November 9, 2016

Catalyst Pharmaceuticals Announces Third Quarter 2016 Financial Results and Provides Corporate Update

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

CORAL GABLES, Fla., Nov. 09, 2016 (GLOBE NEWSWIRE) -- Catalyst Pharmaceuticals, Inc. (Catalyst) (Nasdaq:CPRX), a biopharmaceutical company focused on developing and commercializing innovative therapies for people with rare debilitating diseases, today reported financial results for the third quarter and nine months ended September 30, 2016 and provided a corporate update.

Patrick J. McEnany, Chief Executive Officer of Catalyst stated: "Over the last few months, we have continued to execute our development strategy for Firdapse® (amifampridine phosphate) and further our mission to serve the LEMS and CMS patient communities. We were pleased by our recent receipt of a Special Protocol Assessment agreement with the FDA for the protocol design, clinical endpoints, and statistical analysis approach to be taken in our upcoming, second Phase 3 study evaluating Firdapse for the symptomatic treatment of LEMS. We believe that our receipt of the SPA provides us with a clearly defined development and regulatory pathway to complete the development of this product. We were also gratified to have been granted orphan drug designation for Firdapse for the treatment of myasthenia gravis. Finally, we have launched our new website to make it easier for patients to access information about obtaining Firdapse at no cost through our expanded access program, which is another step in our continuing efforts to serve LEMS and CMS patients."

Q3 and Recent Highlights

- Reached agreement on a Special Protocol Assessment (SPA) with the FDA for second phase 3 clinical trial evaluating Firdapse for the treatment of Lambert-Eaton myasthenic syndrome (LEMS)
- Firdapse granted orphan drug designation by the FDA for the treatment of myasthenia gravis
- Launched new website for its expanded access program
- Publication of CPP-115 Clinical Efficacy Data for Infantile Spasms in *Epilepsy & Behavior Case Reports*
- Ended Q3-2016 with $44.7 million in cash and investments and no debt

Upcoming 2016 Milestones

- Initiate the second Phase 3 trial for Firdapse to treat LEMS
- Continue to activate new sites and recruit patients for the study evaluating Firdapse in the treatment of patients with congenital myasthenic syndromes (CMS)
- Continue to support an investigator-sponsored study evaluating Firdapse for the treatment of MuSK antibody positive myasthenia gravis
- Ongoing development of generic equivalent of Sabril® (vigabatrin)

Financial Results

For the quarter ended September 30, 2016, Catalyst reported a GAAP net loss of $3,953,981 or 5 cents per basic and diluted share, compared to a GAAP net loss of $4,449,038 or 5 cents per basic and diluted share, for the same period in 2015. Excluding non-cash expense of $106,948 attributable to the change in fair value of liability-classified warrants, non-GAAP[1] net loss was $3,847,033 or 5 cents per basic and diluted share for the third quarter of 2016. In comparison, non-GAAP[1] net loss for the third quarter of 2015 was $4,970,769 or 6 cents per basic and diluted share, which excludes non-cash gain of $521,731 attributable to the change in fair value of liability-classified warrants.

For the nine months ended September 30, 2016, Catalyst reported a GAAP net loss of $13,909,132 or 17 cents per basic and diluted share, compared to a GAAP net loss of $14,417,800 or 18 cents per basic and diluted share, for the same period in 2015. Excluding non-cash gain of $779,191 attributable to the change in fair value of liability-classified warrants, non-GAAP[1] net loss was $14,688,323 or 18 cents per basic and diluted share for the nine months ended September 30, 2016. In comparison, non-GAAP[1] net loss for the first nine months of 2015 was $14,093,209 or 18 cents per basic and diluted share, which excludes non-cash expense of $324,591 attributable to the change in fair value of liability-classified warrants.

Research and development expenses for the third quarter of 2016 were $2,493,999 compared to $3,042,671 in the third quarter of 2015. For the nine months ended September 30, 2016 research and development expenses were $8,549,287 compared to $7,969,731 in the same period in 2015. Research and development expenses for the first nine months of 2016 increased when compared to the same period in 2015 due primarily to consulting fees paid on regulatory matters, activities related to the Firdapse expanded access program, including manufacturing of related drug, and costs relating to our studies and trials. We expect that costs related to research and development activities will continue to be substantial throughout the balance of 2016 and into 2017.

General and administrative expenses for the third quarter of 2016 totaled $1,420,015 compared to $1,974,757 in the third quarter of 2015. For the nine months ended September 30, 2016 general and administrative expenses were $6,416,715 as compared to $6,236,942 in the same period in 2015. General and administrative expenses for the first nine months of 2016 increased when compared to the same period in 2015 primarily due to increases in pre-commercialization expenses, payroll and benefits expenses during the first half of 2016, including approximately $600,000 for severance costs related to the reduction-in-force that occurred in May 2016, partly offset by our initiatives to conserve cash. We expect general and administrative expenses during the remainder of 2016 to be consistent with general and administrative expenses during the third quarter of 2016.

As a development-stage specialty pharmaceutical company, Catalyst had no revenues in either the third quarter of 2016 or the third quarter of 2015.

At September 30, 2016, Catalyst had cash and cash equivalents, certificates of deposit and short-term investments of $44.7 million and no debt. Catalyst believes that these resources give it sufficient runway for at least the next year. However, until Catalyst finalizes the details and logistics of its required confirmatory study evaluating Firdapse for the treatment of LEMS, it will be difficult for Catalyst to provide more details regarding how far its existing resources will take it. Notwithstanding, and while there can be no assurance, Catalyst continues to believe that its currently available resources will be sufficient to complete the development of Firdapse and get us to an accepted NDA submission for Firdapse without the need for additional financing.

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), November 9th, 2016.

[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 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.

Conference Call

Catalyst management will host an investment-community conference call and webcast at 8:30 a.m. EST on Thursday, November 10, 2016 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 diseases, including Lambert-Eaton myasthenic syndrome (LEMS), congenital myasthenic syndromes (CMS), infantile spasms, and Tourette's Disorder. Firdapse® for the treatment of LEMS has received Breakthrough Therapy Designation from the U.S. Food and Drug Administration (FDA) 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 infantile spasms, epilepsy and other neurological conditions associated with reduced GABAergic signaling, like post-traumatic stress disorder and Tourette's Disorder. 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 whether the receipt of breakthrough therapy designation for Firdapse will expedite the development and review of Firdapse by the FDA or the likelihood that the product will be found to be safe and effective, the timing on Catalyst's second trial evaluating Firdapse for the treatment of LEMS and whether the trial will be successful, whether Catalyst's assumptions in its updated business plan will be accurate and the impact of unanticipated events or delays in projected activities on Catalyst's cash requirements and on Catalyst's ability to get to an accepted NDA submission for Firdapse without the need for additional funding, what clinical trials and studies will be required before Catalyst can resubmit an NDA for Firdapse for the treatment of CMS and whether any such required clinical trials and studies will be successful, whether the investigator-sponsored study evaluating Firdapse for the treatment of MuSK-MG will be successful, whether any NDA for Firdapse resubmitted to the FDA will ever be accepted for filing, the timing of any such NDA filing or acceptance, whether, if an NDA for Firdapse is accepted for filing, such NDA will be given a priority review by the FDA, whether Firdapse will ever be approved for commercialization, whether Catalyst will be the first company to receive approval for amifampridine (3,4-DAP), giving it 7-year marketing exclusivity for its product, whether CPP-115 will be determined to be safe for humans, what additional testing will be required before CPP-115 is "Phase 2 ready", whether CPP-115 will be determined to be effective for the treatment of infantile spasms, post-traumatic stress disorder, Tourette's Disorder or any other indications, whether Catalyst can successfully design and complete a bioequivalence study of its version of vigabatrin compared to Sabril that is acceptable to the FDA, whether any such bioequivalence study the design of which is acceptable to the FDA will be successful, whether any ANDA that Catalyst submits for a generic version of Sabril will be accepted for filing, whether any ANDA for Sabril accepted for filing by the FDA will be approved (and the timing of any such approval), whether any of Catalyst's product candidates will ever be approved for commercialization or successfully commercialized, and those other factors described in Catalyst's Annual Report on Form 10-K for the fiscal year 2015 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.

CATALYST PHARMACEUTICALS, INC.
STATEMENTS OF OPERATIONS (unaudited)

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2016	**2015**	**2016**	**2015**
Operating costs and expenses:				
Research and development	$ 2,493,999	$ 3,042,671	$ 8,549,287	$ 7,969,731
General and administrative	1,420,015	1,974,757	6,416,715	6,236,942
Total operating costs and expenses	3,914,014	5,017,428	14,966,002	14,206,673
Loss from operations	(3,914,014)	(5,017,428)	(14,966,002)	(14,206,673)
Other income, net	66,981	46,659	277,679	113,464
Change in fair value of warrants liability	(106,948)	521,731	779,191	(324,591)
Loss before income taxes	(3,953,981)	(4,449,038)	(13,909,132)	(14,417,800)
Provision for income taxes	-	-	-	-
Net loss	$ (3,953,981)	$ (4,449,038)	$(13,909,132)	$(14,417,800)
Net loss per share - basic and diluted	$ (0.05)	$ (0.05)	$ (0.17)	$ (0.18)
Weighted average shares outstanding - basic and diluted	82,870,649	82,470,139	82,867,140	80,205,864

CATALYST PHARMACEUTICALS, INC.
CONDENSED BALANCE SHEETS

	September 30, 2016	December 31, 2015
	(unaudited)	
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 17,638,100	$ 28,235,016
Certificates of deposit	568,031	3,717,229

Short-term investments	26,538,304	26,444,150
Prepaid expenses and other current assets	310,855	1,504,738
Total current assets	45,055,290	59,901,133
Property and equipment, net	249,038	191,549
Deposits	8,888	8,888
Total assets	$ 45,313,216	$ 60,101,570
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	$ 1,055,324	$ 1,794,127
Accrued expenses and other liabilities	940,271	1,646,476
Total current liabilities	1,995,595	3,440,603
Accrued expenses and other liabilities, non-current	185,095	176,293
Warrants liability, at fair value	229,172	1,008,363
Total liabilities	2,409,862	4,625,259
Total stockholders' equity	42,903,354	55,476,311
Total liabilities and stockholders' equity	$ 45,313,216	$ 60,101,570

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