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 7, 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

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**

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 7, 2019, the Company issued a press release announcing its results of operations for the three and six months ended June 30, 2019 and providing a corporate update. A copy of the press release is attached hereto as Exhibit 99.1.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

99.1 Press release issued by the Company on August 7, 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 Pharmaceuticals, Inc.

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

Dated: August 7, 2019

Exhibit 99.1

Catalyst Pharmaceuticals Announces Second Quarter 2019 Financial Results and Provides Corporate Update

- Firdapse® Launch Momentum Continues with Second Quarter Net Revenues of $28.8 Million

-409 Adult LEMS Patients Active on Firdapse as of June 30, 2019

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

CORAL GABLES, Fla., August 7, 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 reported financial results for the second quarter ended June 30, 2019 and provided a corporate update.

"We are very pleased with the continued strength of the commercial launch of Firdapse®, the first and only evidence-based, FDA approved drug for the treatment of adult patients with Lambert-Eaton myasthenic syndrome (LEMS). We are greatly encouraged by the support we continue to receive from LEMS patients and their healthcare providers," said Patrick J. McEnany, Chairman and Chief Executive Officer of Catalyst Pharmaceuticals. "While the launch remains our greatest area of focus, we are also enthused with the advances we continue to make with our ongoing clinical programs, as well as our effort to expand our reach with Firdapse to other countries without an approved therapy for LEMS."

Q2-19 Financial Results

- Product revenue, net in the second quarter 2019 was $28.8 million
- Reported net income of $11.0 million, or $0.11 per basic and $0.10 per diluted share, in the second quarter of 2019, compared with a net loss of $6.0 million, or $0.06 per basic and diluted share, for the second quarter of 2018.
- Selling, general and administrative expenses for the second quarter of 2019 totaled $9.0 million as compared to $2.6 million in the second quarter of 2018.
- Research and development expenses for the second quarter of 2019 were $4.6 million as compared to $3.7 million for the second quarter of 2018.
- Ended June 30, 2019 with $64.9 million in cash and investments and no funded debt.

Recent Developments and Highlights

- Initiated commercial launch of Firdapse for LEMS on January 15, 2019.
- Had 409 adult LEMS patients on Firdapse as of June 30, 2019, compared to 337 patients on March 31, 2019.
- As of today, 138 patients previously naïve to any form of 3,4-DAP are enrolled in Catalyst Pathways.
- Amended our Firdapse license agreement to expand the commercial territory to include Japan.
- Global expansion of Firdapse for LEMS underway in Canada and Japan.

- Filed federal lawsuit against U.S. Food and Drug Administration challenging the approval of Ruzurgi™ for the treatment of pediatric LEMS patients (ages 6 to under 17).

Upcoming Milestones

- Expect to complete enrollment for the MuSK-MG trial in the second half of 2019 and to report top-line results from this trial in the first half of 2020.
- Expect top-line results from Phase 3 trial for CMS in the second half of 2019.
- Expect top-line results for SMA Type 3 proof of concept trial in the first half of 2020.

Financial Results

For the quarter ended June 30, 2019, Catalyst reported net income of $10,959,948, or $0.11 per basic and $0.10 per diluted share, compared to a net loss of $5,965,140, or $0.06 per basic and diluted share, for the same period in 2018. For the six months ended June 30, 2019, Catalyst reported net income of $10,315,445, or $0.10 per basic and diluted share, as compared to a net loss of $11,665,032, or $0.11 per basic and diluted share, for the same period in 2018.

Research and development expenses for the second quarter of 2019 were $4,629,364 as compared to $3,704,824 in the second quarter of 2018. For the six months ended June 30, 2019, research and development expenses were $7,937,323 as compared to $6,963,866 in the same period in 2018. Research and development expenses for the three and six months ended June 30, 2019 primarily consisted of expenses in medical and regulatory affairs and quality assurance programs, as well as expenses from our ongoing clinical trials and studies evaluating Firdapse for the treatment of other ultra-orphan neuromuscular diseases and our Expanded Access Program. Research and development expenses in the comparable period in 2018, primarily consisted of consulting expenses as the Company prepared to submit an NDA for Firdapse for the treatment of LEMS, as well as expenses from Catalyst's ongoing clinical trials and studies and its Expanded Access Program. The Company expects that costs related to research and development activities will continue to be substantial throughout 2019 as it continues its on-going clinical trials and studies in MuSK-MG, CMS and SMA Type 3 and its Expanded Access Program for Firdapse.

Selling, general and administrative expenses for the second quarter of 2019 totaled $8,987,722 as compared to $2,631,031 in the second quarter of 2018. For the six months ended June 30, 2019, selling, general and administrative expenses were $17,404,182 as compared to $5,305,429 in the same period in 2018. The increase when compared to the same period in 2018 is primarily due to increased selling expenses, including costs of commercial system implementation, of the Company's sales force and supporting personnel, product launch expenses, market access and market research expenses, and professional fees associated with Catalyst's suit against the FDA. The Company expects selling, general and administrative expenses to increase in 2019, as the Company continues to build its infrastructure and commercial and patient programs in support of Firdapse sales activities in 2019, and prosecutes its lawsuit against the FDA.

Catalyst launched its first product, Firdapse, in January 2019. Product revenue, net for the quarter and six months ended June 30, 2019 were $28,837,900 and $41,286,338, respectively. Cost of sales for the quarter and six months ended June 30, 2019 were $4,261,625 and $5,973,413, respectively.

At June 30, 2019, Catalyst had cash and cash equivalents and investments of $64.9 million and no funded debt. Catalyst believes that its existing capital resources will be sufficient to support its planned operations for at least the next 12 months.

More detailed financial information and analysis may be found in the Company's Quarterly Report on Form 10-Q, which was filed with the Securities and Exchange Commission (SEC) on August 7, 2019.

Conference Call

Catalyst management will host an investment-community conference call and webcast at 8:30 a.m. ET, tomorrow, Thursday, August 8, 2019 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

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 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 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 myasthenia gravis and CMS. 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, even if Catalyst is successful in commercializing Firdapse, Catalyst will achieve sustained profitability, (ii) the effect on Catalyst's business and future results of operations of the recent approval by the FDA of Ruzurgi for the treatment of pediatric LEMS patients (ages 6 to under 17); (iii) whether Catalyst's suit against the FDA seeking to vacate the FDA's approval of Ruzurgi will be successful; (iv) whether Firdapse will ever be approved for commercialization for the treatment of MuSK-MG, CMS, SMA Type 3, or any other disease, and (v) 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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CATALYST PHARMACEUTICALS, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS (unaudited)

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	2019	2018	2019	2018
Product revenue, net	$ 28,837,900	$ —	$ 41,286,338	$ —
Operating costs and expenses:				
Cost of sales	4,261,625	—	5,973,413	—
Research and development	4,629,364	3,704,824	7,937,323	6,963,866
Selling, general and administrative	8,987,722	2,631,031	17,404,182	5,305,429
Total operating costs and expenses	17,878,711	6,335,855	31,314,918	12,269,295
Operating income (loss)	10,959,189	(6,335,855)	9,971,420	(12,269,295)
Other income, net	450,410	370,715	793,676	604,263
Net income (loss) before income taxes	11,409,599	(5,965,140)	10,765,096	(11,665,032)
Provision for income taxes	449,651	—	449,651	—
Net income (loss)	$ 10,959,948	$ (5,965,140)	$ 10,315,445	$ (11,665,032)
Net income (loss) per share:				
Basic	$ 0.11	$ (0.06)	$ 0.10	$ (0.11)
Diluted	$ 0.10	$ (0.06)	$ 0.10	$ (0.11)
Weighted average shares outstanding:				
Basic	102,869,202	102,596,446	102,808,897	102,577,005
Diluted	105,928,970	102,596,446	105,098,930	102,577,005

CATALYST PHARMACEUTICALS, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

	June 30, 2019 (unaudited)	December 31, 2018
ASSETS		
Current Assets:		
Cash and cash equivalents	$23,417,512	$16,559,400
Short-term investments	36,503,442	36,922,213
Accounts receivable, net	10,376,427	—
Inventory	269,879	56,012
Prepaid expenses and other current assets	1,488,603	1,649,781
Total current assets	72,055,863	55,187,406
Investments	5,008,400	5,008,243
Operating lease right-of-use asset	1,013,590	—
Property and equipment, net	147,619	245,425
Deposits	8,888	8,888
Total assets	$78,234,360	$60,449,962
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	$ 3,328,726	$ 2,337,367
Accrued expenses and other liabilities	10,822,803	7,173,987
Total current liabilities	14,151,529	9,511,354
Accrued expenses and other liabilities, non-current	—	154,799
Operating lease liability, net of current portion	801,264	—
Total liabilities	14,952,793	9,666,153
Total stockholders' equity	63,281,567	50,783,809
Total liabilities and stockholders' equity	$78,234,360	$60,449,962