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): April 8, 2020

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

Securities registered pursuant to Section 12(b) of the Act:

Title of Each Class	Name of Exchange on Which Registered	Ticker Symbol
Common Stock, par value $0.001 per share	**NASDAQ Capital Market**	**CPRX**

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 April 8, 2020, the Company issued a press release providing an update on the impact of the COVID-19 pandemic on its business activities. 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 April 8, 2020.

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: April 8, 2020

Exhibit 99.1

Catalyst Pharmaceuticals Provides Update on Impact of COVID-19 Pandemic on its Business Activities

- ***Safety of personnel, patients and healthcare providers remains our top priority***
- ***Drug supply remains well-stocked with patients having access to uninterrupted supply of Firdapse® (amifampridine) 10mg***
- ***Catalyst partners with First Responders Children's Foundation to support COVID-19 EMERGENCY RESPONSE FUND***

CORAL GABLES, Fla., April 08, 2020 (GLOBE NEWSWIRE) — Catalyst Pharmaceuticals, Inc. (Catalyst) (Nasdaq: CPRX), a commercial-stage biopharmaceutical company focused on developing and commercializing innovative therapies for people with rare debilitating, chronic neuromuscular and neurological diseases, today provided an update on certain impacts of COVID-19 on its business operations.

"We are committed to protecting the safety and well-being of our personnel, the entire LEMS community, healthcare providers, patients in clinical trials, and clinical trial site employees, and this will remain our priority throughout these challenging times," said Patrick J. McEnany, Chairman and Chief Executive Officer of Catalyst Pharmaceuticals. Mr. McEnany continued, "Additionally, well before the COVID-19 pandemic, we had worked diligently to establish our supply chain to ensure that LEMS patients would have access to Firdapse® without interruption, no matter the circumstances."

Protecting Catalyst Team and Communities

On March 16th, Catalyst implemented a number of safety related initiatives among its employees, including a travel ban and a work from home policy for all employees. This included Catalyst's customer-facing employees, who are working remotely and utilizing telephone and web-based technologies to provide support to patients and their healthcare providers.

Catalyst is following the guidance from the U.S. Centers for Disease Control and Prevention (CDC) and will continue to assess when it is appropriate for our team to return to normal work practices.

Corporate Partnership with First Responders Children's Foundation to Support COVID-19 Emergency Response Fund

Catalyst announced today a corporate partnership with First Responders Children's Foundation to support the COVID-19 Emergency Response Fund. The Foundation has established this fund to provide emergency grants to first responder families enduring financial hardship due to the COVID-19 pandemic. For the past 20 years, First Responders Children's Foundation has been providing college scholarships to children of first responders who have lost a parent in the line of duty.

“First Responders Children’s Foundation would like to thank Catalyst for supporting the Foundation and for the company’s contribution to the COVID-19 Emergency Response Fund,” said Jillian Crane, President of First Responders Children’s Foundation. “The support of Catalyst has allowed the Foundation to provide much needed financial assistance to first responders on the front lines during these challenging times.”

Firdapse Manufacturing and Supply

Our Firdapse supply chain remains robust and ready for any contingencies that arise due to the COVID-19 outbreak, and thus far we have observed no disruptions in the production of Firdapse. We reiterate that we are committed to providing patients with the ability to obtain an uninterrupted supply of Firdapse. As we reported on our fourth quarter and year end conference call a few weeks ago, we have an adequate supply of Firdapse to address patients’ needs through December and are pleased to report that we have just completed a manufacturing campaign that will provide an additional six months of inventory beyond December. Like Catalyst, our U.S. manufacturing partners have implemented contingency plans to remain in operation, and we are confident in their ability to continue to produce domestically our active ingredient and finished Firdapse product. We are committed to meeting our patients needs for Firdapse and believe that our supply chain will remain solid and uninterrupted through the current COVID-19 outbreak and beyond.

Financial Outlook

On our March 16th fourth quarter and year end conference call, we reported full-year 2019 net revenues of $102 million and reiterated our net revenue guidance in the range of $135 to $155 million for full-year 2020. We continue to assess the potential impact that COVID-19 could have on our revenue and expect to provide an update during our first quarter 2020 results call next month. Thus far the impact that we have seen has been minimal, but we will continue to evaluate our yearly guidance based on this dynamic environment.

Catalyst ended 2019 in a strong financial position. The Company reported that it had $94.5 million of cash and investments as of December 31, 2019 and that it had increased its cash and investments by approximately $36 million during full year 2019. Also, as of today, Catalyst continues to have no funded debt.

Clinical Development Timelines

At this time, we continue to believe that we will report top-line results from our Phase 3 trial for MuSK-MG in the current quarter, but the worldwide travel restrictions and social distancing requirements of the COVID-19 pandemic have put a strain on clinical trial staff and their availability for study close-out activities. Catalyst is continuing to monitor sites through remote means in accordance with guidance recently provided by the FDA and is working with sites remotely on data entry and data checking, to the extent that sites will allow and study coordinators are able. Catalyst is fortunate that enrollment had been completed, and the trial was nearly finished, before the advent of the COVID-19 health emergency. However, many activities at trial sites need to occur before our study can be unblinded. Assuming this trial is successful, we hope to submit an sNDA for Firdapse for MuSK-MG by the end of this year. We expect that we will be able to provide more current information on our clinical programs during our first quarter earnings call that is scheduled for next month.

In addition, we had planned to report top-line results from our SMA Type 3 proof-of-concept trial in the current quarter. However, the Serbian government has recently imposed temporary new regulations for clinical trials requiring all clinical activities not needed for patient safety to be halted. Although fully recruited,

screened, and ready to start, our SMA trial subjects in Serbia were not yet initiated when the pandemic began, and, due to this recent decision by the Serbian government, they are not permitted to start. In light of these regulations, we now know that it will not be possible for us to report top-line results from this trial before the end of this quarter.

About Catalyst Pharmaceuticals

Catalyst Pharmaceuticals is a commercial-stage biopharmaceutical company focused on developing and commercializing innovative therapies for people with rare debilitating, chronic neuromuscular and neurological diseases, including Lambert-Eaton myasthenic syndrome (LEMS), anti-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 LEMS was approved in November 2018 by the U.S. Food & Drug Administration ("FDA"), and Firdapse is now commercially available in the United States. 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 MuSK-MG and SMA Type 3 and has received Orphan Drug Designation from the FDA for myasthenia gravis.

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) the impact of the effects of the COVID-19 pandemic on Catalyst's 2020 net product revenues and on the timeline for reporting the top-line results from Catalyst's MuSK-MG trial and SMA Type 3 proof-of-concept study, and (ii) those factors described in Catalyst's Annual Report on Form 10-K for the fiscal year 2019 and Catalyst's 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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