Company s expected target product profile for edasalonexent in DMD; the Company s ability to obtain financing on acceptable terms and in a timely manner to fund the Company s planned Phase 3 clinical trial in DMD to evaluate the efficacy and safety of edasalonexent for registration purposes; 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 Company s most recent Quarterly Report on Form 10-Q, particularly in the Risk Factors section, which is on file with the Securities and Exchange Commission. Except as otherwise required by law, the Company disclaims any intention or obligation to update any forward-looking statements as a result of developments occurring after the date of this Current Report on Form 8-K.

EXHIBIT INDEX

| Exhibit Number | Description of Exhibit |
|-------------------|--|
| 99.1 | Press release issued by the Company on October 4, 2017 |
| 99.2 | Slide presentation disclosing data from the open-label extension of the Company s MoveDMD clinical trial |
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SIGNATURES

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.

By: /s/ Jill C. Milne

Jill C. Milne

President and Chief Executive Officer

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Date: October 4, 2017