# **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 1, 2012

# CATALYST PHARMACEUTICAL PARTNERS, INC.

(Exact Name Of Registrant As Specified In Its Charter) 001-33057

(Commission File Number)

Delaware (State or other jurisdiction of incorporation)

> 355 Alhambra Circle Suite 1500 Coral Gables, Florida

(Address of principal executive offices)

Registrant's telephone number, including area code:

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 CFR240.14d-2(b))

Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c)) 

(I.R.S. Employer Identification No.)

76-0837053

33134 (Zip Code)

(305) 529-2522

#### Item 7.01 Regulation FD Disclosure

On November 1, 2012, the Company posted on its website "Frequently Asked Questions" ("FAQ") regarding the Company's recently announced strategic collaboration with BioMarin Pharmaceutical, Inc. and the Company's licensing of the North American rights for Firdapse<sup>™</sup>. The FAQ is furnished as Exhibit 99.1 to this Form 8-K and is incorporated herein by reference.

The information in Item 7.01 of this Current Report on Form 8-K, including the FAQ attached as Exhibit 99.1 hereto, shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities under that Section. The information in Item 7.01 of this Current Report shall not be incorporated by reference into any filing or other document pursuant to the Securities Act of 1933, as amended, or the Exchange Act except as shall be expressly set forth by specific reference in such filing or document.

### Item 9.01 Financial Statements and Exhibits.

- (c) <u>Exhibits</u>
- 99.1 Information posted on Company's website on November 1, 2012

# 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 Pharmaceutical Partners, Inc.**

By: /s/ Alicia Grande

Alicia Grande Vice President, Treasurer and CFO

Dated: November 1, 2012

#### CATALYST PHARMACEUTICAL PARTNERS, INC.

# FREQUENTLY ASKED QUESTIONS REGARDING FIRDAPSE AND THE COLLABORATION BETWEEN CATALYST AND BIOMARIN PHARMACEUTICAL, INC. TO DEVELOP FIRDAPSE FOR COMMERCIALIZATION IN NORTH AMERICA

#### NOVEMBER 1, 2012

On October 31, 2012, Catalyst Pharmaceutical Partners, Inc. ("Catalyst") issued a press release announcing that it had entered into a strategic collaboration for the rights to Firdapse<sup>™</sup> in North America with BioMarin Pharmaceutical, Inc. ("BioMarin"). The key components of the collaboration include Catalyst licensing the exclusive North American rights to Firdapse and BioMarin making a \$5 million investment in Catalyst to rapidly advance the Firdapse program in the United States. For more details about the collaboration, see Catalyst's Current Report on Form 8-K filed with the U.S. Securities and Exchange Commission ("SEC") on October 31, 2012. Further, since this FAQ includes forward-looking statements, see "Special Note Regarding Forward-Looking Statements" at the end of this FAQ.

The following frequently asked questions provide additional information to the market responsive to several questions that analysts and market participants have asked Catalyst following up on the issuance of the press release.

#### What is Firdapse? What is Lambert-Eaton Myasthenic Syndrome?

Firdapse is amifampridine phosphate or 3,4-diaminopyridine phosphate (3,4-DAP). It has received an orphan drug designation in the U.S. and orphan medicinal product designation in the European Union for the treatment of Lambert-Eaton Myasthenic Syndrome ("LEMS").

LEMS is an autoimmune neuromuscular disease in which the release of acetylcholine is decreased at the neuromuscular junction, resulting in muscle weakness. Firdapse, acting through another mechanism, increases acetylcholine release, thus relieving this weakness.

Patients with LEMS typically present with fatigue, muscle pain and stiffness that is generally more marked in the proximal muscles, most often of the legs and trunk. Other symptoms may include reduced reflexes, drooping eyelids, facial weakness and swallowing problems. Patients often report a dry mouth, impotence, constipation and light headedness on standing. On occasion, these problems can be life threatening when the weakness involves respiratory muscles. Around 50% of those with LEMS have an underlying malignancy, most commonly small cell lung cancer. LEMS is therefore regarded as a paraneoplastic syndrome (a condition that arises as a result of cancer elsewhere in the body).

#### What is the North American prevalence for LEMS?

The total population for North American countries is around 465 million, including the U.S. (315 million), Canada (35 million) and Mexico (115 million).

Orphanet and the British Medical Journal estimate the prevalence of LEMS at 1 per 100,000 in population. Therefore, there are an estimated 4,650 LEMS patients in North America (U.S.—3,150; Canada—350 and Mexico—1,150).

#### What are BioMarin's Firdapse European revenues?

BioMarin has reported that its sales of Firdapse in Europe were \$6.4 million in 2010, \$13.1 million in 2011, and \$10.8 million for the first three quarters of 2012. An analyst report on BioMarin published in 2012 by Citicorp ("Citi") estimated BioMarin's Firdapse EU revenues aggregating \$16M in 2012, growing to \$50M by 2017. Citi's estimated range of associated net present value (NPV) for BioMarin's "Firdapse" business in Europe, which varies by discount rate assumptions, is between \$70 million and \$100 million.

Catalyst believes that the reason for the limited Firdapse sales in the EU to date by BioMarin is compounding pharmacy competition, reimbursement issues and the fact that this product has not been actively promoted by BioMarin as a result of other product priorities. Catalyst does not expect to face these challenges in North America.

#### Why did BioMarin out-license Firdapse for North America?

Citi estimates total BioMarin revenues of \$487 million in 2012, growing to \$822 million by 2015. Given this increase in real dollar growth as opposed to percentage revenue growth, Catalyst believes that Firdapse, with its significant but smaller potential market size, increasingly became a lower priority for BioMarin. Catalyst believes that BioMarin felt that placing Firdapse with a smaller specialty pharmaceutical company focused on CNS orphan drugs would help to maximize the product's success in North America.

#### Why did Catalyst in-license Firdapse for North America?

Catalyst is focused on diseases and disorders of the central nervous system, and increasingly CNS orphan drugs. Catalyst's lead program, CPP-109, is targeting various addictions and Tourette's Disorder, which is a CNS orphan indication. Catalyst's other program, CPP-115, will target addiction, infantile spasms/West Syndrome (also a CNS orphan indication) and/or refractory complex partial seizures. Firdapse is a strategic fit with Catalyst's CNS orphan drug focus, but is also in Phase III development, so it represents a late-stage opportunity as Catalyst advances toward becoming a commercial-stage company.

## What is the potential market opportunity for Firdapse in North America?

Assuming the North American market is similar to the EU market on LEMS prevalence, Firdapse adoption and Firdapse pricing, Catalyst believes that the potential revenue opportunity in the North American market for Firdapse could ultimately be about \$50 million annually. Potential upside to the North American market estimate could be driven by more favorable pricing in the U.S. than the EU, and possible expansion into Myasthenia Gravis (U.S. prevalence of 60,000) and/or Congenital Myasthenic Syndrome (U.S. prevalence of 1,500), both of which are also CNS orphan markets.

# What is the design of the U.S. clinical trial for Firdapse, including primary endpoint(s), secondary endpoint(s), targeted enrollment and timing, among other key factors?

The trial is designed as a randomized, double-blind, placebo-controlled, discontinuation trial in approximately 30 LEMS patients. After patients have been treated with amifampridine for at least 91 days, they are randomly assigned to either continue on amifampridine or be discontinued to placebo over a 2-week period. They are then returned to open label amifampridine treatment for a 2-year follow-up period. The primary endpoint is change in muscle strength during the discontinuation period as determined using a validated questionnaire (Quantitative Myasthenia Gravis score). The secondary endpoint is change in walking speed (Timed 25-foot walking test) during a 2-week, double-blind testing period. The trial is ongoing at approximately 10 sites in the U.S. and Europe. Further details regarding the trial and its design can be found on www.clinicaltrials.gov (NCT01377922).

Based on input received from the U.S. Food and Drug Administration ("FDA") at a pre-IND meeting and its subsequent review of the protocol, data from this single Phase III trial will be sufficient to support approval of Firdapse as a treatment for LEMS.

#### What is Firdapse's exclusivity and IP position in North America?

The FDA granted orphan drug designation for Firdapse on November 12, 2009. Orphan drugs in the U.S. are granted a seven-year period of marketing exclusivity from the date of drug approval, and, if Catalyst is the first to obtain approval of the product in the U.S., it expects to receive seven year marketing exclusivity for Firdapse for LEMS.

In addition, no drug product containing amifampridine for any indication has been approved by the FDA. Therefore, Catalyst's amifampridine, if it is the first to obtain approval of the product in the U.S., will also be eligible for five-year new chemical entity exclusivity, which provides a five-year period of marketing exclusivity for all indications.

There is a pending composition of matter patent that, if issued, will protect Firdapse until February, 2027, which includes five years of patent term extension that is expected under the Patent Term Restoration Act. Catalyst may also pursue other patents in order to seek to protect the exclusivity of the drug.

#### Are there other companies developing amifampridine (3,4-DAP) for the treatment of LEMS?

Catalyst believes that Firdapse is the only version of amifampridine phosphate (3,4-DAP) in Phase III trials for LEMS. However, Catalyst is aware that another pharmaceutical company is conducting a Phase II clinical trial in the U.S. for its version of amifampridine (3,4-DAP) for the treatment of LEMS.

#### What is the Firdapse development cost and timeline?

Catalyst expects to spend about \$17 million to complete all of the remaining development activities needed to file an NDA for Firdapse. The pivotal Phase III trial is already in progress and Catalyst expects to complete the trial and other development activities

to file the NDA in approximately 24 months. A pre-IND meeting was held with the FDA regarding the development program, and the tasks that must be completed in order to file an NDA have been vetted with the FDA. Catalyst is initially targeting the second half of 2015 for approval.

Catalyst will also be obligated to pay certain milestone payments upon acceptance of a filing of an NDA for Firdapse for the treatment of LEMS and upon the unconditional approval by the FDA of an NDA for Firdapse for the treatment of LEMS.

#### Will Catalyst need to raise more capital?

Like most public life science companies in the research and development stage that do not have approved products in the market generating revenues, profits and incremental cash flows, Catalyst funds its operations through equity offerings, as well as grants and other non-dilutive financing. As Catalyst has done in the past, it expects to be opportunistic in raising capital in the equity markets to support its ongoing operations, including the costs of developing Firdapse.

#### What is the conversion price range for the conversion of the \$5 million investment that BioMarin has made into Catalyst?

On October 26, 2012, BioMarin invested \$5 million into Catalyst. Initially, such amount is being treated as a loan to Catalyst. However, the amount of the loan shall automatically convert into shares of Catalyst's authorized but unissued common stock on the earlier of: (i) March 31, 2013, or (ii) the date that is thirty (30) days after Catalyst publicly releases top-line data from its Phase II(b) clinical trial evaluating the use of its product candidate, CPP-109, for the treatment of cocaine addiction. The conversion price of the shares of common stock to be acquired by BioMarin upon conversion of its \$5 million investment will be the "dollar weighted average price" of Catalyst's common stock for the fifteen (15) business day period prior to the conversion date, multiplied by 0.9, *provided, however*, that the conversion price shall not be less than \$0.75 per share or more than \$2.50 per share. If the conversion of BioMarin's investment into shares of Catalyst's outstanding common stock were to take place today, BioMarin would own between 5.4% (at the high end) and 16.1% (at the low end) of Catalyst's outstanding common stock.

### What is the rationale for the conversion price range?

Typically, when in-licensing products, the licensee makes an up-front cash payment. No such payment was made by Catalyst as part of this arrangement. Catalyst believes that the high side of the collar on the conversion price reflects BioMarin's seeking of an upside from their investment in lieu of an up-front cash payment.

#### Why did Catalyst complete this transaction at this time?

Catalyst's Board of Directors and management believe that the opportunity to license the North-American rights to a late-stage orphan drug such as Firdapse is a transformative event and a strategic fit for Catalyst, adding substantially to Catalyst's opportunities for long term growth and success.

#### **Special Note Regarding Forward-Looking Statements**

These FAQs contain "forward-looking statements" within the meaning of the Securities Exchange Act of 1934, as amended. Forward-looking statements are identified by words such as "believe," "anticipate," "expect," "intend," "plan," "will," "may" and other similar expressions. In addition, any statements that refer to expectations or other characterizations of future events or circumstances are forward-looking statements. Catalyst based these forward-looking statements on management's current expectations about future events.

All forward-looking statements involve risks and uncertainties. Some of the forward-looking statements found in these FAQs include the projected ultimate revenues from sales of Firdapse in North America and the projected development costs of Firdapse. There can be no assurance that the estimate of development costs for Firdapse will prove to be accurate, that Catalyst will be able to raise amounts required to fund such product development efforts, to pay required milestone payments, as well as to pay the costs of developing its other product candidates and the costs of operating its business, or, if Catalyst is successful in commercializing Firdapse in North America, as to the revenues from sales of such product that Catalyst will ultimately be able to achieve. Further, there can be no assurance that Catalyst will ever be able to obtain approval of an NDA for Firdapse (or as to the timing of any such approval), will be the first to obtain approval of its version of amifampridine for the treatment of LEMS in the United States (and thereby obtain the seven-year marketing exclusivity granted to orphan drugs in the U.S.), will ever be able to commercialize Firdapse in the United States or whether patent protection for Firdapse in the United States will be available. Such factors could adversely affect Catalyst's future business, financial condition and results of operations. Catalyst's future business will also be affected by the risk and other factors set forth in Catalyst's filings with the SEC, including its Annual Report on Form 10-K for the year ended December 31, 2011, its Quarterly Report on Form 10-Q for the quarter and six months ended June 30, 2012, and its Current Report on Form 8-K that was filed on October 31, 2012 reporting on its collaboration with BioMarin for Firdapse.

The forward-looking statements contained in these FAQs reflect Catalyst's current beliefs based upon information now available, and Catalyst assumes no obligation to update any of the forward-looking statement contained herein.