
**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): June 24, 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 June 24, 2015, the Company issued a press release announcing top-line results from an open-label, proof of concept trial of CPP-109 (vigabatrin) to treat patients suffering from Tourette's Disorder that were refractory to all other previous treatments.

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 June 24, 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: June 24, 2015



Catalyst Pharmaceuticals Announces Encouraging Top-Line Results in Proof-of-Concept Trial of Vigabatrin in Patients with Treatment-Refractory Tourette's Disorder

CORAL GABLES, Fla., June 24, 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 in an open-label, proof-of-concept trial of CPP-109 (vigabatrin) used to treat patients suffering from Tourette's Disorder (TD) that were refractory to all other previous treatments. One of four patients demonstrated a very clear, clinically significant reduction in tics, and two others showed about a 25% reduction in tics, but without subjective clinical improvement.

Patrick J. McEnany, Catalyst's Chief Executive Officer stated "We see these data as promising despite the small number of subjects, single center, open-label design trial." Mr. McEnany went on to say, "These top-line results demonstrate an encouraging signal of activity in adult treatment-refractory patients with Tourette's Disorder. We believe that CPP-109's mechanism of action validates the potential for CPP-115 to be a candidate for the treatment of Tourette's Disorder. We are evaluating our options and will be meeting with the Co-Principal Investigators of the trial, as well as other key opinion leaders, to determine the next steps in development."

This proof-of-concept trial of CPP-109 (Vigabatrin) for Treatment-Refractory Tourette's Disorder was conducted by Barbara Coffey M.D., M.S., Co-Principal Investigator and Chief of the Tics and Tourette's Clinical and Research Program at the Icahn School of Medicine at Mount Sinai in New York, in collaboration with Dr. Jonathan D. Brodie at the NYU Langone Medical Center, the Co-Principal Investigator and lead inventor of this use of GABA-AT inhibitors. The trial was designed to obtain preliminary data regarding clinical effect, dosage, and tolerability, of vigabatrin in subjects at least 18 years of age with a DSM-IV-TR diagnosis of Tourette's Disorder, who exhibited unsatisfactory response to all prior treatments.

Dr. Coffey said "The clinical signal from this small open label trial, despite its limitations, is encouraging and warrants further investigation. The only formally approved medications to treat Tourette's Disorder are first generation antipsychotic drugs which block D2 dopamine receptors; however, they are infrequently used in clinical practice because of their severe and unacceptable side effects." Dr. Coffey continued, "Of particular note is that these patients were refractory to all previous treatments; one of the subjects has elected to continue treatment, and has remained on vigabatrin for two years. Drugs in the GABA-aminotransferase inhibitor class may offer new hope to treatment-refractory TD patients who have no other acceptable options." Dr. Brodie added "The positive long term response generated by even a single refractory patient opens the possibility that appropriately monitored GABA-AT inhibitors may offer an additional clinical alternative in the care of younger patients who may require longer term treatment".

The 8-week clinical trial was designed as an open label trial to evaluate the potential effect of GABA aminotransferase inhibition as a mechanism for reducing tics in patients with treatment-refractory Tourette's Disorder. Vigabatrin was used as a "research surrogate" to demonstrate the utility of GABA-aminotransferase (GABA-AT) blockade, with the expectation that upon successfully demonstrating the utility of this mechanism, further development activities would focus on the potentially safer, more potent GABA-AT inhibitor, CPP-115.

During the trial, each subject's Yale Global Tic Severity Score (YGTSS), Clinical Global impression for Tics (CGI-Tics: the doctor's assessment of motor and vocal tic symptom severity), and Global Assessment of Functioning score (GAF: an assessment of psychological, social, and occupational impairment) were collected at baseline (prior to treatment) and at various points during treatment. There was a statistically significant change between baseline and week six of treatment (the last point at which subjects were on the maximum dose) for all the tic assessments, and a clinically significant change for all of the assessments in one of the four subjects. This subject was featured as a treatment success on [Mount Sinai Hospital's Patient Stories for the Tics and Tourette's Program web page](#). Two other subjects also showed a measurable change in tic assessments, but without subjective improvement. Visual field testing was conducted before and after treatment, and no significant alterations to vision were detected. One of the subjects has remained on vigabatrin for two years, and periodic visual field testing has shown no alteration in the subject's field of vision.

In recent years, GABA-ergic drugs have become an active and promising area of research to identify potential Tourette's Disorder treatments. Recent research at the University of Nottingham in the United Kingdom suggests that increased GABA in the supplementary motor area of the brain down-regulates tics associated with Tourette's Disorder. GABA-AT inhibitors, like vigabatrin and its potentially safer, more potent analog, CPP-115, would increase GABA, effectively increasing the gain of this down-regulating pathway.

About Tourette's Disorder

Tourette's Disorder (TD) occurs in all ethnic groups; males are affected three to four times more often than females. The Centers for Disease Control and Prevention (CDC) reported in 2009 TD prevalence estimates from a national, telephone-based survey in which they asked parents if their children had received a diagnosis of the disorder. The trial found that three of every 1,000 children have TD, but it is thought that this underestimates the true occurrence of the disorder. The prevalence of TD in adults is expected to be significantly less than in children as tic symptoms generally abate in later adolescence or early adulthood.

Tourette's Disorder (TD) is a neurodevelopmental disorder characterized by multiple tics, which are repetitive, non-rhythmic involuntary movements and vocalizations that persist for more than one year. Onset occurs in most children by about age five to six years. Some of the more common simple motor tics include eye blinking, facial grimacing, shoulder shrugging, and head or neck jerking. Common simple vocal tics, include grunting, throat clearing, coughing and squeaking. Among the most dramatic and disabling complex tics are those that result in self-harm, such as punching or poking oneself, or complex vocal tics such as coprolalia (uttering swear words) or echolalia (repeating the words or phrases of others). Many patients with TD experience additional neurobehavioral problems including inattention, hyperactivity and impulsivity, and obsessive-compulsive symptoms such as intrusive thoughts/worries and repetitive rituals.

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 designation for 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 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.

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