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): May 29, 2019

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

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. ☐

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

Item 1.01 Entry Into a Material Definitive Agreement

On May 29, 2019, the Company and BioMarin Pharmaceutical Inc. ("BioMarin") entered into that certain Amendment No. 2 to License Agreement ("the Amendment"), amending in certain respects the current License Agreement in place between BioMarin and the Company (the "License Agreement") relating to Firdapse®.

Under the current License Agreement, the Company has licensed the rights to commercialize Firdapse® in North America. Under the Amendment, the Company's commercial territory has been expanded to include Japan. Further, after the achievement of a certain milestone in Japan, the Company will have an option to further expand the commercial territory covered by its License Agreement to include most of Asia, as well as Central and South America.

Under the Amendment, the Company will pay royalties on net sales in Japan of a similar percentage to the royalties that the Company is currently paying under the original License Agreement for North America.

The Amendment is attached as Exhibit 10.1 to this Current Report on Form 8-K and is incorporated herein by reference. Portions of the Agreement have been redacted pursuant to Item 601(b)(10) of Regulation S-K.

Item 8.01 Other Events

On May 30, 2019, the Company issued a press release announcing that it had entered into the Amendment. A copy of the press release is attached as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

10.1	Amendment No. 2 to License Agreement, made and entered into effective as of May 29, 2019, by and between BioMarin and the Company (certain identified information has been excluded from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed).
99.1	Press release issued by the Company on May 30, 2019.

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 Pharmaceutical Partners, Inc.

By: /s/ Alicia Grande
Alicia Grande
Vice President, Treasurer and CFO

Dated: May 30, 2019

Exhibit 10.1

EXECUTION COPY

CERTAIN IDENTIFIED INFORMATION HAS BEEN EXCLUDED FROM THIS EXHIBIT BECAUSE IT IS BOTH (I) NOT MATERIAL AND (II) WOULD BE COMPETITIVELY HARMFUL IF PUBLICLY DISCLOSED SUCH INFORMATION HAS BEEN MARKED HEREIN WITH [***]

AMENDMENT NO. 2 TO LICENSE AGREEMENT

This **AMENDMENT NO. 2 TO LICENSE AGREEMENT** (herein referred to as "**Amendment No. 2**") is made and entered effective as of the 29th day of May, 2019 (the "**Amendment Effective Date**"), by and between BioMarin Pharmaceutical Inc., a Delaware corporation (hereinafter, "**BioMarin**") and Catalyst Pharmaceuticals, Inc., a Delaware corporation (hereinafter, "**Catalyst**"), each herein referred to individually as "**Party**" and collectively as "**Parties**".

WHEREAS, the Parties desire to amend that certain License Agreement between BioMarin and Catalyst, dated as of October 26, 2012, as previously amended by Amendment No. 1 thereto, dated as of April 8, 2014 (collectively, the "**Current Agreement**"), to expand the Territory under the Current Agreement and to make certain other changes, all as more particularly set forth herein; and

WHEREAS, following the Amendment Effective Date, the Current Agreement, as modified by this Amendment No. 2 (collectively, the "**Agreement**") shall govern the relationship between the Parties with respect to the matters set forth herein.

NOW, THEREFORE, in consideration of the premises and mutual covenants herein contained, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties hereto agree as follows:

1. **Defined Terms**. The following defined terms are used in this Amendment No. 2. Capitalized terms not otherwise defined in this Amendment No. 2 shall have the meaning ascribed to such terms in the Current Agreement.

   a. **"APAC"** means the countries of Australia; Indonesia; Malaysia; New Zealand; Peoples Republic of China (including Hong Kong and Macau); Philippines; Singapore; South Korea; Taiwan; Thailand; and Vietnam.

   b. **"Latam"** means all of the countries in Central and South America, excluding Mexico.

   c. "**MHLW**" means the Ministry of Health, Labor and Welfare of Japan and any successor agency or entity that may be established hereafter.

   d. **"Japan"** means the Country State of Japan.

   e. **"Japan MAA"** means an application for a license issued by the MHLW pursuant applicable Japanese laws, including the Pharmaceuticals and Medical Devices Law of 2014 (as may be amended), permitting an entity to sell or import a medical product (including, but not limited to, a pharmaceutical product) within Japan.

2. **Expansion of the Territory**. Under Section 1.60 of the Current Agreement, the Territory is defined as "the U.S., Canada, and Mexico and their respective territories, protectorates and possessions." On the Amendment Effective Date, the Territory as defined in the Current Agreement (the "**Original Territory**"), and the license granted to Catalyst under Section 2.1 of the Current Agreement, shall be expanded to include, Japan and its territories, protectorates and possessions. Further, upon acceptance by the MHLW of a Japan MAA for a Licensed Product for LEMS, the Territory, and the license granted to Catalyst under Section 2.1 of the Agreement, shall be further expanded to also include all the countries in

Latam and all the countries in APAC, and each of their respective territories, protectorates and possessions. For purposes of this Amendment No. 2, the "**Expanded Territories"** shall mean the territories described above that are or may in the future be granted to Catalyst under this Amendment No. 2, and the term "**Territory**" when sometimes used in the Agreement shall collectively refer to the Original Territory and the Expanded Territory.

3. **Other Obligations in the Current Agreement Modified to Include Expanded Territories.** All of the obligations set forth in the Current Agreement with respect to all matters, including without limitation, BioMarin's retained rights under Section 2.3 of the Current Agreement and Catalyst's exclusivity under Section 2.7 of the Current Agreement, shall be modified to expand the rights of Catalyst and restrict the rights of BioMarin with respect to the Expanded Territories.

4. **Diligent Development and Commercialization for Japan.**

(a) In addition to Catalyst's obligations under Section 3.3 of the Agreement, Catalyst shall use Diligent Efforts to develop at least one Licensed Product for LEMS in Japan. Diligent Efforts shall include, (i) [***] and (ii) [***].

(b) In addition to Catalyst's obligations under Section 6.2 of the Agreement, Catalyst shall use Diligent Efforts to Commercialize at least one Licensed Product for LEMS in Japan.

(c) If MHLW requests information regarding a Licensed Product that BioMarin has in its possession, it will supply it to Catalyst within a reasonable period of time for use by Catalyst in connection with its application to the MHLW.

(c) Any failure by Catalyst to comply with the development or commercialization obligations with respect to Japan that are set forth in subsections (a) and (b) of this Section 4 shall be deemed to be a material breach of the Agreement with respect to its license for the Expanded Territories, and for which BioMarin may exercise its termination rights with respect to Catalyst's license for the Expanded Territories in accordance with Section 13.1 of the Agreement, or any other available remedies at law or in equity, with respect to Catalyst's license for the Expanded Territories. However, any breach by Catalyst of its development or commercialization obligations in subsections (a) and (b) of this Section 4 with respect to the Expanded Territories shall not be deemed to be a violation of the Agreement with respect to the License granted to Catalyst for the Original Territory.

5. **Transfer of Regulatory Correspondence.** Within thirty (30) days of the Amendment Effective Date, BioMarin shall transfer to Catalyst [***]. Further, within 30 days of the Amendment Effective Date, BioMarin shall transfer to Catalyst the regulatory filing that it previously made in Japan that is described on **Exhibit A** to Catalyst.

6. **Payments**. Section 7.4(a) of the Current Agreement is hereby amended to require Catalyst to pay royalties to BioMarin on Net Sales of a Licensed Product in the Expanded Territory at a Royalty Rate equal to: (a) [***] of Net Sales on the first [***] of Calendar Year Net Sales in the Expanded Territory, and (b) [***] of Net Sales on the portion of Calendar Year Net Sales in the Expanded Territory above [***]. For avoidance of doubt, royalties payable on Net Sales in the Original Territory shall not be aggregated with Net Sales in the Expanded Territory for purposes of determining the royalties due on Net Sales in Expanded Territory.

7. **No Violation; Material Information.** This Amendment No. 2 does not violate any of the agreements that BioMarin has previously entered into under which it obtained the rights to the Licensed Products and the Licensed Technology, including [***] and any approvals required by any such parties have been obtained. Further, the information that BioMarin has provided to Catalyst with respect to the status of its discussions and regulatory filings to date with the MHLW constitute all of the material information that BioMarin currently has in its possession regarding its efforts to seek the approval of a Licensed Product in Japan

8. **No Regulatory Filings**. BioMarin hereby confirms [***].

9. **No Other Effect**. Except as expressly modified in this Amendment No. 2, the Agreement shall continue in full force and effect in accordance with its terms.

10. **Publicity.** The Parties agree that Catalyst may make a public announcement of the execution of this Amendment No. 2 substantially in the form of the press release attached as **Exhibit B**, which shall be issued with seven (7) days of the Amendment Effective Date. Any other publication, news release or other public announcement relating to this Amendment No. 2 or to the performance hereunder, shall first be reviewed and approved by both Parties; provided, however, that any disclosure which is required by law as advised by the disclosing Party's counsel, including without limitation, Catalyst reporting the material terms of this Amendment No. 2 in its filings with the U.S. Securities and Exchange Commission ("**SEC**") and filing a copy of this Amendment No. 2 as an exhibit to its filings with the SEC, may be made without the prior consent of the other Party, although the other Party shall be given prompt notice of any such legally required disclosure, and to the extent practicable, shall provide the other Party an opportunity to seek an appropriate protective order, confidential treatment, or similar remedy limiting the subsequent use and disclosure of any information required to be disclosed. Neither Party shall be required to seek the permission of the other Party to repeat any information relating to this Agreement that has already been publicly disclosed by such Party, or by the other Party, in accordance with this section or Section 11.4 of the Original Agreement, provided such information remains accurate as of such time and provided the frequency and form of such disclosure are reasonable.

11. **Full Force and Effect.** Catalyst and BioMarin hereby agree that, as of the Amendment Effective Date, the Agreement, as modified by this Amendment No. 2, is in full force and effect and both parties are in full compliance with the Agreement. The Parties further agree that to the extent that, prior to the Amendment Effective Date, there have been any violations of the Current Agreement by either Party, then any and all such violations are hereby waived.

12. **Representations and Warranties.** Each of the Parties represents to the other Party that all corporate formalities required to enter into this Amendment No. 2 have been obtained and that each such party has the rights to grant the rights and take on the obligations provided in this Amendment No. 2.

13. **Counterparts, Etc.** This Amendment No. 2 may be executed in any number of counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.

14. **Binding Effect.** This Amendment No. 2 shall inure to the benefit of and be binding upon the Parties hereto and their respective heirs, successors, trustees, transferees and assigns.

[Signatures on Next Page]

IN WITNESS WHEREOF, the Parties hereto, intending to be legally bound hereby, have caused this Amendment No. 2 to be executed and delivered by their proper and duly authorized officers effective as of the Amendment Effective Date.

CATALYST PHARMACEUTICALS, INC.

/s/ Patrick J. McEnany

BY: Patrick J. McEnany

ITS: CEO

BIOMARIN PHARMACEUTICAL INC.

/s/ G. Eric Davis

BY: G. Eric Davis

ITS: EVP, General Counsel

EXHIBIT A

REGULATORY FILING

[***]

EXHIBIT B

PRESS RELEASE

Catalyst Pharmaceuticals Announces Expansion of Firdapse License to Include Japan

CORAL GABLES, Fla., May 30, 2019 (GLOBE NEWSWIRE) — Catalyst Pharmaceuticals, Inc. (Catalyst) (Nasdaq:CPRX), a biopharmaceutical company focused on developing and commercializing innovative therapies for people with rare debilitating, chronic neuromuscular and neurological diseases, today announced that it has amended its license agreement for Firdapse® to expand its commercial territory. The original license was for North America, and has been amended to include Japan. Upon the achievement of a certain milestone in Japan, Catalyst will have the option to expand the territory further to include most of Asia and Central and South America.

"We are pleased to have expanded the scope of our license to include Japan and possibly other territories, as we believe that Japan represents an attractive strategic opportunity for Catalyst," said Patrick J. McEnany, Chairman and Chief Executive Officer of Catalyst Pharmaceuticals, Inc. "The available treatment options for LEMS patients in Japan are very limited and without an approved evidence-based therapy. We look forward to working with the regulatory authorities in Japan to potentially advance Firdapse as a new treatment option for LEMS patients and their families," McEnany added.

There are currently no approved therapies available to treat LEMS in Japan. In addition, Firdapse will seek to qualify for Orphan Drug Designation in Japan. Japan has the world's third largest economy.

The original license was signed in October of 2012. Under the recently amended license, Catalyst will pay royalties of a similar percentage of its net revenues derived in Japan as in its original License Agreement.

About Catalyst Pharmaceuticals

Catalyst Pharmaceuticals is a 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), congenital myasthenic syndromes (CMS), 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 recently approved 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, CMS, and SMA Type 3 and has received Orphan Drug Designation from the FDA for CMS and myasthenia gravis. 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 will be successful in filing an application in Japan to commercialize Firdapse; (ii) even if Catalyst is successful in obtaining approval of an application to commercialize Firdapse in Japan, whether Catalyst can successfully commercialize Firdapse in Japan on a profitable basis; (iii) whether Catalyst will

be successful in commercializing Firdapse in the United States, (iv) whether, even if Catalyst is successful in commercializing Firdapse in the United States, Catalyst will become profitable, (v) the effect on Catalyst's business and future results of operations of the recent approval by the FDA of an NDA for Jacobus Pharmaceuticals for their version of 3,4-DAP for the treatment of pediatric LEMS patients; (vi) whether Firdapse will ever be approved for the treatment of MuSK-MG, CMS, SMA Type 3, or any other disease, and (vii) those other 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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Exhibit 99.1

Catalyst Pharmaceuticals Announces Expansion of Firdapse License to Include Japan

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