

**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): August 14, 2020

CATALYST PHARMACEUTICALS, INC.

(Exact Name Of Registrant As Specified In Its Charter)

Delaware
(State or other jurisdiction
of incorporation)

001-33057
(Commission
File Number)

76-0837053
(I.R.S. Employer
Identification No.)

**355 Alhambra Circle
Suite 1250
Coral Gables, Florida**
(Address of principal executive offices)

33134
(Zip Code)

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

Not Applicable

Former Name or Former address, if changed since last report

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

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

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

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

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

Emerging Growth Company

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

Item 1.01 Entry Into a Material Definitive Agreement

On August 14, 2020, Catalyst Pharmaceuticals, Inc. (the “Company”) and KYE Pharmaceuticals, Inc. (“KYE”) entered into that certain License & Supply Agreement (the “Agreement”). Pursuant to the Agreement, the Company will license to KYE the Canadian rights for Firdapse® for the treatment of Lambert-Eaton Myasthenic Syndrome (“LEMS”). Pursuant to the Agreement, KYE will pay to the Company an up-front payment, based upon approval and product supply, and data protection milestones based on achievements of sales and regulatory milestones, and a sharing of defined net sales upon commercialization.

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

Item 8.01 Other Events

On August 18, 2020, the Company issued a press release announcing the Agreement. A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

10.1 [License & Supply Agreement, dated as of August 14, 2020, between KYE Pharmaceuticals, Inc. and the Company \(Certain identified information has been excluded from the exhibit because it both \(i\) is not material and \(ii\) would be competitively harmful if publicly disclosed\).](#)

99.1 [Press release issued by the Company on August 18, 2020.](#)

104 Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURES

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

Catalyst Pharmaceuticals, Inc.

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

Dated: August 20, 2020

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

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

License & Supply Agreement

KYE PHARMACEUTICALS INC.

- and -

CATALYST PHARMACEUTICALS, INC

Dated as of: **14 AUGUST 2020**

THIS LICENSE & SUPPLY AGREEMENT is made as of 14th August 2020 (“**Effective Date**”) by and between **KYE Pharmaceuticals Inc.**, 2233 Argenta Road Suite 302 and 302A, Mississauga Ontario Canada L5N 2X7 Canada, a corporation incorporated under the laws of Ontario, Canada (“**KYE**”) and **Catalyst Pharmaceuticals, Inc.**, 355 Alhambra Circle, Suite 1250 Coral Gables, Florida (“**CATALYST**”) a corporation incorporated under the laws of the state of Florida, United States of America.

WHEREAS:

- A. CATALYST has significant experience in developing, registering, manufacturing and supplying pharmaceutical products;
- B. KYE has significant experience in registering, marketing and selling pharmaceutical products and carries on business in Canada;
- C. CATALYST possesses a Health Canada NDS in relation to the Product herein referred to as the “Dossier”.
- D. Subject to the terms and conditions of this Agreement, CATALYST wishes to license the Health Canada Approved Dossier to KYE and KYE wishes to license the Health Canada Approved Dossier from CATALYST to allow KYE to market and sell the Product in the Canada; and
- E. Subject to the terms and conditions of this Agreement, KYE wishes to engage with CATALYST to be KYE’s exclusive supplier of the Product in Canada, and CATALYST wishes to supply the Product to KYE exclusively for sale in Canada.

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

ARTICLE 1 - INTERPRETATION

- 1.1 *Definitions.* In addition to the terms defined elsewhere in this Agreement, the terms set forth below shall be defined in this Agreement (including the recitals) as follows:
 - i. “**Affiliate**” means, in respect of any party, a legal entity controlling, controlled by or under common control with that party, control meaning ownership of more than 50% of the capital or the voting power in such entity.
 - ii. “**Agreement**” means this License & Supply Agreement, together with all schedules attached hereto and all modifications and amendments hereto.
 - iii. “**API**” means the active pharmaceutical ingredient of the Product(s), being any substance or mixture of substances that when used in the manufacture of the Product becomes the active ingredient thereof.

- iv. “**API Supplier**” means any third party who supplies the API used to manufacture the Product.
- v. “**Applicable Laws**” means, with respect to any Person, any domestic or foreign, federal, state or local statute, treaty, law, ordinance, rule, regulation, administrative interpretation, order, writ, injunction, judicial decision, decree or other requirement of any Governmental Authority applicable to such Person or any of such Person’s respective properties, assets, officers, directors, employees, consultants or agents (in connection with such officers’, directors’, employees’, consultants’ or agents’ activities on behalf of such Person) as it relates to this Agreement.
- vi. “**Business Day**” in relation to each Party means any day other than a Saturday, a Sunday, or any statutory or public holiday on which banks are generally closed for regular business in the jurisdiction in which the Party’s offices are located as specified in **Section 18.1** hereof.
- vii. “**Commercially Reasonable Efforts**” means exercising such reasonable efforts and diligence in accordance with a Party’s reasonable business, legal, financial, medical and scientific judgment and in a manner consistent with and in accordance with the efforts and resources such Party would use for a pharmaceutical product owned, licensed in, or controlled by such Party which is of similar market potential at a similar stage of its product life cycle, taking into account the competitiveness of the marketplace (including the number of competing products and differing pricing and reimbursement status), the proprietary position of such product, issues of safety and efficacy, the regulatory environment and the profitability of such product
- viii. “**Defective**” means any Product which fails to comply with the representations and warranties set out in **Section 8.8 and 12.3** and as a result is rendered unfit for sale.
- ix. “**Development**” means all activities relating to the development of the Product as required: (i) to produce an acceptable product formulation, manufacturing protocol and stability profile; (ii) to establish the Product’s efficacy and safety profile; all as further described in **Section 3** hereof
- x. “**DMF**”, where applicable, means a drug master file governing the development and manufacture of the API.
- xi. “**Facility**” means the manufacturing facilities of CATALYST or its Affiliate or subcontractor where the Product is manufactured.
- xii. “**GCP**” means current Good Clinical Practices as established under Applicable Law.
- xiii. “**GLP**” means current Good Laboratory Practices as established under Applicable Law.

- xiv. “**GMP**” means current Good Manufacturing Practices for the manufacture of finished pharmaceutical products in effect from time to time in the Reference Jurisdiction, which set minimum standards to ensure that pharmaceutical products meet established requirements for identity, strength, quality and purity, as established under Applicable Law
- xv. “**Health Canada**” means the department of the Government of Canada whose authority oversees the regulation, approval, and sale of drug products in Canada from time to time.
- xvi. “**Intellectual Property Rights**” means any patent, trade secret, right in unpatented know-how, right of confidence and any other intellectual or industrial property right of any nature whatsoever in any part of the world, whether registered or unregistered, but excludes any Trade-mark rights.
- xvii. “**IP Claim**” means any claim, action or demand commenced or made against any Party by a third party in relation to the Product that is based upon the contention that CATALYST’S attempt to obtain a Marketing Authorization for the Product in Canada, and/or the marketing and sale of the Product in Canada by KYE infringes the Intellectual Property Rights of any third party in Canada.
- xviii. “**Launch Date**” means the date upon which the Product is released and first becomes available for commercial supply and sale in Canada.
- xix. “**Losses**” means any out-of-pocket damages, liabilities, obligations, costs, expenses or losses, including reasonable legal fees and expenses, court costs, arbitration fees, penalties, fines, and amounts paid in settlement of claims.
- xx. “**Market**” means, sell, offer to sell, promote, advertise, market, import and/or distribute.
- xxi. “**Marketing Authorization**” means the approval granted by Health Canada following review of the New Drug Submission, as required to permit KYE to promote, market, distribute and sell the Product in Canada.
- xxii. “**NDS**” means a New Drug Submission filed with Health Canada pursuant to the Food and Drug Regulations Part C.08.002 (1), (2) and (3) that includes the documentation resulting from the development of the Product and: (i) describes the processes, techniques, studies and data in relation to the Product; and (ii) has been prepared by CATALYST in electronic Common Technical Document (eCTD) format as per the current Health Canada requirements.
- xxiii. “**Net Sales**” means [***]
- xxiv. “**Packaging**” means all material used to prepare fully packaged Product, including containers, cartons, labelling, blister packs, inserts and shipping cases, as applicable.

- xxv. “**Party**” means any party to this Agreement referred to individually, and “**Parties**” means the Parties to this Agreement referred to collectively.
- xxvi. “**Pharmacovigilance**” means certain obligations regarding the collection and assessment of data pertaining to, and the monitoring and prevention of, adverse effects associated with the Product.
- xxvii. “**Product**” means the pharmaceutical product that the subject of this Agreement, as described in **Schedule A** and amended upon mutual agreement of the Parties.
- xxviii. “**Product Monograph**” means a factual, scientific document on the Product approved by Health Canada that, devoid of promotional material, describes the properties, claims, indications and conditions of use of the drug and contains any other information that may be required for optimal, safe and effective use of the drug.
- xxix. “**Quality Agreement**” means a Quality Assurance/Quality Control Agreement to be entered into by the Parties which will set forth certain obligations of the Parties in relation to the manufacture, packaging, quality control and testing of the Product in accordance with GMP.
- xxx. “**Quarter**” means the following three (3) month periods during a calendar year: (i) from January 1 to March 31; (ii) from April 1 to June 30; (iii) from July 1 to September 30; and (iv) from October 1 to December 31.
- xxxi. “**Regulatory Authority**” means the applicable foreign governmental regulatory health authorities in a jurisdiction, outside of Canada, responsible for regulating the manufacture, distribution, and sale of pharmaceutical products.
- xxxii. “**Safety Data Exchange Agreement (SDEA)**” means a pharmacovigilance agreement to be entered into by both Parties which will set forth certain obligations of the Parties in relation to drug product safety in accordance with Good Pharmacovigilance Practices and Applicable Laws.
- xxxiii. “**Specifications**” means the specifications for the Product as set out in the approved NDS in Canada as conditions of the Marketing Authorization.
- xxxiv. “**Supply Price**” means the unit cost to be paid by KYE to CATALYST for the right to use the Marketing Authorization, Licensed Know How and the right to import, market and sell the Product within Canada, as per **Schedule A** of this Agreement.
- xxxv. “**Trademarks**” means any trademarks, trade names, trade-dress, logos, whether or not registered, for the Product. For clarity this includes the trademark FIRDAPSE® which is registered in Canada by CATALYST.

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

ARTICLE 2 - LICENSE

- 2.1 *License*. Subject to the terms and conditions of this Agreement, CATALYST hereby grants to KYE: the exclusive license (i) to the NDS and Marketing Authorization for the Product in Canada, including the right for KYE to obtain a Marketing Authorization under KYE's name in Canada after approval of the NDS by Health Canada; and (ii) to the Trademarks, in each case, solely for use in Canada to Market the Product within Canada. Nothing herein shall limit CATALYST's research and development activities and clinical trial investigating additional indications and other activities other than the sale and distribution of Product in Canada.
- 2.2 *Right to License*. CATALYST represents and warrants to KYE that the NDS is, and the Marketing Authorization if obtained, will be owned or licensed by CATALYST or its Affiliates, and CATALYST has the right to grant to KYE the license provided for in this Agreement.
- 2.3 *Restrictions*. KYE shall not:
- i. Sub-license or subcontract the Product and Marketing Authorization to a third-party without the prior written consent of CATALYST or as expressly authorized under this Agreement;
 - ii. use or register the NDS or any information or data contained therein, in any jurisdiction other than Canada;
 - iii. use the NDS or any information or data contained therein for any purpose except as contemplated under this Agreement; or
 - iv. Market, directly or indirectly, any Product which has been manufactured and supplied to KYE in any jurisdiction outside of Canada and shall prohibit (and strictly enforce such prohibition) its contractors or Affiliates, from doing so.

ARTICLE 3 - PRODUCT DEVELOPMENT

- 3.1 *Regulatory Status*. CATALYST represents and warrants to KYE that it submitted an NDS for the Product to Health Canada, the NDS has been accepted by Health Canada for review and the NDS is currently under review with Health Canada.
- 3.2 *Development Activities*. CATALYST represents and warrants that all Development Activities performed by or on behalf of CATALYST in connection with the Product have been performed in a good scientific manner and in compliance in all material respects with Applicable Law. The Parties hereby acknowledge that any other local tests or studies required by Health Canada for approval of the Product in Canada shall be the responsibility of CATALYST, of which CATALYST shall bear the related costs of such tests and studies.

- 3.3 *Authority for Development Activities.* For clarity and not without limiting the foregoing, CATALYST has full discretion and authority regarding research, clinical development and clinical trial activities relating to the PRODUCT for indications (in addition to LEMS) within Canada, including without limitation, the selection and operation of clinical sites within Canada.

ARTICLE 4 - MARKETING AUTHORIZATION

- 4.1 *Marketing Authorization Deadline.* If, despite CATALYST's Reasonable Commercial Efforts, after eighteen (18) months from the effective date of this Agreement, Health Canada has not granted to CATALYST the Marketing Authorization in Canada for any reason, or CATALYST is unable to deliver commercial product that meets all conditions of the Marketing Authorization, either Party shall be entitled to terminate this Agreement upon delivering written notice to the other Party. Termination shall otherwise be without further obligation or liability on the part of either Party other than the confidentiality obligations herein.
- 4.2 *Maintenance.* Once the Marketing Authorization has been granted to CATALYST, in a mutually agreed upon timeframe, CATALYST shall transfer or assist KYE in having the Marketing Authorization granted to KYE for the purpose of ongoing maintenance of the regulatory file in Canada. Once the Marketing Authorization in the name of KYE is obtained, it will be KYE's responsibility, at its own expense, to maintain and update its Marketing Authorization and for all communications with Health Canada relating to maintenance of the Marketing Authorization. as may be required, provided that during the term of this Agreement CATALYST shall provide all necessary manufacturing data and technical information as may be required by Health Canada and as set out in **Section 6.3**. KYE will promptly provide copies of all communications and with Health Canada and Supplemental New Drug Submissions to CATALYST for its records. CATALYST will use Commercially Reasonable Efforts to assist KYE with all requests to the API manufacturer(s) but shall not be held responsible in the case the API manufacturer(s) will not agree to comply with such requests.
- 4.3 *Designation of Manufacturer.* The NDS for the Product, and any subsequent submissions for the purpose of maintaining the regulatory file, will state that CATALYST or designated subcontractor is the manufacturer and supplier of the Product.

ARTICLE 5 - EXCLUSIVITY AND COMMERCIALIZATION

5.1 *Exclusive License in Canada.* CATALYST hereby agrees to exclusively supply the Product to KYE in Canada for the Term of the Agreement.

5.2 *Exclusive Licensing Fee.* KYE agrees to pay the following one-time license payments:

- i. Upon attainment of the Marketing Authorization and the delivery of commercial product that meets the conditions of the Marketing Authorization in Canada \$US [***]. If the Marketing Authorization is obtained prior to the approval of any other 3,4-diaminopyridine product for LEMS, then KYE will pay an additional \$US [***] for a total Milestone Payment of \$US [***]; regardless of delivery date of commercial product. The additional \$US [***] will be payable upon KYE executing a Letter of Intent with the Pan Canadian Pharmaceutical Alliance for the provincial reimbursement of the Product.
- ii. KYE will pay CATALYST a one-time milestone payment of \$US [***] upon Marketing Approval for the first alternative indication in Canada. KYE will pay CATALYST (A) a further one-time milestone payment of \$US [***] when Net Sales of the Product in any calendar twelve (12) month period after such Marketing Approval are [***]Canadian Dollars (\$CAN [***]) greater than the Net Sales of the Product in the twelve (12) month calendar period immediately prior to such Marketing Approval, and (B) a further one-time milestone payment of \$US [***]when Net Sales of the Product in any calendar twelve (12) month period after such Marketing Approval are [***] Canadian Dollars (\$CAN [***]) greater than the Net Sales of the Product in the twelve (12) month calendar period immediately prior to such Marketing Approval. KYE will use Commercially Reasonable Efforts to Market all alternative indications for the Product. For the avoidance of doubt, there will be no further milestones payments for any subsequent alternative indications.

- 5.3 *Exclusive Supplier.* During the Term of this Agreement, KYE shall source and purchase the Product for sale in Canada exclusively from CATALYST and shall not Market any product that could be considered as a substitute or competitive with the Product. This provision shall apply even in the event of assignment of this Agreement.
- 5.4 *General Diligence Obligation:* KYE will exercise Commercially Reasonable Efforts to Market the Product to customers in Canada during the Term at its sole cost and expense in accordance with the terms of this Agreement and with Applicable Law. Such efforts shall include, without limitation, the Launch of the Product, the preparation and delivery to CATALYST of: (i) an annual marketing plan for the Product (the first of which shall be delivered prior to the Product's Launch); and (ii) sales projections for the Product on an annual basis. KYE will provide CATALYST an opportunity to comment on such annual marketing plans, and will consider CATALYST's comments in good faith, but the final marketing plan shall be determined by KYE.
- 5.5 *Pricing:* KYE shall have final decision-making authority for determining the selling price for the Product in Canada subject to the provisions set forth herein. KYE will use Commercially Reasonable Efforts to obtain and maintain pricing and reimbursement approvals for the Products for Canada, [***].
- 5.6 *Bartering and Bundling Prohibited:* KYE shall not accept or solicit any bartered goods or services relating to the sale of a Product. The Product shall not serve as a loss leader or be bundled with other products to serve as a loss leader. The term "**loss leader**" shall refer to a situation in which (1) the Product is sold on terms that are less favorable than terms that could otherwise have been obtained in order to benefit sales of one or more products other than a Product and/or (2) the Product's price is discounted to induce the sale of other products. In addition to and without limiting CATALYST's other remedies hereunder, the Net Sales shall be adjusted to reverse any discounts in such bundling and loss leader arrangement which were given to a customer that were in excess of the then customary discounts for a Product (or, in the absence of relevant data for the Product, other similar products under similar market conditions).
- 5.7 *Reports:* After the Launch of the Product, KYE shall within forty-five (45) days after the completion of each calendar year during the Term, provide to CATALYST, a report describing the selling resources deployment, including without limitation, budget and spend on marketing of the Product for such year, as well as a report summarizing the status of reimbursement approvals and pricing approvals and filing in terms of formulary listings and reimbursement pricing tiers for the Product in Canada.

- i. KYE shall provide to CATALYST such other information and materials with respect to its activities in connection with marketing of the Product as CATALYST shall reasonably request from time to time, including information regarding its pre-launch marketing plans, including providing to CATALYST a pre-launch marketing plan as soon as practicable but in no event later than six (6) month from the Effective Date.
 - ii. For the avoidance of doubt, KYE, at its own cost and expense, shall be responsible for training of all sales representatives who are, or will be, marketing the Products in Canada, development of websites, advertising, and supporting materials (including, without limitation, print advertising, brochures, leaflet and similar materials).
 - iii. CATALYST shall use Commercially Reasonable Efforts to provide to KYE copies of all CATALYST training materials, marketing plans, advertising and supporting materials (including, without limitation, print advertising, brochures, leaflet and similar materials) as KYE may reasonably request from time to time for use in the development of its own training and promotional materials for Canada.
- 5.8 *Trademarks:* KYE hereby acknowledges that CATALYST has been granted an exclusive license to use of the Trademarks in Canada, and that CATALYST is sublicensing the Trademarks to KYE for use in Canada in connection with the Product during the Term of this Agreement. KYE shall not, during the Term or thereafter, register, use, or attempt to obtain any right in and to any Trademarks or in and to any name, logo or trademark confusingly similar thereto, including, without limitation, by adding to or supplementing the Trademarks with additional words or phrases. CATALYST shall have the right to exercise quality control over KYE's use of the Trademarks to a degree reasonably necessary to maintain the validity of the Trademarks, as applicable, and to protect the goodwill associated therewith. CATALYST shall be solely responsible for the filing, prosecution and maintenance of the Trademarks in the Canada and all costs and expenses related thereto.

ARTICLE 6 - MANUFACTURE OF PRODUCT

- 6.1 *Supply Obligation.* Subject to the terms and conditions of this Agreement, CATALYST shall manufacture and supply to KYE the quantities of the Product ordered by KYE hereunder for commercial import and sale in Canada.
- 6.2 *API.* [***]

- 6.3 *Restrictions on Changes to Product.* The Parties acknowledge that, once the NDS has been approved by Health Canada and the Marketing Authorization has been successfully transferred to KYE, any change whatsoever to the Product or any related process, method or procedure may impact the regulatory status of the Product in Canada. Without limitation to any other provision of this Agreement, CATALYST shall not make any changes whatsoever to the Product without first informing KYE who will obtain all necessary approvals from Health Canada. Examples of such changes include, changes to the API Supplier, the Facility, methods of manufacture or other processes, or any other changes. KYE will use Commercially Reasonable Efforts to submit any changes without delay and shall pay all fees and charges payable to Health Canada which may be required to update the Marketing Authorization in connection with any change to the Product.
- 6.4 *Packaging.* CATALYST shall supply the Product to KYE fully packaged, labelled, and ready for sale. CATALYST shall label and package the Product in accordance with the label text and Packaging Specifications set forth in the approved NDS as conditions of the Marketing Authorization. KYE shall promptly inform CATALYST of any changes to the labelling and/or packaging required by Health Canada.
- 6.5 *Manufacturing Facility.*
- (1) Product Manufacturer. All Product supplied to KYE pursuant to this Agreement shall be manufactured only by CATALYST's designated Facility described in **Schedule A**, or at such other Affiliate or subcontractor as may be mutually agreed between the Parties in writing, such agreement not to be reasonably withheld, and which complies with the requirements of this **Section 6**. If CATALYST has the Product manufactured on its behalf, CATALYST shall cause and obligate its Facility to comply with all provisions hereof applicable to the manufacture of the Product, and any reference to CATALYST in such provisions shall, as appropriate, be deemed to include a reference to the applicable Facility of CATALYST. For avoidance of doubt, CATALYST shall not manufacture the Product in any other Facility that will result in a delay in supply to KYE, and until approval has been obtained from Health Canada (if applicable) and satisfactory audit, if necessary, and GMP status of the Facility are verified by KYE in writing.
 - (2) Location of Facility. CATALYST shall not change the location of the Facility without the prior written consent of KYE, which consent shall not be unreasonably withheld except as described in Exhibit A.
 - (3) Qualification of Facility. CATALYST shall be required to maintain the Facility in compliance with all Applicable Laws. CATALYST shall throughout the term of this Agreement obtain and maintain, at its own cost, any and all licenses, permits, orders, authorizations and consents (including facility licenses and permits) as required by Applicable Law to manufacture the Product for supply to KYE in Canada in compliance with GMP, or as otherwise required to perform CATALYST's obligations under this Agreement.

6.6 *Inspections.*

- (1) KYE Inspections. During the term of this Agreement and as long as KYE is not distributing a product that can be substituted in some manner for the Product, until one year after the expiration date for the last Product supplied hereunder, and thereafter in the event a claim against KYE regarding use of the Product is threatened or commenced, CATALYST shall permit KYE's representatives to enter the Facility, upon reasonable prior notice and during normal business hours, for the purpose of inspecting the Facility and quality control procedures and confirming compliance with all Applicable Laws, the Quality Agreement and this Agreement. The date of such an inspection shall be mutually agreed by the Parties and designated subcontractor and shall have a duration of maximum two (2) working Business Days. KYE will be responsible for any costs associated with an inspection requested by KYE.
 - (2) If during any such inspection KYE discovers evidence in which the Facility has not complied with Applicable Law or the Quality Agreement, then KYE shall present such findings to CATALYST. CATALYST shall make Commercially Reasonable Efforts to (1) coordinate with the Facility to provide to KYE a written plan for correcting such deficiencies, including a proposed timetable for implementing such corrections, and (2) ensure that such deficiencies are corrected, at the Facility's and/or CATALYST's sole expense, as soon as reasonably practicable. CATALYST shall not be held responsible in case the Facility does not agree to correct the deficiencies identified. In the event KYE requests a material change to the Facility that is not to correct non-compliance with Applicable Law or the Quality Agreement, KYE will present the requested change to CATALYST for approval, such approval not to be unreasonably withheld. If CATALYST approves such change, CATALYST will present request to the Facility for implementation and KYE will be responsible for the cost for changes requested by KYE and accepted by the Facility.
 - (3) Inspection by Governmental Authorities. If CATALYST receives any notification of any inspection of the Facility by any Regulatory Authority, or any warning letter or similar correspondence from any Regulatory Authority relating to the Product, then CATALYST shall (i) promptly provide KYE with notice of the inspection and all notices, correspondence and related documents received by CATALYST from the applicable Regulatory Authorities; (ii) promptly furnish KYE with copies of all reports and notices received by CATALYST as a result of any such inspection; (iii) provide to KYE a written plan for correcting such deficiencies documented by the Regulatory Authorities, including a proposed timetable for implementing such corrections; and (iv) ensure that any deficiencies are corrected, at CATALYST's expense, as soon as reasonably possible. CATALYST shall not be held responsible in case the Facility does not agree to correct the deficiencies identified.
- 6.7 *Quality Assurance/Quality Control.* The Parties shall enter into a separate Quality Agreement before the earlier of: (i) the first commercial supply of any Product; and (ii) eight (8) weeks from the signing of this Agreement. The terms of the Quality Agreement shall apply to all Product manufactured and supplied by CATALYST pursuant to this Agreement. In the event of a conflict between the Quality Agreement and this Agreement with respect to quality-related matters, including compliance with GMP and all other quality obligations, the provisions of the Quality Agreement shall prevail. In the event of a conflict between the Quality Agreement and this Agreement with respect to any commercial matters, including allocation of risk, liability, and financial responsibility, then the provisions of this Agreement shall prevail.

ARTICLE 7 - PHARMACOVIGILANCE

7.1 Both Parties agree to mutually respect and be responsible for their respective Pharmacovigilance systems for the Product. Legal responsibility in respect of pharmacovigilance and other regulatory requirements or agreements, rests with the Marketing Authorization Holder(s) in their respective jurisdictions meaning for Catalyst, the US and for KYE, Canada. Regular safety data exchange will occur according to current guidelines on Good Pharmacovigilance Practice, FDA and Health Canada requirements and in accordance with the Pharmacovigilance Agreement. In addition to the provisions hereof, the Parties shall enter into a separate Safety Data Exchange Agreement (SDEA), the terms of which shall apply to the Product manufactured and supplied by CATALYST pursuant to this Agreement. In the event of a conflict between the Pharmacovigilance Agreement and this Agreement with respect to any safety-related matters, including compliance with all regulatory obligations, the provisions of the Pharmacovigilance Agreement shall prevail. In the event of a conflict between the Pharmacovigilance Agreement and this Agreement with respect to any commercial matters, including allocation of risk, liability, and financial responsibility, then the provisions of this Agreement shall prevail.

ARTICLE 8 - PRODUCT SUPPLY

8.1 *Forecasts and Purchase Orders.*

(1) [***]

(2) [***]

8.2 [***]

8.3 *Price & Payment.*

(1) Method of Payment. [***]

(2) Delays in payment. [***]

(3) Product Purchase Pricing and Reporting. [***]

<u>Calendar Year Net Sales</u>	<u>Quarterly Transfer Price Rate</u>
[***]	[***]%
[***]	[***]%

[***]

- (4) Sales Milestone Payment: As part of the Product Supply Price KYE will pay CATALYST a one-time sales milestone payment of \$US [***] when KYE's Net Sales of the Product exceed \$CAN [***] in a consecutive twelve (12) month period. KYE shall report this to CATALYST within five (5) days after the end of the calendar month in which it occurs. KYE shall make payment to CATALYST within ten (10) Business Days of said notification in accordance with Section 8.3(1).
- (5) CATALYST Audit Rights: KYE shall maintain accurate and complete books and records of the Net Sales in such form and in such reasonable detail as to enable CATALYST to verify the Net Sales. Upon the written request of CATALYST, which shall not more than once per calendar year unless discrepancies of five percent (5%) or greater in the aggregate Transfer or Supply Price paid or particular bona fide concerns exist (in which event such audits may be on a quarterly basis), KYE shall permit an independent certified public accounting firm selected by CATALYST to have access during normal business hours to such of the records of KYE as may be reasonably necessary to verify the accuracy of the Net Sales of the Product, and Supply Price for the Product for any calendar year ending not more than three (3) full years prior to the date of such request. The accounting firm must execute a confidentiality agreement with KYE prior to being given access to KYE's records. If such accounting firm concludes that there are discrepancies in the reporting or calculation of the Net Sales or the Supply Price, such accounting firm shall recalculate such amounts and: (a) KYE shall pay any additional sums underpaid to CATALYST within thirty (30) calendar days of such re-determination; or (b) CATALYST, at its option, shall repay or, credit KYE for any overpaid amounts. The fees and expenses charged by such accounting firm shall be paid by CATALYST. However, if the audit discloses that the aggregate Supply Price and/or Transfer Price relating to the Product to CATALYST was underpaid during the audit period by more than five per cent (5%), then KYE shall pay the reasonable fees and expenses charged by the accounting firm. Each Party shall forthwith pay any amounts discovered to be due by it to the other pursuant to an audit. The results of such audit shall be final and binding on the Parties.

- 8.4 *Taxes*: KYE shall deduct or withhold from payments to CATALYST only those taxes that are required or enacted by Applicable Laws and shall use all reasonable and legal efforts to minimize the tax withholding obligations hereunder. KYE shall submit to CATALYST appropriate proof of payment of tax withholdings as well as official receipts within a reasonable period of time not to exceed sixty (60) days following any tax payment. KYE shall provide CATALYST reasonable assistance, which shall include the provision of such documentation as may be required by the tax authority, in order to allow CATALYST obtain the benefit of any present or future treaty against double taxation which may apply to such payments or to claim an exemption from or obtain a repayment or a reduction of such tax. The Parties acknowledge that as of the Effective Date, provided that CATALYST has delivered a properly executed NR301 claiming eligibility under the Canada-US Tax Treaty in respect of the payments hereunder and certification that such payments are not attributable to a permanent establishment in Canada, there are no applicable withholding taxes under applicable law. For the avoidance of doubt, CATALYST shall remain liable for all withholding taxes related to this Agreement and this Section 8.4 shall survive termination of the Agreement.
- 8.5 *Delivery*. Delivery of each order of the Product shall be made ex-works (*Incoterms 2010*). Each planned delivery shall be accompanied by advanced notice specifying the Product, KYE's purchase order number and the quantity of Product to be delivered. Upon written request by KYE, CATALYST will assist with transportation logistics and arrange for delivery of the products to the destination port or airport in Canada. In such case, the cost of the transportation and other direct costs will be communicated by CATALYST to KYE in advance of the shipment. KYE will be charged separately on the specific invoice for the Product issued by CATALYST to KYE.
- 8.6 *Delays*.
- (1) Notice. CATALYST shall notify KYE as soon as possible of any potential delay in the delivery of any Product shipment for which a purchase order was accepted.
- (2) Remedy for Late Delivery. If CATALYST fails to deliver any shipment of the Product to the agreed upon port of entry by the delivery date specified by KYE in a purchase order submitted in accordance with the terms of this Agreement, and the delay is not due to the failure to receive any materials to be procured by KYE, then the following shall apply (without limitation to CATALYST's indemnification obligations):
- i. If delivery of a Product shipment is more than ninety (90) days late from the issued purchase order delivery date, then KYE shall be entitled to cancel its purchase order regarding the late shipment upon ten (10) Business Days written notice.
 - ii. If delivery of a Product shipment is more than one hundred and eighty (180) days late from the issued purchase order delivery date, then KYE shall be entitled to cancel its purchase order regarding the late shipment upon ten (10) Business Days written notice if it has not done so already. In addition, should three (3) or more purchase orders be more than one hundred and eighty (180) days late from the issued Purchase Order delivery date due to CATALYST actions in any calendar year, then KYE may terminate the Agreement and return the Marketing Authorization to CATALYST.

- 8.7 *Testing.* CATALYST shall test as outlined in the NDS all Product prior to delivery to KYE to ensure that the Product meets the Specifications. Upon the delivery of each shipment of Product, CATALYST shall provide to KYE a certificate of analysis in accordance with the terms of the Quality Agreement and which verifies that the Product complies with the Specifications. CATALYST shall be responsible for all applicable release testing of the Product in accordance with the requirements of the Quality Agreement and all applicable GMPs and other Applicable Laws.
- 8.8 *Defective Product.*
- (1) Notification. If any shipment of Product is Defective in relation to any matter discoverable upon visual inspection made with reasonable care, then KYE will notify CATALYST within thirty (30) days of receipt of the Product. If any shipment of Product is Defective in relation to any matter which is not discoverable upon visual inspection made with reasonable care, then KYE will immediately notify CATALYST upon discovery. CATALYST shall promptly notify KYE as to whether it confirms or disputes that the Product is Defective. Pending resolution of KYE's claim, KYE shall not be obligated to make any payment to CATALYST in relation to any Product which KYE justifiably and reasonably claims in good faith to be Defective.
- (2) Review; Independent Testing Laboratory. If CATALYST does not agree with a claim by KYE that any Product is Defective, then the Parties shall submit information regarding the disputed shipment to each other for review. If the Parties cannot agree as to whether the Product is Defective within four (4) weeks of KYE's initial claim, then upon the request of either Party the dispute shall be submitted to a mutually acceptable independent laboratory with a minimum of ten (10) years of experience in testing pharmaceutical products and complying with guidelines and regulations in Canada. The independent laboratory shall act as an expert whose determination shall be final and binding upon the Parties, except in the case of manifest error. If the independent laboratory determines that the Product is not Defective, then KYE shall pay for the Product (if it has not already done so) within thirty (30) days of receiving notice of the independent laboratory's decision. The costs of the independent laboratory shall be borne by the Party with whom the independent laboratory disagrees.
- (3) Remedy for Defective Product. If any Product delivered by CATALYST to KYE is finally agreed or determined to be Defective by CATALYST or by an independent laboratory as described in 8.8(2), then CATALYST shall, at KYE's discretion, and without limitation to CATALYST's indemnification obligations, either replace the Defective Product at no additional cost to KYE or (to the extent that KYE has already paid for the Defective Product) give credit to KYE for the Defective units and all costs paid by KYE in relation thereto (including freight, insurance and all applicable taxes). KYE will, at CATALYST's expense and in accordance with CATALYST's written instructions, either return or destroy all Defective Product.

- 8.9 *Manufacturing Process Events.* If a manufacturing process event occurs during the manufacture of any Product batch which is likely to materially affect the safety, efficacy or regulatory status of the Product in Canada, CATALYST shall notify KYE as soon as reasonably possible (but in any event within two (2) Business Days of becoming aware of the process event). KYE and CATALYST shall consult with each other as to the disposition of all affected batches of the Product, which disposition shall be at the expense of CATALYST. CATALYST agrees to report to KYE, on a semi-annual basis, any atypical process events, regardless of whether they are or are not likely to materially affect the safety, efficacy, or regulatory status of the Product. No Product may be reworked unless the rework procedure is in conformity with GMP and the Quality Agreement or otherwise agreed in writing between the Parties.

ARTICLE 9 - RECORDS

- 9.1 *Records.* CATALYST shall maintain all records necessary to comply with all Applicable Laws relating to the Development, testing, manufacture, packaging, storage and supply of the Product, and the performance of its obligations under this Agreement. All such records shall be maintained for such period as may be required pursuant to Applicable Laws; provided, however, that all records relating to the manufacture, stability and quality control (including deviations) of each batch of the Product shall be retained at least until the second anniversary of the end of the approved shelf life for all Product from such batch.
- 9.2 *Samples and Batch Records.* CATALYST shall prepare and maintain batch records and file samples, properly stored, for each lot or batch of Product manufactured and shipped hereunder in compliance with all GMPs and other Applicable Laws pertaining thereto. KYE will retain samples properly stored in Canada in conformity with GMP and the Quality Agreement.
- 9.3 *Ongoing Stability.* CATALYST shall, at its own cost, conduct ongoing stability studies for the Product according to specifications that meet the conditions of the Marketing Authorization in Canada and shall create and compile all other data and documentation required by GMP, regulatory and any other Applicable Laws. CATALYST will provide the results of ongoing stability on such Product to KYE, free of charge, upon reasonable request.
- 9.4 *Inspection of Books and Records.* During the term of this Agreement, and thereafter for a period of two (2) years from the end of the shelf life of the last Product supplied by the CATALYST to KYE under this Agreement, either Party may, at reasonable times upon reasonable prior notice, inspect the manufacturing books and records of the other Party, including audits of any manufacturer, pertaining to its obligations under this Agreement for purposes of ensuring compliance with the terms of this Agreement.

ARTICLE 10 - PRODUCT RECALL

- 10.1 *Product Recall.*

- (1) If any Regulatory Authority or other governmental agency issues or requests a recall or takes similar action in connection with the Product in Canada, or if either Party reasonably determines after consultation with the other Party that an event has occurred which may result in the need for a recall or market withdrawal of the Product, then the Party notified of or wishing to implement such recall or similar action shall, within one (1) Business Day, inform the other Party thereof. The Parties shall promptly discuss and work together to effect an appropriate course of action to implement any recall, provided that neither Party shall be prohibited from unilaterally taking any action which it determines in good faith it is required to take to minimize risk to public health and safety or to comply with Applicable Laws, KYE shall be responsible for notifying Health Canada of any recall of the Product in Canada once it becomes the Marketing Authorization holder.
- (2) Without limitation to the Parties' respective indemnification obligations under this Agreement regarding third party claims, if a Party (the "**Innocent Party**") is reasonably required to incur any out-of-pocket expenses due to a Product recall in Canada ("**Recall Expenses**"), and if the reason for the recall in Canada is a matter for which the other Party (the "**Responsible Party**") is obligated to indemnify the Innocent Party as provided in **Article 16** of this Agreement, then the Responsible Party shall be liable for all Recall Expenses of both Parties. Without limitation, the Recall Expenses for which the Responsible Party shall be liable include notification expenses, costs for the return of recalled Product, costs of reporting to Health Canada, costs to destroy recalled Product, and customer fees and penalties arising due to the recall. The Innocent Party shall provide to the Responsible Party documentation which verifies all Recall Expenses for which liability or reimbursement is claimed.
- (3) If a recall is not due to the fault or responsibility of either Party, then the Parties shall share the Recall Expenses equally.
- (4) The Parties will cooperate and assist each other on all Recalls. If possible, the Parties shall discuss and agree on Recall Expenses prior to being incurred, provided that neither Party shall be prohibited from unilaterally taking any action or incurring any reasonable Recall Expenses which it determines in good faith it is required to take or incur to minimize risk to public health and safety or to comply with Applicable Laws.

ARTICLE 11 - INTELLECTUAL PROPERTY RIGHTS

- 11.1 *Reservation of Rights.* Except for the exclusive license granted to KYE under this Agreement, no right, title, or interest is granted, whether expressly or by implication, to any technology or Intellectual Property Rights owned by either Party. Each Party hereby reserves all rights not expressly granted under this Agreement.
- 11.2 *Trademarks.* CATALYST shall be responsible for the selection, registration and maintenance of all Trademarks used by KYE in connection with the Product in Canada. KYE shall not acquire or assert any right, title, and interest in and to the Trademarks or marks substantially similar to the Trademarks. KYE shall not use any Trademark in connection with the Marketing of the Product other than as contemplated herein.

11.3 *IP Claims.*

- (1) Intellectual Property Representation. CATALYST represents and warrants that, to the best of its knowledge, the manufacture of the Product by CATALYST (including the route of synthesis, formulation and manufacturing process) for supply to KYE and the distribution and sale of the Product by KYE in Canada in accordance with the provisions of this Agreement does not, infringe upon the Intellectual Property Rights of any third party in the country of manufacture. CATALYST also represents and warrants that it does not own or license any granted or pending patent applications in Canada with respect to the Product, including any patents/applications relating to the use or manufacturing of the Product.
- (2) Termination Due to IP Claim. If an IP Claim is threatened or commenced against any Party, and if the Parties reasonably determine that the likelihood and consequences of an unfavourable rulings warrants that KYE refrain from Marketing the Product in Canada, or if KYE agrees to refrain from Marketing the Product in Canada pursuant to a settlement of an IP Claim, or if a court of competent jurisdiction makes a final determination that the Marketing of the Product in Canada infringes the Intellectual Property Rights in Canada of a third party and all rights to appeal have been exhausted or expired, then KYE may terminate this Agreement upon delivering written notice to the CATALYST.

ARTICLE 12 - REPRESENTATIONS & WARRANTIES

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

- i. it has full corporate power and authority and has taken all corporate action necessary to enter and perform its obligations under this Agreement; and
- ii. this Agreement is its legal, valid, and binding obligation, enforceable in accordance with the terms and conditions hereof.
- iii. it has not violated and will not violate any provision of the U.S. Foreign Corrupt Practices Act of 1977, the OECD Convention on Bribery of Foreign Public Officials in International Business Transactions, Canadian Corruption of Foreign Officials Act and the rules and regulations thereunder and any other similar foreign or domestic law or regulation; or made or make any bribe, rebate, payoff, influence payment, kickback or other unlawful payment in connection with this Agreement and it has policies and procedures to ensure, and which are reasonably expected to ensure, continued compliance with the provisions of this paragraph.

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

- i. Technical Expertise. CATALYST has and throughout the term of this Agreement will continue to have the technical expertise, experience and personnel necessary to manufacture (including use of contract manufacturers) and supply the Product in the manner contemplated by this Agreement;

- ii. Agreement Will Not Cause Breach. The execution, delivery and performance of this Agreement by CATALYST will not result in CATALYST's violation of or default under any Applicable Laws or any material agreement or instrument by which CATALYST is bound;
 - iii. No Lawsuits. To the best of its knowledge, and as of the date hereof, there have not been any claims, lawsuits, arbitrations, legal or administrative or regulatory proceedings, charges, or complaints or investigations by any third party or government authority threatened, commenced, pending or proceeding against CATALYST, and CATALYST has not received any notice thereof, which relate to NDS, the Product, the API, or CATALYST's right to develop, manufacture, use or sell the Product and/or the API, or which could materially prevent CATALYST from complying with its obligations under this Agreement; and
 - iv. Information. To the best of its knowledge, all information relating to the Product delivered to KYE or to be delivered to KYE during the term of this Agreement by or on behalf of CATALYST was and shall be, as of the date of delivery, in all material respects accurate and correct and CATALYST is not and shall not be aware of any information which would be required to be disclosed to make such information not misleading.
- 12.3 *CATALYST Manufacturing and Supply Warranty*. CATALYST warrants and represents to KYE that all Product delivered to KYE hereunder shall:
- i. comply with the applicable purchase order given in accordance with this Agreement;
 - ii. be manufactured by CATALYST in accordance with (i) the terms of this Agreement and the Quality Agreement, (ii) the requirements of the Marketing Authorization, and (iii) all applicable GMPs and Applicable Laws;
 - iii. be manufactured at the Facility which is approved by the Regulatory Authorities and subject to **Sections 6.3 and 6.5** of this Agreement;
 - iv. not be adulterated or misbranded under any Applicable Laws in Canada;
 - v. have at least [***] of the approved Product shelf-life remaining at the time of delivery to agreed upon destination port or airport, and
 - vi. be free from unacceptable defects in material, manufacturing, and workmanship when delivered to KYE for the shelf-life of the Product, subject to the provisions of Article 10.
- 12.4 *KYE General Warranties*. KYE represents and warrants to CATALYST that:
- i. Agreement Will Not Cause Breach. The execution, delivery, and performance of this Agreement by KYE will not result in KYE's violation of or default under any Applicable Laws or any material agreement or instrument by which KYE is bound; and

- ii. **No Lawsuits.** As of the date hereof there have not been any claims, lawsuits, arbitrations, legal or administrative or regulatory proceedings, charges, or complaints or investigations by any third party or government authority threatened, commenced, pending or proceeding against KYE, and KYE has not received any notice thereof, which could prevent KYE from complying with its material obligations under this Agreement.
 - iii. Without limiting anything herein, KYE shall comply with all Applicable Laws in performing this Agreement, including all marketing, promotional material or advertising activities conducted by it.

KYE shall be responsible for all price reporting for the Products to all governmental agencies, as well as any Third-Party pricing publications in Canada and shall do so accurately and in a timely manner.
- 12.5 *Disclaimer.* EXCEPT FOR THE WARRANTIES AND REPRESENTATIONS PROVIDED OR REFERENCED IN THIS AGREEMENT, THE PARTIES MAKE NO OTHER WARRANTIES OR REPRESENTATIONS TO EACH OTHER, EXPRESS OR IMPLIED, INCLUDING THOSE WITH RESPECT TO THE PRODUCT, WHETHER STATUTORY OR OTHERWISE, AND EACH PARTY SPECIFICALLY DISCLAIMS ALL OTHER WARRANTIES, INCLUDING ANY IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE.

ARTICLE 13 - COVENANTS OF CATALYST

- 13.1 *Compliance.* CATALYST's at its designated Facility shall manufacture and supply the Product and shall otherwise comply with its obligations under this Agreement all in strict compliance with all applicable GMPs, GLPs, the Laws in the Reference Jurisdiction, and all applicable licenses, governmental permits or applications in the Reference Jurisdiction.
- 13.2 *Permits and Licences:* CATALYST shall throughout the term of this Agreement, at its expense, obtain and maintain any and all licenses, permits, orders, authorizations and consents required by the Regulatory Authorities to perform its obligations under this Agreement as developer and registered manufacturer of the Product.

ARTICLE 14 - COVENANTS OF KYE

- 14.1 *Compliance.* KYE shall be solely responsible for compliance with all Applicable Laws in Canada relating to the Marketing of the Product.
- 14.2 *Permits and Licenses.* KYE shall throughout the term of this Agreement, at its expense, obtain and maintain any and all licenses, permits, orders, authorizations and consents required by Health Canada to perform its obligations under this Agreement as Marketing Authorization holder and as importer and distributor of the Product.

14.3 *Sale of Product.* KYE shall use its Commercially Reasonable Efforts to Market the Product in Canada. KYE shall be responsible for all costs and expenses incurred in marketing and commercializing the Product in the Canada.

14.4 *Expansion of Monograph.* KYE shall use Commercially Reasonable Efforts to submit Supplemental New Drug Submissions to Health Canada based on the corresponding FDA submission in order to obtain approval in Canada and expand the indications in the Product Monograph, subject to Section 4.4 of this Agreement.

ARTICLE 15 - TERM & TERMINATION

15.1 *Term.* This Agreement shall commence upon the date hereof, and, unless terminated earlier in accordance with the provisions hereof, shall continue for a period of [***] from the Launch Date (the “**Initial Term**”). This Agreement shall automatically renew (“**Renewal Term**”) for successive [***] year periods if Net Sales of the Product exceed \$CAN [***] over a [***] month period in the last year of the Initial Term or \$CAN [***] during the first [***] of any Renewal Term. If this sales threshold is not exceeded during the applicable period, this Agreement will only renew upon the mutual agreement of both Parties.

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

- i. if a Party files a petition in bankruptcy or is adjudged as bankrupt, or a petition in bankruptcy is filed against it and is not dismissed within sixty (60) days, or it becomes insolvent, takes advantage of legislation for creditor relief, has a receiver or receiver-manager appointed in relation to its assets, or discontinues its business, then the other Party may terminate this Agreement immediately upon delivering written notice of termination;
- ii. if a Party violates or fails to perform any of its material undertakings, agreements, covenants or obligations under this Agreement (excluding matters otherwise specifically addressed with a termination right elsewhere in this Agreement) and the failure is not capable of cure or, if capable of cure, is not remedied within sixty (60) days (or fifteen (15) Business Days in the event of a payment default) after receipt of written notice from the non-defaulting Party, then the non-defaulting Party may terminate this Agreement immediately upon delivering written notice of termination; and
- iii. if a Party wilfully or fraudulently misrepresents any fact, information or report required to be made or disclosed under this Agreement, then the other Party may terminate this Agreement immediately upon delivering written notice of termination.
- iv. [***]

- [***]
- [***]
- [***]
- [***]

15.3 *Termination – Effect on Confidential Information and Intellectual Property.*

- (1) Expiration of Term/Termination Due to Fault of CATALYST. If the term of this Agreement expires pursuant due to a fault of Catalyst or if this Agreement is terminated by KYE pursuant to **Section 15.2** (Insolvency, Default or Fraud), **18.3** (Assignment Without Consent) or **18.6** (Force Majeure), (i) the Parties shall continue to honor their obligations under all outstanding, and binding, purchase orders including, but not limited to payment and supply obligations in accordance with their terms; (ii) the applicable provisions of this Agreement with respect to indemnity and other matters shall remain in full force and effect; (iii) upon expiration or written notice of termination of the Agreement, KYE may, where permitted by Applicable Law, purchase from CATALYST through purchase orders for a period of nine (9) months post notice of termination and sell the remaining Product in its inventory. KYE shall return ownership of the Health Canada NDS and the Marketing Authorization. Each Party shall destroy all of the other Party's Confidential Information in its possession (whatever the format) except for documents that must be retained in order to comply with Applicable Laws, which information may be retained, but only for so long as required and subject to the confidentiality obligations herein.
- (2) Other Reasons for Termination. If this Agreement is terminated by CATALYST pursuant to **15.2** (Insolvency, Default or Fraud, [***]), **18.3** (Assignment Without Consent) or **18.6** (Force Majeure), or if this Agreement is terminated pursuant to **11.3(2)** (IP Claim), then KYE shall not have any further rights in relation to the Health Canada Approved NDS, and neither Party shall be under any further obligation to the other in relation to the Product in Canada. KYE shall return the Health Canada Approved NDS to CATALYST and shall have no rights in relation thereto. KYE will, at its own cost, promptly transfer to CATALYST ownership of any Marketing Authorization which has been granted to KYE for the Product in Canada. Each Party shall destroy all of the other Party's Confidential Information in its possession (whatever the format) except for documents that must be retained in order to comply with Applicable Laws, which information may be retained, but only for so long as required and subject to the confidentiality obligations herein.

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

ARTICLE 16 - INDEMNIFICATION & INSURANCE

- 16.1 *Indemnification of CATALYST.* KYE shall defend, indemnify, and hold harmless CATALYST, its Affiliates and their respective officers, directors, employees, agents and representatives from and against all Losses arising in connection with any third-party claim, action, cause of action or demand resulting from:
- i. any breach of this Agreement by KYE;
 - ii. any negligent or intentionally wrongful act or omission of KYE or any person acting on KYE's behalf;
 - iii. KYE's specific written instructions to CATALYST regarding the Product Packaging;
 - iv. the transportation, storage (after delivery to KYE), or Marketing of the Product; and
 - v. any infringement claim as to any patent granted after the Effective Date provided that CATALYST shall equally share (50%/50%) with KYE such Losses.
- 16.2 *Indemnification of KYE.* CATALYST shall defend, indemnify, and hold harmless KYE, its Affiliates and their respective officers, directors, employees, agents and representatives from and against all Losses arising in connection with any third-party claim, action, cause of action or demand resulting from:
- i. any breach of this Agreement by CATALYST;
 - ii. the negligent or intentionally wrongful act or omission of CATALYST or any person acting on the CATALYST's behalf;
 - iii. any infringement claim as to a patent granted prior to the Effective Date;
 - iv. the manufacture of any Product that is Defective;
 - v. as to any patent granted prior to the Effective Date and equally share (50%/50%) with KYE any Losses resulting from any infringement claim as to any patent granted after the Effective Date; and

- vi. Any infringement claims involving use of a Trademark.
- 16.3 *Indemnification Procedure.* If either Party (the “**Indemnified Party**”) becomes aware of any event, circumstance, assertion, demand, suit, action, claim or proceeding in respect of which the other Party (the “**Indemnifying Party**”) is obliged to indemnify the Indemnified Party pursuant to this Agreement, then the Indemnified Party shall promptly give written notice thereof to the Indemnifying Party. The notice shall specify the nature and amount of the third-party claim, to the extent that such information is available. The Indemnifying Party shall, at its expense, assume control of the negotiation, settlement, defence or other handling of the third-party claim for and on behalf of the Indemnified Party. The Indemnifying Party shall have the sole right to select and direct legal counsel to defend the claim. The Indemnified Party may, at its own expense, appoint its own legal counsel to participate in defending the claim, in which case the Indemnifying Party’s counsel will consult with the Indemnified Party’s counsel and will give the Indemnified Party’s counsel the opportunity to provide comments on the defense strategy. The Indemnified Party shall cooperate with the Indemnifying Party, including assisting in the location and production of evidence and having its employees and other representatives testify in any court proceeding, if necessary, all at the Indemnifying Party’s reasonable cost. If the Indemnifying Party assumes control of the claim, the Indemnified Party shall not settle or compromise the claim without the prior written consent of the Indemnifying Party, which shall not be unreasonably withheld, and in any event an Indemnifying Party may settle without the consent of the Indemnified Party if there no admission of fault by the Indemnified Party and the Indemnified Party has no further obligations in respect of the claims.. The Indemnifying Party shall not settle the claim or consent to judgment without the Indemnified Party’s written approval, which approval shall not to be unreasonably withheld. If the Indemnifying Party fails to assume control of the defence of any third party claim, or, having elected to assume control, thereafter fails to diligently defend the claim, then the Indemnified Party shall be entitled to contest, settle or pay the amount of the claim in good faith, and the Indemnifying Party shall be bound by the results obtained by the Indemnified Party with respect to the claim and shall remain liable to indemnify the Indemnified Party in relation thereto.
- 16.4 *Insurance.* CATALYST and KYE shall, during the term of this Agreement and for a period of [***] after the expiration date of the last unit of Product sold in Canada, maintain a policy of general commercial liability and of product liability insurance for the Product insuring against, among other things, personal injury, death and damage to property. The said policy shall have a general commercial liability limit of not less than [***] per occurrence and in the aggregate and a product liability limit of not less than [***] per occurrence and in the aggregate and shall be maintained with a financially sound and reputable insurer.
- 16.5 *Survival.* The expiration or earlier termination of this Agreement shall not relieve any Party hereto from any obligations which accrued prior to such expiration or earlier termination, and shall not destroy or diminish the binding force and effect of any of the terms and conditions of this Agreement that expressly or by implication come into or continue in effect on or after termination or expiration. Without limiting the foregoing, the obligations set forth in this **Article 16**, **Article 17** and **Section 8.4** shall survive the termination of this Agreement and remain in full force and effect for an indefinite period after termination

- 16.6 *Disclaimer.* NOTWITHSTANDING ANYTHING TO THE CONTRARY CONTAINED HEREIN, NEITHER PARTY SHALL BE LIABLE TO THE OTHER FOR ANY SPECIAL, CONSEQUENTIAL, INCIDENTAL, OR INDIRECT DAMAGES OR EXPENSES, WHETHER IN CONTRACT, TORT OR OTHERWISE IN CONNECTION WITH OR ARISING OUT OF THIS AGREEMENT.

ARTICLE 17 - CONFIDENTIALITY

- 17.1 *Confidentiality.* During the term of this Agreement and for five (5) years thereafter, each Party shall maintain in strict confidence the Confidential Information (as defined below) of the other Party. A Party may not use the Confidential Information of the other Party for any purpose other than the purposes contemplated under this Agreement, and shall not disclose such Confidential Information to any third party (including in connection with any publications, presentations or other disclosures) except to its employees, agents, consultants or advisors who have a need to know such Confidential Information to achieve the purposes of this Agreement, or as otherwise contemplated herein for the purposes of this Agreement. Each Party shall ensure that any person to whom it discloses the other Party's Confidential Information is informed of the confidential nature of and duty not to disclose the information and is obligated to maintain the confidentiality thereof to the same or greater extent as provided herein. Each Party may also disclose such of the Confidential Information of the other Party as may be required by Applicable Law or by any governmental authority having jurisdiction, provided that the Party required to disclose shall, if possible, notify the other Party prior to disclosing any Confidential Information and provide such other Party with a reasonable opportunity to contest or limit the scope of the required disclosure and assist the other Party in obtaining any protective orders as may be appropriate.
- 17.2 *Definition.* “**Confidential Information**” means all proprietary technical information, marketing, business and financial information, scientific data, information marked confidential and all other information which a reasonable person would treat confidentially that relates to the Product or the business of a Party. Confidential Information shall not include any information which the receiving Party can show:
- i. was known to or in the possession of the receiving Party prior to its receipt from the disclosing Party;
 - ii. is readily available to the public other than through any act or omission of the receiving Party in contravention of this Agreement or any other agreement between the Parties;
 - iii. was disclosed by a third party not under an obligation of confidentiality to the disclosing Party; or

- iv. is subsequently independently developed by the receiving Party without use of the Confidential Information as demonstrated by written records.
- 17.3 *No Publicity.* Except as required by Applicable Law, neither Party shall originate any publicity, news release or other public announcements, written or oral, whether to the public press, to stockholders, or otherwise, relating to this Agreement or any amendment hereto without the prior written approval of the other Party, which approval shall not be unreasonably withheld. Nothing in the provision shall be deemed to prevent a Party from making such disclosures or announcements that, in the opinion of legal counsel, are legally required of such Party; provided that in any event the non-disclosing Party shall have the right to review any such disclosure and revise such disclosure to the extent it relates to the use of the non-disclosing Party's name or Confidential Information.

ARTICLE 18 - MISCELLANEOUS

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

In the case of the CATALYST at:

Catalyst Pharmaceuticals, Inc.
355 Alhambra Circle, Suite 1250
Coral Gables, FL 33134

Attention: Brian Elsbernd, Chief Legal and Compliance Officer

Email: belsbernd@catalystpharma.com

With a copy (which shall not constitute notice) to:

Torys LLP
179 Wellington Street West
30th Floor
Toronto, On Canada 1N

Attn: Cheryl Reicin

Email: creicin@torys.com

And in the case of KYE at:

KYE Pharmaceuticals Inc.
2233 Argentia Road Suites 302 and 302A
Mississauga, ON
Canada
L5N 2X7

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

- 18.2 *Relationship of the Parties.* The relationship of the Parties is that of independent contractors. This Agreement does not constitute any one Party hereto as the agent or legal representative of the other Party for any purpose whatsoever. Neither of the Parties grants to the other any right or authority to assume or create any obligation or responsibility, express or implied, on behalf of it or in its name in any manner whatsoever, unless otherwise agreed to in writing by the other Party.
- 18.3 *Assignment.* This Agreement shall be binding upon and inure to the benefit of the Parties hereto and their respective successors and permitted assigns. Except as otherwise expressly provided herein, KYE may not assign or transfer its rights or obligations under this Agreement, in whole or in part, or effect a change of control, without the prior written consent of the other Party, which consent shall not be unreasonably withheld or delayed. Any assignment or transfer by KYE other than in accordance with the terms hereof shall be void and shall entitle the CATALYST to terminate this Agreement. CATALYST may assign or transfer its rights and obligations hereunder or effect a change of control.
- 18.4 *No Waiver; Remedies.* No Party to this Agreement shall be deemed or taken to have waived any provision of this Agreement unless such waiver is in writing, and then such waiver shall be limited to the circumstances set forth in such written waiver. No failure or delay on the part of a Party in exercising any right, power or remedy shall operate as a waiver thereof, nor shall any single or partial exercise of any such right, power or remedy preclude any other or further exercise thereof or the exercise of any other right, power or remedy. All remedies provided for hereunder shall be cumulative of and in addition to any and all other remedies which any Party may have under this Agreement and/or under Applicable Law, and the exercise of any one or more of such remedies shall not preclude the exercise of any others.
- 18.5 *Time.* Time shall be of the essence of this Agreement and every part hereof.

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

18.7 *Governing Law & Dispute Resolution*.

- (1) This Agreement shall be governed by and construed in accordance with the laws of the State of New York. Each Party waives any defenses to inconvenient forum.
- (2) All disputes arising in connection with this Agreement shall be determined by arbitration in accordance with the Rules of Arbitration of the American Arbitration Association the place of arbitration shall be New York City, and the language of arbitration shall be English. Within twenty (20) days of one Party notifying the other Party that it wishes to commence an arbitration, each Party shall nominate two (2) candidates (for a total of four (4) candidates) to be the sole arbitrator. If the Parties are unable to agree on one arbitrator from the four (4) candidates within seven (7) days of exchanging names of candidates, then within five (5) days thereafter, each Party shall select one (1) arbitrator and those two (2) selected arbitrators shall select a third arbitrator as promptly practicable but in any event within seven (7) days after they are selected. The mutually selected arbitrator shall serve as the chair of the arbitration panel. All candidates for arbitrators and selected arbitrators shall have experience and familiarity with pharmaceutical distribution and license agreements. The determination of any such arbitration shall be final and binding on the Parties and no appeal shall lie therefrom. Any award rendered may be entered in any court having jurisdiction. Responsibility for the costs of the arbitration proceeding shall be determined in the discretion of the arbitration panel. The Parties shall keep all details of the arbitration proceeding and arbitral award strictly confidential and shall use all reasonable efforts to take such action as may be appropriate to prevent the unauthorized disclosure of the proceedings, any information disclosed in connection therewith and the award granted, including requiring all participants (including any witnesses) to agree to abide by such confidentiality. Notwithstanding the foregoing, neither Party shall be precluded from applying to a court of competent jurisdiction for any relief in the nature of injunction, specific performance, or other equitable remedy.

- 18.8 *Severability.* If any provision in this Agreement is held to be invalid, void or unenforceable, then that provision shall be severed from this Agreement, and the remainder of this Agreement shall not be affected thereby and shall be enforced to the fullest extent permitted by Applicable Law. The Parties agree to renegotiate any such invalid, void or unenforceable provision in good faith in order to provide a reasonably acceptable alternative consistent with the basic purposes of this Agreement and to as closely as possible give effect to the intent of the invalid, void or unenforceable provision.
- 18.9 *Entire Agreement.* This Agreement (including the Schedules attached hereto and any Quality Agreement and Safety Data Exchange Agreement (SDEA) entered into by the Parties,) constitutes the entire agreement between the Parties with respect to the subject matter hereof, and all prior or agreements, whether written or oral, are superseded hereby. This Agreement may be amended only in writing executed by the Parties.
- 18.10 *Headings.* The captions and headings contained herein are for convenience of the Parties and in no way define, limit, or describe the scope of this Agreement.
- 18.11 *Language.* The language of this Agreement and all proceedings taken in relation thereto shall be English.
- 18.12 *Currency.* Unless otherwise specifically provided, all references to money amounts are expressed in terms of United States dollars and all payments made pursuant to this Agreement shall be made in that currency.
- 18.13 *Counterparts and Delivery.* This Agreement may be executed in any number of counterparts, each of which shall be deemed an original and all of which, taken together, shall constitute one and the same instrument. This Agreement may be executed and delivered by pdf or other form of electronic transmission, and the Parties may rely on a pdf or electronic signature as though it were an original signature.

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

KYE Pharmaceuticals Inc.

By: /s/ Douglas Reynolds
Name: Douglas Reynolds
Title: President
I have authority to bind the corporation

CATALYST Pharmaceuticals, Inc

By: /s/ Pat McEnany
Name: Pat McEnany
Title: President and CEO
I have authority to bind the corporation

Schedule A: Product Information

SCHEDULE A

PRODUCT INFORMATION



Catalyst Pharmaceuticals and KYE Pharmaceuticals Announce Agreement to Make Firdapse® (amifampridine phosphate) Available to LEMS Patients in Canada

CORAL GABLES, Fla., August 18, 2020 (GLOBE NEWSWIRE) -- Catalyst Pharmaceuticals, Inc. (Catalyst) (Nasdaq: CPRX), a commercial-stage biopharmaceutical company focused on developing and commercializing innovative therapies for people with rare debilitating, chronic neuromuscular and neurological diseases, and KYE Pharmaceuticals Inc. ("KYE"), a private company headquartered in Mississauga, Ontario and focused on bringing medicines that fulfill clinically significant unmet needs to the Canadian market, today announced that the companies have entered into an exclusive license agreement under which KYE will commercialize Firdapse® in Canada. Firdapse® is indicated for the symptomatic treatment of Lambert-Eaton myasthenic syndrome (LEMS) in adults. Under the terms of the agreement, Catalyst will supply Firdapse® to KYE and KYE will be responsible for promotion, sales, advertisement, marketing, product importation and distribution. KYE will also be responsible for the ongoing maintenance of the regulatory file and future communications with Health Canada.

Patrick J. McEnany, Catalyst's Chairman and CEO, said, "Catalyst remains focused on making a meaningful impact in the lives of those suffering from rare diseases. We are excited to partner with the experienced team at KYE in making Firdapse® available to LEMS patients throughout Canada."

Doug Reynolds, KYE Co-Founder and President, said, "Partnering with Catalyst to make Firdapse® available to LEMS patients in Canada allows us to continue fulfilling our goal to bring critically needed medicines to Canadian patients and the healthcare community. We look forward to working with the experienced and talented Catalyst team in the years ahead."

About Lambert-Eaton Myasthenic Syndrome (LEMS)

Lambert-Eaton myasthenic syndrome, or LEMS, is a rare autoimmune disorder, most often characterized by muscle weakness of the limbs. The disease is caused by an autoimmune reaction where antibodies are formed against voltage gated potassium channels in the connection between nerves and the muscles they communicate with. In approximately 50% of cases, LEMS is associated with an underlying malignancy, most commonly small-cell lung cancer, and in some individuals, LEMS is the first symptom of such malignancy. LEMS generally affects the extremities, especially the legs. As the disease most affects the parts of limbs closest to the trunk, difficulties with climbing stairs or rising from a sitting position are commonly noted. Physical exercise and high temperatures tend to worsen the symptoms. Other symptoms occasionally seen include weakness of the muscles of the mouth, throat, and eyes. Individuals affected with LEMS also may have a disruption of the autonomic nervous system, including dry mouth, constipation, blurred vision, impaired sweating, and/or hypotension.

About Catalyst Pharmaceuticals

Catalyst Pharmaceuticals is a commercial-stage biopharmaceutical company focused on developing and commercializing innovative therapies for people with rare debilitating, chronic neuromuscular and neurological diseases, including Lambert-Eaton myasthenic syndrome (LEMS), anti-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 LEMS was approved in November 2018 by the U.S. Food & Drug Administration ("FDA"), and Firdapse® is now commercially available in the United States. Further, Canada's national healthcare regulatory agency, Health Canada, recently approved the use of Firdapse® (amifampridine) for the treatment of patients in Canada with LEMS.

Firdapse® is currently being evaluated in clinical trials for the treatment of MuSK-MG and SMA Type 3 and has received Orphan Drug Designation from the FDA for myasthenia gravis.

About KYE Pharmaceuticals

KYE Pharmaceuticals is a private company headquartered in Canada focused on bringing medications to the Canadian market which fulfill clinically significant and unmet needs. KYE has licensed many innovative products and was founded on an entrepreneurial spirit that optimizes our team's strengths and brings unique value to our partners, Canadian healthcare professionals, and most importantly, our patients. For more information please visit www.kyepharma.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 KYE can successfully commercialize Firdapse® in Canada, (ii) whether any such commercialization of Firdapse® in Canada will be on a profitable basis, (iii) the impact of competition from Ruzurgi® on sales of Firdapse® in Canada, (iv) the impact in the United States if an amifampridine product is purchased in Canada for use in the United States, and (v) those factors described in Catalyst's Annual Report on Form 10-K for the fiscal year 2019 and Catalyst's other filings with the U.S. Securities and Exchange Commission (SEC), could adversely affect Catalyst. Copies of Catalyst's filings with the SEC are available from the SEC, may be found on Catalyst's website, or may be obtained upon request from Catalyst. Catalyst does not undertake any obligation to update the information contained herein, which speaks only as of this date.

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