

**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): August 11, 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
<b>Common Stock, par value \$0.001 per share</b>	<b>NASDAQ Capital Market</b>	<b>CPRX</b>

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.

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**Item 8.01 Other Events**

On August 11, 2020, the Company issued a press release announcing that the United States Patent and Trademark Office (USPTO) has issued a Notice of Allowance for U.S. Patent Application Serial Number 14/128,672. The allowed application, “Methods of Administering 3,4-Diaminopyridine”, claims a method of treating a human patient diagnosed with a 3,4-DAP sensitive disease by administering 3,4-DAP (or salts thereof) to slow acetylating patients having certain mutations in each allele of the NAT2 gene.

A Notice of Allowance is issued after the USPTO determines that the prosecution on the merits of a patent has been completed. The patent can then be granted from an application upon payment of the patent issue fee. The Company expects the patent to issue in the next few months. Once issued, the patent would be expected to expire no earlier than June 29, 2032. The expiration of this patent could also be extended based on delays in patent prosecution, if any. This extension, if any, will be calculated after the patent has been issued. The Notice of Allowance and the allowed claims for this application are posted on the USPTO public PAIR website.

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 August 11, 2020.](#)

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





**Catalyst Pharmaceuticals Announces Notice of Allowance of a U.S. Patent Application for “Methods of Administering 3,4-Diaminopyridine”**

*-The allowed claims are directed to methods of treating patients with a 3,4-DAP sensitive disease comprising administering 3,4-DAP or a salt thereof to slow acetylating patients having certain mutations in each allele of the NAT2 gene*

**CORAL GABLES, Fla., August 11, 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 the United States Patent and Trademark Office (USPTO) has issued a Notice of Allowance for U.S. Patent Application Serial Number 14/128,672. The allowed application, “Methods of Administering 3,4-Diaminopyridine”, claims a method of treating a human patient diagnosed with a 3,4-DAP sensitive disease by administering 3,4-DAP (or salts thereof) to slow acetylating patients having certain mutations in each allele of the NAT2 gene.

A Notice of Allowance is issued after the USPTO determines that the prosecution on the merits of a patent has been completed. The patent can then be granted from an application upon payment of the patent issue fee. Catalyst expects the patent to issue in the next few months. Once issued, the patent would be expected to expire no earlier than June 29, 2032. The expiration of this patent could also be extended based on delays in patent prosecution, if any. This extension, if any, will be calculated after the patent has been issued. The Notice of Allowance and the allowed claims for this application are posted on the USPTO public PAIR website.

“The receipt of this Notice of Allowance from the USPTO represents an important milestone in expanding our Firdapse® intellectual property portfolio and adds to Catalyst’s options for further developing the Firdapse® franchise,” said Dr. Steven Miller, Chief Operating Officer and Chief Scientific Officer. Dr. Miller continued, “Notably, we believe that the comprehensive nature of the allowed claims in the resulting patent will provide Catalyst with additional protection through at least June of 2032. This will permit us to continue, and possibly expand, our research efforts for other indications, as well as improved formulations for Firdapse®.”

Upon issuance of this patent, Catalyst will seek to list this patent in the FDA’s “Orange Book” (the FDA’s list of all approved drugs in the United States). When a patent is listed in the FDA’s Orange Book for an approved drug, no generic equivalent of the drug may be approved by the FDA unless the generic drug applicant can prove that they do not infringe the listed patent or until the applicant successfully challenges the validity of the listed patent.

## 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) when the patent will officially be issued, (ii) when the patent, once officially issued, will expire, (iii) the scope of protection from competition provided by the patent, and (iv) 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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