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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**  
Washington, D.C. 20549

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**FORM 8-K**

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**CURRENT REPORT PURSUANT TO SECTION 13 OR 15(d) OF  
THE SECURITIES EXCHANGE ACT OF 1934**

**Date of Report (Date of Earliest Event Reported): December 16, 2015**

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**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) 529-2522**

**Not Applicable**

Former Name or Former address, if changed since last report

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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 December 16, 2015, the Company issued a press release announcing top-line results from its Phase 1(b) double-blind, placebo controlled safety and tolerance study of CPP-115 in normal healthy volunteers. The results showed significant increases in brain levels of the surrogate marker for potential efficacy, gamma-aminobutyric acid (GABA). The main adverse effect of prolonged elevated brain GABA, somnolence, was also observed.

A copy of the Company's press release is attached as Exhibit 99.1 to this Form 8-K and is incorporated herein by reference.

**Item 9.01 Financial Statements and Exhibits.**

(d) Exhibits

99.1 Press release issued by the Company on December 16, 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: December 16, 2015



### **Catalyst Pharmaceuticals Announces Top-Line Results in Phase 1(b) Trial of CPP-115**

**CORAL GABLES, Fla., Dec 16, 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 announced top line results from its Phase 1(b) double-blind, placebo controlled safety and tolerance study of CPP-115 in normal healthy volunteers. The results showed significant increases in brain levels of the surrogate marker for potential efficacy, gamma-aminobutyric acid (GABA). The main adverse effect of prolonged elevated brain GABA, somnolence, was also observed.

While the primary objective of this study was to obtain safety and tolerance data for CPP-115 administered over 14 days, brain GABA levels were measured as a surrogate marker of potential efficacy, since CPP-115 is a second generation GABA aminotransferase inhibitor. Specifically, this study examined GABA levels in both the POC (Parietal-Occipital Cortex) a grey matter rich region thought to be associated with epilepsy, and which was previously studied for vigabatrin, and the SMA (Supplementary Motor Area), which is thought to be associated with Tourette's Disorder. The maximum brain GABA increases, in both brain regions, ranged from about 150% to over 200% of baseline levels, as measured by magnetic resonance spectroscopy (MRS).

Patrick J. McEnany, Catalyst's Chief Executive Officer stated "These data are promising, because they provide evidence that CPP-115 significantly raises brain GABA, a mechanism known to effectively treat epilepsy, infantile spasms, and potentially Tourette's disorder. CPP-115 was also found to be even more potent than anticipated, which may indicate that a lower dose of CPP-115 has the potential to effectively treat these diseases. A low drug dose may reduce or eliminate the risk of visual field defects, a side effect associated with vigabatrin."

Steven Miller, Ph.D., Catalyst's Chief Operating Officer and Chief Scientific Officer stated "We expect to receive the full results of this study early next year, including additional data from laboratory safety tests, pharmacokinetic modeling, and brain levels of CPP-115 as determined from MRS data of the patients in this study. Once we obtain the full results of this study, we intend to determine the steps required to make CPP-115 "Phase 2 ready," including a Phase 1 dose ranging study evaluating CPP-115 at lower doses."

#### **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, double-blinded randomized pivotal Phase 3 trial resulting in positive top-line data on both co-primary endpoints. 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. 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, 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, 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 infantile spasm, post-traumatic stress disorder, Tourette's Disorder or 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 files 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 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.*

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