# 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): October 26, 2012

## CATALYST PHARMACEUTICAL PARTNERS, 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 1500 Coral Gables, Florida (Address of principal executive offices)

33134 (Zip Code)

Registrant's telephone number, including area code: (305) 529-2522

Not Applicable

Former Name or Former address, if changed since last report

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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))

## Item 1.01 Entry Into a Material Definitive Agreement

On October 26, 2012, Catalyst Pharmaceutical Partners, Inc. (the "Company") entered into a strategic collaboration with BioMarin Pharmaceutical Inc. ("BioMarin") for Firdapse<sup>TM</sup> ("Firdapse<sup>TM</sup> or the "Product"), a Phase III orphan drug for the treatment of Lambert-Eaton Myasthenic Syndrome ("LEMS"), which is a rare, debilitating and sometimes fatal autoimmune disease with the primary symptoms of muscle weakness. The key components of the collaboration include Catalyst licensing the exclusive North American rights to the Product pursuant to the terms of a License Agreement, dated as of October 26, 2012, between the Company and BioMarin (the "License Agreement") and BioMarin making a \$5,000,000 investment in the Company pursuant to the terms of a Convertible Promissory Note and Note Purchase Agreement, dated as of October 26, 2012, between the Company and BioMarin (the "Investment Agreement") to rapidly advance the development of Firdapse<sup>TM</sup> in the United States.

## Investment Agreement

On October 26, 2012, the Company and BioMarin entered into the Investment Agreement pursuant to which BioMarin has invested \$5,000,000 into the Company. Initially, such amount shall be treated as a loan to the Company. However, the amount of the loan shall automatically convert into shares of the Company's authorized but unissued common stock on the earlier of: (i) March 31, 2013, or (ii) the date that is thirty (30) days after the Company 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 Date"), except in certain limited circumstances as more particularly described below and in the Investment Agreement. As previously reported, the Company currently expects to be in a position to release the top-line data from its Phase II(b) clinical trial during the first half of November 2012. The conversion price of the shares of the Company's common stock to be acquired by BioMarin upon conversion of its \$5 million investment in the Company will be the "dollar weighted average price" (as defined in the Investment Agreement) of the Company'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.

The Investment Agreement also provides that the Company will use the \$5 million solely for the purpose of developing the Product and that for such period that BioMarin owns more than 10% of the Company's outstanding common stock, BioMarin will exclusively use the exemption from registration provided under Rule 144 to make sales of the Company shares acquired in the investment transaction. The Company also agreed in the Investment Agreement not to make certain asset sales or sales of the Company's securities during the period between the date of the Investment Agreement and the Conversion Date without the prior written consent of BioMarin. Finally, the Investment Agreement provides that the Company is obligated to repay the \$5 million to BioMarin, with interest, if an "event of default" (as defined in the Investment Agreement) occurs prior to the conversion of the loan amount into shares of the Company's common stock.

The foregoing description of the Investment Agreement is qualified in its entirety by reference thereto. A copy of the Investment Agreement is Exhibit 10.1 to this Current Report on Form 8-K, and is incorporated fully herein by this reference.

The Product and Development Plans for the Product in the United States

Firdapse<sup>TM</sup> is a proprietary form of 3,4-diaminopyridine (amifampridine phosphate), or 3,4-DAP, for the treatment of LEMS. BioMarin acquired the rights to Firdapse<sup>TM</sup> in October 2009 as a result of its acquisition of Huxley Pharmaceuticals, Inc. ("Huxley"). Firdapse<sup>TM</sup> was granted marketing approval in the European Union ("EU") in December 2009, which, because Firdapse<sup>TM</sup> had previously been granted orphan medicinal product designation in the EU, included ten year marketing exclusivity in the EU. BioMarin will continue to sell Firdapse<sup>TM</sup> in the EU following this transaction.

Pursuant to the License Agreement, the Company will license the rights to Firdapse<sup>TM</sup> in North America. At present, BioMarin is conducting a Phase III clinical trial of Firdapse<sup>TM</sup> (the "Phase III Trial"), which trial will be transferred to and continued by the Company pursuant to the License Agreement. The Phase III Trial began in the second quarter of 2011 and is a double-blind, placebo-controlled randomized discontinuation study followed by an open-label extension period in approximately 30 patients across 10 sites in the U.S. and Europe. The primary objective of the trial is to evaluate the efficacy and safety, including the long-term safety, of Firdapse<sup>TM</sup>. The primary endpoint is a change from baseline in the Quantitative Myasthenia Gravis score at 14 days and the secondary endpoint is change from baseline in the timed 25-foot walk test at 14 days. At present, the Company expects to complete the double-blind treatment portion of the Phase III trial in the second half of 2014.

The U.S. Food and Drug Administration ("FDA") has previously granted orphan drug designation to Firdapse<sup>TM</sup> for the treatment of LEMS, which means that if the Company is the first to obtain approval of the Product in the United States, it will be eligible to obtain seven year marketing exclusivity in the United States.

LEMS is a rare autoimmune disease with the primary symptoms of muscle weakness. The muscle weakness in LEMS is caused by autoantibodies to voltage gated calcium channels leading to a reduction in the amount of acetylcholine released from nerve terminals. The prevalence of LEMS is estimated at approximately 3,000 patients in the United States and Canada. Approximately 50 percent of LEMS patients diagnosed have small cell lung cancer. Patients with LEMS typically present with fatigue, muscle pain and stiffness. The weakness is generally more marked in the proximal muscles, particularly of the legs and trunk. Other problems include reduced reflexes, drooping of the eyelids, facial weakness and problems with swallowing. Patients often report dry mouth, impotence, constipation and feelings of light headedness on standing. These problems can be life threatening when the weakness involves respiratory muscles. A diagnosis of LEMS is generally made on the basis of clinical symptoms, electromyographic testing and the presence of autoantibodies against voltage gated calcium channels.

There are no approved drugs in the United States for the treatment of LEMS. Current options rely on intravenous immunoglobulin, plasmapheresis and/or immuno suppressant drugs. Firdapse<sup>TM</sup> is the only version of amifampridine phosphate (3,4-DAP) in Phase III trials for LEMS. However, the Company believes 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.

While the Company's initial efforts will be on seeking the approval of Firdapse<sup>TM</sup> for the treatment of LEMS in the United States, the Company also intends to explore other potential orphan central nervous system indications for Firdapse<sup>TM</sup>, such as Myasthenia Gravis and Congenital Myasthenic Syndrome.

### License Agreement

On October 26, 2012, the Company and BioMarin entered into the License Agreement pursuant to which the Company licensed the North American rights to the Product. As part of the License Agreement, the Company will take over the Phase III Trial and will be obligated to use its diligent efforts to seek to obtain regulatory approval for and to commercialize the Product in the United States. The Company is obligated to use diligent efforts to complete the double-blind treatment phase of the Phase III trial within 24 months of entering into the License Agreement, and BioMarin has the right to terminate the License Agreement if such treatment phase has not been completed in such 24-month period (unless the Company is using diligent effort to pursue the completion of such treatment phase and has spent at least \$5 million in connection with the conduct of the Phase III Trial during such 24 month period). The Company currently anticipates that the remaining development program costs required to file a New Drug Application ("NDA") for the Product will be approximately \$17 million.

Under the License Agreement, the Company has agreed to make: (i) certain royalty payments to BioMarin based on the Company's net sales in North America; (ii) certain royalty payments to a third-party licensor of the rights being sublicensed to the Company based on the Company's net sales in North America, and (iii) certain milestone payments to such third-party licensor and to the former stockholders of Huxley that BioMarin is obligated to make (which milestone payments are due, in part, upon acceptance by the FDA of a filing of an NDA for Firdapse™ for the treatment of LEMS, and, in part, on the unconditional approval by the FDA of an NDA for Firdapse™ for the treatment of LEMS). The Company has also agreed to share in the cost of certain postmarketing studies that are being conducted by BioMarin if such studies are required as a condition for approval of the Product by the FDA.

The Company is submitting, simultaneously with the filing of this Form 8-K a FOIA Confidential Treatment Request to the Securities and Exchange Commission pursuant to Rule 24b-2 under the Securities Exchange Act of 1934, as amended, requesting that it be permitted to redact certain portions of the License Agreement. The omitted material will be included in the request for confidential treatment.

The foregoing description of the License Agreement is qualified in its entirety by reference to the License Agreement. A redacted copy of the License Agreement is attached as Exhibit 10.2 to this Current Report on Form 8-K.

## **Item 3.02 Unregistered Sales of Equity Securities**

The information set forth in Item 1.01 of this Current Report on Form 8-K relating to the Agreement is incorporated by reference into this Item 3.02 in its entirety.

## **Item 8.01 Other Events**

On October 31, 2012, the Company and BioMarin issued a press release announcing that they had entered into the License Agreement and the Investment Agreement. A copy of the press release is attached as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

## Item 9.01 Financial Statements and Exhibits.

- (d) Exhibits
- 10.1 Convertible Promissory Note and Note Purchase Agreement, dated as of October 26, 2012, between BioMarin Pharmaceutical, Inc. and Catalyst Pharmaceutical Partners, Inc.
- 10.2 License Agreement, dated as of October 26, 2012, between BioMarin Pharmaceutical, Inc. and Catalyst Pharmaceutical Partners, Inc.
- 99.1 Press release issued by the Company and BioMarin on October 31, 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: October 31, 2012

THIS NOTE AND THE SHARES OF COMMON STOCK ISSUABLE UPON CONVERSION HEREOF HAVE NOT BEEN REGISTERED OR QUALIFIED UNDER THE SECURITIES ACT OF 1933, AS AMENDED, OR APPLICABLE STATE SECURITIES LAWS. THESE SECURITIES ARE SUBJECT TO RESTRICTIONS ON TRANSFERABILITY AND RESALE AND THEY MAY NOT BE SOLD, OFFERED FOR SALE, PLEDGED, HYPOTHECATED, OR OTHERWISE TRANSFERRED EXCEPT PURSUANT TO REGISTRATION, QUALIFICATION OR EXEMPTION UNDER THE SECURITIES ACT OF 1933, AS AMENDED, AND APPLICABLE STATE SECURITIES LAWS.

## **CONVERTIBLE PROMISSORY NOTE AND NOTE PURCHASE AGREEMENT**

Principal Amount: \$5,000,000.00 Effective Date: As of October 26, 2012

## 1. Terms.

- 1.1 <u>Agreement of the Parties</u>. The parties hereby enter into this Convertible Promissory Note and Note Purchase Agreement ("<u>Agreement</u>") for the purpose of evidencing their agreement with respect to the matters set forth herein. Pursuant to this Agreement, **BioMarin Pharmaceutical, Inc.**, a Delaware corporation ("<u>BioMarin</u>") is lending \$5,000,000 to **Catalyst Pharmaceutical Partners, Inc.**, a Delaware corporation (the "<u>Company</u>") on the Effective Date, which amount is being evidenced by this Agreement. Further, BioMarin has agreed, unless an Event of Default has occurred prior to the Conversion Date, to the automatic conversion of the Principal Amount (defined below) into shares of the Company's authorized but unissued common stock (the "<u>Common Stock</u>") on the Conversion Date (defined below), all in the manner set forth herein. Finally, this Agreement is being entered into simultaneously with that certain **License Agreement**, of even date herewith, between the parties, which relates to the future product development and licensing of the pharmaceutical product "Firdapse". Together, this Agreement and the License Agreement reflect the complete agreement of the parties.
- 1.2 <u>The Note</u>. For value received, the Company, hereby promises to pay to BioMarin, the principal amount of **FIVE MILLION AND NO/100 (\$5,000,000) DOLLARS** ("<u>Principal Amount</u>") without interest, on or before March 31, 2013 ("<u>Maturity Date</u>"), as more particularly set forth in Article II of this Agreement.
- 1.3 <u>Maturity</u>. On the Maturity Date, the Principal Amount shall automatically convert into shares of the Company's authorized but unissued common stock, par value \$0.001 per share (the "<u>Common Stock</u>") in the manner set forth in Section 2.1 below. Unless an Event of Default has occurred prior to the Conversion Date, the Principal Amount shall never be payable in cash.
- 1.4 <u>No Prepayment</u>. The Principal Amount may not be prepaid, in whole or in part, at any time by the Company except in accordance with the provisions of Section 9.2.

### 2. Conversion.

2.1 <u>Automatic Conversion</u>. The Principal Amount shall automatically be converted into a number of shares of Common Stock (the "<u>Conversion Shares</u>") determined by dividing the Principal Amount then outstanding (the "<u>Conversion Amount</u>") by the Conversion Price (as defined in Section 2.2 below) on the earlier of: (a) thirty (30) days after announcement by the

Company of the top-line data from the Company's Phase II(b) clinical trial evaluating the use of CPP-109 (the Company's formulation of vigabatrin, a GABA aminotransferase inhibitor) for the treatment of cocaine addiction (currently expected during the first half of November 2012), or (b) March 31, 2013. The date on which the Conversion Amount shall automatically convert into the Conversion Shares shall be referred to as the "Conversion Date."

- 2.2 "Conversion Price" shall mean the "dollar weighted average price" of the 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. For purposes of this Section 2.2, the term "dollar weighted average price of the Common Stock" means the "dollar volume-weighted average price" for the Common Stock on the NASDAQ Capital Market (the "Principal Market") during the period beginning at 9:30:01 a.m., New York time (or such other time as the Principal Market publicly announces is the official open of trading), and ending at 4:00:00 p.m., New York time (or such other time as the Principal Market publicly announces is the official close of trading), over the applicable fifteen (15) business day period, as reported by Bloomberg through its "Volume at Price" function or, if the foregoing does not apply, the "dollar volume-weighted average price" of the Common Stock in the over-the-counter market on the electronic bulletin board for such security during the period beginning at 9:30:01 a.m., New York time (or such other time as the Principal Market publicly announces is the official open of trading), and ending at 4:00:00 p.m., New York time (or such other time as the Principal Market publicly announces is the official close of trading), over the applicable fifteen (15) business day period, as reported by Bloomberg, or, if no "dollar volume-weighted average price" is reported for such security by Bloomberg for such hours, the average of the highest closing bid price and the lowest closing ask price of any of the market makers for such security, over the applicable fifteen (15) business day period, as reported in the "pink sheets" by OTC Markets LLC. If the "dollar weighted average price" of the Common Stock cannot be calculated for such security on such date on any of the foregoing bases, the "dollar weighted average price" shall be the fair market value of the Common Stock as mutually determined by the Company and BioMarin. If the Company at any time on or after the Effective Date subdivides (by any stock split, stock dividend, recapitalization or otherwise) one or more classes of its outstanding shares of Common Stock into a greater number of shares, the Conversion Price in effect immediately prior to such subdivision shall be proportionately reduced. If the Company at any time on or after the Effective Date combines (by combination, reverse stock split or otherwise) one or more classes of its outstanding shares of Common Stock into a smaller number of shares, the Conversion Price in effect immediately prior to such combination shall be proportionately increased.
- **3.** <u>Company's Representations and Warranties</u>. The Company hereby represents and warrants to BioMarin that all of the following statements are true and complete as of the Effective Date of this Agreement and will be true and complete as of the Conversion Date as though made on the Conversion Date:
  - 3.1 <u>Organization and Validity.</u> The Company has been duly organized and is validly existing as a corporation in good standing under the laws of the State of Delaware. The Company has no ownership interest in any other entity. The Company has the corporate power and authority to own its properties and conduct its business as currently being carried on, and is duly qualified to do business as a foreign corporation in good standing in each jurisdiction in which it owns or leases real property or in which the conduct of its business makes such qualification necessary and in which the failure to so qualify would have or is reasonably likely to result in a material adverse effect upon the business, prospects, properties, operations, condition (financial or otherwise) or results of operations of the Company or in its ability to perform its obligations under this Agreement ("Material Adverse Effect").

- 3.2 <u>Power and Authority</u>. The Company has the power and authority to enter into this Agreement and to perform and to discharge its obligations hereunder and thereunder. This Agreement has been duly authorized, executed and delivered by the Company, and constitutes a valid, legal and binding obligation of the Company, enforceable against the Company in accordance with its terms, except as such enforceability may be limited by bankruptcy, insolvency, reorganization or similar laws affecting the rights of creditors generally and subject to general principles of equity.
- 3.3 No Conflict. The Company's execution, delivery and performance of this Agreement will not (a) result in a breach or violation of any of the terms and provisions of, or constitute a default under, any law, rule, judgment, regulation or decree to which the Company is subject, or by which any property or asset of the Company is bound or affected ("Applicable Law"), (b) conflict with, result in any violation or breach of or loss of a benefit under, or give rise to the creation or imposition of any lien, encumbrance, security interest, claim or charge upon any property or assets of the Company pursuant to, or constitute a default (or an event that with notice or lapse of time or both would become a default) under, or give to others any right of termination, amendment, acceleration or cancellation (with or without notice, lapse of time or both) of, any written, oral, implied or other agreement, contract, understanding, arrangement, instrument, note, guaranty, indemnity, representation, warranty, deed, assignment, power of attorney, certificate, purchase order, work order, insurance policy, benefit plan, commitment, covenant, assurance or undertaking of any nature: (i) to which the Company is a party; (ii) by which the Company or any of its assets is or may become bound or under which the Company has, or may become subject to, any obligation; or (iii) under which the Company has or may acquire any right or interest (collectively, "Contracts"), or (c) result in a breach or violation of any of the terms and provisions of, or constitute a default under, the Company's charter or bylaws.
- 3.4 SEC Documents. (a) The Company has timely filed or furnished all reports, schedules, forms, statements and other documents with the Securities and Exchange Commission (the "SEC") required to be filed or furnished by the Company (the "SEC Documents"). As of their respective dates of filing, (i) the SEC Documents complied as to form, and all reports schedules, forms, statements and other documents required to be filed with the SEC after the date hereof will comply as to form, in all material respects with the requirements of the Securities Act of 1933, as amended (the "Securities Act"), or the Securities Exchange Act of 1934, as amended (the "Exchange Act"), as the case may be, and the rules and regulations of the SEC promulgated thereunder applicable thereto, and (ii) except to the extent amended or superseded by a subsequent filing with the SEC, none of the SEC Documents contained (and none of the reports schedules, forms, statements and other documents required to be filed with the SEC after the date hereof will contain) any untrue statement of a material fact or omit to state a material fact required to be stated therein or necessary in order to make the statements therein, in light of the circumstances under which they were made, not misleading.
- 3.5 <u>Consents and Approvals</u>. All material consents, approvals, orders, authorizations and filings required on the part of the Company in connection with the execution, delivery or performance of this Agreement, including delivery of the Conversion Shares, have been obtained or made.

3.6 Capitalization. All of the issued and outstanding shares of capital stock of the Company are duly authorized and validly issued, fully paid and nonassessable, have been issued in compliance with federal and state securities laws, and conform to the description thereof in the Company's most recent SEC Documents. As of October 12, 2012, there were 34,741,520 shares of Common Stock issued and outstanding and no shares of preferred stock, par value \$0.001 per share, of the Company issued and outstanding and 11,465,572 shares of Common Stock were issuable upon the exercise of all options, warrants and convertible securities outstanding as of such date at a weighted average exercise price of \$1.18 per share. The exercise price of each option issued under the Company's stock option or other employee benefit plans has been no less than the fair market value of a share of common stock as determined on the date of grant of such option. All grants of options were validly issued and properly approved by the board of directors of the Company (or a duly authorized committee thereof) in material compliance with all Applicable Laws and regulations and recorded in the Company's financial statements in accordance with GAAP and no such grants involved "back dating," "forward dating" or similar practice with respect to the effective date of grant. Except for the issuance of options or restricted stock in the ordinary course of business and the issuance of shares and warrants in the Company's August 2012 registered direct offering, all as more particularly disclosed in the SEC Documents, since June 30, 2012, the Company has not entered into or granted any convertible or exchangeable securities, options, warrants, agreements, contracts or other rights in existence to purchase or acquire from the Company any shares of the capital stock of the Company or any other equity participations in the Company. The Conversion Shares to be issued hereunder have been reserved out of the Company's authorized and unissued Common Stock, solely for the purpose of effecting the Conversion, by all necessary corporate action, have been duly authorized and, upon Conversion in accordance with the terms of this Agreement, will be validly issued, fully paid and non-assessable and free of any preemptive or similar rights, and will conform to the description thereof contained in the SEC Documents.

3.7 No Litigation. Except as described in the SEC Documents, there is no suit, claim, action, proceeding, hearing, notice of violation, investigation, arbitration or demand letter pending or, to the knowledge of the Company, threatened against or affecting the Company or its assets or properties. The Company is not subject to any material notice, court decision, agency guideline, order, writ, injunction, award, judgment or decree of any Federal, state, local or foreign government, any court of competent jurisdiction or any administrative, regulatory (including any stock exchange) or other governmental agency, commission or authority (each, a "Governmental Authority").

## 3.8 Financial Statements; Controls.

(a) The audited financial statements and the unaudited quarterly financial statements (including, in each case, the notes thereto) of the Company included in the SEC Documents when filed complied as to form in all material respects with the published rules and regulations of the SEC with respect thereto, have been prepared in all material respects in accordance with accounting principles generally accepted in the United States ("GAAP") (except, in the case of unaudited quarterly statements, as permitted by Form 10-Q of the SEC or other rules and regulations of the SEC) applied on a consistent basis during the periods involved (except as may be indicated in the notes thereto) and fairly present in all material respects the financial position of the Company as of the dates thereof and the results of its operations, cash flow and stockholders' equity for the periods then ended (subject, in the case of unaudited quarterly statements, to customary year-end adjustments). Except for those liabilities and obligations (a) specifically reserved against or provided for in the balance sheet of the Company as of June 30, 2012 (or the notes thereto) included in the SEC Documents, (b) incurred in the ordinary course of business consistent with past practice since June 30, 2012, which, individually or in the aggregate,

have not had and would not reasonably be expected to have a Material Adverse Effect, (c) disclosed in the SEC Documents filed subsequent to June 30, 2012, or (d) incurred under this Agreement or in connection with the transactions contemplated hereby, the Company has not incurred any liabilities or obligations of any nature, whether or not accrued, absolute, determined, determinable, fixed or contingent and whether or not required to be recorded or reflected on a balance sheet under GAAP (each, a "Liability").

- (b) The Company has established and maintains disclosure controls and procedures (as defined in Rule 13a-15 under the Exchange Act). Such disclosure controls and procedures are designed to ensure that information required to be disclosed in the Company's periodic reports filed or submitted under the Exchange Act is recorded, processed, summarized and reported within the required time periods. Such disclosure controls and procedures are effective in timely alerting the Company's principal executive officer and principal financial officer to material information required to be included in the Company's periodic reports required under the Exchange Act.
- (c) The Company has established and maintains a system of internal control over financial reporting (as defined in Rule 13a-15 under the Exchange Act). Such internal controls are designed to provide reasonable assurance regarding the reliability of the Company's financial reporting and the preparation of Company financial statements for external purposes in accordance with GAAP. The Company has disclosed, based on its most recent evaluation of internal controls prior to the date of this Agreement, to the Company's auditors and audit committee (i) any significant deficiencies and material weaknesses in the design or operation of internal controls which are reasonably likely to adversely affect the Company's ability to record, process, summarize and report financial information and (ii) any fraud, whether or not material, that involves management or other employees who have a significant role in internal controls. The chief executive officer and chief financial officer of the Company have made all certifications required by, and would be able to make such certifications as of the date hereof as if required to be made as of the date hereof pursuant to, Sections 302 and 906 of the Sarbanes-Oxley Act of 2002 and any related rules and regulations promulgated by the SEC and the statements contained in any such certifications are complete and correct, and the Company is otherwise in compliance with all applicable effective provisions of the Sarbanes-Oxley Act of 2002.
- 3.9 <u>Absence of Certain Changes or Events</u>. Since June 30, 2012, the Company has conducted its businesses in all material respects in the ordinary course of business consistent with past practice. Since June 30, 2012, there has not been any Material Adverse Effect. There has not been any action taken by the Company from June 30, 2012 through the date hereof that, if taken during the period beginning on the Effective Date and ending on the Conversion Date, would constitute a breach of Section 8.2.
- 3.10 Permits. The Company holds, and is in compliance with, all franchises, grants, authorizations, licenses, permits, easements, consents, certificates and orders ("Permits") of any Governmental Authority (including without limitation, those administered by the Food and Drug Administration of the U.S. Department of Health and Human Services (the "FDA") and those Governmental Authorities performing functions similar to those performed by the FDA) required for the conduct of its business, and all such Permits are in full force and effect in each case, except where the failure to hold or comply with any of them would not be material.

- 3.11 Compliance with Contracts. The Company is not in violation of its certificate of incorporation or bylaws. Each material Contract that is or would be required to be disclosed by the Company pursuant to Item 601(b)(10) of Regulation S K of the SEC is valid and is in full force and effect and constitutes the legal, valid and binding obligation of the Company, in each case in accordance with its respective terms and, to the knowledge of the Company, constitutes the legal, valid and binding obligation of the other parties thereto in accordance with its respective terms, and is enforceable in accordance with its respective terms, except as such enforceability may be limited by bankruptcy, insolvency, reorganization or similar laws affecting the rights of creditors generally and subject to general principles of equity. The Company is not in material breach of or default under any such material Contract, and, to Company's knowledge, no other party is in a material breach of or default under any such material Contract.
- 3.12 <u>Properties</u>. The Company has good and marketable title to all property (whether real or personal) described in the SEC Documents as being owned by it that are material to the business of the Company, in each case free and clear of all liens, claims, security interests, other encumbrances or defects, except those that are not reasonably likely to result in a Material Adverse Effect. The property held under lease by the Company is held by it under valid, subsisting and enforceable leases with only such exceptions with respect to any particular lease as do not interfere in any material respect with the conduct of the business of the Company.
- 3.13 Intellectual Property. The Company owns or possesses the valid right to use all patents, patent applications, trademarks, service marks, trade names, trademark registrations, service mark registrations, copyrights, copyright registrations, licenses, trade secret rights, inventions, software, databases, formulae, know how, and similar rights (including trade secrets and other unpatented and/or unpatentable proprietary confidential information, systems, or procedures) (collectively, "Intellectual Property") necessary for the conduct of the business of the Company as currently carried on and as described in the SEC Documents. To the knowledge of the Company, no action or use by the Company will involve or give rise to any infringement of, or license or similar fees for, or any misappropriation of any Intellectual Property Rights of others. Except as disclosed in the SEC Documents, the Company has not received any material challenge, which is to its knowledge still pending, by any other person or entity Person to the rights of the Company with respect to any Intellectual Property owned or used by the Company. Except as set forth in the SEC Documents, all licenses for the use of the Intellectual Property described in the SEC Documents are valid, binding upon, and enforceable by or against the parties thereto in accordance to their respective terms. The Company has complied in all material respects with, and is not in material breach of, nor to its knowledge has it received any asserted or threatened claim of material breach of, any Intellectual Property license, and the Company has no knowledge of any material breach or anticipated breach by any other person or entity of any such Intellectual Property license. Except as described in the SEC Documents, no material claim has been made against the Company alleging the infringement by the Company of any Intellectual Property of any other person or entity. The Company has taken all commercially reasonable steps with respect to the material Intellectual Property currently used in its business to protect, maintain and safeguard its Intellectual Property, including the execution of appropriate nondisclosure and confidentiality agreements. The consummation of the transactions contemplated by this Agreement will not result in the loss or impairment of or payment of any additional amounts with respect to, nor require the consent of any other Person in respect of, the Company's right to own, use, or hold for use any of the Intellectual Property Rights as owned, used or held for use in the conduct of the business as currently conducted. The Company has taken all commercially reasonable actions with respect to the material Intellectual Property currently used in its business to obtain ownership of all works of authorship and inventions made by its employees, consultants and contractors during the time they were employed by or under contract with the Company.

- 3.14 <u>Compliance with Laws</u>. The Company has materially complied with, is not in material violation of and has not received any notice of violation relating to any law, rule or regulation relating to the conduct of its business, or the ownership or operation of its property and assets, including, without limitation, (A) the Currency and Foreign Transactions Reporting Act of 1970, as amended, or any money laundering laws, rules or regulations, (B) any laws, rules or regulations related to health, safety or the environment, including those relating to the regulation of hazardous substances, (C) the Sarbanes-Oxley Act and the rules and regulations of the Commission thereunder, (D) the Foreign Corrupt Practices Act of 1977 and the rules and regulations thereunder, and (E) the Employment Retirement Income Security Act of 1974 and the rules and regulations thereunder.
- 3.15 Product Development. The clinical, pre-clinical and other studies and tests conducted by or on behalf of or sponsored by the Company were and, if still pending, are being conducted in accordance with all Applicable Laws (including, without limitation, those administered by the FDA or by any Governmental Authority performing functions similar to those performed by the FDA). The descriptions of the results of such studies and tests that are described or referred to in the SEC Documents are accurate and complete in all material respects and fairly present the published data derived from such studies and tests, and the Company has no knowledge of other studies or tests the results of which are materially inconsistent with or otherwise call into question the results described or referred to in the SEC Documents. The Company has not received any notices or other correspondence from the FDA or any other Governmental Authority performing functions similar to those performed by the FDA with respect to any ongoing clinical or pre-clinical studies or tests requiring the termination or suspension of such studies or tests. Except to the extent disclosed in the SEC Documents, as of the date of this Agreement the Company is not aware of any studies, tests or trials, the results of which the Company believes would have an adverse effect on the development of the Company's product candidates. For the avoidance of doubt, the Company makes no representation or warranty that the results of any studies, tests or preclinical or clinical trials conducted by or on behalf of the Company will be sufficient to obtain governmental approval from the FDA or any foreign, state or local governmental body exercising comparable authority.
- 3.16 Filings. Except as would not be reasonably expected to result in a Material Adverse Effect, the Company has not failed to file with the applicable regulatory authorities (excluding the FDA or any Governmental Authority performing functions similar to those performed by the FDA) any filing, declaration, listing, registration, report or submission that is required to be so filed. The Company has not failed to file with the FDA or any Governmental Authority performing functions similar to those performed by the FDA, any filing, declaration, listing, registration, report or submission that is required to be so filed. All such filings were in material compliance with Applicable Laws when filed and no deficiencies have been asserted by any applicable Governmental Authority (including, without limitation, the FDA or any Governmental Authority performing functions similar to those performed by the FDA) with respect to any such filings, declarations, listings, registrations, reports or submissions.
- 3.17 <u>Insurance</u>. The Company carries, or is covered by, insurance in such amounts and covering such risks as is adequate for the conduct of its business and the value of its properties and as is customary for companies engaged in similar businesses in similar industries.
- 3.18 <u>Labor</u>. No labor dispute with the employees of the Company exists or to the knowledge of the Company, are imminent that are reasonably likely to result in a Material Adverse Effect.

- 3.19 Solvency. The Company is not as of the date hereof, and after giving effect to the transactions contemplated hereby, will not be Insolvent (as defined below). For purposes of this Section 3.19, "Insolvent" means, with respect to the Company, (i) the present fair saleable value of the Company's assets is less than the amount required to pay the Company's total Liabilities, (ii) the Company is unable to pay its debts and Liabilities, subordinated, contingent or otherwise, as such debts and Liabilities become absolute and matured, (iii) the Company intends to incur or believes that it will incur debts that would be beyond its ability to pay as such debts as they mature or (iv) the Company has unreasonably small capital with which to conduct the business in which it is engaged as such business is now conducted and is proposed to be conducted.
- 3.20 <u>Affiliate Transactions</u>. The Company is not a party to any material Contract with any (i) officer or director of the Company, other than as part of such person's employment or service with the Company, (ii) beneficial owner of five percent (5%) or more of any voting securities of the Company or (iii) any affiliate of the Company, in each case of the type that would be required to be reported by the Company pursuant to Item 404 of Regulation S-K promulgated by the SEC.
- 3.21 <u>Brokers and Other Advisors</u>. There is no broker, investment banker, financial advisor or other intermediary that has been retained by or is authorized to act on behalf of the Company that is entitled to any broker's, financial advisor's or other fee or commission in connection with the transactions contemplated by this Agreement based upon arrangements made by or on behalf of the Company.
- **4.** <u>BioMarin Representations and Warranties</u>. BioMarin hereby represents and warrants to Company that all of the following statements are true and complete as of the Effective Date of this Agreement and that such statements will be true and complete as of the Conversion Date as though made on the Conversion Date:
  - 4.1 <u>Authority; Enforceability</u>. BioMarin has all requisite power and authority to execute and deliver this agreement and to carry out its provisions. All actions on BioMarin's part required for the lawful execution and delivery of this Agreement have been taken. Upon its execution and delivery, this Agreement will constitute a valid and binding obligation of BioMarin, enforceable in accordance with its terms, except (a) as limited by applicable bankruptcy, insolvency, reorganization, moratorium or other laws of general application affecting enforcement of creditors' rights, and (b) as limited by general principles of equity.
  - 4.2 <u>Purchase Entirely for Own Account</u>. BioMarin is making the investment contemplated by this Agreement (and is agreeing to the automatic Conversion of the Conversion Amount into the Conversion Shares) for BioMarin's own account as a principal, and not as a nominee or agent, for investment purposes only, and not with a view to, or for, resale, distribution or fractionalization thereof in whole or in part and no other Person has a direct or indirect beneficial interest in the Conversion. Further, BioMarin does not have any contract, undertaking, agreement or arrangement with any Person to sell, transfer or grant participations to such Person or to any third Person, with respect to the Conversion Shares.

## 4.3 Restricted Securities.

(a) BioMarin understands that the Conversion Shares have not been and will not be registered under the Securities Act, and are being sold pursuant to the exemptions from registration contained in Section 4(2) under the Securities Act and Regulation D thereunder, which are applicable to transactions by an issuer not involving any public offering, and that the Company's reliance on this exemption is based in part on the representations made by BioMarin herein.

- (b) BioMarin understands that the Conversion Shares have not been and will not be registered under the "Blue Sky" securities laws of any jurisdiction and are being sold pursuant to exemptions contained in such laws, and that the Company's reliance on this exemption is based in part on the representations made by BioMarin herein.
- (c) BioMarin understands and agrees that until the shares of Common Stock issuable to BioMarin are registered or transferred pursuant to the provisions of Rule 144 under the Securities Act ("Rule 144"), the certificates representing such shares, whether upon initial issuance or upon any transfer thereof, shall bear a legend, prominently stamped or printed thereon, reading substantially as follows:

THESE SECURITIES HAVE NOT BEEN REGISTERED OR QUALIFIED UNDER THE SECURITIES ACT OF 1933, AS AMENDED, OR APPLICABLE STATE SECURITIES LAWS. THESE SECURITIES ARE SUBJECT TO RESTRICTIONS ON TRANSFERABILITY AND RESALE AND THEY MAY NOT BE SOLD, OFFERED FOR SALE, PLEDGED, HYPOTHECATED, OR OTHERWISE TRANSFERRED EXCEPT PURSUANT TO REGISTRATION, QUALIFICATION OR EXEMPTION UNDER THE SECURITIES ACT OF 1933, AS AMENDED, AND APPLICABLE STATE SECURITIES LAWS.

- 4.4 Accredited Investor. BioMarin is an "accredited investor" as such term is defined in Rule 501 of Regulation D promulgated under the Act.
- 4.5 <u>Consequences of Investment and Advisors</u>. BioMarin acknowledges that the Company does not make any representation or warranty regarding the financial or tax consequences to BioMarin arising from the Conversion in accordance with this Agreement or as to the present fair market value of such Common Stock, and that the Company shall in no event be liable to the BioMarin for any adverse tax or accounting liability that may arise should the fair market value of the Common Stock be in excess of or less than the deemed consideration paid therefor. BioMarin acknowledges that it has sought the advice of its own legal, financial and/or tax advisors with regard to the financial and/or tax consequences arising from the transactions contemplated herein.
- 4.6 <u>Information</u>. BioMarin acknowledges that no private placement memorandum or similar offering documents have been prepared or distributed in connection with this Agreement, but in lieu thereof BioMarin has had access to the SEC Documents. BioMarin has relied on the information contained therein and in such other documents as BioMarin has elected to review, and has not relied upon any oral representations or been furnished any other offering literature or written information, except other information (if any) provided by the Company on BioMarin's request. BioMarin has been provided with an adequate opportunity to ask questions of the Company's management and to review any documents that BioMarin deems material.
- 4.7 <u>Brokers and Other Advisors</u>. There is no broker, investment banker, financial advisor or other intermediary that has been retained by or is authorized to act on behalf of the BioMarin that is entitled to any broker's, financial advisor's or other fee or commission in connection with the transactions contemplated by this Agreement based upon arrangements made by or on behalf of BioMarin.

- **5. Rule 144 Reporting.** With a view to making available to BioMarin the benefits of certain rules and regulations of the SEC which may permit the sale of the Conversion Shares to the public without registration, the Company agrees to use its reasonable best efforts to:
  - 5.1 Make and keep public information available, as those terms are understood and defined in Rule 144 or any similar or analogous rule promulgated under the Securities Act, at all times after the Effective Date of this Agreement;
  - 5.2 Use reasonably commercial efforts to file with the SEC, in a timely manner, all reports and other documents required of the Company under the Exchange Act; and
  - 5.3 So long as BioMarin owns any Conversion Shares, furnish to BioMarin forthwith upon request: a written statement by the Company as to its compliance with the reporting requirements of Rule 144, and of the Exchange Act; a copy of the most recent annual or quarterly report of the Company; and such other reports and documents as BioMarin may reasonably request in availing itself of any rule or regulation of the SEC allowing it to sell any such Conversion Shares without registration.
- **6.** <u>Rule 144 Compliance</u>. BioMarin agrees that so long as it owns ten percent (10%) or more of the Company's outstanding common stock, it will comply with all requirements under Rule 144 as if it is an affiliate of the Company in connection with all sales of the Company's common stock, including without limitation complying with: (i) the manner of sale provision that is set forth in section (f) of Rule 144, and (ii) the limitation on the amount of securities that may be sold in any three month period that is set forth in section (e) of Rule 144.
- 7. <u>Status as Debt until Conversion</u>. The Note shall be unsecured, and all amounts due hereunder shall be treated as unsecured indebtedness of the Company until the same shall have been actually converted into Conversion Shares. Similarly, until conversion of the Conversion Amount into Conversion Shares, BioMarin shall not be treated as a stockholder of the Company with respect to the Conversion Shares.

## 8. Obligations of the Company.

- 8.1 <u>Use of Proceeds</u>. The Company shall use the Principal Amount solely for the purpose of developing Firdapse. Notwithstanding anything to the contrary set forth herein, this covenant shall survive the issuance of the Conversion Shares.
- 8.2 <u>Conduct of Business</u>. During the period beginning on the Effective Date and ending on the Conversion Date, except as specifically consented in writing by BioMarin (which consent may not be unreasonably withheld), the Company shall carry on its business in the ordinary course of business, consistent with past practice and in material compliance with Applicable Law (including using its best efforts to maintain compliance with the continuing listing requirements of the NASDAQ Capital Market). Except as contemplated by this Agreement, during the period beginning on the Effective Date and ending on the Conversion Date, the Company shall not, without BioMarin's written consent (which consent may be withheld by the BioMarin in its sole discretion):
  - (a) voluntarily liquidate, dissolve or wind-up its business and affairs; declare, set aside or pay any dividends on, or make any other distributions (whether in cash, stock or property) in respect of, any of its capital stock; or effect any stock split, combination of shares, recapitalization, reclassification or other change in the capital structure of the Company;

- (b) (i) sell or license all or substantially all of the Company's rights with respect to, in a single transaction or a series of transactions, assets of the Company representing twenty-five (25%) or more of the assets of the Company, or (ii) enter into any merger, consolidation, business combination, recapitalization, liquidation, dissolution, binding share exchange or similar transaction involving the Company pursuant to which any Person or group (or the stockholders of any Person) would own, directly or indirectly, twenty-five percent (25%) or more of any class of equity securities of the Company or of the surviving entity in a merger or the resulting direct or indirect parent of the Company or such surviving entity;
- (c) sell in a single transaction or a series of transactions (i) such number of shares of the Company's authorized but unissued common stock equal to more than 25% of the outstanding shares of the Company at the date of this Agreement, and (ii) shares of the Company's authorized but unssued common stock at a per share price of less than \$1.50 per share; or
  - (d) authorize any of, or commit or agree to take any of, the foregoing actions.
- 8.3 <u>Release of Data</u>. The Company shall publicly announce the top-line data from the Company's Phase II(b) clinical trial evaluating the use of CPP-109 (the Company's formulation of vigabatrin, a GABA aminotransferase inhibitor) for the treatment of cocaine addiction as soon as reasonably practicable after the Effective Date.
- 8.4 <u>Indemnification</u>. The Company shall indemnify, defend and hold BioMarin, its affiliates, partners, shareholders, directors, officers, employees, agents and assigns harmless from and against any and all claims, damages, liabilities, demands, costs and expenses (including, without limitation, reasonable attorneys' fees and costs) arising from or in connection with (a) the Company's breach of any representation, warranty or covenant set forth in this Agreement, and (b) any violation (or alleged violation) by the Company of the Securities Act, any state securities laws or any rule or regulation thereunder applicable to the Company and relating to action or inaction required of the Company in connection with this Agreement.

## 9. Default.

- 9.1 Events of Default. The occurrence of any of the following prior to the Conversion of the Principal Amount into the Conversion Shares constitutes an "Event of Default" hereunder: (a) Company fails or refuses to promptly effect the Conversion of the Principal Amount on the Maturity Date and to promptly deliver the certificates representing the Conversion Shares to BioMarin; (b) the Company breaches in a material respect a representation or warranty contained in Section 3, or (c) a receiver or the like is appointed for any part of the Company's property or assets, Company makes a general assignment for the benefit of creditors, or the Company becomes a debtor or alleged debtor in a case under the U.S. Bankruptcy Code or becomes the subject of any other bankruptcy or similar proceeding for the general adjustment of its debts, and the same is not dismissed or discharged within sixty (60) days of filing.
- 9.2 <u>BioMarin's Actions Upon Default</u>. Upon the occurrence of any Event of Default, BioMarin, at its option, may accelerate payment of the outstanding Principal Amount under this Note, causing the same to become immediately due and payable, upon written notice to the Company, but without further demand, notice or other action by BioMarin. In such a case, BioMarin shall have all rights available to it under applicable law. This Section 9.2 shall not limit BioMarin's rights to seek equitable relief pursuant to Section 10.7, including specific performance, upon an Event of Default.

9.3 <u>Default Interest</u>. Upon an Event of Default, the interest payable on the Principal Amount shall automatically increase to ten percent (10%) per annum (with such interest calculated based on a 365-day year and accruing on a daily basis), or, if lower, the maximum amount of interest permitted by applicable law.

## 10. General Provisions.

10.1 Notices. Unless otherwise provided, any notice to BioMarin or Company hereunder must be in writing and in English and must be (a) delivered by hand or by overnight courier with tracking capabilities, (b) mailed postage prepaid by first class, registered, or certified mail, or (c) delivered by facsimile followed by delivery via either of the methods set forth in Sections 10.1(a) and (b), to the persons at the addresses indicated below:

## **BIOMARIN**

BioMarin Pharmaceutical, Inc. 105 Digital Drive Novato, California 94949 Attn: Chief Executive Fax: (415) 382-7889

## **COMPANY**

Catalyst Pharmaceutical Partners, Inc. 355 Alhambra Circle Suite 1500 Coral Gables, Florida 33134 Attention: Chief Executive Officer

Fax: (305) 529-0933

## with a copy to (which shall not constitute notice):

BioMarin Pharmaceutical, Inc. 105 Digital Drive Novato, California 94949 Attn: General Counsel Fax: (415) 382-7889

## with a copy to (which shall not constitute notice):

Philip B. Schwartz, Esq. Akerman Senterfitt 350 East Las Olas Blvd, Suite 1600 Fort Lauderdale, Florida 33301 Fax: (305) 349-4833

Any such notice shall be deemed given on the date received, except any notice received after 5:30 p.m. (in the time zone of the receiving party) on a Business Day or received on a non-Business Day shall be deemed to have been received on the next Business Day. A Party may add, delete, or change the person or address to which notices should be sent at any time upon written notice delivered to the other Parties in accordance with this Section 10.1.

10.2 <u>Successors and Assigns</u>. The rights and obligations of Company and BioMarin under this Agreement will bind and benefit their respective successors and assigns. Neither this Agreement nor any rights, interests or obligations hereunder may be assigned or otherwise transferred by either the Company or BioMarin, by operation of law or otherwise, in whole or in part, without the other's prior written consent. Notwithstanding the foregoing, (a) BioMarin may transfer the Conversion Shares, except to the extent that such transfer is otherwise restricted by this Agreement and (b) no consent of the Company is required for an assignment or transfer by BioMarin, in whole or in part, to (i) an Affiliate of BioMarin or (ii) a successor-in-interest of BioMarin by reason of merger or consolidation or sale of all or substantially all of the assets of BioMarin relating to the subject matter of this Agreement.

- 10.3 <u>Amendment and Waiver</u>. This Agreement and any provision hereof may be terminated, amended or waived only in writing by the party against which enforcement of such termination, amendment or waiver is sought. Delay or failure to exercise any right may not be construed as waiver of such or any other right, nor will a waiver of a breach or provision constitute a continuing waiver or a waiver of any other breach or provision.
  - 10.4 Governing Law. This Agreement shall be governed by the laws of New York, without regard to its principles of conflicts of law.
- 10.5 <u>Jurisdiction and Venue.</u> Each of the parties: (a) submits to the jurisdiction of any court of the United States located in the State of New York (or, if any such court of the United States located in the State of New York declines to accept jurisdiction over a particular matter, any state court located in the State of New York) in any legal suit, action or proceeding arising out of or relating to this Agreement; (b) agrees that all claims in respect of the action or proceeding shall be heard or determined in such court; and (c) agrees not to bring any action or proceeding arising out of or relating to this Agreement in any other court. Each of the parties waives any defense of inconvenient forum to the maintenance of any action or proceeding so brought and waives any bond, surety or other security that might be required of any other party with respect thereto. Any party may make service on any other party by sending or delivering a copy of the process to the party to be served at the address and in the manner provided for the giving of notices in Section 10.1. Each party agrees that a final judgment in any action or proceeding so brought shall be conclusive and may be enforced by suit on the judgment or in any other manner provided by law. Nothing in this Agreement shall affect the right to serve process in any other manner permitted by law, statute, rule or regulation. To the extent provided by any law, statute, rule or regulation, should either party, after being so served, fail to appear or answer to any summons, complaint, process or papers so served within the number of days prescribed by law after the mailing thereof, such party shall be deemed in default and an order or judgment may be entered by the court against such party as demanded or prayed for in such summons, complaint, process or papers.
- 10.6 Waiver of Right to Jury Trial. THE PARTIES TO THIS AGREEMENT WAIVE (TO THE EXTENT PERMITTED BY APPLICABLE LAW) TRIAL BY JURY IN ANY LITIGATION IN ANY COURT WITH RESPECT TO, IN CONNECTION WITH, OR ARISING OUT OF THIS AGREEMENT, OR THE MATTERS COVERED BY THIS AGREEMENT AND HEREBY AGREE THAT THIS SECTION IS A SPECIFIC AND MATERIAL ASPECT OF THIS AGREEMENT AND ACKNOWLEDGE THAT THEY WOULD NOT ENTER INTO THIS AGREEMENT IF THIS SECTION WERE NOT PART OF THIS AGREEMENT.
- 10.7 <u>Specific Performance</u>. The parties hereto agree that irreparable damage would occur in the event any provision of this Agreement was not performed in accordance with the terms hereof and that the parties shall be entitled to seek specific performance of the terms hereof, in addition to any other remedy at law or equity without the necessity of demonstrating the inadequacy of monetary damages.
- 10.8 <u>Attorneys' Fees</u>. In the event that any suit or action is instituted to enforce any provision in this Agreement, the prevailing party in such dispute shall be entitled to recover from the losing party such reasonable fees and expenses of attorneys and accountants, which shall include all fees, costs and expenses of appeals.
- 10.9 Entire Agreement. This Agreement, the License Agreement and their attached schedules and exhibits constitute the entire agreement between the parties as to the subject matter hereof and thereof and supersede and merge all prior and contemporaneous negotiations, representations, agreements, and understandings regarding the same.

10.10 Counterparts. This Agreement may be executed in counterparts with the same effect as if both parties had signed the same document. All such counterparts shall be deemed an original, shall be construed together, and shall constitute one and the same instrument. Any such counterpart, to the extent delivered by means of a fax machine or by .pdf, .tif, .gif, .jpeg or similar attachment to electronic mail (any such delivery, an "Electronic Delivery") shall be treated in all manner and respects as an original executed counterpart and shall be considered to have the same binding legal effect as if it were the original signed version thereof delivered in person. No party hereto shall raise the use of Electronic Delivery to deliver a signature or the fact that any signature or agreement or instrument was transmitted or communicated through the use of Electronic Delivery as a defense to the formation of a contract, and each such party forever waives any such defense, except to the extent that such defense relates to lack of authenticity.

10.11 Interpretation. All headings used herein are used for convenience only and shall not be used to construe or interpret this Agreement. All references in this Agreement to sections shall, unless otherwise provided, refer to sections hereof. If any provision or portion of this Agreement is determined to be invalid or unenforceable, this Agreement will automatically be amended to substitute, for the invalid or unenforceable provisions, new enforceable provisions which most closely approximate the intent and economic effect of the invalid provisions, and the remaining provisions will, as so amended, continue in full force and effect. No representation, warranty or disclosure given by Company in connection with this Agreement or this transaction (including representations, warranties or disclosures set forth in any related document) will be affected by any investigation or lack of investigation by BioMarin. This Agreement shall not be interpreted for or against BioMarin or Company on the basis of which party's counsel prepared such documents.

[Signatures on Following Page]

**IN WITNESS WHEREOF**, Company and BioMarin have caused this Convertible Promissory Note and Note Purchase Agreement to be signed in their name, by their duly authorized representative, as of the date set forth above.

## CATALYST PHARMACEUTICAL PARTNERS, INC.

By: /s/ Patrick J. McEnany

Name: Patrick J. McEnany

Title: Chairman, President and CEO

## BIOMARIN PHARMACEUTICAL, INC.

By: /s/ G. Eric Davis

Name: G. Eric Davis

Title: SVP, General Counsel

## CONFIDENTIAL TREATMENT REQUESTED

Redacted portions are indicated by [\*\*\*\*]1

## LICENSE AGREEMENT

THIS LICENSE AGREEMENT (the "Agreement") is made and entered into effective as of October 26, 2012 (the "Effective Date") by and between BIOMARIN PHARMACEUTICAL INC., a Delaware corporation having offices at 105 Digital Drive, Novato, CA 94901 ("BioMarin"), and CATALYST PHARMACEUTICAL PARTNERS, INC., a Delaware corporation having offices at 355 Alhambra Circle, Suite 1500, Coral Gables, Florida, 33134 ("Catalyst").

## RECITALS

**WHEREAS,** BioMarin possesses expertise, intellectual property rights and proprietary technology related to amifampridine phosphate (marketed as Firdapse<sup>TM</sup>) and its use for treating Lambert Eaton Myasthenic Syndrome ("**LEMS**");

**WHEREAS,** Catalyst possesses expertise in the research, development, manufacturing and commercialization of human pharmaceuticals, with a focus on neurological disorders:

**WHEREAS**, BioMarin desires to grant to Catalyst, and Catalyst desires to receive, exclusive rights to develop and commercialize products incorporating the Licensed Compound in all Indications in the Territory (as such terms are defined below); and

WHEREAS, concurrently with this Agreement, the Parties are entering into a Convertible Promissory Note and Note Purchase Agreement (the "Catalyst Note Purchase Agreement") under which, in exchange for a payment of U.S. \$5,000,000, Catalyst shall issue to BioMarin a convertible promissory note convertible into shares of Common Stock of Catalyst, as set forth in such Catalyst Note Purchase Agreement.

**Now, THEREFORE,** in consideration of the premises and mutual covenants herein contained, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties hereto agree as follows:

## ARTICLE 1 DEFINITIONS

**1.1 "Affiliate"** means a person, corporation, partnership or other entity that controls, is controlled by or is under common control with a Party. For purposes of this Section 1.1, the word "**control"** (with a correlative meaning, the terms "controlled by" or "under the common control with") means the actual power, either directly or indirectly through one or more intermediaries, to direct the management and policies of such entity, whether through the ownership of at least fifty percent (50%) of the voting stock of such entity, or by contract or otherwise.

<sup>[\*\*\*\*]</sup> Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934.

- 1.2 "BioMarin Invention" means an Invention that is invented solely by or on behalf of BioMarin or its Affiliates.
- 1.3 "BioMarin Ongoing Study" means the studies set forth on Exhibit A.
- **1.4 "Calendar Quarter"** means each three (3) month period commencing January 1, April 1, July 1, or October 1.
- **1.5 "Calendar Year"** means each twelve (12) month period commencing January 1.
- 1.6 "Catalyst Invention" means an Invention that is invented solely by or on behalf of Catalyst or its Affiliates.
- 1.7 "Catalyst Know-How" means all Know-How:
- (a) Controlled by Catalyst and/or its Affiliates as of the Effective Date that: (i) covers a Licensed Compound, a Licensed Product, or the manufacture or use of a Licensed Compound or Licensed Product; or (ii) is necessary or useful for the Development, Manufacture, or Commercialization of Licensed Products in the Field; or
  - (b) Controlled by Catalyst and/or its Affiliates during the term of this Agreement, and is a Catalyst Invention.

## 1.8 "Catalyst Patent" means all Patents:

- (a) Controlled by Catalyst and/or its Affiliates as of the Effective Date that (i) claim a Licensed Compound, a Licensed Product, or the manufacture or use of a Licensed Compound or Licensed Product; or (ii) are necessary or useful for the Development, Manufacture, or Commercialization of Licensed Products in the Field; or
- **(b)** Controlled by Catalyst and/or its Affiliates during the term of this Agreement that (i) claim a Catalyst Invention; or (ii) are a continuation, divisional, continuation-in-part (solely to the extent claiming subject matter disclosed in a Patent described in **clause (a)** above), foreign counterpart, substitution, extension, registration, confirmation, reissue, re-examination, supplementary protection certificates, confirmation patents, patent of additions or renewal of, or issue from, any Patent described in **clause (a)** above.
  - 1.9 "Catalyst Technology" means the Catalyst Know-How, the Catalyst Patents, and Catalyst's interest in Joint Inventions and Joint Patents.
- **1.10 "Clinical Trial"** means a human clinical trial of a Licensed Product that would satisfy the requirements of 21 C.F.R. §312.21 (as amended from time to time) or other comparable regulation imposed by an applicable Regulatory Authority in any country other than the U.S.
- **1.11 "Combination Product"** means a pharmaceutical product that contains both (a) a Licensed Product or Licensed Compound and (b) one or more other active pharmaceutical ingredients for which rights are not included in the license granted in Section 2.1, but, with respect to the items in (b), which may each or collectively form the basis for a separate product.
- **1.12 "Commercialization"** means the marketing, promotion, sale, offer for sale and/or distribution of a Licensed Product. **"Commercialize"** has a correlative meaning.

- **1.13 "Confidential Information"** means all information (whether in written, oral, electronic, visual, tangible, or other form) and materials, including, without limitation, biological and other tangible materials, that are disclosed by one Party to the other Party prior to the Effective Date or during the term of this Agreement that is not subject to the provisions of Section 11.2.
- **1.14 "Controlled"** means, with respect to any intellectual property right, that the Party owns or has a license to such intellectual property right and has the ability to grant to the other Party a license, sublicense, or access (as appropriate) to, such intellectual property right as provided for herein without violating the terms of any agreement or other arrangements with any Third Party existing at the time such Party would be first required hereunder to grant the other Party such license, sublicense, or access.
- **1.15 "Development"** means all activities, including research, pre-clinical development activities, Clinical Trials and supporting laboratory studies, relating to obtaining, maintaining or expanding Regulatory Approval(s) of a Licensed Product. **"Develop"** and **"Developing"** have correlative meanings. For clarity, Development includes Post-Marketing Studies and excludes Manufacturing and Commercialization.
  - **1.16 "Development Plan"** has the meaning set forth in Section 3.4.
- 1.17 "Diligent Efforts" means, with respect to a Party's obligations under this Agreement to Manufacture, Develop or Commercialize a Licensed Product, the carrying out of such obligations or tasks with a level of efforts and resources consistent with the efforts of such Party with respect to the research, development or commercialization of a similar pharmaceutical product as such Licensed Product with similar market potential, profit potential or strategic value resulting from its own research efforts, taking into account technical and regulatory factors, target product profiles, product labeling, past performance, costs, economic return, the regulatory environment and competitive market conditions in the therapeutic market or niche, all based on conditions then prevailing. Diligent Efforts requires that the Party: (a) promptly assign responsibility for such obligations or tasks to specific employee(s) who are held accountable for progress and monitor such progress on an on-going basis, (b) set and consistently seek to achieve specific and meaningful objectives for carrying out such obligations, and (c) consistently make and implement decisions and allocate resources designed to advance progress with respect to such objectives.
  - **1.18 "Dollars" or "\$"** means the legal tender of the U.S.
- **1.19 "Drug Approval Application"** means a New Drug Application (each, a "**NDA**"), as defined in the United States Public Health Service Act or the United States Food, Drug, and Cosmetic Act, as amended, and the regulations promulgated thereunder, or any corresponding foreign application in a country other than the U.S.
  - 1.20 "EMA" means European Medicines Agency, and any successor thereto.
  - 1.21 "Executive Officer" means, with respect to each Party, the Chief Executive Officer of such Party, or another officer designated by such person.
- 1.22 "EU" means the European Union, as constituted as of the Effective Date and as its membership may be altered from time to time and any successor thereto.
  - **1.23 "EUSA License"** has the meaning set forth in Section 2.6(a).

- 1.24 "FDA" means the U.S. Food and Drug Administration, and any successor thereto.
- 1.25 "Field" means all human or animal Indications.
- **1.26 "Firdapse"** means Licensed Product in the form which, as of the Effective Date, is the subject of BioMarin's U.S. Regulatory Filings, the specifications of which are described on **Exhibit B-1**.
- **1.27 "First Commercial Sale"** means, with respect to a country in the Territory, the first sale to a Third Party of a Licensed Product in such country by Catalyst, its Affiliate, or Sublicensee.
  - **1.28 "GAAP"** means U.S. generally accepted accounting principles, consistently applied.
- **1.29 Huxley Stock Purchase Agreement** means the Stock Purchase Agreement dated October 20, 2009, as amended on March 26, 2010, by and among BioMarin Pharmaceutical Inc., Huxley Pharmaceuticals, Inc. ("**Huxley**") and the stockholders of Huxley set forth on the signature pages to the Huxley Stock Purchase Agreement ("**Former Stockholders of Huxley**").
  - **1.30 "IND"** means an investigational new drug application in the U.S. or any equivalent Regulatory Filing in a foreign country.
- **1.31 "IND-Enabling Study"** means an in vivo animal study for a Licensed Product designed to provide data that can be used to support a filing of an IND for such Licensed Product. An IND-Enabling Study may include, without limitation, a GLP toxicology study and pharmacokinetic study.
  - **1.32 "Indication"** means the treatment, prevention, detection, diagnosis, prognosis, monitoring or predisposition testing of any disease, state or condition.
- **1.33 "Invention"** means any and all inventions and improvements thereto, as determined under U.S. patent laws, relating to a Licensed Compound, a Licensed Product, or the Manufacture or use of a Licensed Compound or Licensed Product, that are conceived, reduced to practice or discovered by or on behalf of a Party (and/or its Affiliates) after the Effective Date during a Party's performance of obligations or exercise of rights under this Agreement.
- 1.34 "Joint Development Costs" means all Third Party and out-of-pocket costs incurred by or on behalf of either Party or an Affiliate, calculated in accordance with GAAP consistently applied, that are reasonably and directly allocable to the Joint Post-Marketing Studies. Joint Development Costs shall include costs of contract research organizations and other Third Party vendors; costs of the Licensed Compound and/or Licensed Product; and other out-of-pocket costs actually incurred by each Party, but shall specifically exclude corporate overhead of each Party, and all internal FTE costs.
  - **1.35 "Joint Invention"** means an Invention invented jointly by or on behalf of both Parties (and/or their Affiliates).
  - 1.36 "Joint Patent" means a Patent claiming a Joint Invention.
  - **1.37 "Joint Post-Marketing Study"** has the meaning set forth in Section 3.5.
- **1.38 "Know-How"** means inventions, discoveries, trade secrets, information, experience, data, formulas, procedures and results, including without limitation physical, chemical, biological, toxicological, pharmacological, clinical, and veterinary data, dosage regimens, control assays and product specifications, but excluding any Patents.

- **1.39 "Knowledge"** means, with respect to a Party, the good faith understanding of the facts and information in the possession of an officer of such Party or its Affiliates, without any duty to conduct any additional investigation with respect to such facts and information by reason of the execution of this Agreement. For purposes of this definition, an "officer" means any person in the position of vice president, senior vice president, president or chief executive officer of a Party.
- **1.40 "Licensed Compound"** means (a) 3,4-Diaminopyridine, the chemical structure of which is set forth on **Exhibit B-2**; and (b) any derivatives, isomers, metabolites, prodrugs, acid forms, base forms, or modified versions of such compound in (a).

## **1.41 "Licensed Know-How"** means all Know-How:

- (a) Controlled by BioMarin and/or its Affiliates as of the Effective Date that: (i) covers a Licensed Compound, a Licensed Product, or the manufacture or use of a Licensed Compound or Licensed Product; or (ii) is necessary or useful for the Development, Manufacture, or Commercialization of Licensed Products in the Field; or
- **(b)** Controlled by BioMarin and/or its Affiliates during the term of this Agreement, and is (i) a BioMarin Invention or (ii) an "Improvement" (as defined in the EUSA License) under the EUSA License.

## 1.42 "Licensed Patent" means all Patents:

- (a) Controlled by BioMarin and/or its Affiliates as of the Effective Date that (i) claim a Licensed Compound, a Licensed Product, or the manufacture or use of a Licensed Compound or Licensed Product; or (ii) are necessary or useful for the Development, Manufacture, or Commercialization of Licensed Products in the Field; or
- (b) Controlled by BioMarin and/or its Affiliates during the term of this Agreement that (i) claim a BioMarin Invention; (ii) claim an "Improvement" (as defined in the EUSA License); (iii) claim a Licensed Compound, a Licensed Product, or the manufacture or use of a Licensed Compound or Licensed Product; or (iv) are a continuation, divisional, continuation-in-part (solely to the extent claiming subject matter disclosed in a Patent described in clause (a) above), foreign counterpart, substitution, extension, registration, confirmation, reissue, re-examination, supplementary protection certificates, confirmation patents, patent of additions or renewal of, or issue from, any Patent described in clause (a) above.

Licensed Patents shall include the Patents set forth on Exhibit C.

- **1.43 "Licensed Product"** means any pharmaceutical product that contains a Licensed Compound, either alone or with one or more other pharmaceutical ingredients, and including all formulations, line extensions and modes of administration thereof.
- **1.44 "Licensed Technology"** means the Licensed Know-How, the Licensed Patents, the Licensed Trademarks, and BioMarin's interest in Joint Inventions and Joint Patents.
  - **1.45 "Licensed Trademarks"** means the trademarks set forth on **Exhibit D**.

**1.46 "Manufacturing"** means all activities related to the production, manufacture, processing, filling, finishing, packaging, labeling, inspection, receiving, holding and shipping of the Licensed Compound and/or Licensed Products, or any raw materials or packaging materials with respect thereto, or any intermediate of any of the foregoing, including process and cost optimization, process qualification and validation, commercial manufacture, stability and release testing, quality assurance and quality control. For clarity, **"Manufacture"** has a correlative meaning.

**1.47 "Marks"** has the meaning set forth in Section 9.5.

1.48 "Net Sales" means:

- (a) [\*\*\*\*]
- **(b)** [\*\*\*\*]
- (c) [\*\*\*\*]

Net Sales shall be determined in accordance with GAAP with respect to the transactions in question.

- **1.49 "Party"** means BioMarin or Catalyst individually, and "Parties" means BioMarin and Catalyst collectively.
- **1.50 "Patents"** means (a) U.S. patents, re-examinations, reissues, renewals, extensions and term restorations, and foreign counterparts thereof, and (b) pending applications for U.S. patents, including, without limitation, provisional applications, continuations, continuations-in-part, divisional and substitute applications, inventors' certificates, and extensions, and foreign counterparts of any of the foregoing.
- 1.51 "Phase 3 Clinical Trial" means a human Clinical Trial of a Licensed Product on sufficient numbers of patients to establish the safety and efficacy of a Licensed Product for the desired claims and Indications, as more precisely defined by 21 C.F.R. § 312.21(c) (or its successor regulation) and corresponding rules and regulations in other countries and that is designed to support a Drug Approval Application without further clinical studies. For clarity, a phase 2/3 trial designed to support a filing for Regulatory Approval shall be deemed a Phase 3 Clinical Trial.
- **1.52 "Post-Marketing Study"** means a product support clinical trial of a Licensed Product that is commenced after receipt of Regulatory Approval in the country where such trial is conducted. Post-Marketing Studies may include epidemiological studies, modeling and pharmacoeconomic studies, "post-marketing surveillance trials" and investigator-sponsored clinical trials studying a Licensed Product.
- **1.53 "Regulatory Approval"** means, with respect to a Licensed Product and a particular regulatory jurisdiction, the approval of a Drug Approval Application by the applicable regulatory authority in such regulatory jurisdiction and any other regulatory approvals required to sell such Licensed Product in such regulatory jurisdiction.
- **1.54 "Regulatory Authority"** means the applicable national (e.g., the FDA), supra-national, regional, state or local regulatory agency, department, bureau, commission, council or other governmental entity that, in each case, governs the approval of a Licensed Product in such applicable regulatory jurisdiction.
- **1.55 "Regulatory Exclusivity"** means any exclusive marketing rights or data exclusivity rights conferred by any Regulatory Authority with respect to a Licensed Product other than Patents, including, without limitation, rights conferred in the U.S. under the Hatch-Waxman Act or the FDA Modernization Act of 1997 (including pediatric exclusivity), under the Orphan Drug Act (implemented under the rules set forth in 21 CFR Part 316), or rights similar thereto outside the U.S. designed to prevent the entry of generic product(s) onto the market.

- **1.56 "Regulatory Filings"** means all applications, filings, dossiers and the like submitted to a Regulatory Authority in a particular jurisdiction for the purpose of obtaining Regulatory Approval of a Licensed Product from that regulatory authority with respect to such jurisdiction. Regulatory Filings shall include, but not be limited to, all INDs and Drug Approval Applications for Licensed Product.
  - 1.57 "Royalty Term" means the term during which royalties are payable for a given Licensed Product, as determined under Section 7.4(b).
  - **1.58 "ROW"** means the entire world, excluding the Territory.
  - 1.59 "Sublicensee" means any Third Party granted a sublicense (in whole or in part) to the rights licensed to Catalyst pursuant to Section 2.1 hereof.
  - **1.60 "Territory"** means the U.S., Canada, and Mexico and their respective territories, protectorates and possessions.
  - **1.61 "Third Party"** means any person or entity other than a Party or its Affiliates.
  - 1.62 "U.S." means the United States of America.

## ARTICLE 2 LICENSE

- **2.1 License to Catalyst.** Subject to the terms and conditions of this Agreement, BioMarin hereby grants to Catalyst, under the Licensed Technology:
- (a) an exclusive (even as to BioMarin and its Affiliates), royalty-bearing license, including the right to grant and authorize sublicenses in accordance with Section 2.2, to Commercialize Licensed Products in the Field in the Territory;
- **(b)** a co-exclusive (with BioMarin and its Affiliates as provided in Section 2.3(b)), royalty-bearing license to use, Develop, Manufacture and import Licensed Products in the Field in the Territory; and
- (c) a non-exclusive license: (i) subject to Section 3.6(b), to Develop Licensed Products in the Field in the ROW solely to support Regulatory Filings and Regulatory Approvals for Licensed Products in the Territory; and (ii) to Manufacture Licensed Products in the ROW solely to support Development and Commercialization of Licensed Products in the Field in the Territory, in each case, (i) and (ii), which shall be royalty-bearing with respect to Licensed Products Commercialized in the Territory.
- **2.2 Sublicensing.** The licenses granted to Catalyst in Sections 2.1 are freely sublicensable; provided that (a) Catalyst shall comply with the terms of Section 2.2 of the EUSA License, (b) Catalyst shall provide to BioMarin and EUSA within 30 days of the effective date of any sublicense with the name of each Sublicensee of its rights under this Article 2 and a copy of the applicable sublicense agreement (provided that Catalyst may redact portions of such sublicense agreement (or amendments) to the extent that such portions solely relate to any sublicensees' proprietary information, technology, or research, development, or commercialization plans and as reasonably necessary to comply with any confidentiality provisions of such sublicense; and (c) Catalyst shall remain responsible and liable for each Sublicensee's compliance with the applicable terms and conditions of this Agreement.

- **2.3 BioMarin Retained Rights.** For the avoidance of doubt, BioMarin shall retain, under the Licensed Technology:
- (a) the exclusive rights under the Licensed Technology to Develop, use, Commercialize, Manufacture and import Licensed Products in the ROW, subject to the license granted in Section 2.1(c); and
- **(b)** the co-exclusive (with Catalyst) rights under the Licensed Technology to use, Develop, Manufacture and import Licensed Products in the Field in the Territory, subject to Section 3.6(c).
- **2.4 No Non-Permitted Use.** Catalyst hereby covenants that it shall not, nor shall it cause or permit any Affiliate or Sublicensee to, use or practice, directly or indirectly, any Licensed Technology for any purposes other than those expressly permitted by this Agreement.
- **2.5 No Other Licenses.** Neither Party grants to the other Party any rights or licenses in or to any intellectual property, whether by implication, estoppel, or otherwise, other than the license rights that are expressly granted under this Agreement.

## 2.6 Third Party Agreements.

- (a) The license granted to Catalyst in Section 2.1 includes a sublicense under Licensed Technology that is licensed to BioMarin (or its Affiliate) by EUSA Pharma SAS ("EUSA") pursuant to an Exclusive License and Sublicense Agreement between EUSA and BioMarin Huxley Ltd. (as successor to Huxley Pharmaceuticals, Inc.), dated April 23, 2009, as amended on September 30, 2009 and March 26, 2010 (such license agreement, the "EUSA License"). Such sublicense is subject to the limitations set forth in Sections 5 and 6 of the EUSA License that set forth constraints on BioMarin's ability to prosecute or enforce Licensed Patents licensed pursuant to such license. As further set forth in Section 7.5 below, Catalyst shall be responsible for paying to BioMarin certain milestones and royalties owed by BioMarin or its Affiliates to EUSA under the EUSA License. BioMarin shall not make any amendment to the EUSA License that would materially alter Catalyst's rights hereunder without the prior written consent of Catalyst.
- **(b)** Catalyst shall be solely responsible for obtaining, at its sole expense, any agreements with Third Parties required in order for Catalyst to perform research, Development, Manufacturing, and Commercialization activities with respect to Licensed Products ("**Third Party Agreements**"). Without limiting the generality of the foregoing, Catalyst and its Affiliates shall not be permitted to credit against amounts due under this Agreement any costs and expenses that they incur under or as a result of such Third Party Agreements. Catalyst shall use reasonable commercial efforts to negotiate Third Party Agreements that (i) may be assigned to BioMarin in accordance with Section 13.5(c)(vi), and (ii) provide for the sublicense to BioMarin, pursuant to Section 13.5(c)(i), of any Know-How or Patents that claim or cover Licensed Products and that are licensed by Catalyst from a Third Party. Catalyst shall also cause such Third Parties engaged by it to be bound by written obligations of confidentiality consistent with those contained herein and, as applicable, by obligations requiring the assignment of intellectual property and work product to Catalyst, sufficient to enable Catalyst to comply with its obligations under Section 13.5(c).
- **2.7 Exclusivity.** Catalyst hereby covenants that during the term of this Agreement, except as permitted under this Agreement, including Section 2.1, or as otherwise permitted with the prior written consent of BioMarin, Catalyst and its Affiliates will not

research, develop or seek regulatory approval, commercialize or distribute, personally or through the intermediary of a Third Party or its Affiliates or subsidiaries, products containing the Licensed Compound in the ROW. Notwithstanding Section 2.3(b), during the term of this Agreement, except as permitted with the prior written consent of Catalyst, BioMarin and its Affiliates will not research, develop or seek regulatory approval, commercialize or distribute, personally or through the intermediary of a Third Party or its Affiliates or subsidiaries, products containing the Licensed Compound in the Territory for any Indication other than LEMS.

**2.8 License to BioMarin.** Catalyst hereby grants to BioMarin a non-exclusive license during the term of this Agreement under Catalyst Know-How that relates to the Manufacture of Licensed Compound or Licensed Product, to Manufacture Licensed Products solely to support Development and Commercialization of Licensed Products for the LEMS Indication in the ROW.

## ARTICLE 3 DEVELOPMENT

- **3.1 Overview.** Catalyst shall be solely responsible, at its sole cost, for the Development of Licensed Products in the Field in the Territory; provided that BioMarin shall be responsible for fifty percent (50%) of the Joint Post-Marketing Studies as described in Section 3.5.
- 3.2 Technology Transfer. BioMarin shall and shall cause its Affiliates to transfer to Catalyst, at Catalyst's reasonable request, and at mutually agreed times during the Transfer Period and in a mutually agreed manner, the Licensed Technology, including, without limitation, all pre-clinical and clinical data generated or compiled in connection with Development of Licensed Product and all testing techniques, technology and other Licensed Know-How. BioMarin and its Affiliates shall transfer the Licensed Technology to Catalyst for a period of six (6) months, or such longer period as the Parties may mutually agree upon in order for all Licensed Technology that is required or reasonably useful for Catalyst's conduct of the Ongoing Study and other Development activities hereunder to be transferred in full to Catalyst (the "Transfer Period"). During the Transfer Period, BioMarin shall, at Catalyst's reasonable request, provide technical consultation to Catalyst with respect to the Licensed Technology by email, teleconference, and in-person meetings during BioMarin's normal business hours.
- **3.3 Diligent Development.** Each Party shall use Diligent Efforts to carry out, in a timely fashion and in good scientific manner, its responsibilities under Article 3, including, in the case of Catalyst, its obligations under the Development Plan. Additionally, Catalyst shall use Diligent Efforts to: (a) Develop at least one Licensed Product for LEMS in the U.S.; (b) take all other actions necessary to either satisfy BioMarin's obligations or allow BioMarin to satisfy its obligations (i) to EUSA under the EUSA License and (ii) to the Former Stockholders of Huxley under the Huxley Stock Purchase Agreement, in each case, (i) and (ii), relating to the Development of Licensed Product in the Territory; and (c) complete the double-blind treatment phase of the LMS-002 U.S. Phase 3 Clinical Trial within twenty-four (24) months of the Effective Date, provided that BioMarin complies with its supply obligations under Section 5.1. Any failure by Catalyst to comply with the obligations as set forth in this Section 3.3 shall be deemed to be a material breach of this Agreement, for which BioMarin may exercise its termination rights in accordance with Section 13.2 or any other available remedies at law or in equity.
- **3.4 Development Plan.** Catalyst's Development of Licensed Products hereunder shall be governed by a comprehensive, multi-year plan (the **"Development Plan"**). The Development Plan shall provide a planned Development program that is designed to generate the non-clinical, clinical and regulatory information required for submitting Drug Approval Applications and to obtain Regulatory Approvals for Licensed Products in the Territory. The Development Plan shall also include the Joint Post-Marketing Studies (and budgets covering such studies). Catalyst shall be responsible for: (i) preparing an initial Development Plan to be provided to BioMarin within forty-five (45) days of the Effective Date;

and (ii) preparing updates to the Development Plan, to be provided to BioMarin on an annual basis (or on an ad hoc basis to add a Joint Post-Marketing Study), along with the reports required under Section 3.7(c), within forty-five (45) days of each full calendar year during which Catalyst is required to perform under the Development Plan.

## 3.5 Jointly-Funded Post-Marketing Studies.

- (a) In General. The Parties shall collaborate on and jointly fund (i.e., on a 50/50 basis) Post-Marketing Studies, with respect to the treatment of LEMS with Firdapse, that are required by both the FDA and the EMA as a condition of granting Regulatory Approval ("Joint Post-Marketing Studies"). The attached Schedule 3.5 contains a list of post-marketing studies currently required by the EMA, which list shall be updated by BioMarin as additional post-marketing studies for the EU are identified. The Parties agree that to the extent such EU post-marketing studies are necessary or useful as post-marketing studies for the Territory, then Catalyst shall notify BioMarin and those studies shall be deemed Joint Post-Marketing Studies hereunder. For clarity, except as set forth in this Section 3.5, Catalyst shall be solely responsible, at its sole cost, for all other Post-Marketing Studies required by Regulatory Authorities in the Territory.
- **(b) Responsibilities.** For any such Joint Post-Marketing Study described in clause (a), the Parties will collaborate on the drafting of a detailed plan and budget for such Post-Marketing Study, which sets forth the responsibilities of each Party with respect to such study (**"Study Plan"**). BioMarin will be responsible for conducting the Joint Post-Marketing Studies listed in **Schedule 3.5** and, unless otherwise agreed in a Study Plan, BioMarin will be responsible for conducting any other Joint Post-Marketing Studies. The Parties will make good faith efforts to discuss and agree upon such Study Plan in a timely fashion. Upon the Parties' mutual agreement on the Study Plan, the Development Plan shall be amended to add such Study Plan, and the study described therein will be designated as a Joint Post-Marketing Study, the costs of which will be shared in accordance with Section 3.7(b).
- (c) Records; Reports. Each Party shall keep complete and accurate scientific records relating to the Joint Post-Marketing Studies and will make such records reasonably available to the other Party for review and/or copying. Such scientific records shall be maintained in accordance with good scientific practices. Each Party shall also keep detailed records of the Joint Development Costs it incurs, including all supporting documentation for such expenses, and will keep such records for at least three (3) years after the date that such expense was incurred. Each Party shall submit to the other Party: (a) oral reports regarding study activities and results for which it is responsible on a regular basis, as reasonably requested by the other Party, but no less frequently than once per month; and (b) written reports by electronic mail detailing study activities and results for which it is responsible, including all data and conclusions, descriptions of methods used, and specifications.

## 3.6 Coordination on Clinical Trials.

- **(a) Performance of BioMarin Ongoing Study.** Promptly following the Effective Date, the Parties will discuss, plan, and collaborate on the transfer of responsibilities to Catalyst for the BioMarin Ongoing Study listed on **Exhibit A**. The Parties shall complete the transfer of such responsibilities within three (3) months from the Effective Date (or such longer period as the Parties may mutually agree upon).
- **(b) Performance by Catalyst in the ROW.** Prior to conducting any Clinical Trial of a Licensed Product in the ROW in support of a Regulatory Filing or Regulatory Approval in the Territory, Catalyst shall discuss and coordinate with BioMarin on the selection of clinical sites in the ROW, and BioMarin shall have final decision-making authority over the selection and use of any such clinical sites in the ROW by or on behalf of Catalyst, its Affiliate, or Sublicensee.

**(c) Performance by BioMarin in the Territory.** Prior to conducting any Clinical Trial of a Licensed Product in the Territory in support of a Regulatory Filing or Regulatory Approval in the ROW, BioMarin shall discuss and coordinate with Catalyst on the selection of clinical sites in the Territory, and Catalyst shall have final decision-making authority over the selection and use of any such clinical sites in the Territory by or on behalf of BioMarin, its Affiliate, or Sublicensee.

(d) Joint Development Committee. Within thirty (30) days of the Effective Date, the Parties shall establish a joint Development committee (the "JDC"). The JDC shall consist of four (4) members, two (2) of whom shall be designated by BioMarin and two (2) of whom shall be designated by Catalyst. Each Party shall have the right at any time and from time to time to designate a replacement, on a permanent or temporary basis, for any or all of its previously-designated members of the JDC. The JDC shall review and discuss each Party's proposed Clinical Trials of Licensed Product in the Territory and the ROW, including the design of such Clinical Trials and the selection of clinical sites, and any other Development matters raised for discussion at JDC meetings. If a Party wishes to conduct and/or fund any Clinical Trial(s) (or authorize or facilitate any investigator initiated study) of Licensed Product in the Territory or the ROW, such Party shall request a JDC meeting sufficiently in advance to allow meaningful review and discussion by the JDC of such Party's proposed Clinical Trial (including the design thereof). The JDC shall hold meetings promptly following such request by a Party and at such other times as its members may determine, at a time and place mutually agreed upon by the Parties (including, as agreed, by teleconference or videoconference). Each Party's representatives on the JDC shall give reasonable consideration to the comments of the other Party's representatives on the JDC, but the JDC will only have consultative powers only and, except as set forth in Sections 3.6(b) and 3.6(c), neither Party will have final decision-making authority on the JDC. In addition, either Party may withdraw from the JDC at anytime.

## 3.7 Development Costs.

(a) In General. Except for the Joint Development Costs described in clause (b), Catalyst shall be responsible for one hundred percent (100%) of (i) all Development costs incurred by or on behalf of Catalyst for the Territory on and after the Effective Date, and (ii) Third Party and out-of-pocket costs incurred by or on behalf of BioMarin or its Affiliates on or after the Effective Date in connection with the conduct of the BioMarin Ongoing Study ("Out-of-Pocket Ongoing Study Costs") until responsibilities for the BioMarin Ongoing Study have been fully transferred to Catalyst, subject to the following: (i) as of the Effective Date, BioMarin estimates that the total Out-of-Pocket Ongoing Study Costs that BioMarin or its Affiliates will incur, until transfer of responsibilities for the BioMarin Ongoing Study, are \$[\*\*\*\*]; (ii) if, at any time prior transfer of responsibilities for the BioMarin Ongoing Study, BioMarin anticipates that the total Out-of-Pocket Ongoing Study Costs will exceed the foregoing estimate (a "Cost Overrun"), BioMarin will promptly notify Catalyst of the amount of the anticipated Cost Overrun and the reason(s) for such Cost Overrun; and (iii) Catalyst shall have no obligation to pay for any Cost Overrun that is not approved in advance by Catalyst. For the avoidance of doubt, Catalyst shall have no obligation to pay or reimburse BioMarin for any Development costs incurred by or on behalf of BioMarin or its Affiliates on or after the Effective Date other than Out-of-Pocket Ongoing Study Costs in accordance with this Section 3.7(a). Catalyst shall reimburse BioMarin for Out-of-Pocket Ongoing Study Costs in accordance with such invoices or other appropriate supporting documentation as Catalyst may reasonably request.

- **(b) Joint Development Costs.** The Parties shall each be responsible for fifty Percent (50%) of the Joint Development Costs incurred in connection with the performance by BioMarin (or Catalyst, if Catalyst is designated as the conducting Party under a Study Plan) of the Joint Post-Marketing Studies up to the amounts budgeted in Schedule 3.5 or, as applicable, in the agreed Study Plan (subject to Section 7.2(a)). The Parties shall reimburse each other for their respective shares of such Joint Development Costs in accordance with Section 7.2(a).
- **(c) Development Reports.** Within forty-five (45) days after each full calendar year during which Catalyst is required to perform under the Development Plan, Catalyst shall provide BioMarin with a written report that summarizes, in reasonable detail, all Development activities performed by Catalyst and its Affiliates and Third Party contractors during such year. Catalyst shall also promptly (i) provide BioMarin with any additional information reasonably requested by BioMarin regarding Development of Licensed Products by or on behalf of Catalyst or its Affiliates, and (ii) notify BioMarin upon Catalyst's initiation of any IND-Enabling Studies, Clinical Trials or Regulatory Filings relating to Licensed Product.
- **3.8 Standards of Conduct.** Catalyst shall perform, and shall cause its Affiliates and Third Party contractors to perform, all Development activities for Licensed Products in good scientific manner and in compliance with all applicable laws, rules and regulations.

## ARTICLE 4 REGULATORY MATTERS

4.1 Ownership of Regulatory Dossier. BioMarin agrees to transfer and hereby does assign to Catalyst (and Catalyst hereby agrees to receive from BioMarin) all of BioMarin's right, title and interest to U.S. IND Number 106263 for Firdapse, free and clear of all liens, claims and encumbrances. Additionally, BioMarin shall notify the FDA in writing that it is transferring such IND to Catalyst, and Catalyst shall notify the FDA in writing that it is accepting such IND and all responsibilities associated therewith, including without limitation, the responsibility for reporting adverse events. Catalyst shall own all other Regulatory Filings with respect to Licensed Products in the Territory and BioMarin agrees to transfer and hereby does assign to Catalyst any and all of BioMarin's right, title and interest in any such Regulatory Filings, free and clear of all liens, claims and encumbrances. BioMarin shall take any and all actions reasonably requested by Catalyst to effect the foregoing transfers and assignments, and, as soon as practicable after the Effective Date, BioMarin shall deliver to Catalyst copies of all Regulatory Filings and submissions, correspondence, notices and other communications to or from Regulatory Authorities, in each case relating to Licensed Product in the Territory. In addition, as soon as practicable after the Effective Date, BioMarin shall provide to Catalyst electronic copies of all Regulatory Filings, including all amendments thereto, submitted by or on behalf of BioMarin or any of its Affiliates in the EU.

## 4.2 Regulatory Filings.

(a) Territory. After transfer of ownership, Catalyst shall be responsible for all Regulatory Filings with respect to Licensed Products in the Territory. BioMarin shall have a right to review the content and subject matter of each Drug Approval Application to be filed in the Territory, all correspondence submitted to Regulatory Authorities in the Territory related to Clinical Trial design, all proposed labeling of Licensed Products and post-Regulatory Approval labeling changes, in each case relating to Licensed Product. Catalyst shall promptly provide BioMarin with copies of all material written or electronic communications received by it from, or sent by it to, Regulatory Authorities in the Territory with respect to obtaining and maintaining, Regulatory Approvals for Licensed Products (it being understood that routine adverse event filings – i.e., not relating to serious adverse events as defined by applicable law – shall not fall within the meaning of maintenance) and copies of all material contact reports produced by Catalyst.

- **(b) ROW.** BioMarin shall have the sole right and responsibility (without obligation) to make Regulatory Filings with respect to Licensed Products in the ROW. Catalyst shall have a right to review the content and subject matter of each Drug Approval Application to be filed in the ROW, all correspondence submitted to Regulatory Authorities in the ROW related to Clinical Trial design, all proposed labeling of Licensed Products and post-Regulatory Approval labeling changes, in each case relating to Licensed Product. BioMarin shall promptly provide Catalyst with copies of all material written or electronic communications received by it from, or sent by it to, Regulatory Authorities in the ROW with respect to obtaining and maintaining, Regulatory Approvals for Licensed Products (it being understood that routine adverse event filings i.e., not relating to serious adverse events as defined by applicable law shall not fall within the meaning of maintenance) and copies of all material contact reports produced by BioMarin.
- **4.3 Regulatory Data.** In addition to BioMarin's technology transfer obligations under Section 3.2, each Party shall provide the other Party on a timely basis copies of all material pre-clinical and clinical data generated or compiled in connection with its Development or Commercialization of Licensed Products (via electronic copies of such data in a form that may be analyzed and manipulated by the other Party). For clarity, this shall also include all analytical data obtained with respect to Licensed Products, descriptions of the manufacturing processes for Licensed Compounds and Licensed Products (and any material changes thereto), case report forms and patient medical records generated during Clinical Trials, and any data generated during post-marketing studies. Catalyst shall provide such information to BioMarin on an annual basis, along with the development reports required under Section 3.7. In addition, either Party shall provide such information within 30 days when requested by the other Party to support Regulatory Filings in the ROW or in the Territory.

## 4.4 Rights of Reference.

- (a) BioMarin, its Affiliate or sublicensee shall have the right to cross reference, file or incorporate by reference any regulatory filing or drug master file (as defined in the U.S. Code of Federal Regulations or any comparable law in the Territory), and any data contained therein, for any Licensed Products, or any components thereof, made in the Territory (including all Regulatory Approvals) in order to support regulatory filings by BioMarin, its Affiliate, or sublicensee in the ROW and to enable BioMarin, its Affiliate, or sublicensee to Develop, manufacture, or Commercialize Licensed Products in the ROW.
- **(b)** Catalyst, its Affiliates or sublicensees shall have the right to cross reference, file or incorporate by reference any regulatory filing or drug master file (as defined in the U.S. Code of Federal Regulations or any comparable law in the ROW), and any data contained therein, for any Licensed Products, or any components thereof, made in the ROW (including all Regulatory Approvals) in order to support regulatory filings by Catalyst, its Affiliates, or sublicensees in the Territory and to enable Catalyst, its Affiliates, or sublicensees to Develop, manufacture, or Commercialize Licensed Products in the Territory.
- **4.5 Recalls.** Any decision to initiate a recall or withdrawal of a Licensed Product in the Territory shall be made by Catalyst. In the event of any recall or withdrawal of Licensed Product in the Territory, Catalyst shall take any and all necessary action to implement such recall or withdrawal in accordance with applicable law, with assistance from BioMarin as reasonably requested by Catalyst and at Catalyst's sole expense. The costs of any such recall or withdrawal in the Territory, including any out-of-pocket expenses incurred by BioMarin, shall be borne solely by Catalyst.

4.6 Pharmacovigilance Agreement. Subject to the terms of this Agreement, and within three (3) months after the Effective Date, Catalyst and BioMarin (under the guidance of their respective Pharmacovigilance Departments, or equivalent thereof) shall define and finalize the responsibilities the Parties shall employ to protect patients and promote their well-being in a written Agreement (hereafter referred to as the "Pharmacovigilance Agreement"). These responsibilities shall include mutually acceptable guidelines and procedures for the receipt, investigation, recordation, communication, and exchange (as between the Parties) of adverse event reports, pregnancy reports, and any other information concerning the safety of any Licensed Product. Such guidelines and procedures shall be in accordance with, and enable the Parties and their Affiliates to fulfill, local and national regulatory reporting obligations to government authorities. Furthermore, such agreed procedures shall be consistent with relevant ICH guidelines, except where said guidelines may conflict with existing local regulatory safety reporting requirements, in which case local reporting requirements shall prevail. The Pharmacovigilance Agreement will provide for a worldwide safety database to be maintained by BioMarin for Firdapse. Each Party hereby agrees to comply with its respective obligations under such Pharmacovigilance Agreement (as the Parties may agree to modify it from time to time) and to cause its Affiliates and Sublicensees to comply with such obligations.

## ARTICLE 5 MANUFACTURING

- **5.1 Clinical Supply of Firdapse.** BioMarin shall deliver (or cause to be delivered) to Catalyst, free of charge, BioMarin's clinical inventory of Firdapse and placebo reserved for the BioMarin Ongoing Study, as set forth in **Exhibit E**, to be used by Catalyst as its clinical supply for the BioMarin Ongoing Study. In addition to the quantities set forth in **Exhibit E**, Catalyst may place orders for, and BioMarin shall sell and deliver (or cause to be delivered) to Catalyst, up to a maximum amount of [\*\*\*\*] kilograms of the active pharmaceutical ingredient of Firdapse ("API"), at a per kilogram cost of [\*\*\*\*]€. In order to purchase the API, Catalyst must place one or more orders for API (up to [\*\*\*\*] kilograms total) no later than June 30, 2013, and Catalyst must provide to BioMarin written notice of the quantity of API to be purchased at least sixty (60) days prior to the delivery date specified in such notice.
- **5.2 Stability Testing of Clinical Supply of Firdapse.** BioMarin shall continue stability testing, and shall provide stability reporting to Catalyst, of BioMarin's clinical inventory of Firdapse and placebo as set forth in **Exhibit E** until the earlier of (a) the terminal expiration date(s) of such clinical inventory, or (b) the failure of such clinical inventory to meet the product specifications set forth in U.S. IND Number 106263. BioMarin shall use Diligent Efforts to transfer all analytical methodology used for the stability testing of BioMarin's clinical inventory of Firdapse to a Third Party contract manufacturer, selected by Catalyst, in a time frame that will enable such Third Party contract manufacturer to initiate and conduct stability testing of all additional clinical supplies for the BioMarin Ongoing Study.
- **5.3 Additional Supply of Firdapse for Clinical and Commercial Use.** BioMarin will provide reasonable assistance to Catalyst in obtaining manufacturing contracts with the following Third Party contract manufacturers for the supply of Firdapse (active pharmaceutical ingredient and finished product): [\*\*\*\*]. Catalyst will Manufacture, either itself or through a Third Party contract manufacturer, its additional requirements for Development and Commercialization of Firdapse in the Territory, and Catalyst shall bear all associated costs and expenses.
- **5.4 Other Licensed Products.** Catalyst shall have sole responsibility for Manufacturing all Licensed Products (other than Firdapse) for Development and Commercialization in the Territory, and Catalyst shall bear all associated costs and expenses.

# ARTICLE 6 COMMERCIALIZATION

- **6.1** Commercialization in the Territory. Catalyst shall have sole responsibility for Commercializing all Licensed Products in the Territory, as provided in this Article 6, and Catalyst shall bear all of the costs and expenses, except Joint Post-Marketing Studies costs and expenses, incurred in connection with all such Commercialization activities.
- **6.2 Diligent Commercialization.** Catalyst shall use Diligent Efforts to: (a) Commercialize at least one Licensed Product for LEMS in the U.S.; and (b) take all other actions necessary to either satisfy BioMarin's obligations or allow BioMarin to satisfy its obligations (i) to EUSA under the EUSA License and (ii) to the Former Stockholders of Huxley under the Huxley Stock Purchase Agreement, in each case, (i) and (ii), relating to the Commercialization of Licensed Product in the Territory. Any failure by Catalyst to comply with the obligations set forth in this Section 6.2 shall be deemed to be a material breach of this Agreement, for which BioMarin may exercise its termination rights in accordance with Section 13.2 or any other available remedies at law or in equity.
- **6.3 Reports.** At least once per Calendar Year, Catalyst will reasonably inform BioMarin regarding the Commercialization of Licensed Products throughout the Territory. Catalyst shall provide BioMarin with a written report that summarizes, in reasonable detail, all Commercialization activities performed by Catalyst, its Affiliates, Sublicensees, and Third Party contractors during such year. Such reports submitted by Catalyst shall cover subject matter at a level of detail reasonably sufficient to enable BioMarin to determine Catalyst's compliance with its diligence obligations pursuant to Section 6.2.
- **6.4 Standards of Conduct.** Each Party shall perform, or shall ensure that its respective Affiliates, sublicensees, and subcontractors perform, all Commercialization activities in a good scientific and ethical business manner and in compliance with applicable laws and regulations.
- **6.5 EUSA License.** BioMarin will continue to comply with and perform all of its obligations under the EUSA License, and BioMarin will in good faith consider any concerns reasonably raised by Catalyst with respect to BioMarin's compliance with the EUSA License. BioMarin shall promptly notify Catalyst upon receipt from EUSA of any notice of an alleged breach under the EUSA License and Catalyst shall have the right to promptly discuss with BioMarin any such alleged breach. Catalyst shall have the right, but not the obligation, to cure any breach by BioMarin of its obligations under the EUSA License, and Catalyst may offset any amounts paid by Catalyst to cure such breach against any payments subsequently due to be paid by Catalyst to BioMarin under this Agreement. Promptly after the Effective Date, the Parties shall discuss meeting with EUSA to discuss an amendment of the EUSA License to have EUSA acknowledge the separate territories under this Agreement, and to make such other changes as the Parties deem necessary; provided, that, in the event the EUSA License is amended, the Parties will amend this Agreement accordingly.

# ARTICLE 7 PAYMENTS

**7.1 Upfront Consideration.** Catalyst shall pay to BioMarin such upfront consideration for the rights granted herein as set forth in the Stock Purchase Agreement.

# 7.2 Reimbursement of Joint Development Costs.

- (a) Within five (5) business days after the end of each Calendar Quarter during which BioMarin (or Catalyst, if Catalyst is designated as the conducting Party under a Study Plan) (the "Conducting Party") is conducting any Joint Post-Marketing Studies, the Conducting Party shall compile and exchange accurate and complete information with the other Party (the "Non-Conducting Party") concerning the Conducting Party's Joint Development Costs incurred under Article 3. Such exchanged information shall include a comparison of the Conducting Party's actual Joint Development Costs against budgeted costs set forth in Schedule 3.5 or in the Study Plan or in any other mutually agreed-upon budget, and shall include copies of Third Party invoices or other appropriate supporting documentation. Unbudgeted Joint Development Costs that were reasonably incurred under the circumstances shall be subject to each Party's obligation to share the Joint Development Costs equally, as set forth in Section 3.7(b), so long as such expenses do not exceed in the aggregate the greater of [\*\*\*\*] percent ([\*\*\*\*])%) of the budgeted costs set forth in Schedule 3.5 or in the agreed Study Plan or any other mutually agreed-upon budget.
- **(b)** If, at the time the Conducting Party exchanges information under Section 7.2(a) pertaining to a particular Joint Post-Marketing Study, such Joint Post-Marketing Study has been required by Regulatory Authority in its approval letter to be conducted by the Non-Conducting Party as a condition of granting Regulatory Approval, then, no later than forty-five (45) days after the exchange of the Conducting Party's Development Cost expenditure information, the Parties shall reconcile all Joint Development Cost expenditure amounts through a net payment to the Party incurring greater Joint Development Cost expenditures in such Calendar Quarter.
- (c) If, at the time the Conducting Party exchanges information under Section 7.2(a) pertaining to a particular Joint Post-Marketing Study, such Joint Post-Marketing Study has not been required by Regulatory Authority in its approval letter to be conducted by the Non-Conducting Party as a condition of granting Regulatory Approval, then the Non-Conducting Party shall have no obligation to pay or reimburse any Joint Development Costs allocable to such Joint Post-Marketing Study unless and until such Joint Post-Marketing Study is required by Regulatory Authority in its approval letter to be conducted by the Non-Conducting Party as a condition of granting Regulatory Approval. At such time as a Joint Post-Marketing Study is required by Regulatory Authority in its approval letter to be conducted by the Non-Conducting Party as a condition of granting Regulatory Approval, (i) to the extent such Joint Post-Marketing Study is then ongoing, the Parties shall reconcile Joint Development Costs allocable to such Joint Post-Marketing Study as provided in Section 7.2(b), or (ii) to the extent such Joint Post-Marketing Study is completed, the Non-Conducting Party shall reimburse the Conducting Party an amount equal to the Non-Conducting Party's share of Joint Development Costs incurred under Article 3 for such Joint Post-Marketing Study, within forty-five (45) days of receipt of an invoice for the same, together with copies of Third Party invoices or other appropriate supporting documentation (to the extent not already provided to the Non-Conducting Party pursuant to Section 7.2(a)).
- (d) In accordance with the restrictions and limitations as set forth Section 8.3, each Party will have the right to audit appropriate records of the other Party to verify such Joint Development Costs.
  - **7.3 Supply Costs.** Catalyst shall pay BioMarin for Manufacturing and supply of Firdapse in accordance with the terms set forth in Article 5.

# 7.4 Royalties.

(a) Royalty Rates on Net Sales. Subject to adjustment as described in Section 7.4(b), Catalyst shall pay to BioMarin incremental quarterly royalties on aggregate, cumulative Net Sales of each Licensed Product in the Territory by Catalyst, its Affiliates, or Sublicensees at a royalty rate determined by total Net Sales of such Licensed Product in a Calendar Year as follows:

\*\*\*\*

All royalty payments made by Catalyst to BioMarin hereunder shall be non-creditable and non-refundable.

**(b) Royalty Term.** With respect to each Licensed Product, royalties owed by Catalyst under Section 7.4 will commence, on a country-by-country basis, upon the First Commercial Sale of such Licensed Product in such country in the Territory, and will continue at the rates set forth in Section 7.4, on a country-by-country basis, for [\*\*\*\*] years.

Upon the expiration of the applicable Royalty Term with respect to a particular Licensed Product in the Territory, the license granted to Catalyst under the Licensed Technology for the Licensed Product in the Territory shall become fully-paid, royalty-free, perpetual and irrevocable.

# 7.5 Third Party Agreements and Payments

- (a) Payments. Catalyst shall be responsible for paying to BioMarin the milestone payments and royalties set forth in Exhibit F and owed by BioMarin or its Affiliates to EUSA under the EUSA License and to the Former Stockholders of Huxley under the Huxley Stock Purchase Agreement on account of (i) the grant to Catalyst of the licenses set forth in Section 2.1, and (ii) the research, development, manufacture and/or commercialization of Licensed Products by Catalyst, its Affiliates or Sublicensees in the Territory. Catalyst shall pay to BioMarin the milestone payments and royalties set forth in Exhibit F at least ten (10) days in advance of the applicable due date for such payments to be made under the EUSA License or the Huxley Stock Purchase Agreement ("Third Party Payment Due Date"). BioMarin shall not retain or use for any purpose any such milestone payments or royalties paid by Catalyst and, following receipt of such milestone payments and royalties, BioMarin shall transmit such amounts to EUSA and/or the Former Stockholders of Huxley promptly, but in any event on or before the applicable Third Party Payment Due Date.
- **(b) Reports.** At least ten (10) days in advance of a Third Party Payment Due Date and at least ten (10) days prior to any royalty report required under the EUSA License, Catalyst shall provide a written report to BioMarin with all information reasonably required by or useful to BioMarin to (i) ascertain when an applicable milestone payment or royalty is owed under the EUSA License or the Huxley Stock Purchase Agreement, and (ii) calculate the amounts of applicable royalty and milestone payments due under the EUSA License or the Huxley Stock Purchase Agreement. BioMarin and Catalyst shall cooperate and facilitate such exchange of information, as reasonably necessary to assist Catalyst in complying with the foregoing obligations and to assist BioMarin in complying with its obligations pursuant to the EUSA License and the Huxley Stock Purchase Agreement.

# ARTICLE 8 PAYMENT; REPORTS; AUDITS

# 8.1 Quarterly Royalty Payments and Reports.

- (a) Until the expiration of Catalyst's royalty obligations under Section 7.4(b), Catalyst shall provide to BioMarin preliminary written reports not more than five (5) business days after the end of each Calendar Quarter and follow-on written reports (reconciling the preliminary reports, as necessary) not more than ten (10) business days after the end of each Calendar Quarter covering all sales of Licensed Products for which invoices were sent during such Calendar Quarter in the Territory by Catalyst, its Affiliates, or Sublicensees.
- (b) Each royalty report required under Section 7.5(b) and each such written report required under Section 8.1(a) shall state for the period in question:

  (i) gross sales of Licensed Products in the Territory during the applicable Calendar Quarter, on a Licensed Product-by-Licensed Product and country-by-country basis;
  - (ii) calculation of Net Sales for the applicable Calendar Quarter, along with cumulative Net Sales for the then-current Calendar Year;
  - (iii) a calculation of the amount of royalty payment due on such Net Sales pursuant to Section 7.4; and
  - (iv) a calculation of the amount of royalty payment due to EUSA under the EUSA License.
- **(c)** The information contained in each report under this Section 8.1 shall be considered Confidential Information of Catalyst. Concurrent with the delivery of each follow-on quarterly report, Catalyst shall make the payments due to BioMarin under Section 7.4 and Section 7.5 for the Calendar Quarter covered by such report.
  - 8.2 Non-Creditable, Non-Refundable. All payments made by Catalyst pursuant to this Agreement shall be non-creditable and non-refundable.
- **8.3 Accounting.** Catalyst agrees to keep full, clear and accurate records for a period of at least three (3) years after the relevant payment is owed pursuant to this Agreement, setting forth the sales and other disposition of Licensed Products sold or otherwise disposed of in sufficient detail to enable royalties and compensation payable to BioMarin hereunder to be determined. Catalyst further agrees to permit its books and records to be examined by an independent accounting firm selected by BioMarin and reasonably acceptable to Catalyst (subject to written obligations of confidentiality to Catalyst that are no less stringent than the obligation of confidentiality described in Article 11), at reasonable times and upon reasonable notice, to examine only those records as may be necessary to verify reports provided pursuant to Section 8.1. Such audit shall not be performed more frequently than once per Calendar Year or with respect to any calendar year ending not more than three (3) years prior to such year, nor more frequently than once with respect to records covering any specific period of time. Such examination is to be made at BioMarin's expense, except in

the event that the results of the audit reveal an underpayment of royalties or milestone payments to BioMarin under this Agreement exceeding [\*\*\*\*] percent ([\*\*\*\*]%) over the period being audited, in which case reasonable audit fees for such examination shall be paid by Catalyst. Catalyst further agrees to permit its books and records to be examined by an independent accounting firm selected by EUSA and reasonably acceptable to Catalyst (subject to written obligations of confidentiality to Catalyst that are no less stringent than the obligation of the confidentiality described in Article 11), at reasonable times and upon reasonable notice, to examine only those records as may be necessary to verify reports provided pursuant to Section 8.1. Such audit shall not be performed more frequently than once per Calendar Year or with respect to any calendar year ending not more than three (3) years prior to such year, nor more frequently than once with respect to records covering any specific period of time. Such examination is to be made at EUSA's expense, except in the event that the results of the audit reveal an underpayment of royalties or milestone payments owed to EUSA under this Agreement exceeding [\*\*\*\*] percent ([\*\*\*\*]%) over the period being audited, in which case reasonable audit fees for such examination shall be paid by Catalyst.

- **8.4 Methods of Payments.** All payments due to BioMarin under this Agreement shall be paid in Dollars by wire transfer to a bank in the U.S. designated in writing by BioMarin.
- **8.5 Taxes.** If a law or regulation of any country requires withholding of taxes of any type, levies or other charges with respect to the any amounts payable hereunder to BioMarin, Catalyst shall promptly pay such tax, levy or charge for and on behalf of BioMarin to the proper governmental authority, and shall promptly furnish BioMarin with receipt of such payment. Catalyst shall have the right to deduct any such tax, levy or charge actually paid from payment due BioMarin or be promptly reimbursed by BioMarin if no further payments are due to BioMarin. Catalyst agrees to reasonably assist BioMarin in claiming exemption from such deductions or withholdings under double taxation or similar agreement or treaty from time to time in force and in minimizing the amount required to be so withheld or deducted.
- **8.6 Foreign Exchange.** The rate of exchange to be used in computing the amount of currency equivalent in Dollars of Net Sales invoiced in other currencies shall be made at the closing exchange rates reported in *The Wall Street Journal* (U.S., Western Edition) on the last business day of the applicable Calendar Quarter for which the payment is made.
- **8.7 Late Payments.** Any amounts not paid by Catalyst when due under this Agreement will be subject to interest from and including the date payment is due, up through and including the date upon which BioMarin has collected the funds in accordance herewith at a rate equal to the lesser of (a) the sum of ten percent (10.0%) plus the prime rate of interest quoted in the Money Rates (or equivalent) section of the Wall Street Journal per annum, calculated daily, or (b) the maximum interest rate allowed by law.

# ARTICLE 9 INTELLECTUAL PROPERTY

**9.1 Inventions.** The inventorship of any Inventions shall be determined under U.S. patent law. BioMarin shall own the entire right, title and interest in and to the BioMarin Inventions, and Patents claiming only such BioMarin Inventions (and no Joint Inventions). Catalyst shall own the entire right, title and interest in and to the Catalyst Inventions, and Patents claiming only such Catalyst Inventions (and no Joint Inventions). BioMarin and Catalyst shall each own an undivided one-half interest in and to any and all Joint Inventions and Joint Patents. Except as otherwise specified in this Agreement, BioMarin and Catalyst as joint owners each shall have the right to exploit and to grant licenses under the Joint Inventions without accounting for profits or other consideration, or sharing of any proceeds, to the other Party, in each case without the consent of the other Party.

# 9.2 Patent Prosecution.

(a) Licensed Patents. For each jurisdiction within the Territory, Catalyst shall have the first right to prepare, file, prosecute and maintain each Patent within the Licensed Patents, on behalf of BioMarin or its Affiliate, at Catalyst's sole expense and by counsel of its own choice (including, in Catalyst's discretion, any counsel employed by BioMarin to prepare, file, prosecute or maintain any Licensed Patents prior to the Effective Date), and BioMarin shall promptly disclose to Catalyst any invention disclosures, or other similar documents, submitted to it by its employees, agents or independent contractors describing subject matter that are purported to be BioMarin Inventions as defined hereunder, and all information relating to such BioMarin Inventions in sufficient detail for Catalyst to exercise its right to prepare, file, prosecute and maintain a Patent claiming such BioMarin Invention in each jurisdiction within the Territory. Catalyst shall keep BioMarin reasonably informed and apprised of the status of each such Licensed Patent in the Territory. Catalyst shall provide BioMarin with copies of all official documentation and communications relating to the filing, prosecution, and maintenance of such Licensed Patents in the Territory sufficiently in advance of any initial deadline for a filing response (and at least 30 days in advance) so that BioMarin shall have the opportunity to advise and comment on any filings of applications, responses to office actions, or other material filing or response with respect to the Licensed Patents. Catalyst shall give reasonable consideration to any suggestions or recommendations of BioMarin concerning the preparation, filing, prosecution and maintenance thereof. If, during the term of this Agreement, Catalyst intends not to continue prosecuting or maintaining a Licensed Patent that was licensed to BioMarin Huxley Ltd. by EUSA under the EUSA License (any such Patent, a "EUSA Licensed Patent") in the Territory, Catalyst shall notify BioMarin of such intention at least sixty (60) days prior to any applicable deadline, and BioMarin shall thereupon have the right, but not the obligation, to assume responsibility for the prosecution and maintenance of such EUSA Licensed Patent, for which BioMarin shall bear all associated costs and expenses. For clarity, BioMarin shall retain sole control of and shall be solely responsible for filing, prosecuting and maintaining Licensed Patents in the ROW, at BioMarin's sole discretion and expense.

**(b) Catalyst Patents.** Catalyst shall retain sole control of and shall be solely responsible for filing, prosecuting and maintaining Catalyst Patents in the Territory and ROW, at Catalyst's sole discretion and expense.

# (c) Joint Patents.

(i) Territory. For each jurisdiction in the Territory, Catalyst shall have the first right to prepare, file, prosecute and maintain each Joint Patent, on behalf of BioMarin or its Affiliate, at Catalyst's sole expense. BioMarin shall provide reasonable assistance with such efforts, and Catalyst shall reimburse BioMarin for all costs and expenses incurred by BioMarin in connection with such prosecution and maintenance. Catalyst shall keep BioMarin informed and apprised of the status of each such Joint Patent in the Territory. Catalyst shall provide BioMarin with copies of all documentation and communications relating to the filing, prosecution, and maintenance of such Joint Patents in the Territory sufficiently in advance of any initial deadline for a filing response (and at least 30 days in advance) so that BioMarin shall have the opportunity to advise and comment on any filings of applications, responses to office actions, or other filing or response. Catalyst shall give reasonable consideration to any suggestions or recommendations of BioMarin concerning the preparation, filing, prosecution and maintenance thereof. If, during the term of this Agreement, Catalyst intends not to file or continue prosecuting or maintaining a Joint Patent in the Territory, Catalyst shall notify BioMarin of such intention at least sixty (60) days prior to any applicable deadline, and BioMarin shall thereupon have the right, but not the obligation, to assume responsibility for the prosecution or maintenance of such Joint Patent, for which BioMarin shall bear all associated costs and expenses.

(ii) ROW. For each jurisdiction in the ROW, BioMarin shall have the first right to prepare, file, prosecute and maintain each Joint Patent, on behalf of Catalyst or its Affiliate, at BioMarin's sole expense. Catalyst shall provide reasonable assistance with such efforts, and BioMarin shall reimburse Catalyst for all costs and expenses incurred by Catalyst in connection with such prosecution and maintenance. BioMarin shall keep Catalyst informed and appraised of the status of each such Joint Patent in the ROW. BioMarin shall provide Catalyst with copies of all documentation and communications relating to the filing, prosecution, and maintenance of such Joint Patents in the ROW sufficiently in advance of any initial deadline for a filing response (and at least 30 days in advance) so that Catalyst shall have the opportunity to advise and comment on any filings of applications, responses to office actions, or other filing or response. BioMarin shall give reasonable consideration to any suggestions or recommendations of Catalyst concerning the preparation, filing, prosecution and maintenance thereof. If, during the term of this Agreement, BioMarin intends not to file or continue prosecuting or maintaining a Joint Patent in the ROW, BioMarin shall notify Catalyst of such intention at least sixty (60) days prior to any applicable deadline, and Catalyst shall thereupon have the right, but not the obligation, to assume responsibility for the prosecution or maintenance of such Joint Patent, for which Catalyst shall bear all associated costs and expenses.

(d) Cooperation. BioMarin and Catalyst shall coordinate with each other on the prosecution of the Licensed Patents and Joint Patents in their respective territories (i.e. for Catalyst, the Territory, and for BioMarin, the ROW) to seek a consistent prosecution strategy in each territory. Additionally, Catalyst shall use Diligent Efforts in obtaining patent term extension or supplemental protection certificates or their equivalents in any country in the Territory with respect to Licensed Patents and Joint Patents covering the Licensed Products. If elections with respect to obtaining such patent term extensions are to be made, BioMarin and Catalyst shall discuss and make reasonable efforts to agree upon such elections. BioMarin shall provide such cooperation to Catalyst as Catalyst reasonably deems necessary for the preparation, filing, prosecution and maintenance of Licensed Patents and Joint Patents, and for obtaining and maintaining any patent term extensions, supplementary protection certificates and the like in the Territory, including by making the inventors of any Licensed Patent or Joint Patent reasonably available to Catalyst with respect to responding to any patent office action, and by executing all papers and instruments, and requiring its Affiliates and its and their employees, agents and contractors to execute such papers and instruments, as Catalyst reasonably deems necessary. Catalyst shall reimburse BioMarin for its reasonable expenses incurred in the course of providing such cooperation.

#### 9.3 Patent Enforcement.

- (a) Notice. If either Party becomes aware of any infringement, threatened infringement, or alleged infringement of a Licensed Patent, Catalyst Patent, or Joint Patent by a Third Party (an "Infringement"), it will promptly notify the other Party thereof including available evidence of infringement, provided that each Party shall comply with the obligations set forth in Section 6.1 of the EUSA License regarding notifying EUSA of any actual, potential or alleged infringement of a EUSA Licensed Patent, or of any challenge to the validity of a EUSA Licensed Patent, of which either Party becomes aware.
- **(b) Enforcement in the Territory.** Subject to EUSA's rights under Section 6.2 of the EUSA License with respect to a EUSA Licensed Patent, Catalyst will have the first right (but not the obligation), at its sole expense, to take the appropriate steps to address any Infringement of a Licensed Patent or Joint Patent in the Territory by enforcing such Patent, including without limitation the initiation of a suit, proceeding or other legal action by counsel of its own choice. BioMarin will have the right, at its own expense, to be represented in any such suit, proceeding, or action by counsel of its own choice. If Catalyst fails to take the appropriate steps to address a particular Infringement of a Licensed Patent or Joint Patent within ninety (90) days after the date one Party has provided

notice to the other Party of such Infringement, then BioMarin will have the right (but not the obligation), at its sole expense, to take the appropriate steps to address such Infringement by enforcing such Licensed Patent or Joint Patent, including without limitation the initiation of a suit, proceeding or other legal action by counsel of its own choice. Catalyst will have the right, at its own expense, to be represented in any such suit, proceeding, or action by counsel of its own choice. Catalyst will have the sole right (but not the obligation), at its sole discretion and expense, to take the appropriate steps to address any Infringement of a Catalyst Patent anywhere in the world by enforcing such Catalyst Patent, including without limitation the initiation of a suit, proceeding or other legal action by counsel of its own choice. Catalyst's rights to address any Infringement of a EUSA Licensed Patent in the Territory by enforcing such EUSA Licensed Patent will be subject to EUSA's rights under Section 6.2 and Section 6.4 the EUSA License.

- **(c) Enforcement in the ROW.** BioMarin will have the sole right (but not the obligation), at its sole discretion and expense, to take the appropriate steps to address any Infringement of a Licensed Patent or Joint Patent in the ROW by enforcing such Licensed Patent or Joint Patent, including without limitation the initiation of a suit, proceeding or other legal action by counsel of its own choice.
- (d) Cooperation. If one Party brings any suit, action or proceeding under this Section 9.3, the other Party agrees to be joined as party plaintiff, at such enforcing Party's request and expense, if in the reasonable judgment of the Party bringing such suit, action or proceeding that the other Party is necessary for such action; provided, however, that neither Party will be required to transfer any right, title or interest in or to any property to the other Party or any other party to confer standing on a Party hereunder. The Party not pursuing the suit, action or proceeding hereunder will provide reasonable assistance to the other Party, including by providing access to relevant documents and other evidence and making its employees available, subject to the other Party's reimbursement of any reasonable out-of-pocket expenses incurred by the non-enforcing or defending Party in providing such assistance. Neither Party will settle or otherwise compromise any such suit, action or proceeding in a way that adversely affects the other Party's intellectual property rights or its rights or interests with respect to any Licensed Product without such other Party's prior written consent.
- **(e) Recovery.** Except as otherwise agreed to by the Parties as part of a cost-sharing arrangement, any settlements, damages or other monetary awards (the "Recovery") recovered pursuant to a suit, proceeding, or action in the Territory brought pursuant to Section 9.3(b) or 9.3(c) will be allocated first to the costs and expenses of the Party taking such action, and second, to the costs and expenses (if any) of the other Party (to the extent not otherwise reimbursed), and any remaining amounts will be shared by the Parties as follows: (i) if the applicable suit, proceeding, or action was brought by Catalyst, then such remaining amounts shall be retained by Catalyst and treated as Net Sales; and (ii) if the applicable suit, proceeding, or action was brought by BioMarin, then BioMarin shall retain [\*\*\*\*] percent ([\*\*\*\*]%). BioMarin shall have the sole right to any and all Recoveries obtained pursuant to a suit, proceeding, or action relating to an Infringement of a Licensed Patent in the ROW brought pursuant to Section 9.3(c).

# 9.4 Defense of Infringement Actions.

(a) During the term of this Agreement, each Party shall bring to the attention of the other Party all information regarding potential infringement of Third Party intellectual property rights via the development, manufacture, production, use, importation, offer for sale, or sale of a Licensed Product in the Territory, *provided that* each Party shall comply with the obligations set forth in Section 6.3 of the EUSA License regarding notifying EUSA. Upon the request of either Party, the Parties shall agree on and enter into a "common interest agreement" wherein such Parties agree to their shared, mutual interest in the outcome of such potential dispute.

- **(b)** If Catalyst and/or BioMarin are named as defendant(s) in a patent infringement suit filed by a Third Party concerning the development, manufacture, production, use, importation, offer for sale, or sale of a Licensed Product in the Territory, then Catalyst shall control and defend such suit at its own cost and shall indemnify and <u>hold</u> BioMarin harmless against any such patent or other infringement suits, and any claims, losses, damages, liabilities, expenses, including reasonable attorneys' fees and cost, that may be incurred by BioMarin therein or in settlement thereof. Any and all settlements that restrict the scope or enforceability of the Licensed Technology must be approved by BioMarin, in its reasonable discretion, before execution by Catalyst. BioMarin shall not be required to approve any settlement that does not include as a condition thereof the full release of claims against BioMarin. Catalyst's rights to defend, control the defense of, and/or settle such challenge or claim that is applicable to EUSA or a EUSA Licensed Patent will be subject to EUSA's rights under Section 6.4 the EUSA License.
  - (c) This Section 9.4 shall not be interpreted as placing on either Party a duty of inquiry regarding Third Party intellectual property rights.
- 9.5 Trademarks. Subject to the terms and conditions of this Agreement, BioMarin hereby grants to Catalyst an exclusive, royalty-free right and license, with the right to sublicense, to use the Licensed Trademarks solely in connection with the Commercialization of Licensed Products in the Field in the Territory. Catalyst shall be responsible for the selection, registration, maintenance, and defense of all trademarks, including the Licensed Trademarks, for use in connection with the sale or marketing of Licensed Products in the Field in the Territory (the "Marks"), as well as all expenses associated therewith. All uses of the Marks shall comply with all applicable laws and regulations (including, without limitation, those laws and regulations particularly applying to the proper use and designation of trademarks in the applicable countries). Except for the Licensed Trademarks, Catalyst shall not, without BioMarin's prior written consent, use any trademarks or house marks of BioMarin (including the BioMarin corporate name), or marks confusingly similar thereto, in connection with Catalyst's Development or Commercialization of Licensed Products under this Agreement. Catalyst shall own all Marks (other than the Licensed Trademarks). In addition, Catalyst undertakes not to use, either in writing or verbally, the name of the AP-HP or any of its agents in relation to the exploitation and distribution of the Licensed Products, particularly for promotional purposes, no matter what the medium used (video, poster, press pack, advertising label, etc.) without the prior written consent of the AP-HP. Except to the extent required by laws, rules or regulations, Catalyst shall not under any circumstances be able to reproduce the names and trademarks of EUSA and/or AP-HP, without its prior written consent.
- **9.6 Regulatory** Exclusivity. Catalyst shall use Diligent Efforts to obtain, maintain, and enforce Regulatory Exclusivity, consistent with its obligations under applicable law, with respect to Licensed Products in the Territory.
- **9.7 Patent Marking.** Catalyst shall, and shall require its Affiliates and Sublicensees to, mark Licensed Products sold by it hereunder with appropriate Patent numbers or indicia to the extent permitted by applicable law and regulations, in those countries in which such markings or such notices impact recoveries of damages or equitable remedies available with respect to infringements of Patents.

# ARTICLE 10 REPRESENTATIONS, WARRANTIES, AND COVENANTS

- 10.1 Mutual Representations and Warranties. Each Party hereby represents and warrants to the other Party as of the Effective Date:
- (a) Such Party is a corporation or entity duly organized and validly existing under the laws of the state or other jurisdiction of its incorporation or formation;

- (b) The execution, delivery and performance of this Agreement by such Party has been duly authorized by all requisite corporate action;
- **(c)** Such Party has the corporate power and authority to execute and deliver this Agreement and to perform its obligations hereunder, and such performance does not conflict with or constitute a breach of any agreement of such Party with a Third Party; and
  - (d) Such Party has the right to grant the rights and licenses described in this Agreement.
  - 10.2 BioMarin Representations and Warranties. BioMarin on behalf of itself and its Affiliates hereby represents and warrants to Catalyst that:
- (a) As of the Effective Date, BioMarin has the right to grant the licenses provided in this Agreement, and the Licensed Technology is free and clear of any liens, charges, or encumbrances which would conflict with any rights granted to Catalyst under this Agreement;
- **(b)** BioMarin and its Affiliates have not conveyed or licensed, and will not convey or license during the term of this Agreement, to a Third Party any right, title, or interest in, to or under any Licensed Technology which conflicts with any rights and licenses granted to Catalyst under this Agreement;
- **(c)** As of the Effective Date, to BioMarin's and its Affiliates' Knowledge, the Licensed Patents are not subject to any pending or threatened reexamination, opposition, interference, or litigation proceeding in the Territory;
- **(d)** As of the Effective Date, to BioMarin's and its Affiliates' Knowledge, the granting by BioMarin of the licenses set forth herein and, the performance by BioMarin of the activities contemplated herein shall not infringe any registered trademark or copyright, or issued patent that is registered or issued on or before the Effective Date, or any trade secret right of any Third Party, in the Territory;
- **(e)** As of the Effective Date, BioMarin has not received any written notice of a claim that any issued patent, trade secret or other intellectual property of a Third Party would be infringed or misappropriated by the Manufacture, Development or Commercialization of a Licensed Product in the Territory;
- **(f)** As of the Effective Date and to BioMarin's and its Affiliates' Knowledge, BioMarin and its Affiliates have conducted the Development of Firdapse in the Territory in accordance with applicable law, and neither BioMarin or its Affiliates nor any officer, employee or agent of BioMarin or its Affiliates has knowingly made an untrue statement of a material fact to any Regulatory Authority in the Territory with respect to Firdapse (whether in any submission to such Regulatory Authority or otherwise), or knowingly failed to disclose a material fact required to be disclosed to any Regulatory Authority in the Territory with respect to Firdapse.
- **(g)** As of the Effective Date, the EUSA License is in full force and effect in accordance with its terms, and neither BioMarin nor any of its Affiliates is in breach of such agreement and has not received notice from any party to the EUSA License that BioMarin or any of its Affiliates is in breach of any such agreement;

- (h) As of the Effective Date, BioMarin has provided Catalyst with a true, correct, and complete copy of the EUSA License; and
- (i) Neither BioMarin nor any of its Affiliates shall amend, waive any of its rights, or take or fail to take any other action under the EUSA License in any manner that would result in termination of the EUSA License or materially and adversely affect Catalyst's rights and benefits under this Agreement.
- 10.3 Disclaimer. EXCEPT AS PROVIDED IN SECTIONS 10.1 AND 10.2, THE TECHNOLOGY AND INTELLECTUAL PROPERTY RIGHTS PROVIDED BY EACH PARTY ARE PROVIDED "AS IS" AND EACH PARTY EXPRESSLY DISCLAIMS ANY AND ALL WARRANTIES OF ANY KIND, EXPRESS OR IMPLIED, INCLUDING WITHOUT LIMITATION THE WARRANTIES OF DESIGN, MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, AND NONINFRINGEMENT OF THE INTELLECTUAL PROPERTY RIGHTS OF THIRD PARTIES, ARISING FROM A COURSE OF DEALING, USAGE OR TRADE PRACTICES, IN ALL CASES WITH RESPECT THERETO.

# ARTICLE 11 CONFIDENTIALITY

11.1 Confidentiality. During and after the term of this Agreement, each Party (i) shall maintain in confidence all Confidential Information of the other Party; (ii) shall not use such Confidential Information for any purpose except as permitted by this Agreement; and (iii) shall not disclose such Confidential Information to anyone other than those of its Affiliates, Sublicensees, prospective Sublicensees, employees, consultants, agents or subcontractors who are bound by written obligations of nondisclosure and non-use no less stringent than those set forth in this Article 11 and to whom such disclosure is necessary in connection with such Party's activities as contemplated in this Agreement. Each Party shall ensure that such Party's Affiliates, Sublicensees, prospective Sublicensees, employees, consultants, agents and subcontractors comply with these obligations. Each Party shall notify the other promptly on discovery of any unauthorized use or disclosure of the other's trade secrets or proprietary information.

11.2 Exceptions. The obligations of confidentiality, non-disclosure, and non-use set forth in Section 11.1 shall not apply to the extent the receiving Party (the "Recipient") can demonstrate that the disclosed information (i) was in the public domain at the time of disclosure to the Recipient by the other Party, or thereafter entered the public domain, in each case other than as a result of actions of the Recipient, its Affiliates, employees, agents or subcontractors, in breach of this Agreement; (ii) was rightfully known by the Recipient or its Affiliates (as shown by its written records) prior to the date of disclosure to the Recipient by the other Party; or (iii) was received by the Recipient or its Affiliates on an unrestricted basis from a Third Party rightfully in possession of such information and not under a duty of confidentiality to the other Party. Notwithstanding any other provision of this Agreement, Recipient's disclosure of Confidential Information shall not be prohibited if such disclosure: (a) is in response to a valid order of a court or other governmental body, provided that Recipient provides the other Party with prior written notice of such disclosure in order to permit the other Party to seek a protective order or other confidential treatment of such Confidential Information; or (b) is otherwise required by applicable law or regulation.

# 11.3 Publications.

- (a) Prior to public disclosure or submission for publication of a proposed publication or presentation describing the results of any scientific or clinical activity relating to a Licensed Product, the publishing Party shall send the non-publishing Party a copy of the proposed publication or presentation to be submitted and shall allow the non-publishing Party a reasonable time period (but no less than thirty (30) days from the date of confirmed receipt) in which to determine whether the proposed publication contains subject matter for which patent protection should be sought (prior to publication of such proposed publication) for the purpose of protecting an invention, or whether the proposed publication contains the Confidential Information of the non-publishing Party, or whether the proposed publication contains information that is reasonably likely to have a material adverse impact on the Development or Commercialization of such Licensed Product in the Territory or ROW, as applicable to the non-publishing Party. Following the expiration of applicable time period for review, the publishing Party shall be free to submit such proposed publication for publication and publish or otherwise disclose to the public such scientific or clinical results, subject to the procedures set forth in Section 11.3(b).
- **(b)** If the non-publishing Party believes that the subject matter of the proposed publication contains Confidential Information or a patentable invention of the non-publishing Party, or information that is reasonably likely to have a material adverse impact on the Development or Commercialization of such Licensed Product, then prior to the expiration of the applicable time period for review, the non-publishing Party shall notify the publishing Party in writing of its determination that such proposed publication contains such information or subject matter for which patent protection should be sought. On receipt of such written notice from the non-publishing Party, the publishing Party shall delay public disclosure of such information or submission of the proposed publication for an additional period of sixty (60) days (or such shorter period mutually agreed by the Parties) to permit preparation and filing of a patent application on the disclosed subject matter. The publishing Party shall thereafter be free to publish or disclose such information, except that the publishing Party may not disclose any Confidential Information of the non-publishing Party in violation of Sections 11.1 and 11.2 hereof, and the publishing Party shall discuss and agree with the non-publishing Party on the removal of information from such disclosure that is reasonably likely to have a material adverse impact on the Development or Commercialization of the Licensed Product in the non-publishing Party's territory.
- **11.4 Publicity**. The Parties agree that the public announcement of the execution of this Agreement shall be substantially in the form of the press release attached as **Exhibit G**, which shall be issued at a time to be mutually agreed by the Parties. Any other publication, news release or other public announcement relating to this Agreement or to the performance hereunder, shall first be reviewed and approved by both Parties; provided, however, that any disclosure which is required by law as advised by the disclosing Party's counsel may be made without the prior consent of the other Party, although the other Party shall be given prompt notice of any such legally required disclosure and to the extent practicable shall provide the other Party an opportunity to comment on the proposed disclosure. Neither Party shall be required to seek the permission of the other Party to repeat any information relating to this Agreement that has already been publicly disclosed by such Party, or by the other Party, in accordance with this Section 11.4, provided such information remains accurate as of such time and provided the frequency and form of such disclosure are reasonable.

# ARTICLE 12 INDEMNIFICATION

**12.1 Mutual Indemnification.** Subject to Section 12.2, each Party ("**Indemnitor**") hereby agrees to indemnify, defend and hold harmless the other Party ("**Indemnitee**"), its Affiliates, and their respective directors, employees and agents from and against any and

all Third Party suits, claims, actions, demands, liabilities, expenses and/or losses, including reasonable legal expenses and reasonable attorneys' fees ("Losses") to the extent such Losses result from: (a) any breach of warranty by the Indemnitor contained in this Agreement; (b) any breach of this Agreement or applicable law by the Indemnitor, its Affiliates or (sub)licensees, or their respective directors, employees and agents; (c) any negligence or willful misconduct of the Indemnitor, its Affiliates or (sub)licensees, or their respective directors, employees and agents in the performance of the Agreement; (d) criminal investigations of, defense of criminal charges against, and criminal penalties levied on, the Indemnitor, its Affiliates, or their respective directors, employees and agents; (e) breach of a contractual or fiduciary obligation owed by the Indemnitor or its Affiliates to a Third Party (including misappropriation of trade secrets); (f) the Manufacture, use, handling, storage, Development, Commercialization or other disposition of Licensed Products by the Indemnitor, its Affiliates or (sub)licensees, or their respective directors, employees and agents; and/or (g) in the case of Catalyst as the Indemnitor, any breach of the EUSA License that results from Catalyst's failure to perform under this Agreement by Catalyst or its Affiliates, Sublicensees or other agents. For the avoidance of doubt, the foregoing indemnity obligation of the Indemnitor shall not apply to the extent of any Losses for which the Indemnitee has an obligation to indemnify pursuant to this Section 12.1, as to which Losses each Party shall indemnify the other to the extent of their respective liability for the Losses.

12.2 Procedure. In the event of a claim by a Third Party against a Party entitled to indemnification under this Agreement ("Indemnified Party"), the Indemnified Party shall promptly notify the other Party ("Indemnifying Party") in writing of the claim and the Indemnifying Party shall undertake and solely manage and control, at its sole expense, the defense of the claim and its settlement. The Indemnified Party shall cooperate with the Indemnifying Party, including, as requested by the Indemnifying Party entering into a joint defense agreement. The Indemnified Party may, at its option and expense, be represented in any such action or proceeding by counsel of its choice. The Indemnifying Party shall not be liable for any litigation costs or expenses incurred by the Indemnified Party without the Indemnifying Party's written consent. The Indemnifying Party shall not settle any such claim unless such settlement fully and unconditionally releases the Indemnified Party from all liability relating thereto, unless the Indemnified Party otherwise agrees in writing.

12.3 Insurance. Catalyst, at its own expense, shall obtain and maintain in effect, in a form and with insurers reasonably acceptable to BioMarin, which shall designate BioMarin as an additional insured, during the term of this Agreement: (i) commercial general liability insurance with a minimum limit of indemnity of Five Million Dollars (\$5,000,000) per occurrence and in the aggregate; (ii) clinical trial liability insurance with a minimum limit of indemnity of Five Million Dollars (\$5,000,000 per occurrence and in the aggregate, which insurance must meet all regulations of the countries where the Clinical Trials will take place, including with respect to the coverage limits if greater than the ones above; and (iii) product liability insurance with a minimum limit of indemnity of Twenty Million Dollars (\$20,000,000) per occurrence and in the aggregate; *provided*, however, that Catalyst shall not be required to obtain such product liability insurance until prior to Catalyst's launch of Licensed Product in the U.S. It is understood that such insurance shall not be construed to limit Catalyst's liability with respect to its indemnification obligations under Article 12. Catalyst shall provide fifteen (15) days prior written notice to any cancellation of its insurance policy, and shall provide BioMarin with copies of any such insurance policy upon request.

12.4 Limitation of Liability. EXCEPT FOR AMOUNTS PAYABLE TO THIRD PARTIES BY A PARTY FOR WHICH IT SEEKS REIMBURSEMENT OR INDEMNIFICATION PROTECTION FROM THE OTHER PARTY PURSUANT TO SECTION 12.1, AND EXCEPT FOR BREACH OF SECTION 2.7 or 11.1 HEREOF: (A) IN NO EVENT SHALL EITHER PARTY, ITS DIRECTORS, OFFICERS, EMPLOYEES, AGENTS OR AFFILIATES BE LIABLE TO THE OTHER PARTY FOR ANY

INDIRECT, INCIDENTAL, SPECIAL, PUNITIVE, EXEMPLARY OR CONSEQUENTIAL DAMAGES, WHETHER BASED UPON A CLAIM OR ACTION OF CONTRACT, WARRANTY, NEGLIGENCE, STRICT LIABILITY OR OTHER TORT, OR OTHERWISE, ARISING OUT OF THE AGREEMENT; AND (B) EXCEPT AS SET FORTH BELOW, IN NO EVENT SHALL BIOMARIN'S LIABILITY FOR DIRECT DAMAGES DUE TO CATALYST UNDER THIS AGREEMENT EXCEED ONE MILLION DOLLARS (\$1,000,000) (THE "LIABILITY CAP"). NOTWITHSTANDING THE FOREGOING, TO THE EXTENT THAT BIOMARIN IS OBLIGATED TO INDEMNIFY CATALYST FOR LOSSES PURSUANT TO SECTION 12.1 AND BIOMARIN HAS INSURANCE COVERAGE(S) FOR SUCH LOSSES, BIOMARIN'S LIABILITY TO CATALYST UNDER THIS AGREEMENT SHALL BE THE GREATER OF: (A) THE AMOUNTS PAID OR REIMBURSED BY BIOMARIN'S INSURANCE CARRIERS WITH RESPECT TO SUCH LOSSES AND (B) THE AMOUNT OF THE LIABILITY CAP.

# ARTICLE 13 TERM AND TERMINATION

**13.1 Term.** The term of this Agreement shall begin on the Effective Date and, unless earlier terminated in accordance with the terms of this Article 13, will expire on the date on which Catalyst does not and will not have any additional payment obligations to BioMarin under this Agreement.

#### 13.1 Termination for Breach.

(a) Subject to the terms and conditions of this Section 13.2, a Party (the "non-breaching Party") shall have the right, in addition to any other rights and remedies, to terminate this Agreement in the event the other Party (the "breaching Party") is in material breach of any of its obligations under this Agreement. The non-breaching Party shall first provide written notice to the breaching Party, which notice shall identify with particularity the alleged breach. The breaching Party shall have a period of ninety (90) days, or fifteen (15) days in the case of any default of payment of undisputed amounts, after such written notice is provided to cure such breach; provided, however, that if any breach (other than payment default) is otherwise curable but cannot reasonably be cured within ninety (90) days, then if the breaching Party submits to the non-breaching Party a reasonable plan to cure such breach, then the non-breaching Party's right to terminate shall be delayed so long as the breaching Party continues to make such efforts to cure such breach in accordance with such plan. If such breach is not cured within such period, this Agreement may be terminated at end of such period by written notice from the non-breaching Party. Notwithstanding the foregoing, if at any time during the term of this Agreement, BioMarin receives written notice of a material breach under the EUSA License which notice is based on Catalyst's failure to perform under this Agreement, BioMarin shall give written notice to Catalyst describing in detail the nature of such breach and Catalyst shall have sixty (60) days from receipt of such notice to cure such breach (or, if such breach is capable of being cured but cannot be cured within such 60-day period, Catalyst has commenced and diligently continued actions to cure such breach provided always that, in such instance, such cure must have occurred within ninety (90) days from receipt of such notice to cure such breach). Notwithstanding the foregoing, the Parties acknowledge that termination for a Party's material breach under this Agreement may not be the appropriate remedy, when taking into consideration factors such as (i) whether the adverse effect of termination on the breaching Party is disproportionate to the damages caused by such material breach, and (ii) whether the non-breaching Party may be adequately compensated for the breach other than through termination, such as through remedies in law or equity.

**(b)** If the alleged breaching Party disputes in good faith the existence or materiality of a breach specified in a notice provided by the other Party or disputes whether termination of this Agreement would be the appropriate remedy for such breach, and

such alleged breaching Party provides the other Party written notice of such dispute within the applicable cure period set forth above, then the other Party shall not have the right to terminate this Agreement unless and until (i) it has been determined in accordance with Section 14.1(b) that the alleged breaching Party is in material breach of this Agreement and that termination of this Agreement is the appropriate remedy for such breach, and (ii) such breaching Party fails to cure such breach within ninety (90) days (or fifteen (15) days in the case of any default of payment of undisputed amounts) after the conclusion of the dispute resolution procedure.

- (c) Notwithstanding (a) and (b) above, in the event Catalyst fails to complete the double-blind treatment phase of the LMS-002 U.S. Phase 3 Clinical Trial within twenty-four (24) months of the Effective Date and fails to spend at least five million dollars (\$5,000,000) in connection with the conduct of the LMS-002 U.S. Phase 3 Clinical Trial during such twenty-four month period, and provided that BioMarin has complied with its supply obligations under Section 5.1, BioMarin shall have the right to terminate this Agreement immediately upon giving Catalyst written notice of termination, provided that BioMarin gives Catalyst such written notice of termination within thirty (30) days after expiration of such twenty-four month period.
- 13.2 Termination at Will. Catalyst may terminate this Agreement at any time by giving (i) at least ninety (90) days prior written notice, if such termination occurs prior to the First Commercial Sale of a Licensed Product, or (ii) one hundred and eighty (180) days prior written notice, if such termination occurs after First Commercial Sale of a Licensed Product; provided that a ninety (90) day notice period shall apply in the event the FDA revokes Regulatory Approval or otherwise prohibits Commercialization of a Licensed Product in the U.S. due to safety or efficacy reasons. During such ninety (90) or one hundred eighty (180) day notice period, Catalyst shall continue to perform all of its obligations under this Agreement, including complying with its diligence obligations under Sections 3.3 and 6.2, and Catalyst shall not take any action that would reasonably be expected to materially adversely affect the further Development and Commercialization of Licensed Products during such notice period.
- **13.3 Termination for Patent Challenge.** BioMarin may terminate this Agreement in its entirety if Catalyst or its Affiliates, directly or indirectly, individually or in association with any other person or entity, brings an action before any court or agency challenging the validity, enforceability or scope of any Licensed Patent anywhere in the Territory or the ROW.

# 13.4 Effects of Termination.

- (a) Upon the expiration, but not an earlier termination, of this Agreement with respect to a particular country and a particular Licensed Product in the Territory, the license granted to Catalyst under the Licensed Technology for such Licensed Product in such country in the Territory shall become fully-paid, royalty-free, perpetual and irrevocable.
  - **(b)** Upon early termination (but not expiration) of this Agreement for any reason:
- (i) Each Party shall promptly return to the other Party all relevant records and materials in its possession or control containing or comprising the other Party's Confidential Information and to which the Party does not retain rights hereunder (including assignments of any Regulatory Approvals or Regulatory Filings, Patents, trademarks and Confidential Information of such Party solely to the extent related to Licensed Products).
- (ii) The Parties shall proceed, as expeditiously as possible, to wind-up all of Catalyst's or its Affiliates' Development and Commercialization of Licensed Product then on-going in the Territory and transition such Development and Commercialization to BioMarin or its designee(s), in accordance with all applicable laws and such procedures as the Parties may

mutually agree to adopt. In the event that Catalyst or its Affiliates is then-performing any Development activities, the Parties shall promptly work together in good faith to adopt a plan to wind-down such Development activities in an orderly fashion or, at BioMarin's election, promptly transition such Development activities to BioMarin or its designee(s), in either case with due regard for patient safety and the rights of any subjects that are participants in any Clinical Trials, and take any actions deemed reasonably necessary or appropriate to avoid any human health or safety problems and to be in compliance with all applicable laws.

- (iii) All licenses granted by BioMarin to Catalyst under this Agreement shall terminate, and all rights under the Licensed Technology shall revert to BioMarin; provided, however that the licenses granted to Catalyst shall continue in effect on a non-exclusive basis during wind-up and transition of Development and Commercialization to BioMarin or its designee(s) and shall be limited to such wind-up and transition activities; and provided further, however, that if this Agreement is terminated by Catalyst pursuant to Section 13.2 for BioMarin's uncured material breach, Catalyst and its Affiliates and Sublicensees may continue, to the extent that Catalyst, its Affiliates and/or its Sublicensees continue to have an inventory of Licensed Products, to fulfill orders received from customers for Licensed Products in the Territory for a period not to exceed twelve (12) months after the effective date of termination, subject to Catalyst's continued obligation to make payments in connection therewith in accordance with Article 7.
- (iv) Catalyst and its Affiliates shall discontinue making any representation regarding its status as a licensee of or distributor for BioMarin, for the Licensed Products. Except in connection with any wind-up or transition activities and in connection with the sale of inventory pursuant to Section 13.5(b) (iii), Catalyst and its Affiliates shall cease conducting any activities with respect to the Manufacturing, Development or Commercialization of any Licensed Products.
- (v) BioMarin shall have the right to Manufacture, Develop and Commercialize Licensed Products in the Territory itself or with one or more Third Parties, and shall have the right, without obligation to Catalyst, to take any such actions in connection with such activities as BioMarin (or its designee), at its discretion, deems appropriate.
- **(c)** In the event of early termination (but not expiration) of this Agreement (other than termination by Catalyst pursuant to Section 13.2 for BioMarin's uncured material breach), the following shall also apply (i.e., in addition to Section 13.5(b)):
- (i) Catalyst shall grant to BioMarin a worldwide, exclusive (even as to Catalyst), irrevocable, royalty free, fully paid up license (with full rights to sublicense), under the Catalyst Technology, and shall assign to BioMarin (or cause to be assigned), its rights, title, and interest with respect to any Joint Invention or Joint Patent.
- (ii) Unless prohibited by applicable laws, Catalyst shall transfer and assign or cause to be transferred and assigned to BioMarin (or to the extent not so transferable or assignable, Catalyst shall take all reasonable actions to make available to BioMarin the benefits of) all Regulatory Approvals and Regulatory Filings, including INDs, NDAs and other similar regulatory applications owned or filed by Catalyst or its Affiliates that relate to Licensed Products. Catalyst shall also take such actions and execute such other instruments, assignments and documents as may be necessary to effect the transfer of rights thereunder to BioMarin and shall provide full copies of all such Regulatory Approvals and Regulatory Filings that are in Catalyst's possession.
- (iii) Catalyst will transfer and assign to BioMarin all Patent filings, dockets and other materials related to the filing, prosecution, and maintenance of Licensed Patents and Joint Patents in the Territory by Catalyst under Section 9.2(a) and 9.2(c)(i).

- (iv) Catalyst will provide to BioMarin copies of all material reports and data, including clinical and non-clinical data and reports, obtained or generated by or on behalf of Catalyst or its Affiliates pursuant to this Agreement that relate to Licensed Products, within sixty (60) days of such termination, except where Catalyst has already provided such report or data under Article 3, and BioMarin shall have the right to use any such information in Developing and Commercializing Licensed Products, and to license any Third Parties to do so;
- (v) If Catalyst used one or more Marks with regard to Licensed Products in a country, Catalyst shall grant to BioMarin an exclusive (even as to Catalyst), worldwide, fully-paid, royalty-free, irrevocable license, with the right to sublicense, to use such Mark(s) solely in connection with the development and commercialization of the Licensed Products. For clarity, BioMarin shall under no circumstance receive any rights under the Catalyst housemarks, except with respect to selling off existing inventory.
- (vi) At BioMarin's request, Catalyst shall promptly provide to BioMarin copies of all clinical trial, contract manufacturing, or service agreements entered into by Catalyst or its Affiliates with respect to Licensed Products. At BioMarin's request, Catalyst shall promptly assign (or cause to be assigned), such agreements to BioMarin, to the extent such assignment is permitted under such agreement.
- (vii) Catalyst shall transfer to BioMarin, at a price equal to one hundred percent (100%) of Catalyst's manufacturing cost (or, in the case of Firdapse supplied by BioMarin to Catalyst under Article 5, the amount invoiced by BioMarin) for each such Licensed Product, all quantities of Licensed Products in the possession of Catalyst or its Affiliates (including, without limitation, Clinical Trial supplies and Licensed Products intended for commercial sale), except for any quantities of Licensed Products required for any wind-up or transition activities.
- **13.5 Cross Default; Remedies for Material Breach.** The Parties expressly acknowledge and agree any uncured material breach by Catalyst of the Catalyst Note Purchase Agreement shall constitute a material breach of this Agreement.
- 13.6 Survival; Accrued Rights. The rights and obligations of the Parties under the following provisions of this Agreement shall survive expiration or any termination of this Agreement: Articles 1 (to the extent necessary to give force to, or otherwise understand, surviving provisions), 11 (excluding Section 11.3), 12 (excluding Section 12.3) and 14, and Sections 3.5(c) (with respect to maintenance of records), 7.2 (with respect to Joint Development Costs incurred but not paid prior to termination), 8.1 (with respect to royalties owed but not paid prior to termination), 8.3, 13.5, 13.7, 15.8 and 15.10. In any event, expiration or termination of this Agreement shall not relieve the Parties of any liability which accrued hereunder prior to the effective date of such expiration or termination nor preclude either Party from pursuing all rights and remedies it may have hereunder or at law or in equity with respect to any breach of this Agreement, nor prejudice either Party's right to obtain performance of any obligation.

# ARTICLE 14 DISPUTES; GOVERNING LAW

# 14.1 Disputes.

(a) Executive Officers. Unless otherwise set forth in this Agreement, in the event of a dispute arising under this Agreement between the Parties, the Parties shall refer such dispute to the respective Executive Officers, and such Executive Officers

shall attempt in good faith to resolve such dispute. Either Party may initiate such informal dispute resolution by sending written notice of the dispute to the other Party, and, within twenty (20) days after such notice, such Executive Officers shall meet for attempted resolution by good faith negotiations. If such Executive Officers are unable to resolve such dispute within thirty (30) days of their first meeting for such negotiations (or such longer period as such Executive Officers may agree upon in writing), either Party may seek to have such dispute resolved in accordance with Section 14.1(b).

**(b) Arbitration.** Subject to Section 14.1(c), any dispute arising under this Agreement, or other legal proceeding relating to this Agreement or the enforcement of any provision of this Agreement, if not resolved by the Executive Officers pursuant to Section 14.1(a), shall be finally resolved by binding arbitration administered by JAMS pursuant to JAMS' Streamlined Arbitration Rules and Procedures then in effect (the "JAMS Rules"), and judgment on the arbitration award may be entered in any court having jurisdiction thereof. The arbitration shall be conducted by a single, neutral arbitrator who shall have experience with respect to the matter(s) to be arbitrated. If, within thirty (30) days after initiation of arbitration, the Parties are unable to agree on a single arbitrator, the arbitrator shall be appointed by JAMS. The place of arbitration shall be San Francisco, California. Either Party may apply to the arbitrator for interim injunctive relief until the arbitration award is rendered or the controversy is otherwise resolved. Nothing contained herein shall be construed to permit the arbitrator to award punitive, exemplary or similar damages. Each Party shall bear its own costs and expenses and attorneys' fees and an equal share of the arbitrators' fees and any administrative fees of arbitration. Except to the extent necessary to confirm an award or as may be required by law, neither a Party nor an arbitrator may disclose the existence, content, or results of an arbitration without the prior written consent of both Parties. In no event shall an arbitration be initiated after the date when commencement of a legal or equitable proceeding based on the dispute, controversy or claim would be barred by the applicable California statute of limitations. The Parties agree that, in the event of a dispute over the nature or quality of performance under this Agreement, and, as provided in Section 13.2(b), neither Party may terminate this Agreement until final resolution of the dispute through arbitrator determines tha

#### (c) Disputes Relating to Patents and Trademarks and Equitable Relief.

- (i) Any dispute, controversy or claim arising out of, relating to or in connection with: (i) the scope, validity, enforceability or infringement of any Patent rights covering the research, development, manufacture, use or sale of any Licensed Product; or (ii) any Marks, shall in each case be submitted to a court of competent jurisdiction in the territory in which such Patent or trademark rights were granted or arose.
- (ii) Any dispute, controversy or claim arising out of, relating to or in connection with the need to seek preliminary or injunctive measures or other equitable relief (e.g., in the event of a potential or actual breach of the exclusivity provisions in Section 2.7 or the confidentiality and non-use provisions in Article 11) need not be resolved through the procedure described in Section 14.1(a) but may be immediately brought in any court of competent jurisdiction.
- **14.2 Governing Law**. The validity, performance, construction, and effect of this Agreement shall be governed by the laws of the State of California, without regard to conflicts of law principles that would provide for application of the law of another jurisdiction.

# ARTICLE 15 MISCELLANEOUS

- **15.1 Assignment.** Either Party may assign this Agreement (a) to any Affiliate of such Party without the prior written consent of the other Party, provided that such Party provides the other Party with written notice of such assignment and remains fully liable for the performance of such Party's obligations hereunder by such Affiliate, or (b) without the prior written consent of the other Party, to its successor in interest by way of merger, acquisition, or sale of all or substantially all of its assets to which this Agreement relates, provided that such Party provides the other Party with written notice of such assignment. Any other assignment of this Agreement by a Party requires the prior written consent of the other Party. Any assignment in violation of this Section 15.1 shall be null and void. This Agreement shall be binding on and shall inure to the benefit of the permitted successors and assigns of the Parties hereto. Notwithstanding the foregoing, in the event that a Party assigns this Agreement to its successor in interest by way of merger, acquisition, or sale of all or substantially all of its assets to which this Agreement relates, the intellectual property rights of such successor in interest, and of any of its Affiliates as of just prior to such assignment, as existing immediately prior to the closing of such transaction, shall be automatically excluded from the rights licensed to the other Party under this Agreement.
- **15.2 Force Majeure.** If either Party shall be delayed, interrupted in or prevented from the performance of any obligation hereunder by reason of force majeure including an act of God, fire, flood, earthquake, war (declared or undeclared), public disaster, act of terrorism, strike or labor differences, or any other cause beyond such Party's control, such Party shall not be liable to the other therefor; and the time for performance of such obligation shall be extended for a period equal to the duration of the force majeure which occasioned the delay, interruption or prevention. The Party invoking such force majeure rights of this Section 15.2 must notify the other Party by courier or overnight dispatch (e.g., Federal Express) within a period of fifteen (15) days of both the first and last day of the force majeure unless the force majeure renders such notification impossible in which case notification will be made as soon as possible. If the delay resulting from the force majeure exceeds six (6) months, both Parties shall consult together to find an appropriate solution.
- **15.3 Performance by Affiliates.** A Party may discharge any obligations and exercise any right hereunder through any of its Affiliates. Each Party hereby guarantees the performance by its Affiliates of its obligations under this Agreement, and shall cause its Affiliates to comply with the provisions of this Agreement in connection with such performance. Any breach by a Party's Affiliate of any of such Party's obligations under this Agreement shall be deemed a breach by such Party, and the other Party may proceed directly against such Party without any obligation to first proceed against such Party's Affiliate.
- **15.4 Maintenance of Records Required by Law or Regulation.** Each Party shall keep and maintain all records required by law or regulation with respect to Licensed Products and shall make copies of such records available to the other Party upon request.
- **15.5 Export Control.** This Agreement is made subject to any restrictions concerning the export of products or technical information from the U.S. or other countries which may be imposed upon or related to BioMarin or Catalyst from time to time. Each Party agrees that it shall not export, directly or indirectly, any technical information acquired from the other Party under this Agreement or any products using such technical information to a location or in a manner that at the time of export requires an export license or other governmental approval, without first obtaining the written consent to do so from the appropriate agency or other governmental entity.

**15.6 Entire Agreement.** This Agreement constitutes the entire agreement between the Parties with respect to the subject matter herein and, effective on the Effective Date, supersedes all previous agreements between the Parties with respect to the subject matter herein, whether written or oral. This Agreement shall not be changed or modified orally, but only by an instrument in writing signed by both Parties.

15.7 Severability. If any provision of this Agreement is declared invalid by a court of last resort or by any court or other governmental body from the decision of which an appeal is not taken within the time provided by law, then and in such event, this Agreement will be deemed to have been terminated only as to the portion thereof that relates to the provision invalidated by that decision and only in the relevant jurisdiction, but this Agreement, in all other respects and all other jurisdictions, will remain in force; provided, however, that if the provision so invalidated is essential to the Agreement as a whole, then the Parties shall negotiate in good faith to amend the terms hereof as nearly as practical to carry out the original intent of the Parties, and, failing such amendment, either Party may submit the matter for resolution pursuant to Article 14.

**15.8 Notices**. Any notice or report required or permitted to be given under this Agreement shall be in writing and shall be mailed by certified or registered mail, or sent by confirmed facsimile, as follows and shall be effective at the time of such confirmation or five (5) days after such mailing, as applicable:

# If to BioMarin:

BioMarin Biopharmaceutical Inc. 105 Digital Drive Novato, CA 94949 Attention: General Counsel Fax: (415) 506-6425

# If to Catalyst:

Catalyst Pharmaceutical Partners 355 Alhambra Circle, Suite 1500 Coral Gables, Florida, 33134 Attention: Chief Executive Officer

Fax: (305) 529-0933

**15.9 Further Assurances.** The Parties agree to reasonably cooperate with each other in connection with any actions required to be taken as part of their respective obligations under this Agreement, and shall (a) furnish to each other such further information; (b) execute and deliver to each other such other documents; and (c) do such other acts and things (including working collaboratively to correct any clerical, typographical, or other similar errors in this Agreement), all as the other Party may reasonably request for the purpose of carrying out the intent of this Agreement.

**15.10 Agency**. Neither Party is, nor will be deemed to be an employee, agent or representative of the other Party for any purpose. Each Party is an independent contractor, not an employee or partner of the other Party. Neither Party shall have the authority to speak for, represent or obligate the other Party in any way without prior written authority from the other Party.

- **15.11 No Waiver**. Any omission or delay by either Party at any time to enforce any right or remedy reserved to it, or to require performance of any of the terms, covenants or provisions hereof, by the other Party, shall not constitute a waiver of such Party's rights to the future enforcement of its rights under this Agreement. Any waiver by a Party of a particular breach or default by the other Party shall not operate or be construed as a waiver of any subsequent breach or default by the other Party.
- **15.12 Interpretation; No Strict Construction; Headings.** This Agreement shall be interpreted in the English language. This Agreement has been prepared jointly and shall not be strictly construed against either Party. Ambiguities, if any, in this Agreement shall not be construed against any Party, irrespective of which Party may be deemed to have authored the ambiguous provision. The headings of each Article and Section in this Agreement have been inserted for convenience of reference only and are not intended to limit or expand on the meaning of the language contained in the particular Article or Section. The term "including" as used herein means "including without limitation" and shall not limit the generality of any description preceding such term.
  - 15.13 Counterparts. This Agreement may be executed in counterparts, all of which taken together shall be regarded as one and the same instrument.
- **15.14 Non Compete**. During the Term of this Agreement, Catalyst is prohibited from commercializing or distributing personally or through the intermediary of a Third Party or its Affiliates or subsidiaries, products likely to be in competition with a Licensed Product in territories in which the Licensed Product is approved or under development. The term "products likely to be in competition with a Licensed Product," is understood to refer to any commercialized drug product labeled for the treatment of LEMS. However, it is agreed that this Section 15.14 shall not apply to a Combination Product and/or to a product that is used in synergy with a Licensed Product. For the sake of clarity it is agreed that Catalyst is allowed to develop, make, have made, distribute, exploit and commercialize any product in any indication.

[Signature Page Follows]

IN WITNESS WHEREOF, the Parties have executed this License Agreement through their duly authorized representatives to be effective as of the Effective Date.

BIOMARIN PHARMACEUTICAL INC.

CATALYST PHARMACEUTICAL PARTNERS, INC.

 By:
 /s/ G. Eric Davis

 Name:
 G. Eric Davis

 Title:
 SVP, General Counsel

By: /s/ Patrick J. McEnany
Name: Patrick J. McEnany
Title: Chairman, President and CEO

# EXHIBIT A BIOMARIN ONGOING STUDY

LMS-002 U.S. Phase 3 Clinical Trial

# EXHIBIT C

# LICENSED PATENTS

SERIALNO 10/467,082 United States TITLE FILE EXP COUNTRY
3,4-DIAMINOPYRIDINE TARTRATE AND PHOSPHATE,
PHARMACEUTICAL COMPOSITIONS AND USES /20/2004 Pending
THEREOF

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# EXHIBIT D LICENSED TRADEMARKS

COUNTRY CA	TMARK FIRDAPSE	APPNO 1,461,708	REGNO	ALLOWED	FILED 12/4 /2009	REG
MX	FIRDAPSE	1051553	1146443	REGISTERED	12/2 /2009	3 /3 /2010
US	FIRDAPSE	77/830,438		ALLOWED	9 /19/2009	



# **NEWS RELEASE**

For Further Information Contact: Patrick J. McEnany Catalyst Pharmaceutical Partners Chief Executive Officer (305) 529-2522 pmcenany@catalystpharma.com

Eugenia Shen BioMarin Pharmaceutical Inc. (415) 506-6570

# FOR IMMEDIATE RELEASE

Melody Carey Rx Communications Group Co-President (917) 322-2571 mcarey@rxir.com

15) 506-6570	
	Catalyst Pharmaceutical Partners and BioMarin Pharmaceutical Enter into
	Strategic Collaboration for Firdapse™ in North America
	BioMarin to Make \$5 Million Strategic Equity Investment in Catalyst
Catalyst Licenses North Ame	erican Rights to Firdapse™, a Phase III Orphan Drug for the Treatment of Lambert-Eaton Myasthenic Syndrome (LEMS)

Catalyst Expects Top-Line CPP-109 Phase II(b) Data During First Half of November

CORAL GABLES, FL, October 31, 2012 — Catalyst Pharmaceutical Partners, Inc. (Nasdaq: CPRX) and BioMarin Pharmaceutical Inc. (Nasdaq: BMRN) today announced that they have entered into a strategic collaboration for the rights to Firdapse<sup>™</sup> in North America. Firdapse<sup>™</sup> is an orphan product, which has been approved in the European Union (EU) and is undergoing a Phase III clinical trial in the United States, for the treatment of Lambert-Eaton Myasthenic Syndrome (LEMS), a rare, debilitating and sometimes fatal autoimmune disease with the primary symptoms of muscle weakness. The key components of the collaboration include Catalyst licensing the exclusive North American rights to Firdapse<sup>™</sup> and BioMarin making a \$5 million investment in Catalyst to rapidly advance the Firdapse<sup>™</sup> program in the United States.

Patrick J. McEnany, Catalyst's Chief Executive Officer, stated: "As part of this arrangement, we are gaining access to a late-stage U.S. orphan drug targeting LEMS, a disease of the central nervous system for which there is not currently an effective treatment approved in the United States. Our existing product candidates are focused on addiction and central nervous system orphan indications like Infantile Spasms/West Syndrome and Tourette's Disorder, and adding Firdapse<sup>TM</sup> is consistent with our product development strategy. The relationship with BioMarin is exciting and strategically important, as it provides Catalyst with another orphan drug candidate and near-term funding towards the completion of the currently underway Phase III trial for Firdapse<sup>TM</sup>."

Under the terms of the collaboration, Catalyst and BioMarin have entered into a:

- Convertible Promissory Note and Note Purchase Agreement under which BioMarin has invested \$5 million in Catalyst, which will convert on a mandatory basis into Catalyst common stock at a future date. The conversion price will be based on the dollar weighted average of Catalyst's common stock during the 15 business day period prior to the conversion date. Catalyst has covenanted to BioMarin that the \$5 million investment will be used solely for the purpose of developing Firdapse™ in the United States.
- License Agreement in which Catalyst receives the exclusive rights to Firdapse<sup>TM</sup> for all indications in North America. Catalyst will be responsible for all future costs of developing and commercializing Firdapse<sup>TM</sup> in North America, and will share equally the cost of various post-marketing studies in the EU, the data from which is also anticipated to be included in the Firdapse<sup>TM</sup> registration package in the United States. Subject to certain criteria, Catalyst will also owe royalty payments to BioMarin, and milestone and royalty payments to the former shareholders of Huxley Pharmaceuticals and to a third-party licensor of the rights being sublicensed to Catalyst.

Mr. McEnany continued: "Additionally, as previously announced, we are continuing to communicate closely with the Department of Veterans Affairs Cooperative Studies Program (VACSP), the collaborator responsible for the management, verification and statistical analyses of the data being collected in our Phase II(b) trial for the treatment of cocaine addiction. Based on information received to date, we continue to expect that we will receive and be in a position to report the top-line results from our trial during the first half of November 2012."

#### About Firdapse<sup>TM</sup>

Firdapse<sup>TM</sup>, also known as amifampridine phosphate, 3,4-diaminopyridine or 3,4-DAP, is a potassium channel blocker. It delays repolarization of the pre-synaptic neuron, causing voltage gated Ca2+ channels to remain open longer. The increased Ca2+ influx causes more acetylcholine to be released, making it more likely that a muscle action potential will be initiated, thereby reducing muscle weakness. BioMarin acquired the rights to Firdapse<sup>TM</sup> as part of its acquisition of Huxley Pharmaceuticals in 2009. Since then, BioMarin has commercialized Firdapse<sup>TM</sup> in the EU for LEMS, where it has orphan medicinal product designation.

In the United States, where it also has orphan drug designation, Firdapse<sup>TM</sup> is in a Phase III, multicenter, double-blind, placebo-controlled, randomized discontinuation study followed by an open-label extension period to evaluate the efficacy and safety of Firdapse<sup>TM</sup> in patients with LEMS. Upon completion of this transaction, Catalyst will be responsible for the overall management and continuing this already initiated study. The estimated enrollment for the U.S. Phase III study is 30 LEMS patients. In addition to LEMS, other potential orphan central nervous system indications for Firdapse<sup>TM</sup> include Myasthenia Gravis and Congenital Myasthenic Syndrome, among others.

#### **About United States Orphan Drug Designation**

Orphan drug designation is granted by the U.S. Food & Drug Administration (FDA) Office of Orphan Drug Products to promote the development of drugs and biologics for the treatment of rare diseases and disorders that affect fewer than 200,000 persons in the United States. The key benefit includes a 7-year period of market exclusivity if Firdapse<sup>TM</sup> is the first of its type approved for the specified indication or if it demonstrates superior safety, efficacy or a major contribution to patient care versus another drug of its type previously granted the designation for the same indication. Other potential benefits include tax credits for certain clinical research costs, annual grant funding, clinical trial design assistance and waiver of Prescription Drug User Fee Act (PDUFA) filing fees.

# **About LEMS**

Lambert-Eaton Myasthenic Syndrome is a rare autoimmune disease with the primary symptoms of muscle weakness. The muscle weakness in LEMS is caused by autoantibodies to voltage gated calcium channels leading to a reduction in the amount of acetylcholine released from nerve terminals. The prevalence of LEMS is estimated at approximately 3,000 patients in the United States and Canada. Approximately 50 percent of LEMS patients diagnosed have small cell lung cancer. Patients with LEMS typically present with fatigue, muscle pain and stiffness. The weakness is generally more marked in the proximal muscles, particularly of the legs and trunk. Other problems include reduced reflexes, drooping of the eyelids, facial weakness and problems with swallowing. Patients often report dry mouth, impotence, constipation and feelings of light headedness on standing. These problems can be life threatening when the weakness involves respiratory muscles. A diagnosis of LEMS is generally made on the basis of clinical symptoms, electromyographic testing and the presence of autoantibodies against voltage gated calcium channels.

# **About Catalyst Pharmaceutical Partners**

Catalyst Pharmaceutical Partners, Inc. is a development-stage specialty pharmaceutical company focused on the development and commercialization of prescription drugs targeting diseases and disorders of the central nervous system. Catalyst has two products in development and is currently evaluating its lead product candidate, CPP-109 (vigabatrin, a GABA aminotransferase inhibitor), for the treatment of cocaine addiction and Tourette's Disorder. CPP-109 has been granted "Fast Track" status by the FDA for the treatment of cocaine addiction. Catalyst also expects to evaluate CPP-109 for the treatment of other addictions. Catalyst is also developing CPP-115, another GABA aminotransferase inhibitor that is more potent than vigabatrin and has reduced side effects (e.g., visual field defects, or VFDs) from those associated with vigabatrin. Catalyst is planning to develop CPP-115 for several indications, including drug addiction, epilepsy and for use in other selected central nervous system indications. CPP-115 has been granted orphan drug designation for the treatment of infantile spasms by the FDA and orphan medicinal product designation by the European Commission. Catalyst believes that it controls all current intellectual property for drugs that have a mechanism of action related to the inhibition of GABA aminotransferase. For additional information, please visit <a href="https://www.catalystpharma.com">www.catalystpharma.com</a>.

# **About BioMarin Pharmaceutical**

BioMarin Pharmaceutical Inc. develops and commercializes innovative biopharmaceuticals for serious diseases and medical conditions. Its product portfolio comprises four approved products and multiple clinical and pre-clinical product candidates. Approved products include Naglazyme® (galsulfase) for mucopolysaccharidosis VI (MPS VI), a product wholly developed

and commercialized by BioMarin; Aldurazyme® (laronidase) for mucopolysaccharidosis I (MPS I), a product which BioMarin developed through a 50/50 joint venture with Genzyme Corporation; Kuvan® (sapropterin dihydrochloride) Tablets, for phenylketonuria (PKU), developed in partnership with Merck Serono, a division of Merck KGaA of Darmstadt, Germany; and Firdapse™ (amifampridine), which has been approved by the European Commission for the treatment of Lambert-Eaton Myasthenic Syndrome (LEMS). Product candidates include GALNS (N-acetylgalactosamine 6-sulfatase), which is currently in Phase III clinical development for the treatment of MPS IVA, amifampridine phosphate (3,4-diaminopyridine phosphate), which is currently in Phase III clinical development for the treatment of LEMS in the U.S., PEG-PAL (PEGylated recombinant phenylalanine ammonia lyase), which is currently in Phase II clinical development for the treatment of PKU, BMN-701, a novel fusion protein of insulin-like growth factor 2 and acid alpha glucosidase (IGF2-GAA), which is currently in Phase I/II clinical development for the treatment of Pompe disease, BMN-673, a poly ADP-ribose polymerase (PARP) inhibitor, which is currently in Phase I/II clinical development for the treatment of genetically-defined cancers, and BMN-111, a modified C-nutriuretic peptide, which is currently in Phase I clinical development for the treatment of achondroplasia. For additional information, please visit <a href="https://www.bmrn.com">www.bmrn.com</a>.

# Forward-Looking Statements

This press release contains forward-looking statements. Forward-looking statements involve known and unknown risks and uncertainties which may cause actual results in future periods to differ materially from the statements made herein. A number of factors, including whether Firdapse™ will be approved for commercialization in the U.S., whether Catalyst will have sufficient resources to complete the development of Firdapse™ in the U.S., whether Catalyst's current Phase II(b) trial evaluating its product candidate CPP-109 for the treatment of cocaine addiction will be successful, whether Catalyst's current product candidates, CPP-109 and CPP-115, will ever be approved for commercialization in the U.S., and those other factors described in Catalyst's and BioMarin's filings with the U.S. Securities and Exchange Commission (SEC), could adversely affect the forward-looking statements made in this release. Copies of Catalyst's and BioMarin's filings with the SEC are available from the SEC, may be found on the respective company's website or may be obtained upon request from the respective company. Neither Catalyst nor BioMarin undertake any obligation to update the information contained herein, which speaks only as of this date.

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