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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

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**FORM 8-K/A**

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**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**

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**CATALYST PHARMACEUTICAL PARTNERS, INC.**

(Exact Name Of Registrant As Specified In Its Charter)

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**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 CFR 240.14d-2(b))
  - Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))
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**Item 1.01 Entry Into a Material Definitive Agreement**

On October 31, 2012, the Company filed a Form 8-K in connection with its entering into a License Agreement, dated as of October 26, 2012 (the "License Agreement"), with BioMarin Pharmaceutical, Inc. ("BioMarin"). This Form 8-K/A amends the original Form 8-K as filed to file another redacted copy of the License Agreement pursuant to the Company's request for confidential treatment with the Securities and Exchange Commission.

**Item 9.01 Financial Statements and Exhibits.**

(d) Exhibits

- 10.1 License Agreement, dated as of October 26, 2012, between BioMarin Pharmaceutical, Inc. and Catalyst Pharmaceutical Partners, Inc. (portions of this exhibit have been omitted and filed separately with the Securities and Exchange Commission pursuant to a request for confidential treatment.)

**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

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Alicia Grande

Vice President, Treasurer and CFO

Dated: January 3, 2013

**CONFIDENTIAL TREATMENT REQUESTED**

Redacted portions are indicated by [\*\*\*\*]<sup>1</sup>

**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™) 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>1</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, salt 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 this Section 3.7(a) within forty-five (45) days of Catalyst’s receipt of a statement from BioMarin summarizing in reasonable detail all such Out-of-Pocket Ongoing Study Costs incurred, together 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 ([\*\*\*\*]%) of such remaining amounts and Catalyst shall receive [\*\*\*\*] 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 hold 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 arbitration. The Parties further agree that any payments made pursuant to this Agreement pending resolution of the dispute shall be refunded if the arbitrator determines that such payments are not due.

**(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

By: /s/ Patrick J. McEnany

Name: G. Eric Davis

Name: Patrick J. McEnany

Title: SVP, General Counsel

Title: Chairman, President and CEO



**EXHIBIT A**  
**BIOMARIN ONGOING STUDY**

LMS-002 U.S. Phase 3 Clinical Trial

A-1

**EXHIBIT B-1**

**FIRDAPSE SPECIFICATIONS**

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B-1

EXHIBIT B-2

LICENSED COMPOUND

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B-2

**EXHIBIT C**

**LICENSED PATENTS**

<u>SERIAL NO</u>	<u>TITLE</u>	<u>FILE</u>	<u>EXP</u>	<u>COUNTRY</u>
10/467,082 United States	3,4-DIAMINOPYRIDINE TARTRATE AND PHOSPHATE, PHARMACEUTICAL COMPOSITIONS AND USES THEREOF	01 /20/2004	02/1/2022	US Pending
PCT/US2012/044904	METHODS OF ADMINISTERING 3,4- DIAMINOPYRIDINE	PCT/US2012/044904	National Phase date 12/30/2013	WIPO pending

EXHIBIT D

LICENSED TRADEMARKS

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

EXHIBIT E  
CLINICAL SUPPLY OF FIRDAPSE

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E-1

EXHIBIT F

APPLICABLE MILESTONE PAYMENTS AND ROYALTIES UNDER THE EUSA LICENSE AND THE  
HUXLEY STOCK PURCHASE AGREEMENT

[\*\*\*]

**EXHIBIT G**  
**PRESS RELEASE**  
**SEE ATTACHED**



SCHEDULE 3.5

EU POST-MARKETING STUDIES

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