

**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 10, 2020

CATALYST PHARMACEUTICALS, INC.

(Exact Name Of Registrant As Specified In Its Charter)

Delaware
(State or other jurisdiction
of incorporation)

001-33057
(Commission
File Number)

76-0837053
(I.R.S. Employer
Identification No.)

**355 Alhambra Circle
Suite 1250
Coral Gables, Florida**
(Address of principal executive offices)

33134
(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 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.

Item 8.01 Other Events

On August 10, 2020, the Company issued a press release announcing its results of operations for the three and six months ended June 30, 2020 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 10, 2020.](#)

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: August 10, 2020



Catalyst Pharmaceuticals Announces Second Quarter 2020 Financial Results and Provides Business Update

- Firdapse® Second Quarter Net Revenues of \$29.6 Million

- Health Canada Approves Marketing Authorization for Firdapse® for Treating LEMS Patients

- MuSK-MG Phase 3 Trial did not Achieve Statistical Significance for Primary or Secondary Endpoints

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

CORAL GABLES, Fla., August 10, 2020 (GLOBE NEWSWIRE) — Catalyst Pharmaceuticals, Inc. (Catalyst) (Nasdaq:CPRX), a commercial-stage 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, 2020 and provided a business update.

“Despite operating under COVID-19 conditions, I am quite pleased with the resiliency of our team and the operating results that were achieved during the second quarter. Additionally, as physicians’ practices begin to open again to in-person meetings with patients and sales representatives, we are beginning to see an improvement in new LEMS patient enrollments in Catalyst Pathways and are hopeful that this is a start of a trend,” said Patrick J. McEnany, Chairman and Chief Executive Officer of Catalyst Pharmaceuticals. “On a separate note, we are disappointed that the top-line results of our Phase 3 study for Firdapse® in anti-MuSK antibody positive myasthenia gravis patients did not replicate the robust positive results that were observed in the 2017 proof-of-concept study. We intend to continue to analyze the data and meet with our neuromuscular key opinion leaders to decide on our path forward for this program.”

Q2-20 Financial Results

- Product revenue, net in the second quarter 2020 was \$29.6 million compared to \$28.8 for the second quarter 2019.
- Reported net income of \$9.8 million, or \$0.09 per basic and diluted share, in the second quarter of 2020, compared with net income of \$11.0 million, or \$0.11 per basic and \$0.10 per diluted share, for the second quarter of 2019.
- Research and development expenses for the second quarter of 2020 were \$4.3 million as compared to \$4.6 million for the second quarter of 2019.
- Selling, general and administrative expenses for the second quarter of 2020 totaled \$10.8 million as compared to \$9.0 million in the second quarter of 2019.
- The Company’s total operating expenses for the second quarter 2020 were \$19.3 million.
- Ended June 30, 2020 with \$115.1 million in cash and investments and no funded debt.

Corporate Highlights and Milestones

- Announced receipt of marketing authorization from Health Canada for Firdapse® for the treatment of patients in Canada with LEMS.
- Announced Jeffrey Del Carmen promotion to Chief Commercial Officer.
- Recently met with the Japanese PMDA and believe we have reached a tentative agreement for an acceptable and efficient regulatory plan.
- Continued on-going evaluation of potential acquisition of products or companies.

MuSK-MG Phase 3 Study Results

- Firdapse® was safe and well tolerated during the MSK-002 study and demonstrated a safety profile similar to that seen for Firdapse® in the treatment of LEMS.
- The primary endpoint, the Myasthenia Gravis Activities of Daily Living (MG-ADL) assessment, did not achieve statistical significance (p=0.2196).
- The secondary endpoint, the Quantitative Myasthenia Gravis (QMG) assessment, did not achieve statistical significance (p=0.3736).
- We plan to complete the full analysis of data and findings and to meet with our neuromuscular advisors to decide our path forward for the MuSK-MG indication.
- Detailed results of this study will be made available in a future scientific forum.

Other Firdapse® Development Programs

- Enrollment in proof-of-concept spinal muscular atrophy type-3 study has been completed and we expect to report top-line data before year-end.
- Firdapse® long-acting formulation development program continues on schedule.
- Investigator studies for two additional neuromuscular indications are expected to commence later this year.

COVID-19 Impact

- Issued a no travel and remote work policy for all Catalyst employees on March 16th.
- Diligently working to reduce COVID-19 impact on new enrollments and revenues.
- We believe that our current base of LEMS patients on reimbursed Firdapse® is fairly stable and very compliant to their medication regimen.
- Have not experienced any disruptions in the supply chain or production of Firdapse® and believe the safety stock of Firdapse® is more than adequate for current anticipated needs.
- Proudly partnered with First Responder's Children's Foundation/COVID-19 Emergency Response Fund, which provides emergency grants to support frontline emergency and healthcare workers and their families enduring financial hardship during this COVID-19 pandemic.

Balance Sheet and Key Activities in 2020

At June 30, 2020, Catalyst had cash and cash equivalents and investments of \$115.1 million and no funded debt.

The Company plans to continue investing in the following key activities in 2020:

- Expansion of U.S. commercialization of Firdapse®.
- On-going development programs evaluating Firdapse® for the treatment of MuSK-MG and SMA Type 3, and our Expanded Access Program for Firdapse®.

- Continue support for our Firdapse® long acting formulation and other development programs.
- Support Canada pre-commercialization activities for Firdapse®.
- Continue Japan regulatory activities to seek marketing authorization for Firdapse®.

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 10, 2020.

Non-GAAP Financial Measures

Excluding expenses related to stock-based compensation of \$1.8 million, non-GAAP¹ net income for the second quarter of 2020 was \$11.6 million, or \$0.11 per basic and diluted share. This compares to a non-GAAP¹ net income of \$11.9 million, or \$0.12 per basic share and \$0.11 per diluted share, excluding stock-based compensation expense of \$925 thousand, for the second quarter of 2019. Excluding expenses related to stock-based compensation of \$3.3 million, non-GAAP¹ net income for the six months ended June 30, 2020 was \$23.5 million, or \$0.23 per basic share and \$0.22 per diluted share. This compares to a non-GAAP¹ net income of \$12.2 million, or \$0.12 per basic and diluted share, excluding stock-based compensation expense of \$1.9 million, for the six months ended June 30, 2019.

Conference Call

Catalyst management will host an investment-community conference call and webcast at 8:30 a.m. ET, tomorrow, Tuesday, August 11, 2020 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 commercial-stage biopharmaceutical company focused on developing and commercializing innovative therapies for people with rare debilitating, chronic

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 income (loss) the expense associated with non-cash stock-based compensation. Non-GAAP income (loss) per share is calculated by dividing non-GAAP income (loss) by the weighted average common shares outstanding.

neuromuscular and neurological diseases, including Lambert-Eaton myasthenic syndrome (LEMS), anti-MuSK antibody positive myasthenia gravis (MuSK-MG) 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 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) the impact of the effects of the COVID-19 pandemic on Catalyst's 2020 net product revenues and on the timeline for reporting the top-line results from Catalyst's SMA Type 3 proof-of-concept study; (ii) whether, even if Catalyst is successful in commercializing Firdapse®, Catalyst will achieve sustained profitability; (iii) the effect on Catalyst's business and future results of operations of the approval by the FDA of Ruzurgi® for the treatment of pediatric LEMS patients (ages 6 to under 17); (iv) whether Catalyst's suit against the FDA seeking to vacate the FDA's approval of Ruzurgi® will be successful; (v) whether Firdapse® will ever be approved for commercialization for the treatment of MuSK-MG, SMA Type 3, or any other disease; (vi) whether Catalyst can successfully commercialize Firdapse® in Canada; (vii) whether Catalyst is able to successfully complete the clinical trial required for Catalyst to seek approval to commercialize Firdapse® for sale in Japan; (viii) whether Catalyst will ever be approved for commercialization in Japan; and (ix) those other factors described in Catalyst's Annual Report on Form 10-K for the fiscal year 2019 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,	
	2020	2019	2020	2019
Product revenue, net	\$ 29,604,764	\$ 28,837,900	\$ 58,741,236	\$ 41,286,338
Operating costs and expenses:				
Cost of sales	4,139,873	4,261,625	8,290,739	5,973,413
Research and development	4,349,643	4,629,364	8,572,454	7,937,323
Selling, general and administrative	10,833,358	8,987,722	20,896,406	17,404,182
Total operating costs and expenses	19,322,874	17,878,711	37,759,599	31,314,918
Operating income (loss)	10,281,890	10,959,189	20,981,637	9,971,420
Other income, net	111,269	450,410	447,502	793,676
Net income (loss) before income taxes	10,393,159	11,409,599	21,429,139	10,765,096
Provision for income taxes	613,172	449,651	1,223,137	449,651
Net income (loss)	<u>\$ 9,779,987</u>	<u>\$ 10,959,948</u>	<u>\$ 20,206,002</u>	<u>\$ 10,315,445</u>
Net income (loss) per share:				
Basic	<u>\$ 0.09</u>	<u>\$ 0.11</u>	<u>\$ 0.20</u>	<u>\$ 0.10</u>
Diluted	<u>\$ 0.09</u>	<u>\$ 0.10</u>	<u>\$ 0.19</u>	<u>\$ 0.10</u>
Weighted average shares outstanding:				
Basic	<u>103,414,523</u>	<u>102,869,202</u>	<u>103,410,881</u>	<u>102,808,897</u>
Diluted	<u>106,730,423</u>	<u>105,928,970</u>	<u>106,433,862</u>	<u>105,098,930</u>

CATALYST PHARMACEUTICALS, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

	<u>June 30, 2020</u> (unaudited)	<u>December 31, 2019</u>
ASSETS		
Current Assets:		
Cash and cash equivalents	\$ 115,052,248	\$ 89,511,710
Short-term investments	—	5,007,050
Accounts receivable, net	6,762,262	10,536,997
Inventory	1,827,924	1,956,792
Prepaid expenses and other current assets	7,521,253	4,351,074
Total current assets	<u>131,163,687</u>	<u>111,363,623</u>
Operating lease right-of-use asset	71,711	793,252
Property and equipment, net	167,514	210,467
Deposits	8,888	8,888
Total assets	<u>\$ 131,411,800</u>	<u>\$ 112,376,230</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	\$ 5,804,778	\$ 4,117,447
Accrued expenses and other liabilities	14,405,597	19,981,295
Total current liabilities	<u>20,210,375</u>	<u>24,098,742</u>
Operating lease liability, net of current portion	—	647,532
Total liabilities	<u>20,210,375</u>	<u>24,746,274</u>
Total stockholders' equity	111,201,425	87,629,956
Total liabilities and stockholders' equity	<u>\$ 131,411,800</u>	<u>\$ 112,376,230</u>