

CATALYST PHARMACEUTICALS, INC.

FORM 8-K (Current report filing)

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Address	355 ALHAMBRA CIRCLE SUITE 1250 CORAL GABLES, FL 33134
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**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): August 9, 2017

CATALYST PHARMACEUTICALS, INC.

(Exact Name Of Registrant As Specified In Its Charter)

Delaware
(State or other jurisdiction
of incorporation)

001-33057
(Commission
File Number)

76-0837053
(I.R.S. Employer
Identification No.)

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

33134
(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 CFR 240.14d-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 August 9, 2017, the Company issued a press release announcing its results of operations for the three and six months ended June 30, 2017 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 August 9, 2017.

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: August 9, 2017



Catalyst Pharmaceuticals Announces Second Quarter 2017 Financial Results and Provides Corporate Update

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

CORAL GABLES, Fla., August 9, 2017 (GLOBE NEWSWIRE) — Catalyst Pharmaceuticals, Inc. (Catalyst) (Nasdaq:CPRX), a biopharmaceutical company focused on developing and commercializing innovative therapies for people with rare debilitating neuromuscular and neurological diseases, today reported financial results for the second quarter ended June 30, 2017 and provided a corporate update.

“We continue to make progress towards completion of enrollment in our confirmatory Phase 3 trial of Firdapse[®] in LEMS patients,” said Patrick J. McEnany, Chief Executive Officer of Catalyst. “We look forward to receiving top-line results from our Phase 3 trial, and assuming the trial is successful, to resubmitting an NDA for Firdapse[®] for the treatment of LEMS before the end of the year. We also remain committed to the development of Firdapse[®] for other indications, including congenital myasthenic syndromes and MuSK antibody positive myasthenia gravis. Additionally, we expect to recommence our efforts to develop a commercialization plan for Firdapse[®] before the end of the year so as to be in a position to launch the product in 2018 if we are successful in obtaining FDA approval to commercialize the product.”

Mr. McEnany continued: “We are also continuing our efforts to seek a partner for the development of CPP-115 and for our generic version of Sabril[®]. Although no agreements have been entered into to date and there can be no assurance, we are hopeful that we can bring these efforts to a successful conclusion in the second half of 2017.”

Q2 and Recent Highlights

- Joined the broad-market Russell 3000[®] Index, effective June 26
- Presented overview of CPP-115 program at the Antiepileptic Drug and Device Trials XIV Symposium
- Received a 2017 Beacon Award for contributions in the Life Sciences & Healthcare category
- Presentation by investigator of clinical data from the recently completed proof of concept study of Firdapse for the treatment of MuSK-MG at the 13th International Conference on Myasthenia Gravis and Related Disorders in May 2017
- Ended the second quarter with \$35.1 million in cash and investments and no debt

Upcoming Milestones

- Complete enrollment in LEMS (LMS-003) and CMS (CMS-001) clinical trials
- Expect top-line results from second Phase 3 trial for LEMS; and NDA submission for Firdapse[®] in second-half 2017

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- Define our regulatory path forward for the MuSK-MG pivotal, multi-center trial
 - Reinitiate pre-commercialization activities for a potential 2018 launch of Firdapse during second half 2017
 - Expect top-line results from CMS trial in the first half of 2018

Second Quarter 2017 Financial Results

For the quarter ended June 30, 2017, Catalyst reported a GAAP net loss of \$3,879,901, or \$0.05 per basic and diluted share, compared to a GAAP net loss of \$4,568,914, or \$0.06 per basic and diluted share, for the same period in 2016. Excluding the non-cash gain of \$210,331 attributable to the change in fair value of liability-classified warrants, Non-GAAP¹ net loss was \$4,090,232 or \$0.05 per basic and diluted share for the second quarter of 2017. In comparison, Non-GAAP¹ net loss for the second quarter of 2016 was \$4,721,697, or \$0.06 per basic and diluted share, which excludes non-cash gain of \$152,783 attributable to the change in fair value of liability-classified warrants.

For the six months ended June 30, 2017, Catalyst reported a GAAP net loss of \$8,847,030, or \$0.11 per basic and diluted share, as compared to a GAAP net loss of \$9,955,151, or \$0.12 per basic and diluted share, for the same period in 2016. Excluding non-cash expense of \$186,904 attributable to the change in fair value of liability-classified warrants, Non-GAAP¹ net loss was \$8,660,126 or \$0.10 per basic and diluted share for the first six months of 2017. In comparison, Non-GAAP¹ net loss for the first six months of 2016 was \$10,841,290, or \$0.13 per basic and diluted share, which excludes non-cash gain of \$886,139 attributable to the change in fair value of liability-classified warrants.

Research and development expenses for the second quarter of 2017 were \$2,451,751 compared to \$2,508,897 in the second quarter of 2016. For the six months ended June 30, 2017, research and development expenses were \$5,265,680 as compared to \$6,055,288 in the same period in 2016. Research and development expenses for the first six months of 2017 continued to be substantial as the Company continued its ongoing trials evaluating Firdapse[®] for the treatment of LEMS and CMS. The Company expects that costs related to research and development activities will continue to be substantial throughout the balance of 2017 and into 2018 as it continues its clinical studies and trials and works to resubmit an NDA for Firdapse[®].

General and administrative expenses for the second quarter of 2017 totaled \$1,729,520 as compared to \$2,305,555 in the second quarter of 2016. For the six months ended June 30, 2017, general and administrative expenses were \$3,595,462 as compared to \$4,996,700 in the same period in 2016. The decrease when compared to the same period in 2016 is primarily due to decreased employee costs due to a reduction in headcount, and a decrease in recruiting expenses and consulting costs for pre-commercialization activities, as part of our initiatives to conserve cash. The Company expects general and administrative expenses, excluding pre-commercialization expenses, to remain consistent for the balance of 2017. The Company also expects pre-commercialization expenses (which are reported in G&A) to increase in the second half of 2017 as the Company recommences its efforts to develop a commercialization plan for Firdapse[®].

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 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.

As a development-stage biopharmaceutical company, Catalyst had no revenues in either the second quarter of 2017 and 2016 or the first six months of 2017 and 2016.

At June 30, 2017, Catalyst had cash and cash equivalents and short-term investments of \$35.1 million and no debt. Catalyst believes that its existing capital resources will be sufficient to support its planned operations through at least the next 12 months.

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 August 9, 2017.

Conference Call

Catalyst management will host an investment-community conference call and webcast at 8:30 a.m. EDT on Thursday, August 10th, 2017 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 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, and possibly refractory Tourette's Disorder. 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 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, the timing of Catalyst's second trial evaluating Firdapse for the treatment of LEMS and whether the trial will be successful, whether Catalyst's

assumptions in its updated business plan will be accurate and the impact of unanticipated events or delays in projected activities on Catalyst's cash requirements and on Catalyst's ability to get to an accepted NDA submission for Firdapse without the need for additional funding, what clinical trials and studies will be required before Catalyst can resubmit an NDA for Firdapse for the treatment of CMS and whether any such required clinical trials and studies will be successful, whether any NDA for Firdapse resubmitted to the FDA will ever be accepted for filing, the timing of any such NDA filing or acceptance, whether, if an NDA for Firdapse is accepted for filing, such NDA will be given a priority review by the FDA, whether Catalyst can successfully design and complete a registration trial evaluating Firdapse for the treatment of MuSK-MG that is acceptable to the FDA, whether any such future trial evaluating Firdapse for the treatment of MuSK-MG will be successful, whether Catalyst can obtain the funding required to conduct such a trial, whether Firdapse will ever be approved for commercialization, whether Catalyst will be the first company to receive approval for amifampridine (3,4-DAP), giving it 5-year marketing exclusivity for its product, whether CPP-115 will be determined to be safe for humans, what additional testing will be required before CPP-115 is "Phase 2 ready", whether CPP-115 will be determined to be effective for the treatment of refractory infantile spasms or possibly Tourette's Disorder or for any other indications, whether Catalyst can successfully design and complete a bioequivalence study of its version of vigabatrin compared to Sabril that is acceptable to the FDA, whether any such bioequivalence study the design of which is acceptable to the FDA will be successful, whether any ANDA that Catalyst submits for a generic version of Sabril will be accepted for filing, whether any ANDA for Sabril accepted for filing by the FDA will be approved (and the timing of any such approval), whether any of Catalyst's product candidates will ever be approved for commercialization or successfully commercialized, and those other factors described in Catalyst's Annual Report on Form 10-K for the fiscal year 2016 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.

STATEMENTS OF OPERATIONS (unaudited)

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	2017	2016	2017	2016
Operating costs and expenses:				
Research and development	\$ 2,451,751	\$ 2,508,897	\$ 5,265,680	\$ 6,055,288
General and administrative	1,729,520	2,305,555	3,595,462	4,996,700
Total operating costs and expenses	4,181,271	4,814,452	8,861,142	11,051,988
Loss from operations	(4,181,271)	(4,814,452)	(8,861,142)	(11,051,988)
Other income, net	91,039	92,755	201,016	210,698
Change in fair value of warrants liability	210,331	152,783	(186,904)	886,139
Loss before income taxes	(3,879,901)	(4,568,914)	(8,847,030)	(9,955,151)
Provision for income taxes	—	—	—	—
Net loss	\$ (3,879,901)	\$ (4,568,914)	\$ (8,847,030)	\$ (9,955,151)
Net loss per share – basic and diluted	\$ (0.05)	\$ (0.06)	\$ (0.11)	\$ (0.12)
Weighted average shares outstanding – basic and diluted	83,905,827	82,870,649	83,441,650	82,865,366

CATALYST PHARMACEUTICALS, INC.

CONDENSED BALANCE SHEETS

	June 30, 2017 <u>(unaudited)</u>	December 31, 2016 <u></u>
ASSETS		
Current Assets:		
Cash and cash equivalents	\$ 8,583,727	\$13,893,064
Short-term investments	26,547,663	26,512,753
Prepaid expenses and other current assets	621,558	1,047,944
Total current assets	<u>35,752,948</u>	<u>41,453,761</u>
Property and equipment, net	218,289	244,204
Deposits	8,888	8,888
Total assets	<u>\$35,980,125</u>	<u>\$41,706,853</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	\$ 692,345	\$ 933,176
Accrued expenses and other liabilities	1,148,080	1,161,359
Total current liabilities	<u>1,840,425</u>	<u>2,094,535</u>
Accrued expenses and other liabilities, non-current	170,519	181,162
Warrants liability, at fair value	—	122,226
Total liabilities	<u>2,010,944</u>	<u>2,397,923</u>
Total stockholders' equity	<u>33,969,181</u>	<u>39,308,930</u>
Total liabilities and stockholders' equity	<u>\$35,980,125</u>	<u>\$41,706,853</u>