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): January 6, 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 January 6, 2020, the Company issued a press release providing a corporate update including preliminary net product revenue for 2019, the status of the Company's clinical development programs and other corporate matters. A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

99.1 Press release issued by the Company on January 6, 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: January 6, 2020

Exhibit 99.1

Catalyst Pharmaceuticals Pre-Announces Estimated Firdapse® Revenues and Provides Updates on Advancement of Clinical Development Programs

- Firdapse 2019 Net Product Revenues Expected to be Approximately $102 Million

- Anticipates Full Year 2020 Firdapse Net Product Revenues to be in the Range of $135 million to $155 million

- MuSK-MG Clinical Trial Has Met Enrollment Goals and is on Schedule to Report Top-Line Results in First Half of 2020

- Company is Accelerating Business Development Activities

CORAL GABLES, Fla., January 06, 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 a corporate update including preliminary net revenue for 2019, the status of Catalyst's clinical development programs and other corporate matters.

"Catalyst has completed its first year as a commercial-stage company following the successful U.S. launch of Firdapse® (amifampridine) for the treatment of adult LEMS patients last January," said Patrick J. McEnany, Chairman and Chief Executive Officer of Catalyst Pharmaceuticals. "In reviewing the launch metrics that we established, we are pleased that Catalyst has exceeded all expectations for product revenues and the number of patients who are currently being treated with Firdapse, including the many individuals who for the first time have received a medicine to treat Lambert-Eaton myasthenic syndrome (LEMS). In 2020 we will roll out additional programs to assist LEMS patients and their healthcare providers. Furthermore, we are on track for completing the MuSK-MG trial and reporting top-line data in the first half of this year as we focus on expanding the possible use of Firdapse as a treatment for other indications, while at the same time we aim to broaden our entire product pipeline."

Corporate Highlights

Preliminary Unaudited 2019 Financial Results

- Catalyst expects to report Firdapse® net product revenues for the treatment of LEMS of approximately $30 million for the fourth quarter of 2019 and Firdapse net product revenues of approximately $102 million for the year 2019.

- Catalyst expects to report year-end cash and investments of approximately $95 million and no funded debt.
- No near-term need to raise cash for operations through an equity offering.

The above information is based on preliminary unaudited information and management estimates for the full year 2019, and is subject to the completion of Catalyst's financial closing procedures. Catalyst expects to report its 2019 results of operations on or before March 16, 2020.

2020 Financial Guidance

- Catalyst anticipates full year 2020 Firdapse net product revenues for treating adult LEMS patients to be in the range of $135 to $155 million.
- Catalyst anticipates GAAP R&D and SG&A expense for the full year 2020 to be approximately $65 million, which includes approximately $4 million in non-cash compensation.

Advancing Neuromuscular Portfolio in 2020

- Anti-MuSK antibody positive myasthenia gravis (MuSK-MG)
    - 750 Myasthenia Gravis patients were screened to identify the 60 plus MuSK-MG patients who are participating in the trial. Note that only about 5-8% of the estimated 60,000 myasthenia gravis patients are MuSK antibody positive.
    - Enrolled more than 60 MuSK antibody positive patients in 2019, and anticipate enrolling a few more patients in the next few weeks.
        - Enrollment beyond 60 patients is for ethical reasons due to qualified MuSK-MG diagnosed patients already in the queue for enrollment that have a strong desire to participate in the trial.
    - Remain on track to report top line results in the first half of 2020.
    - Assuming positive data we would expect to file a supplemental new drug application (sNDA) with the FDA about year end.
- Congenital Myasthenic Syndromes (CMS)
    - Extensive briefing package submitted to FDA for review including our results from first and only double-blind, placebo-controlled study of amifampridine in genetically confirmed CMS subjects.
    - FDA has advised us that the results of the study do not support any types of CMS and amifampridine does not appear to have a clinically meaningful benefit in the CMS patient population. They further stated that controlled clinical data demonstrating efficacy would need to be provided to support review of any indication for CMS.

- Catalyst will continue to provide Firdapse to CMS patients who are already enrolled in the CMS expanded access program and wish to remain on therapy.

- Spinal Muscular Atrophy Type 3 (SMA)
  - SMA-001 study (n=12) is ongoing, with five subjects having already completed the study.
  - Additional site has been opened for the study and on-target to report top-line data in the first half of 2020.
- Long-acting formulation of amifampridine
  - Primary formulation development contractor retained, and formulation development is ongoing.
  - Gastro-intestinal tract drug absorption characterization in human beings is expected to be completed in 2020.
  - Initial formulation candidates are expected to be completed, and their drug release and absorption properties are expected to be determined in 2020.
- Additional neuromuscular conditions to be studied in 2020
  - Kennedy's disease.
  - Hereditary neuropathy with liability to pressure palsies (HNPP).

Commercial status

- Nearly completed commercial expansion that:
  - Almost doubles the field sales team,
  - Adds a newly established partnership with a rare-disease experienced inside sales agency to generate interest among a much larger group of over 9,000 potential prescribers and institution providers targets, and
  - Increases digital non-personal promotional activities to supplement awareness generation created by the field sales and inside sales teams.
- Added experienced digital and social media focused marketer to enhance all Catalyst on-line communication with LEMS patient community.
- Catalyst Pathways patient/caregiver satisfaction levels remain high at 4.8 to 5.0 stars (n=290 respondents), resulting in significantly fewer transitions to competitive therapies in November and December.

Portfolio Expansion through Business Development

- Board of Directors' direction to develop a formal process for evaluating additional rare disease opportunities
    - Ideally acquisitions or in licensing opportunities in neuromuscular or neurology therapeutic areas.
- Currently interviewing candidates for the executive level business development position who will oversee this program and bring further focus and formality to these efforts.
- Strong balance sheet and expected availability of conventional loans would support a range of various opportunities.

Litigation Update on Challenge to FDA Approval of Ruzurgi®

- Catalyst filed its Motion for Summary Judgement on December 18, 2019; Defendants' response is due on January 17, 2020 and our Reply is due by February 7, 2020.
- If the briefing schedule is not delayed, we would expect a decision mid-year 2020.

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 and CMS. Firdapse (amifampridine) 10 mg tablets is the first and only approved drug in Europe for the symptomatic treatment in adults with LEMS.

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 Catalyst's forecast of expected net revenues for 2019 and 2020, and its forecast of year end 2019 cash and investment, will prove accurate, (ii) whether Catalyst's forecast of 2020 SG&A and R&D expenses will prove accurate, (iii) whether Catalyst will report top line results from its MuSK-MG clinical trial and its SMA Type 3 proof of concept study during the first half of 2020, and whether those trials will be successful, (iv) whether Catalyst will ever be approved to commercialize Firdapse for the treatment of MuSK-MG and SMA Type 3, (v) whether Catalyst can develop and obtain the right to commercialize a long acting formulation of Firdapse, (vi) whether Catalyst can successfully increase its sales of Firdapse through the expansion of its commercial team, (vii) whether Catalyst can successfully source future acquisitions or in licensing opportunities and obtain non-dilutive financing for such opportunities,

(viii) whether Catalyst will be successful in its lawsuit to overturn the FDA's approval of Ruzurgi; (ix) whether any proof-of-concept pilot studies that Catalyst undertakes evaluating Firdapse for the treatment of additional neuromuscular diseases will be successful, and (x) those factors described in Catalyst's Annual Report on Form 10-K for the fiscal year 2018 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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