

**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): October 19, 2020

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) 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 CFR 240.14d-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 October 19, 2020, the Company issued a press release announcing the filing of a lawsuit in the U.S. District Court for New Jersey against Jacobus Pharmaceuticals, Inc. (“Jacobus”) and a lawsuit in the U.S. District Court for the Western District of Pennsylvania against PantherRx Rare LLC (“PantherRx”) for infringement of U.S. Patent No. 10,793,893 (the “893 patent”). The 893 patent is exclusively licensed to the Company and covers certain methods for treating disease using amifampridine drug products, including the Company’s Firdapse®, in patients who are slow metabolizers of amifampridine.

The lawsuit arises from Jacobus’s and PantherRx’s sales and marketing of Ruzurgi® (amifampridine, 10mg). The lawsuit alleges that the Ruzurgi® product infringes the 893 patent when administered in accordance with its product labeling. The lawsuit seeks damages and injunctive relief to prevent further marketing of Ruzurgi® in violation of the Company’s patent rights.

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 October 19, 2020.](#)

104 Cover Page Interactive Data File (embedded within the Inline XBRL document)

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: October 19, 2020



Catalyst Pharmaceuticals Announces Filing of Patent Infringement Actions Against Jacobus Pharmaceuticals and PantherRx

CORAL GABLES, Fla., October 19, 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 announced that it has filed a lawsuit in the U.S. District Court for New Jersey against Jacobus Pharmaceuticals, Inc. (Jacobus), and a lawsuit in the U.S. District Court for the Western District of Pennsylvania against PantherRx Rare LLC (PantherRx) for infringement of U.S. Patent No. 10,793,893 (the '893 patent). The '893 patent is exclusively licensed to Catalyst Pharmaceuticals and covers certain methods for treating disease using amifampridine drug products, including Catalyst's Firdapse® product, in patients who are slow metabolizers of amifampridine.

The lawsuit arises from Jacobus' and PantherRx's sales and marketing of Ruzurgi® (amifampridine, 10 mg). The lawsuit alleges that the Ruzurgi® product infringes the '893 patent when administered in accordance with its product labeling. The lawsuit seeks damages and injunctive relief to prevent further marketing of Ruzurgi® in violation of Catalyst's patent rights.

"Catalyst has invested significant resources in neuromuscular drug discovery and in building an intellectual property portfolio that aids in the discovery and development of drugs for the treatment of rare neurodegenerative diseases that are without a safe and effective FDA approved therapy," said Patrick J. McEnany, Chairman and CEO of Catalyst. "We intend to diligently and vigorously protect our patent rights for the benefit of our company and our stockholders and prevent infringing use by others. Catalyst remains confident in its patent portfolio, and has filed several additional patent applications claiming priority from the '893 patent to enhance the protection of the Firdapse® patent estate."

About Firdapse®

Firdapse® (amifampridine) 10 mg tablets is an oral, nonspecific, voltage-dependent, potassium (K⁺) channel blocker that causes depolarization of the presynaptic membrane and slows or inhibits repolarization. This action results in the opening of slow voltage-dependent calcium (Ca²⁺) channels, allowing for a subsequent influx of Ca²⁺. In turn, it induces the exocytosis of synaptic vesicles containing Acetylcholine (ACh) to release more ACh into the synaptic cleft, enhancing neuromuscular transmission, and providing for improved muscle function.

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 commercially available in the United States. Further, Canada's national healthcare regulatory agency, Health Canada, recently approved the use of Firdapse® (amifampridine) for the treatment of patients in Canada with LEMS.

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 scope of protection from competition provided by the patent, (ii) whether Catalyst's lawsuits will be successful, and (iii) those factors described in Catalyst's Annual Report on Form 10-K for fiscal year 2019 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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