
**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): July 31, 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:

<u>Title of Each Class</u>	<u>Name of Exchange on Which Registered</u>	<u>Ticker Symbol</u>
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

Change of meeting format to a virtual Annual Meeting.

On August 3, 2020, the Company issued a press release announcing that, due to the continuing coronavirus (COVID-19) pandemic and out of concern for the health and safety of its stockholders and employees, the format for the Company's 2020 Annual Meeting of Stockholders (the "Annual Meeting"), which will be held on **Thursday, August 20, 2020 at 9:00 AM eastern time**, has been changed to a virtual-only meeting format. There will be no in-person meeting.

Stockholders will be able to attend the Annual Meeting and submit questions and vote their shares during the Annual Meeting, from any location that has internet connectivity. Only stockholders of record at the close of business on June 22, 2020 ("Record Date") will be entitled to attend the virtual Annual Meeting. Any stockholder wishing to attend the virtual Annual Meeting should register for the meeting by August 19, 2020. To register for the Annual Meeting, stockholders should follow these instructions as applicable to the nature of their ownership of the Company's common stock:

- *Registered Stockholders.* If your shares are registered in your name with Continental Stock Transfer & Trust Company ("Continental"), and you wish to attend the online-only virtual Annual Meeting, go to www.cstproxy.com/catalystpharma/2020, enter the control number you received on your proxy card (printed in the box and marked with an arrow) and click on the "*Click Here to Preregister for the Online Meeting*" link at the top of the page. Just prior to the start of the meeting you will need to log back into the meeting site using your control number. Pre-registration is recommended but is not required to attend.
- *Street Name Stockholders.* Street name stockholders who wish to attend the online-only virtual Annual Meeting must obtain a legal proxy by contacting their account representative at the bank, broker, or other nominee that holds their shares and email a copy (a legible photograph is sufficient) of their legal proxy to proxy@continentalstock.com. Street name stockholders who email a valid legal proxy will be issued a meeting control number that will allow them to register to attend and participate in the online-only Annual Meeting. After contacting Continental, a street name stockholder will receive an e-mail prior to the meeting with a link and instructions for entering the virtual Annual Meeting. Street name stockholders should contact Continental at least five (5) business dates prior to the Annual Meeting date.

Stockholders participating in the virtual Annual Meeting will be in a listen-only mode and will not be able to speak during the webcast. However, in order to maintain the interactive nature of the virtual meeting, virtual attendees are able to: (i) vote using the online meeting website, and (ii) submit questions or comments to Catalyst's officers during the meeting via e-mail or the virtual meeting webcast. Starting Monday, August 17, 2020, stockholders may submit questions or comments before or during the meeting through the virtual meeting portal by typing in the "*Submit a Question*" box.

Stockholders will also have the option to call in to the virtual Annual Meeting by telephone and listen (in listen-only mode) by calling:

Within the U.S. and Canada	1-888-965-8995 (toll free)
Outside the U.S. and Canada	1-415-655-0243 (standard rates apply)
Passcode for telephone access:	09485747#

On August 3, 2020, Catalyst filed a Supplement to its proxy statement, dated July 6, 2020, relating to the matters to be considered at the Annual Meeting.

A copy of the Company's press release is attached as Exhibit 99.1 to this Form 8-K and is incorporated herein by reference.

Comment on Magistrate Judge's Report and Recommendation

On July 31, 2020, the Company issued a press release commenting on the report and recommendation of the Magistrate Judge involved in its suit against the FDA recommending to the District Judge handling the Company's lawsuit that she grant the FDA's and Jacobus' motions for summary judgment and deny the Company's motion for summary judgment.

A copy of the Company's press release is attached as Exhibit 99.2 to this Form 8-K 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 3, 2020.](#)

99.2 [Press release issued by the Company on July 31, 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: August 3, 2020



Catalyst Pharmaceuticals Announces Change to a Virtual Meeting Format for the 2020 Annual Meeting of Stockholders

CORAL GABLES, Fla., August 3, 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 a change in the format of its 2020 Annual Meeting of Stockholders (the “Annual Meeting”) from an in-person meeting to a virtual-only meeting format. The change is being made as a result of the coronavirus outbreak (COVID-19) and in order to protect the health and safety of Catalyst’s stockholders and employees. There will be no in-person meeting. As previously announced, the Annual Meeting will be held on Thursday, August 20, 2020 at 9:00 a.m. eastern time.

Stockholders will be able to attend the Annual Meeting and submit questions and vote their shares during the Annual Meeting, from any location that has internet connectivity. Only stockholders of record at the close of business on June 22, 2020 (“Record Date”) will be entitled to attend the virtual Annual Meeting. To register for the Annual Meeting, you should follow these instructions as applicable to the nature of your ownership of our common stock:

- **Registered Stockholders.** If your shares are registered in your name with Continental Stock Transfer & Trust Company (“Continental”), and you wish to attend the online-only virtual Annual Meeting, go to www.cstproxy.com/catalystpharma/2020, enter the control number you received on your proxy card (printed in the box and marked with an arrow) and click on the “Click Here to Preregister for the Online Meeting” link at the top of the page. Just prior to the start of the meeting you will need to log back into the meeting site using your control number. Pre-registration is recommended but is not required to attend.
- **Street Name Stockholders.** Street name stockholders who wish to attend the online-only virtual Annual Meeting must obtain a legal proxy by contacting their account representative at the bank, broker, or other nominee that holds their shares and email a copy (a legible photograph is sufficient) of their legal proxy to proxy@continentalstock.com. Street name stockholders who email a valid legal proxy will be issued a meeting control number that will allow them to register to attend and participate in the online-only Annual Meeting. After contacting Continental, a street name stockholder will receive an e-mail prior to the meeting with a link and instructions for entering the virtual Annual Meeting. Street name stockholders should contact Continental at least five (5) business dates prior to the Annual Meeting date.

Stockholders participating in the virtual Annual Meeting will be in a listen-only mode and will not be able to speak during the webcast. However, in order to maintain the interactive nature of the virtual meeting, virtual attendees are able to: (i) vote using the online meeting website, and (ii) submit questions or comments to Catalyst’s officers during the meeting via e-mail or the virtual meeting webcast. Starting Monday, August 17, 2020 at 9:00

AM eastern time, stockholders may submit questions or comments before or during the meeting through the virtual meeting portal by typing in the “*Submit a Question*” box.

Stockholders will also have the option to call in to the virtual Annual Meeting by telephone and listen (in listen-only mode) by calling:

Within the U.S. and Canada	1-888-965-8995 (toll free)
Outside the U.S. and Canada	1-415-655-0243 (standard rates apply)
Passcode for telephone access:	09485747#

We encourage you to access the Annual Meeting 15 minutes prior to the start time. Online check-in will begin at 8:45 a.m. eastern time.

On or about July 6, 2020, Catalyst filed with the SEC and mailed to its stockholders a proxy statement (the “Proxy Statement”) containing information about the matters to be considered at the Annual Meeting. In connection with the matters described in this press release, Catalyst is filing with the SEC and making available to its stockholders a supplement to its Proxy Statement (“Supplement”), containing additional information about the matters to be considered at the Annual Meeting. Catalyst’s Proxy Statement, its Supplement, and its annual report for the year ended December 31, 2019, are available for download on Catalyst’s website at <https://ir.catalystpharma.com/financial-information/annual-reports> and on Continental’s website at <https://www.cstproxy.com/catalystpharma/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.

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 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.

Investor Contact

Brian Korb
Solebury Trout
(646) 378-2923
bkorb@troutgroup.com

Media Contact

David Schull
Russo Partners
(212) 845-4271
david.schull@russopartnersllc.com

Company Contact

Patrick J. McEnany
Catalyst Pharmaceuticals
Chief Executive Officer
(305) 420-3200
pmcenany@catalystpharma.com

###



**Catalyst Pharmaceuticals Comments on Magistrate Judge’s
Report and Recommendation in its Lawsuit against the FDA**

CORAL GABLES, Fla., July 31, 2020 (GLOBE NEWSWIRE) — Catalyst Pharmaceuticals, Inc. (Catalyst) (Nasdaq: CPRX), today reported that the Magistrate Judge considering Catalyst’s lawsuit against the FDA has filed a Report and Recommendation in which she recommends to the District Judge handling the case that she grant the FDA’s and Jacobus’ motions for summary judgement and deny Catalyst’s motion for summary judgement. Catalyst is currently reviewing the Magistrate Judge’s decision, which it believes to be incorrect as a matter of law, and intends to pursue the case further with the District Judge. The decision on whether to grant or deny Catalyst’s motion for summary judgement remains with the District Judge handling the case.

Patrick J. McEnany, the Company’s Chairman and CEO, stated: “We are obviously very disappointed with the Magistrate Judge’s recommendation, which we believe is contrary to the plain language of the Orphan Drug Act. If this recommendation is correct on the law, it means that the FDA can effectively eliminate the benefits of exclusivity under the Orphan Drug Act, which we believe will chill the incentive for drug companies like Catalyst to spend the millions of dollars necessary to develop an orphan drug.”

Mr. McEnany continued: “This recommendation does not alter the fact that Jacobus Pharmaceuticals is not permitted under applicable law to market its amifampridine product to adult LEMS patients in the United States, and Catalyst intends to continue to aggressively take all steps necessary to protect Firdapse®’s exclusivity under the Orphan Drug Act.”

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). 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.

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 will successfully convince the District Judge to grant Catalyst's motion for summary judgment in light of the recommendation of the Magistrate Judge, (ii) whether Catalyst can continue to successfully market its product despite the lower price charged by Jacobus for its amifampridine drug, and (iii) 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.

Investor Contact

Brian Korb
Solebury Trout
(646) 378-2923
bkorb@troutgroup.com

Company Contact

Patrick J. McEnany
Catalyst Pharmaceuticals
Chief Executive Officer
(305) 420-3200
pmcenany@catalystpharma.com

Media Contact

David Schull
Russo Partners
(212) 845-4271
david.schull@russopartnersllc.com

###