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 6, 2018

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. ☐

Item 8.01 Other Events.

On August 6, 2018, the Company issued a press release announcing the appointment of Jason James as Senior Vice President of Commercial Operations and Analytics, Jeff Del Carmen as Senior Vice President of Sales and Marketing, Kevin Rohrbach as Senior Director of Patient Engagement/Advocacy, and Maria Pandolfo as Senior Director of Patient Services. The Company also announced the addition of three Senior Medical Science Liaisons (MSLs) to its team, bringing the total of its MSLs to five. A copy of this press release is attached hereto as Exhibit 99.1.

On August 7, 2018, the Company issued a press release announcing its results of operations for the three and six months ended June 30, 2018 and providing a corporate update. A copy of this press release is attached hereto as Exhibit 99.2.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

99.1 Press release issued by the Company on August 6, 2018.

99.2 Press release issued by the Company on August 7, 2018.

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 7, 2018

Exhibit 99.1

Catalyst Pharmaceuticals Expands Commercial Leadership Team

— Augments Medical Affairs Team with 3 Additional Medical Science Liaisons

CORAL GABLES, Fla., August 6, 2018 (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 the appointment of several key members to its commercial leadership team. Catalyst has appointed Jason James as Senior Vice President of Commercial Operations & Analytics, Jeff Del Carmen as Senior Vice President of Sales and Marketing, Kevin Rohrbach as Senior Director of Patient Engagement/Advocacy, and Maria Pandolfo as Senior Director of Patient Services. Catalyst has also added three Senior Medical Science Liaisons (MSL) to its team, bringing the total of its MSL's to five.

"We are pleased to have such talented and successful people joining the Catalyst team as we continue to build our commercial and medical affairs capabilities," said Patrick J. McEnany, Chairman and Chief Executive Officer of Catalyst Pharmaceuticals. "Dan Brennan, our recently hired Chief Commercial Officer is doing a superb job building out his commercial leadership team. Adding these leaders to our organization brings us deep product launch experience for drugs to treat rare neurological diseases and will strengthen our ability to execute as we prepare for the potential commercial launch of Firdapse®." Mr. McEnany continues, "We are also pleased to have recently hired 3 additional seasoned MSL's with a wealth of experience working with the neuromuscular physician community."

Jason James-Sr. Vice President of Commercial Operations & Analytics

Mr. James has approximately 20 years of experience in pharmaceutical commercial operations and analytics. Most recently, Mr. James served as Group Vice President of Corporate Analytics at Horizon Pharma, where he was responsible for supporting the analytical business narrative across the Orphan, Rheumatology, and Primary Care Business Units. Prior to taking on that role, Mr. James held several leadership positions at Horizon including VP of Corporate Analytics and Executive Director of Business Development Analytics. Prior to joining Horizon, Mr. James was a Senior Director at Lundbeck (US) where he led a team responsible for supporting the pre and post-launch analytics of multiple CNS products. Mr. James received a B.S. degree in Finance from the Indiana University Kelley School of Business.

Jeff Del Carmen-Sr. Vice President of Sales & Marketing

Mr. Del Carmen brings over 22 years of experience in pharmaceutical sales and product management. Most recently, Mr. Del Carmen served as VP of Business Development at Paragon Biosciences evaluating commercial assets to expand Paragon's portfolio. Previously, Mr. Del Carmen was Senior Director-Rare Disease Marketing at Marathon Pharmaceuticals. From 2011 to 2016 Mr. Del Carmen was with Lundbeck (US), with the last two years as Movement Disorder-National Sales Director. Prior to joining Marathon, Mr. Del Carmen served a short stint as Vice President of Sales at Insys Therapeutics. Mr. Del Carmen received a B.A degree in Economics from the University of Dayton and an MBA degree from the University of Wisconsin.

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), congenital myasthenic syndromes (CMS), MuSK antibody positive myasthenia gravis, spinal muscular atrophy (SMA) type 3, and infantile spasms. Firdapse® (amifampridine phosphate) has received Breakthrough Therapy Designation from the U.S. Food and Drug Administration (FDA) for the treatment of LEMS and Orphan Drug Designation for LEMS, CMS and myasthenia gravis. Firdapse is the first and only approved drug in Europe for symptomatic treatment in adults with LEMS.

Catalyst is also developing CPP-115 to treat refractory infantile spasms. CPP-115 has been granted U.S. Orphan Drug Designation for the treatment of infantile spasms by the FDA and has been granted E.U. Orphan Medicinal Product Designation for the treatment of West syndrome by the European Commission. In addition, Catalyst is developing a generic version of Sabril® (vigabatrin).

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 Firdapse will ever be approved for commercialization, (ii) whether, even if Firdapse is approved for commercialization, Catalyst will be successful in commercializing Firdapse, (iii) whether Catalyst will be the first company to receive an approval for amifampridine (3,4-DAP), giving it 5-year marketing exclusivity for its product, and (iv) those other factors described in Catalyst's Annual Report on Form 10-K for the fiscal year 2017 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.

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

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Exhibit 99.2

Catalyst Pharmaceuticals Announces Second Quarter 2018 Financial Results and Provides Corporate Update

—Company to Host Quarterly Conference Call at 8:30 am ET Tomorrow

CORAL GABLES, Fla., August 7, 2018 (GLOBE NEWSWIRE) — Catalyst Pharmaceuticals, Inc. (Nasdaq: CPRX), a biopharmaceutical company focused on developing and commercializing innovative therapies for people with rare debilitating, chronic neuromuscular and neurological diseases, today reported financial results for the second quarter ended June 30, 2018 and provided a corporate update.

"This quarter we were pleased to announce the FDA acceptance of our NDA for Firdapse® for Lambert-Eaton myasthenic syndrome (LEMS) and to receive Priority Review Status for our NDA," said Patrick J. McEnany, Chairman and Chief Executive Officer of Catalyst Pharmaceuticals. "With the previous grant of Breakthrough Therapy Designation, the Priority Review underscores the robust potential of Firdapse and the need for a safe and effective FDA-approved treatment for LEMS. The recent appointment of our Chief Commercial Officer, Dan Brennan, provides us with extensive commercial experience that will help us build a commercial platform to prepare for a potential launch of Firdapse."

Q2-18 and Recent Highlights

- FDA Acceptance of NDA and Priority Review Status of Firdapse for LEMS
- Appointed Daniel J. Brennan as Chief Commercial Officer and expanded commercial leadership team with key hires
- Recently added three additional medical science liaisons to the medical affairs team
- Continued progress with pre-commercialization activities for a potential launch of Firdapse
- Ended June 30, 2018 with $73.4 million in cash and investments and no debt

Upcoming Milestones

- Prescription Drug User Fee Act (PDUFA) goal date of November 28, 2018 for Firdapse
- Enroll first patients in SMA Type 3 proof of concept trial in the second half of 2018
- Potential launch of Firdapse for LEMS in early 2019
- Expect top-line results from Phase 3 CMS (CMS-001) trial in the first half of 2019
- Expect top-line results from Phase 3 trial for MuSK-MG in the second half of 2019

Financial Results

For the quarter ended June 30, 2018, Catalyst reported a GAAP net loss of $5,965,140, or $0.06 per basic and diluted share, compared to a GAAP net loss of $3,879,901, or $0.05 per basic and diluted share, for the same period in 2017. For the second quarter of 2018, Non-GAAP[1] net loss was the same as GAAP net loss, as there were no Non-GAAP[1] adjustments. In comparison, Non-GAAP[1] net loss for the second quarter of 2017 was $4,090,232 or $0.05 per basic and diluted share, which excludes non-cash gain of $210,331 attributable to the change in fair value of liability-classified warrants.

For the six months ended June 30, 2018, Catalyst reported a GAAP net loss of $11,665,032, or $0.11 per basic and diluted share, as compared to a GAAP net loss of $8,847,030, or $0.11 per basic and diluted share, for the same period in 2017. For the six months ended June 30, 2018, Non-GAAP[1] net loss was the same as GAAP net loss, as there were no Non-GAAP[1] adjustments. In comparison, Non-GAAP[1] net loss for the first six months of 2017 was $8,660,126, or $0.10 per basic and diluted share, which excludes non-cash loss of $186,904 attributable to the change in fair value of liability-classified warrants.

Research and development expenses for the second quarter of 2018 were $3,704,824 compared to $2,451,751 in the second quarter of 2017. For the six months ended June 30, 2018, research and development expenses were $6,963,866 as compared to $5,265,680 in the same period in 2017. The increase in research and development expenses for the first six months of 2018 was primarily due to increases in consulting expenses as Catalyst prepared to submit its NDA for Firdapse during the first quarter of 2018, milestone expenses in connection with the acceptance of Catalyst's NDA submission in May 2018, expenses from Catalyst's medical affairs program, and compensation and related personnel costs, as Catalyst's expands its headcount to support currently ongoing trials and programs. Catalyst expects that costs related to research and development activities will continue to be substantial throughout 2018 as it continues its on-going clinical studies and Expanded Access Program for Firdapse.

General and administrative expenses for the second quarter of 2018 totaled $2,631,031 as compared to $1,729,520 in the second quarter of 2017. For the six months ended June 30, 2018, general and administrative expenses were $5,305,429 as compared to $3,595,462 in the same period in 2017. The increase when compared to the same period in 2017 is primarily due to increases in pre-commercialization expenses, headcount and corporate expenses as Catalyst builds up its infrastructure and commercial programs in preparation for a potential launch of Firdapse in 2019. Catalyst expects general and administrative expenses, including pre-commercialization expenses, to continue to increase in 2018 as Catalyst continues to expand its operations in preparation for a potential launch of Firdapse in 2019.

As a development-stage biopharmaceutical company, Catalyst had no revenues in either the second quarter of 2018 and 2017 or the first six months of 2018 and 2017.

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1 Statements made in this press release include a non-GAAP financial measure. Such information is provided as additional information and not as an alternative to Catalyst's financial statements presented in accordance with U.S. generally accepted accounting principles (GAAP). This non-GAAP financial measure is intended to enhance an overall understanding of Catalyst's current financial performance. Catalyst believes that the non-GAAP financial measure presented in this press release provides investors and prospective investors with an alternative method for assessing Catalyst's operating results in a manner that Catalyst believes is focused on the performance of ongoing operations and provides a more consistent basis for comparison between periods. The non-GAAP financial measure in this press release excludes from the calculation of net loss the expense (or the income) associated with the change in fair value of the liability-classified warrants. Non-GAAP net loss per share is calculated by dividing non-GAAP net loss by the weighted average common shares outstanding.

At June 30, 2018, Catalyst had cash and investments of $73.4 million and no debt. Catalyst believes that its existing capital resources will be sufficient to support its planned operations through 2019 (without considering revenues and cash receipts that may be received in 2019 if Catalyst is successful in obtaining an approval of Firdapse and launching the product in 2019, of which there can be no assurance).

More detailed financial information and analysis may be found in Catalyst's Quarterly Report on Form 10-Q, which was filed with the Securities and Exchange Commission (SEC) on August 7, 2018.

Conference Call

Catalyst management will host an investment-community conference call and webcast at 8:30 a.m. ET, tomorrow, Wednesday, August 8, 2018 to discuss the financial results and provide a corporate update. Investors who wish to participate in the conference call may do so by dialing (877) 407-8912 for domestic and Canadian callers or (201) 689-8059 for international callers. Those interested in listening to the conference call live via the internet may do so by visiting the Investors page of the company's website at www.catalystpharma.com and clicking on the webcast link on the Investors home page. A webcast replay will be available on the Catalyst website for 30 days following the call by visiting the Investor page of the company's website at www.catalystpharma.com.

About Catalyst Pharmaceuticals

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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

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CATALYST PHARMACEUTICALS, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS (unaudited)

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	2018	2017	2018	2017
Operating costs and expenses:				
Research and development	$ 3,704,824	$ 2,451,751	$ 6,963,866	$ 5,265,680
General and administrative	2,631,031	1,729,520	5,305,429	3,595,462
Total operating costs and expenses	6,335,855	4,181,271	12,269,295	8,861,142
Loss from operations	(6,335,855)	(4,181,271)	(12,269,295)	(8,861,142)
Other income, net	370,715	91,039	604,263	201,016
Change in fair value of warrants liability	—	210,331	—	(186,904)
Loss before income taxes	(5,965,140)	(3,879,901)	(11,665,032)	(8,847,030)
Provision for income taxes	—	—	—	—
Net loss	$ (5,965,140)	$ (3,879,901)	$ (11,665,032)	$ (8,847,030)
Net loss per share – basic and diluted	$ (0.06)	$ (0.05)	$ (0.11)	$ (0.11)
Weighted average shares outstanding – basic and diluted	102,596,446	83,905,827	102,577,005	83,441,650

CATALYST PHARMACEUTICALS, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

	June 30, 2018 (unaudited)	December 31, 2017
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 9,887,939	$57,496,702
Short-term investments	58,520,956	26,516,711
Prepaid expenses and other current assets	677,341	1,173,744
Total current assets	69,086,236	85,187,157
Investments	5,005,321	—
Property and equipment, net	187,131	191,385
Deposits	8,888	8,888
Total assets	$74,287,576	$85,387,430
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	$ 922,593	$ 1,945,575
Accrued expenses and other liabilities	2,159,435	2,320,587
Total current liabilities	3,082,028	4,266,162
Accrued expenses and other liabilities, non-current	143,335	157,456
Total liabilities	3,225,363	4,423,618
Total stockholders' equity	71,062,213	80,963,812
Total liabilities and stockholders' equity	$74,287,576	$85,387,430