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): December 18, 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 December 18, 2018, the Company issued a press release announcing that it has signed a Definitive Agreement with Endo International plc's subsidiary, Endo Ventures Limited, for the further development and commercialization of generic Sabril® (vigabatrin) tablets. 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 December 18, 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: December 18, 2018

Catalyst Pharmaceuticals Announces Definitive Agreement with Endo for Vigabatrin Tablets

CORAL GABLES, Fla., December 18, 2018 (GLOBE NEWSWIRE) — Catalyst Pharmaceuticals, Inc. (Catalyst) (Nasdaq: CPRX), a biopharmaceutical company focused on developing and commercializing innovative therapies for people with rare debilitating, chronic neuromuscular and neurological diseases, today announced that it has signed a Definitive Agreement with Endo International plc's (NASDAQ: ENDP) subsidiary, Endo Ventures Limited, for the further development and commercialization of generic Sabril® (vigabatrin) tablets through Endo's U.S. Generic Pharmaceuticals segment, doing business as Par Pharmaceutical. Pursuant to the agreement, Catalyst will receive an up-front payment, milestone payments based on achievement of regulatory approvals, and a sharing of defined net profits upon commercialization.

"We are very happy to work with Endo, to bring generic Sabril® tablets to market. Endo is an established leader in the generic vigabatrin marketplace," said Patrick J. McEnany, Chairman and Chief Executive Officer of Catalyst Pharmaceuticals. "Our search for an appropriate partner for this product was long but rewarding with this result. We look forward to bringing to market this important medication to improve the lives of patients."

"Generic vigabatrin tablets will complement our current powder vigabatrin offering and will expand the number of patients that can benefit from having access to a high-quality, generic vigabatrin option," said Brandon Rockwell, Senior Vice President, Business Development and Strategy of Endo.

Vigabatrin comes in two dosage forms – a powder sachet and a tablet. Par Pharmaceutical brought the first generic version of the powder sachet to market but at this time there is no approved generic version of the tablets.

About Catalyst Pharmaceutical

Catalyst Pharmaceutical is a biopharmaceutical company focused on developing and commercializing innovative therapies for people with rare debilitating, chronic neuromuscular and neurological diseases, including LEMS, congenital myasthenic syndromes (CMS), MuSK antibody positive myasthenia gravis (MuSK-MG), and spinal muscular atrophy (SMA) type 3. Catalyst's new drug application for Firdapse® (amifampridine) 10 mg tablets for the treatment of adults with Lambert-Eaton Myasthenic Syndrome (LEMS) was recently approved by the U.S. Food & Drug Administration ("FDA"), and Firdapse® is expected to be commercially available in the United States early in the first quarter of 2019. Prior to its approval, Firdapse for LEMS had received breakthrough therapy designation and orphan drug designation from the FDA.

Firdapse® is currently being evaluated in clinical trials for the treatment of CMS, MuSK-MG and SMA type 3 and has received Orphan Drug Designation from the FDA for CMS and myasthenia gravis. Firdapse (amifampridine) 10 mg tablets is the first and only approved drug in Europe for the symptomatic treatment in adults with LEMS.

About Endo International plc

Endo International plc (NASDAQ: ENDP) is a highly focused generics and specialty branded pharmaceutical company delivering quality medicines to patients in need through excellence in development, manufacturing and commercialization. Endo has global headquarters in Dublin, Ireland, and U.S. headquarters in Malvern, PA. Learn more at www.endo.com.

About Par Pharmaceutical

Par Pharmaceutical, headquartered in Chestnut Ridge, NY, develops, manufactures and markets safe, innovative and cost-effective generic pharmaceutical products that help improve patient quality of life. Par, among the top leaders in the U.S. generics industry, possesses a portfolio that includes sterile injectables, alternative dosage forms and many other differentiated products. Par is advancing a research and development (R&D) pipeline of approximately 200 potential new products. Par is an operating company of Endo International plc. Learn more at www.parpharm.com.

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 milestone payments that are to be paid under Catalyst's agreement with Endo will ever be earned and paid; (ii) whether an ANDA for generic vigabatrin tablets will ever be approved by the FDA; (iii) whether Endo, even if vigabatrin tablets are approved for commercialization, will be successful in marketing the product, (iv) whether Catalyst will earn royalties on sales of generic vigabatrin tablets; (v) whether Catalyst can successfully market Firdapse and become profitable; (vi) whether Firdapse will ever be approved for the treatment of CMS, MuSK-MG, SMA type 3, or any other disease; and (vii) 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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