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 13, 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 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. ☐

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading symbol(s)	Name of each exchange on which registered
Common Stock	**CPRX**	**Nasdaq Capital Market**

Item 8.01 Other Events

On May 13, 2019, the Company issued a press release announcing its results of operations for the quarter ended March 31, 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 May 13, 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: May 13, 2019

Exhibit 99.1

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

-Firdapse® Launch Off to Strong Start with First Quarter Net Revenues of $12.4 Million

-81 Patients Without Previous Access to any Form of Amifampridine Have Been Prescribed Firdapse

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

CORAL GABLES, Fla., May 13, 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 first quarter ended March 31, 2019 and provided a corporate update.

“The first quarter of this year was very critical for us, as we became a fully-integrated biopharmaceutical company with the commercial launch of Firdapse”, said Patrick J. McEnany, Chairman and Chief Executive Officer of Catalyst Pharmaceuticals. “We are pleased that the Firdapse launch is off to an excellent start and while it is still early, with much work to be done, it is especially gratifying to see the number of patients that were previously naive to any form of amifampridine that are now being effectively treated with Firdapse. We continue to be motivated by the very positive response that we are receiving from patients and healthcare providers. Lastly, we continue to make progress in clinical development of our robust pipeline of other potential indications for Firdapse.”

Mr. McEnany continued, “We were extremely surprised with the FDA’s decision to approve Jacobus Pharmaceuticals’ NDA for amifampridine in the treatment of LEMS in a pediatric population between the ages of 6 and less than 17. According to a Jacobus spokesperson there are less than 15 pediatric LEMS patients in the U.S. We are currently assessing our options and we expect to have more to say in that regard in the coming days.”

Q1-19 Financial Results

- Total net revenue in the first quarter 2019 was $12.4 million
- Selling, general and administrative expenses for the first quarter of 2019 totaled $8.4 million as compared to $2.7 million in the first quarter of 2018. The increase is primarily attributed to commercial launch expenses, as well as the patient services programs to support Firdapse.
- Research and development expenses for the first quarter of 2019 were $3.3 million in line with the first quarter of 2018.
- Ended March 31, 2019 with $50.6 million in cash and investments and no funded-debt.
- Reported a net loss of $645,000 or $(0.01) per basic and diluted share, compared with a net loss of $5.7 million, or $(0.06) per basic and diluted share, for the first quarter of 2018.

Recent Developments and Highlights

- Received FDA approval of Firdapse new drug application on November 28, 2018
- Initiated commercial launch of Firdapse for LEMS on January 15, 2019

- 409 unique LEMS patients prescribed Firdapse as of May 9, 2019
- 380 LEMS patients active on Firdapse as of May 9, 2019
- 214 unique prescribers that have written at least one Firdapse prescription as of May 9, 2019
- 81 unique patients prescribed Firdapse that had previously been naive to any form of amifampridine
- Published LMS-003 Phase 3 clinical data for Firdapse in the *Journal of Clinical Neuromuscular Disease*

Upcoming Milestones

- Expect top-line results from Phase 3 trial for MuSK-MG in the second half of 2019
- 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 March 31, 2019, Catalyst reported a net loss of $644,503, or $0.01 per basic and diluted share, compared to a net loss of $5,699,892, or $0.06 per basic and diluted share, for the same period in 2018.

Catalyst launched its first product, Firdapse, in January 2019. Related product revenues, net for the quarter ended March 31, 2019 were $12,448,438. Cost of sales for the same quarter were $1,711,788.

Research and development expenses for the first quarter of 2019 were $3,307,959, in line with the comparable period in 2018 with expenses of $3,259,042. Research and development expenses for the first three months of 2019 primarily consisted of expenses in medical, regulatory affairs and quality assurance programs, as well as expenses from our Firdapse clinical trials, studies and Expanded Access Program. Research and development expenses in the comparable period in 2018, primarily consisted of consulting expenses as we prepared to submit our NDA for Firdapse for the treatment of LEMS during March 2018, as well as expenses from our Firdapse clinical trials, studies and 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 first quarter of 2019 totaled $8,416,460 as compared to $2,674,398 in the first quarter of 2018. The increase when compared to the same period in 2018 is primarily due to increased selling expenses, including the cost of our sales force and supporting personnel, product launch expenses, market access and market research expenses. The Company expects selling, general and administrative expenses to increase in 2019, as we continue to build up our infrastructure and commercial and patient programs in support of Firdapse sales activities in 2019.

At March 31, 2019, Catalyst had cash and cash equivalents and investments of $50.6 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 year.

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 May 10, 2019.

Conference Call

Catalyst management will host an investment-community conference call and webcast at 8:30 a.m. ET, today, Monday, May 13, 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 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 commercializing Firdapse, (ii) whether, even if Catalyst is successful in commercializing Firdapse, Catalyst will become profitable, (iii) 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; (iv) whether Firdapse will ever be approved 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 March 31,	
	2019	2018
Product revenue, net	$ 12,448,438	$ —
Operating costs and expenses:		
Cost of sales	1,711,788	—
Research and development	3,307,959	3,259,042
Selling. general and administrative	8,416,460	2,674,398
Total operating costs and expenses	13,436,207	5,933,440
Loss from operations	(987,769)	(5,933,440)
Other income, net	343,266	233,548
Loss before income taxes	(644,503)	(5,699,892)
Provision for income taxes	—	—
Net loss	$ (644,503)	$ (5,699,892)
Net loss per share – basic and diluted	$ (0.01)	$ (0.06)
Weighted average shares outstanding – basic and diluted	102,747,923	102,557,350

CATALYST PHARMACEUTICALS, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

	March 31, 2019 (unaudited)	December 31, 2018
ASSETS		
Current Assets:		
Cash and cash equivalents	$19,081,714	$16,559,400
Short-term investments	26,551,064	36,922,213
Accounts receivable, net	7,251,381	—
Inventory	96,587	56,012
Prepaid expenses and other current assets	1,881,266	1,649,781
Total current assets	54,862,012	55,187,406
Investments	4,991,600	5,008,243
Operating lease right-of-use asset	1,074,020	—
Property and equipment, net	140,320	245,425
Deposits	8,888	8,888
Total assets	$61,076,840	$60,449,962
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	$ 2,940,086	$ 2,337,367
Accrued expenses and other liabilities	6,086,029	7,173,987
Total current liabilities	9,026,115	9,511,354
Accrued expenses and other liabilities, non-current	—	154,799
Operating lease liability, net of current portion	875,098	—
Total liabilities	9,901,213	9,666,153
Total stockholders' equity	51,175,627	50,783,809
Total liabilities and stockholders' equity	$61,076,840	$60,449,962