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): December 18, 2018

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 1250** **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

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 ☐

Item 1.01 Entry Into a Material Definitive Agreement

On December 18, 2018, Catalyst Pharmaceuticals, Inc. (the "Company") and Endo Ventures Limited ("Endo") entered into that certain Development, License and Commercialization Agreement (the "Agreement"). Pursuant to the Agreement, Endo will further develop and commercialize generic Sabril® (vigabatrin) tablets through Endo's U.S. Generic Pharmaceuticals segment, doing business as Par Pharmaceutical. The Company will receive an up-front payment, milestones based on achievements of regulatory approvals, and a sharing of defined net profits upon commercialization.

The Agreement is attached to this Current Report on Form 8-K as Exhibit 10.1 and is incorporated herein by reference. Portions of the Agreement have been omitted and filed separately with the SEC pursuant to a request for confidential treatment.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

10.1 Development, License and Commercialization Agreement by and between the Company and Endo Ventures Limited, dated as of December 18, 2018 (portions of this exhibit have been omitted and filed separately with the SEC pursuant to a request for confidential treatment.)

SIGNATURES

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

Catalyst Pharmaceuticals, Inc.

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

Dated: December 26, 2018

[***] Text omitted and filed separately with the Securities and Exchange Commission/Confidential Treatment Requested under 17 C.F.R. Section 240.24b-2

THIS DEVELOPMENT, LICENSE AND COMMERCIALIZATION AGREEMENT (this "**Agreement**") is entered into and effective as of December 18, 2018 (the "**Effective Date**") by and between Endo Ventures Limited, an Irish company, with offices located at First Floor, Minerva House, Simmonscourt Road, Ballsbridge, Dublin 4, Ireland ("**EVL**"), and Catalyst Pharmaceuticals, Inc., a Delaware corporation, with offices located at 355 Alhambra Circle Suite 1250, Coral Gables, FL, USA ("**Catalyst**").

W I T N E S S E T H

WHEREAS, Catalyst has undertaken certain development activities relating to the preparation of a generic pharmaceutical formulation of the Product [***]; and

WHEREAS, Catalyst desires to (a) continue development activities with respect to the Product together with EVL and (b) [***] to enable EVL to manufacture or have manufactured, and market and distribute, a generic version of the Brand Product (as defined below) in the Territory, subject to the terms and provisions hereof.

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

ARTICLE 1. DEFINITIONS

Capitalized terms used in this Agreement shall have the following definitions:

"**Acquisition Cost**" means the cost of manufacturing or acquiring the Product by EVL and/or its Affiliates, calculated in accordance with GAAP, as applicable, but without any duplication of any such costs, as follows:

(a) if the Product is manufactured by EVL (or its Affiliates) (x) **[***]**, plus (y) **[***]**, or

(b) if the Product is manufactured by a Third Party Manufacturer, (x) **[***]**, plus (y) **[***]**.

"**Affiliate(s)**" means, with respect to a Party, any Person that is directly or indirectly controlled by, controlling, or is under common control with such Party. For purposes of this definition only, the term "control" (including, with correlative meaning, the terms "controlling", "controlled by", and "under common control with"), as used with respect to the applicable Party, means the possession, directly or indirectly, of the power to direct or cause the direction of the management and policies of the applicable Person, whether through ownership of interests

representing equity, securities, or partnership interests or by contract, or otherwise. Ownership of more than fifty percent (50%) of such equity, securities or partnership interests in a Person, or greater than fifth percent (50%) interests in the income of such Person shall, without limitation, be deemed to be control for purposes of this definition.

"**Agreement**" has the meaning given to such term in the introductory paragraph of this Agreement.

"**ANDA**" means an Abbreviated New Drug Application pursuant to 21 U.S.C. § 355(j) *et seq*., and the regulations promulgated thereunder, as such application may be amended or supplemented from time to time.

"**ANDA Transfer**" has the meaning set forth in Section 4.1.2.

"**Anti-Corruption Laws**" has the meaning set forth in Section 9.3.1.

"**API**" means, with respect to the Product, the active pharmaceutical ingredient(s) in such Product.

"**Applicable Laws**" means all laws, rules, regulations and guidelines of any Governmental Authority with jurisdiction over the development, manufacturing, exportation, importation, promotion, marketing, sale or distribution of the API or the Product and/or the performance of a Party's obligations under this Agreement, to the extent applicable and relevant, and including specifically all cGMP or similar standards or guidelines of the FDA and other applicable Regulatory Authorities and compendial guidelines (*e.g.*, United States Pharmacopeia or European Pharmacopeia), as well as Export Control Laws, and the FCPA and other Anti-Corruption Laws, in each case to the extent applicable to the performance of a Party's obligations under this Agreement.

"**Bioequivalence Studies**" means any bioequivalence study conducted by or on behalf of Catalyst or its Affiliates which is undertaken to satisfy the FDA's requirements for bioequivalence in connection with establishing that a Drug Product subject to an ANDA is a Therapeutic Equivalent of the Brand Product referenced in such ANDA.

"**Brand Product**" means the reference listed drug product, Sabril®, that is the subject of NDA No. 020427, as may be amended or supplemented from time to time.

"**Business Day**" means any day (other than a Saturday or Sunday) on which banking institutions in New York, New York, United States, and in Dublin, Ireland are open for business.

"**Calendar Quarter**" means a three (3) consecutive month period ending on March 31, June 30, September 30 or December 31.

"**Catalyst**" has the meaning given to such term in the introductory paragraph of this Agreement.

"**Catalyst Indemnitee**" has the meaning set forth in Section 10.2.

"**Catalyst Intellectual Property**" means Intellectual Property that (i) is Controlled by Catalyst and/or its Affiliates and (ii) covers the Product.

"**cGMP**" means all current good manufacturing practices as may be applicable, including: (a) as required by the provisions of 21 C.F.R., parts 210 and 211 and all applicable rules, regulations, orders and guidances of the FDA and other applicable Regulatory Authorities; and (b) ICH, Guidance for Industry Q7a Good Manufacturing Practice Guidance for Active Pharmaceutical Ingredients.

"**Code**" has the meaning set forth in Section 12.6.2.

"**Commercial Launch**" means the first commercial sale in the Territory of the Product by EVL, its Affiliate or sublicensee, as the case may be, to a Third Party.

"**Commercialize**" or "**Commercialization**" means the marketing, promotion, sale (and offer for sale or contract to sell), distribution, importation or other commercial exploitation of the Product. Commercialization shall include commercial activities conducted in preparation for Commercial Launch.

"**Commercially Reasonable Efforts**" means (a) with respect to product development efforts, the carrying out of such obligations or tasks with the level of effort and resources consistent with commercially reasonable practices normally devoted by a pharmaceutical company to their research, development or manufacturer of a similar pharmaceutical product owned by it (or to which it has exclusive rights) at a similar stage of development, a similar market potential, a similar profit potential and strategic value, and (b) with respect to Commercialization, the carrying out of such obligations or tasks with a level of effort and resources consistent with commercially reasonable practices normally devoted by a pharmaceutical company based on conditions then prevailing including issues of safety and efficacy, product profile, competiveness of alternative products in the market place, pricing and reimbursement for the Product, the likely timing of the Product's entry into the market and other relevant technical and commercial factors.

"**Competitive Product**" has the meaning set forth in Section 2.2.1.

"**Compliance Event**" has the meaning set forth in Section 9.3.4.

"**Confidential Information**" means, with respect to a Disclosing Party, all non-public information of any kind whatsoever (including data, materials, compilations, formulae, models, patent disclosures, procedures, processes, projections, protocols, results of experimentation and testing, specifications, strategies, techniques and all non-public Intellectual Property as defined herein), and all tangible and intangible embodiments thereof of any kind whatsoever (including materials, samples, compositions, documents, drawings, patent applications, records and reports) of the Disclosing Party and/or its Affiliates, which are disclosed by the Disclosing Party and/or its Affiliate to the Receiving Party and/or its Affiliate, including any and all copies, replication or embodiments thereof. Confidential Information of both Parties includes the terms, conditions and provisions of this Agreement and Protected Personal Information.

Notwithstanding the foregoing, and except for Protected Personal Information, Confidential Information of a Disclosing Party shall not include information that the Receiving

Party can establish by competent proof to have (a) been publicly known prior to disclosure of such information by the Disclosing Party and/or its Affiliate to the Receiving Party and/or its Affiliate, (b) become publicly known, without fault on the part of the Receiving Party and/or its Affiliate, subsequent to disclosure of such information by the Disclosing Party and/or its Affiliate to the Receiving Party and/or its Affiliate, (c) been received by the Receiving Party and/or its Affiliate from a source rightfully having possession of, and the right to disclose, such information free of an obligation of confidentiality, (d) been otherwise rightfully known by the Receiving Party and/or its Affiliate prior to disclosure of such information by the Disclosing Party and/or its Affiliate to the Receiving Party and/or its Affiliate, or (e) been independently developed by employees or agents of the Receiving Party and/or its Affiliate without the use of Confidential Information of the Disclosing Party and/or its Affiliate.

"**Controlled**" means the legal or regulatory right (whether by ownership, license or otherwise) to grant access, right, title, a license or a sublicense to Intellectual Property without violating the terms of any Third Party agreement, court order, or other arrangement or legal obligation.

"**Cost of Goods Sold**" means **[***]**.

"**Data Protection Laws**" has the meaning set forth in Section 9.3.2.

"**Disclosing Party**" means the Party disclosing Confidential Information hereunder to the other Party.

[***]

[***]

"**DMF**" means a drug master file for the API to be used in the Product, which has been filed by **[***]** with the FDA pursuant to 21 C.F.R. § 314.420 (or, if applicable, any other Applicable Laws outside of the United States).

"**Drug Product**" means a drug product, as defined in 21 C.F.R. § 314.3, for administration to human subjects.

"**Effective Date**" has the meaning given to such term in the introductory paragraph of this Agreement.

"**EVL**" has the meaning given to such term in the introductory paragraph of this Agreement.

"**EVL Facility**" means the facility of EVL or its Affiliate designated in writing by EVL to Catalyst.

"**EVL Indemnitee**" has the meaning set forth in Section 10.1.

"**Export Control Laws**" means all applicable U.S. laws and regulations relating to (a) economic and trade sanctions and embargoes imposed by the Office of Foreign Assets Control of

the U.S. Department of Treasury or (b) the export or re-export of commodities, technologies, or services, including the Export Administration Act of 1979, 24 U.S.C. §§ 2401-2420, the International Emergency Economic Powers Act, 50 U.S.C. §§ 1701-1706, the International Traffic in Arms Regulations, 22 C.F.R. parts 120-130, the Trading with the Enemy Act, 50 U.S.C. §§ 1 *et. seq*., the Arms Export Control Act, 22 U.S.C. §§ 2778 and 2779, and the International Boycott Provisions of Section 999 of the U.S. Internal Revenue Code of 1986 (as amended).

"**FCPA**" means U.S. Foreign Corrupt Practices Act (15 U.S.C. Section 78dd-1, *et. seq*.) as amended.

"**FDA**" means the United States Food and Drug Administration, and any successor agency thereto.

"**FD&C Act**" means the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 *et seq*, as amended.

"**Force Majeure Event**" has the meaning set forth in Section 14.12.

"**Freight Charges**" means **[***]**.

"**Further Development Work**" means the development activities necessary or desirable to support obtaining Regulatory Approval for [***] which are either described in Exhibit A attached hereto to the extent of the respective amount budgeted for such activities on such Exhibit and any additional activities and costs to the extent approved by each of the Parties during a meeting of the JSC in writing in the exercise of their respective sole discretion, acting reasonably.

"**GAAP**" means generally accepted accounting principles in effect in the United States from time to time, consistently applied.

"**Generic Equivalent**" means a pharmaceutical product that has received FDA approval for marketing in the Territory pursuant to an ANDA as a generic version of the Brand Product.

"**Government Official**" means any (a) officer, employee of a government or any department, agency or instrument of a government; (b) person acting in an official capacity for or on behalf of a government or any department, agency, or instrument of a government; (c) officer or employee of a company or business owned in whole or part by a government; (d) officer or employee of a public international organization such as the World Bank or United Nations; (e) officer or employee of a political party or any person acting in an official capacity on behalf of a political party; and/or (f) candidate or relative of any candidate for political office.

"**Governmental Authority**" means any court, tribunal, arbitrator, agency, legislative body, commission, official, authority, department, regulatory body or other instrumentality of (i) any government in the Territory, or (ii) any national, federal, state, province, region, county, city or other political subdivision of any such government or any supranational organization of which any such country is a member, which has competent and binding authority to decide, mandate, regulate, enforce, or otherwise control the activities of the Parties or their Affiliates contemplated by this Agreement.

"**Gross Amount**" means the gross amount invoiced for the Product sold by EVL, its Affiliates or a sublicensee, as the case may be, in the Territory.

"**Healthcare Professional**" means any member of the medical, pharmacy or nursing professions or any other person who in the course of his or her professional activities may prescribe, purchase, supply or administer a medicinal product.

"**Indemnitee**" has the meaning set forth in Section 10.3.

"**Indemnitor**" has the meaning set forth in Section 10.3.

"**Insolvency Event**" means, with respect to a Party:

(a) a voluntary case or proceeding under any applicable bankruptcy, insolvency, or other similar law is commenced by such Person, or such Person consents to the entry of an order for relief in an involuntary case or proceeding under any such law or against such Person, or such Person consents to the appointment of or taking possession by a receiver, liquidator, assignee, trustee, custodian, sequestrator, conservator, supervisor, rehabilitator (or other similar official) of such Person or for any material portion of such Person's assets and properties, or such Person makes a general assignment for the benefit of creditors, or such Person fails generally to pay, or admits in writing its inability to pay, its debts as they become due or takes any company action in furtherance of the foregoing;

(b) the commencement of an involuntary case or proceeding under any applicable bankruptcy, insolvency, or other similar law against such Person, and such case or proceeding is not dismissed within ninety (90) days;

(c) the entry by a Governmental Authority having jurisdiction over such Person of a decree or order appointing a receiver, liquidator, assignee, custodian, trustee, sequestrator, conservator, supervisor, rehabilitator (or similar official) for such Person or for any material portion of such Person's assets and properties, or ordering the winding-up, supervision, or liquidation of such Person's affairs; or

(d) the taking of any formal action by such Person, its board of directors (or similar governing body) or holders of its voting securities authorizing any of the foregoing.

"**Intellectual Property**" means all of the following: (i) patent applications, continuation applications, continuation-in-part applications, divisional applications, and United States patents corresponding to any of the foregoing that may grant or may have been granted on any of the foregoing, including reissues, re-examinations and extensions and any supplemental protection certificates, or the like; (ii) all Know-How, work product, trade secrets, inventions (whether patentable or otherwise), data, processes, techniques, procedures, compositions, devices, methods, formulas, protocols and information, whether patentable or not; (iii) copyrightable works, copyrights and applications, registrations and renewals; (iv) logos, trademarks, service marks, and all applications and registrations relating thereto; (v) other proprietary rights; (vi) any regulatory exclusivities or the like; and (vii) copies and tangible embodiments of any one or more of the foregoing, including the Bioequivalence Studies. For purposes of clarity, data, information and methods related to the Product and its components developed in connection with this Agreement shall be considered Intellectual Property, whether or not patentable, confidential, or otherwise subject to intellectual property protection laws.

"**Interfering Event**" means any of the following events: (i) pending litigation concerning [***] or the Product or (ii) any litigation, threatened in writing by a Third Party that the development or manufacture of the Product by any of the Parties or a Third-Party manufacturer infringes any intellectual property rights of any Third Party; (iii) government restrictions due to safety issues or concerns, including a disruption or halt in operations of the Vigabatrin REMS Program; (iv) inability to manufacture sufficient launch quantities of the Product due to unavailability of API, materials or components; (v) the receipt of non-saleable product from a contract manufacturing organization; or (vi) an API supplier warning letter.

"**JSC**" has the meaning set forth in Section 3.2.1.

"**Know-How**" means all of the following: manufacturing protocols and methods, product specifications, analytical methods and assays, processes, formulations, product designs, plans, trade secrets, ideas, concepts, manufacturing information, engineering and other manuals and drawings, standard operating procedures, flow diagrams, chemical data, pharmacological data, pharmacokinetic data, toxicological data, pharmaceutical data, physical and analytical data, safety data, quality assurance data, quality control and clinical data, technical information, other data, and research records.

"**Label**," "**Labeled**" or "**Labeling**" refers to such labels and other written, printed or graphic matter, (i) upon any container or wrapper utilized with the Product, or (ii) accompanying the Product, including Package inserts.

"**Liabilities**" has the meaning set forth in Section 10.1.

"**Milestone Payment**" has the meaning set forth in Section 6.2.

"**Negative Amount**" has the meaning set forth in Section 6.1.2(c).

"**Net Profit Report**" has the meaning set forth in Section 6.1.2(b).

"**Net Profits**" means Net Sales, less (i) the Acquisition Cost, (ii) the Sales & Distribution Expenses, and (iii) the REMS Payments. For the avoidance of doubt, there shall be no deductions for the costs of Further Development Work in determining Net Sales and Net Profits.

"**Net Sales**" means the Gross Amount, less the following deductions (provided no such deduction shall be duplicative of another deduction used to determine Net Sales or Net Profits), to the extent accrued, paid or allowed in accordance with GAAP:

(a) **[***]**;

(b) **[***];**

(c) **[***]**;

(d) **[***]**;

(e) **[***]**;

(f) **[***]**;

(g) **[***]**; and

(h) **[***]**.

"**OFAC**" has the meaning set forth in Section 9.3.3.

"**Orange Book**" means the FDA publication *Approved Drug Products with Therapeutic Equivalence Evaluations*, as may be amended from time to time.

"**Package**," "**Packaged**" or "**Packaging**" means all primary containers, including bottles, cartons, shipping cases or any other like matter used in packaging or accompanying a Product.

"**Party**" means EVL or Catalyst, as applicable, and "**Parties**" means both EVL and Catalyst.

"**Person**" means an individual, corporation, partnership, limited liability company, firm, association, joint venture, estate, trust, governmental or administrative body or agency, or any other entity.

"**Proceedings**" means governmental, judicial, administrative or adversarial proceedings (public or private), litigation, suits, patent oppositions, arbitration, disputes, claims, causes of action or investigations.

"**Product**" means the Drug Product **[***]** that references the Brand Product, including all dosage strengths, and all packaging configurations thereof.

"**Product Claim**" has the meaning set forth in Section 10.5.

[***].

"**Protected Personal Information**" has the meaning set forth in Section 9.3.2.

"**Receiving Party**" means the Party receiving Confidential Information hereunder from the other Party.

"**Regulatory Approval**" means the applicable approval(s) from Regulatory Authorities necessary to market a Drug Product and/or an active pharmaceutical ingredient, including all applicable product and/or establishment licenses, registrations, permits or other authorizations as may be necessary for the commercial manufacture, commercialization, use, storage, importation, transport, promotion, pricing, distribution or sale thereof.

"**Regulatory Authority(ies)**" means the Governmental Authority(ies) in the Territory with authority over the manufacture, market approval, sale, distribution, packaging or use of a Drug Product in the Territory (including the grant of Regulatory Approval by the FDA).

"**Regulatory Documentation**" means the following to the extent related to the Product, owned and maintained by or on behalf of Catalyst and/or its Affiliates or otherwise in the possession of Catalyst or its Affiliates: the [***] and batch records relevant to the Product.

"**REMS**" has the meaning set forth in Section 4.4.

"**REMS Payments**" means **[***]**.

"**Representatives**" has the meaning set forth in Section 8.1.

"**Royalty**" has the meaning set forth in Section 6.1.1.

"**Sales & Distribution Expenses**" means **[***]**.

"**Specifications**" means the specifications for the manufacture of the Product as described in [***].

"**Stable**" means a Drug Product that meets FDA requirements for stability for purposes of Regulatory Approval.

"**Tax**" or "**Taxes**" shall mean all taxes, including income, corporation, gross receipts, transfer, excise, property, sales, harmonized sales, use, value-added, license, payroll, withholding, social insurance, employment insurance, employer health, franchise or other governmental taxes, imposed by any Taxing Authority (including any interest, penalties or additional tax attributable thereto).

"**Taxing Authority**" shall mean any Governmental Authority, exercising any authority to impose, regulate or administer the imposition of Taxes.

"**Term**" has the meaning set forth in Section 12.1.

"**Territory**" means the United States of America, and its commonwealths, territories, districts and possessions, including the District of Columbia, Commonwealth of Puerto Rico, US Virgin Islands, Guam, American Samoa; and any installation, territory, location or jurisdiction under the purview of the FDA or control of the United States government; and any United States military bases and installations worldwide.

"**Therapeutic Equivalent**" has the meaning given to it by the FDA in the current edition of the Orange Book.

"**Third Party**" or "**Third Parties**" means any Person other than a Party or its Affiliates.

"**Third Party Manufacturer**" has the meaning set forth in Section 5.1.

"**Third Party Supply Agreement**" has the meaning set forth in Section 5.1.

ARTICLE 2. LICENSE AND EXCLUSIVITY

2.1 License Grant.

2.1.1 Catalyst hereby grants to EVL an exclusive (even as to Catalyst), irrevocable (subject to Section 12.6), license (with the right to sublicense as set forth in Section 2.1.2) under the Catalyst Intellectual Property to manufacture, have manufactured, distribute, have distributed, use, market, have marketed, sell, have sold, import, and export for the purpose of Commercialization of the Product in the Territory, pursuant to the terms of this Agreement.

2.1.2 The license granted under Section 2.1.1 is sublicensable by EVL, in whole or in part. Any such sublicense shall be consistent with the terms of this Agreement, unless any variations thereof are agreed in writing between the Parties, and shall not otherwise diminish EVL's obligations hereunder. EVL shall cause its sublicensees to comply with the terms of this Agreement.

2.2 Exclusivity; Non-Competition.

2.2.1 Except as expressly set forth in this Agreement, during the Term, Catalyst, by itself, its Affiliate or through any Third Party, shall not, directly or indirectly, develop, seek Regulatory Approval for, manufacture, import, market, sell, distribute, or otherwise Commercialize any Drug Product that is a Therapeutic Equivalent of the Product ("**Competitive Product**") or otherwise work on the development of, or supply of any Competitive Product (i) in the Territory, or (ii) to any Third Party outside the Territory which Catalyst knows, or should know, that such Third Party intends to import such Competitive Product in the Territory.

2.2.2 Except as expressly set forth in this Agreement, during the Term, EVL, by itself, its Affiliate or through any Third Party, shall not, directly or indirectly, develop, seek Regulatory Approval for, manufacture, import, market, sell, distribute, or otherwise Commercialize any Competitive Product or otherwise work on the development of, or supply of any Competitive Product (i) in the Territory, or (ii) to any Third Party outside the Territory which EVL knows, or should know, that such Third Party intends to import such Competitive Product in the Territory.

ARTICLE 3. DEVELOPMENT AND COMMERCIALIZATION

3.1 Development.

3.1.1 Catalyst shall exercise Commercially Reasonable Efforts to develop, or cause the development of, a final finished, Stable dosage form of the Product conforming to the Specifications, except that Catalyst will be excused from the duty to exercise such efforts to the extent that the Third Party out-of-pocket costs which would be required to be expended for such purpose are not included in the Further Development Work. Notwithstanding the foregoing, the Parties shall collaborate on any development activities necessary or desirable after the date hereof to support obtaining Regulatory Approval for [***] in the Territory.

3.1.2 In connection with the activities of Catalyst under Section 3.1.1, EVL shall provide reasonable assistance with respect to Further Development Work and the commercial manufacturing process validation for the Product. The Parties shall share equally in the costs and expenses incurred by EVL and Catalyst after the date hereof in connection with such Further Development Work. Either Party may on a monthly basis until the expiration of the Calendar Quarter following the date of obtaining Regulatory Approval issue reasonably detailed invoices to the other Party setting forth the costs incurred by such Party as a part of the Further Development Work, half of which amounts shall be reimbursed by the other Party within sixty (60) days following the receipt of such invoice.

3.1.3 In connection with such Further Development Work, each Party shall promptly transfer to the other Party all data, information and materials generated or obtained in connection with the Product, including with respect to the components thereof, and all associated methods and analytical testing.

3.2 Joint Steering Committee.

3.2.1 Promptly following the date hereof, but in no event later than thirty (30) days thereafter, EVL and Catalyst will form a joint steering committee (the "**JSC**") to provide executive oversight and to facilitate information sharing between the Parties with respect to any Further Development Work.

3.2.2 The JSC will be composed of an equal number of representatives appointed by each of EVL and Catalyst. Each individual appointed will be an employee or contractor of such Party or such Party's Affiliate. Each Party may replace any of its JSC representatives at any time upon written notice to the other Party, which notice may be given by e-mail, sent to the other Party. Each JSC representative will be subject to confidentiality obligations no less stringent than those in Article 8.

3.2.3 The JSC will hold meetings within five (5) Business Days after receiving communications from the FDA regarding the Product to determine what, if any, Further Development Work is required and the approved costs in connection therewith. The JSC may meet in person or by audio or video conference as its representatives may mutually agree. No action taken at a meeting will be effective unless at least one representative of each Party is present or participating. Neither Party will unreasonably withhold attendance of at least one representative of such Party at any meeting of the JSC for which reasonable advance notice was provided. Each Party shall bear the costs and expenses incurred by its own JSC representatives in participating in the JSC meetings.

3.2.4 The Parties will endeavor in good faith to reach unanimous agreement with respect to all matters within the JSC's authority. Should the JSC not be able to reach unanimous agreement with respect to such matter at a duly called meeting of the JSC, either Party may refer such matter for resolution to a Vice-President or other executive officer of each Party having decision making authority on such matter and designated in writing by such Party to the other

Party within thirty (30) days following the Effective Date, and such executive officers will attempt to resolve the matter in good faith. If the executive officers fail to resolve such matter within twenty (20) Business Days after the date on which the matter is referred to the executive officers (unless a longer period is agreed to by the Parties), then decisions regarding such matter may be finally determined in accordance with the procedures set forth in Section 14.10.

3.3 Commercial Scale-Up. At EVL's request, Catalyst shall, at its own cost and expense, provide reasonable assistance with respect to EVL's preparation for Commercial Launch of the Product by making knowledgeable Catalyst personnel available for consultation with EVL, it being understood that for the purposes hereof 'reasonable assistance' shall mean the provision of assistance consistent with Catalyst's business, to the best of Catalyst's abilities with its then-currently existing and available resources.

3.4 Product Commercialization.

3.4.1 EVL shall exercise its Commercially Reasonably Efforts to Commercialize the Product. Subject to complying with its obligations under the preceding sentence, EVL shall have the sole and exclusive right to make determinations regarding the Commercialization of the Product in the Territory, including the timing of the Commercial Launch and responsibility for all sales/marketing and promotional activities.

3.4.2 Upon the Commercial Launch, EVL (or its Affiliate) will market and sell the Product, from the EVL Facility or such other facility as EVL may elect in its sole discretion, under EVL's (or its Affiliate's) label in a manner consistent with EVL's normal practices with respect to its other Drug Products.

3.5 Updates. Catalyst shall keep EVL informed and provide regular updates of the progress on the Regulatory Approval of the [***], communications with Regulatory Authorities related to the Product or Regulatory Approval thereof, and EVL shall keep Catalyst informed and provide regular updates of the progress on the Commercial Launch.

ARTICLE 4. REGULATORY MATTERS

4.1 Regulatory Approvals and Applications.

4.1.1 **[***]**.

4.1.2 **[***]**.

4.1.3 **[***]**

4.1.4 **[***]**.

4.1.5 **[***]**.

4.1.6 **[***]**.

4.2 Product Inserts and Labeling. EVL shall be solely responsible for the text and regulatory compliance of all package Labels, Product inserts and other Labeling used in connection with obtaining Regulatory Approval in the Territory for the [***].

4.3 Product Regulatory Reporting; Compliance With Applicable Laws. From and after the ANDA Transfer, EVL shall be solely responsible for adverse event reporting to the FDA, investigation and analysis of end-user complaints and otherwise complying with Applicable Laws with respect to the Commercialization of the Product and ownership of the Regulatory Approval. EVL shall have responsibility for communicating with the end-users to support the complaint handling process.

4.4 REMS. FDA has determined that a Risk Evaluation and Mitigation Strategy ("**REMS**") is necessary to assure safe use of the Product. The Product is currently subject to the FDA-approved single shared system Vigabatrin REMS Program. EVL will have sole discretion over the evaluation and management of the Vigabatrin REMS Program. The REMS Payments will not include any historical setup fee for the REMS Program. The Parties shall each bear half of the incremental setup cost that either Party bears that are specific to the Product as a part of the Further Development Work.

ARTICLE 5. MANUFACTURE

5.1 Third Party Manufacture of Product. During the Term and subject to Section 5.2, EVL shall engage **[***]** (or its Affiliate) or a Third Party manufacturer of the Product mutually agreed upon by the Parties (a "**Third Party Manufacturer**") pursuant to a manufacture and supply agreement with such Third Party Manufacturer (the "**Third Party Supply Agreement**"), which EVL will exercise Commercially Reasonable Efforts to enter into as soon as reasonably practicable after the Effective Date. EVL shall also collaborate in good faith with Catalyst in connection with the preparation and completion of the Third Party Supply Agreement which collaboration shall include affording Catalyst the opportunity to review and comment upon drafts of the Third Party Supply Agreement and accommodating to the extent practicable the reasonable comments of Catalyst on such agreement. At any time during the Term, EVL shall be entitled to engage a different manufacturer of the Product mutually agreed upon by the Parties.

5.2 Manufacture by EVL. At any time during the Term, and subject to the terms of the Third Party Supply Agreement, EVL shall be entitled to become the exclusive manufacturer of the Product in the Territory by providing written notice thereof to Catalyst. Following the ANDA Transfer, EVL shall use commercially reasonable efforts to transfer the manufacturing of the Product in the Territory to EVL or one of its Affiliates.

ARTICLE 6. FINANCIAL PROVISIONS

6.1 Royalties.

6.1.1 **Royalty Rates**. EVL shall pay to Catalyst a royalty (the "**Royalty**") equal to **[***]** percent (**[***]**%) of the Net Profits accruing during the Term.

6.1.2 **Payment of Royalties**.

(a) Following Commercial Launch, within sixty (60) days of the end of each Calendar Quarter during the Term, EVL shall pay to Catalyst the Royalties accrued during the preceding Calendar Quarter.

(b) EVL shall, concurrently with payment of Royalties and in any event within sixty (60) days of the end of each Calendar Quarter during the Term, provide to Catalyst a written report (in the form attached as Exhibit B hereto) outlining the details surrounding the calculation of Net Profits, Net Sales, deductions from Net Profits and Net Sales and calculation of the Royalties due to Catalyst pursuant to Section 6.1.1 (the "**Net Profit Report**").

(c) Subject to Section 6.1.2(d), EVL shall pay such amount relating to the share of the Net Profit payable pursuant to Section 6.1.1 to Catalyst and set forth in the Net Profit Report; provided, however, that in the event that the amount otherwise payable under Section 6.1.1 equals a negative amount ("**Negative Amount**"), then EVL shall be permitted to carry over such Negative Amount to apply against future Calendar Quarters; provided, further, that if such Negative Amount is not fully recovered within the following two Calendar Quarters or EVL does not have continuing payment obligations pursuant to Section 6.1.1, then EVL may invoice Catalyst for the unrecovered Negative Amount and Catalyst shall pay such unrecovered Negative Amount to EVL within thirty (30) days of such invoice, by wire transfer of immediately available funds to a bank account designated in writing by EVL.

(d) In the event there is a Negative Amount in two consecutive Calendar Quarters, the JSC shall meet not later than ten (10) days after issuance of the Net Profit Report for the second consecutive Calendar Quarter to discuss the commercial viability of the Product and endeavor in good faith to reach unanimous agreement with respect to the future Commercialization of the Product under this Agreement. Should the JSC not be able to reach unanimous agreement with respect to such future Commercialization within such ten (10) day period, either Party may refer such matter for resolution to the Chief Executive Officer of each Party and such Chief Executive Officers will attempt to resolve the matter in good faith within ten (10) days after the JSC has failed to reach unanimous agreement. In the event that the Chief Executive Officers cannot resolve such matter within such ten (10) day period, Catalyst may, upon delivery of written notice to EVL, terminate this Agreement effective as of the last day of the calendar month following such written notice.

(e) EVL shall make all payments under this Agreement free and clear of all tax deductions and withholdings, unless any such tax deduction or withholding is required by law in effect at the time of payment. Any Tax required to be withheld on amounts payable under this Agreement by EVL to Catalyst will be paid by EVL on behalf of Catalyst to the appropriate Governmental Authority, and EVL will furnish Catalyst with official receipts evidencing the payment of such Tax. Any such Tax required to be withheld will be treated as having been paid to Catalyst for all purposes of this Agreement.

6.2 Milestone Payment.

6.2.1 Subject to the terms and conditions of this Agreement, upon achievement of certain milestones, EVL shall make milestone payments to Catalyst as set forth below (each, a "**Milestone Payment**"). For the avoidance of doubt, each Milestone Payment shall be payable one-time only upon the first occurrence of the event triggering the respective milestone set forth below:

(a) **[***]** ($**[***]**) upon execution of this Agreement by both Parties; and

(b) **[***]** Dollars ($**[***]**) if upon Commercial Launch no Generic Equivalent had been commercially sold in the Territory by or on behalf of a Third Party; or

(c) **[***]** Dollars ($**[***]**) if upon Commercial Launch a Generic Equivalent had already been commercially sold in the Territory by or on behalf of a Third Party.

6.2.2 EVL shall make the applicable Milestone Payments payable to Catalyst under Section 6.2.1 (as applicable) within thirty (30) days following the completion of, and its receipt of an invoice for, the occurrence of the corresponding event, except for the Milestone Payment under Section 6.2.1(a), which shall be paid by EVL to Catalyst on the date hereof. Upon the occurrence of the applicable event for which a Milestone Payment is due and payable, Catalyst shall provide written notice thereof to EVL, along with an invoice for the corresponding Milestone Payment; provided, however, that Catalyst shall not be obligated to submit an invoice for the Milestone Payment under Section 6.2.1(a).

6.3 Payment; Expenses.

6.3.1 All payments under this Article 6 shall be made by wire transfer of immediately available funds to a bank account designated in writing by Catalyst.

6.3.2 Each Party shall bear its own costs and expenses associated with its responsibilities under this Agreement, except as expressly set forth in this Agreement. Any amounts payable under this Agreement which are not paid within thirty (30) days of their due date shall bear interest at a rate equal to **[***]** percent (**[***]**%) per annum, which shall be computed on the basis of a 365 day year.

6.4 Records and Audits. EVL and its Affiliates shall keep and maintain or cause to be maintained books and records pertaining to the calculation of Cost of Goods Sold, Net Sales and Net Profits during the Term and for two (2) years thereafter. Such books and records shall be maintained in accordance with GAAP and with all records and details necessary to enable Catalyst to verify the foregoing. All factors included in the determination of the Cost of Goods Sold, Net Sales and Net Profits shall be specific to the Product, reasonably documented, and available for independent audit purposes. Catalyst shall have the right once per calendar year, at its own expense, during the Term and for two (2) years thereafter, to have an independent public accountant, reasonably acceptable to EVL, audit the relevant financial books and records of account of EVL for up to the preceding three (3) years during normal business hours, upon reasonable advance notice, to determine or verify the applicable Cost of Goods Sold, Net Sales and Net Profits. If errors are found, any undisputed deficiency shall be paid within sixty (60) days following delivery of written documentation reasonably substantiating such deficiency. If errors

are discovered as a result of such audit in Catalyst's favor exceeding ten percent (10%) of Net Profits for the period audited (which shall be no less than one (1) year), EVL shall reimburse Catalyst for the reasonable expense of such audit. In the event that there is any overpayment by EVL revealed (a) by an examination and review conducted on behalf of Catalyst, or (b) by an examination and review of a Net Profit Report by EVL's accountants within one (1) year of delivery of such Net Profit Report, then EVL shall be permitted to carry over such overpayment and apply it against its payment obligations pursuant to Section 6.1.1 for future Calendar Quarters; provided, however, that if such overpayment is not fully recovered within the following two Calendar Quarters or EVL does not have continuing payment obligations pursuant to Section 6.1.1, then EVL may invoice Catalyst for the unrecovered overpayment and Catalyst shall pay such unrecovered overpayment to EVL within thirty (30) days of such invoice, by wire transfer of immediately available funds to a bank account designated in writing by EVL.

6.5 Accounting.

(a) The Parties acknowledge that any expenses or costs deducted from Net Sales under this Agreement may be based upon accruals, which accruals will be recognized and adjusted in compliance with GAAP; provided, however, that when the actual results become known relative to any accrued amount, any difference between the actual results and the accrual shall be accounted for in the subsequent payments due hereunder (subject to customary processing delays).

(b) To the extent that the difference between such accruals and the actual results has led to an underpayment, EVL shall pay Catalyst the amount of such underpayment on the next date payment is due to Catalyst hereunder. To the extent that the difference between such accruals and the actual results has led to an overpayment to Catalyst, EVL may, at its option, set-off such overpayments against subsequent payments to be made to Catalyst or issue an invoice for the amount of such overpayment, which shall be paid by Catalyst within forty-five (45) days after Catalyst's receipt thereof.

(c) After the Term, EVL shall continue to reflect such deductions for accruals, and by the date that is twenty-four (24) months following the expiration of the Term or termination of this Agreement, as applicable, EVL shall reconcile (and give to Catalyst a report of such reconciliation of) all accrued calculations and deductions used in determining Net Sales with actual processed credits. If the report shows an underpayment to Catalyst, EVL shall pay Catalyst the amount of the underpayment at the time it gives the report to Catalyst. If the report shows an overpayment to Catalyst, Catalyst shall pay EVL the amount of the overpayment within thirty (30) days after receipt of such reconciliation.

ARTICLE 7. INTELLECTUAL PROPERTY

7.1 General Ownership.

7.1.1 Except as expressly provided in this Agreement, each Party shall own its own Intellectual Property consistent with United States or other applicable international patent, trademark, and copyright law.

7.1.2 Each Party that owns any particular Intellectual Property shall, as between the Parties, have the sole and exclusive right to control the filing for, prosecution, maintenance and enforcement of such Intellectual Property in its sole discretion.

7.2 Product Intellectual Property.

7.2.1 EVL and Catalyst shall coordinate with each other with respect to Intellectual Property matters, including strategic decisions relating to potential Intellectual Property litigation and any other litigation arising from or relating to the Product in the Territory.

7.2.2 Intellectual Property that is jointly invented or jointly conceived during the Term under this Agreement shall be jointly owned by the Parties, unless otherwise agreed in writing. Employees of Catalyst, whether serving as advisors or consultants to EVL or serving EVL in any other capacity, shall be considered employees of Catalyst for the purpose of determining ownership of Intellectual Property.

7.2.3 For the avoidance of doubt, Intellectual Property covering inventions or improvements that are created or conceived in the course of developing the Product shall be owned solely by a Party if only its employees create or conceive such invention or improvement.

7.3 Notification. The Parties shall promptly notify each other of any allegation that any activity undertaken pursuant to this Agreement infringes or may infringe the Intellectual Property rights of any Third Party. Each Party shall assist and cooperate with the other Party in the defense of any Proceeding relating to the Product (including consenting to being named as a nominal party thereto).

ARTICLE 8. CONFIDENTIALITY AND PUBLIC DISCLOSURE

8.1 Treatment of Confidential Information.

A Receiving Party shall retain in strict confidence, and not disclose, divulge or otherwise communicate to any other Person, any Confidential Information of the Disclosing Party, whether received prior to or after the Effective Date, and shall not use any such Confidential Information for any purpose, except pursuant to the terms of, and as required to carry out such Receiving Party's obligations under, this Agreement, except that each Receiving Party may disclose Confidential Information of the Disclosing Party to the officers, directors, employees, agents, accountants, attorneys, consultants, subcontractors or other representatives of the Receiving Party or its Affiliates (the "**Representatives**") who, in each case, (a) need to know such Confidential Information for the limited purposes of the implementation and performance by the Receiving Party of this Agreement, (b) will use the Confidential Information only for such limited purposes, and (c) are bound by confidentiality obligations no less protective than those set forth in this Agreement.

8.1.1 A Receiving Party shall use at least the same standard of care in complying with its confidentiality obligations hereunder as it uses to protect its own Confidential Information of comparable sensitivity and to prevent and restrain the unauthorized disclosure of such Confidential Information by any of its Representatives, but in no event less than a reasonable standard of care. The Receiving Party shall be liable for any breach by any of its Representatives of the restrictions set forth in this Agreement.

8.1.2 Without limiting the generality of any of the foregoing, the Parties shall not make any disclosure of Confidential Information that would be reasonably likely to preclude the Disclosing Party from obtaining U.S. or foreign patents on any patentable invention or discovery described or otherwise embodied in such Party's Confidential Information.

8.1.3 The Confidential Information of each Party includes information from Third Parties subject to confidentiality restrictions and disclosed by one Party to the other Party.

8.2 Release from Restrictions.

8.2.1 A Receiving Party may disclose Confidential Information to the extent that such Confidential Information disclosure is made in response to a valid order or subpoena of a court of competent jurisdiction in the Territory or other Governmental Authority of competent jurisdiction or otherwise required by law, in the reasonable opinion of counsel to the Receiving Party; provided, however, that, to the extent practicable, the Receiving Party shall first provide written notice to the Disclosing Party reasonably in advance under the circumstances in order to give the Disclosing Party a reasonable opportunity to quash such order or subpoena or to obtain a protective order requiring that the Confidential Information or documents that are the subject of such order or subpoena to be held in confidence by such court or Governmental Authority or, if disclosed, be used only for the purposes for which such order or subpoena was issued; and provided further that whether a disclosure order or subpoena is quashed or a protective order is obtained, any Confidential Information that may be disclosed in response to such court or Governmental Authority order or subpoena shall be limited to information that, in the reasonable opinion of counsel to the Receiving Party, is legally required to be disclosed in such response to such order or subpoena.

8.2.2 A Receiving Party may also disclose Confidential Information to the extent that such disclosure is made (i) to a Governmental Authority as required in connection with any filing, application or request for Regulatory Approval with respect to the Product, (ii) to comply with the reporting requirements of any Applicable Laws or any securities exchange on which the securities of the Receiving Party or its Affiliates are traded or (iii) to a Third Party to which a Receiving Party has a contractual obligation related to the Product, but only to the extent such information is required by such contractual obligation, provided that in each case (clauses (i), (ii) and (iii)), reasonable measures are taken to seek confidential treatment of such Confidential Information.

8.2.3 A Receiving Party may disclose this Agreement to a Third Party in connection with or in conjunction with (i) a proposed merger, consolidation, sale of assets that includes those related to this Agreement, (ii) a permitted assignment of this Agreement or (iii) loan financing, raising of capital, or sale of securities; provided, however, that the disclosing Party obtains an agreement for confidential treatment thereof on terms no less protective than those contained herein.

8.2.4 Any Confidential Information disclosed pursuant to this Section 8.2 shall maintain its confidentiality protection and nonuse restrictions for all purposes other than such disclosure.

8.3 No Implied Rights. Except as otherwise expressly set forth in this Agreement, nothing herein shall be construed as granting any Receiving Party any right, title, interest in or ownership of the Confidential Information, proprietary information or Intellectual Property of the Disclosing Party. For the avoidance of doubt, specific information disclosed as part of Confidential Information shall not be deemed to be in the public domain or in the prior possession of the Receiving Party merely because it is embraced by more general information in the public domain or by more general information in the prior possession of the Receiving Party.

8.4 Survival of Confidentiality Obligations. The confidentiality obligations of the Parties contained in this Article 8 shall remain binding on both Parties during the Term and for a period of five (5) years after the expiration of the Term or the termination of this Agreement, regardless of the cause of such expiration or termination.

8.5 Disclosure of Terms and Use of Party's Name.

8.5.1 No press release, public announcement, confirmation or other communication to the public or Third Parties regarding the existence or terms of this Agreement or related matters shall be made by either Party without the prior written consent of the other Party, including with respect to the form, content and timing of such press release, public announcement, confirmation or other communication to the public or Third Parties, except as provided Section 8.2 or in the following sentence. The Parties agree that a press release may be issued by Catalyst at or after the Effective Date in the form included on Exhibit C and that the Parties may make communication of any information specifically included in such press release.

8.5.2 Except as required by Applicable Laws or as to Labeling activities, no right, express or implied, is granted by this Agreement to either Party to use in any manner the name of the other Party or its Affiliates or any other trade name or trademark of such other Party or its Affiliates in connection with the performance of this Agreement. For clarity, it is understood that nothing herein shall prohibit either Party from using the name of the other Party (i) in certain of such Party's disclosure documents, including those filed or disclosed in order to comply with its obligations under Applicable Laws or the listing standards or agreements of any national or international securities exchange, The New York Stock Exchange or The NASDAQ Stock Market or other similar laws of a Governmental Authority, (ii) to respond to an inquiry of a Governmental Authority, or (iii) in a judicial, administrative or arbitration Proceeding, or from disclosing the fact that it has granted or obtained a license to any Intellectual Property of such other Party so long as such use of the other Party's name is limited to statements of fact and is not done in a manner to suggest or imply endorsement by such other Party.

8.6 Third Party Information

8.6.1 Catalyst has not and shall not (i) violate or misappropriate the trade secrets, know-how, or confidential information, or knowingly violate or misappropriate any other proprietary rights, of any Third Party in developing the Product, and will not communicate any

Third Party trade secrets to EVL or its Affiliates in connection with its rights and obligations under this Agreement without receiving permission from such Third Party and informing EVL of communication of such trade secrets, or (ii) provide or disclose any documents or information to EVL or its Affiliates unless Catalyst is the owner thereof, or otherwise has the full and legal right to do so.

8.6.2 EVL shall not (i) violate or misappropriate the trade secrets, know-how, or confidential information, or knowingly violate or misappropriate any other proprietary rights, of any Third Party in connection with its rights and obligations under this Agreement, and will not communicate any Third Party trade secrets to Catalyst in connection with its rights and obligations under this Agreement without receiving permission from such Third Party and informing Catalyst of communication of such trade secrets, or (ii) provide or disclose any documents or information to Catalyst unless EVL is the owner thereof, or otherwise has the full and legal right to do so.

8.7 Remedies. Each Party acknowledges and agrees that: (i) it will be too speculative to measure the damages that would be suffered by the other Party if such Party fails to comply with the obligations set forth in this Article 8 or in Article 12 and that, in the event of any such failure, such other Party will be irreparably harmed and will not have an adequate remedy at law, (ii) such other Party shall, therefore, be entitled, in addition to any other rights and remedies, to seek specific performance of such Party's obligations and to seek immediate injunctive relief without having to post a bond, and (iii) such non-complying Party shall not assert, as a defense to any proceeding for such specific performance or injunctive relief, that such other Party will not be irreparably harmed or that such other Party has an adequate remedy at law.

ARTICLE 9. REPRESENTATIONS AND WARRANTIES AND COVENANTS

9.1 By EVL. EVL hereby represents, warrants and covenants that:

(a) EVL is a company duly organized and validly existing under the laws of Ireland;

(b) EVL has the corporate power and authority to enter into and be bound by the terms and conditions of this Agreement and to perform its obligations hereunder and the execute this Agreement;

(c) EVL has taken all necessary corporate action on its part to authorize the execution and delivery of this Agreement and this Agreement has been duly executed and delivered on behalf of EVL and constitutes a legal, valid, binding obligation, enforceable against EVL in accordance with its terms, subject to bankruptcy, insolvency, reorganization, moratorium or other similar laws affecting the enforceability of creditors' rights generally and other general equitable principles which may limit the right to obtain certain remedies;

(d) EVL is subject to no legal, contractual or other restrictions, limitations or conditions that conflict with its rights and obligations under this Agreement or that might affect adversely its ability to perform hereunder, including Section 2.2;

(e) EVL has not misappropriated and will not misappropriate trade secrets of any Third Party in the provision of services and the performance of its obligations under this Agreement or otherwise in connection with the Product;

(f) EVL itself or through its Affiliates has maintained and will maintain appropriate skilled personnel and facilities to carry out its obligations under this Agreement;

(g) No EVL employees or other Persons performing services on behalf of EVL under this Agreement have been debarred, or are the subject of debarment Proceedings, under Section 306 of the FD&C Act; and if EVL becomes aware that a Person performing on its behalf under this Agreement has been debarred, or has become the subject of debarment Proceedings, under Section 306 of the FD&C Act, EVL shall promptly notify Catalyst and shall prohibit such Person from performing on its behalf under this Agreement; and

(h) EVL and its Affiliates have not and shall not (i) promise, offer, or give anything of value to any government employee or individual acting in an official capacity for the purpose of securing any improper or undue advantage, (ii) accept or receive any unlawful contributions, payments, expenditures, or gifts, (iii) do business with any person that is the subject of sanctions imposed or administered by the U.S. Treasury Department's Office of Foreign Assets Control or the UN Security Council or any governmental agency in a jurisdiction in which EVL and its Affiliates are organized or doing business, and EVL and its Affiliates are not the subject of any such sanctions, or (iv) violate any applicable export restriction, anti-boycott regulation, or other applicable laws.

9.2 By Catalyst. Catalyst hereby represents, warrants and covenants that:

(a) Catalyst is a corporation duly organized, validly existing and in good standing under the laws of the jurisdiction of its formation;

(b) Catalyst has the corporate power and authority to enter into and be bound by the terms and conditions of this Agreement and to perform its obligations hereunder;

(c) Catalyst has taken all necessary corporate action on its part to authorize the execution and delivery of this Agreement and this Agreement has been duly executed and delivered on behalf of Catalyst and constitutes a legal, valid, binding obligation, enforceable against Catalyst in accordance with its terms, subject to bankruptcy, insolvency, reorganization, moratorium or other similar laws affecting the enforceability of creditors' rights generally and other general equitable principles which may limit the right to obtain certain remedies;

(d) Catalyst is subject to no legal, contractual or other restrictions, limitations or conditions which conflict with either of its rights and obligations under this Agreement or which might affect adversely its ability to perform hereunder, including Section 2.2;

(e) Catalyst has not misappropriated and will not misappropriate trade secrets of any Third Party in the provision of services and the performance of its obligations under this Agreement or otherwise in connection with the Product;

(f) Catalyst has maintained and will maintain appropriate skilled personnel and facilities to carry out its obligations under this Agreement, consistent with prudent business practices of Catalyst;

(g) No Catalyst employees or other Persons performing services on behalf of Catalyst under this Agreement have been debarred, or are the subject of debarment Proceedings, under Section 306 of the FD&C Act; and if Catalyst becomes aware that a Person performing on its behalf under this Agreement has been debarred, or has become the subject of debarment Proceedings, under Section 306 of the FD&C Act, Catalyst shall promptly notify EVL and shall prohibit such Person from performing on its behalf under this Agreement;

(h) Catalyst and its Affiliates have not and shall not (i) promise, offer, or give anything of value to any government employee or individual acting in an official capacity for the purpose of securing any improper or undue advantage, (ii) accept or receive any unlawful contributions, payments, expenditures, or gifts, (iii) do business with any person that is the subject of sanctions imposed or administered by the U.S. Treasury Department's Office of Foreign Assets Control or the UN Security Council or any governmental agency in a jurisdiction in which Catalyst and its Affiliates are organized or doing business, and Catalyst and its Affiliates are not the subject of any such sanctions, or (iv) violate any applicable export restriction, anti-boycott regulation, or other Applicable Laws;

(i) All Bioequivalence Studies were conducted in accordance with all Applicable Laws (which the Parties acknowledge does not include the draft FDA guidance otherwise related to such studies); and

(j) **[***]**.

9.3 Compliance with Laws.

9.3.1 **Anti-Corruption Laws**. Each Party represents and warrants to the other Party that, to the knowledge of such Party, such Party, with respect to the conduct of its business as of the Effective Date, has been and is in compliance in all material respects with all Applicable Laws. Each Party shall comply, and shall cause its employees and subcontractors to comply, with all Applicable Laws in its performance of activities contemplated under this Agreement. Without limiting the generality of the foregoing, each Party agrees that it will comply with, and will not take any action that will cause the other Party or its Affiliates to be in breach of all Applicable Laws for the prevention of fraud, kickbacks, bribery, corruption, racketeering, money laundering or terrorism, including the FCPA, each, as amended from time to time (collectively, "**Anti-Corruption Laws**"). Each Party agrees that it has not, and covenants that it will not, in connection with the performance of this Agreement, give, promise, authorize, ratify or offer, or take any act in furtherance of offering or giving anything of value, directly or indirectly: (i) to any individual, including Government Officials; or (ii) to an intermediary for payment to any individual, including Government Officials; (iii) or to any sick fund, health insurer or Healthcare Professional or employee or officer of such sick fund, health insurer or Healthcare Professional; or (iv) to any political party. It is the intent of the Parties that no payments or transfers of value shall be made, promised, authorized, ratified or offered with the purpose or effect of public or commercial bribery, acceptance or acquiescence in extortion, kickbacks or other unlawful or improper means of security an improper advantage or obtaining or retaining business.

9.3.2 **Data Protection Laws**. From time to time during the Term, either Party may provide the other Party with personal information that falls under the protection of certain data security and privacy laws ("**Protected Personal Information**"). Each Party agrees to comply with all Applicable Laws relating to the use, storage, collection or other processing of such Protected Personal Information, including without implied limitation the General Data Protection Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC ("**Data Protection Laws**"). The Parties agree to use good-faith efforts to agree upon and implement any security protocols and information handling guidelines that such Party's legal advisors recommend in connection with such Party's compliance with such Data Protection Laws.

9.3.3 **OFAC Compliance**. Each Party acknowledges and expressly agrees that certain laws of the United States of America and other countries, including, without limitation, the United States Export Control Regulations, the United States Anti-Money Laundering laws, the United States Anti-Terrorism laws and the FCPA, and U.S. sanctions programs administered by the Office of Foreign Assets Control ("**OFAC**") and the Bureau of Industry and Security, among others, may result in the imposition of sanctions on the other Party or its Affiliates in the event that, directly or indirectly, products are exported to or imported from, or payments are sent to or received from various countries or regions, including, without limitation, Iran, North Korea, Syria, Sudan, the Crimea region of Ukraine, or any country embargoed by Executive Order or otherwise, or to or from certain individuals designated or identified as sanctioned by the U.S. government, including persons in Russia and Ukraine. Each Party warrants that it has searched OFAC's Consolidated Sanctions List, available at https://sdnsearch.ofac.treas.gov, in order to ensure compliance with all applicable sanctions regulations.

9.3.4 **Compliance Event Reporting**. Each Party agrees that if it learns of any violation of Data Protection Laws, Applicable Laws, Export Control Laws or Anti-Corruption Laws by an employee or sub-contractor that performs any function under this Agreement (a "**Compliance Event**"), it will immediately notify the other Party in writing of such Compliance Event and the measures it has taken and intends to take to remedy such Compliance Event and to prevent its recurrence.

ARTICLE 10. INDEMNIFICATION

10.1 Indemnification by Catalyst. Subject to Section 10.3, Catalyst shall defend, indemnify and hold harmless each of EVL and its Affiliates, and each of their respective directors, officers and employees (each, an "**EVL Indemnitee**") from and against any and all liabilities, damages, settlements, penalties, fines, costs or expenses (including reasonable attorneys' fees and other expenses of litigation) (collectively, "**Liabilities**") arising, directly or indirectly, out of or in connection with Third Party claims, suits, actions, demands or judgments to the extent arising out of or relating to (i) any breach by Catalyst of any representation, warranty, agreement, undertaking or covenant under this Agreement; (ii) any negligence, gross negligence or willful misconduct by Catalyst or its Affiliates, past or present employees or agents; (iii) any arrangement entered into

by Catalyst (or its Affiliates) and a Third Party, providing for any royalty or other payment obligation with respect to the Product, or (iv) any patient's participation in the Bioequivalence Studies, except, in each case, for those Liabilities for which EVL has an obligation to indemnify the Catalyst Indemnitees pursuant to Section 10.2, as to which Liabilities each Party shall indemnify the other Party to the extent of its respective liability for such Liabilities.

10.2 Indemnification by EVL. Subject to Section 10.3, EVL shall defend, indemnify and hold harmless each of Catalyst and its Affiliates, and each of their respective directors, officers and employees (each, a "**Catalyst Indemnitee**") from and against any and all Liabilities arising, directly or indirectly, out of or in connection with Third Party claims, suits, actions, demands or judgments to the extent arising out of or relating to (i) any breach by EVL of any representation, warranty, agreement, undertaking or covenant under this Agreement; (ii) any negligence, gross negligence or willful misconduct by EVL or its Affiliates or sublicensees, past or present employees or agents; or (iii) product liability claims arising from the manufacture of the Product by EVL or its Affiliates, except, in each case, for those Liabilities for which Catalyst has an obligation to indemnify the EVL Indemnitees pursuant to Section 10.1, as to which Liabilities each Party shall indemnify the other Party to the extent of its respective liability for such Liabilities.

10.3 Notice and Procedures. If a Catalyst Indemnitee or an EVL Indemnitee (the "**Indemnitee**") intends to claim indemnification under this Article 10, it shall promptly notify the other Party (the "**Indemnitor**") in writing of any such alleged Liabilities. The failure to deliver written notice to the Indemnitor within a reasonable time after the commencement of any claim or action shall not relieve the Indemnitor of any obligation to the Indemnitee under this Section 10.3 except to the extent that the Indemnitor is materially prejudiced by such delay.

10.3.1 In the event that the Indemnitor does not assume and pursue in a timely and diligent manner the defense of any Third Party claim (but in no event later than thirty (30) days, or such shorter period as required under Applicable Laws), then the Indemnitor shall be deemed to have ceded control of such claim and the Indemnitee shall be entitled to appoint counsel of its own choice for such defense, at the cost and expense of the Indemnitor.

10.3.2 In the event that the Indemnitor assumes such defense, the Indemnitor shall have the right to control the defense thereof with counsel of its choice, provided that such counsel is reasonably acceptable to Indemnitee; and provided further that any Indemnitee shall have the right to retain its own counsel at its own expense, for any reason, including if representation of the Indemnitee by the counsel retained by the Indemnitor would be inappropriate due to actual or potential conflicts or differing interests between such Indemnitee and such Indemnitor reasonably represented by such counsel in such proceeding. The Indemnitee, its employees and agents, shall reasonably cooperate with the Indemnitor and its legal representatives in the investigation of any Liabilities covered by this Article 10.

10.3.3 The obligations of this Section 10.3 shall not apply to amounts paid in settlement of any claim, demand, action or other proceeding if such settlement is effected without the consent of the Indemnitor (unless the Indemnitor is deemed to have ceded control of the applicable Third Party claim under this Section 10.3).

10.3.4 Only Catalyst or EVL may claim indemnity under this Article 10 (on its own behalf or on behalf of its Indemnitees), and other Persons may not directly claim indemnity hereunder.

10.4 Other Product Liability Claims. To the extent either Party incurs any Liabilities arising from or in connection with any product liability claim with respect to the Product to the extent arising from the actions not subject to the indemnity obligations set forth in Section 10.1 or Section 10.2 (a "**Product Claim**"), then each Party shall be liable for such portion of the Liabilities in accordance with such Party's allocation of the Net Profits pursuant to Section 6.1.1; provided, however, such Liabilities shall be shared initially by offsetting against the portion of Net Profits otherwise payable or retained pursuant to Section 6.1.1 and in the event of any shortfall thereafter, each Party's share thereof shall be paid in accordance with such allocation. EVL shall have sole control in addressing, defending, managing and conducting any negotiations, litigation, threatened litigation or settlement regarding such Product Claim, using counsel of its choice. In the event that EVL does not respond to the Product Claim against Catalyst within (a) sixty (60) days following the notice of such claim or (b) ten (10) days before the time limit, if any, set forth in the appropriate laws and regulations for the filing of a response to such Product Claim, whichever comes first, Catalyst shall have the right to control any such Product Claim, using counsel of its own choice. In the event of a Product Claim, the non-controlling Party shall cooperate fully with the controlling Party, including, if a party in such Product Claim, and the controlling Party shall keep the non-controlling Party and/or the non-controlling Party's designated legal counsel reasonably informed as to the progress of such action. Neither Party shall enter into any settlement of the Product Claim, without the prior written consent of the other, such consent not to be unreasonably withheld, delayed or conditioned. Notwithstanding this Section 10.4, (a) Catalyst's maximum aggregate liability pursuant to this Section 10.4 shall not exceed an amount equal to $**[***]**, and (b) Catalyst shall have no liability under this Section 10.4 for product liability claims arising from the manufacture of the Product by any manufacturer other than **[***]**.

10.5 Exclusive Remedy. The rights of the EVL Indemnitees and the Catalyst Indemnitees under this Article 10 shall be the sole and exclusive remedy of the EVL Indemnitees and the Catalyst Indemnitees, as the case may be, with respect to matters covered hereunder other than as provided in Article 8 and the termination provisions of Article 12.

ARTICLE 11. LIMITATION OF LIABILITY

NOTWITHSTANDING ANYTHING TO THE CONTRARY IN THIS AGREEMENT, EXCEPT WITH RESPECT TO A BREACH OF ARTICLE 8 AND EXCEPT WITH RESPECT TO AMOUNTS PAYABLE ON LIABILITIES PURSUANT TO THE INDEMNIFICATION OBLIGATIONS SET FORTH IN ARTICLE 10, NO PARTY SHALL BE LIABLE TO THE OTHER FOR ANY CONSEQUENTIAL, INCIDENTAL OR INDIRECT DAMAGES, INCLUDING FOR LOST PROFITS, OR LOSS OF OPPORTUNITY OR USE OF ANY KIND SUFFERED BY THE A PARTY, WHETHER IN CONTRACT, TORT OR OTHERWISE.

ARTICLE 12. TERM AND TERMINATION

12.1 Term. Unless earlier terminated pursuant to this Article 12, the term of this Agreement shall continue in force from the Effective Date until the date that is ten (10) years following the Commercial Launch (the "**Term**").

12.2 Termination for Breach. Either Party may terminate this Agreement, or suspend performance under this Agreement upon written notice to the other Party at any time during the Term, if the other Party is in material breach of this Agreement and such other Party has not cured such material breach within sixty (60) days after notice requesting cure of such breach; provided, however, that if such breach is not capable of cure within sixty (60) days, but is capable of cure, and the breaching Party has promptly commenced, and is and continues diligently pursuing in good faith the remedy of any such breach, then such cure period shall be extended for such period as may be reasonably required to effectuate such cure.

12.3 Termination for Insolvency. Either Party may terminate this Agreement in the event that the other Party suffers an Insolvency Event, by delivery of written notice thereof by the other Party.

12.4 Termination for Force Majeure Event. Either Party may terminate this Agreement pursuant to and in accordance with Section 14.12 in connection a Force Majeure Event.

12.5 Termination for Other Events. The applicable Party may terminate this Agreement upon delivery of written notice to the other Party as follows:

(a) EVL may terminate this Agreement if the [***] has not been approved by the FDA by January 1, 2021;

(b) EVL may terminate this Agreement upon EVL's reasonable determination that the Product is not commercially viable; or

(c) Catalyst may terminate this Agreement if the Commercial Launch has not occurred within 24 months of the [***] having been approved by the FDA, unless the failure to launch arises out of or is related to an Interfering Event.

12.6 Effect of Expiration or Termination.

12.6.1 Expiration of the Term or termination of this Agreement for any reason shall be without prejudice to:

(a) Each Party's right to receive all payments due and payable from the other Party as of the effective date of such termination, if any, pursuant to the terms of this Agreement;

(b) EVL's right to sell, at its option but subject to the Commercial Launch, the Product remaining in its inventory at the time of termination (in which event, Net Profits on such sales shall continue to be shared as set forth above in Section 6.1.1) for up to twelve (12) months following the time of termination (and any remaining unsold inventory shall be destroyed by EVL or its Affiliates) provided that Catalyst or its assigns may elect to purchase from EVL the saleable inventory of the Product at EVL's Acquisition Cost; and

(c) any other legal, equitable, or administrative remedies as to which either Party is or may become entitled.

12.6.2 In the event that this Agreement is terminated by Catalyst pursuant to Section 12.4 or EVL pursuant to Section 12.5(a) or Section 12.5(b), such termination shall automatically result in an offer by EVL to transfer its right, title, interest, ownership and control of the [***] and any and all other assets owned by EVL or its Affiliates related solely to the Product (other than assets that bear EVL's or any of its Affiliate's name or logo) to Catalyst or its designee free and clear of any adverse claims, liens or payment obligations; and Catalyst or its designee shall have the right, at its sole discretion, to accept such offer by delivering written notice thereof within twenty (20) Business Days following the date of such notice. In the event of such acceptance, (i) Catalyst shall, subject to Section 12.7 (as applicable), (x) in the event Catalyst elects to continue the Commercialization (at its sole discretion), be responsible for, at its own expense, all activities in connection with such Commercialization, as well as any Liabilities deriving therefrom, including the obligation to defend, indemnify and hold harmless each EVL Indemnitee from any Liabilities asserted against EVL for such Commercialization by Catalyst or its designated Affiliate, and (y) make a payment to EVL in an amount equal to **[***]** Dollars ($**[***]**) within five (5) days of completion of [***] from EVL or its Affiliate to Catalyst or its designee; (ii) EVL shall have no further obligation to indemnify a Catalyst Indemnitee pursuant to Section 10.2 for events occurring after the aforementioned [***] pursuant to this Section 12.6.2 except such indemnification obligations shall remain for Product sold by EVL, its Affiliates or sublicensees; and (iii) the license granted by Catalyst to EVL pursuant to Section 2.1.1 shall terminate. Each Party shall reasonably cooperate with each other in connection herewith, including (i) negotiating in good faith appropriate documentation addressing the provisions in this Section 12.6.2, (ii) filing a transfer of ownership letters as required by 21 CFR § 314.72, in forms mutually agreed between Catalyst and EVL, to effectuate the [***] from EVL or its Affiliate to Catalyst or its designee, and (iii) using commercially reasonable efforts to complete the [***] from EVL or its Affiliate to Catalyst or its designee as soon as practicable, but in any event within forty-five (45) days of Catalyst's acceptance of EVL's offer pursuant to this Section 12.6.2.

12.6.3 In the event that the Agreement is terminated by Catalyst pursuant to Section 12.2, Section 12.3 or Section 12.5(c), (i) EVL shall, for no additional consideration, transfer its right, title, interest, ownership and control of the [***] and any and all other assets owned by EVL or its Affiliates related solely to the Product (other than assets that bear EVL's or any of its Affiliate's name or logo) to Catalyst or its designee, (ii) in the event Catalyst elects to continue the Commercialization (at its sole discretion), Catalyst shall, subject to Section 12.7 (as applicable), be responsible for, at its own expense, all activities in connection with such Commercialization, as well as any Liabilities deriving therefrom, including the obligation to defend, indemnify and hold harmless each EVL Indemnitee from any Liabilities asserted against EVL for such Commercialization by Catalyst or its designated Affiliate, (iii) EVL shall have no further obligation to indemnify a Catalyst Indemnitee pursuant to Section 10.2 for events occurring after the aforementioned [***] pursuant to this Section 12.6.3,

except such indemnification obligations shall remain for Product sold by EVL, its Affiliates or sublicensees; and (iv) the license granted by Catalyst to EVL pursuant to Section 2.1.1 shall terminate. Each Party shall reasonably cooperate with each other in connection herewith, including (i) negotiating in good faith appropriate documentation addressing the provisions in this Section 12.6.3, (ii) filing a transfer of ownership letters as required by 21 CFR § 314.72, in forms mutually agreed between Catalyst and EVL, to effectuate the [***] from EVL or its Affiliate to Catalyst or its designee, and (iii) using commercially reasonable efforts to complete the [***] a from EVL or its Affiliate to Catalyst or its designee as soon as practicable, but in any event within forty-five (45) days of such termination of this Agreement.

12.6.4 In the event that the Term of the Agreement expires, or EVL wishes to terminate this Agreement pursuant to Section 12.2 or Section 12.3, then (i) EVL shall retain its right, title, interest, ownership and/or control of the [***], and (ii) the license granted by Catalyst to EVL pursuant to Section 2.1.1 shall continue in full force and effect.

12.6.5 All licenses and rights to licenses granted under or pursuant to this Agreement are, and shall otherwise be deemed to be, for purposes of Section 365(n) of the United States Bankruptcy Code (the "**Code**"), licenses of rights to "intellectual property" as defined under Section 101(35A) of the Code. EVL, as the licensee of such rights under this Agreement, shall retain and may fully exercise all of its rights and elections under the Code, and upon commencement of a bankruptcy proceeding by or against Catalyst under the Code, shall be entitled to a complete duplicate of, or complete access to (as EVL deems appropriate), any such intellectual property and all embodiments of such intellectual property. Such intellectual property and all embodiments thereof shall be promptly delivered to EVL (i) upon any such commencement of a bankruptcy proceeding upon written request therefor by EVL, unless Catalyst elects to continue to perform all of its obligations under this Agreement or (ii) if not delivered under (i) above, upon the rejection of this Agreement by or on behalf of Catalyst, upon written request therefor by EVL, and each Party hereby acknowledges and agrees that the foregoing shall serve as its consent to such transfer of the intellectual property and all embodiments thereof. The foregoing provisions of this Section 12.6.4 are without prejudice to any rights EVL may have arising under the Code or other Applicable Law.

12.7 Survival. In addition to specific indications throughout this Agreement that Articles and Sections of this Agreement shall survive expiration and termination of this Agreement, Article 1, Article 8, Article 10, Article 11, Article 12, Article 13, and Article 14, and Section 4.1.1, Section 6.3, Section 6.4, Section 6.5, and Section 7.1, and any other provisions necessary and proper to give effect to the intention of the Parties as to the effect of the Agreement after termination shall survive any expiration or termination of this Agreement. In addition, unless otherwise expressly set forth herein, no expiration of the Term or termination of this Agreement shall have any effect on any payment, obligation accruing or arising prior to such expiration or termination or relieve either Party from obligations that are expressly indicated to survive termination or expiration of this Agreement.

ARTICLE 13. INSURANCE

13.1 Insurance

13.1.1 Each Party shall obtain and maintain at all times during the Term, prudent comprehensive general liability coverage appropriate to its activities with reputable and financially secure insurance carriers to cover its activities related to this Agreement. Additionally such insurance coverage shall include product liability coverage of an appropriate amount, not less than **[***]** US dollars ($**[***]**) per occurrence, for so long as the Product is being sold pursuant to this Agreement. Notwithstanding the foregoing, each Party shall, at its own cost and expense, obtain and maintain in full force and effect at all times during the Term, and (with respect to claims made insurance) for a period of six (6) years thereafter:

(a) commercial general liability insurance covering bodily injury and property damage with limits no less than **[***]** Dollars ($**[****]**) per occurrence and **[***]** Dollars ($**[***]**) in the aggregate; and

(b) products and completed operations liability insurance (including coverage for all Product used in clinical trials) with limits no less than **[***]** Dollars ($**[***]**) per occurrence and **[***]** Dollars ($**[***]**) in the aggregate.

13.1.2 All of the foregoing insurance policies shall be obtained from an insurance carrier or carriers having a current A.M. Best rating of at least A- Class VIII.

13.1.3 Upon written request, a Party shall provide the other Party with a certificate of insurance evidencing such coverage. Each Party shall provide the other Party with written notice within thirty (30) days of any material change in the terms or coverage of such insurance policies or their lapse, cancellation or termination.

13.1.4 All insurance policies obtained by either Party pursuant to this Agreement shall be primary and not contributing to any other insurance, self-insurance or captive insurance maintained by the other party to the extent of such Party's indemnification obligations hereunder; provided, however, that notwithstanding the foregoing, (a) EVL may self-insure with respect to its product liability obligations hereunder, and (b) the insurance policies required under Section 13.1.1 shall not be construed to limit either Party's liability with respect to its indemnification obligations under this Agreement.

ARTICLE 14. MISCELLANEOUS

14.1 Interpretation and Construction. Unless the context of this Agreement otherwise requires, (i) the terms "**include**," "**includes**," or "**including**" shall be deemed to be followed by the words "**without limitation**" unless otherwise indicated; (ii) words using the singular or plural number also include the other, (iii) the terms "**hereof**," "**herein**," "**hereby**," and derivative or similar words refer to this entire Agreement; (iv) the terms "**Article**," "**Section**" and "**Exhibit**" refer to the specified Article, Section and Exhibit of this Agreement, and (v) words of any gender include each other gender. Whenever this Agreement refers to a number of days, unless otherwise specified, such number shall refer to calendar days. The headings and paragraph captions in this Agreement are for reference and convenience purposes only and shall not affect the meaning or interpretation of this Agreement. This Agreement shall not be interpreted or constructed in favor of or against either Party because of its effort in preparing it.

14.2 Independent Contractor Status. It is understood and agreed that nothing in this Agreement nor any agreement related hereto is intended to nor shall create a partnership between the Parties. The Parties are independent contractors and are engaged in the operation of their own respective businesses, and neither Party is to be considered the agent, partner, joint venturer or employee of the other Party for any purpose whatsoever and neither Party shall have any authority to enter into any contracts or assume any obligations for the other Party nor make any representations or warranties on behalf of such other Party.

14.3 Performance by Affiliates.

14.3.1 Catalyst recognizes that EVL may perform some or all of its obligations under this Agreement through one (1) or more of its Affiliates; provided, however, that EVL shall remain responsible for such performance by its Affiliates and shall cause its Affiliates to comply with the provisions of this Agreement in connection with such performance as if it were a party hereto.

14.3.2 In connection therewith, EVL may in its discretion have all or some of EVL's obligations and duties hereunder, including the commercialization of the Product in the Territory, be fulfilled by one or more of EVL's Affiliates, without any further action or notice. Without limiting the foregoing, any obligation or duty of EVL which is performed, satisfied or fulfilled by an Affiliate of EVL shall be deemed to have been performed, satisfied or fulfilled by EVL. EVL shall cause all of its Affiliates involved in any activities in connection with this Agreement to comply in all respects with all terms and conditions of this Agreement, and any breach by any such Affiliate of any of the terms of this Agreement shall be deemed a breach by EVL.

14.4 Waiver. The waiver by either Party of a breach of any term or provision contained herein shall not be effective unless provided in writing and shall in no way be construed as a waiver of any succeeding breach of such term or provision or the waiver of such term or provision itself.

14.5 Assignment. This Agreement shall be binding upon and inure to the benefit of each of the Parties and their respective successors and approved assigns; provided, however, that neither Party may assign this Agreement, in whole or in part, without the prior written consent of the other Party, unless such assignment is (i) to an Affiliate of the assigning Party, or (ii) in connection with a merger or acquisition or sale of all or substantially all of the assets of the assigning Party to which this Agreement relates; provided further, however, that notwithstanding the foregoing, each Party shall provide written notice (at least ten (10) days in the event of clause (i)) of any assignment of this Agreement in accordance with the terms hereof to the other Party. Any assignment of this Agreement not in accordance with this provision shall be null and void *ab initio*.

14.6 Modification. This Agreement may not be changed, modified, amended or supplemented except by an express written instrument signed by both Parties.

14.7 Severability. If any provision of this Agreement shall be held illegal or unenforceable, that provision shall be limited or eliminated to the minimum extent necessary so that this Agreement shall otherwise remain in full force and effect and enforceable.

14.8 Further Assurances. Each Party shall execute, acknowledge and deliver such further instruments and documents, and to do all such other acts, as may be reasonably necessary or appropriate in order to carry out the purposes and intent of this Agreement.

14.9 Notices.

14.9.1 Any notice or other communication to be given under this Agreement by any Party to the other Party shall be in writing and shall be either (a) personally delivered, (b) mailed by registered or certified mail, postage prepaid with return receipt requested, (c) delivered by overnight express delivery service or same-day local courier service, or (d) delivered by facsimile transmission (followed by a copy by the preceding methods in clause (a), (b) or (c)), to the email address of the applicable Party as set forth below, or to such other address as may be designated by the Parties from time to time in accordance with this Section 14.9.

14.9.2 Notices delivered personally, by overnight express delivery service or by local courier service shall be deemed given as of actual receipt. Mailed notices shall be deemed given three (3) Business Days after mailing. Notices delivered by facsimile transmission shall be deemed given upon receipt by the sender of the transmission confirmation (in the case of a facsimile transmission) if transmitted before 5:00 p.m. (recipient's local time) on a Business Day, and otherwise on the following Business Day.

If to EVL:
Endo Ventures Limited
First Floor, Minerva House
Simmonscourt Road
Ballsbridge
Dublin 4
Attention: Senior Vice President, Head of International Pharmaceuticals
Email: garella.rahul@endo.com
Facsimile Number: +353 1 268 2029

With a copy to:
Par Pharmaceutical, Inc.
6 Ram Ridge Road
Chestnut Ridge, NY 10977
Attention: Legal
Email: Par.NoticeDept@parpharm.com
Facsimile Number: (845) 573-5600

If to Catalyst:
Catalyst Pharmaceuticals Inc.
355 Alhambra Circle, Suite 1250
Coral Gables, FL, USA 33134
Attention: Brian Elsbernd, Senior Vice President of Legal and Compliance
Email: belsbernd@catalystpharma.com
Facsimile Number: (305) 569-0233

14.10 Governing Law and Jurisdiction. This Agreement shall be governed by and construed in accordance with the laws of the State of New York, without reference to the choice of law principles thereof other than those that may permit designation of New York law. The Parties irrevocably agree that the State and Federal Courts located in the State, City, and County of New York, shall have exclusive jurisdiction to deal with any disputes arising out of or in connection with this Agreement and that venue is proper in such Courts. Each Party hereby expressly consents and submits to the personal jurisdiction of the Federal and State Courts in the State, City and County of New York.

14.11 Attorney Fees. In the event that either Party institutes any legal suit, action, or proceeding against the other Party arising out of this Agreement, the prevailing Party in the suit, action or proceeding shall be entitled to receive, in addition to all other damages to which it may be entitled, the costs incurred by such party in conducting the suit, action, or proceeding, including reasonable attorneys' fees and expenses and court costs.

14.12 Force Majeure. A Party shall not be liable for non-performance or delay in performance of its obligations hereunder to the extent that and solely for so long as such non-performance or delay in performance is not due to its negligence or breach of this Agreement and is caused by any event reasonably beyond the control of such Party, including wars, hostilities, revolutions, riots, civil commotion, national emergency, unavailability of supplies, epidemics, fire, flood, earthquake, force of nature, explosion, terrorist act, embargo, or any other Act of God, or any law, proclamation, regulation, ordinance, or other act or order of any court or Governmental Authority (each, a "**Force Majeure Event**"). In the event of any such Force Majeure Event, the delayed Party may defer its performance for the duration of such Force Majeure Event, provided that the delayed Party gives the other Party written notice thereof promptly and, in any event, within two (2) Business Days of discovery thereof, and uses its good faith efforts to cure the excused breach. If either Party is unable to perform its obligations hereunder as a result of a Force Majeure Event for a period of ninety (90) days or longer and is not continuously exercising diligent good faith efforts to remedy, overcome or work around the Force Majeure Event, then the other Party shall have the right, upon its issuance of written notice to the other Party, to terminate this Agreement.

14.13 Entire Agreement. This Agreement and any Exhibits attached hereto constitute the entire agreement between EVL and Catalyst with respect to the Product and supersede all prior representations, understandings and agreements with respect to the Product. In the event of a conflict between this Agreement and any Exhibits attached hereto, this Agreement shall prevail over any such Exhibit.

14.14 Counterparts. This Agreement may be executed in one or more counterparts, including by transmission of facsimile or PDF copies of signature pages, each of which shall for all purposes are deemed to be an original and all of which shall constitute one instrument.

14.15 Third Party Beneficiaries. Except as provided in Section 10.1 and Section 10.2, (i) no term or provision of this Agreement is intended to be, or shall be, for the benefit of any Person (including any sub-contractor, or any individual member of the control group utilized for the bioequivalence studies) that is not a party hereto, and (ii) no such other Person shall have any right or cause of action hereunder.

14.16 Cumulative Rights. The rights and remedies of each of the Parties under or pursuant to this Agreement are cumulative, may be exercised as often as such Party considers appropriate and are in addition to its rights and remedies under general law.

[*Signature page follows*]

IN WITNESS WHEREOF, the Parties hereto have executed this Development, License and Commercialization Agreement to be effective as of the Effective Date.

ENDO VENTURES LIMITED

By: /s/ Rahul Garella
Name: Rahul Garella
Title: SVP International Pharmaceuticals

CATALYST PHARMACEUTICALS INC.

By: /s/ Patrick J. McEnany
Name: Patrick J. McEnany
Title: Chief Executive Officer

Exhibit A

[***]

Exhibit B

FORM OF
NET PROFIT REPORT

[***]

Exhibit C

FORM OF PRESS RELEASE

CATALYST PHARMACEUTICALS ANNOUNCES DEFINITIVE AGREEMENT WITH ENDO FOR VIGABATRIN TABLETS

CORAL GABLES, Fla., December XX, 2018 (GLOBE NEWSWIRE) — Catalyst Pharmaceuticals, **Inc. (Catalyst) (Nasdaq: CPRX),** a biopharmaceutical **company focused on developing and commercializing innovative** therapies for people with rare debilitating, chronic neuromuscular and neurological diseases, today announced that it has signed a Definitive Agreement with Endo International plc's (NASDAQ: ENDP) subsidiary, Endo Ventures Limited, for the further development and commercialization of generic Sabril® (vigabatrin) tablets through Endo's U.S. Generic Pharmaceuticals segment, doing business as Par Pharmaceutical. Pursuant to the agreement, Catalyst will receive an up-front payment, milestone payments based on achievement of regulatory approvals, and a sharing of defined net profits upon commercialization.

"We are very happy to work with Endo, to bring generic Sabril® tablets to market. Endo is an established leader in the generic vigabatrin marketplace," said Patrick J. McEnany, Chairman and Chief Executive Officer of Catalyst Pharmaceuticals. "Our search for an appropriate partner for this product was long but rewarding with this result. We look forward to bringing to market this important medication to improve the lives of patients."

"Generic vigabatrin tablets will complement our current powder vigabatrin offering and will expand the number of patients that can benefit from having access to a high-quality, generic vigabatrin option," said Brandon Rockwell, Senior Vice President, Business Development and Strategy of Endo.

Vigabatrin comes in two dosage forms – a powder sachet and a tablet. Par Pharmaceutical brought the first generic version of the powder sachet to market but at this time there is no approved generic version of the tablets.

About Catalyst Pharmaceutical

Catalyst Pharmaceutical is a biopharmaceutical company focused on developing and commercializing innovative therapies for people with rare debilitating, chronic neuromuscular and neurological diseases, including LEMS, congenital myasthenic syndromes (CMS), MuSK antibody positive myasthenia gravis (MuSK-MG), and spinal muscular atrophy (SMA) type 3. Catalyst's new drug application for Firdapse® (amifampridine) 10 mg tablets for the treatment of adults with Lambert-Eaton Myasthenic Syndrome (LEMS) was recently approved by the U.S. Food & Drug Administration ("FDA"), and Firdapse® is expected to be commercially available in the United States early in the first quarter of 2019. Prior to its approval, Firdapse for LEMS had received breakthrough therapy designation and orphan drug designation from the FDA.

Firdapse® is currently being evaluated in clinical trials for the treatment of CMS, MuSK-MG and SMA type 3 and has received Orphan Drug Designation from the FDA for CMS and myasthenia gravis. Firdapse (amifampridine) 10 mg tablets is the first and only approved drug in Europe for the symptomatic treatment in adults with LEMS.

About Endo International plc

Endo International plc (NASDAQ: ENDP) is a highly focused generics and specialty branded pharmaceutical company delivering quality medicines to patients in need through excellence in development, manufacturing and commercialization. Endo has global headquarters in Dublin, Ireland, and U.S. headquarters in Malvern, PA. Learn more at www.endo.com.

About Par Pharmaceutical

Par Pharmaceutical, headquartered in Chestnut Ridge, NY, develops, manufactures and markets safe, innovative and cost-effective generic pharmaceutical products that help improve patient quality of life. Par, among the top leaders in the U.S. generics industry, possesses a portfolio that includes sterile injectables, alternative dosage forms and many other differentiated products. Par is advancing a research and development (R&D) pipeline of approximately 200 potential new products. Par is an operating company of Endo International plc. Learn more at www.parpharm.com.

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 the milestone payments that are to be paid under Catalyst's agreement with Endo will ever be earned and paid; (ii) whether an ANDA for generic vigabatrin tablets will ever be approved by the FDA; (iii) whether Endo, even if vigabatrin tablets are approved for commercialization, will be successful in marketing the product, (iv) whether Catalyst will earn royalties on sales of generic vigabatrin tablets; (v) whether Catalyst can successfully market Firdapse and become profitable; (vi) whether Firdapse will ever be approved for the treatment of CMS, MuSK-MG, SMA type 3, or any other disease; and (vii) those other factors described in Catalyst's Annual Report on Form 10-K for the fiscal year 2017 and its other filings with the U.S. Securities and Exchange Commission (SEC), could adversely affect Catalyst. Copies of Catalyst's filings with the SEC are available from the SEC, may be found on Catalyst's website, or may be obtained upon request from Catalyst. Catalyst does not undertake any obligation to update the information contained herein, which speaks only as of this date.

Investor Contact
Brian Korb
Solebury Trout
(646) 378-2923
bkorb@troutgroup.com

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

Media Contact
David Schull
Russo Partners
(212) 845-4271
david.schull@russopartnersllc.com

###