UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 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): May 9, 2018

CATALYST PHARMACEUTICALS, INC.
(Exact Name Of Registrant As Specified In Its Charter)

Delaware	**001-33057**	**76-0837053**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(I.R.S. Employer Identification No.)**

355 Alhambra Circle Suite 1250 Coral Gables, Florida	**33134**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (305) 420-3200

Not Applicable
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:

☐ 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 CFR240.14d-2(b))

☐ 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 ☐

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. ☐

Item 8.01 Other Events

On May 9, 2018, the Company issued a press release announcing its results of operations for the quarter ended March 31, 2018 and providing a corporate update. A copy of the press release is attached hereto as Exhibit 99.1.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

99.1 Press release issued by the Company on May 9, 2018.

SIGNATURES

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

Catalyst Pharmaceuticals, Inc.

By: /s/ Alicia Grande
Alicia Grande
Vice President, Treasurer and CFO

Dated: May 9, 2018

Exhibit 99.1

Catalyst Pharmaceuticals Announces First Quarter 2018 Financial Results and Provides Corporate Update

—Company to Host Quarterly Conference Call at 8:30 am ET Tomorrow

CORAL GABLES, Fla., May 9, 2018 (GLOBE NEWSWIRE) — Catalyst Pharmaceuticals, Inc. (Nasdaq: CPRX), a biopharmaceutical company focused on developing and commercializing innovative therapies for people with rare debilitating, chronic neuromuscular and neurological diseases, today reported financial results for the first quarter ended March 31, 2018 and provided a corporate update.

“We are pleased to continue to deliver on our key objectives for 2018, recently marked with the resubmission of our New Drug Application of Firdapse® for the symptomatic treatment of Lambert-Eaton myasthenic syndrome (LEMS),” said Patrick J. McEnany, Chairman and Chief Executive Officer of Catalyst Pharmaceuticals. “With a positive Type C meeting in the first quarter, we are confident that our NDA resubmission for Firdapse includes all that is required to be accepted for review by the FDA. We are working diligently on the development of our comprehensive patient services program, which is part of our commitment to the LEMS community. This program will have, among other features, a personalized program that provides patient and physician education, assistance with access, and treatment support for patients and their caregivers. Lastly, we continue to make progress in the clinic for the other potential indications that we are pursuing with Firdapse. I look forward to providing updates on our progress throughout the year.”

Q1-18 and Recent Highlights

- Resubmitted NDA for Firdapse for the treatment of LEMS
- Initiated sites and enrolled the first patient in the Phase 3 trial for MuSK-MG
- Continued progress with pre-commercialization activities for a potential launch of Firdapse
- Held positive Type C meeting with the FDA to discuss Firdapse NDA submission for LEMS
- Ended March 31, 2018 with $77.9 million in cash and investments and no debt

Upcoming Milestones

- Expect the FDA’s decision regarding acceptance of the NDA for Firdapse in the second quarter of 2018
- Complete enrollment in the Phase 3 CMS (CMS-001) trial in second half of 2018
- Expect top-line results from Phase 3 CMS (CMS-001) trial in the first quarter of 2019
- Enroll first patient in SMA Type 3 proof of concept trial conducted in Italy

Financial Results

For the quarter ended March 31, 2018, Catalyst reported a GAAP net loss of $5,699,892, or $0.06 per basic and diluted share, compared to a GAAP net loss of $4,967,129, or $0.06 per basic and diluted share, for the same period in 2017. For the first quarter of 2018, Non-GAAP[1] net loss was the same as GAAP net loss as there were no Non-GAAP[1] adjustments. Non-GAAP[1] net loss for the first quarter of 2017 was $4,569,894, or $0.06 per basic and diluted share, which excludes non-cash loss of $397,235 attributable to the change in fair value of liability-classified warrants.

Research and development expenses for the first quarter of 2018 were $3,259,042 compared to $2,813,929 in the first quarter of 2017. The increase in research and development expenses for the first three months of 2018 was primarily due to consulting expenses as we prepared to submit our NDA for Firdapse for the treatment of LEMS during March 2018, offset by a decrease in clinical expenses, including related drug costs. The Company expects that costs related to research and development activities will continue to be substantial throughout 2018 as it continues its on-going clinical studies and Expanded Access Program for Firdapse.

General and administrative expenses for the first quarter of 2018 totaled $2,674,398 as compared to $1,865,942 in the first quarter of 2017. The increase when compared to the same period in 2017 is primarily due to increased pre-commercialization expenses. The Company expects general and administrative expenses, including pre-commercialization expenses, to increase in 2018 as we expand our operations and headcount to build up our infrastructure and commercial programs in preparation for a potential Firdapse launch in 2019.

As a development-stage biopharmaceutical company, Catalyst had no revenues in either the first quarter of 2018 and 2017.

At March 31, 2018, Catalyst had cash and cash equivalents and short-term investments of $77.9 million and no debt. Catalyst believes that its existing capital resources will be sufficient to support its planned operations through 2019 (without considering revenues and cash receipts that may be received in 2019 if Catalyst is successful in obtaining and approval of Firdapse and launching the product in 2019, of which there can be no assurance).

More detailed financial information and analysis may be found in the Company’s Quarterly Report on Form 10-Q, which was filed with the Securities and Exchange Commission (SEC) on May 9, 2018.

[1] Statements made in this press release include a non-GAAP financial measure. Such information is provided as additional information and not as an alternative to Catalyst’s financial statements presented in accordance with U.S. generally accepted accounting principles (GAAP). This non-GAAP financial measure is intended to enhance an overall understanding of Catalyst’s current financial performance. Catalyst believes that the non-GAAP financial measure presented in this press release provides investors and prospective investors with an alternative method for assessing Catalyst’s operating results in a manner that Catalyst believes is focused on the performance of ongoing operations and provides a more consistent basis for comparison between periods. The non-GAAP financial measure in this press release excludes from the calculation of net loss the expense (or the income) associated with the change in fair value of the liability-classified warrants. Non-GAAP net loss per share is calculated by dividing non-GAAP net loss by the weighted average common shares outstanding.

Conference Call

Catalyst management will host an investment-community conference call and webcast at 8:30 a.m. ET, tomorrow, Thursday, May 10, 2018 to discuss the financial results and provide a corporate update. Investors who wish to participate in the conference call may do so by dialing (877) 407-8912 for domestic and Canadian callers or (201) 689-8059 for international callers. Those interested in listening to the conference call live via the internet may do so by visiting the Investors page of the company's website at www.catalystpharma.com and clicking on the webcast link on the Investors home page. A webcast replay will be available on the Catalyst website for 30 days following the call by visiting the Investor page of the company's website at www.catalystpharma.com.

About Catalyst Pharmaceuticals

Catalyst Pharmaceuticals is a biopharmaceutical company focused on developing and commercializing innovative therapies for people with rare debilitating, chronic neuromuscular and neurological diseases, including Lambert-Eaton myasthenic syndrome (LEMS), congenital myasthenic syndromes (CMS), MuSK antibody positive myasthenia gravis, and infantile spasms. Firdapse has received Breakthrough Therapy Designation from the U.S. Food and Drug Administration (FDA) for the treatment of LEMS and Orphan Drug Designation for LEMS, CMS and myasthenia gravis. Firdapse is the first and only approved drug in Europe for symptomatic treatment in adults with LEMS.

Catalyst is also developing CPP-115 to treat refractory infantile spasms. CPP-115 has been granted U.S. Orphan Drug Designation for the treatment of infantile spasms by the FDA and has been granted E.U. Orphan Medicinal Product Designation for the treatment of West syndrome by the European Commission. In addition, Catalyst is developing a generic version of Sabril® (vigabatrin).

Forward-Looking Statements

This press release contains forward-looking statements. Forward-looking statements involve known and unknown risks and uncertainties, which may cause Catalyst's actual results in future periods to differ materially from forecasted results. A number of factors, including (i) whether the results of the LMS-003 trial, combined with the results of the Company's previous Phase 3 trial, will be acceptable to the FDA as support for an approval of Firdapse for the treatment of LEMS, (ii) whether the results of the abuse liability studies undertaken by Catalyst will be acceptable to the FDA as support for an approval of Firdapse, (iii) whether the NDA submitted for Firdapse will be accepted by the FDA, and the timing of any such acceptance, (iv) whether the receipt of breakthrough therapy designation for Firdapse will expedite the development and review of Firdapse by the FDA or the likelihood that the product will be found to be safe and effective, (v) whether, if an NDA for Firdapse is accepted for filing, such NDA will be given a priority review by the FDA, (vi) whether Firdapse will ever be approved for commercialization, (vii) whether Catalyst will be the first company to receive an approval for amifampridine (3,4-DAP), giving it 5-year marketing exclusivity for its product, and (viii) those other factors described in Catalyst's Annual Report on Form 10-K for the fiscal year 2017 and its other filings with the U.S. Securities and Exchange Commission (SEC), could adversely affect Catalyst. Copies of Catalyst's filings with the SEC are available from the SEC, may be found on Catalyst's website, or may be obtained upon request from Catalyst. Catalyst does not undertake any obligation to update the information contained herein, which speaks only as of this date.

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CATALYST PHARMACEUTICALS, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS (unaudited)

	For the Three Months Ended March 31,	
	2018	**2017**
Revenues	$ —	$ —
Operating costs and expenses:		
Research and development	3,259,042	2,813,929
General and administrative	2,674,398	1,865,942
Total operating costs and expenses	5,933,440	4,679,871
Loss from operations	(5,933,440)	(4,679,871)
Other income, net	233,548	109,977
Change in fair value of warrants liability	—	(397,235)
Loss before income taxes	(5,699,892)	(4,967,129)
Provision for income taxes	—	—
Net loss	$ (5,699,892)	$ (4,967,129)
Net loss per share – basic and diluted	$ (0.06)	$ (0.06)
Weighted average shares outstanding – basic and diluted	102,557,350	82,972,316

CATALYST PHARMACEUTICALS, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

	March 31, 2018 (unaudited)	December 31, 2017
ASSETS		
Current Assets:		
Cash and cash equivalents	$19,600,591	$57,496,702
Short-term investments	58,342,578	26,516,711
Prepaid expenses and other current assets	992,828	1,173,744
Total current assets	78,935,997	85,187,157
Property and equipment, net	183,370	191,385
Deposits	8,888	8,888
Total assets	$79,128,255	$85,387,430
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	$ 805,023	$ 1,945,575
Accrued expenses and other liabilities	1,926,371	2,320,587
Total current liabilities	2,731,394	4,266,162
Accrued expenses and other liabilities, non-current	150,395	157,456
Total liabilities	2,881,789	4,423,618
Total stockholders' equity	76,246,466	80,963,812
Total liabilities and stockholders' equity	$79,128,255	$85,387,430