
**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 10, 2015

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 1500
Coral Gables, Florida
(Address of principal executive offices)

33134
(Zip Code)

Registrant's telephone number, including area code: (305) 529-2522

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))
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Item 8.01 Other Events

On August 10, 2015, the Company issued a press release announcing its results of operations for the three and six months ended June 30, 2015. 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 10, 2015.

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 10, 2015



Catalyst Pharmaceuticals Announces Second Quarter 2015 Financial Results and Provides Corporate Update

- Company to host quarterly conference call at 8:30am ET tomorrow

CORAL GABLES, Fla., Aug 10, 2015 (GLOBE NEWSWIRE) — **Catalyst Pharmaceuticals, Inc.** (Nasdaq:CPRX), a biopharmaceutical company focused on developing and commercializing innovative therapies for people with rare debilitating diseases, today reported financial results for the second quarter and six months ended June 30, 2015.

“This quarter we have been working diligently to advance regulatory and commercial affairs and are pleased with the initiation of our rolling NDA submission to the FDA for Firdapse® for the symptomatic treatment of Lambert-Eaton myasthenic syndrome (LEMS)” said Patrick J. McEnany, Catalyst’s Chief Executive Officer. “We expect to complete our submission during Q4, putting us on schedule for a potential approval by the middle of 2016. We are working on a pathway to include certain types of congenital myasthenic syndromes (CMS) in the initial label, in addition to LEMS. Additionally, we are on schedule with our key commercial strategic imperatives to support the successful launch of Firdapse®.”

Mr. McEnany added, “We recently reported top-line results in our proof-of-concept trial of vigabatrin in patients with treatment-refractory Tourette’s Disorder and are hoping to move forward using CPP-115 as a candidate for future trials.”

Q2 and Recent Highlights:

- Development and advancement of comprehensive commercialization and pre-launch plan
- Presented at the annual meeting of the American Academy of Neurology (AAN) in Philadelphia, PA
- Announced top-line results in proof-of-concept trial of Vigabatrin in patients with treatment-refractory Tourette’s Disorder
- Joined Russell 2000®, 3000® and Global Indexes
- Appointed Dr. Gary Ingenito as Chief Medical Officer
- Initiated rolling NDA submission for Firdapse® for the treatment of LEMS

Upcoming 2015 Milestones:

- Expected completion of NDA submission of Firdapse® for the treatment of LEMS during Q4
- Announcement of topline results from a Phase 1(b) multiple dose safety and tolerance study for CPP-115 in Q4
- Developing additional data to support use of Firdapse® in the treatment of certain types of CMS
- Exploration of additional indications for Firdapse® including a subset of Myasthenia Gravis (antibody positive MuSK)
- Hiring of a permanent chief commercial officer

Financial Results

For the quarter ended June 30, 2015, Catalyst reported a GAAP net loss of \$4,558,503, or 6 cents per basic and diluted share, compared to a GAAP net loss of \$3,198,020, or 5 cents per basic and diluted share, for the same period in 2014. Excluding non-cash gain of \$333,956 attributable to the change in fair value of liability-classified warrants, Non-GAAP¹ net loss was \$4,892,459 or 6 cents per basic and diluted share for the second quarter of 2015. In comparison, Non-GAAP¹ net loss for the second quarter of 2014 was \$2,974,429, or 5 cents per basic and diluted share, which excludes non-cash expense of \$223,591 attributable to the change in fair value of liability-classified warrants.

For the six months ended June 30, 2015, Catalyst reported a GAAP net loss of \$9,968,762, or 13 cents per basic and diluted share, compared to a GAAP net loss of \$7,009,139, or 12 cents per basic and diluted share, for the same period in 2014. Excluding non-cash expense of \$846,322 attributable to the change in fair value of liability-classified warrants, Non-GAAP¹ net loss was \$9,122,440 or 12 cents per basic and diluted share for the first six months of 2015. In comparison, Non-GAAP¹ net loss for the first six months of 2014 was \$6,450,034, or 11 cents per basic and diluted share, which excludes non-cash expense of \$559,105 attributable to the change in fair value of liability-classified warrants.

Research and development expenses for the second quarter of 2015 were \$2,577,508 compared to \$2,098,958 in the second quarter of 2014. For the six months ended June 30, 2015 research and development expenses were \$4,927,060 compared to \$4,847,641 in the same period in 2014. Research and development expenses increased when compared to the same period in 2014 as we increased activities related to our NDA filing for Firdapse[®] and ongoing studies and trials and decreased activities related to our completed Phase 3 trial for Firdapse[®]. We expect that our research and development spend for the rest of the year will increase as we prepare for and submit our NDA for Firdapse[®] and as we increase activities in other ongoing studies and trials.

General and administrative expenses for the second quarter of 2015 totaled \$2,319,822 compared to \$891,215 in the second quarter of 2014. For the six months ended June 30, 2015 general and administrative expenses were \$4,262,185 as compared to \$1,650,897 in the same period in 2014. The increase when compared to the same period in 2014 is primarily due to increases in pre-commercialization expenses and headcount, in preparation for the future commercialization of Firdapse[®].

As a development-stage biopharmaceutical company, Catalyst had no revenues in the second quarter of 2015 and 2014 or the first six months of 2015 and 2014.

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.

At June 30, 2015, Catalyst had cash and cash equivalents, certificates of deposit and short-term investments of \$67.4 million and no debt. This includes proceeds from our February 2015 offering in which we sold 11.5 million shares of our common stock, and raised net proceeds of approximately \$34.9 million. We believe that these resources give us sufficient runway through anticipated approval and subsequent product launch of Firdapse®, assuming approval in 2016.

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 10, 2015.

Conference Call

Catalyst management will host an investment-community conference call and webcast at 8:30 a.m. EDT on Tuesday, August 11, 2015 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 diseases, including Lambert-Eaton myasthenic syndrome (LEMS), congenital myasthenic syndromes (CMS), infantile spasms, and Tourette's Disorder. Catalyst's lead candidate, Firdapse® for the treatment of LEMS, recently completed testing in a global, multi-center, pivotal Phase 3 trial resulting in positive top-line data. Firdapse® for the treatment of LEMS has received Breakthrough Therapy Designation from the U.S. Food and Drug Administration (FDA) and orphan drug designations for LEMS and CMS. Firdapse® is the first and only European approved drug for symptomatic treatment in adults with LEMS.

Catalyst is also developing CPP-115 to treat infantile spasms, epilepsy and other neurological conditions associated with reduced GABAergic signaling, like post-traumatic stress disorder and 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.

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, what clinical trials and studies will be required before Catalyst can submit an NDA for Firdapse® for the treatment of CMS and whether any such required clinical trials and studies will be successful, whether an NDA for Firdapse® will ever be accepted for filing by the FDA, 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 will be the first company to receive approval for amifampridine (3,4-DAP), giving it 7-year marketing exclusivity for its product, whether CPP-115 will be determined to be safe for humans, whether CPP-115 will be determined to be effective for the treatment of infantile spasm, post-traumatic stress disorder, Tourette's Disorder or any other indications, 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 2014 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.

Investor Contact

Brian Korb
The Trout Group LLC
(646) 378-2923
bkorb@troutgroup.com

Media Contacts

David Schull
Matt Middleman, M.D.
Russo Partners
(212) 845-4271
(212) 845-4272
david.schull@russopartnersllc.com
matt.middleman@russopartnersllc.com

Company Contact

Patrick J. McEnany
Catalyst Pharmaceuticals
Chief Executive Officer
(305) 529-2522
pmcenany@catalystpharma.com

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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,	
	2015	2014	2015	2014
Operating costs and expenses:				
Research and development	\$ 2,577,508	\$ 2,098,958	\$ 4,927,060	\$ 4,847,641
General and administrative	2,319,822	891,215	4,262,185	1,650,897
Total operating costs and expenses	4,897,330	2,990,173	9,189,245	6,498,538
Loss from operations	(4,897,330)	(2,990,173)	(9,189,245)	(6,498,538)
Other income, net	4,871	15,744	66,805	48,504
Change in fair value of warrants liability	333,956	(223,591)	(846,322)	(559,105)
Loss before income taxes	(4,558,503)	(3,198,020)	(9,968,762)	(7,009,139)
Provision for income taxes	—	—	—	—
Net loss	<u>\$ (4,558,503)</u>	<u>\$ (3,198,020)</u>	<u>\$ (9,968,762)</u>	<u>\$ (7,009,139)</u>
Net loss per share – basic and diluted	<u>\$ (0.06)</u>	<u>\$ (0.05)</u>	<u>\$ (0.13)</u>	<u>\$ (0.12)</u>
Weighted average shares outstanding – basic and diluted	<u>82,037,560</u>	<u>66,167,556</u>	<u>79,054,960</u>	<u>60,186,297</u>

CATALYST PHARMACEUTICALS, INC.

CONDENSED BALANCE SHEETS

	June 30, 2015 (unaudited)	December 31, 2014
ASSETS		
Current Assets:		
Cash and cash equivalents	\$37,221,453	\$ 9,096,778
Certificates of deposit	3,716,399	3,715,383
Short-term investments	26,465,464	26,462,962
Prepaid expenses and other current assets	861,268	4,552,698
Total current assets	68,264,584	43,827,821
Property and equipment, net	63,294	71,377
Deposits	8,888	8,888
Total assets	<u>\$68,336,766</u>	<u>\$43,908,086</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	\$ 1,316,292	\$ 1,814,210
Accrued expenses and other liabilities	1,236,955	4,040,816
Total current liabilities	2,553,247	5,855,026
Accrued expenses and other liabilities, non-current	12,452	15,839
Warrants liability, at fair value	2,979,038	2,794,891
Total liabilities	5,544,737	8,665,756
Total stockholders' equity	62,792,029	35,242,330
Total liabilities and stockholders' equity	<u>\$68,336,766</u>	<u>\$43,908,086</u>