UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
PURSUANT TO SECTION 13 OR 15(d)
OF THE SECURITIES EXCHANGE ACT OF 1934

Date of Report (Date of Earliest Event Reported): June 28, 2021

CATALYST PHARMACEUTICALS, INC.
(Exact Name Of Registrant As Specified In Its Charter)

Delaware	**001-33057**	**76-0837053**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(I.R.S. Employer Identification No.)**

355 Alhambra Circle **Suite 801** **Coral Gables, Florida**	**33134**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (305) 420-3200

Not Applicable
Former Name or Former address, if changed since last report

Securities registered pursuant to Section 12(b) of the Act:

Title of Each Class	Name of Exchange on Which Registered	Ticker Symbol
Common Stock, par value $0.001 per share	**NASDAQ Capital Market**	**CPRX**

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR240.14d-2(b))

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

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this Chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging Growth Company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 1.01 Entry Into a Material Definitive Agreement

On June 28, 2021, Catalyst Pharmaceuticals, Inc. (the "Company") and DyDo Pharma, Inc. ("DyDo") entered into that certain License & Supply Agreement (the "Agreement"). Pursuant to the Agreement, the Company will license to DyDo the Japanese rights for Firdapse® for the treatment of Lambert-Eaton Myasthenic Syndrome ("LEMS"). Under the terms of the Agreement, DyDo will have joint rights to develop Firdapse®, and exclusive rights to commercialize the product, in Japan. DyDo will be responsible for funding all clinical, regulatory, marketing and commercialization activities in Japan. The Company will be responsible for clinical and commercial supply, as well as providing support to DyDo in its efforts to obtain regulatory approval for the product from the Japanese regulatory authorities. Subject to the satisfaction of terms and conditions as set forth in the Agreement, the Company will receive an upfront payment and be eligible to receive further development and sales milestones for Firdapse®, as well as a transfer price on product supplied to DyDo.

The Agreement is attached to this Current Report on Form 8-K as Exhibit 10.1 and is incorporated herein by reference. Certain identified information has been excluded from the exhibit because it both (i) is not material and (ii) would be competitively harmful if publicly disclosed.

Item 8.01 Other Events

On June 28, 2021, the Company issued a press release announcing the Agreement. A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

10.1	License & Supply Agreement, dated as of June 28, 2021, between DyDo Pharma, Inc. and the Company (Certain identified information has been excluded from the exhibit because it both (i) is not material and (ii) would be competitively harmful if publicly disclosed).
99.1	Press release issued by the Company on June 28, 2021.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Catalyst Pharmaceuticals, Inc.

By: /s/ Alicia Grande
Alicia Grande
Vice President, Treasurer and CFO

Dated: June 30, 2021

Exhibit 10.1

CONFIDENTIAL

CERTAIN IDENTIFIED INFORMATION HAS BEEN EXCLUDED FROM THIS EXHIBIT BECAUSE IT BOTH (I) IS NOT MATERIAL AND (II) WOULD BE COMPETITIVELY HARMFUL IF PUBLICLY DISCLOSED

TEXT OMITTED FROM THIS EXHIBIT IS MARKED WITH [***]

License and Supply Agreement

CATALYST PHARMACEUTICALS, INC.

- and -

DYDO PHARMA, INC.

Dated as of: June 28, 2021

LICENSE AND SUPPLY AGREEMENT

THIS LICENSE and SUPPLY AGREEMENT (this "Agreement") is made as of June 28, 2021 (the "**Effective Date**") by and between **Catalyst Pharmaceuticals, Inc.**, 355 Alhambra Circle, Suite 801 Coral Gables, Florida, a corporation incorporated under the laws of the state of Delaware, United States of America ("**CATALYST**"), and **DyDo Pharma, Inc.**, 2-2-7 Nakanoshima, Kita-ku, Osaka, a corporation incorporated under the laws of Japan **("DYDO")**.

RECITALS

WHEREAS, CATALYST markets and sells in the United States amifampridine 10 mg immediate release tablets (marketed as Firdapse®), and holds certain intellectual property and other rights related to that Product; and

WHEREAS, DYDO has expertise in developing, marketing and selling pharmaceutical products in Japan; and

WHEREAS, subject to and in accordance with the terms and conditions of this Agreement, CATALYST and DYDO desire to have (a) CATALYST license to DYDO certain rights to develop and commercialize the Product in the Territory; (b) DYDO develop and commercialize the Product in the Territory; and (c) CATALYST supply to DYDO the Product exclusively for sale in the Territory.

NOW, THEREFORE, in consideration of the mutual covenants contained herein and other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the Parties hereto agree as follows:

ARTICLE 1.
DEFINITIONS

1.1 *Definitions*. In addition to the terms defined elsewhere in this Agreement, the terms set forth below (including correlative terms) shall be defined in this Agreement (including the recitals) as follows:

i. "**Additional Formulation**" means [***]

ii. "**Affiliate**" means, in respect of any party, a legal entity controlling, controlled by or under common control with that party, with control meaning ownership of more than 50% of the capital or the voting power in such entity.

iii. "**API**" means the active pharmaceutical ingredient of the Product, namely amifampridine phosphate.

iv. "**API Supplier**" means any third party who supplies the API used to manufacture the Product.

v. "**Applicable Laws**" means, with respect to any person, any domestic or foreign, federal, state or local statute, treaty, law, ordinance, rule, regulation, administrative interpretation, order, writ, injunction, judicial decision, decree or other requirement of any governmental authority applicable to such person or any of such person's respective properties, assets, officers, directors, employees, consultants or agents (in connection with such officers', directors', employees', consultants' or agents' activities on behalf of such person) as it relates to this Agreement, including PMD Act.

vi. "**Business Day**" in relation to each Party means any day other than a Saturday, a Sunday, or any statutory or public holiday on which banks are generally closed for regular business in the jurisdiction in which either Parties' offices are located as specified in Section 18.1 hereof.

vii. "**Calendar Year**" means a twelve (12) -month period from January 1 of any year to December 31 of the same year.

viii. **"CATALYST License"** means that certain License Agreement dated as of October 26, 2012 between BioMarin Pharmaceutical Inc., a Delaware corporation ("BioMarin"), and CATALYST, as amended by Amendment No. 1 to License Agreement dated as of April 8, 2014, and Amendment No. 2 to License Agreement dated as of May 29, 2019, and as assigned by BioMarin to SERB S.A ("**SERB**") on January 21, 2020.

ix. **"Combination Product"** means a pharmaceutical product that contains both (a) the Product and (b) one or more other active pharmaceutical ingredients (not including the API) or medical device which forms the basis for a separate product.

x. "**Commercially Reasonable Efforts**" means exercising such reasonable efforts and diligence required in the exercise of "Diligent Efforts" under the CATALYST License to the extent such Diligent Efforts are analogous to such efforts in question under this Agreement.

xi. **"Complaint"** means complaint which direct or indirect customers of DYDO, including agents, wholesalers, hospitals, medical institutes, doctors, physicians, medical practitioners, patients and patient groups, reasonably brought to DYDO of Defects or any other abnormality of the Products actually delivered to any of those.

xii. **"Compound"** means amifampridine that is chemically known as 3,4-Diaminopyridine and includes any of its salt formulations that are metabolized in the human body into 3,4-Diaminopyridine.

xiii. "**Contract Manufacturer**" means contract manufacturers and suppliers engaged by CATALYST relevant to the Product Marketed in the Territory and identified in **Schedule A** of this Agreement.

xiv. "**Contract Manufacturing Agreement**" means that certain [***]

and all agreements between [***] and CATALYST related to the manufacturing of the Product including the Product Agreement dated [***]

xv. "**Defective**" means any Product which, when delivered to DYDO, fails to comply with (i) the Specifications for manufacturing of the Product set forth in the Regulatory Approval, (ii) GMP or (iii) Applicable Laws.

xvi. "**Development**" means all activities relating to the development of the Product for use in the Field in the Territory as required to: (i) establish the Product's efficacy and safety profile; (ii) obtain and maintain Regulatory Approval; and (iii) obtain Orphan Drug Designation of the Product in the Territory. For the avoidance of doubt, Development includes performing bridging studies, clinical trials, clinical studies and post-approval clinical studies, but does not include any Additional Formulation of the Product.

xvii. "**DMF**", where applicable, means a drug master file governing the development and manufacture of the API.

xviii. "**Facility**" means the manufacturing facilities of CATALYST or DYDO or any of their respective Affiliates or subcontractors where the Product is manufactured.

xix. "**FDA**" means the U.S. Food and Drug Administration.

xx. "**Field**" means the treatment of Lambert-Eaton myasthenic syndrome ("LEMS") in humans.

xxi. "**GLP**" means current Good Laboratory Practices as established under Applicable Law.

xxii. "**GMP**" means current Good Manufacturing Practices for the manufacture of finished pharmaceutical products in effect from time to time as established under Applicable Laws which set minimum standards to ensure that pharmaceutical products meet established requirements for identity, strength, quality and purity.

xxiii. "**Intellectual Property Rights**" means any patent, trade secret, right in Know-How, right of confidence and any other intellectual or industrial property right of any nature whatsoever in any part of the world, whether registered or unregistered, but excludes any Trademark rights.

xxiv. "**IP Claim**" means any claim, action or demand commenced or made against any Party by a Third Party in relation to the Product that is based upon the contention that DYDO's attempt to obtain a Regulatory Approval for the Product in the Territory, and/or the Marketing and Packaging of the Product in the Territory by DYDO infringes the Intellectual Property Rights of any Third Party in the Territory.

xxv. "**Know-How**" means inventions, discoveries, trade secrets, information, experience, data, formulas, procedures and results, including physical, chemical, biological, toxicological, pharmacological, clinical and veterinary data, dosage regimens, control assays and product specifications, but excluding any Patents.

xxvi. "**Launch**" means to release and become available for first commercial sale by DYDO under the Marketing Authorization.

xxvii. "**Launch Date**" means the date of Launching.

xxviii. **"Licensor"** means the entity to whom CATALYST has obligations under the CATALYST License.

xxix. "**Losses**" means any out-of-pocket damages, liabilities, obligations, costs, expenses or losses, including reasonable legal fees and expenses, court costs, arbitration fees, penalties, fines, and amounts paid in settlement of claims.

xxx. "**Market**" means, sell, offer to sell, promote, advertise, market, import and/or distribute.

xxxi. **"Marketing Authorization"** means the marketing authorization approved by the MHLW under Article 14 of PMD Act which is necessary to market the Products in the Territory.

xxxii. **"MHLW"** means the Minister of Health, Labor and Welfare of Japan, the Ministry of Health, Labor and Welfare of Japan, or other department or agency which is delegated by the minister or ministry such as the Pharmaceuticals and Medical Devices Agency ("PMDA") or any other governmental unit of the government of Japan or prefectural government having authority over the regulation, development, approval, and sale, distribute, manufacture and packaging of drug products in the Territory from time to time under Applicable Laws including PMD Act.

xxxiii. "**Net Sales**" means:

[***]

xxxiv. "**NHI Price**" means the National Health Insurance price for the Product as set by the MHLW.

xxxv. "**Orphan Drug Designation**" means the designation that the MHLW may grant if (1) the number of patients who may use the drug are less than 50,000 in Japan, (2) the drug is indicated for the treatment of patients with serious diseases, including the difficult-to-treat diseases and (3) there is no appropriate alternative drug or treatment, or higher efficacy or safety is expected compared with existing products. Orphan Drug Designation provides an extension of the re-examination period up to 10 years. In case the MHLW or the government of Japan revise or replace such system for orphan drugs, the revised or similar system shall apply.

xxxvi. "**Packaging**" means all material used to prepare fully packaged Product, including containers, cartons, labelling, blister packs, inserts and shipping cases, as applicable.

xxxvii. "**Party**" means any party to this Agreement referred to individually, and "Parties" means the Parties to this Agreement referred to collectively.

xxxviii. "**PMD Act**" means the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices (Act No. 145 of August 10, 1960, as amended)

xxxix. "**Pharmacovigilance**" means certain obligations or activities regarding the collection and assessment of data pertaining to patient safety, and the monitoring and prevention of adverse events (including product complaints) associated with the Product and shall include all such obligations or activities required by Applicable Laws.

xl. "**Product**" means the pharmaceutical product that is the subject of this Agreement, as described in **Schedule A** of this Agreement, attached hereto and incorporated herein by reference.

xli. "**Quality Agreement**" means a Quality Assurance/Quality Control Agreement to be entered into by the Parties which will set forth certain obligations of the Parties in relation to the manufacture, packaging, quality control and testing of the Product in accordance with GMP.

xlii. "**Quarter**" means the following three (3) month periods during a calendar year: (i) from January 1 to March 31; (ii) from April 1 to June 30; (iii) from July 1 to September 30; and (iv) from October 1 to December 31.

xliii. **"Regulatory Application"** means an application for Regulatory Approval within the Territory such as an application for Marketing Authorization granted by the MHLW pursuant to the PMD Act.

xliv. "**Regulatory Approval**" means the approval of a regulatory application by the applicable regulatory authority and any other regulatory approvals required to sell a pharmaceutical product in the Territory.

xlv. "**Regulatory Authority**" means the applicable governmental regulatory health authorities in the Territory responsible for regulating the manufacture, distribution, and sale of pharmaceutical products such as the MHLW.

xlvi. "**Specifications**" has the meaning set forth in Section 4.4(b).

xlvii. **"Territory"** means Japan and its territories, protectorates and possessions.

xlviii. **"Third Party"** means any person or entity other than the Parties or Affiliates of either Party.

xlix. "**Trademarks**" means any trademarks, trade names, trade-dress, logos, whether or not registered, for the Product including (i) the registration of "Firdapse" in English characters under trademark no. 5344437 in Japan, (ii) the registration of "Firdapse" in Japanese characters under trademark no. 6246392 in Japan, and (iii) any subsequently registered trademark for the Product.

l. "**Transfer Price**" means the unit cost for the Product to be paid by DYDO to CATALYST for the right to use the Regulatory Approval, licensed Know How and the right to import, market and sell the Product within the Territory, as per **Schedule A** of this Agreement.

1.2 *Interpretation of "Include"*. Where the words "include", "includes" or "including" are used in this Agreement, they shall mean, respectively, "include without limitation", "includes without limitation", or "including without limitation".

ARTICLE 2.
LICENSE

2.1 *License*. Subject to the terms and conditions of this Agreement, CATALYST hereby grants to DYDO (a) an exclusive right and license under the Intellectual Property Rights and interest in the Trademarks controlled by or licensed to CATALYST (the "**Licensed Technology**") to Market, and take other necessary steps to commercialize and exploit the Product in the Field in the Territory, and (b) a co-exclusive with CATALYST and its Licensor right and license under the Licensed Technology to Develop and obtain Regulatory Approval of the Product in Field in the Territory and to complete final packaging and labeling of the Product in accordance with Applicable Laws, in each case for sale in the Field in the Territory. For the avoidance of doubt, CATALYST hereby grants to DYDO a co-exclusive with CATALYST and its Licensor right to use all necessary information controlled by or licensed to CATALYST including efficacy data, safety data, de-identified patient data, manufacturing data, stability data, test reports, study reports, common technical documents and any other supporting documents related to non-clinical studies, clinical studies, post-marketing studies, manufacturing, and any other activities for DYDO to Develop and Market the Product in the Territory. During the Term of this Agreement and so long as DYDO is not in material breach of the Agreement, CATALYST will not grant to a Third Party any rights set forth herein on the Product or any Combination Product in the Field in the Territory without prior written consent of DYDO.

2.2 *Restrictions*. DYDO shall not:

(a) Sublicense or subcontract the Licensed Technology to a Third Party without the prior written consent of CATALYST which will not be unreasonably withheld by CATALYST;

(b) use or register the Regulatory Approval or any information or data contained therein, in any jurisdiction other than the Territory;

(c) use the Regulatory Approval or any information or data contained therein for any purpose except as contemplated under this Agreement;

(d) Market, directly or indirectly, the Product in any jurisdiction outside of the Territory and shall prohibit (and strictly enforce such prohibition) its sublicensees, contractors and Affiliates from doing so;

(e) Manufacture the Product, except as specifically allowed herein; or

(f) Market, directly or indirectly, any Combination Product without the prior written consent of CATALYST.

DYDO shall provide CATALYST, within fifteen (15) days of the effective date of any sublicenses, with the name of each sublicensee of its rights under this Article 2 and a copy of the applicable sublicense agreement (provided that DYDO may redact portions of such sublicense agreement to the extent that such portions solely relate to any sublicensee's proprietary information, technology, or research, development or commercialization plans or as reasonably necessary to comply with any confidentiality provisions of such sublicense), and DYDO shall remain responsible and liable for each sublicensee's compliance with the applicable terms and conditions of this Agreement.

ARTICLE 3.
PRODUCT DEVELOPMENT

3.1 *Overview*. DYDO shall be solely responsible at its sole cost and expense for the Development of the Product in the Territory. DYDO will exercise its Commercially Reasonable Efforts to perform the Development of the Product in a timely fashion, in a good scientific manner and in compliance with all Applicable Laws. Promptly after completion of the clinical trials required as a part of Development of the Product, DYDO shall prepare and file a Regulatory Application with the Regulatory Authority to obtain Regulatory Approval of the Product. Subject to the other terms and conditions of this Agreement, CATALYST shall exercise its Commercially Reasonable Efforts to support the Development and the Regulatory Application of the Product in the Territory by DYDO in order to assist DYDO in its efforts to obtain Regulatory Approval of the Product; provided, that CATALYST shall not be obligated to incur any costs or expenses in so doing. Subject to the foregoing, such support will include: (i) responding to the reasonable inquiries of DYDO which are made by DYDO during the process of completing the Regulatory Application regarding non-clinical studies, clinical studies and manufacturing of the Product, (ii) GCP inspection of either the clinical studies performed by CATALYST and its Licensors (including BioMarin) or (if such sites remain available for such inspection) the sites at which such clinical studies were performed and (iii) analysis of clinical data if determined to be required by a Regulatory Authority. If CATALYST elects to require the filing with the Regulatory Authorities in Japan of a DMF related to the Product and such filing is not requested or required by either DYDO or such Regulatory Authorities, then CATALYST will bear the cost of such filing.

3.2 *Development Plan*. DYDO will prepare and provide to CATALYST a proposed plan to obtain and maintain Regulatory Approval of the Product in the Territory within forty-five (45) days of the Effective Date. The Development Plan shall set forth a comprehensive program that is designed to generate the non-clinical, clinical and regulatory information required for submitting the Regulatory Application and to obtain and maintain Regulatory Approval for the Product in the Territory. CATALYST may provide to DYDO comments on such plan, DYDO will consider such comments in good faith and (subject to the other terms and conditions of this Agreement) DYDO will have final authority on whether or not to incorporate such comments into such plan. The completed version of such plan is called the "**Development Plan**." DYDO shall provide written updates to such Development Plan as part of development reports required by Section 3.4 and periodically as may be necessary to document in the Development Plan any material changes to the plan to obtain Regulatory Approval, and shall provide copies of such updated Development Plan to CATALYST.

3.3 *Joint Development Committee*. Within sixty (60) 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 CATALYST and two (2) of whom shall be designated by DYDO. 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, and to have non-members of the JDC who are employed by or contractors of such Party attend JDC meetings. The JDC shall review and discuss the proposed Development activities including the design of clinical trials and the selection of clinical sites. Prior to the conduct of any clinical trials included in the Development activities, DYDO 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 any request by a Party and at such other times (which, until Regulatory Approval has been obtained, is expected to be at least every six (6) months) as its members may determine at a time and place mutually agreed upon by the Parties, including, as agreed, by telephone conference or video conference. 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 and no decisions which may bind either Party shall be made by the JDC.

3.4 *Development Reports.* Within fifteen (15) days after each full calendar year during which DYDO is required to perform under the Development Plan, DYDO shall provide CATALYST with a written report that summarizes, in reasonable detail, all Development activities performed by DYDO and its Affiliates and Third Party contractors during such year. DYDO shall also promptly (i) provide CATALYST with any additional information reasonably requested by CATALYST regarding Development of the Product by or on behalf of DYDO or its Affiliates, and (ii) notify CATALYST upon DYDO's initiation of any clinical trials or regulatory filings relating to Product.

3.5 *Reserved Rights.* Nothing in this Agreement shall prevent CATALYST from conducting Development of the Product, or obtaining the regulatory approval and pursuing commercialization of the Product outside the Territory, including any ongoing and planned clinical studies.

3.6 *Maintenance.* DYDO will undertake any and all clinical studies, phase IV clinical studies and any other post-regulatory approval studies as may be required in accordance with the Regulatory Approval of the Product and otherwise take all such actions necessary to maintain such Regulatory Approval of the Product in effect.

3.7 *Additional Product Development.*

[***]

ARTICLE 4.
REGULATORY APPROVAL

4.1 *Regulatory Application and Other Filings.* DYDO shall be solely responsible at its sole cost and expense (subject to the other terms and conditions of this Agreement) for all regulatory filings (including the Regulatory Application) with respect to the Product in the Territory. DYDO shall, prior to making any such regulatory filing (including the Regulatory Application), provide CATALYST with a substantially final draft of such proposed regulatory filing. DYDO shall consider in good faith any comments provided to DYDO by CATALYST with respect to such proposed filing, and (subject to the other terms and conditions of this Agreement) DYDO will have final authority over the contents of any such proposed filing. Notwithstanding the foregoing, the specifications of the Product included in the dossier for the first filing of the Regulatory Application will be the specifications for the Product sold in the United States and approved by the FDA. DYDO will promptly provide to CATALYST copies of all material written or electronic communications received by it from, or sent by it to any Regulatory Authority in the

Territory with respect to obtaining and maintaining Regulatory Approval for the Product and copies of all material contacts reports produced by DYDO (all such material written or electronic communications and contact reports, collectively, the "**Communications**"). Such Communications may be provided by DYDO to CATALYST in Japanese, provided that DYDO promptly provides to CATALYST a summary, prepared in English, of all of the material contents of such Communications (which, with respect to the Regulatory Application, need only identify such Communications as such). Subject to the permission of the applicable Regulatory Authority, DYDO will allow representatives of CATALYST to attend meetings with Regulatory Authorities in the Territory which are related to the Product.

4.2 *Regulatory Data.* DYDO will provide CATALYST on a timely basis with copies of all material pre-clinical and clinical data generated or compiled in connection with the development or commercialization of the Product via electronic copies of such data in a form that may be analyzed and manipulated by CATALYST. For clarity, this shall include all analytical data obtained with respect to the Product, case report forms, patient exposure data, pregnancy registry data, if applicable, and patient medical records generated during clinical trials, and any data generated during post-marketing studies or during commercialization. Further, it shall include all other clinical trial and available post-approval patient safety and registry study data, including historical regulatory data contained in patient registry filings and files. Such data will be considered to be timely provided if it is provided promptly (within thirty (30) calendar days) following request.

4.3 *Pharmacovigilance Agreement.* Subject to the terms and conditions of this Agreement, and within three (3) months after the Effective Date, CATALYST and DYDO shall finalize the responsibilities of the Parties to protect patients and promote their well-being in a written agreement (the "**Pharmacovigilance Agreement**") to be entered into by the Parties that will include a safety data exchange agreement and the obligations of the Parties to fulfill their respective reporting responsibilities. Such obligations of CATALYST shall include informing DYDO about safety data of the Product sold outside of the Territory including the European Union. Legal responsibility in respect of pharmacovigilance and other regulatory requirements as between the Parties shall reside with the respective holder of the Regulatory Approval in the respective jurisdictions meaning for CATALYST, the US, and for DYDO, the Territory. In the event of a conflict between the Pharmacovigilance Agreement and this Agreement with respect to any safety-related matters, including compliance with all regulatory obligations, the provisions of the Pharmacovigilance Agreement shall prevail. In the event of a conflict between the Pharmacovigilance Agreement and this Agreement with respect to any commercial matters, including allocation of risk, liability and financial responsibility, the provisions of this Agreement shall prevail.

4.4 *Specifications.*

(a) DYDO will exercise Commercially Reasonable Efforts to obtain Regulatory Approval for the Product and exercise Commercially Reasonable Efforts to cause such Regulatory Approval to incorporate the specifications for the Product which are the same as those specifications which have been approved by the FDA.

(b) In the event the Regulatory Authority requires changes to those specifications which have been approved by the FDA, DYDO will immediately inform CATALYST and the Parties will exercise commercially reasonable efforts to achieve agreement on the feasibility of those changes to the specifications. Subject to either the Regulatory Authority approving the specifications for the Product sold in the United States and approved by the FDA or achieving such agreement of the Parties on the changed specifications, the specifications which are approved by the Regulatory Authority will be the specifications for the Product in the Territory (the "**Specifications**"). The Specifications may not be changed without first obtaining the mutual written approval of the Parties.

(c) If the Parties are unable to agree on changes to the specifications, then either Party may terminate the Agreement by providing a written notice to the other Party. As a result of this termination, DYDO shall become exempted in any case from the Milestone Payment due on Regulatory Approval (JPY [***]) to CATALYST, and CATALYST shall become prohibited from, directly or indirectly, Marketing the Product in the Territory except as set forth in Section 4.4(d).

(d) If this Agreement is terminated under Section 4.4(c), then [***]

ARTICLE 5.
EXCLUSIVITY AND COMMERCIALIZATION

5.1 Commercialization Obligation. DYDO will exercise Commercially Reasonable Efforts to Market the Product to customers in the Territory during the Term at its sole cost and expense in accordance with the terms of this Agreement and Applicable Laws. Such efforts shall include the Launch of the Product, the preparation and delivery to CATALYST of: (i) an annual marketing plan for the Product (the first of which shall be delivered prior to the Launch Date); and (ii) sales projections for the Product on an annual basis. DYDO will provide CATALYST an opportunity to comment on such annual marketing plans, and will consider CATALYST's comments in good faith, but the final marketing plan shall be determined by DYDO subject to complying with the other terms and conditions of this Agreement.

5.2 *Exclusive Supplier; Non-Competition*. During the Term of this Agreement, (i) DYDO shall purchase all of its requirements for the Product from and shall source and purchase the Product for sale in the Territory exclusively from CATALYST, and (ii) DYDO shall not directly or indirectly Develop or Market any other potassium channel blocker or any competitive product developed or commercialized for use in the Field in the Territory or support any such activities. During the Term of this Agreement, except as provided in this Agreement with respect to an AI Product or an AF Product, CATALYST shall not directly or indirectly Market in the Territory any potassium channel blocker or any competitive product developed or commercialized for use in the Field in the Territory or support any such activities.

5.3 *Reports*. After the Launch of the Product, DYDO shall within sixty (60) days after the completion of each calendar year during the Term, provide to CATALYST, a report describing the selling resources deployment, including budget and spend on marketing of the Product for such year, as well as a report summarizing the status of reimbursement approvals and pricing approvals and filings in terms of formulary listings and reimbursement pricing tiers for the Product in the Territory.

(a) DYDO shall provide to CATALYST such information and promotional, marketing and advertising materials with respect to its Market activities regarding the Product as CATALYST shall reasonably request from time to time, including providing to CATALYST a pre-Launch marketing plan prior to initially filing the Regulatory Application. CATALYST shall provide DYDO, initially within six (6) months of Effective Date, and thereafter upon DYDO's reasonable request without delay, with such information and specimen copies of CATALYST's currently used promotional, marketing and advertising materials with respect to its Market activities for the Product in the United States to the extent that such promotional, marketing and advertising materials may support DYDO to Market and make Marketing and pre-Marketing plans for the Product in the Territory. DYDO shall not be required to provide CATALYST with such information and promotional, marketing and advertising materials with more granularity than those provided by CATALYST.

(b) For the avoidance of doubt, DYDO, at its own cost and expense, shall be responsible for training of all sales representatives who are, or will be, Marketing the Products in the Territory, development of websites, advertising, and supporting materials (including, without limitation, print advertising, brochures, leaflet and similar materials).

5.4 *Trademarks*.

(a) DYDO hereby acknowledges that CATALYST has been granted an exclusive and royalty free license to use the Trademarks in the Territory, and that CATALYST is sublicensing the Trademarks to DYDO for use in the Territory in connection with the Product during the Term of this Agreement. DYDO shall not, during the Term or thereafter, register, use, or attempt to obtain any right in and to any Trademarks or in and to any name, logo or trademark confusingly similar thereto, including, without limitation, by adding to or supplementing the Trademarks with additional words or phrases. CATALYST shall have the right to exercise quality control over DYDO's use of the Trademarks to a degree reasonably necessary to maintain the validity of the Trademarks, as applicable, and to protect the goodwill associated therewith. CATALYST shall be solely responsible for the filing, prosecution and maintenance of the Trademarks in Japan, and all costs and expenses related thereto.

(b) In the event that a Regulatory Authority indicates that the use of the brand name Firdapse or its phonetic spelling in Japanese language is unacceptable in Japan, [***]

ARTICLE 6.
MANUFACTURE OF PRODUCT

6.1 *Supply Responsibility*. Subject to the terms and conditions of this Agreement, CATALYST will be responsible for manufacturing and supply Product necessary for the clinical and commercial use in the Territory.

6.2 *Manufacturing Accreditation.* DYDO, having CATALYST as an intermediary between DYDO and Contract Manufacturers, will be responsible for the accreditation process of all manufacturing sites, as per regulatory requirements and to the extent required by DYDO or Applicable Laws. The Parties will equally share up to US$[***] (US$[***] for each Party) of Third Party expenses related to activities required by DYDO and related to any required accreditation of the US supply chain to provide DYDO with Product for sale in Japan. DYDO will be solely responsible for any such expenses which it incurs over US$[***]. CATALYST will be solely responsible for any Third Party expenses arising from activities requested by CATALYST relating to the accreditation of the US supply chain to provide DYDO with Product for sale in Japan to the extent (if any) such activities are outside or beyond the scope of activities which are either requested by DYDO or any Regulatory Authority or within the scope of DYDO's responsibilities.

6.3 *Restrictions on Changes to Product*. The Parties acknowledge that, once the Regulatory Approval has been obtained, any change whatsoever to the Product or any related process, method or procedure may impact the regulatory status of the Product in the Territory. Without limitation to any other provision of this Agreement, neither CATALYST nor its Contract Manufacturer will make any changes whatsoever to the Product without first informing DYDO and, to the extent any such changes result in any change in the Specifications which would require Regulatory Approval, obtaining DYDO's agreement to such changes. DYDO will obtain all necessary approvals from the applicable Regulatory Authorities for any such changes agreed upon by DYDO. DYDO will use Commercially Reasonable Efforts to submit any changes without delay and shall pay all fees and charges payable to the applicable Regulatory Authorities which may be required to update the Regulatory Approval in connection with any change to the Product.

6.4 *Packaging*. CATALYST shall supply the Product to DYDO in [***] count labeled bottles for both clinical and commercial purposes. Product supplied for clinical trial purposes shall be in the form of US approved, commercially available Product manufactured for sale in the US market and will be provided to DYDO for use research purposes only and may be provided under labeling used for such bottles in the United States. For Product supply for commercial purposes, DYDO will provide at its expense the final template for the label and artwork for the Product approved for use in Japan and suitable for use on the bottle in which CATALYST supplies such Product. A sample bottle on which the label and artwork would be affixed shall be provided to DYDO at a reasonable time prior to filing the initial Regulatory Application. CATALYST shall provide DYDO with a sample bottle with a sample of the printed label and artwork attached for final approval by DYDO of such label and artwork.

6.5 *Manufacturing Facility*. All Product supplied to DYDO pursuant to this Agreement shall be manufactured only by CATALYST's designated Facility described in **Schedule A**, or at such other Affiliate or subcontractor as may be mutually agreed between the Parties in writing, such agreement not to be reasonably withheld, and which complies with the requirements of this Section 6.

6.6 *Inspections*. If DYDO or CATALYST (as applicable, the "**Recipient**") receives any notification of any inspection of the Facility by any regulatory authority, relating directly or indirectly to the Product in the Territory, then the Recipient shall (i) notify the other Party of the notice of the inspection within three (3) Business Day. If DYDO or CATALYST is in receipt of any Form FDA-483 or any warning letter or similar correspondence from any Regulatory Authority that is directly or indirectly related to the Product, then the Recipient shall (ii) notify the other Party within five (5) Business Days and will provide a copy (redacted as necessary) of such report/letter/communication. The Recipient (iii) will furnish the other Party with copies (redacted as necessary) of reports, notices or other communications received as a result of any such inspection; (iv) provide to the other Party a written plan for correcting such deficiencies documented by the Regulatory Authorities, including a proposed timetable for implementing such corrections; (v) ensure that any of the foregoing deficiencies are corrected as soon as reasonably possible; and (vi) exercise its Commercially Reasonable Efforts in order not to disrupt supply of the Product in the Territory. Notwithstanding the foregoing, the Parties shall not be held responsible for any non-compliance with the foregoing clauses (i) through (vi) of this section to the extent such Party's contract manufacturers or vendors do not so comply; provided, that each Party shall cooperate in good faith with the other Party and exercise its commercially reasonable efforts to enforce such compliance by its contract manufacturers and vendors to the extent that it is contractually entitled to do so.

6.7 *Quality Assurance/Quality Control*. The Parties shall enter into a separate Quality Agreement before the earlier of: (i) the first commercial supply of any Product by CATALYST to DYDO; and (ii) six (6) months from the signing of this Agreement. The terms of the Quality Agreement shall among other things (a) include both Parties' obligation to notify the other of deviations from Specifications, (b) address how to handle Complaints between the Parties and (c) apply to all Product manufactured and supplied by CATALYST pursuant to this Agreement. In the event of a conflict between the Quality Agreement and this Agreement with respect to quality-related matters, including compliance with GMP and all other quality obligations, the provisions of the Quality Agreement shall prevail. In the event of a conflict between the Quality Agreement and this Agreement with respect to any commercial matters, including allocation of risk, liability, and financial responsibility, then the provisions of this Agreement shall prevail.

ARTICLE 7.
MILESTONE AND OTHER PAYMENTS; REPORTING OF NET SALES

7.1 *Milestones and Other Payments*. DYDO shall make the following payments to CATALYST upon the occurrence or achievement of the respective associated event (each a "**Milestone Payment**"), as follows:

Event	Payment
Effective Date	JPY [***] (the "**Up-Front Payment**")
Upon acceptance of filing of the Regulatory Application for the Product by the Regulatory Authority (the "**Filing Milestone**")	JPY [***]
Upon the first Regulatory Approval of the Product	JPY [***]
Upon the first time that Net Sales of the Product in any consecutive 12-month period exceed JPY [***]	JPY [***]
Upon the first time that Net Sales of the Product in any consecutive 12-month period exceed JPY [***]	JPY [***]

All Milestone Payments shall be non-cancellable and non-refundable and shall be made by bank or wire transfer of funds available for immediate credit. Except for the Up-Front Payment (which shall be made on or before thirty (30) Business Days after the Effective Date), all of the foregoing payments shall be made within twenty (20) Business Days following the occurrence of the associated event triggering such payment obligation.

7.2 *Quarterly Reports.*

(a) DYDO shall provide to CATALYST preliminary written reports not more than four (4) Business Days after the end of each Calendar Quarter and follow-on written reports (reconciling the preliminary reports, as necessary) not more than nine (9) Business Days after the end of each Calendar Quarter covering all sales of the Product for which invoices were sent during such Calendar Quarter in the Territory by DYDO, its Affiliates, or Sublicensees.

(b) Each report required under Section 7.2(a) shall certify for the period in question:

(i) gross sales of Product in the Territory during the applicable Calendar Quarter;

(ii) calculation of Net Sales for the applicable Quarter, along with cumulative Net Sales for the then-current Calendar Year, reported in both JPY and US Dollars in accordance with the exchange rate specified in Section 18.13; and

(iii) such other information as CATALYST may reasonably request to facilitate the performance by CATALYST of its obligation to timely report "Net Sales" under the CATALYST License and pay the applicable royalty with respect thereto.

Such reports shall be certified by DYDO to CATALYST as accurate and complete in accordance with the terms of this Agreement.

(c) The information contained in each report under this Section 7.2 shall be considered Confidential Information of CATALYST and DYDO. DYDO and CATALYST shall cooperate with one another to facilitate the performance by CATALYST of its obligations under the CATALYST License described in Section 7.2(b)(iii).

7.3 *Accounting*. DYDO agrees to keep full, clear and accurate records for a period of at least seven (7) years after the relevant Net Sales report pursuant to this Agreement, setting forth the sales and other disposition of Products sold or otherwise disposed of in sufficient detail to enable the Milestone Payments and royalties and compensation payable by CATALYST to Licensor to be determined. DYDO further agrees to permit its books and records to be examined by an independent accounting firm selected by CATALYST or Licensor reasonably acceptable to DYDO (subject to written obligations of confidentiality to DYDO that are no less stringent than the obligation of confidentiality described in Article 17), at reasonable times and upon reasonable notice, to examine only those records as may be necessary to verify reports provided pursuant to Section 7.2. Such audit shall not be performed more frequently than once per Calendar Year for any Calendar Year ending not more than three (3) years prior to such year, nor more frequently than once for each of CATALYST and Licensor with respect to records covering any specific period of time. Such examination is to be made at CATALYST's or Licensor's (as applicable) expense, except in the event that the results of the audit reveal an underpayment of royalties payable to Licensor under the CATALYST License or Milestone Payments to CATALYST under this Agreement exceeding five percent (5%) over the period being audited or a delay in payment of any Milestone Payments (which shall refer to the case where, because Net Sales have not been correctly reported, a Milestone Payment dependent on reaching a certain level of Net Sales has not been paid when it should have been paid), in which case reasonable audit fees for such examination shall be paid by DYDO.

ARTICLE 8.
PRODUCT SUPPLY

8.1 *Forecasts and Purchase Orders*.

[***]

8.2 *Batch Size and Minimum Order Quantity*. [***]

8.3 *Price and Payment*.

(1) Method of Payment. All payments made by DYDO to CATALYST pursuant to this Agreement shall be made within thirty (30) days of DYDO's receipt of the invoice by bank or wire transfer or as CATALYST may otherwise direct. Payment shall not constitute approval or disapproval of any Product shipment.

(2) Delays in Payment. If DYDO fails to pay the invoice issued for any shipment of the Product or any other amount due from it to CATALYST on a timely basis, interest at the rate of [***] percent ([***]%) on the unpaid amount per month of delay shall be due from DYDO to CATALYST.

(3) Product Purchase Pricing. CATALYST shall supply the Product to DYDO for both clinical use and commercial sale at the Transfer Price as stated in **Schedule A**. The Transfer Price is inclusive of all royalties and trademark fees.

8.4 *Taxes*. DYDO shall deduct or withhold from payments to CATALYST only those taxes that are required by Applicable Laws to be so withheld, each Party will cooperate with the other Party to obtain the benefit of the tax treaty applicable between the US and Japan prior to any payment being made by DYDO under this Agreement and each Party shall use commercially reasonable efforts to minimize the tax withholding obligations hereunder. DYDO shall submit to CATALYST appropriate proof of payment of tax withholdings as well as official receipts within a reasonable period of time not to exceed sixty (60) days after the end of each Quarter.

8.5 *Delivery*. Delivery of each order of the Product shall be made [***]

8.6 *Vision System Inspection.* If DYDO requires computerized vision system inspection of the bulk tablets prior to packaging, any additional costs attributed to enabling or performing the inspection will be paid by DYDO. For the avoidance of doubt, any change in the Specifications or the protocols for release of the Product by CATALYST's Contract Manufacturer requires the prior written approval of both Parties.

8.7 *Testing*. CATALYST or its Contract Manufacturers shall test all Product prior to delivery to DYDO to ensure that the Product meets the Specifications. Upon the delivery of each shipment of Product, CATALYST or its Contract Manufacturers shall provide to DYDO a certificate of analysis which verifies that the Product complies with the Specifications. DYDO will perform the final quality control testing based on the Regulatory Approval and then release all quantities of the Product for both clinical and commercial purposes.

8.8 *Defective Product.*

(1) Notification. If any shipment of Product is Defective in relation to any matter discoverable upon visual inspection made by DYDO with reasonable care, then DYDO will notify CATALYST as soon as practicable (to allow time for DYDO and CATALYST to collaborate about the issue before notifications are required to be issued to Contract Manufacturers) and in any event within twenty-seven (27) days of receipt of the Product. DYDO shall be deemed to have accepted the Products within twenty-seven (27) days of receipt of the Products, except to the extent that DYDO has notified CATALYST as set forth herein. If any shipment of Product is Defective in relation to any matter which is not discoverable upon visual inspection made by DYDO with reasonable care, then DYDO will immediately notify CATALYST upon discovery. CATALYST will initiate an investigation with Patheon and will notify DYDO of the outcome of the investigation, and as to whether it confirms or disputes that the Product is Defective.

(2) Review; Independent Testing Laboratory. If CATALYST does not agree with a claim by DYDO that any Product is Defective, then the Parties shall submit information regarding the disputed shipment to each other for review. If the Parties cannot agree as to whether the Product is Defective, then upon the request of either Party the dispute shall be submitted to a mutually acceptable independent laboratory with a minimum of ten (10) years of experience in testing pharmaceutical products and complying with guidelines and regulations in the United States. The independent laboratory shall act as an expert whose determination shall be final and binding upon the Parties, except in the case of manifest error. If the independent laboratory determines that the Product is not Defective, then DYDO shall pay for the Product (if it has not already done so) within thirty (30) days of receiving notice of the independent laboratory's decision. The costs of the independent laboratory shall be borne by the Party with whom the independent laboratory disagrees.

(3) Remedy for Defective Product. If any Product delivered by CATALYST to DYDO is finally agreed or determined to be Defective by CATALYST or by an independent laboratory as described in 8.8(2), then CATALYST shall, at DYDO's discretion, and without limitation to CATALYST's indemnification obligations, either replace the Defective Product at no additional cost to DYDO or (to the extent that DYDO has already paid for the Defective Product) give credit to DYDO for the Defective units and all costs paid by DYDO in relation thereto (including freight, insurance and all applicable taxes). DYDO will, at CATALYST's expense and in accordance with CATALYST's written instructions, either return or destroy all Defective Product. All claims made concerning Defective Products must be made pursuant to Article 8.8(1). In the case where DYDO shall fail to notify in accordance with Article 8.8(1), DYDO shall be deemed to have waived any remedies with respect to Defective Products.

ARTICLE 9.
RECORDS

9.1 *Records*. CATALYST or its Contract Manufacturer shall maintain all records necessary to comply with all Applicable Laws relating to the testing, manufacture, packaging, storage and supply of the Product, and the performance of its obligations under this Agreement and all relevant Contract Manufacturing Agreements. All such records shall be maintained for such period as may be required per GMP and pursuant to Applicable Laws; provided, however, that all records relating to the manufacture, stability and quality control (including deviations) of each batch of the Product shall be retained at minimum until the first anniversary of the end of the approved shelf life for all Product from such batch.

9.2 *Samples and Batch Records*. CATALYST or Contract Manufacturer shall prepare and maintain batch records and file samples, properly stored, for each lot or batch of Product manufactured and shipped hereunder in compliance with all GMPs and other Applicable Laws pertaining thereto. DYDO will retain samples properly stored in the Territory in conformity with GMP and Regulatory Authority requirements.

9.3 *Ongoing Stability*. CATALYST or its Contract Manufacturer, at their own cost, shall conduct ongoing stability studies for the Product according to the Specifications and the Contract Manufacturing Agreement. Any additional stability studies requested by DYDO shall be performed at the expense of DYDO.

ARTICLE 10.
PRODUCT RECALL

10.1 *Product Recall*.

(1) If any Regulatory Authority issues or requests a recall or takes similar action in connection with the Product in the Territory, or if either Party reasonably determines after consultation with the other Party that an event has occurred which may result in the need for a recall or market withdrawal of, or other corrective action regarding, the Product, then the Party notified of or wishing to implement such recall or other action shall inform the other Party thereof. The Parties shall promptly discuss and work together to effect an appropriate course of action to implement any recall or other corrective actions, provided that neither Party shall be prohibited from unilaterally taking any action, including recall of the Products, which it determines in good faith it is required to take to minimize risk to public health and safety or to comply with Applicable Laws. DYDO shall be responsible for notifying the applicable Regulatory Authority of any recall or other corrective action related to the Product in the Territory.

(2) Without limitation to the Parties' respective indemnification obligations under this Agreement regarding third party claims, if a Party (the "**Innocent Party**") is reasonably required to incur any out-of-pocket expenses due to a Product recall in the Territory ("**Recall Expenses**"), and if the reason for the recall or other corrective action in the Territory is a matter for which the other Party (the "**Responsible Party**") is obligated to indemnify the Innocent Party as provided in Article 16 of this Agreement, then the Responsible Party shall be liable for all Recall Expenses of both Parties. Without limitation, the Recall Expenses for which the Responsible Party shall be liable include notification expenses, costs for the return of recalled Product, costs to destroy recalled Product, and customer fees and penalties arising due to the recall. The Innocent Party shall provide to the Responsible Party documentation which verifies all Recall Expenses for which liability or reimbursement is claimed.

(3) If a recall is not due to the fault or responsibility of either Party, then the Parties shall share the Recall Expenses equally.

(4) The Parties will cooperate and assist each other on all recalls or other corrective action. If possible, the Parties shall discuss and agree on Recall Expenses prior to being incurred, provided that neither Party shall be prohibited from unilaterally taking any action or incurring any reasonable Recall Expenses which it determines in good faith it is required to take or incur to minimize risk to public health and safety or to comply with Applicable Laws.

ARTICLE 11.
INTELLECTUAL PROPERTY RIGHTS

11.1 *Reservation of Rights*. Except for the licenses granted to DYDO under this Agreement, no right, title, or interest is granted, whether expressly or by implication, to any technology or Intellectual Property Rights owned by either Party. Each Party hereby reserves all rights not expressly granted under this Agreement.

11.2 *Trademarks*. Subject to Section 5.4, CATALYST shall be responsible for the selection, registration and maintenance of all Trademarks used by DYDO in connection with the Product in the Territory, at CATALYST's cost. DYDO shall not acquire or assert any right, title, and interest in and to the Trademarks or marks substantially similar to the Trademarks. DYDO shall not use any Trademark in connection with the Marketing of the Product other than as contemplated herein.

11.3 *IP Claims*.

(1) Intellectual Property Representation. CATALYST represents and warrants that, to the best of its knowledge without investigation, the manufacture of the Product by or on behalf of CATALYST (including the route of synthesis, formulation and manufacturing process) for supply to DYDO and the distribution and sale of the Product by DYDO in the Territory in accordance with the provisions of this Agreement does not infringe upon the Intellectual Property Rights of any Third Party in the United States or the Territory. CATALYST also represents and warrants that it does not own or license any granted or pending patent applications in the Territory with respect to the Product, including any patents/applications relating to the use or manufacturing of the Product.

(2) Defense of IP Claims. 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 by the development, manufacture, production, use, importation, offer for sale, or sale of the Product in the Territory. 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. If CATALYST and/or DYDO are named as defendant(s) in any IP Claim filed by a Third Party concerning the development, manufacture, production, use, importation, offer for sale, or sale of the Product in the Territory, then CATALYST shall lead and control the defense of such IP Claim; provided, that, any settlement of such IP Claim shall require the consent of DYDO which shall not be unreasonably withheld. CATALYST and DYDO shall each bear half of all Losses in connection with such IP Claims.

(3) Termination Due to IP Claim. If an IP Claim is threatened or commenced against any Party, and if the Parties reasonably determine that the likelihood and consequences of an unfavorable ruling warrants that DYDO refrain from Marketing the Product in the Territory, or if DYDO agrees to refrain from Marketing the Product in the Territory pursuant to a settlement of an IP Claim, or if a court of competent jurisdiction makes a final determination that the Marketing of the Product in the Territory infringes the

Intellectual Property Rights in the Territory of a Third Party and all rights to appeal have been exhausted or expired, then either DYDO or CATALYST may terminate this Agreement upon delivering written notice to the other Party. In no event will Milestone Payments under Article 7.1 which have already been paid by DYDO to CATALYST be reimbursed by CATALYST to DYDO.

11.4 *Patent Enforcement.*

(a) **Notice**. If either Party becomes aware of any infringement, threatened infringement, or alleged infringement of a licensed patent or other exclusivity rights in the Territory (an "**Infringement**"), it will promptly notify the other Party thereof including available evidence of Infringement.

(b) **Enforcement in the Territory**. DYDO will have the first right (but not the obligation), at its sole expense, to take the appropriate steps to address any Infringement by enforcing such rights, 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 participate in (but not control) such suit, proceeding or action by counsel of its own choice. If DYDO fails to take the appropriate steps to address a particular Infringement within ninety (90) days after the date one Party has provided notice to the other Party of such Infringement, then CATALYST or Licensor will have the right (but not the obligation), at its sole expense, to take the appropriate steps to address such Infringement including the initiation of a suit, proceeding or other legal action by counsel of its own choice. DYDO will have the right, at its own expense, to participate in (but not control) such suit, proceeding or action by counsel of its own choice.

(c) **Enforcement Outside the Territory**. CATALYST or Licensor will have the sole right (but not the obligation), at is sole discretion and expense, to take the appropriate steps to address any infringement of rights to exclusivity outside of the Territory.

(d) **Cooperation**. If one Party brings any suit, action or proceeding under this Section 11.4, 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 nor 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 the 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 11.4(b) will be allocated first to the costs or 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 DYDO, then DYDO shall retain [***] percent ([***]%) of such remaining amounts and CATALYST shall receive [***] percent ([***]%); (ii) if the applicable suit, proceeding, or action was brought by CATALYST, then CATALYST shall retain [***] percent ([***]%) of such remaining amounts and DYDO shall receive [***] percent ([***]%); and (iii) if the applicable suit, proceeding or action was brought by Licensor, then Licensor shall retain [***] percent ([***]%) and DYDO shall retain [***] percent ([***]%). CATALYST shall have the sole right to any and all Recoveries obtained pursuant to a suit, proceeding, or action relating to an enforcement brought pursuant to Section 11.4(c).

ARTICLE 12.
REPRESENTATIONS AND WARRANTIES

12.1 *Mutual Representations and Warranties*. Each Party represents and warrants to the other Party as follows, which representations and warranties shall be true as at the date hereof and throughout the term of this Agreement:

(a) it has full corporate power and authority and has taken all corporate action necessary to enter and perform its obligations under this Agreement;

(b) this Agreement is its legal, valid, and binding obligation, enforceable in accordance with the terms and conditions hereof; and

(c) it has not violated and will not violate any provision of the U.S. Foreign Corrupt Practices Act of 1977, the OECD Convention on Bribery of Foreign Public Officials in International Business Transactions, and the rules and regulations thereunder and any other similar foreign or domestic law or regulation; or made or make any bribe, rebate, payoff, influence payment, kickback or other unlawful payment in connection with this Agreement and it has policies and procedures to ensure, and which are reasonably expected to ensure, continued compliance with the provisions of this paragraph.

12.2 *CATALYST General Warranties*. CATALYST represents and warrants to DYDO as follows:

(a) Agreement Will Not Cause Breach. The execution, delivery and performance of this Agreement by CATALYST will not result in CATALYST's violation of or default under any Applicable Laws or any material agreement or instrument by which CATALYST is bound;

(b) No Lawsuits. To the best of its knowledge, and as of the date hereof, there have not been any claims, lawsuits, arbitrations, legal or administrative or regulatory proceedings, charges, or complaints or investigations by any Third Party or government authority threatened, commenced, pending or proceeding against CATALYST, and CATALYST has not received any notice thereof, which relate to the Product, the API, or CATALYST's right to develop, manufacture, use or sell the Product and/or the API, or which could materially prevent CATALYST from complying with its obligations under this Agreement; and

(c) License. CATALYST to its knowledge has the right to grant DYDO all the licenses to DYDO set forth in this Agreement.

12.3 *DYDO General Warranties*. DYDO represents and warrants to CATALYST that:

(a) Agreement Will Not Cause Breach. The execution, delivery, and performance of this Agreement by DYDO will not result in DYDO's violation of or default under any Applicable Laws or any material agreement or instrument by which DYDO is bound; and

(b) No Lawsuits. To the best of its knowledge, and as of the date hereof, there have not been any claims, lawsuits, arbitrations, legal or administrative or regulatory proceedings, charges, or complaints or investigations by any Third Party or government authority threatened, commenced, pending or proceeding against DYDO, and DYDO has not received any notice thereof, which could prevent DYDO from complying with its material obligations under this Agreement.

12.4 *Disclaimer*. EXCEPT FOR THE WARRANTIES AND REPRESENTATIONS PROVIDED OR REFERENCED IN THIS AGREEMENT, THE PARTIES MAKE NO OTHER WARRANTIES OR REPRESENTATIONS TO EACH OTHER, EXPRESS OR IMPLIED, INCLUDING THOSE WITH RESPECT TO THE PRODUCT, WHETHER STATUTORY OR OTHERWISE, AND EACH PARTY SPECIFICALLY DISCLAIMS ALL OTHER WARRANTIES, INCLUDING ANY IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE.

ARTICLE 13.
COVENANTS OF CATALYST

13.1 *Compliance*. CATALYST shall comply and will exercise its Commercially Reasonable Efforts to cause its Contract Manufacturer to comply with all applicable GMPs, GLPs, Applicable Laws, and all applicable licenses, governmental permits or applications.

13.2 *Permits and Licenses*. Subject to the other terms and conditions of this Agreement, CATALYST or its Contract Manufacturer shall throughout the term of this Agreement, at its expense, obtain and maintain any and all licenses, permits, orders, authorizations and consents required to perform its obligations under this Agreement as manufacturer of the Product.

ARTICLE 14.
COVENANTS OF DYDO

14.1 *Compliance*. DYDO shall be solely responsible for compliance with all Applicable Laws in the Territory relating to the Marketing of the Product. Without limiting anything herein, DYDO shall comply with all Applicable Laws in performing this Agreement, including all marketing, promotional material or advertising activities conducted by it. DYDO shall be responsible for all price reporting for the Products to all governmental agencies, as well as any Third Party pricing publications in the Territory and shall do so accurately and in a timely manner.

14.2 *Permits and Licenses*. DYDO shall throughout the Term of this Agreement, at its expense, obtain and maintain any and all licenses, permits, orders, authorizations and consents required by Applicable Laws to perform its obligations under this Agreement as Regulatory Approval holder and as importer and distributor of the Product.

ARTICLE 15.
TERM AND TERMINATION

15.1 *Term*. This Agreement shall commence upon the Effective Date, and, unless terminated earlier in accordance with the provisions hereof, shall continue for so long as the Product maintains exclusivity against competition by a generic version of the Product marketed for the same indication as the Product (the "**Initial Term**"). The Parties may, in the exercise of their respective discretion mutually agree to renew the Term of this Agreement for subsequent terms of one year each (each "**Renewal Term**"; the Initial Term and each Renewal Term shall be collectively referred to as the "**Term**") with the same terms and conditions as previously in effect.

15.2 *Termination*. If any one or more of the following events occur, then this Agreement may be terminated as set forth herein:

(a) if, at any time following the third anniversary of the Launch Date, DYDO elects to terminate the Agreement in its discretion, without cause, then DYDO shall provide CATALYST with twelve months prior written notice and this Agreement will terminate on the first anniversary date of such written notice;

(b) if a Party files a petition in bankruptcy or is adjudged as bankrupt, or a petition in bankruptcy is filed against it and is not dismissed within sixty (60) days, or it becomes insolvent, takes advantage of legislation for creditor relief, has a receiver or receiver-manager appointed in relation to its assets, or discontinues its business, then the other Party may terminate this Agreement immediately upon delivering written notice of termination;

(c) if a Party materially breaches any of its undertakings, agreements, covenants or obligations under this Agreement (excluding matters otherwise specifically addressed with a termination right elsewhere in this Agreement) and the failure is not capable of cure or, if capable of cure, is not remedied within sixty (60) days (or five (5) Business Days in the event of a payment default) after receipt of written notice from the non-defaulting Party, then the non-defaulting Party may terminate this Agreement immediately upon delivering written notice of termination;

(d) if a Party willfully or fraudulently misrepresents any fact, information or report required to be made or disclosed under this Agreement, then the other Party may terminate this Agreement immediately upon delivering written notice of termination;

(e) if the rights of CATALYST to the Licensed Technology in the Territory are terminated under the CATALYST License, this Agreement shall automatically terminate; and

(f) if a Party elects to terminate this Agreement in accordance with a right granted to such Party under another provision of this Agreement including Sections 4.4(c), 11.3 or 18.5 or **Schedule A**.

15.3 *Expiration; Termination.*

(a) *Effect on Confidential Information and Regulatory Approval*. If this Agreement expires or is terminated for any reason, (i) the unperformed obligations of each Party shall remain in effect except that, in the event of the termination of this Agreement by CATALYST under Sections 15.2(b), (c) or (d) or Section 11.3(3), CATALYST may, but shall not be required to, fulfill any outstanding unfulfilled purchase orders; (ii) the applicable provisions of Article 16 of this Agreement with respect to indemnity and other matters shall remain in full force and effect; and (iii) DYDO will immediately transfer without charge (except as provided in Section 15.3(c)) all Regulatory Approvals and all related assets of DYDO related exclusively to the Product (such as customer lists related to sales of the Product) to CATALYST or its designee, shall deliver all such tangible assets to CATALYST or its designees, and shall cooperate with CATALYST or its designee to ensure that the Regulatory Approvals may be validly owned and exercised by CATALYST or its designee; provided, that, upon completion of the transfer of any inventory of the Product from DYDO to CATALYST, CATALYST shall reimburse DYDO for the Transfer Price paid by DYDO to CATALYST for any unexpired inventory so transferred and third party out of pocket shipping costs to transfer such inventory. Each Party shall destroy all of the other Party's Confidential Information in its possession (whatever the format, except that information in archival electronic records maintained in the normal course of business need not be destroyed) except for documents that must be retained in order to comply with Applicable Laws, which information may be retained, but only for so long as required and subject to the confidentiality obligations herein.

(b) *Wind-up Activities*. Upon expiration or termination of this Agreement for any reason:

(i) The Parties shall proceed, as expeditiously as possible, to wind-up all of DYDO's or its Affiliates' Development and Marketing of Product then on-going in the Territory and transition of such Development and Marketing to CATALYST 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 DYDO 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 CATALYST's election, promptly transition such Development activities to CATALYST 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.

(ii) All licenses granted by CATALYST to DYDO under this Agreement shall terminate, and all rights under the Licensed Technology shall revert to CATALYST; *provided, however* that the licenses granted to DYDO shall continue in effect on a non-exclusive basis during wind-up and transition of Development and DYDO Marketing to CATALYST or its designee(s) and shall be limited to such wind-up and transition activities.

(iii) DYDO and its Affiliates shall discontinue making any representation regarding its status as a licensee of or distributor for CATALYST for the Products. Except in connection with any wind-up or transition activities, DYDO and its Affiliates shall cease conducting any activities with respect to the Development or Marketing of any Licensed Products unless specifically authorized to do so in writing by CATALYST after the termination and only to the extent they are authorized to do so.

(iv) DYDO shall transfer and assign or cause to be transferred and assigned to CATALYST or its designee (or to the extent not so transferable or assignable, DYDO shall take all reasonable actions to make available to CATALYST or its designee the benefits of), without charge, all Regulatory Approvals and regulatory filings, and other similar regulatory applications, permits or licenses owned or filed by DYDO or its Affiliates, and all other assets of DYDO or its Affiliates related exclusively to the Product. DYDO 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 CATALYST or its designee and shall provide full copies of all such Regulatory Approvals and regulatory filings that are in DYDO's possession without charge.

(v) DYDO will provide to CATALYST without charge copies of all material reports and data, including clinical and non-clinical data and reports, obtained or generated by or on behalf of DYDO or its Affiliates pursuant to this Agreement that relate to the Product, within sixty (60) days of such expiration or termination, except where CATALYST has already provided such report or data under Article 4.

(vi) At CATALYST's request, DYDO shall promptly provide to CATALYST without charge copies of all clinical trial, contract manufacturing, or service agreements entered into by DYDO or its Affiliates with respect to the Product. At CATALYST's request, DYDO shall promptly assign (or cause to be assigned), such agreements to CATALYST or its designee without charge.

(c) In the event of a termination of this Agreement by CATALYST pursuant to the terms contained in **Schedule A**, then CATALYST shall reimburse DYDO for any reasonable, necessary and documented third party out of pocket costs (not including legal fees or expenses) incurred by DYDO to effectuate the transfers to CATALYST or its designee required by this section.

15.4 *Termination under Section 15.2(e).* In the event of the termination of this Agreement under Section 15.2(e) after obtaining Regulatory Approval and payment of the applicable Milestone Payments, CATALYST agrees to [***]

15.5 *Termination Not Exclusive Remedy*. Except as may otherwise be expressly provided for herein, termination of this Agreement due to a Party's breach shall be without limitation to any other remedy a non-defaulting Party may have because of the breach.

ARTICLE 16.
INDEMNIFICATION AND INSURANCE

16.1 *Indemnification of CATALYST*. DYDO shall defend, indemnify, and hold harmless CATALYST, its Affiliates and their respective officers, directors, employees, agents and representatives from and against all Losses arising in connection with any Third Party claim, action, cause of action or demand resulting from:

(a) any breach of this Agreement by DYDO;

(b) any negligent or intentionally wrongful act or omission of DYDO or any person acting on DYDO's behalf;

(c) DYDO's specific written instructions to CATALYST regarding the Product Packaging; and

(d) the transportation, storage (after shipment to DYDO), or Marketing of the Product.

16.2 *Indemnification of DYDO*. CATALYST shall defend, indemnify, and hold harmless DYDO, its Affiliates and their respective officers, directors, employees, agents and representatives from and against all Losses arising in connection with any Third Party claim, action, cause of action or demand resulting from:

(a) any breach of this Agreement by CATALYST;

(b) the negligent or intentionally wrongful act or omission of CATALYST or any person acting on CATALYST's behalf; and

(c) the manufacture of any Product that is Defective;

16.3 *Indemnification Procedure*. If either Party (the "**Indemnified Party**") becomes aware of any event, circumstance, assertion, demand, suit, action, claim or proceeding in respect of which the other Party (the "**Indemnifying Party**") is obliged to indemnify the Indemnified Party pursuant to this Agreement, then the Indemnified Party shall promptly give written notice thereof to the Indemnifying Party. The notice shall specify the nature and amount of the Third Party claim, to the extent that such information is available. The Indemnifying Party shall, at its expense, assume control of the negotiation, settlement, defense or other handling of the Third Party claim for and on behalf of the Indemnified Party. The Indemnifying Party shall have the sole right to select and direct legal counsel to defend the claim. The Indemnified Party may, at its own expense, appoint its own legal counsel to participate in defending the claim, in which case the Indemnifying Party's counsel will consult with the Indemnified Party's counsel and will give the Indemnified Party's counsel the opportunity to provide comments on the defense strategy. The Indemnified Party shall cooperate with the Indemnifying Party, including assisting in the location

and production of evidence and having its employees and other representatives testify in any court proceeding, if necessary, all at the Indemnifying Party's reasonable cost. If the Indemnifying Party assumes control of the claim, the Indemnified Party shall not settle or compromise the claim without the prior written consent of the Indemnifying Party, which shall not be unreasonably withheld, and in any event an Indemnifying Party may settle without the consent of the Indemnified Party if there is no admission of fault by the Indemnified Party and the Indemnified Party has no further obligations in respect of the claims. The Indemnifying Party shall not settle the claim or consent to judgment without the Indemnified Party's written approval, which approval shall not to be unreasonably withheld. If the Indemnifying Party fails to assume control of the defense of any Third Party claim, or, having elected to assume control, thereafter fails to diligently defend the claim, then the Indemnified Party shall be entitled to contest, settle or pay the amount of the claim in good faith, and the Indemnifying Party shall be bound by the results obtained by the Indemnified Party with respect to the claim and shall remain liable to indemnify the Indemnified Party in relation thereto.

16.4 *Insurance*. CATALYST and DYDO shall, during the Term of this Agreement and for a period of five (5) years after the expiration date of the last unit of Product sold in the Territory, maintain a policy of general commercial liability, of clinical trial liability insurance and of product liability insurance for the Product insuring against, among other things, personal injury, death and damage to property. The said policy shall have a general commercial liability (including product liability) limit of not less than [***] Japanese Yen (JPY[***]) per occurrence and [***] Japanese Yen (JPY[***]) in the aggregate and a clinical trial limit of not less than [***] Japanese Yen (JPY[***]) per occurrence and [***] Japanese Yen (JPY[***]) in the aggregate and shall be maintained with a financially sound and reputable insurer.

16.5 *Survival*. The expiration or earlier termination of this Agreement shall not relieve any Party hereto from any obligations which accrued prior to such expiration or earlier termination, and shall not destroy or diminish the binding force and effect of any of the terms and conditions of this Agreement that expressly or by implication come into or continue in effect on or after termination or expiration. Without limiting the foregoing, the obligations set forth in this Article 16, Article 17 and Section 8.4 shall survive the termination of this Agreement and remain in full force and effect for an indefinite period after termination

16.6 *LIMITATION OF LIABILITY*.

(a) NOTWITHSTANDING ANYTHING TO THE CONTRARY CONTAINED IN THIS AGREEMENT, NEITHER PARTY SHALL BE LIABLE TO THE OTHER FOR ANY SPECIAL, CONSEQUENTIAL, INCIDENTAL, OR INDIRECT DAMAGES OR EXPENSES (INCLUDING LOST USE, LOST PROFITS AND LOSS OF BUSINESS), WHETHER IN CONTRACT, TORT OR OTHERWISE IN CONNECTION WITH OR ARISING OUT OF THIS AGREEMENT, EVEN IF A PARTY HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES.

(b) EACH PARTY ACKNOWLEDGES THAT THE FOREGOING LIMITATIONS OF LIABILITY REFLECT THE ALLOCATION OF RISK SET FORTH IN THIS AGREEMENT AND THAT NEITHER PARTY WOULD ENTER INTO THIS AGREEMENT ABSENT THESE LIMITATIONS OF LIABILITY.

ARTICLE 17.
CONFIDENTIALITY

17.1 *Confidentiality*. During the term of this Agreement and for five (5) years thereafter, each Party shall maintain in strict confidence the Confidential Information (as defined below) of the other Party. A Party may not use the Confidential Information of the other Party for any purpose other than the purposes contemplated under this Agreement, and shall not disclose such Confidential Information to any Third Party (including in connection with any publications, presentations or other disclosures) except to its (and, in the case of DYDO, its Parent's) employees, agents, consultants or advisors who have a need to know such Confidential Information to achieve the purposes of this Agreement, in connection with any financing or sale of business transaction, as may be required by the CATALYST License, or as otherwise contemplated herein for the purposes of this Agreement. Each Party shall ensure that any person to whom it discloses the other Party's Confidential Information is informed of the confidential nature of and duty not to disclose the information and is obligated to maintain the confidentiality thereof to the same or greater extent as provided herein. Each Party may also disclose such of the Confidential Information of the other Party as may be required by Applicable Law or by any governmental authority having jurisdiction, provided that the Party required to disclose shall, if possible, notify the other Party prior to disclosing any Confidential Information and provide such other Party with a reasonable opportunity to contest or limit the scope of the required disclosure and assist the other Party in obtaining any protective orders as may be appropriate.

17.2 *Definition*. "**Confidential Information**" means all proprietary technical information, marketing, business and financial information, scientific data, information marked confidential and all other information which a reasonable person would treat confidentially that relates to the Product or the business of a Party. Confidential Information shall not include any information which the receiving Party can show:

(a) was known to or in the possession of the receiving Party prior to its receipt from the disclosing Party;

(b) is readily available to the public other than through any act or omission of the receiving Party in contravention of this Agreement or any other agreement between the Parties;

(c) was disclosed by a Third Party not under an obligation of confidentiality to the disclosing Party; or

(d) is subsequently independently developed by the receiving Party without use of the Confidential Information as demonstrated by written records.

17.3 *No Publicity*. Except as required by Applicable Law, neither Party shall originate any publicity, news release or other public announcements, written or oral, whether to the public press, to stockholders, or otherwise, relating to this Agreement or any amendment hereto without the prior written approval of the other Party, which approval shall not be unreasonably withheld. Nothing in the provision shall be deemed to prevent a Party from making such

disclosures or announcements that, in the opinion of legal counsel, are legally required of such Party; provided that in any event the non-disclosing Party shall have the right to review any such disclosure and revise such disclosure to the extent it relates to the use of the non-disclosing Party's Confidential Information; provided, that, (i) the Parties may make a public announcement of the execution of this Agreement in the form of a mutually approved press release; (ii) CATALYST may report the material terms of this Agreement in its filings with US Securities and Exchange Commission and file a copy of this Agreement as an exhibit to its filings with the SEC if, in the opinion of CATALYST's legal counsel, such report or filing is legally required; and (iii) neither Party shall be required to seek the permission of the other Party to repeat any information related to this Agreement that has already been publicly disclosed.

ARTICLE 18.
MISCELLANEOUS

18.1 *Notice*. Any notice or other document required or permitted to be given pursuant to this Agreement shall be in writing, in English, and shall be delivered by hand or by internationally recognized overnight courier or by email, in each case addressed to the Party to whom it is to be given at the contact information shown below or at such other contact information as the Party to whom such notice is to be given shall have last notified the other Party in accordance with the provisions of this section:

In the case of CATALYST at:

Catalyst Pharmaceuticals, Inc.
355 Alhambra Circle, Suite 801
Coral Gables, FL 33134
Attention: Brian Elsbernd, Chief Legal and Compliance Officer
Email: belsbernd@CATALYSTpharma.com

And in the case of DYDO at:

DyDo Pharma, Inc.
Nakanoshima Central Tower Bldg. 18F, 2-2-7
Nakanoshima, Kita-ku, Osaka, 530-0005
Attention: Hideki Matsubara, Head of Business Development
Email: hideki-matsubara@dydo.co.jp

Any such notice or other document shall be deemed to have been given and received on the date of delivery, provided that if delivery is other than during business hours (9:00 a.m. to 5:00 p.m., local time) on a Business Day in the place of receipt, such notice shall be deemed to have been given and received on the first Business Day thereafter.

18.2 *Relationship of the Parties.* The relationship of the Parties is that of independent contractors. This Agreement does not constitute any one Party hereto as the agent or legal representative of the other Party for any purpose whatsoever. Neither of the Parties grants to the other any right or authority to assume or create any obligation or responsibility, express or implied, on behalf of it or in its name in any manner whatsoever, unless otherwise agreed to in writing by the other Party.

18.3 *Assignment*. This Agreement shall be binding upon and inure to the benefit of the Parties hereto and their respective successors and permitted assigns. Except as otherwise expressly provided herein, DYDO may not assign or transfer it rights or obligations under this Agreement, in whole or in part, or effect a change of control, without the prior written consent of the other Party, which consent shall not be unreasonably withheld or delayed. Any assignment or transfer by DYDO other than in accordance with the terms hereof shall be void and shall entitle the CATALYST to terminate this Agreement. CATALYST may assign or transfer its rights and obligations hereunder or effect a change of control.

18.4 *No Waiver; Remedies*. No Party to this Agreement shall be deemed or taken to have waived any provision of this Agreement unless such waiver is in writing, and then such waiver shall be limited to the circumstances set forth in such written waiver. No failure or delay on the part of a Party in exercising any right, power or remedy shall operate as a waiver thereof, nor shall any single or partial exercise of any such right, power or remedy preclude any other or further exercise thereof or the exercise of any other right, power or remedy. All remedies provided for hereunder shall be cumulative of and in addition to any and all other remedies which any Party may have under this Agreement and/or under Applicable Law, and the exercise of any one or more of such remedies shall not preclude the exercise of any others. The prevailing Party in any litigation hereunder shall be entitled to recovery of its attorney’s fees from the non-prevailing Party.

18.5 *Time*. Time shall be of the essence of this Agreement and every part hereof.

18.6 *Force Majeure*. If either Party is prevented from complying, either totally or in part, with any of the terms or provisions of this Agreement by reason of force majeure, including fire, flood, earthquake, storm, general strike, lockout, riot, war, terrorism, rebellion, accident, infestation, epidemic/pandemic, governmental action, acts of God and/or any other cause or

externally induced casualty beyond its reasonable control, whether similar to the foregoing matters or not (a "**Force Majeure Event**"), then, upon written notice by the Party liable to perform to the other Party, the requirements of this Agreement or such of its provisions as may be affected, and to the extent so affected, shall be suspended during the period of such disability, provided that the Party asserting force majeure shall bear the burden of establishing the existence of such Force Majeure Event by clear and convincing evidence, and provided further that the Party prevented from complying shall use its Commercially Reasonable Efforts to remove such disability, and shall continue performance with the utmost dispatch whenever such causes are removed, and shall notify the other Party of the Force Majeure Event not more than five (5) Business Days from the time of the event. When such circumstances arise, the Parties shall discuss what, if any, modification of the terms of this Agreement may be required in order to arrive at an equitable solution. If a Force Majeure Event continues for a period of longer than six (6) consecutive months or one hundred eighty (180) days in any twelve (12) month period, then the Party unaffected by such event may terminate this Agreement upon giving not less than thirty (30) days written notice of termination to the other Party, provided that if the Force Majeure Event ceases within such thirty (30) day period this Agreement shall remain in full force and effect.

18.7 *Governing Law and Dispute Resolution*.

(a) This Agreement shall be governed by and construed in accordance with the laws of the State of Delaware.

(b) Any controversy or claim arising out of or relating to this contract, or the breach thereof, shall be determined by arbitration administered by the International Centre for Dispute Resolution in accordance with its International Arbitration Rules. The Parties and Parent expressly contemplate and agree that Parent may be joined as an additional party and shall be subject to the jurisdiction of the arbitration tribunal. All disputes shall be heard by a single arbitrator, unless the claim amount exceeds [***] USD or the claim involves the enforcement (including by specific performance) of section 15.3, in which case the dispute shall be heard by a panel of three arbitrators. The place of arbitration shall be Wilmington, Delaware, United States. The language of the arbitration shall be English. Within 20 days after the commencement of arbitration, each Party shall select a person to serve as an arbitrator. The two selected arbitrators shall then select the presiding arbitrator within 30 days after completion of the appointment of the Party selections. If any arbitrators are not selected within these time periods, the International Centre for Dispute Resolution shall, at the written request of any Party, complete the appointments that have not been made. The arbitrator, or arbitration tribunal if applicable, shall follow IBA's Rules on the Taking of Evidence in International Arbitration, as amended. Except as may be required by law, neither a Party nor its representatives may disclose the existence, content, or results of any arbitration hereunder without the prior written consent of all Parties. Such award of the arbitrator, or arbitration tribunal if applicable, shall be the final award.

18.8 *CATALYST License*. DYDO acknowledges that CATALYST's rights to the Licensed Technology arise under the CATALYST License. Notwithstanding any provision of this Agreement to the contrary, CATALYST and DYDO hereby expressly agree that: (i) it is the intent of the Parties that the terms of this Agreement and the terms of the CATALYST License be read in concert with one another such that the terms do not conflict; (ii) in the event of any conflict between this Agreement and the CATALYST License, as between CATALYST and DYDO the terms,

covenants, conditions, and limitations of this Agreement shall control; and (iii) each Party shall not do or fail to do or permit to be done anything under this Agreement which would result in a breach or default under any term, covenant, or condition of the CATALYST License.

18.9 *Severability*. If any provision in this Agreement is held to be invalid, void or unenforceable, then that provision shall be severed from this Agreement, and the remainder of this Agreement shall not be affected thereby and shall be enforced to the fullest extent permitted by Applicable Law. The Parties agree to renegotiate any such invalid, void or unenforceable provision in good faith in order to provide a reasonably acceptable alternative consistent with the basic purposes of this Agreement and to as closely as possible give effect to the intent of the invalid, void or unenforceable provision.

18.10 *Entire Agreement*. This Agreement (including the Schedules attached hereto and any Quality Agreement and any Pharmacovigilance Agreement entered into by the Parties) constitutes the entire agreement between the Parties with respect to the subject matter hereof, and all prior or agreements, whether written or oral, are superseded hereby. This Agreement may be amended only in writing executed by the Parties.

18.11 *Headings*. The captions and headings contained herein are for convenience of the Parties and in no way define, limit, or describe the scope of this Agreement.

18.12 *Language*. The language of this Agreement and all proceedings, reports, plans, related agreements or other communications between the Parties undertaken in relation thereto shall be English unless otherwise set forth herein.

18.13 *Currency*. Unless otherwise specifically provided, all references to money amounts are expressed in terms of United States dollars and all payments shall be made in US Dollars. Milestone Payments and the Transfer Price shall be converted from JPY to US Dollars using the exchange rate as published by the Wall Street Journal (U.S., Western Edition, https://www.wsj.com/market-data/currencies) on the invoice date of which the applicable payment. Net Sales shall be reported in Japanese Yen and CATALYST shall use the same published exchange rate in effect for the last Business Day of the applicable Quarter for which Net Sales is being reported.

18.14 *Counterparts and Delivery*. This Agreement may be executed in any number of counterparts, each of which shall be deemed an original and all of which, taken together, shall constitute one and the same instrument. This Agreement may be executed and delivered by pdf or other form of electronic transmission, and the Parties may rely on a pdf or electronic signature as though it were an original signature.

18.15 *Parent Guaranty*. DyDo Group Holdings, Inc., a corporation incorporated under the laws of Japan ("**Parent**"), has entered into this Agreement to unconditionally guaranty the payment and performance by DYDO of each and all of DYDO's obligations under this Agreement and Parent agrees to be liable under this guaranty without the necessity for any prior demand or notice by CATALYST to DYDO or Parent.

IN WITNESS WHEREOF, the Parties and Parent hereto have executed this Agreement as of the Effective Date.

DyDo Pharma, Inc.

By: /s/ Yasunori Inaoka
Name: Yasunori Inaoka
Title: President and Representative Director

Catalyst Pharmaceuticals, Inc.

By: /s/ Patrick J. McEnamy
Name: Pat McEnany
Title: President and CEO

DyDo Group Holdings, Inc.

By: /s/ Tomiya Takamatsu
Name: Tomiya Takamatsu
Title: President

SCHEDULE A
PRODUCT INFORMATION

[***]

Catalyst Pharmaceuticals Announces Exclusive License and Supply Agreement with DyDo Pharma for the Development and Commercialization of Firdapse® in Japan

CORAL GABLES, Fla., June 28, 2021 (GLOBE NEWSWIRE) — Catalyst Pharmaceuticals, Inc. ("Catalyst") (Nasdaq: CPRX), a commercial-stage, patient-centric biopharmaceutical company focused on in-licensing, developing and commercializing novel high-quality medicines for patients living with rare diseases, today announced that it has entered into an exclusive license and supply agreement with DyDo Pharma, Inc. ("DyDo Pharma") for the development and commercialization of Firdapse® (amifampridine) Tablets 10 mg in Japan for the treatment of Lambert-Eaton myasthenic syndrome ("LEMS"). LEMS is a rare autoimmune neuromuscular disorder characterized by debilitating and progressive muscle weakness and fatigue.

Under the terms of the agreement, DyDo Pharma will have joint rights to develop Firdapse® (amifampridine phosphate), and exclusive rights to commercialize the product, in Japan. DyDo Pharma will be responsible for funding all clinical, regulatory, marketing and commercialization activities in Japan. Catalyst will be responsible for clinical and commercial supply, as well as providing support to DyDo Pharma in its efforts to obtain regulatory approval for the product from the Japanese regulatory authorities. Subject to the satisfaction of terms and conditions as set forth in the License and Supply Agreement, Catalyst will receive an upfront payment and be eligible to receive further development and sales milestones for Firdapse®, as well as a transfer price on product supplied to DyDo Pharma.

"DyDo Pharma's experienced team and commitment to rare diseases makes the company an attractive choice for Catalyst for the development and distribution of our amifampridine product for the treatment of LEMS in Japan," said Patrick J. McEnany, Chairman and CEO of Catalyst. "Given the limited availability of treatment options for LEMS in Japan, we look forward to working with DyDo Pharma to address this unmet medical need by hopefully providing a new treatment option for patients and their families."

"We are very pleased to have acquired a license for the Japanese rights for Firdapse®, which Catalyst sells in the United States," said Yasunori Inaoka, president and representative director of DyDo Pharma. "Going forward, we will pursue development with the goal of obtaining marketing authorization approval for Firdapse® as a treatment for LEMS in Japan, so that we can offer a new therapeutic option to Japanese LEMS patients who with their families are currently suffering in the absence of an approved treatment."

MTS Health Partners, L.P. served as financial advisor to Catalyst on the transaction.

About Firdapse® (amifampridine) Tablets 10 mg

Firdapse® is an oral, nonspecific, voltage-dependent, potassium (K+) channel blocker that causes depolarization of the presynaptic membrane and slows or inhibits repolarization. This action results in the opening of slow voltage-dependent calcium (Ca2+) channels, allowing for a subsequent influx of Ca2+. In turn, it induces the exocytosis of synaptic vesicles containing Acetylcholine (ACh) to release more ACh into the synaptic cleft, enhancing neuromuscular transmission, and providing for improved muscle function.

Firdapse® was granted orphan drug designation by the Ministry of Health, Labour and Welfare in Japan and has previously been approved for use in the United States, Europe, and Canada for the treatment of adults with LEMS.

About Catalyst Pharmaceuticals

Catalyst Pharmaceuticals is a commercial-stage, patient-centric biopharmaceutical company focused on in-licensing, developing and commercializing novel high-quality medicines for patients living with rare diseases. With exceptional patient focus, Catalyst is committed to developing a robust pipeline of cutting-edge, first- or best-in-class medicines for other rare diseases. Catalyst's New Drug Application for Firdapse® (amifampridine) 10 mg tablets for the treatment of adults with LEMS was approved in 2018 by the U.S. Food & Drug Administration ("FDA"), and Firdapse® is commercially available in the United States as a treatment for adults with LEMS. Further, Canada's national healthcare regulatory agency, Health Canada, recently approved the use of Firdapse® (amifampridine) for the treatment of patients in Canada with LEMS.

Firdapse® is currently being evaluated in clinical trials for the treatment of MuSK-MG and has received Orphan Drug Designation from the FDA for myasthenia gravis.

About DyDo Pharma

DyDo Pharma is the rare disease pharmaceutical wholly-owned subsidiary of DyDo Group Holdings. DyDo Group Holdings, Inc. operates through the following segments: Domestic Beverage Business, International Beverage Business, Pharmaceutical-related Business, Food Business and Other business. The Domestic Beverage Business accounts for more than 70% of total sales, and beverages are sold through vending machines that are widely prevalent in Japan. The company was founded on January 27, 1975 and is headquartered in Osaka, Japan.

Catalyst's Forward-Looking Statements

This press release contains forward-looking statements. Forward-looking statements involve known and unknown risks and uncertainties, which may cause Catalyst's actual results in future periods to differ materially from forecasted results. A number of factors, including (i) whether DyDo Pharma can obtain regulatory approval for the commercialization of Firdapse® in Japan, (ii) whether the clinical trial that will be required to be completed in Japan to obtain the right to commercialize Firdapse® in Japan will be successful, (iii) whether, if approved, DyDo can successfully commercialize Firdapse® in Japan, (iv) whether any such commercialization of Firdapse® in Japan will be on a profitable basis, and (v) those factors described in Catalyst's Annual Report on Form 10-K for the fiscal year 2020 and Catalyst's other filings with the U.S. Securities and Exchange Commission (SEC), could adversely affect Catalyst. Copies of Catalyst's filings with the SEC are available from the SEC, may be found on Catalyst's website, or may be obtained upon request from Catalyst. Catalyst does not undertake any obligation to update the information contained herein, which speaks only as of this date.

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Company Contact
Patrick J. McEnany
Catalyst Pharmaceuticals
Chief Executive Officer
(305) 420-3200
pmcenany@catalystpharma.com

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