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 18, 2023

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 801** **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 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

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

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 2.01 Completion of Acquisition or Disposition of Assets

On July 19, 2023, Catalyst Pharmaceuticals, Inc. (the "Company") completed its acquisition from Santhera Pharmaceuticals Holdings AG ("Santhera") of an exclusive license for North America for vamorolone, a potential treatment for patients suffering with Duchenne Muscular Dystrophy ("DMD"). The license is for exclusive commercial rights in the U.S., Canada, and Mexico, as well as the right of first negotiation in Europe and Japan should Santhera pursue partnership opportunities. Additionally, the Company will hold North American rights for any future approved indications of vamorolone.

As previously disclosed, the Company will make an all-cash purchase payment of $75 million to acquire the license pursuant to a License Agreement, dated June 19, 2023, by and between Santhera, its wholly owned subsidiary, Santhera Pharmaceuticals (Schweiz) AG, and the Company (the "License Agreement"). Simultaneously, pursuant to an Investment Agreement, dated as of June 19, 2023, between Santhera and the Company (the "Investment Agreement"), as amended by that certain Amendment to Investment Agreement dated July 18, 2023, the Company has made a strategic equity investment into Santhera by acquiring 1,414,688 of Santhera's post reverse-split ordinary shares (representing approximately 11.26% of Santhera's outstanding ordinary shares following the transaction) at an investment price of CHF 9.477 (corresponding to a mutually agreed volume-weighted average price prior to signing), with the approximately $15 million USD in equity investment proceeds to be used by Santhera for Phase IV studies in DMD and further development of additional indications for vamorolone. Catalyst will also be obligated under certain circumstances to make milestone payments and to pay royalties to Santhera.

The foregoing descriptions of the License Agreement and the Investment Agreement do not purport to be complete and are qualified in their entirety by reference to the full text of such agreements, copies of which were attached as **Exhibit 10.1**, and **Exhibit 10.2**, respectively, to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission ("SEC") on June 23, 2023. The amendment to the Investment Agreement is attached as **Exhibit 10.3** hereto and is incorporated herein by reference.

Forward-Looking Statements

This Current Report on Form 8-K includes forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Any statements, other than statements of historical fact, including any statements containing the words "believes," expects," "anticipates," "plans," "estimates," and similar expressions, are forward-looking statements. These forward-looking statements are based on the Company's current intentions, beliefs and expectations regarding future events. The Company cannot guarantee that any forward-looking statement will be accurate. The reader should realize that if underlying assumptions prove inaccurate or unknown risks or uncertainties materialize, actual results could differ materially from expectations. The reader is, therefore, cautioned not to place undue reliance on any forward-looking statement. Any forward-looking statement speaks only as of the date of this Form 8-K, and, except as required by law, the Company does not undertake to update any forward-looking statement to reflect new information, events or circumstances.

Item 8.01 Other Events

On July 19, 2023, the Company issued a press release announcing the closing of the transactions contemplated by the License Agreement and the Investment Agreement. A copy of the press release is attached as **Exhibit 99.1** to this Form 8-K and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits

10.1	License and Collaboration Agreement, executed and delivered as of June 19, 2023, by and between Santhera, its wholly owned subsidiary Santhera Pharmaceuticals (Schweiz) AG, and the Company (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the SEC on June 23, 2023).
10.2	Investment Agreement, dated as of June 19, 2023, by and between Santhera and the Company (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed with the SEC on June 23, 2023).
10.3	Amendment to the Investment Agreement, dated as of July 18, 2023, between Santhera and the Company
99.1	Press release issued by the Company on July 19, 2023
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: July 21, 2023

Exhibit 10.3

Homburger

Amendment to the Investment Agreement

dated as of July 18, 2023

between

Santhera Pharmaceuticals Holding AG (the **Company)**
Hohenrainstrasse 24
4133 Pratteln
Switzerland

and

Catalyst Pharmaceuticals, Inc. (the **Investor)**
355 Alhambra Circle
Suite 801
Coral Gables, Florida 33134
USA

(each the Company and the Investor a **Party** and together the **Parties**)

Whereas

A. As of June 19, 2023, the Parties entered into an investment agreement (the **Investment Agreement**) regarding the private placement of 14,146,882 pre-Reverse Split Treasury Shares of the Company with the Investor.

B. The Parties wish to amend the Investment Agreement by way of this amendment agreement (the **Amendment Agreement**).

Now, therefore, the Parties agree as follows:

1. Unless otherwise defined in this Amendment Agreement, capitalized terms used herein shall have the meanings ascribed to them in the Investment Agreement.

2. The Parties agree that Article 5.2(b) of the Investment Agreement shall be deleted in its entirety without replacement.

3. Save as varied by this Amendment Agreement, all terms and conditions of the Investment Agreement shall remain in full force and effect as set forth therein.

4. Article 7 (General Provisions) of the Investment Agreement shall apply *mutatis mutandis* to this Amendment Agreement.

5. This Amendment Agreement shall be exclusively governed by and construed in accordance with the substantive laws of Switzerland, excluding its conflict of laws principles.

6. Disputes under this Amendment Agreement shall be resolved by binding arbitration conducted in the manner and at the place set forth in the applicable provision of the License and Collaboration Agreement.

[Signatures on next page]

Executed as of the date written on the cover page to this Amendment Agreement.

Santhera Pharmaceuticals Holding AG

/s/ Andrew Smith	/s/ Oliver Strub
Andrew Smith	Oliver Strub
CFO	General Counsel

[*signature page to the Amendment Agreement*]

Executed as of the date written on the cover page to this Amendment Agreement.

Catalyst Pharmaceuticals, Inc.

/s/ Patrick J. McEnany
Patrick J. McEnany
Chairman and CEO

[*signature page to the Amendment Agreement*]

Exhibit 99.1

Catalyst Pharmaceuticals Acquires Exclusive North American License For Vamorolone for Duchenne Muscular Dystrophy from Santhera Pharmaceuticals

Vamorolone is a Promising Best-In-Class Dissociative Anti-Inflammatory Steroid Treatment for Duchenne Muscular Dystrophy

Synergistic Novel Asset Leverages Catalyst's Expertise and Bolsters Catalyst's Rare Neuroscience Portfolio

Granted FDA Fast Track, Orphan Drug Designation, and a PDUFA Action Date of October 26, 2023

Catalyst Expects to Launch Vamorolone in the U.S. Early in Q1 2024, Subject to Regulatory Approval

CORAL GABLES, Fla., July 19, 2023 — Catalyst Pharmaceuticals, Inc. ("Catalyst" or "Company") (Nasdaq: CPRX), today announced the completion of its acquisition from Santhera Pharmaceuticals Holdings ("Santhera") of an exclusive license for North America for vamorolone, a potential treatment for patients suffering with Duchenne Muscular Dystrophy. The license is for exclusive commercial rights in the U.S., Canada, and Mexico, as well as the right of first negotiation in Europe and Japan should Santhera pursue partnership opportunities. Additionally, Catalyst will hold North American rights for any future approved indications of vamorolone.

Vamorolone is a promising best-in-class dissociative anti-inflammatory steroid treatment for Duchenne Muscular Dystrophy ("DMD"). In clinical studies, vamorolone demonstrated efficacy with a significant reduction of steroid-associated side effects and benefits for bone health, growth, and behavior, offering the potential to address an important unmet medical need in DMD patients. Vamorolone has received FDA Orphan Drug and Fast Track designations and has been granted a PDUFA action date of October 26, 2023.

"With the addition of vamorolone, we have accomplished another important milestone in the execution of our portfolio expansion strategy," stated Patrick J. McEnany, Chairman and CEO of Catalyst. "The license for vamorolone reflects our strategic focus on opportunities where we can not only apply novel technology to address critical unmet patient needs, but where we can leverage Catalyst's existing integrated capabilities and infrastructure to commercialize the drug efficiently. We believe that vamorolone, if approved, has the potential to deliver significant near and long-term value and to be a very meaningful advancement to the current standard of care paradigm for DMD patients."

Mr. McEnany continued, "Vamorolone fortifies our neuromuscular portfolio with an innovative therapy that, in clinical studies, demonstrated an enhanced safety and tolerability profile as compared to prednisone. We plan to include vamorolone for DMD patients in our *Catalyst Pathways*® specialty pharmacy program to help ensure that all patients have access to the full patient benefits of the program. Our planned strategy to facilitate access to vamorolone underscores our steadfast commitment to improving the lives of patients suffering from rare neurological conditions."

Duchenne Muscular Dystrophy, or DMD, the most common form of muscular dystrophy, is a rare, fatal neuromuscular disorder characterized by progressive muscular dysfunction, leading to loss of ambulation, respiratory failure, and death. Corticosteroids are the current standard of care for treating DMD; however, this treatment is associated with significant side effect burdens. The U.S. prevalence for DMD is estimated to be between 11,000 and 13,000 patients. Of patients currently being treated for DMD, approximately 75% receive concomitant steroid treatment.

Transaction Details

As previously disclosed, Catalyst has made an all-cash purchase payment of $75 million to acquire the license. Simultaneously, Catalyst has made a strategic equity investment into Santhera by acquiring 1,414,688 of Santhera's post reverse-split ordinary shares (representing approximately 11.26% of Santhera's outstanding ordinary shares following the transaction) at an investment price of CHF 9.477 (corresponding to a mutually agreed volume-weighted average price prior to signing), with the approximately $15 million USD in equity investment proceeds to be used by Santhera for Phase IV studies in DMD and further development of additional indications for vamorolone. Catalyst will also be obligated under certain circumstances to make milestone payments and to pay royalties to Santhera.

Vamorolone Commercial Operational Plan

- Catalyst expects to launch vamorolone early in the first quarter of 2024, assuming regulatory approval on the PDUFA date of October 26, 2023.
- Catalyst anticipates minimal sales and marketing personnel expansion with fewer than 10 additional team members required, resulting from the exceptional synergy within its existing neuromuscular franchise.
- Catalyst plans to incorporate vamorolone for DMD into its *Catalyst Pathways*® specialty pharmacy program to ensure that patients have access to full patient benefits.

Further details on the vamorolone commercial operational plan will be discussed during the Company's second-quarter 2023 financial results conference call, which is expected to be held in the second week of August. Catalyst also expects to discuss on a preliminary basis the anticipated accounting treatment for the transaction on the conference call.

About Vamorolone

Vamorolone is an investigational drug candidate with a mode of action based on binding to the same receptor as glucocorticoids but modifying its downstream activity and as such, is considered a dissociative anti-inflammatory steroid drug [2-5]. This mechanism has shown the potential to 'dissociate' efficacy from steroid safety concerns, and therefore vamorolone could emerge as an alternative to existing corticosteroids, the current standard of care in children, adolescent, and adult patients with DMD. In the pivotal VISION-DMD study, vamorolone met the primary endpoint Time to Stand (TTSTAND) velocity versus placebo (p=0.002) at 24 weeks of treatment and showed a good safety and tolerability profile [1]. The most commonly reported adverse events versus placebo from the VISION-DMD study were cushingoid features, vomiting, and vitamin D deficiency. Adverse events were generally of mild to moderate severity.

Vamorolone has been granted Orphan Drug status for DMD in the U.S. and Europe and has received Fast Track and Rare Pediatric Disease designations by the U.S. FDA and Promising Innovative Medicine (PIM) status from the UK MHRA for DMD. Vamorolone is an investigational medicine and is currently not approved for use by any health authority.

Vamorolone will be eligible for 7 years of orphan drug exclusivity upon approval and also has issued and pending patents that could provide protection to 2040.

References:

[1] Guglieri M et al (2022). JAMA Neurol. 2022;79(10):1005-1014.doi:10.1001/jamaneurol.2022.2480. Link.
[2] Mah JK et al (2022). JAMA Netw Open. 2022;5(1):e2144178. doi:10.1001/jamanetworkopen.2021.44178. Link.
[3] Guglieri M et al (2022) JAMA. doi:10.1001/jama.2022.4315
[4] Heier CR et al (2019). Life Science Alliance DOI: 10.26508
[5] Liu X et al (2020). Proc Natl Acad Sci USA 117:24285-24293

About Duchenne Muscular Dystrophy

Duchenne Muscular Dystrophy (“DMD”) is a rare inherited X-chromosome-linked disease, which almost exclusively affects males. DMD is characterized by muscle inflammation and damage which are present at birth or shortly thereafter. Inflammation leads to fibrosis of muscle and is clinically manifested by progressive muscle degeneration and weakness. Major milestones in the disease are the loss of ambulation, the loss of self-feeding, the start of assisted ventilation, and the development of cardiomyopathy. DMD reduces life expectancy to before the fourth decade due to respiratory and/or cardiac failure. Corticosteroids are the current standard of care for the treatment of DMD.

About Catalyst Pharmaceuticals

With exceptional patient focus, Catalyst is committed to developing and commercializing innovative first-in-class medicines that address rare neurological and epileptic diseases. Catalyst’s U.S. commercial product portfolio consists of FIRDAPSE® (amifampridine) Tablets 10 mg, approved for the treatment of Lambert-Eaton myasthenic syndrome (“LEMS”) for adults and children ages six to seventeen. In January 2023, Catalyst acquired the U.S. commercial rights of FYCOMPA® (perampanel) CIII, a prescription medicine approved in people with epilepsy aged four and older alone or with other medicines to treat partial-onset seizures with or without secondarily generalized seizures, and with other medicines to treat primary generalized tonic-clonic seizures for people with epilepsy aged 12 and older. Further, Canada’s national healthcare regulatory agency, Health Canada, has approved the use of FIRDAPSE for the treatment of adult patients in Canada with LEMS.

For more information, visit the Company's website at www.catalystpharma.com. For Full Prescribing and Safety Information for FIRDAPSE®, please visit www.firdapse.com. For Full Prescribing Information, including Boxed WARNING for FYCOMPA®, please visit www.fycompa.com.

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 the NDA for vamorolone will be approved by the PDUFA date, or at all, (ii) whether, if the NDA for vamorolone is approved by the FDA, the product can be successfully commercialized by Catalyst in the licensed territory, (iii) whether if vamorolone is commercialized by Catalyst, the results of operations will prove to be accretive to Catalyst, (iv) whether Catalyst and Santhera will successfully develop additional indications for vamorolone and obtain the approvals required to commercialize the product in the licensed territory for those additional indications, (v) whether, if vamorolone is commercialized by Catalyst, the drug will be successfully integrated into Catalyst's business activities, and (vi) those factors described in Catalyst's Annual Report on Form 10-K for the 2022 fiscal year, Catalyst's Quarterly Report on Form 10-Q for the first quarter of 2023, and Catalyst's other filings with the 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.

Source: Catalyst Pharmaceuticals, Inc.

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