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): November 9, 2020

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 November 9, 2020, the Company issued a press release announcing its results of operations for the three and nine months ended September 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 November 9, 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: November 9, 2020

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

- Firdapse® Third Quarter Net Revenues of $29.2 Million

- Company Ends Third Quarter with $127.1 Million in Cash and Investments

- U.S. Patent Issued for Firdapse® and Expires April 7, 2034

- Firdapse® Approved in Canada in the Third Quarter and Recently Launched

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

CORAL GABLES, Fla., November 09, 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 third quarter ended September 30, 2020 and provided a business update.

“I am pleased to report on a very productive third quarter and on our continued commercial execution under challenging conditions and remain confident that we will continue to see more success as physicians and other providers adapt to this virtual working environment. Also, we are very encouraged by the number of new LEMS patient starts that were initiated over the past 2 months and are hopeful that this is the beginning of a trend,” said Patrick J. McEnany, Chairman and Chief Executive Officer of Catalyst Pharmaceuticals. Mr. McEnany added, “Additionally, during the third quarter we were excited to announce the issuance of our U.S. patent for Firdapse®, which we believe significantly fortifies our intellectual property position. We continue to work diligently alongside partners to protect Firdapse® and to ensure that we are able to advance and make available therapeutics for patients suffering from rare neurological conditions.”

Q3-20 Financial Results

- Product revenue, net in the third quarter of 2020 was $29.2 million, compared to $30.9 million for the third quarter of 2019.
- Operating income for the third quarter of 2020 was $11.7 million, compared to $13.8 million in the third quarter of 2019.
- Reported net income of $43.3 million, or $0.42 per basic and $0.41 per diluted share, in the third quarter of 2020, compared with net income of $13.6 million, or $0.13 per basic and diluted share, for the third quarter of 2019.
- Net income in the third quarter of 2020 includes $31.3 million ($0.30 per basic and $0.29 per diluted share) of benefit from recording of deferred tax asset, upon reversal of valuation allowance.

- Research and development expenses for the third quarter of 2020 were $3.7 million as compared to $4.6 million for the third quarter of 2019.
- Selling, general and administrative expenses for the third quarter of 2020 totaled $10.0 million as compared to $8.1 million in the third quarter of 2019.

Corporate Highlights and Milestones

- U.S. Patent for Firdapse® for "Methods of Administering 3,4-Diaminopyridine" issued.
- District Court's ruling against us in our lawsuit versus the FDA.
- Appeal to the 11th Circuit Court of Appeals has been made in lawsuit versus FDA and court has granted request for an expedited hearing.
- Executed license agreement with KYE Pharmaceuticals to make Firdapse® available to LEMS patients in Canada.
- Launched legal challenge to Health Canada's decision to overlook Firdapse® data exclusivity.
- Actively engaged in evaluation of potential acquisition of products or companies.

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.
- Continuing the evaluation of the data from the MuSK-MG trial to determine the future of the program.
- Firdapse® long-acting formulation development program continues on schedule.
- Proof-of-concept studies for other additional neuromuscular indications are expected to commence in the near future.

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 patient starts, enrollments and revenues.
- We believe that our current base of LEMS patients on reimbursed Firdapse® remains 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 currently 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 September 30, 2020, Catalyst had cash and cash equivalents and investments of $127.1 million and no funded debt.

The Company plans to continue investing in the following key activities in 2020 and 2021:

- 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 November 9, 2020.

Non-GAAP Financial Measures

Excluding expenses related to stock-based compensation of $1.5 million, non-GAAP[1] net income for the third quarter of 2020 was $44.8 million, or $0.43 per basic and $0.42 per diluted share. This compares to non-GAAP[1] net income of $14.4 million, or $0.14 per basic share and $0.13 per diluted share, excluding stock-based compensation expense of $817 thousand, for the third quarter of 2019. Excluding expenses related to stock-based compensation of $4.8 million, non-GAAP[1] net income for the nine months ended September 30, 2020 was $68.3 million, or $0.66 per basic share and $0.64 per diluted share. This compares to a non-GAAP[1] net income of $26.6 million, or $0.26 per basic and $0.25 per diluted share, excluding stock-based compensation expense of $2.7 million, for the nine months ended September 30, 2019.

Conference Call

Catalyst management will host an investment-community conference call and webcast at 8:30 a.m. ET, tomorrow, Tuesday, November 10, 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 neuromuscular and neurological diseases, including Lambert-Eaton myasthenic syndrome (LEMS), anti-MuSK antibody positive myasthenia gravis (MuSK-MG) and spinal muscular atrophy

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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 measures in this press release exclude 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.

(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 commercially available in the United States. Further, Canada's national healthcare regulatory agency, Health Canada, recently approved the use of Firdapse® (amifampridine) for the treatment of patients in Canada with LEMS.

Firdapse® is currently 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.

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 positive cash flow and 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 ultimately be successful; (v) whether Firdapse® will ever be approved for commercialization for the treatment of MuSK-MG, SMA Type 3, or any other disease, and (vi) 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 September 30,		For the Nine Months Ended September 30,	
	2020	2019	2020	2019
Revenues:				
Product revenue, net	$ 29,166,658	$ 30,897,444	$ 87,907,894	$ 72,183,782
Revenues from collaborative arrangements	150,000	—	150,000	—
Total revenues	29,316,658	30,897,444	88,057,894	72,183,782
Operating costs and expenses:				
Cost of sales	3,878,760	4,387,461	12,169,499	10,360,874
Research and development	3,749,233	4,597,039	12,321,687	12,534,362
Selling, general and administrative	9,984,961	8,067,792	30,881,367	25,471,974
Total operating costs and expenses	17,612,954	17,052,292	55,372,553	48,367,210
Operating income (loss)	11,703,704	13,845,152	32,685,341	23,816,572
Other income, net	33,567	393,415	481,069	1,187,091
Net income (loss) before income taxes	11,737,271	14,238,567	33,166,410	25,003,663
Income tax provision (benefit)	(31,602,596)	608,388	(30,379,459)	1,058,039
Net income (loss)	$ 43,339,867	$ 13,630,179	$ 63,545,869	$ 23,945,624
Net income (loss) per share:				
Basic	$ 0.42	$ 0.13	$ 0.61	$ 0.23
Diluted	$ 0.41	$ 0.13	$ 0.60	$ 0.23
Weighted average shares outstanding:				
Basic	103,535,431	102,974,105	103,452,025	102,864,571
Diluted	106,316,241	107,045,234	106,386,617	105,821,609

CATALYST PHARMACEUTICALS, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

	September 30, 2020 (unaudited)	December 31, 2019
ASSETS		
Current Assets:		
Cash and cash equivalents	$117,105,973	$ 89,511,710
Short-term investments	10,002,749	5,007,050
Accounts receivable, net	5,871,893	10,536,997
Inventory	4,747,538	1,956,792
Prepaid expenses and other current assets	5,614,052	4,351,074
Total current assets	143,342,205	111,363,623
Deferred tax assets	31,347,442	—
Operating lease right-of-use asset	12,167	793,252
Property and equipment, net	149,119	210,467
Deposits	8,888	8,888
Total assets	$174,859,821	$112,376,230
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	$ 2,005,340	$ 4,117,447
Accrued expenses and other liabilities	16,226,609	19,981,295
Total current liabilities	18,231,949	24,098,742
Operating lease liability, net of current portion	—	647,532
Total liabilities	18,231,949	24,746,274
Total stockholders' equity	156,627,872	87,629,956
Total liabilities and stockholders' equity	$174,859,821	$112,376,230