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

FORM 8-K

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

Date of Report (Date of Earliest Event Reported): June 19, 2023

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

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

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

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

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

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))

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

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

Emerging Growth Company ☐

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

Item 1.01 Entry into a Material Definitive Agreement

On June 19, 2023, Catalyst Pharmaceuticals, Inc. (the "Company") entered into a License and Collaboration Agreement (the "License Agreement") and an Investment Agreement (the "Investment Agreement", and together with the License Agreement, the "Agreements")) with Santhera Pharmaceuticals Holding AG ("Santhera"), under which the Company will enter into an exclusive North America license, manufacturing and supply agreement for Santhera's investigational product candidate, vamorolone, a dissociative steroid currently under FDA review for the treatment of Duchenne Muscular Dystrophy ("DMD").

Under the terms of the License Agreement, the Company will make a $75 million upfront payment for the license for vamorolone. Additionally, pursuant to the terms of the Investment Agreement, the Company will make a $15 million investment into Santhera at a price of CHF 0.9477 ($1.08 USD) per share, a mutually agreed upon volume-weighted average price prior to signing, with the investment proceeds to be used by Santhera for Phase IV studies in DMD and further development of additional indications. Additionally, Santhera may receive future regulatory and commercial milestone payments tied to FDA approval and calendar year sales of vamorolone, as well as commercial royalties. Further, Catalyst and Santhera will enter into a Joint Steering Committee to oversee the development of vamorolone for indications beyond DMD.

The Agreements are structured as all-cash transactions with no financing contingencies. The transaction is expected to be completed in the third quarter of 2023, subject to customary closing conditions and regulatory clearances in the United States.

The foregoing descriptions of the License Agreement and the Investment Agreement do not purport to be complete and are qualified in their entirety by reference to the full text of such agreements, copies of which are attached as **Exhibit 10.1**, and **Exhibit 10.2**, respectively, to this Form 8-K and are incorporated herein by reference.

Forward-Looking Statements

This Current Report on Form 8-K includes forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Any statements, other than statements of historical fact, including statements regarding the timing and ability of the parties to consummate the transaction contemplated by the Agreements satisfaction of conditions in connection with the Transaction, the parties' ability to meet expectations regarding the timing and completion of the transaction and any other statements containing the words "believes," expects," "anticipates," "plans," "estimates," and similar expressions, are forward-looking statements. These forward-looking statements are based on the Company's current intentions, beliefs and expectations regarding future events. The Company cannot guarantee that any forward-looking statement will be accurate. The reader should realize that if underlying assumptions prove inaccurate or unknown risks or uncertainties materialize, actual results could differ materially from expectations. The reader is, therefore, cautioned not to place undue reliance on any forward-looking statement. Any forward-looking statement speaks only as of the date of this Form 8-K, and, except as required by law, the Company does not undertake to update any forward-looking statement to reflect new information, events or circumstances.

Item 8.01 Other Events

On June 20, 2023, the Company issued a press release announcing the Agreements. A copy of the press release is attached as **Exhibit 99.1** to this Form 8-K and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits

10.1	License and Collaboration Agreement, executed and delivered as of June 19, 2023, by and between Santhera, its wholly-owned subsidiary, Santhera Pharmaceuticals (Schweiz) AG, 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).
10.2	Investment Agreement, dated as of June 19, 2023, by and between Santhera and the Company (certain identified information has been excluded from the exhibit because it both (i) is not material and (ii) would be competitively harmful if publicly disclosed).
99.1	Press release issued by the Company on June 20, 2023
104	Cover Page Interactive Data File (embedded within the inline XBRL document)

SIGNATURES

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

Catalyst Pharmaceuticals, Inc.

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

Dated: June 23, 2023

EXHIBIT 10.1

Certain identified information has been excluded from this exhibit because it is both (i) not material, and (ii) would likely cause competitive harm to the registrant if publicly disclosed. [***] indicates that information has been redacted.

LICENSE AND COLLABORATION AGREEMENT

This Cooperation, Supply and Commercialization Agreement, executed and delivered as of June 19, 2023 (the "Execution Date"), is by and between **Santhera Pharmaceuticals (Schweiz) AG** and **Santhera Pharmaceuticals Holding AG**, both corporations organized under the laws of Switzerland and having their principal office at Hohenrainstrasse 24, 4133 Pratteln, Switzerland (collectively, "Santhera"), and **Catalyst Pharmaceuticals Inc.**, a corporation organized under the laws of Delaware, U.S. and having its principal office at 355 Alhambra Circle, Suite 801, Coral Gables, FL 33134, U.S. ("Catalyst"). Each of Catalyst and Santhera may be referred to herein as a "Party" or collectively as the "Parties".

RECITALS

a) ReveraGen BioPharma Inc., a corporation organized under the laws of Delaware and having its principal office at 155 Gibbs Street, Suite 433, Rockville, MD 20850, U.S. ("ReveraGen"), as licensor, and Actelion Pharmaceuticals Ltd, Allschwil, Switzerland, as licensee, had entered into the license, development and commercialization agreement in relation to the Compound and the Product (as defined below) effective on 15 April 2016, and such agreement, as amended, has been transferred by Actelion Pharmaceuticals Ltd to Idorsia Pharmaceuticals Ltd, Allschwil, Switzerland ("Idorsia") in June 2017, and subsequently further amended (as amended, the "ReveraGen Agreement").

b) As per September 1, 2020, Idorsia has assigned its right, title and interest deriving from the ReveraGen Agreement to Santhera, such that Santhera has become a successor to Idorsia with respect to its rights and obligations under the ReveraGen Agreement, and ReveraGen has consented to such assignment.

c) Immediately following the assignment, Santhera has exercised the option right to acquire an exclusive license under the ReveraGen Agreement for the Compound and the Product in any and all uses in all countries of the world according to the ReveraGen Agreement.

d) Catalyst desires to obtain from Santhera a (sub-)license of certain intellectual property rights in relation to the Product for the purpose, *inter alia*, of development and commercialization in the Territory, and Santhera is willing to grant such rights and licenses to such intellectual property rights, and to supply the Product to Catalyst, on the terms and conditions set forth herein.

Now, therefore, the Parties agree as follows:

1. **Definitions**

Capitalized terms used in this Agreement and not otherwise defined herein shall have the meanings set forth below:

1.1 "Acquired Party" has the meaning set forth in Section 2.7 (Non-Compete During the Term).

1.2 "Acquirer" has the meaning set forth in Section 2.7 (Non-Compete During the Term).

1.3 "Additional Clinical Trials" means clinical trials which are not required to obtain or maintain Regulatory Approval in any country in the Territory and that are solely for the benefit of one or more countries or regions outside the Territory, including any clinical trials or studies that are required to be conducted by the European Medicines Agency, or any successor thereto, and are not required by the FDA.

1.4 “Additional Development” has the meaning set forth in Section 4.1(b) (Additional Development).

1.5 “Additional Development Proposal” has the meaning set forth in Section 4.1(b) (Additional Development).

1.6 “Additional Indication” means indications other than the Initial Indication, which may include, BMD, Pediatric Ulcerative Colitis or any other indications other than the Initial Indication.

1.7 “Affiliate” with respect to a Party or other Person, means any Person that, directly or indirectly, through one or more intermediaries, controls, is controlled by, or is under common control with such Party or such other Person. For purposes of this definition only, “control” herein means (a) the direct or indirect ownership of more than fifty percent (50.0%) (or such maximum lesser percentage allowed to be owned by a foreign owner in a particular jurisdiction) of the outstanding voting securities of such Party or other Person, or (b) if such Person directly or indirectly possesses the power to direct or cause the direction of the management and policies of a Party or other Person by any means whatsoever.

1.8 “Agreement” means this License and Collaboration Agreement, together with all exhibits attached hereto, as the same may be modified and in effect from time to time.

1.9 “Anti-Corruption Laws” has the meaning set forth in Section 10.1(g) (Representations, Warranties and Covenants of the Parties).

1.10 “Applicable Laws” means all applicable laws, statutes, codes, regulations, judgments, orders, implementing legislation, or ordinances of any kind whatsoever of a Governmental Authority, as any of the same may be amended from time to time, and all applicable directives, regulations, promulgations, codes, guidance and guidelines promulgated thereunder and having jurisdiction over or related to the Development, Manufacturing, and/or Commercialization of the Compound and/or the Product including, to the extent applicable, good laboratory practices, good clinical practices, Good Manufacturing Practices, Good Distribution Practices, and good warehousing practices.

1.11 “Binding Forecast” has the meaning set forth in Section 6.5(b) (Forecasts).

1.12 “BMD” means Becker’s Muscular Dystrophy or Becker Muscular Dystrophy.

1.13 “Business Day” means when measuring performance by Santhera, any day other than (a) a Saturday or a Sunday in the city of Basel, Switzerland, or (b) a bank or other public holiday in Basel, Switzerland, and when measuring performance by Catalyst, any day other than (c) a Saturday or a Sunday in the U.S., or (d) a bank or other public holiday in the city of Miami, Florida, U.S. For the avoidance of doubt, references in this Agreement to “days” shall mean calendar days.

1.14 “Calendar Quarter” means each of the three (3) month periods beginning from January 1, April 1, July 1, and October 1.

1.15 “Calendar Year” means the period from January 1 to December 31 of a year.

1.16 “Catalyst” has the meaning set forth in the ingress to the Recitals.

1.17 “Catalyst Indemnitees” has the meaning set forth in Section 12.1 (Santhera Indemnification).

1.18 “Catalyst Invention” has the meaning set forth in Section 7.1 (Ownership of Inventions).

1.19 “CEO” means Chief Executive Officer.

1.20 “C.F.R.” means U.S. Code of Federal Regulations.

1.21 “CMO” means a contract manufacturing organization.

1.22 “COGs” has the meaning set forth in Section 1.127 (Supply Price).

1.23 “Combination Product” has the meaning set forth in Section 3.6 (Sales of Combination Products).

1.24 “Commercialize”, “Commercializing” and “Commercialization” means to market, advertise, promote, distribute, sell, offer for sale, store, import, export, offer pricing and obtain reimbursement approvals for any of the foregoing, and includes Phase 4 Program Activities. Commercialization shall not include any activity comprising Manufacturing or Development.

1.25 “Commercially Reasonable Efforts” means the carrying out of obligations under this Agreement with those efforts and resources that Catalyst would reasonably use were it developing or commercializing its own pharmaceutical compound or product that is of similar market and profit potential and of similar risk profile at a similar stage in its product life as the Product, taking into account available pre-clinical and clinical data, anticipated product labeling, anticipated financial return, relevant medical and clinical considerations, anticipated regulatory environment and competitive market conditions, all as measured by the facts and circumstances at the time such efforts are due. It is understood that the potential for the Product may change from time to time based upon changing scientific, business, marketing, return on investment and other relevant considerations. Commercially Reasonable Efforts will be determined on a market-by-market and indication-by-indication basis for a particular Product, and it is anticipated that the level of efforts will change over time, reflecting changes in the status of the Product and the markets involved.

1.26 “Competing Product” means any product (irrespective of its formulation) that (a) is Developed, Commercialized, or has received Regulatory Approval for the treatment of the Initial Indication or for any other indication for which the Product has received Regulatory Approval in the Territory (or, prior to that time, for one or more of the same indication(s) for which a Product is being Developed in any country in the Territory); (b) is a steroidal drug; and (c) is not the Product.

1.27 “Compound” means [***].

1.28 “Confidential Disclosure Agreement” means the Confidential Disclosure Agreement between the Parties [***].

1.29 “Confidential Information” means all information and data disclosed by or on behalf of one Party (the “Disclosing Party”) to the other Party or its Affiliates (the “Receiving Party”) in connection with this Agreement, or under the Confidential Disclosure Agreement, and/or learned by the Receiving Party hereunder, regardless of form, including a formula, pattern, compilation, program, method, technique, process, biological material, gene sequence, chemical structure or activity, design, source code, business plan, business opportunity, customer or personnel list, or financial statement proprietary to the Disclosing Party or its Affiliates, except any portion thereof which the Receiving Party can show by competent evidence:

(a) is known to the Receiving Party before receipt thereof under this Agreement or any other agreement between the Parties hereto providing for confidentiality;

(b) is disclosed to the Receiving Party on a non-confidential basis by a Third Party, who is under no obligation of confidentiality to the Disclosing Party with respect to such information and who otherwise has a right to make such disclosure;

(c) was, is or becomes published, as evidenced by a written version thereof, or generally known in the trade, scientific or medical community through no fault of the Receiving Party; or

(d) is independently developed by the Receiving Party, without use of or reliance on the Disclosing Party's Confidential Information, by persons having no access thereto.

1.30 "Control" or "Controlled" means, with respect to any information or intellectual property right, possession by a Party of the ability (whether by ownership, license or otherwise) to assign, grant access to or grant a license or sublicense under such intellectual property rights or information to the other Party of the scope set forth herein ("Access"), without breaching the terms of any agreement or other arrangement with a Third Party as of the time such Party would first be required hereunder to grant the other Party such Access.

1.31 "Core European Markets" has the meaning set forth in Section 2.8 (Right of First Negotiation).

1.32 "Cover" or "Covering" means, with respect to a Product and a country, that the making, using, selling, offering for sale or importing of such Product would, but for a license granted under the Licensed Patents, infringe a Valid Claim of the Licensed Patents in the country in which the activity occurs.

1.33 "Defective Product" means a Product which fails to conform with Product Specifications and/or which has not been Manufactured in accordance with Applicable Laws, including Good Manufacturing Practices, or the Quality Agreement, it being clarified that unless otherwise agreed by the Parties, a Product may not be deemed Defective if the alleged defect is solely attributable to Catalyst's acts or omissions (e.g. in terms of proper storage of the Product after receipt), or if the alleged defect solely results from closely following and complying with (x) the definition by Catalyst in writing of the content, or parts thereof, of the Secondary Packaging or (y) Catalyst's written information and instructions, if any, regarding Applicable Laws in the Territory related to Primary Packaged Product or Secondary Packaged Product.

1.34 "Develop", "Developing" and "Development" mean non-clinical (including potential development of formulation) and clinical research and/or development activities reasonably related to or intended to lead to the generation and submission of data and information to a Regulatory Authority, and includes Required Studies. Development shall not include any activity comprising Manufacturing or Commercialization.

1.35 "Disclosing Party" has the meaning set forth in Section 1.29 (Confidential Information).

1.36 "Dispute" means any dispute between the Parties regarding the validity, interpretation, construction or governance of, the compliance with, or the breach or termination of this Agreement.

1.37 "DOJ" means the U.S. Department of Justice.

1.38 "Dollars" or "$**"** means the lawful currency of the U.S.

1.39 "Effective Date" has the meaning set forth in Section 8.3 (Effective Date).

1.40 "Europe" means the countries of the European Union at the Effective Date, the United Kingdom, and Switzerland.

1.41 "Exclusive License" has the meaning set forth in Section 2.1 (Grant to Catalyst).

1.42 "Execution Date" has the meaning set forth in the ingress to the Recitals.

1.43 "FDA" means the U.S. Food and Drug Administration or any successor agency that is responsible for Regulatory Approval of pharmaceutical products in the U.S.

1.44 "FFDCA" means the U.S. Federal Food, Drug, and Cosmetic Act.

1.45 "Field" means the treatment and/or prevention of all human diseases and conditions.

1.46 "First Commercial Sale" means, with respect to a country in the Territory, the first sale, on an arm's length basis, to a Third Party for monetary value of a Product for use or consumption by an end-user after all Regulatory Approvals that are required for the Commercialization of such Product in such country in the Territory have been obtained, other than to a Sublicensee of Catalyst or any of its Affiliates. For the avoidance of doubt, any sale prior to receipt of all Regulatory Approvals necessary to commence regular commercial sales in a region of the Territory, such as so-called "treatment IND sales (clinical trial sample sales)," "named patient sales," "compassionate use sales" and samples shall not be construed as a First Commercial Sale.

1.47 "First Commercial Sale Year" means the Calendar Year in which the First Commercial Sale of the Product occurs.

1.48 "Force Majeure" means occurrences beyond the reasonable control of the Party affected, including acts of God, embargoes, terrorism, materials shortages or failure of any supplier (where such shortage or failure is attributable to an event of Force Majeure suffered by such supplier), fire, flood, epidemic, explosion, earthquake, hurricanes, storms, tornadoes, pandemics, riots, wars, civil disorder, failure of public utilities or common carriers, rebellion or sabotage, and including, without limitation, governmental restrictions not arising due to any act or omission of the affected Party; provided, however, that the payment of amounts due and owing hereunder shall not be excused by reason of a Force Majeure affecting the payor.

1.49 "Forecast" has the meaning set forth in Section 6.5(a) (Forecasts).

1.50 "FTC" means U.S. Federal Trade Commission.

1.51 "GAAP" means the Generally Accepted Accounting Principles in the U.S., as established by the Financial Accounting Standards Board ("FASB") and included in the Accounting Standards Codification ("ASC") consistently applied and effective for the specified period.

1.52 "Generic Version" means, with respect to a Product sold by Catalyst (or any of its Affiliates or Sublicensees) in a particular country in the Territory for a particular indication, any product that (a) is approved for sale in such country in reliance on the prior Regulatory Approval of such Product as obtained by Catalyst, its Affiliate or Sublicensee for the relevant indication(s) as determined by the applicable Regulatory Authority; and (b) is sold by a Third Party that is not a Sublicensee or Affiliate of Catalyst authorized to market and sell such product and that has not otherwise been authorized, directly or indirectly, by Catalyst (or any of its Affiliates or Sublicensees) to market and sell such product.

1.53 "Global Additional Development" has the meaning set forth in Section 4.1(b) (Additional Development).

1.54 "Good Distribution Practice" means standards, practices and procedures regarding the distribution of pharmaceutical products promulgated or endorsed by a Regulatory Authority or any Applicable Laws.

1.55 “Good Manufacturing Practices” means the requirements for Current Good Manufacturing Practice promulgated under the FFDCA, including, as applicable, as set forth in sections 501(a)(2)(B) and (h) of the FFDCA (21 U.S.C. §§ 351(a)(2)(B) and (h)); section 520(f) of the FFDCA (21 U.S.C. § 360j(f)); 21 C.F.R. part 4; 21 C.F.R. parts 210 and 211; and 21 C.F.R. part 800; and foreign equivalents applicable to any other region of the Territory, in each case, including any guidance regarding such requirements.

1.56 “Governmental Authority” means any nation or government, any provincial, state, regional, local or other political subdivision thereof, any supranational organization of sovereign states, and any entity, department, commission, bureau, agency, authority, board, court, official or officer, domestic or foreign, exercising executive, judicial, regulatory or administrative functions of or pertaining to government.

1.57 “Government Official” means any official, officer, director, employee, agent or representative of (1) a national, federal, provincial, regional, territorial, state, district, municipal or local government or of any agency, board or instrumentality thereof; (2) an entity owned or controlled by a Government Authority; or (3) a public international organization. For the avoidance of doubt, the officials and employees (including doctors) of public or government-administered hospitals, institutions, universities and other medical institutions or facilities shall be deemed Government Officials under this Agreement.

1.58 “Gross Sales” means [***].

1.59 ”HSR Act” means the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended from time to time.

1.60 ”HSR Filing” means filings by the Parties with the U.S. Federal Trade Commission and the Antitrust Division of the Department of Justice of a Notification and Report Form for Certain Mergers and Acquisitions (as that term is defined in the HSR Act) with respect to the matters set forth in this Agreement, together with all required documentary attachments thereto.

1.61 “ICC” means International Chamber of Commerce.

1.62 “Idorsia” has the meaning set forth in recital a) (Recitals).

1.63 “IND” means an investigational new drug application, clinical trial application or equivalent application filed with an applicable Regulatory Authority, which application is required to commence human clinical trials in an applicable country.

1.64 “Indemnified Party” has the meaning set forth in Section 12.3 (Claims Procedures).

1.65 “Indemnifying Party” has the meaning set forth in Section 12.3 (Claims Procedures).

1.66 “Initial Indication” means the treatment of Duchenne Muscular Dystrophy.

1.67 “Initial Indication NDA” has the meaning set forth in Section 4.2(c) (Regulatory Approvals).

1.68 “Initial Payment” has the meaning set forth in Section 3.1 (Initial Payment).

1.69 “Initiating Party” has the meaning set forth in Section 7.11(d) (Litigation).

1.70 “Investigational Medicinal Product” means a pharmaceutical form of an active substance or placebo being tested or used as a reference in a clinical trial, including products already with a marketing authorization but used or assembled (formulated or packaged) for purposes of the clinical trial in a way different from the authorized form or from authorized indication, or when used to gain further information about the authorized form.

1.71 "Investment Agreement" means a separate agreement governing an equity investment of Catalyst in Santhera and executed by the Parties on or around the Execution Date.

1.72 "Joint Invention(s)" has the meaning set forth in Section 7.4 (Joint Inventions).

1.73 "Joint Patents" has the meaning set forth in Section 7.4 (Joint Inventions)

1.74 "JSC" has the meaning set forth in Section 5.1 (Joint Steering Committee).

1.75 "Know-How" means all proprietary information, inventions (whether or not patentable), improvements, practices, formulae, trade secrets, techniques, methods, procedures, knowledge, results, test data (including pharmacological, toxicological, pharmacokinetic and non-clinical and clinical information and test data, analytical and quality control data, related reports, structure-activity relationship data and statistical analyses), protocols, master files, processes, process diagrams, vendor lists, specifications, models, designs, correspondence, regulatory filings and other information regarding discovery, Manufacture, Development, pricing, cost, and Commercialization. Know-How shall not include any Patent Right.

1.76 "Licensed Intellectual Property" means the Licensed Patents, Santhera's interest in Joint Inventions and Joint Patents, and Licensed Know-How.

1.77 "Licensed Know-How" means any and all Know-How, regardless of form, related to the Compound or Product (a) Controlled by Santhera or any of its Affiliates as of the Effective Date or (b) that comes into the Control of Santhera or any of its Affiliates during the Term, in each case that is not in the public domain. Licensed Know-How includes Santhera Inventions and all Know-How licensed to Santhera pursuant to the ReveraGen Agreement. In addition, the content of Regulatory Approvals, including data used by Santhera for obtaining Regulatory Approvals, to the extent Controlled by Santhera or its Affiliates, regardless of form, shall be considered to be Licensed Know-How for purposes of this Agreement.

1.78 "Licensed Patents means (a) the patents and patent applications listed on Exhibit 1.78 (Licensed Patents) hereto and all related Patent Rights in the Territory, (b) any patents or patent applications in the Territory Controlled by Santhera or its Affiliates not included in (a) to the extent claiming inventions related to the Compound or a Product, and conceived or reduced to practice before the Effective Date, and (c) any patents or patent applications in the Territory not included in (a) or (b) to the extent (i) claiming any inventions conceived or reduced to practice after the Effective Date by or on behalf of Santhera or any of its Affiliates, whether solely or jointly with a Third Party, in the course of performance of any activities related to the Compound or a Product, including Patent Rights claiming Santhera Inventions but excluding Patent Rights claiming Joint Inventions, or (ii) Controlled by Santhera or its Affiliates and related to the Compound and/or any Product. Licensed Patents includes all patents, patent applications and related Patent Rights in the Territory licensed to Santhera pursuant to the ReveraGen Agreement ("ReveraGen Patents").

1.79 "Loss" has the meaning set forth in Section 12.1 (Catalyst Indemnification).

1.80 "Manufacture" and "Manufacturing" mean all activities related to (a) developing the ability to manufacture clinical and commercial quantities of a compound or product, and (b) the synthesis, making, production, processing, purifying, formulating, filling, finishing, packaging, labeling, shipping, and holding of a compound or product or any intermediate thereof, including process development, process qualification and validation, scale-up, non-clinical, clinical and commercial production and analytic development, product characterization, stability testing, quality assurance, and quality control

1.81 "Manufacturing License" has the meaning set forth in Section 2.1 (Grant to Catalyst).

1.82 "Manufacturing Transfer Date" has the meaning set forth in Section 6.3 (Transfer of Manufacturing Responsibility).

1.83 "Material Adverse Effect" means any effect, change, event, circumstance or development, that alone or together with other effects, changes, events, circumstances or developments, has or would reasonably be expected to have a material adverse effect on the business, condition (financial or otherwise), assets, liabilities, property or results of operations of Santhera.

1.84 "NDA" means a new drug application or marketing authorization application or its equivalent filed with and accepted for filing by a Regulatory Authority.

1.85 "NDA Transfer Date" has the meaning set forth in Section 4.2(c) (Regulatory Approvals).

1.86 "Net Sales" means, with respect to a given period of time and a given country in the Territory, the Gross Sales of the Product less applicable Sales Deductions and Allowances.

1.87 "Originator" means the original owner of certain Licensed Patents relating to the Compound hereto, currently being ReveraGen, and any of its successors and assignees, which has licensed the relevant Licensed Patents to Santhera pursuant to the ReveraGen Agreement.

1.88 "Party" has the meaning set forth in the ingress to the Recitals.

1.89 "Pass-through Costs" the meaning set forth in Section 1.127 (Supply Price).

1.90 "Patent Challenge" means any dispute or challenge of the validity, patentability or enforceability of any Licensed Patent or any claim thereof, in any legal or administrative proceedings, including in a court of law, before the U.S. Patent and Trademark Office or other agency or tribunal in any jurisdiction, or in arbitration including, without limitation, by reexamination, *inter partes* review, opposition, interference, post-grant review or declaratory judgment action.

1.91 "Patent Expiration Date" means the expiration date of the last to expire Valid Claim of the Licensed Patents, determined on a country-by-country basis in the Territory, Covering the Compound or the Product, the Manufacturing of the Compound or the Product, and/or the Product's use in the Field in the Territory.

1.92 "Patent Rights" means any and all patents and patent applications, including divisionals, continuations, continuations-in-part, reissues, renewals, substitutions, registrations, re-examinations, revalidations, extensions, supplementary protection certificates, pediatric exclusivity periods and the like of any such patents and patent applications, and foreign equivalents of the foregoing.

1.93 "Person" means any individual, firm, corporation, partnership, limited liability company, trust, business trust, joint venture company, Governmental Authority, association or other entity.

1.94 "Phase 4 Program Activities" means research activities and studies relating to Products that are undertaken voluntarily after receipt of Regulatory Approval and are designed to enhance marketing or scientific knowledge of the Product or generate data that are not required by a Regulatory Authority as a condition of receiving or maintaining Regulatory Approval, including studies designed to obtain real-world data and resulting real-world evidence, clinical outcomes assessments, patient reported outcomes, observational studies and other outcomes research for value generation, post-marketing surveillance studies, quality of life assessments, pharmacoeconomics, epidemiological models, studies to support market access, and other data generation studies or activities that, in each case, are not Required Studies.

1.95 "Primary Packaging" means the primary container or bottle of the Product. Primary Packaged Product means Product after placed in Primary Packaging. The steps of Primary Packaging and Secondary Packing are shown in Exhibit 1.95 (Overview on Primary Packaging and Secondary Packaging). The details of specification of Primary Packaging shall be set forth in the Quality Agreement.

1.96 "Product" means the drug product containing the Compound for any and all uses in the Field in all current and future formulations, and in any dosage strength, presentation, or package configuration, and for any mode of administration, including any Combination Product.

1.97 "Product Exclusivity" means (a) any period during which the FDA, Health Canada or other Regulatory Authority in a region of the Territory grants any exclusive marketing rights or data exclusivity rights with respect to the Product (other than patents), including orphan drug exclusivity, new chemical entity exclusivity, or pediatric exclusivity, in each case to the extent the grant conveys to the beneficiary thereof the right to exclude others from marketing or selling such Product for the relevant indication or (b) the period from the Effective Date to the Patent Expiration Date, whichever of (a) and (b) is longer. The determination of the existence of Product Exclusivity shall be made on a country-by-country, product-by-product and indication-by-indication basis.

1.98 "Product Specifications" means the specifications of the Product (including Primary Packaging and Secondary Packaging) set forth in the Quality Agreement, as subsequently amended by the Parties, including based on the requirements set forth by the FDA.

1.99 "Prosecution and Maintenance" or "Prosecute and Maintain," with respect to a particular Patent Right, means all activities associated with the preparation, filing, prosecution and maintenance of such Patent Right (and patent application(s) derived from such Patent Right), as well as re-examinations, reissues, applications for patent term adjustments and extensions, supplementary protection certificates and the like with respect to that Patent Right, together with the conduct of interferences, derivation proceedings, *inter partes* review, post-grant review, the defense of oppositions and other similar proceedings with respect to that Patent Right.

1.100 "Purchase Order" has the meaning set forth in Section 6.6(a) (Purchase Orders; Confirmation).

1.101 "Quality Agreement" means a quality agreement of the Product to be separately executed between the Parties.

1.102 "Recall" has the meaning set forth in Section 6.11(b) (Complaints; Safety Notifications; Recall).

1.103 "Receiving Party" has the meaning set forth in Section 1.29 (Confidential Information).

1.104 "Regulatory Approval" means (a) any approvals, licenses, permits, registrations or authorizations of, notice to, or filing with any federal, state or local regulatory agency, department, bureau or other governmental entity of any jurisdiction, wherever located in the world, for which a Party, an Affiliate of a Party, or a Third Party acting on behalf of a Party or its Affiliate is the applicant, sponsor, licensee, permittee or holder as of the Effective Date, or becomes the applicant, sponsor, licensee, permittee or holder thereafter, necessary for the clinical testing, Manufacture, Commercialization or other use of a Product in a regulatory jurisdiction (including NDA approvals) or (b) any subset of the foregoing as the context may require.

1.105 “Regulatory Authority” means the FDA and any national, supra-national, regional, state or local regulatory agency, department, bureau, commission, council, or other Governmental Authority involved in granting Regulatory Approval in the Territory.

1.106 “Regulatory Documentation” means all Regulatory Filings, Regulatory Approvals, correspondence, meeting minutes, and other materials reflecting submissions or communications with a Regulatory Authority concerning the Compound or any Product and all supporting documents with respect thereto, including all adverse event files and complaint files; and safety and quality databases and adverse event information.

1.107 “Regulatory Filings” means all applications (including INDs), filings, submissions, approvals, such as for HSR Filing and NDA approvals (including supplements, amendments, pre- and post-approvals, and pricing and reimbursement approvals), licenses, registrations, permits, notifications, and authorizations (including marketing and labeling authorizations) or waivers with respect to the testing, research, Development, registration, Manufacture (including formulation), and/or Commercialization of a Product made to or received from any Regulatory Authority in a regulatory jurisdiction.

1.108 “Required Study” means any study of the Product conducted prior to or after receipt of Regulatory Approval due to a request or requirement of a Regulatory Authority as a condition of receiving such Regulatory Approval. Required Study includes a study of the Product required to be conducted after obtaining Regulatory Approval on a conditional basis (such as post-marketing approval studies and observational studies if required as a condition of receiving such Regulatory Approval) and a study of the Product requested or required by a Regulatory Authority prior to and in order to obtain Regulatory Approval.

1.109 “ReveraGen” has the meaning set forth in recital a).

1.110 “ReveraGen Agreement” has the meaning set forth in recital a).

1.111 “ReveraGen Patents” has the meaning set forth in Section 1.78 (“Licensed Patents”).

1.112 “Right of Reference” has the meaning set forth in Section 4.3 (Right of Reference).

1.113 “ROFN Exercise Notice” has the meaning set forth in Section 2.8 (Right of First Negotiation).

1.114 “ROFN Negotiation Period” has the meaning set forth in Section 2.8 (Right of First Negotiation).

1.115 “ROFN Transaction” has the meaning set forth in Section 2.8 (Right of First Negotiation).

1.116 “ROFN Transaction Notice” has the meaning set forth in Section 2.8 (Right of First Negotiation).

1.117 “Royalty” or “Royalties” means the royalty payments due to Santhera pursuant to Section 3.4 [***].

1.118 “Royalty Term” means the period during which Net Sales of the Product by Catalyst and its Affiliates and Sublicensees will be subject to Royalties due to Santhera under this Agreement, which obligation shall commence upon First Commercial Sale and shall continue in full force on a country-by country and product-by-product basis until the later of (a) expiration of Product Exclusivity in the applicable country in the Territory covering the relevant Product and indication, and (b) ten (10) years from First Commercial Sale of the Product in the applicable country in the Territory.

1.119 “Safety Notification” has the meaning set forth in Section 6.11(d) (Complaints; Safety Notifications; Recall).

1.120 “Sales Deductions and Allowances” means [***].

1.121 “Santhera” has the meaning set forth in the ingress to the Recitals.

1.122 “Santhera Indemnitees” has the meaning set forth in Section 12.1 (Catalyst Indemnification).

1.123 “Santhera Invention” has the meaning set forth in Section 7.1 (Ownership of Inventions).

1.124 “Secondary Packaging” means the manufacturing step of processing Primary Packaged Product into fully packaged and final Product ready for Commercialization to end-users in the Territory. Secondary Packaged Product means Primary Packaged Product after Secondary Packaging. The steps of Primary Packaging and Secondary Packaging are shown in Exhibit 1.95 (Overview on Primary Packaging and Secondary Packaging). The details of specification of Secondary Packaging shall be set forth in the Quality Agreement.

1.125 “Sublicensee” has the meaning set forth in Section 2.5 (Sublicensing).

1.126 “Successor(s)” means a person or entity (a) to whom all or substantially all of a Party’s assets or business is to be assigned or transferred in connection with a sale of all or substantially all of the assets or business of such Party to which this Agreement relates, or a merger or other business combination involving all or substantially all of the assets or business of a Party, or (b) to whom this Agreement is assigned other than in breach of Section 14.4.

1.127 “Supply Price” means [***].

1.128 “Tax” or “Taxes” means any and all taxes, assessments, levies, tariffs, duties or other charges or impositions in the nature of a tax imposed by any Governmental Authority, including income, estimated income, gross receipts, profits, business, license, occupation, franchise, capital stock, real or personal property, sales, use, transfer, value added, employment or unemployment, social security, disability, alternative or add-on minimum, customs, excise, stamp, environmental, commercial rent or withholding taxes.

1.129 “Term” has the meaning set forth in Section 9.1 (Term).

1.130 “Territory” means North America (U.S., Canada, and Mexico and their territories and possessions)

1.131 “Territory Additional Development” has the meaning set forth in Section 4.1(b) (Additional Development).

1.132 “Third Party” means a person or entity other than Santhera and its Affiliates, and Catalyst and its Affiliates.

1.133 “Trademark” means the Product-specific trademark, whether registered or non-registered, for use on and in connection with any Products in either region of the Territory under this Agreement.

1.134 "Unit" means one (1) bottle of one hundred (100) ml of solution of Compound containing four (4) grams of active pharmaceutical ingredient.

1.135 "U.S." means the United States of America, including all of its territories.

1.136 "U.S.C." means U.S. Code.

1.137 "U.S. Food and Drug Regulation" has the meaning set forth in Section 10.1(g) (Representations, Warranties and Covenants of the Parties).

1.138 "Valid Claim" means a claim of an issued and unexpired patent, which has not been held permanently revoked, unenforceable or invalid by a decision of a court or other governmental agency of competent jurisdiction, unappealable or unappealed within the time allowed for appeal.

2. **License Grants**

2.1 Grant to Catalyst. Subject to the terms and conditions of this Agreement, Santhera hereby grants to Catalyst, as of the Effective Date,

(a) an exclusive (even as to Santhera and its Affiliates, subject to Santhera's rights pursuant to Section 2.3 (Reserved Rights and Grant-Back License to Santhera), royalty-bearing, sublicensable (subject to Section 2.5 (Sublicensing)), transferable (in accordance with Section 14.4 (Assignment)) license and sublicense under the Licensed Intellectual Property to research, Develop and have Developed (subject to Santhera's Development rights and obligations relating to the Compound or Products in the Territory in accordance with Sections 4.1 (Development) and 4.2 (Regulatory Approvals) of this Agreement), use, Commercialize and otherwise exploit the Compound and the Products in the Field in the Territory (the "Exclusive License"); and

(b) a non-exclusive, sublicensable (subject to Section 2.5 (Sublicensing)), transferable (in accordance with Section 14.4 (Assignment)) license under the Licensed Intellectual Property to Manufacture and have Manufactured the Compound and the Products in and outside the Territory for purposes of Development, filing for and obtaining Regulatory Approval and Commercializing the Compound and the Products in the Field in the Territory (the "Manufacturing License"), exercisable under the circumstances provided in Section 6.3 (Transfer of Manufacturing Responsibility).

2.2 Transfer of Licensed Know-How. Promptly following the Effective Date, subject to Santhera's receipt of the Initial Payment, Santhera shall disclose or transfer copies of all Licensed Know-How necessary or reasonably useful to practice the Exclusive License to Catalyst (excluding any such Licensed Know-How related to the Manufacture of the Compound or Products), which disclosure or transfer shall be completed as soon as reasonably practicable and in any event no later than [***] after the Effective Date, and shall provide reasonable technical support and assistance to Catalyst with respect to the use and practice of such Licensed Know-How during the period of disclosure and transfer of such Licensed Know-How, at no additional cost to Catalyst. During the Term, Santhera shall disclose or transfer copies of any additional Licensed Know-How necessary or reasonably useful to practice the Exclusive License (excluding any such Licensed Know-How related to the Manufacture of the Compound or Products) to Catalyst as promptly as practicable, to the extent that such Licensed Know-How arises after the Effective Date or otherwise has not previously been provided or made available to Catalyst.

2.3 Reserved Rights and Grant-Back License to Santhera. Subject to the terms and conditions of this Agreement, Santhera reserves the right under the Licensed Intellectual Property, and Catalyst shall grant and hereby grants to Santhera, during the Term, a non-exclusive, sublicensable, royalty-free license under the Catalyst Inventions and Patent Rights and Know-How Controlled by Catalyst or its Affiliates claiming the Catalyst Inventions, to the extent required for Santhera and its Affiliates and its permitted subcontractors to conduct, or engage in, [***].

2.4 Grant to Santhera. Subject to the terms and conditions of this Agreement, Catalyst permits Santhera and its Affiliates and subcontractors to use those Catalyst trademarks, trade names, trade dress, copyright and artwork (if any) specified in writing by Catalyst to Santhera, solely for the purpose of Manufacturing and having Manufactured the Compound and Products for supply to Catalyst pursuant to this Agreement.

2.5 Sublicensing. Catalyst shall have the right to sublicense, through one or more tiers of sublicenses, the rights granted under the Exclusive License and the Manufacturing License (when Catalyst has the right to practice the Manufacturing License) to its Affiliates and to Third Parties (each such Third Party, a "Sublicensee") without Santhera's prior written consent; provided that Catalyst shall remain responsible for Catalyst's and any such Affiliate's and Sublicensee's compliance with all applicable obligations under this Agreement. Catalyst shall provide Santhera with an abstract of each sublicense agreement with any Sublicensee (which may have financial and other sensitive information redacted) in English, within [***] after execution of each sublicense agreement.

2.6 No Implied Licenses. Except as specifically set forth in this Agreement, neither Party shall acquire any license or other intellectual property interest, by implication or otherwise, in any Know-How or other information disclosed to it by the other Party or under any Patent Rights, Know-How or other intellectual property rights Controlled by the other Party or its Affiliates.

2.7 Non-Compete During Term.

(a) During the Term, each Party shall not, and shall cause its Affiliates and permitted licensees or sublicensees with respect to the Compound or Products (in the case of Santhera) or Sublicensees (in the case of Catalyst), not to, engage (independently or for or with any Third Party) in Manufacturing, Developing or Commercializing any Competing Product in the Territory.

(b) Notwithstanding Section 2.7(a), if a Party undergoes a Change of Control with a Third Party (such Third Party, together with its Affiliates existing prior to such Change of Control, an "Acquirer"), the Acquirer shall have the right to engage in the Development, Manufacture, use and Commercialization of a Competing Product in the Territory and such conduct shall not constitute a breach by such Party of its obligations set forth in Section 2.7(a); provided that (i) such Acquirer Develops, Manufactures, uses and Commercializes the Competing Products in the Territory independently of the activities conducted pursuant to this Agreement and does not use any Licensed Intellectual Property or Confidential Information of the other Party in the conduct of such Development, Manufacture, use and Commercialization of the Competing Products in the Territory, and (ii) such Party and such Acquirer institute commercially reasonable technical and administrative procedures and safeguards designed to ensure that the requirement set forth in the foregoing clause (i) are met, including by creating firewalls to prevent disclosure of non-public plans or non-public information relating to the Licensed Intellectual Property or the Licensed Products or any Confidential Information of the other Party, to any personnel (including sales teams) of such Party, its Affiliates or such Acquirer (and its Affiliates), who are conducting any activities with such respect to the applicable Competing Product (except to senior management or executive personnel in the course of carrying out their management or executive functions).

(c) In the event that either Party or any of its Affiliates that is subject to the restrictions set forth in Section 2.7(a) merges or consolidates with, or otherwise acquires a Third Party (whether such transaction occurs by way of a sale of assets, merger, consolidation or similar transaction) (an "Acquired Party") that is engaged in the conduct of Development, Manufacture, use or Commercialization of a Competing Product in the Territory as of the closing of such transaction, such Party or its Affiliate shall not be deemed to be in breach of its obligations set forth in Section 2.7(a); provided that, by the end of the twelve (12) month period immediately following the closing of such transaction, such Party or its Affiliate or its Acquired Party has Divested, or caused to be Divested its interest in the Competing Product in the Territory, and provides the other Party with written confirmation of such Divestiture.

(d) As used herein, "Change of Control" means, with respect to a Party, a transaction with a Third Party(ies) involving, (i) the acquisition, merger or consolidation, directly or indirectly, of such Party, and, immediately following the consummation of such transaction, the shareholders or other owners of such, immediately prior thereto hold, directly or indirectly, as applicable, shares of capital stock of the surviving company representing less than fifty percent (50.0%) of the outstanding shares of such surviving or continuing company, (ii) the sale of all or substantially all of the assets or business of such, or (iii) a Person, or group of Persons acting in concert, acquire more than fifty percent (50.0%) of the voting equity securities or management control of such Party.

(e) As used herein, "Divestiture" means, with respect to a Competing Product, (a) the divestiture of such Competing Product through (i) an outright sale or assignment of all material rights in such Competing Product to a Third Party or (ii) an exclusive out-license to a Third Party of all development and commercialization rights with respect to such Competing Product, with the applicable Party having no further rights or role or ability to influence or exert control, directly or indirectly, with respect to such Competing Product or otherwise collaborate with any Third Party or perform or participate in any activities, with respect to the development or commercialization of such Competing Product or (b) the complete and permanent cessation of (i) all clinical development and commercialization activities with respect to such Competing Product. For clarity, the right of the applicable Party to receive royalties, milestones or other payments in connection with an acquirer's, assignee's or licensee's development or commercialization of a Competing Product pursuant to subsection (a) above, shall be permitted for any such Divestiture, provided that such payments are not consideration for activities performed by or on behalf of, or reimbursement for amounts incurred by, the applicable Party. When used as a verb, "Divest" and "Divested" means to cause a Divestiture.

2.8 Right of First Negotiation. Subject to the terms and conditions of this Agreement, Santhera hereby grants to Catalyst the right of first negotiation (the "ROFN") with respect to any transaction in which Santhera will grant a license or other right to the Compound or Products that includes the right to Commercialize the Compound or Products in the Field in Europe (or in any of Austria, Belgium, France, Germany, Italy, Luxembourg, the Netherlands, Spain or the United Kingdom (the "Core European Markets")) and/or Japan (a "ROFN Transaction"). [***].

2.9 [***]

3. **Consideration**

3.1 Initial Payment. Catalyst shall pay to Santhera a non-refundable and non-creditable one-time initial payment in the amount of seventy-five million Dollars ($ 75,000,000) due within 10 (ten) Business Days of receipt of an invoice from Santhera following the Effective Date (the "Initial Payment").

3.2 Regulatory Milestones.

(a) Catalyst shall pay to Santhera a non-refundable and non-creditable one-time payment in the amount of twenty-six million Dollars ($ 26,000,000) upon Regulatory Approval by the FDA in the U.S. of an NDA for the Product for the Initial Indication. [***].

(b) With respect to each of the first three (3) Additional Indications, [***] for the Product, but not in excess of three (3), regardless of the actual number of Additional Indications or Products Developed and Commercialized in the Territory, Catalyst shall pay Santhera the following [***].

(c) Irrespective of any milestone obligations of Santhera [***]. Catalyst shall also pay to Santhera, in addition, a non-refundable and non-creditable one-time payment in the amount of ten million Dollars ($ 10,000,000) upon Regulatory Approval by the FDA in the U.S. of an NDA for the Product for the Initial Indication. [***].

(d) With respect to the milestone payments due under Section 3.2(a), Santhera shall provide notice to Catalyst of the achievement of such milestone event, shall issue an invoice to Catalyst for the corresponding milestone payment, and shall provide Catalyst with a copy of the invoice received by Santhera from ReveraGen for the corresponding milestone payment. With respect to the milestone payments due under Section 3.2(b), Catalyst shall provide notice to Santhera of the achievement of such milestone event within [***] of the occurrence of the relevant event, and thereafter Santhera shall invoice Catalyst for the applicable milestone payment and shall provide Catalyst with a copy of the invoice received by Santhera from ReveraGen for the corresponding milestone payment. With respect to the milestone payments due under Section 3.2(c), Santhera shall provide notice to Catalyst of the achievement of such milestone event and shall issue an invoice to Catalyst for the corresponding milestone payment. The milestone payments under this Section 3.2 shall be due within [***] after receipt by Catalyst of the corresponding invoice for such milestone payment issued by Santhera or, with respect to the milestone payments due under Section 3.2(a) and Section 3.2(b), [***] after the date of the corresponding invoice for such milestone payment issued to Santhera by ReveraGen (as reflected in the copy of such invoice provided to Catalyst by Santhera), if earlier.

3.3 Sales-Based Milestones. Catalyst shall pay to Santhera the non-refundable, non-creditable amounts set forth in the table below if the applicable amount of Net Sales of all Products in the Territory in a single Calendar Year reach one or more of the Net Sales threshold levels set forth below. Catalyst shall notify Santhera no later than [***] after the end of a Calendar Year during which any sales-based milestone event below was achieved. Each such sales-based milestone payment shall only be payable upon first achievement of such milestone and no amounts shall be due for subsequent or repeated achievement of sales-based milestones. In the event that in a given Calendar Year more than one Net Sales threshold level below is achieved, Catalyst shall pay to Santhera a separate, additional milestone payment with respect to each such threshold level that is achieved in such Calendar Year. Following notice by Catalyst of the achievement of a milestone event set forth in this Section 3.3 (Sales-Based Milestones), Santhera will invoice Catalyst for the applicable milestone payment(s). Each such milestone payment shall be due within [***] after receipt by Catalyst of the corresponding invoice for such milestone payment issued by Santhera.

Event	Milestone Payment Amount
(1) Net Sales of Product in the Territory in the Field in a single Calendar Year amounting to one hundred million Dollars ($ 100,000,000) or more	[***]
(2) Net Sales of Product in the Territory in the Field in a single Calendar Year amounting to one hundred seventy-five million Dollars ($ 175,000,000) or more	[***]
(3) Net Sales of Product in the Territory in the Field in a single Calendar Year amounting to two-hundred million Dollars ($ 200,000,000) or more	[***]

(4) Net Sales of Product in the Territory in the Field in a single Calendar Year amounting to four hundred fifty million Dollars ($ 450,000,000) or more	[***]
(5) Net Sales of Product in the Territory in the Field in a single Calendar Year amounting to six hundred million Dollars ($ 600,000,000) or more	[***]

[***]

3.4 Royalties.

(a) Catalyst shall pay Santhera a Royalty, on a country-by-country basis in the Territory, on the Net Sales during the Royalty Term, as follows:

Net Sales	Marginal Royalty Rate as a Percentage of Net Sales
For Net Sales of Product in the Territory in the Field during a single Calendar Year equal to or less than two hundred fifty million Dollars ($ 250,000,000)	[***]
For Net Sales of Product in the Territory in the Field during a single Calendar Year greater than two hundred fifty million Dollars ($ 250,000,000), but less than or equal to five hundred million Dollars ($ 500,000,000)	[***]
For Net Sales of Product in the Territory in the Field during a single Calendar Year greater than five hundred million Dollars ($ 500,000,000), but less than or equal to seven hundred fifty million Dollars ($ 750,000,000)	[***]

For Net Sales of Product in the Territory in the Field during a single Calendar Year greater than seven hundred fifty million Dollars ($ 750,000,000), but less than or equal to one billion Dollars ($ 1,000,000,000)	[***]
For Net Sales of Product in the Territory in the Field during a single Calendar Year greater than one billion Dollars ($ 1,000,000,000), but less than or equal to two billion Dollars ($ 2,000,000,000)	[***]
For Net Sales of Product in the Territory in the Field during a single Calendar Year greater than two billion Dollars ($ 2,000,000,000)	[***]

[***]

(b) In addition to the Royalty payable under Section 3.4(a), Catalyst shall pay Santhera a Royalty, on a country-by-country basis in the Territory, on the Net Sales during the Royalty Term, as follows (it being clarified that the Royalty obligation under this Section 3.4(b) is independent of Royalties payable by Santhera to ReveraGen or Idorsia [***];

(i) For Net Sales for the Initial Indication only, during the Royalty Term prior to [***] only:

Net Sales	Marginal Royalty Rate as a Percentage of Net Sales
For Net Sales of Product in the Territory for the Initial Indication only during a single Calendar Year equal to or less than one-hundred million Dollars ($ 100,000,000)	[***]

(ii) Additionally, for Net Sales of Product in the Territory for the Initial Indication during the Royalty Term:

Net Sales	Marginal Royalty Rate as a Percentage of Net Sales
For Net Sales of Product in the Territory for the Initial Indication only during a Calendar Year greater than one-hundred million Dollars ($ 100,000,000), but less than or equal to two-hundred million Dollars ($200,000,000)	[***]

For Net Sales of Product in the Territory for the Initial Indication only during a Calendar Year greater than two hundred million Dollars ($ 200,000,000), but less than or equal to three hundred million Dollars ($ 300,000,000)	[***]
For Net Sales of Product in the Territory for the Initial Indication only during a Calendar Year greater than three hundred million Dollars ($ 300,000,000)	[***]

(iii) Additionally, for Net Sales of Product in the Territory for the Additional Indications during the Royalty Term:

Net Sales	Marginal Royalty Rate as a Percentage of Net Sales
For Net Sales of Product in the Territory for Additional Indications during a Calendar Year greater than one hundred fifty million Dollars ($ 150,000,000), but less than or equal to two hundred million Dollars ($ 200,000,000)	[***]
For Net Sales of Product in the Territory for the For Net Sales of Product in the Territory for Additional Indications during a Calendar Year greater than two hundred million Dollars ($ 200,000,000), but less than or equal to three hundred million Dollars ($ 300,000,000)	[***]
For Net Sales of Product in the Territory for the For Net Sales of Product in the Territory for Additional Indications during a Calendar Year greater than three hundred million Dollars ($ 300,000,000)	[***]

[***]

(c) All Royalties due to Santhera under this Agreement will be paid quarterly in Dollars, on a country-by-country basis in the Territory, within [***] after receipt by Catalyst of the valid Royalty invoice issued by Santhera for the corresponding Calendar Quarter as set forth in Section 3.9 below.

3.5 Compulsory Licenses; Generic Competition.

(a) Should a Third Party in any country in the Territory under the right of a compulsory license granted, or ordered to be granted, by a competent Governmental Authority, Manufacture, use or sell any Product, after first notifying Santhera in writing with respect to the circumstances surrounding such compulsory license, Catalyst may reduce the Royalty rate on Net Sales of the applicable Product in such country to a rate equal to that payable by said Third Party to Catalyst as the consideration for the compulsory license or licenses, as the case may be. Royalties received by Catalyst from holders of compulsory licenses shall be treated as Net Sales.

(b) Upon the first commercial sale of a Generic Version of a Product in a particular country for a given indication in the Territory the following shall apply: if the aggregate unit sales of all Generic Version(s) in such country for a given indication over a period of two (2) consecutive Calendar Quarters ("Market Share Period") do not exceed thirty-three percent (33.0%) of the sum total unit sales of such Product and all Generic Version(s) (i.e., based on unit volume market share) in such country for such indication during such Market Share Period, then beginning in the first Calendar Quarter after such Market Share Period, the royalty rates under Section 3.4 with respect to Net Sales of such Product for the pertinent indication in such country shall be reduced by fifty percent (50.0%) for the remainder of the applicable Royalty Term for such Product (and indication as relevant). If the aggregate unit sales of all Genetic Version(s) in such country for a given indication over any Market Share Period exceed thirty-three percent (33.0%) of the sum total unit sales of such Product and all Generic Version(s) in such country for such indication, calculated as provided above, then the Royalty Term for such Product in such country shall terminate for such indication. Such unit sales volume will be based upon IQVIA or other available data. If such volume data is not available for a given country in the Territory, then the Parties will use another mutually agreed upon method to determine the unit volume market share in such country. As necessary, appropriate payment adjustments or true-ups shall be made in the case, for example, where there is a delay in the availability of the applicable IQVIA or other volume data.

3.6 Sales of Combination Products. For clarity, the right to sell a Combination Product, as contemplated in this Agreement, shall not imply any right of Catalyst under any Licensed Intellectual Property to make, use or sell any active pharmaceutical ingredient other than the Compound. In the event that Catalyst, its Affiliates, or their respective Sublicensees sell a Combination Product in a given country (for a single price) that contains a Compound in combination with any other product, active ingredient or proprietary delivery system that is not a Compound (a "Combination Product"):

(a) Where both the Product containing the Compound as the sole active ingredient (a "Single Ingredient Product") and the other product, active ingredient, or proprietary delivery system are sold separately in that country, in finished form, in the same dosage and dosage form, during the applicable Calendar Quarter, the Net Sales of the Combination Product, for the purposes of determining Royalty payments, shall be determined by multiplying the Net Sales of the Combination Product by the fraction A/(A+B) where A is the average sales price in the particular country of the Single Ingredient Product when sold separately in finished form, in the same dosage and dosage form, and B is the average sales price in that country of the other product(s) or delivery system sold separately in finished form, in the same dosage and dosage form;

(b) Where the Single Ingredient Product is sold separately in finished form, in the same dosage and dosage form, in a particular country, but the relevant other product(s) or delivery system is not sold separately, in the same dosage and dosage form, in such country during the applicable Royalty reporting period, then Net Sales shall be determined by multiplying the Net Sales of the Combination Product by the fraction (A/C), where A is the average sales price of the Single Ingredient Product in such country when sold separately in finished form, in the same dosage and dosage form, and C equals the average selling price of the Combination Product for the applicable country;

(c) Where the Single Ingredient Product is not sold separately in finished form, in the same dosage and dosage form as relevant, in a particular country, but the relevant other product(s) or delivery system are sold separately, in the same dosage and dosage form as relevant, in such country during the applicable Royalty reporting period, then Net Sales shall be determined by multiplying the Net Sales of the Combination Product by the fraction (C-B/C), where B is the average sales price in such country of the other product(s) or delivery system sold separately in finished form, in the same dosage and dosage form, and C equals the average selling price of the Combination Product for the applicable country;

(d) If Net Sales of the Single Ingredient Product when included in a Combination Product cannot be determined using the methods above, then the appropriate multiplier shall be based upon the relative value, to the end-user, of the Single Ingredient Product in the Combination Product and the other product(s), active ingredient or delivery system in the Combination Product as negotiated by the Parties in good faith or, if the Parties cannot agree upon such relative value and corresponding multiplier, as determined by a reputable, independent Third Party expert selected by agreement of the Parties (or if the Parties are unable to agree on such expert, each Party shall select an independent expert and both Parties' experts shall select the Third Party expert who shall make the determination).

(e) The foregoing analysis shall be conducted in the U.S., as reasonably required to compare fair market values of the relevant Combination Product components. For each country in the country in the Territory other than the U.S., the determination shall be made by Catalyst in good faith on the basis of the determination that is used in the U.S.

3.7 [***]

3.8 Multiple Royalties. No multiple Royalties shall be due hereunder because any Product is covered by more than one Valid Claim.

3.9 Reporting of Royalties. Until the reporting date following expiration of the obligation of Catalyst to pay Royalties in respect of any Calendar Quarter in which Royalties accrue, beginning with the First Commercial Sale of any Product by Catalyst, its Affiliates or their Sublicensee, Catalyst shall deliver to Santhera quarterly written reports for the preceding Calendar Quarter for each Product showing the Net Sales of such Product subject to Royalty payments sold by or on behalf of Catalyst, its Affiliates and/or Sublicensees during the reporting period on a country-by-country basis in Dollars and local currency. For the avoidance of doubt, Catalyst shall not be obligated to report in respect of any Product in any country where the Royalty Term has expired or been terminated. Such reports will also include detailed information regarding Gross Sales, Sales Deductions and Allowances, Net Sales of Product on which Royalties are paid, and amount of Royalties due or, if no Royalties are due, a statement that no Royalties are due for such Product. Where the Net Sales are being converted from a currency other than Dollars, Catalyst shall translate the amount of such Net Sales at the foreign exchange rates used for the preparation of the consolidated financial statements of Catalyst under GAAP for the same period and consistently applied. Royalty reports shall be due [***] from the end of the respective Calendar Quarter. Upon receipt of such royalty report, Santhera will issue a Royalty invoice which is due and payable by Catalyst [***] from the receipt of such invoice.

3.10 Payments. All payments required to be made under this Agreement are to be paid in Dollars. For conversion of foreign currency to Dollars for the purpose of making any payment hereunder, which is not a Royalty payment (the details for which are set forth in Section 3.9 above), the conversion rate shall be the exchange rate used for the preparation of the consolidated financial statements of Catalyst under GAAP for the day on which such payment obligation accrued. All payments to Santhera shall be made by wire transfer to Santhera's account in accordance with the following instructions (unless amended by written notice):

UBS Switzerland AG
P.O. Box
8098 Zurich
Switzerland

[***]

3.11 Late Payments. In the event that any invoiced amount hereunder is not made when due, such outstanding payment shall accrue interest at an annual rate of five percent (5.0%), computed from the date such payment was due until the date the payment was made.

3.12 Taxes.

(a) Any withholding taxes required on any payments to Santhera shall be borne by Santhera. Catalyst is responsible for deducting all deductions or withholding taxes or similar Taxes (if any) under the applicable tax law from the sums otherwise payable by it hereunder and paying the Taxes to the proper tax authorities within the time required by Applicable Law. For the avoidance of doubt, Catalyst's remittance of such Taxes to the proper tax authorities shall constitute full satisfaction of the applicable payment due to Santhera. Any available receipts reflecting the payment of withheld taxes shall be provided to Santhera. Available receipts for withholdings from any payments shall be transmitted to Santhera. The Parties agree to cooperate with one another and use reasonable efforts to avoid or reduce tax withholding or similar obligations, consistent with Applicable Laws, in respect of payments made by Catalyst to Santhera under this Agreement. Without limiting the generality of the foregoing, Santhera shall provide Catalyst any tax forms and other information that may be reasonably necessary in order for Catalyst to avoid withholding tax or to withhold tax at a reduced rate under an applicable bilateral income tax treaty. Santhera shall use reasonable efforts to provide any such tax forms to Catalyst at least [***] prior to the due date for any payment for which Santhera desires that Catalyst apply for an exemption of withholding tax, or in case of the Initial Payment at least [***] before the due date for payment. Each Party shall provide the other with reasonable assistance to enable the recovery, as permitted by Applicable Laws, of withholding taxes, value added taxes, or similar obligations resulting from payments made under this Agreement, such recovery to be for the benefit of the Party bearing such withholding tax, value added tax or similar obligations, and pursuant to an applicable bilateral income tax treaty.

(b) The amounts set forth herein for all payments made pursuant to this Agreement are exclusive of indirect taxes, including value added tax VAT surcharges and customs. If indirect taxes are chargeable in respect of any such payments, Catalyst shall pay such indirect taxes at the applicable rate in respect of such payments following receipt, where applicable, of an indirect taxes invoice in the appropriate form issued by Santhera in respect of those payments. The Parties shall issue invoices for all amounts payable under this Agreement consistent with indirect tax requirements and irrespective of whether the sums may be netted for settlement purposes. The Parties shall cooperate and use all reasonable efforts to obtain exemption, zero-rating, or other preferential treatment in respect of any indirect tax. Catalyst shall only be responsible for any indirect taxes that are not recoverable by Santhera taking all reasonable steps to recover such indirect taxes as may be practicable.

3.13 Audit Rights.

(a) Audit for Payment; Incorrect Payments. Upon at least [***] prior written notice, but not more frequently than once each Calendar Year, Santhera and the Originator (as third party beneficiary), each individually, shall have the right, at its own cost and expense except as provided hereinafter, for the purpose of verifying the accuracy of any payments required to be made to Santhera pursuant to this Agreement or any payments to be made to the Originator pursuant to the ReveraGen Agreement, to audit all such relevant records in the possession or under the control of Catalyst, its Affiliates and its permitted Sublicensees. Neither Santhera nor the Originator shall be entitled to audit any Calendar Quarter more than once. All audits shall be conducted during normal business hours reasonably acceptable to the Parties at the offices of Catalyst, its Affiliates or permitted Sublicensees in a manner as to not unnecessarily interfere with normal business activities, by an independent certified public accounting firm of internationally recognized standing reasonably acceptable to Catalyst, and no later than three (3) years after the end of the Calendar Quarter to which they pertain. Prior to the commencement of any such audit, the accounting firm conducting such audit for Santhera or the Originator shall enter into a confidentiality agreement with Catalyst. Such accounting firm shall disclose to Santhera and/or the Originator only the results of its audit, including the amount of any underpayment or overpayment. The accounting firm shall collaborate with Catalyst in clarifying potential discrepancies and provide a draft copy of its report for comments by Catalyst before issuance of its final report. The accounting firm shall provide copies of its final report to both Catalyst and Santhera. Catalyst shall pay Santhera the amount of any previous underpayment indicated by such audit within [***] of the date an audit report so concluding is provided to Catalyst, plus interest thereon at the rate of five percent (5.0%) per annum calculated based on the number of days elapsed from the date payment was originally due until the date payment is made. Santhera shall reimburse Catalyst the amount of any previous excess payment indicated by such audit within [***] of the date an audit report so concluding is provided to Santhera. Santhera shall bear the cost of such audit provided that in the event the audit indicates an aggregate underpayment to Santhera for any period in excess of five percent (5.0%), Catalyst shall bear the reasonable costs of such audit. The results of any such audit shall be considered Confidential Information of Catalyst subject to Section 11 (Confidentiality). Santhera shall not, and shall ensure that the Originator will not, disclose such Confidential Information to any Third Party (excluding the Originator as third party beneficiary) or use such Confidential Information for any purpose other than verifying the performance of Catalyst and the information provided by Catalyst to Santhera.

(b) Audit Relating Supply Price. Upon at least [***] prior written notice, but not more frequently than once each Calendar Year, Catalyst or its third party nominee shall have the right, at its own cost and expense except as provided hereinafter, during reasonable business hours reasonably acceptable to the Parties in a manner as to not unnecessarily interfere with Santhera's normal business activities, to inspect and audit the books and records of Santhera for the purpose of verifying information and documents pertaining to the proper calculation of the Supply Price. The audit requirements in Section 3.13(a) (Audit for Payment Reports; Incorrect Payments) shall apply, *mutatis mutandis* to each audit conducted in this Section 3.13(b) (Audit Relating to Supply Price).

3.14 Regulatory Filings. In the event that this Agreement is required to be filed or registered with any Governmental Authority in the Territory in accordance with Applicable Laws other than pursuant to Section 8 (Governmental Approvals) for the purpose of enabling the payments of upfront, milestones and any other payments between the Parties, or to exercise, enforce and enjoy all of the rights and obligations contained in this Agreement or any amendment thereto, Catalyst shall provide prior written notice to Santhera of such Regulatory Filing or registration requirement and cooperate in good faith with Santhera to coordinate such Regulatory Filing or registrations (and any redactions of commercial terms). Notwithstanding the foregoing, the terms of Section 11.2 (Confidentiality of Agreement) shall govern disclosures of this Agreement to any Securities Authority.

4. **Development; Regulatory Matters; Commercialization**

4.1 Development.

(a) Initial Indication Development. Santhera shall conduct and complete all Development, at its own costs and expenses, of the Product for the Initial Indication as required to obtain and maintain Regulatory Approval by the FDA in the U.S. of an NDA for the Product in the Initial Indication, including any and all Required Studies in the U.S. for the Initial Indication; provided that Catalyst shall conduct any Required Studies in the U.S. for the Initial Indication that are required to be conducted after the NDA Transfer Date at Santhera's costs and expenses, and Santhera shall reimburse all such costs and expenses to Catalyst within [***] of receipt of an invoice therefor from Catalyst. Catalyst shall be responsible for all other Development of the Product in the Territory for the Initial Indication, at its own cost and expense, including any Phase 4 Program Activities in the U.S. related to the Product for the Initial Indication subject to Section 4.1(d) (Use of Investment Proceeds).

(b) Additional Development. If either Party proposes to conduct additional Development of a Product in the Field beyond the Initial Indication Development performed pursuant to Section 4.1(a), including Development of Product for any Additional Indication or label expansion or modification ("Additional Development") for (a) the purpose of seeking Regulatory Approval both in and outside the Territory ("Global Additional Development") or (b) the purpose of seeking Regulatory Approval solely in the Territory ("Territory Additional Development"), then the proposing Party shall provide the other Party with a written proposal of such Additional Development (the "Additional Development Proposal"), including a synopsis of the Development activities related to such Additional Development, the potential role of the non-Proposing Party with respect to such Additional Development, the anticipated timeline for such Additional Development, the proposed clinical trial protocols or designs, if applicable, the estimated costs associated with such Additional Development, and, in the case of Global Additional Development, the proposed cost allocation between each Party's territory taking into account the respective value of such Development to each Party's territory (including, with respect to an Additional Indication, the anticipated market value of such Additional Indication using sales data provided by IQVIA or similar Third Party provider) ("Cost Allocation"). For clarity, Global Additional Development does not include any Additional Clinical Trial or other Development that is required solely by a Regulatory Authority or Applicable Laws for obtaining Regulatory Approval in one Party's territory and is not required by Regulatory Authorities or Applicable Laws for obtaining Regulatory Approvals both within and outside the Territory.

(i) Within thirty (30) days of receipt of an Additional Development Proposal, the JSC shall meet to review the Additional Development Proposal and to permit the non-proposing Party an opportunity to ask questions and request additional information from the proposing Party related to the Additional Development Proposal, including whether such Proposal is reasonably likely to have a material adverse effect on obtaining or maintaining Regulatory Approval of any Product or Commercializing any Product, in either case, in the non-proposing Party's territory. The non-proposing Party shall be given the opportunity to (a) comment on the Additional Development Proposal to ensure the study design for a Global Additional Development meets the regulatory requirements of respective Regulatory Authorities, and (b) seek appropriate scientific advice from relevant Regulatory Authorities to ensure the results of the Additional Development Proposal would be sufficient for purposes of a Regulatory Filing in relevant territories.

(ii) If the Parties mutually agree to pursue Global Additional Development, including mutual agreement on the Cost Allocation, then the Parties shall prepare and submit a development plan and budget for such mutually agreed Global Additional Development for review and approval by the JSC (with neither Party having final decision-making authority). Such development plan shall include an allocation between the Parties of responsibilities with respect to such Global Additional Development and an allocation of the Global Additional Development costs (based on the mutually agreed Cost Allocation) to be paid by the Parties subject to Section 4.1(d) (Use of Investment Proceeds).

(iii) If the Parties do not mutually agree to pursue Global Additional Development, Santhera shall have the sole right to pursue such Global Additional Development, at its own cost and expense, for the purpose of obtaining Regulatory Approval and Commercializing the Product outside the Territory. If Santhera elects to pursue such Global Additional Development pursuant to this clause (iii), it shall provide Development reports and data to Catalyst related to such Global Additional Development in accordance with Section 4.1(c) (Summary Development Reports), and Catalyst shall have the right, at any time prior to NDA filing in the U.S. with respect to such Global Additional Development, to opt-in with respect to such Global Additional Development upon payment to Santhera of an amount, to be agreed upon by each Party after good faith negotiations, to compensate Santhera for conducting such Global Additional Development at risk (and any costs incurred in connection with such Global Additional Development after such opt-in shall be shared by the Parties in accordance with an agreed Cost Allocation). For clarity, Santhera shall only have the right to pursue Global Additional Development for the purpose of obtaining Regulatory Approval and Commercializing the Product outside the Territory, and Santhera shall not have the right to seek to obtain Regulatory Approval of the Product for any Additional Indication or label expansion or modification in the Territory. For clarity, Catalyst shall not have the right to pursue any Global Additional Development except pursuant to a development plan as provided in Section 4.1(b)(ii).

(iv) Catalyst shall have the sole right to conduct Territory Additional Development at its cost and expense; provided that Santhera shall have the right, at any time prior to NDA filing in the U.S. with respect to such Territory Additional Development, to opt-in to share costs of such Territory Additional Development upon payment to Catalyst of an amount, to be agreed upon by each Party after good faith negotiations, to compensate Catalyst for conducting such Territory Additional Development at risk (and any costs incurred in connection with such Territory Additional Development after such opt-in shall be shared by the Parties in accordance with an agreed Cost Allocation). If Catalyst plans to conduct Territory Additional Development, it shall prepare a development plan for such Territory Additional Development and shall provide such development plan to the JSC for review and discussion. Catalyst shall conduct such Territory Additional Development in accordance with such development plan and shall provide Development reports related to such Additional Development in accordance with Section 4.1(c) (Summary Development Reports). For clarity, Santhera shall not have the right to pursue any Territory Additional Development.

(v) With respect to any Global Additional Development that the Parties do not mutually agree to pursue and that is conducted solely by Santhera, and with respect to any Territory Additional Development conducted by Catalyst, unless and until the non-conducting Party opts-in and shares costs as provided above, the non-conducting Party shall not have the right to use or reference the data and other Know-How generated from such Development conducted by the other Party, except (a) to satisfy any reporting obligations with Regulatory Authorities in the non-conducting Party's territory or (b) to obtain or maintain Regulatory Approvals of the Product in the non-conducting Party's Territory for the Initial Indication or for any Additional Indication the Parties have mutually agreed to pursue or that Catalyst has pursued as Territory Additional Development.

(vi) Nothing in this Agreement will obligate either Party to agree to conduct or participate in any Additional Development, which agreement may be withheld in each Party's sole discretion. The Parties may also agree to make any Additional Development dependent on a successful renegotiation of existing milestone obligations to a lower amount.

(vii) Santhera may, at its sole discretion and sole cost and expense, perform Additional Clinical Trials, but shall have no obligation to do so. If Santhera (or its Affiliate or licensee) conducts any Additional Clinical Trials, Santhera shall comply with the terms of Section 4.1(c) (Summary Development Reports) with respect such Additional Clinical Trials. To the extent such Additional Clinical Trials have the potential to support the Commercialization of the Product in the Territory, the Parties may separately agree in writing on a contribution by Catalyst to the costs and expenses of such Additional Clinical Trials.

(c) Summary Development Reports. At each regularly scheduled meeting of the JSC, each Party shall provide an update (by means of a slide presentation or otherwise) summarizing its Development activities for the Products, including the results of such activities and the status of each pending and proposed Regulatory Filing, since the last such update. In addition, after the completion of any clinical trial or other study of the Product, the Party responsible for the conduct of such clinical trial or study shall promptly provide the other Party (but in no event more than [***] following receipt) with top-line results of such clinical trial or study. Further, each Party will promptly provide written notice to the other Party, through the JSC, of any significant Development events (*e.g.*, clinical trial initiation or completion, clinical holds, receipt of Regulatory Approvals) that the reporting Party reasonably believes may affect the Development or Commercialization activities of the Product in the other Party's territory or otherwise may be of interest to the other Party.

(d) Use of Investment Proceeds. Santhera will receive equity investment proceeds from Catalyst pursuant to the Investment Agreement (the "Investment Funds"). The Parties agree that the Investment Funds shall be used solely to fund [***].

4.2 Regulatory Approvals.

(a) Santhera shall seek and use Commercially Reasonable Efforts to obtain Regulatory Approval (a) by the FDA in the U.S. of the NDA for the Product for the Initial Indication at its costs and expense, and (b) by the relevant Regulatory Authority in any relevant jurisdiction to the extent required for Manufacturing the Product for use in the Territory in the Initial Indication at its costs and expense.

(b) Catalyst, in its sole discretion, may seek and obtain Regulatory Approval in the Territory for the Product for any and all Additional Indications and for any label expansion, extension or modification (e.g., for sub-populations (e.g., age, gender) or alternative dosing regimens or dosing strengths).

(c) Santhera shall be the applicant and owner of the NDA in the U.S. for the Product for the Initial Indication (the "Initial Indication NDA"). Prior to receipt of Regulatory Approval by the FDA in the U.S. of the Initial Indication NDA, the Parties shall collaborate and work closely together, through the JSC (or any regulatory subcommittee or working team to which the JSC may delegate such authority), to communicate with and coordinate responses to questions, comments and other correspondence from the FDA regarding the Initial Indication NDA, and Catalyst shall have the right to attend (as an observer) all meetings with the FDA regarding the Initial Indication NDA. As promptly as practicable, but in any event within [***], after receipt of Regulatory Approval by the FDA of the Initial Indication NDA, Santhera shall transfer the Initial Indication NDA to Catalyst on a date to be agreed by the Parties (the "NDA Transfer Date"). Santhera shall execute all documents and take all actions as are necessary or reasonably requested by Catalyst to transfer and vest title to Catalyst in the Initial Indication NDA on the NDA Transfer Date and, unless agreed otherwise by the Parties, to transfer and vest title to Catalyst in all other Regulatory Filings for the Compound or Product in the Territory (including any INDs) owned or controlled by Santhera or any of its Affiliates as of the NDA Transfer Date.

(d) Following the NDA Transfer Date, Catalyst (or its Affiliate or Sublicensee) shall be the holder of and shall own all Regulatory Filings, including INDs, NDAs and Regulatory Approvals, for the Products in the Territory in the name of Catalyst (or its Affiliate or Sublicensee, as applicable).

(e) Following the NDA Transfer Date, Santhera shall provide support to Catalyst as regards interactions between Catalyst and any Regulatory Authority in the Territory. Prior to the NDA Transfer Date, and without limiting anything in Section 4.2(c), Catalyst shall have the right to assist and provide input as regards interactions with the FDA and other Regulatory Authorities in the Territory, and Catalyst shall have final decision-making authority regarding approval of final Product label negotiations in the Territory, such approval not to be unreasonably withheld or delayed.

(f) Subject to Section 4.1(a), following the NDA Transfer Date with respect to the Initial Indication NDA, and with respect to all other Regulatory Approvals in the Territory for the Product, Catalyst shall bear any costs and expenses to obtain and maintain any granted Regulatory Approvals for the Product in the Territory.

4.3 Right of Reference. Subject to Section 4.1(b)(v), each Party hereby grants to the other Party, its Affiliates and its Sublicensees the free and perpetual right to reference all (a) toxicology, safety, CMC and/or clinical trial information and data, and (b) Regulatory Filings pertaining to the Product in the Field submitted by or on behalf of such Party and/or its Affiliates and/or Sublicensees (the "Right of Reference"). The grantee-Party (and its Affiliates and licensees and Sublicensees) may use the Right of Reference solely for the purposes of seeking, obtaining and maintaining Regulatory Approvals and Commercializing Products in the grantee-Party's territory and otherwise performing its obligations under this Agreement. Each grantor-Party agrees to provide an appropriate letter of authorization upon request of the other Party to enable use of the Right of Reference, where necessary.

4.4 Pharmacovigilance and Safety.

(a) Pharmacovigilance Agreement. At least one (1) month (or such other time period agreed by the Parties) in advance of any Regulatory Approval in any country in the Territory, the Parties (under the guidance of their respective pharmacovigilance departments, or equivalent thereof) will enter into a written pharmacovigilance agreement setting forth the worldwide pharmacovigilance procedures for and responsibilities of the Parties with respect to the Compound and Products, such as safety data sharing, adverse events reporting and safety signal and risk management (the "Pharmacovigilance Agreement"), which agreement shall be amended by the Parties from time to time as necessary to comply with any changes in Applicable Laws or guidance received from Regulatory Authorities. Such Pharmacovigilance Agreement will provide for the receipt, investigation, recording, communication, and exchange by the Parties of information that a Party becomes aware of in the Territory and globally concerning adverse events in or involving a research subject or, in the case of non-clinical studies, an animal in a toxicology study, and the seriousness thereof, and other safety data, including any such information and other safety data received by either Party from a Third Party (subject to receipt of any required consents from such Third Party). All procedures and responsibilities set forth in the Pharmacovigilance Agreement shall be in accordance with, and enable the Parties to fulfill, local, national and international regulatory reporting obligations under Applicable Laws (including to the extent applicable, obligations contained in ICH guidelines). Subject to compliance with Applicable Law, each Party hereby agrees to comply with its respective obligations under the Pharmacovigilance Agreement (as the Parties may agree to modify it from time to time) and to cause its Affiliates and licensees and Sublicensees (as applicable) to comply with such obligations. It is understood that each Party and its Affiliates and licensees and Sublicensees (as applicable) will have the right to disclose safety data if such disclosure is reasonably necessary to comply with Applicable Laws and Regulatory Authority regulations and requirements in its respective territory. To the extent there is any inconsistency between the terms of the Pharmacovigilance Agreement, once executed, and the terms of this Agreement, the terms of the Pharmacovigilance Agreement shall govern.

(b) The Pharmacovigilance Agreement will include provisions regarding the establishment of a global safety database for the Products that will be owned and maintained by Santhera at its sole cost and expense. Santhera will ensure that each Party, its Affiliates, licensees and Sublicensees are able to access the data, if necessary indirectly, from the global safety database in order to meet legal and regulatory obligations. Santhera shall be responsible, at its cost and expense, for (a) pharmacovigilance with respect to the Products outside the Territory (and in the Territory until the NDA Transfer Date) and (b) for the collection, assessment, and safety reporting of individual case safety reports to Regulatory Authorities, and generating aggregated report(s), risk management plan and responses to any requests from Regulatory Authorities, with respect to Products outside the Territory (and in the Territory until the NDA Transfer Date), and for sharing such information with Catalyst for its compliance with regulatory requirements in the Territory, in each case subject to and in compliance with Applicable Law and the Pharmacovigilance Agreement.

(c) Following the NDA Transfer Date, Catalyst shall be responsible, at its cost and expense, for pharmacovigilance with respect to the Products in the Territory and shall be responsible for the collection, assessment, and safety reporting of individual case safety reports to Regulatory Authorities, and submitting aggregated report(s), risk management plan and responses to any requests from Regulatory Authorities, with respect to Products in the Territory, and for sharing such information with Santhera for its compliance with regulatory requirements outside the Territory, in each case subject to and in compliance with Applicable Law and the Pharmacovigilance Agreement. Subject to the foregoing, in the Territory following the NDA Transfer Date, Catalyst, in collaboration with Santhera, shall be responsible for local medical surveillance, risk management, medical literature review and monitoring within the Territory, and responses to the appropriate Regulatory Authorities within the Territory. For purposes of Catalyst's compliance with regulatory requirements, Santhera shall support Catalyst by providing information, such as surveillance and literature search information, reasonably requested by Catalyst.

4.5 Exchange of Data in Compliance with Applicable Law. Each Party shall ensure that the exchange of data under this Agreement shall comply with Applicable Laws, including any applicable legislation on data protection. To the extent necessary, the Parties shall enter into separate agreements covering relevant aspects of the data exchange and the further processing of such data.

4.6 Commercialization Diligence. Catalyst shall have the exclusive right to Commercialize the Product at its costs throughout the entire Territory, itself or through or with one or more Affiliates and/or permitted Sublicensees, and shall use Commercially Reasonable Efforts to Commercialize the Product throughout the entire Territory. Catalyst shall, at its own costs and expenses, perform all commercial launch readiness and launch activities, including market development, liaising with patient advocacy groups, key opinion leader development, market access strategy, market research, pricing research activities for the Licensed Product. Furthermore, Catalyst shall provide, upon request, senior-level strategic guidance, advice and assistance to Santhera in optimizing the global (i.e. in and outside Territory) launch of the Product for the Initial Indication, provided that Santhera shall not be obligated to follow any recommendations of Catalyst as regards the Commercialization outside the Territory. Catalyst shall send Santhera on a semi-annual basis, a confidential written report reasonably summarizing Catalyst's Commercialization activities concerning the Product in the Territory during the previous period, including (a) the core promotional claims, (b) samples of physical or digital marketing materials and (c) the medical information used by Catalyst in communication regarding the Product with relevant stakeholders (including health care professionals, patients, patient organizations, and payors) in the Territory. If at any time Santhera has a reasonable basis to believe that Catalyst is in breach of its Commercialization diligence obligations under this Section 4.6 (Commercialization Diligence), then Santhera may so notify Catalyst, specifying the basis for its belief, and, without limitation to any other right or remedy available to Santhera hereunder, at Santhera's request, the Parties shall meet within [***] after such notice to discuss in good faith Santhera's concerns and Catalyst's Commercialization plans in the Territory.

4.7 Commercialization and Compliance with Agreement and Applicable Laws. Catalyst shall, and shall cause its Affiliates or permitted Sublicensees to, comply with this Agreement and all Applicable Laws with respect to the Commercialization of Products. While the Product is sold under the same Trademark in and outside of the Territory, the Parties shall reasonably align, via the JSC, on the use of such Trademark in messaging relating to the Product and regarding other cross-border activities (e.g. international fairs, social media). Without limitation to the foregoing, Catalyst shall in all material respects conform its practices and procedures relating to the Commercialization of the Products and to educating the medical community in the Territory with respect to the Products to any applicable industry association regulations, policies, and guidelines, as the same may be amended from time to time, and Applicable Laws. If a Party believes that the other Party is taking or intends to take any action with respect to a Product that could reasonably be expected to have a material adverse effect on obtaining or maintaining Regulatory Approval of any Product in such Party's territory or on Commercialization of any Product in such Party's territory, then such Party may bring the matter to the attention of the JSC and the Parties shall discuss in good faith to resolve such concern.

4.8 No Commercialization outside of a Party's Territory. To the extent such restriction is permitted by Applicable Laws, each Party shall not, and shall cause its Affiliates and licensees and permitted Sublicensees not to, (a) actively sell the Products to Third Parties in the other Party's territory, or (b) sell the Products to, or otherwise support, any Third Parties in such Party's territory for the purpose of distributing or reselling the Products in the other Party's Territory.

5. **Joint Steering Committee**

5.1 Establishment of Joint Steering Committee. Within [***] after the Effective Date, Santhera and Catalyst will assemble a joint steering committee (the "JSC"). Initially, the JSC will be composed of at least four representatives of each Party, with an equal number appointed by each of Santhera and Catalyst (unless the Parties agree otherwise). Each Party will provide a list of its representatives to the other Party within [***] after the Effective Date. Each Party will promptly notify the other Party in writing of any change in its appointed representatives. Each Party may invite its employees and its Affiliates' employees and consultants to attend meetings of the JSC who are bound to obligations of confidentiality, non-use, and assignment of inventions similar to those of that Party's members of the JSC. Promptly following establishment of the JSC, the JSC representatives shall agree upon a charter that will include details regarding the operation of the JSC consistent with this Section 5 (Joint Steering Committee). The JSC may create and delegate certain tasks to subcommittees or working teams (e.g. regulatory subcommittee, safety subcommittee).

5.2 Meetings. The JSC will hold its first meeting promptly, but in any event within [***], after the Effective Date. While in existence, the JSC will meet at least quarterly until the end of the First Commercial Sale Year and thereafter on a semi-annual basis by audio or video teleconference or in person, to be agreed by the Parties. At least one meeting per Calendar Year shall be in person, alternating between a location in Switzerland and in the U.S. (east coast). Each Party will bear its own costs relating to any JSC meeting. For as long as JSC meetings are being held quarterly, such meetings may be scheduled with at least [***] prior notice; for all other JSC meetings, the Parties will endeavor to schedule meetings at least [***] in advance or as necessary to resolve any matters requiring a joint decision.

5.3 Responsibilities. The duties of the JSC will include (i) exchanging information regarding Development and Commercialization in and outside of the Territory, (ii) reviewing any Additional Development Proposals, determining whether to pursue Global Additional Development, and reviewing and approving development plans (including budgets) and Cost Allocations pertaining to Global Additional Development and, if applicable, Cost Allocations pertaining to Territory Additional Development, (iii) agreeing upon schedules for the transfer of Know-How as provided in Sections 2.2 and 6.3, and (iv) discussing and monitoring for the Territory the following matters:

(a) Development, approval by a Regulatory Authority and maintenance of Regulatory Approval as well as life cycle related development activities,

(b) Manufacturing by Santhera for commercial supply of Product until the Manufacturing Transfer Date;

(c) Commercialization of the Product and its related activities, including product strategy, alignment on key global activities, marketing and medical activities,

(d) any matters in relation to the Licensed Intellectual Property,

(e) other matters including monetary disputes.

5.4 Decision-making. If the Parties disagree in the JSC on any issues related to the matters set forth in Section 5.3(iii), either Party may submit such disagreement for discussion by the CEOs of the Parties (it being understood that such matters are subject only to discussion, and not agreement, by the JSC) and, in that event, the CEOs shall meet in person or by videoconference to discuss such matters as promptly as practicable thereafter. If the Parties are unable to reach agreement in the JSC on any matters forth in Section 5.3(ii) (it being understood that the matters in Section forth in 5.3(ii) are the only matters that are subject to agreement by the JSC), either Party may submit such dispute for joint resolution by the CEOs of the Parties as follows:

(a) The submitting Party shall provide notice to the other Party of its decision to submit such dispute for resolution by the CEOs pursuant to this Section. Within [***] as of receipt of such notice, the CEOs shall set a date for their meeting or videoconference, which date shall be no more than [***] of such written notice. Each Party shall bear its own costs and expenses in connection with the CEO discussions.

(b) If the CEOs of the Parties are unable to agree on a resolution, or either Party concludes that the matter will not be so resolved by the CEOs after the notice, then such development plan and budget pertaining to Global Additional Development shall not be approved and the terms of Section 4.1(b)(iii) shall apply, and if a Party believes that the other Party is taking or intends to take any action with respect to a Product that could reasonably be expected to have a material adverse effect on obtaining or maintaining Regulatory Approval of any Product in such Party's territory or on Commercialization of any Product in such Party's territory, then the Parties shall discuss such considerations in good faith in trying to reach a resolution.

For clarity, although the JSC will discuss and monitor the matters set forth in Section 5.3(iv): (A) the terms of Section 6 (Manufacture and Supply) shall govern with respect to matters in Section 5.3(b); (B) the terms of Section 7 (Intellectual Property) shall govern with respect to matters in Section 5.3(d); (C) Catalyst shall have all rights, responsibilities and sole decision-making authority with respect to matters in Sections 5.3(a) and 5.3(c), subject to the terms of Section 4 (Development; Regulatory Matters; Commercialization); and (D) the terms of Section 13 (Governing Law; Dispute Resolution) shall govern with respect to matters in Section 5.3(e).

6. **Manufacture and Supply**

6.1 Manufacture and Supply. Until the Manufacturing Transfer Date and subject to the terms and conditions set forth herein, Catalyst shall purchase all of its requirements for Product Exclusively from Santhera, and Santhera shall manufacture (or have manufactured), supply and sell to Catalyst all of Catalyst's, its Affiliates' and Sublicensees' Product requirements. For clarity, the terms of this Section 6 shall only apply prior to the Manufacturing Transfer Date.

6.2 Manufacture and Supply of Investigational Medicinal Product. This Section 6 primarily governs the manufacture and supply of Product for commercial use in the Territory. Within ninety (90) Business Days from the Effective Date, or no less than six (6) months before the anticipated delivery date from Santhera to Catalyst of any Investigational Medicinal Product, whichever date is earlier, the Parties shall enter into a separate agreement governing the supply, storage, use, labelling, specifications and other aspects of the Investigational Medicinal Product to be manufactured and supplied by Santhera and used by Catalyst in the Territory in clinical trials. Unless otherwise agreed, the principles set forth in this Agreement on supply of Product shall apply mutatis mutandis.

6.3 Transfer of Manufacturing Responsibility. At any time on or [***], Catalyst shall have the right, itself or through any Third Party manufacturer, to Manufacture the Compound and the Product in or outside the Territory for purposes of Development, filing for and obtaining Regulatory Approval and Commercializing the Compound and the Products in the Field in the Territory. Catalyst shall give written notice to Santhera of its election to so Manufacture the Compound and the Product and, upon such written notice, (a) the Manufacturing License shall automatically go into effect, (b) the Parties, through the JSC, shall discuss and agree upon a schedule and plan for transition of the Manufacture of the Compound and the Product for the Territory to Catalyst or its Third Party manufacturer(s), including a technology transfer plan, and (c) if requested by Catalyst, the Parties will use good faith efforts to implement assignments to Catalyst of Santhera's agreements with its Third Party manufacturers ("CMO") to the extent applicable to Manufacture and supply of the Compound and the Product for the Territory, provided that Santhera's agreements with its relevant CMO may remain in place, at Santhera's discretion, to the extent applicable to Manufacture and supply of the Compound and the Product for territories other than the Territory. Without limiting the foregoing, for any such CMO agreement that is not assignable (without the consent of the CMO or otherwise), Santhera will make a good faith effort to obtain consent from the applicable CMO or to otherwise enable the assignment of such agreement to Catalyst to the extent applicable to Manufacture and supply of the Compound and the Product for the Territory. In addition, Santhera and Catalyst shall provide reasonable assistance and cooperation in connection with the transition of the Manufacture of the Compound and Product to Catalyst or its Third Party manufacturers (including, if applicable, CMOs), including implementing the agreed-upon technology transfer plan, in accordance with such schedule agreed upon by the Parties, which assistance shall include: (i) providing an introduction to Santhera's CMO(s) or other Third Party manufacturers for Compound and Product and facilitating negotiations with such entities; (ii) granting any authorizations reasonably requested by Catalyst or its CMOs or other Third Party manufacturers in connection with the Manufacture of the Compound and Product for the Territory; and (iii) transferring to Catalyst and its CMOs or other Third Party manufacturers copies of any reasonably required documentation, information and other Know-How in its possession or control related to the Manufacture of the Compound and Product. Catalyst shall reimburse Santhera for all its reasonable and documented internal and external costs and expenses incurred in the Manufacturing transfer to Catalyst (including for transfer project staff, Third Party consultants, etc.) in accordance with a budget agreed in advance by the Parties. The "Manufacturing Transfer Date" shall be the date on which Catalyst provides written notice to Santhera that Catalyst has contracted with CMOs or other Third Party manufacturers (which may be through assignment of Santhera's CMO agreements for the Territory) or otherwise has established capabilities for the Manufacture of the Compound and the Product for the Territory and no longer requires such Manufacture and supply by Santhera. Santhera shall be free to decide, in its discretion, whether to maintain, after the Manufacturing Transfer Date, capabilities to Manufacture or have Manufactured the Compound and the Product for territories other than the Territory. In any case, Catalyst shall be obligated, from the Manufacturing Transfer Date for the remaining period of the Term, to supply, either directly or through its Third Party manufacturers, to Santhera, its Affiliates or Santhera's licensees all of its or their requirements for the Compound and the Product for purposes of Development, filing for and obtaining Regulatory Approval and Commercializing the Compound and the Products in the Field in territories other than the Territory, subject to the immediately following sentence. The Parties shall in good faith agree on the commercial and other terms of such Manufacturing and supply, provided that such terms shall not be less beneficial for Santhera, its Affiliates or Santhera's licensees than the commercial and other terms applicable to the Manufacturing and supply of Product to Catalyst as per this Agreement or any amendment hereto immediately prior to the Manufacturing Transfer Date. The Parties will discuss whether, when and how, to establish a second supply source for the Compound and the Product.

6.4 Quality Requirements. The Parties shall determine the Product Specifications, and any later amendments thereto, in the Quality Agreement to be executed pursuant to Section 6.11.

6.5 Forecasts.

(a) No later than [***] prior to the expected First Commercial Sale of the Product, and monthly thereafter until the Manufacturing Transfer Date, on or before the fifth (5th) day of each calendar month, Catalyst shall deliver to Santhera in writing a non-binding rolling forecast for reasonably anticipated monthly orders of Product over the subsequent [***] (each, a "Forecast").

(b) The quantities of Product forecasted to be ordered for the first [***] of each rolling Forecast shall represent binding obligations of Catalyst to purchase from Santhera and binding obligations of Santhera to supply Catalyst with such quantities of Product until the Manufacturing Transfer Date (each, a "Binding Forecast").

6.6 Purchase Orders; Confirmation.

(a) Until the Manufacturing Transfer Date, Catalyst shall provide to Santhera written purchase orders for the Product (each, a "Purchase Order"), each of which shall specify the quantity of Product ordered and the delivery date, as well as a specification as to which quantities of Product are to be supplied. The minimum Purchase Order quantity is [***].

(b) With respect to any given month, Catalyst shall not without Santhera's written approval (not to be unreasonably withheld, conditioned or delayed), submit Purchase Orders for Product that aggregate more than [***] over the forecasted amounts for such month contained in the most recent Binding Forecast delivered hereunder. The specified delivery date of a Purchase Order shall be at least [***] after the date of such Purchase Order, provided that the specified delivery date for the first Purchase Order shall be at least [***] after the date of the first Purchase Order.

(c) Within [***] after receipt of a Purchase Order placed pursuant to this Section 6.6 (Purchase Orders; Confirmation), Santhera shall confirm such Order in writing. Subject to Santhera's obligations regarding the Binding Forecast, Santhera may reject any Purchase Order, if such Purchase Order does not comply with this Section 6.6 (Purchase Orders; Confirmation). A Purchase Order will be deemed accepted if Catalyst does not receive Santhera's written rejection within [***] after receipt of said Purchase Order by Santhera. All Purchase Orders not rejected by Santhera pursuant to this Section 6.6 (Purchase Orders; Confirmation) shall be binding on the Parties.

(d) Any Purchase Orders submitted by Catalyst or permitted Sublicensees shall reference this Agreement and shall be governed exclusively by the terms contained herein. Any provision in any Purchase Order, invoice, or similar document furnished by Catalyst or permitted Sublicensees that is in any way inconsistent with the terms and conditions set forth in this Agreement is hereby rejected, unless expressly provided otherwise in writing by Santhera.

(e) [***]

6.7 Delivery; Storage and Handling; Product Risk.

(a) Santhera shall deliver the Product in Secondary Packaging by making available to Catalyst or Catalyst's designee, the Product on the basis of FCA (Incoterms 2020) at a major European airport with direct freight connections to the U.S. Each delivery of Product shall be accompanied by a certificate of analysis and such other documents as shall be required by the Quality Agreement.

(b) Santhera shall deliver all Product in such quantity as agreed in the Purchase Order in compliance with any applicable Good Distribution Practice no later than up to [***] after the delivery date initially specified in the respective Purchase Order and such delivery will still be deemed timely made under this Agreement.

(c) Santhera shall promptly notify Catalyst in writing if at any time Santhera has reason to believe that Santhera will not be able to (i) fill a Purchase Order for Product in accordance with the delivery schedule specified therein and pursuant to the terms and conditions of this Agreement and the Quality Agreement or (ii) supply Product to Catalyst in satisfaction of the most recent Binding Forecast, which notice in either case shall provide Catalyst with information on the extent of the expected shortfall of supply and the reasons for such shortfall. Upon such notice of a supply problem, or in any event upon Santhera's failure to satisfy, within the delivery time frame specified in a Purchase Order, a portion of the Product ordered by Catalyst in compliance with this Agreement and the Quality Agreement, Catalyst and Santhera shall promptly meet and work together, in good faith, to identify an appropriate resolution to the supply problem and to prevent future supply problems. Any agreed resolution to the supply problem shall be set forth in a writing executed by both Parties. Without limiting Catalyst's other remedies hereunder, Santhera shall deliver the Product that is subject to such shortfall as soon as is reasonably practicable following the required delivery date, on a date to be agreed with Catalyst.

(d) If Santhera is unable to Manufacture and deliver quantities of Product as required hereunder then, without prejudice to Catalyst's other rights and remedies hereunder, Santhera shall treat Catalyst equitably as compared to the other recipients of product Manufactured and supplied by Santhera and its Affiliates that rely on the same materials or impacted Manufacturing site. Such equitable treatment shall include: (i) allocating in a fair and reasonable manner available materials or capacity at the affected Manufacturing site between (A) the Products, (B) products Manufactured for commercialization by Santhera or its Affiliates that rely on the same materials or impacted Manufacturing site and (C) products Manufactured for commercialization by Third Parties that rely on the same materials or impacted Manufacturing site, such that Catalyst receives its pro rata share based on the ratio of the Parties' respective forecasted demand; and (ii) not deprioritizing Catalyst when compared to supplying Product to Santhera, its Affiliates, or Third Parties.

(e) After delivery, Catalyst shall, or shall cause Sublicensees to, store and handle the Product in accordance with the Quality Agreement and Applicable Laws, including any applicable Good Distribution Practice.

(f) Except as provided herein with respect to Defective Products, risk of damage or loss as well as ownership of and title as to Product shall pass to Catalyst upon delivery of such Product.

6.8 Acceptance and Rejection by Catalyst; Defective Product.

(a) Catalyst may reject any Defective Product by giving a notice in writing or by e-mail to Santhera, within [***] after delivery to Catalyst's distribution warehouse, of such Defective Product, of Catalyst's rejection, and of the nature of the defect. If Santhera fails to receive such notice within such period, Catalyst will be deemed to have accepted such quantities of delivered Product, subject to Section 6.8(b). Upon Santhera's request, Catalyst shall send samples of the allegedly defective Product to Santhera.

(b) If Catalyst discovers a defect which could not have been discovered through the exercise of reasonable diligence, Catalyst shall give a notice in writing or by e-mail to Santhera, within [***] from discovery, of such hidden defect.

(c) If Santhera does not agree with Catalyst for Catalyst's rejection of any Defective Product, the Parties will first use good faith efforts to resolve such dispute. If the Parties are unable to resolve such dispute, such Product shall be submitted to a recognized Third Party testing service selected by Santhera and reasonably acceptable to Catalyst or permitted Sublicensees. Such Third Party testing service shall determine whether the Product is Defective, and the Parties agree that such testing service's determination shall be final and determinative. The Party against whom the Third Party testing service rules shall bear all costs of the Third Party testing. In case of such Third Party testing, the Parties have the rights and obligations under Section 6.8(d) only upon the Third Party testing service's determination that the Product at issue is, in fact, Defective. If the Third Party testing service rules that the Product is not defective, Catalyst or the relevant permitted Sublicensees shall promptly make all outstanding payments for such Product.

(d) Upon confirmation by Santhera or a Third Party testing service of the respective defect, Catalyst shall, as directed by Santhera and at Santhera's sole cost and expense, either return to Santhera or destroy such Defective Product. Santhera shall, (i) at Catalyst's choice, either deliver Product replacing such Defective Product as soon as practicable and at Santhera's expense, or return all payments made by Catalyst for such Defective Product, and (ii) reimburse Catalyst for reasonable out-of-pocket costs incurred by Catalyst in relation to such Defective Product. Subject to Section 12.1 (Santhera Indemnification) and Section 6.11(f) (Recall), a refund or a replacement delivery as stipulated in this Section 6.8(d) shall constitute the exclusive remedy available to Catalyst for delivery of Defective Product.

6.9 Regulatory Obligations Regarding Manufacture and Supply. Santhera shall Manufacture the Product in accordance with Product Specifications, the Quality Agreement and all Applicable Laws, including Good Manufacturing Practices. No more than once during any Calendar Year (unless any such inspection reveals a material compliance issue, in which event Catalyst shall have the right to conduct additional inspections to verify that such issue has been remediated), upon the reasonable prior written request of Catalyst, Catalyst shall have the right to inspect those portions of the facilities of Santhera or its Third-Party manufacturers where the Product is being Manufactured, during regular business hours and with [***] prior written notice, to ascertain compliance with Applicable Laws, the Product Specifications and the Quality Agreement, subject to the reasonable rules and regulations of Santhera or its Third Party manufacturers, including any confidentiality and health and safety restrictions. Catalyst shall provide all cooperation and reasonable assistance necessary for, or required by, Santhera to fulfill its Manufacturing obligations regarding the Product for the Territory. Santhera shall accommodate inspection and audit requests by the FDA and other Regulatory Authorities related to the Manufacturing of the Product for the Territory, to the extent properly communicated to Santhera with sufficient advance notice. Santhera shall give Catalyst prior notice, to the extent practicable, of any inspections relating to the Product by FDA, or other Regulatory Authority inside or outside the Territory to the extent related to the Products Manufactured for use in the Territory. Upon Catalyst's reasonable written request, Santhera shall, to the extent Santhera has the right to do so, and subject to any confidentiality measures required by a Third Party manufacturer: (a) permit a representative of Catalyst to be present at such inspections relating to the Product by FDA or other Regulatory Authority inside the Territory; (b) disclose to Catalyst the results of any such inspection by FDA or other Regulatory Authority inside or outside the Territory to the extent related to the Products Manufactured for use in the Territory; and (c) implement any measures necessary to respond to the Regulatory Authority in a satisfactory manner. Santhera shall make available to Catalyst any necessary and customary manufacturing and supply records, including historic records, for purposes of allowing Catalyst to meet its obligations as regards safety and quality under Applicable Laws in the Territory.

6.10 Labeling and Packaging.

(a) Santhera shall supply the Product to Catalyst, its Affiliates and/or its respective Sublicensees labeled and with Primary Packaging and Secondary Packaging as per the agreed Product Specifications.

(b) Catalyst shall be responsible to ensure that the agreed Product Specifications for the Primary Packaged Product and Secondary Packaged Product comply with all labelling, bar coding, serialization, regulatory, customs, or other requirements under the Applicable Laws in the Territory.

6.11 Complaints; Safety Notifications; Recall.

(a) The Parties shall negotiate in good faith and enter into a Quality Agreement customary in the industry no later than three (3) months before the anticipated First Commercial Sale of the Product in the Territory.

(b) Each of the Parties shall maintain, or cause to be maintained, such traceability or other records as are necessary to permit a recall, withdrawal, field alert or similar action (each, a "Recall") regarding the Product.

(c) If a Party becomes aware of any Product complaints in or with relevance to the Territory, including complaints on quality, safety, advertising, labeling, packaging or Commercialization of the Product in the Territory by a Regulatory Authority or (other) Governmental Authority, or any information on harm actually or potentially caused to a patient, user or other person, or if a Party considers a Recall necessary, such Party shall promptly notify the other Party. Catalyst shall, after consultation with Santhera, have the final decision-making authority on whether a voluntary Recall is made in any part of the Territory.

(d) Unless otherwise provided in a pharmacovigilance agreement entered into by the Parties in relation to the Product, in case a Product might cause, or already has caused harm to a patient, user or other person, because such Product (potentially) deviates from the Product Specifications or because of other circumstances, each Party shall notify the other Party in writing (such writing, a "Safety Notification") as soon as the respective Party has knowledge of such.

(e) Safety Notifications associated with complaints on Products are to be communicated to the following:

Santhera: Santhera@eu.propharmagroup.com and dspv@santhera.com

Catalyst: by telephone to Primevigilance at +1—844-347-3277, with an email copy to CatalystQA@catalystpharma.com

(f) In the event that a Recall in the Territory regarding Product becomes necessary or Catalyst is required to disseminate information regarding such Product, Catalyst shall notify Santhera promptly and Santhera shall provide Catalyst with all reasonable assistance in connection with such Recall. All costs and expenses associated with any Recall of Product, including the costs and expenses of recalling the Product and the destruction of the recalled Product, shall be borne by Santhera to the extent that such Recall of Product is caused by the Product being a Defective Product upon delivery, or as otherwise caused by Santhera or its Affiliates, licensees or subcontractors. In such case, Santhera shall (a) at Catalyst's option (i) reimburse Catalyst for the amounts paid by Catalyst to Santhera for the Product subject to the Recall, or (ii) deliver to Catalyst as soon as practicable and at no further cost to Catalyst sufficient Product to replace the Products that are the subject of the Recall; and (b) reimburse Catalyst all reasonable out-of-pocket costs incurred by Catalyst arising from the Recall, and all applicable fees and penalties, including the costs and expenses of recalling the Product, the destruction of the recalled Product, and amounts repaid or credited to customers for Product recalled (or in the alternative Catalyst shall be entitled to credit against its subsequent calculations of Net Sales hereunder such amounts repaid or credited to customers for Product recalled). Items (a) and (b) stipulated in this Section 6.11(f) shall constitute the exclusive remedy available to Catalyst for a Recall of Defective Product other than indemnification of Loss as a result of any Third Party claims, actions, or judgments related to the Recall as stipulated under Section 12.1 (Santhera Indemnification).

(g) To the extent that a Recall of Product in the part of the Territory is caused by Catalyst, its Affiliates, or its permitted Sublicensees or subcontractors, Catalyst shall bear all costs and expenses associated with such Recall, shall have no right to a reimbursement or free-of-charge replacement delivery of recalled Product, and shall reimburse Santhera for the reasonable out-of-pocket costs incurred by Santhera arising from the Recall, and applicable fees and penalties, if any, provided that Santhera may also claim indemnification of Loss as a result of any Third Party claims, actions, or judgments related to the Recall as stipulated under Section 12.1 (Catalyst Indemnification).

(h) Catalyst shall retain exclusive responsibility regarding communications to Regulatory Authorities in the Territory, including in relation to any Recall, Safety Notification or adverse drug reaction. Santhera shall provide all reasonably requested and all required cooperation and assistance regarding such Catalyst's communications in the Territory.

6.12 Documentation of Delivered Product. Each shipment of Product constitutes a separate sale and Santhera shall provide to Catalyst a written consignment note for each shipment of Product.

6.13 [***]

7. **Intellectual Property**

7.1 Ownership of Inventions. Each Party shall retain ownership of and title to any invention conceived by or on behalf of such Party or any of its Affiliates and without the inventive contribution of any representative of the other Party or of such other Party's Affiliates, whether solely by or on behalf of such Party or jointly with a Third Party, in the course of performance of any activities under this Agreement (hereinafter either a "Santhera Invention" or a "Catalyst Invention", as the case may be).

7.2 Santhera Inventions. Subject to the Exclusive License and the Manufacturing License granted in Section 2.1 (Grant to Catalyst), Catalyst may not exploit, during or after the Term of this Agreement, any Santhera Invention, or Patent Rights, Know-How or other intellectual property rights related to Santhera Inventions, in any field, nor grant any licenses or sublicenses thereunder, without the prior written consent of Santhera.

7.3 Catalyst Inventions. Subject to the license granted to Santhera under Section 2.3 (Reserved Rights and Grant-Back License to Santhera), Santhera may not exploit, during or after the Term of this Agreement, any Catalyst Invention, or Patent Rights, Know-How or other intellectual property rights related to Catalyst Inventions, in any field, nor grant any licenses or sublicenses thereunder, without the prior written consent of Catalyst.

7.4 Joint Inventions. Inventions relating to the Compound or Product conceived in the course of performance of any activities under this Agreement jointly with the inventive contribution of representatives of Santhera or any of its Affiliates and of representatives of Catalyst or any of its Affiliates, whether or not also jointly with a Third Party ("Joint Invention") shall be jointly owned by the Parties and each Party shall have an equal, undivided interest in Joint Inventions. All Patent Rights claiming Joint Inventions shall be referred to herein as "Joint Patents." Subject to the Exclusive License and the Manufacturing License granted to Catalyst in Section 2.1, and Santhera's reserved rights and grant-back license under Section 2.3, and except as otherwise set out in this Agreement: (a) Catalyst shall be entitled, in the Territory, to practice, license, assign and otherwise exploit its interest under the Joint Inventions and Joint Patents in connection with activities related to the Compound or Product without the duty of accounting or seeking consent from Santhera, and (b) Santhera shall be entitled, outside of the Territory during the Term and worldwide after the termination of this Agreement, to practice, license, assign and otherwise exploit its interest under the Joint Inventions and Joint Patents in connection with activities related to the Compound or Product without the duty of accounting or seeking consent from Catalyst. Each Party will grant and hereby does grant all permissions, consents and waivers with respect to, and all licenses under, Joint Inventions and Joint Patents, throughout the world, necessary to provide the other Party with such rights of use and exploitation of the Joint Inventions and Joint Patents in connection with activities related to the Compound and Product permitted hereby, and will execute documents as necessary to accomplish the foregoing. Neither Party will be entitled, in or outside the Territory, to practice, license, assign and otherwise exploit its interest under the Joint Inventions and Joint Patents in connection with activities other than activities related to the Compound or Product, except as agreed in writing by the Parties, such agreement not to be unreasonably withheld, conditioned or delayed. The determination of inventive contribution by or on behalf of a Party with respect to any invention for purposes of determining ownership as set forth above shall be made in accordance with the laws of inventorship under U.S. patent law.

7.5 Reporting; Employee Obligations. The Parties shall promptly report to each other in writing each Joint Invention and shall reasonably cooperate to memorialize in writing an invention disclosure for each Joint Invention. Each Party shall require all of its employees, Affiliates, and any Third Parties working in relation to this Agreement with it or on its behalf, to assign (or otherwise convey rights) to such Party any inventions made by such employee, Affiliate or Third Party, and to cooperate with such Party in connection with such Party's obligations under this Agreement.

7.6 Transfer of Rights. The Parties agree, and ensure that their respective employees, Affiliates, agents, or Third Parties cooperating with it in relation to this Agreement agree, to execute all papers and otherwise assist such Party as reasonably required, to perfect in such Party the rights, title and other interests owned by such Party under this Section 7 (Intellectual Property). Each Party hereby assigns and automatically and in full transfers to the other Party all (ownership) rights, title and other interests it holds or acquires during the Term, and which the other Party is entitled to under this Section 7 (Intellectual Property), and the other Party herewith accepts such transfer of rights.

7.7 Prosecution and Maintenance.

(a) Joint Patents. Catalyst shall, at its expense, have the first right, but not the obligation, to file, Prosecute and Maintain Joint Patents in the Territory and Santhera shall, at its expense, have the first right, but not the obligation, to file, Prosecute and Maintain Joint Patents outside the Territory. The Party with the first right to Prosecute and Maintain Joint Patents shall be referred to herein as the "Responsible Party." If the Responsible Party intends to abandon or otherwise cease Prosecution or Maintenance of any Joint Patents, the Responsible Party shall provide written notice to the other Party of such intention promptly after the Responsible Party makes such determination, but in no event later than [***] prior to any deadline that must be met in order to avoid such abandonment, and the other Party shall have the right, but not the obligation, to assume responsibility for Prosecution and Maintenance of such Joint Patents at its sole cost and expense. In such case, the other Party shall have no further obligation under Section 7.7(d) with regard to such Joint Patents, except to provide a status update upon written request of the Responsible Party and promptly inform the Responsible Party in the event any such Joint Patents are going to be abandoned by the other Party in any country. The Responsible Party will provide all reasonable cooperation and assistance to the other Party at the other Party's reasonable request and at the other Party's expense in any such Prosecution and Maintenance assumed by the other Party. The ownership or license rights of either Party shall not be affected, notwithstanding any such transfer of responsibility for Prosecution and Maintenance of such Joint Patents.

(b) Santhera Patents. Santhera shall, at its expense, have the first right, but not the obligation, to file, Prosecute and Maintain, in and outside the Territory, all Licensed Patents other than the ReveraGen Patents (collectively, "Santhera Patents"). In addition to the obligations set forth in Section 7.7(d), Santhera shall keep Catalyst reasonably informed through the JSC of Santhera's patent prosecution strategy in the Territory regarding the Santhera Patents. If Santhera intends to abandon or otherwise cease Prosecution or Maintenance of any Santhera Patents in the Territory, Santhera shall provide written notice to Catalyst of such intention promptly after Santhera makes such determination, but in no event later than [***] prior to any deadline that must be met in order to avoid such abandonment, and Catalyst shall have the right, but not the obligation, to assume responsibility for Prosecution and Maintenance of such Santhera Patents in the Territory at its sole cost and expense. In such case, Catalyst shall have no further obligation under Section 7.7(d) with regard to such Santhera Patents, except to provide a status update upon written request of Santhera and promptly inform Santhera in the event any such Santhera Patents are going to be abandoned by Catalyst in any country in the Territory. Santhera will provide all reasonable cooperation and assistance to Catalyst at Catalyst's reasonable request and at Catalyst's expense in any such Prosecution and Maintenance assumed by Catalyst. The ownership or license rights of either Party shall not be affected, notwithstanding any such transfer of responsibility for Prosecution and Maintenance of such Santhera Patents.

(c) ReveraGen Patents. The Parties acknowledge that, pursuant to the ReveraGen Agreement, ReveraGen has the first right, at its discretion and expense, to Prosecute and Maintain the ReveraGen Patents and is obligated to consult with Santhera with respect to any such Prosecution or Maintenance and to keep Santhera reasonably informed of the status of any such Prosecution and Maintenance. Santhera shall keep Catalyst informed through the JSC of all material information Santhera receives from ReveraGen relating to Prosecution and Maintenance of the ReveraGen Patents in the Territory. If Santhera receives written notice from ReveraGen of ReveraGen's decision not to Prosecute and Maintain any ReveraGen Patent in the Territory pursuant to Section 7.4(b) of the ReveraGen Agreement, then Santhera shall provide immediate notice of the same to Catalyst, and Catalyst shall have the right, but not the obligation, to Prosecute and Maintain such ReveraGen Patent in the Territory, at its sole expense. If Catalyst decides not to Prosecute and Maintain such ReveraGen Patent, it shall notify Santhera in writing, and Santhera shall have the right, but not the obligation, to Prosecute and Maintain such ReveraGen Patent in the Territory, at its sole expense. In either such case, the Party that Prosecutes and Maintains such ReveraGen Patent in the Territory shall provide a status update upon written request of the other Party (which update Santhera shall provide to ReveraGen within the time period required under Section 7.4(b) of the ReveraGen Agreement) and shall promptly inform the other Party in the event such ReveraGen Patent is going to be abandoned in any country in the Territory (in which case, Santhera shall promptly inform ReveraGen of the same in accordance with Section 7.4(b) of the ReveraGen Agreement). For clarity, Catalyst shall have no obligation under Section 7.7(d) with regard to Prosecution and Maintenance of such ReveraGen Patent in the Territory. If Catalyst elects to assume Prosecution and Maintenance of any ReveraGen Patent in the Territory in accordance with this Section 7.7(c), Santhera shall inform ReveraGen of the same and shall require ReveraGen, in accordance with Section 7.4(b) of the ReveraGen Agreement, to provide all reasonable cooperation and assistance to Catalyst, at Catalyst's reasonable request and at Catalyst's expense, in any such Prosecution and Maintenance. The ownership or license rights of either Party shall not be affected, notwithstanding any such transfer of responsibility for Prosecution and Maintenance of such ReveraGen Patent.

(d) Consultation; Cooperation. In each case with respect to the Prosecution and Maintenance of Joint Patents in and outside the Territory and the Prosecution and Maintenance of Santhera Patents in the Territory as provided in Sections 7.7(a) and 7.7(b), the responsible Party (the "Filing Party") shall consult with the other Party (the "Non-Filing Party") and keep the Non-Filing Party reasonably informed of the status of any such Prosecution and Maintenance as follows:

(i) The Filing Party shall give the Non-Filing Party an opportunity to review the text of any application before filing, shall consult with the Non-Filing Party with respect thereto, and shall supply the Non-Filing Party with a copy of the application as filed, together with notice of its filing date and serial number.

(ii) The Filing Party shall provide the other Party with copies of all material submissions and correspondence with the patent offices, in sufficient time to allow for review and comment by the Non-Filing Party. The Filing Party will provide the Non-Filing Party and its patent counsel with an opportunity to consult with the Filing Party and its patent counsel regarding the filing and contents of patent applications, amendments, submissions or responses, and the advice and suggestions of the Non-Filing Party and its patent counsel shall be taken into consideration in good faith by the Filing Party and its patent counsel.

(iii) Each Party agrees to execute and deliver, at the reasonable request and sole expense of the Filing Party all papers, instruments and assignments, and to perform any other reasonable acts as the Filing Party may require, in order for such Party to pursue relevant patent applications in accordance with Sections 7.7(a) and 7.7(b). Each Party shall promptly give notice to the other Party of the grant, lapse, revocation, surrender, invalidation or abandonment of any Patent Right for which such Party is responsible under Sections 7.7(a) and 7.7(b) for Prosecution and Maintenance. Upon any transfer of responsibility as envisioned in Sections 7.7(a) and 7.7(b), the Filing Party, at the written request of the other Party, shall undertake all reasonably necessary actions to keep the relevant patent application(s) or patent(s) in force until the transfer of responsibility is completed.

7.8 Expenses. Except as provided otherwise in this Agreement, (a) Santhera shall pay all expenses regarding Santhera Patents and Joint Patents outside the Territory, (b) Catalyst shall pay all expenses regarding Patent Rights claiming Catalyst Inventions and Joint Patents in the Territory and, (c) as between the Parties, Santhera shall be responsible for all expenses regarding ReveraGen Patents.

7.9 Patent Extensions. The Parties agree to cooperate and to take reasonable actions to maximize the protections available for the Product under all patent extension provisions, it being clarified that it is in Santhera's discretion whether or not to ultimately pursue such steps outside the Territory and it is in Catalyst's discretion whether or not to ultimately pursue such steps in the Territory, provided that if Catalyst chooses not to pursue such steps in the Territory, Catalyst shall notify Santhera and Santhera then has the right but not the obligation to pursue such steps in the Territory at its own costs. The Parties shall cooperate with each other in a timely manner, including by providing necessary information and assistance as the other Party may reasonably request, in respect of any such actions to be taken, such as filing of patent term extension applications and supplementary protection certificate applications, to obtain patent term extension or supplementary protection certificates or their equivalents in the Territory where applicable. Santhera agrees to reasonably assist Catalyst in taking all steps reasonably necessary to seek extension of any Licensed Patent wherever possible.

7.10 Patent Listing. Upon NDA Transfer Date, Catalyst shall have the sole authority and discretion to file and maintain with any applicable Regulatory Authority in the Territory during the Term any listing of any applicable Licensed Patents, including all listings in the Approved Drug Products with Therapeutic Equivalence Evaluations pursuant to 21 U.S. Code Section 355 in the U.S. or any comparable law or regulation in any jurisdiction in the Territory other than the U.S. (or any amendment or successor thereto). Santhera shall (with respect to Santhera Patents), and shall require ReveraGen to, in accordance with Section 7.10 of the ReveraGen Agreement (with respect to ReveraGen Patents), execute and deliver to Catalyst any documents necessary or desirable, in Catalyst's reasonable judgment, to complete any such listing. In the event that, due to Applicable Law in a certain country in the Territory, Catalyst is not allowed or in the position to make any such listing itself, then at Catalyst's request, Santhera shall perform such listing (with respect to Santhera Patents) and Santhera shall request ReveraGen to perform such listing pursuant to Section 7.10 of the ReveraGen Agreement. Catalyst shall reimburse Santhera and ReveraGen for all reasonable out-of-pocket expenses incurred by Santhera and ReveraGen, respectively, in performing such listing at Catalyst's request.

7.11 Litigation.

(a) In relation to the Territory, each Party shall promptly provide written notice to the other Party during the Term of this Agreement of (a) any known infringement or suspected infringement of any Licensed Intellectual Property or any Joint Patents by a Third Party; or (b) any suit or other legal action commenced against Catalyst or Santhera, or their respective Affiliates or permitted Sublicensees, or Third Parties, in respect of Compound and/or Product(s), including alleged infringement of Third Party intellectual property rights.

(b) Catalyst shall have the first right, but not the obligation, to take appropriate action in the Territory in relation to infringements, suspected infringements, patent-related Third Party suits, litigation matters or other legal action related to any Licensed Intellectual Property or related to Joint Inventions or Joint Patents at its sole cost and expense and by counsel of its own choice. Santhera shall execute all documents and participate in such suits to the extent reasonably requested by Catalyst, including joining as a co-party as may be necessary, at Catalyst's cost and expense.

(c) If Catalyst decides not to bring or fails to bring any such action or proceeding as permitted pursuant to Section 7.11(b), as the case may be, within the earlier of (i) [***] following notice of alleged infringement, or (ii) [***] before the time limit for the filing of such actions, if any, set forth in the Applicable Laws governing the filing of such actions, Santhera shall have the right, but not the obligation, to bring and control any such action at its sole cost and expense and by counsel of its own choice.

(d) A Party that elects to bring and control legal action in the Territory pursuant to this Section 7.11 (Litigation) shall provide prompt written notice to the other Party of any such action. Each Party shall have the right, at its sole cost and expense, to be represented in any such action by counsel of its own choice. Upon written request, the Party taking such legal action ("Initiating Party") shall keep the other Party informed of the status of any such action and shall upon request make available to the other Party copies of substantive documents filed in such action to the extent permitted under any judicial orders. In the event that a Party is unable to initiate or prosecute any such action permitted hereunder solely in its own name, the other Party will join such action voluntarily and will execute and cause its Affiliates to execute all documents necessary for such Party to initiate, prosecute or maintain such action, at the Initiating Party's expense.

(e) Any damages or other monetary awards recovered pursuant to any suit or proceeding or other legal action in the Territory taken under this Section 7.11 (Litigation) shall be allocated first to the costs and expenses of the Initiating Party, and second to the costs and expenses, if any, of the other Party, with any remaining amounts shared eighty percent (80.0%) to the Initiating Party and twenty percent (20.0%) to the non-Initiating Party; except that, if Catalyst is the Initiating Party and any part or all of such remaining amounts are clearly attributable to lost sales of Products, such part or all of such remaining amounts, as the case may be, shall be included in Net Sales subject to the Royalty payment by Catalyst to Santhera, in lieu of the sharing otherwise provided for in this paragraph;

(f) The Initiating Party shall have the right to control settlement; provided, however, that no settlement shall be entered into without the written consent of the other Party, such consent not to be unreasonably withheld, conditioned or delayed.

7.12 Trademarks. The Products shall be sold in the Territory under Santhera's Trademarks "AGAMREE". For the Term of this Agreement, Catalyst shall be entitled (as part of the Exclusive License and the Manufacturing License, subject to the same modalities as set forth in Section 2 (License Grants)) to use Santhera's Trademark for Commercializing the Product in the Territory. Santhera shall be responsible for the registration, maintenance, and enforcement of the Trademarks in the Territory at its own costs and shall keep Catalyst reasonably informed thereof. At a later stage, Catalyst may sell the Products in the Territory under any of Catalyst's own trademarks, subject to Santhera's prior written approval which shall not be unreasonably withheld or delayed. In such case, Catalyst bears any costs and expenses in relation to developing and filing such trademarks and Santhera is entitled to use such trademarks in accordance with Section 2.4 (Grant to Santhera).

7.13 Recording. If Catalyst deems it necessary or desirable to register or record this Agreement or evidence of this Agreement with any patent office or other appropriate Governmental Authorities in the Territory, Santhera shall, and shall require ReveraGen as applicable in accordance with Section 7.11 of the ReveraGen Agreement to, execute and deliver to Catalyst any documents necessary or desirable, in Catalyst's reasonable judgment, to complete such registration or recording. Catalyst shall reimburse Santhera for all reasonable out-of-pocket expenses incurred by Santhera in complying with the provisions of this Section 7.13 (Recording).

8. **Governmental Approvals**

8.1 Governmental Approvals. If required by Applicable Laws, each of Santhera and Catalyst shall cooperate and use reasonable good faith efforts, as soon as reasonably practicable after Effective Date (or at such later time as may be agreed to in writing by the Parties), to determine the required Regulatory Filings to report the transactions contemplated by this Agreement, to make all such Regulatory Filings and to obtain as soon as practicable all such Regulatory Approvals, if any, and to do all other things necessary or desirable for the consummation of the transactions as contemplated under this Agreement.

8.2 HSR Filing.

(a) If required by the HSR Act, each Party shall use its commercially reasonable efforts to take, or cause to be taken, all actions and to do, or cause to be done, all things reasonably necessary, proper or advisable under the HSR Act to consummate and make effective the transaction contemplated hereby as promptly as practicable, including using its commercially reasonable efforts to obtain or make all necessary or appropriate filings required under the HSR Act and to lift any injunction or other legal bar to the consummation of the transaction contemplated by this Agreement as promptly as practicable after the Execution Date. None of the Parties shall knowingly take, cause or permit to be taken any action which such Party reasonably expects is likely to materially delay or prevent consummation of the transaction contemplated by this Agreement. The Parties shall cooperate in the preparation of any such HSR Filing, if any, and during the review by the FTC or DOJ. Each Party will be responsible for its own legal fees in connection with the preparation of its portion of any HSR Filing, and any HSR Act associated filing fees shall be paid by Catalyst.

(b) In connection with obtaining clearance under the HSR Act, the Parties shall (i) cooperate with each other in connection with any investigation or other inquiry relating to an HSR Filing and the transactions contemplated hereby, (ii) keep the other Party or its counsel informed of any communication received from or given to the FTC or DOJ relating to the HSR Filing and the transactions contemplated hereby (and provide a copy to the other Party if such communication is in writing), (iii) reasonably consult with each other in advance of any meeting or conference with the FTC or DOJ, and, to the extent permitted by the FTC or DOJ, give the other Party or its counsel the opportunity to attend and participate in such meetings and conferences, and (iv) permit the other Party or its counsel to review in advance, and in good faith consider the views of the other Party or its counsel and incorporating these views where appropriate, concerning, any submission, filing or communication (and documents submitted therewith) intended to be given to the FTC or DOJ.

(c) Notwithstanding the foregoing, nothing in this Section 8.2 or otherwise in this Agreement shall require Catalyst or any Catalyst's Affiliate to propose, negotiate, effect or agree to, the sale, divestiture, license or other disposition of any assets or businesses of Catalyst or any Catalyst's Affiliate (including the Product that is the subject of this Agreement) or otherwise take any action that limits the freedom of action with respect to, or its ability to retain any of the businesses, product lines or assets of Catalyst or any Catalyst's Affiliate (including the Product that is the subject of this Agreement).

8.3 Effective Date. Notwithstanding anything in this Agreement to the contrary, this Agreement (other than this Section 8 (Governmental Approvals)), which is binding and effective as of the Execution Date) shall not become effective until the expiration date or earlier termination date of the waiting period (or any extension thereof) under the HSR Act (the "Effective Date"), provided that neither the FTC nor the DOJ have commenced or threatened litigation to enjoin the transactions contemplated by this Agreement nor have the Parties agreed with the FTC or DOJ to postpone closing. If, on the one hundred fiftieth (150th) day after the date of filing under the HSR Act, the waiting period required thereunder has not expired, either Party shall have the right, on written notice to the other Party, to terminate this Agreement, and upon receipt of such notice by the other Party, this Agreement shall be null and void and have no further force and effect; provided, however, that Section 11 (Confidentiality), Section 12.4 (Governing Law; Dispute Resolution), and Section 14.6 (Notices) shall survive. In addition, the Effective Date shall not occur until Santhera provides written certification to Catalyst that there has been no Material Adverse Effect with respect to Santhera since the Execution Date (which will be satisfied by the officer's certificate delivered pursuant to Section 3.2(b)(i) of the Investment Agreement), provided that, if there has been a Material Adverse Effect with respect to Santhera since the Execution Date, Santhera shall provide written notice to Catalyst describing such Material Adverse Effect in reasonable detail, and Catalyst shall have the right, on written notice to Santhera to be made no later than [***] from the date of such written notice from Santhera, to terminate this Agreement, and if Catalyst does not provide written notice of termination to Santhera by the end of such ten (10) day period, the Effective Date shall occur upon the expiration of such ten (10) day period with no further action required by either Party. Upon receipt of such notice of termination by Santhera by the end of such ten (10) day period, this Agreement shall be null and void and have no further force and effect; provided, however, that Section 11 (Confidentiality), Section 12.4 (Governing Law; Dispute Resolution), and Section 14.6 (Notices) shall survive.

9. **Term and Termination**

9.1 Term. The term of this Agreement shall commence on the Effective Date and, unless earlier terminated in accordance with this Section 9, shall remain in force, on a country-by-country basis in the Territory, (a) until the end of the Royalty Term in such country or (b) if Catalyst or its Affiliates or Sublicensees are Commercializing Products in any country in the Territory and are not Manufacturing or having Manufactured by a Third Party Products for the Territory as of the date in clause (a), then this Agreement shall continue in force for so long as Catalyst continues to purchase Products from Santhera pursuant to the terms of this Agreement (the "Term").

9.2 License Following Expiration of Royalty Term. On a country-by-country basis in the Territory, upon the expiration of the Royalty Term for Products in a given country, the Exclusive License and the Manufacturing License in such country with respect to such Licensed Product will become fully paid-up, perpetual, irrevocable, sublicensable (through multiple tiers) and royalty-free.

9.3 Termination Right of Santhera for Failure to Timely Receive Initial Payment. Should the full amount of the Initial Payment not be received by Santhera within the deadline set forth in Section 3.1 (Initial Payment), plus an additional grace period of [***], Santhera shall have the right to immediately terminate this Agreement by written notice to Catalyst.

9.4 Termination for Cause.

(a) Either Party may terminate this Agreement, either in its entirety or on a country-by-country basis in the Territory, as relevant to the material breach, at any time during the Term in the event the other Party commits a material breach of its obligations under this Agreement by giving notice of such breach specifying in reasonable detail the claimed breach to the breaching Party if such breach remains uncured for [***] (or [***] in the case of the breach of a payment obligation, other than a payment obligation disputed in good faith unless unresolved [***] after its due date), measured from the date written notice of such breach specifying in reasonable detail the claimed breach is given to the breaching Party; provided, however, if such breach (other than breach of a payment obligation) is not susceptible of cure within the stated period and the breaching Party uses diligent, good faith efforts to cure such breach, the stated period will be extended by an additional [***].

(b) If the allegedly breaching Party disputes in good faith the allegation that there has been a material breach (including a good faith dispute regarding the payment of money), then such Party may contest the allegation in accordance with Section 13 (Governing Law; Dispute Resolution) and, provided that the allegedly breaching Party gives written notice to the other Party of such dispute and initiates dispute resolution procedures during the applicable cure period, such cure period will toll upon the initiation of such dispute resolution procedures. If, as a result of such dispute resolution process, it is finally determined pursuant to Section 13 (Governing Law; Dispute Resolution) that the breaching Party committed a material breach of this Agreement, then the applicable cure period will resume and if the breaching Party does not cure such material breach within the remainder of such cure period (as such cure period may be extended pursuant to Section 9.4(a)), then this Agreement will terminate effective as of the expiration of such cure period. This Agreement will remain in full force and effect during the pendency of any such dispute resolution proceeding and the applicable cure period. Any such dispute resolution proceeding will not suspend any obligations of either Party hereunder and each Party will use reasonable efforts to mitigate any damages. If, as a result of such dispute resolution proceeding, it is determined that the breaching Party did not commit such material breach (or such material breach was cured in accordance with Section 9.4(a)), then no termination of this Agreement will be effective, and this Agreement will continue in full force and effect.

9.5 Termination by Catalyst Without Cause. At any time following the Effective Date and after the payment of the Initial Payment set forth in Section 3.1 (Initial Payment), as well as the closing of the Investment Agreement, Catalyst shall have the right, exercisable upon [***] prior written notice to Santhera, to terminate this Agreement, either in its entirety or on a country-by-country basis in the Territory.

9.6 Termination by Santhera Without Cause. After the end of the Royalty Term on a country-by-country basis in the Territory, Santhera shall have the right, exercisable upon one hundred eighty (180) days' prior written notice to Catalyst, to terminate this Agreement, either in its entirety (if the Royalty Term has expired in all countries in the Territory) or on a country-by-country basis in the Territory; provided that, in the event that the Manufacturing Transfer Date has not occurred by the date that is [***] from such written notice of termination, the effective date of such termination shall be automatically extended until the Manufacturing Transfer Date has occurred, however, no longer than [***] following Santhera's written notice of termination.

9.7 Termination on Insolvency of a Party.

(a) Either Party shall be entitled to terminate this Agreement by notice to the other Party, if at any time during the Term, (i) the other Party files for or is subject to the institution of bankruptcy, liquidation or receivership proceedings, (ii) the other Party assigns all or a substantial portion of its assets for the benefit of creditors, (iii) a receiver or custodian is appointed for the other Party's business, or (iv) a substantial portion of the other Party's business is subject to attachment or similar process.

(b) All rights and licenses granted under or pursuant to any clause of this Agreement are for the purposes of Section 365(n) of Title 11, U.S. Code (the "Bankruptcy Code") licenses of rights to "intellectual property" as defined in Section 101(56) of the Bankruptcy Code (and any equivalent provisions under the bankruptcy or insolvency laws of any other relevant jurisdiction). The Parties shall retain and may fully exercise all of their respective rights and elections under the Bankruptcy Code or other Applicable Laws in any jurisdiction provided that they comply with the terms of this Agreement.

9.8 [***]

9.9 [***]

9.10 Other Effects of Termination. Upon any early termination of this Agreement before the end of the Term in any such case in its entirety or with respect to any countries in the Territory, and subject only to the limited sell-off rights granted to Catalyst under Section 9.10(d) and to the continuing rights under any licenses under Section 9.2 (License Following Expiration of Royalty Term):

(a) all licenses granted under this Agreement by either Party to the other Party, and any sublicenses granted by either Party under any such license (subject to Section 9.10(b)), shall automatically terminate, and Catalyst, its Affiliates and terminated Sublicensees shall refrain from using the Licensed Intellectual Property and Santhera's trademarks with immediate effect, and shall not hold themselves out as being Santhera's licensees;

(b) if a Sublicensee is then in good standing under its sublicense agreement with Catalyst, then Santhera shall consider whether or not it wants to agree (unless Santhera has agreed in writing in advance) that the sublicense held by such Sublicensee shall become a direct license under the Licensed Intellectual Property granted by Santhera that is the same scope as the sublicense granted by Catalyst on the same terms and conditions set forth in this Agreement;

(c) the Party that has Confidential Information of the other Party shall destroy or return (at the discretion of the Disclosing Party) all such Confidential Information in its possession as of the effective date of termination (with the exception of one copy of such Confidential Information, which may be retained by the Party that received such Confidential Information subject to a continuing obligation of non-use and non-disclosure to confirm compliance with the non-use and non-disclosure provisions of this Agreement and/or to comply with document retention obligations under Applicable Laws), provided that each Party may retain and continue to use such Confidential Information of the other Party to the extent necessary to exercise any surviving rights or obligations under this Agreement;

(d) Catalyst shall not, and shall cause its Affiliates and permitted Sublicensees, not to, use or register any trademark, name, sign, logo, domain name, or social media presence consisting of or containing signs identical or confusingly similar, to the word "AGAMREE", or to Santhera's other Trademarks previously used in relation to the Product in any region of the Territory. To the extent that Catalyst or its Affiliates own upon termination any trademark used in connection with the sale of the Product in any region of the Territory, Catalyst agrees to transfer, and to cause its Affiliates, and permitted Sublicensees, to transfer, such trademark to Santhera upon Santhera's request and without any compensation, and to execute all documents and perform all acts necessary or useful to give effect to such transfer and to register Santhera as the new trademark owner in all relevant registers in the Territory.

(e) Catalyst and its Affiliates and Sublicensees shall have the non-exclusive right, for a period of nine (9) months following termination by Santhera (other than termination by Santhera pursuant to Section 9.4 (Termination for Cause), Section 9.6 (Termination on Insolvency of a Party), or Section 9.8 (Termination by Santhera for Patent Challenge) in which event no such right shall exist) or by Catalyst (other than termination by Catalyst pursuant to Section 9.5 (Termination by Catalyst Without Cause)), to sell-off all inventory of the Products within the Territory then included in the license for such Product, subject to the duty to report Net Sales and pay Royalties related to such sell-off activities. For clarity, no right to sell-off inventory shall exist in case of a termination by Catalyst pursuant to Section 9.5 (Termination by Catalyst Without Cause). Subject to the foregoing, Santhera has the right, but not the obligation, to re-purchase all or part of Catalyst's and its Affiliates' and its permitted Sublicensees' inventory of the Products, provided that such Products have a minimum remaining shelf life of twelve (12) months, at a price equal to the Supply Price paid by Catalyst to Santhera therefor. For this purpose, Catalyst shall provide to Santhera a list of the relevant Product(s) in the inventory of Catalyst, its Affiliates and permitted Sublicensees, including information on the remaining quantities and the remaining shelf life of the relevant Products in the inventory at the effective date of the termination, as well as on the applicable re-purchase prices and the documents allowing to verify such repurchase prices. In case Santhera did not exercise its re-purchase option, (i) at the end of the sell-off period as per this Section 9.10(e), or (ii) upon the effective date of the termination in case no sell-off right is granted as per this Section 9.10(e), Catalyst shall, and shall instruct its Affiliates and permitted Sublicensees to destroy, any remaining Products in the Territory, and shall send Santhera written confirmation of such destruction.

(f) Nothing in this Section 9 (Term and Termination) shall limit any other remedy either Party may have for the other Party's breach of this Agreement.

9.11 [***]

9.12 Survival of Certain Obligations. Expiration or termination of the Agreement shall neither relieve the Parties of any obligation accruing before such expiration or termination nor affect those obligations set forth in this Agreement which, from their context or meaning, are intended to survive termination or expiration of this Agreement including Sections 1 (Definitions), 2.2 (Transfer of Licensed Know-How), 2.3 (Reserved Rights and Grant-Back License to Santhera), 3.9 (Reporting of Royalties), 3.10 (Payments), 3.11 (Late Payments), 3.12 (Taxes), 3.13 (Audit Rights), 4.3 (Right of Reference), 4.5 (Exchange of Data in Compliance with Applicable Law), 7.1 (Ownership of Inventions), 7.2 (Santhera Inventions), 7.3 (Catalyst Inventions), 7.4 (Joint Inventions), 7.6 (Transfer of Rights), 7.7 (Prosecution and Maintenance), 7.8 (Expenses), 7.9 (Patent Extensions), 8.3 (Effective Date), 9 (Term and Termination), 10.4 (Disclaimers), 11 (Confidentiality), 12 (Indemnification; Liability; Insurance), 13 (Governing Law; Dispute Resolution), 14 (General Provisions).

10. **Representations, Warranties and Covenants**

10.1 Representations, Warranties and Covenants of the Parties. Santhera and Catalyst each represents and warrants to the other with respect to itself (or such other person as set forth below) that, as of the Effective Date (or such other pertinent date set forth below):

(a) it is a corporation duly organized, validly existing and in good standing under the laws of its jurisdiction of incorporation and has all requisite corporate power and authority to enter into this Agreement and to perform its obligations under this Agreement;

(b) it is duly authorized by all requisite action to execute, deliver and perform this Agreement and to consummate the transactions contemplated hereby;

(c) the execution, delivery and performance by such Party of this Agreement and its compliance with the terms and provisions hereof does not and will not conflict with or result in a breach of any of the terms and provisions of or constitute a default under (i) a loan agreement, guaranty, financing agreement, agreement affecting a product or other agreement or instrument binding or affecting it or its property; (ii) the provisions of its charter or operative documents or bylaws; or (iii) any order, writ, injunction or decree of any court or other Governmental Authority entered against it or by which any of its property is bound;

(d) it has duly executed and delivered this Agreement;

(e) as of the Effective Date, each of its obligations under this Agreement is a legal, valid and binding obligation upon it, enforceable against it in accordance with the provisions of this Agreement except to the extent of the bankruptcy laws, laws of moratorium, and laws affecting the rights of creditors generally that might be applied with retroactive effect in any future proceeding;

(f) (i) it and its Affiliates have never been, are not currently, and during the Term of this Agreement will not become, a Debarred Entity and (ii) no debarred person or Debarred Entity has performed or rendered, or will perform or render, any services or assistance on its behalf relating to the Compound or the Product. If there exists a threat of debarment or any such debarment occurs, whether official or *de facto*, the effected Party shall promptly notify the other Party. "Debarred Entity" shall mean a corporation, partnership or association that has been debarred by the FDA pursuant to 21 U.S.C. §335a (a) or (b), or by any other Governmental Authority under Applicable Laws, or an employee, partner, shareholder, member, subsidiary or affiliate of a Debarred Entity;

(g) it and any of its Affiliates shall at all times comply with all Applicable Laws relating to its activities under this Agreement;

(i) neither it, nor any of its Affiliates, nor to its knowledge any director, officer, agent, employee, or other person acting on behalf of the respective Party or any of its Affiliates is aware of or has taken any action, or will knowingly during the Term of this Agreement take any action, directly or indirectly, that would result in a violation by such persons or each Party of Applicable Laws, including the FFDCA, title 21 of the Code of Federal Regulations, and guidelines promulgated by the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use, as applicable, and all other Applicable Laws (the "U.S. Food and Drug Regulation");

(ii) neither it, nor any of its Affiliates, nor to its knowledge any director, officer, agent, employee, or other person acting on behalf of the respective Party or any of its Affiliates is aware of or has taken any action, or will during the Term of this Agreement take any action, directly or indirectly, that would result in a violation by such persons or each Party of Applicable Laws on anti-corruption, anti-bribery, anti-money-laundering, sanctions or similar laws, including the U.S. Foreign Corrupt Practices Act, any sanctions, trade embargoes, or export controls implemented, administered, or enforced by the U.S. Department of the Treasury's Office of Foreign Assets Control or the U.S. Departments of State or Commerce, or any anti-bribery, anti-corruption, anti-money-laundering or sanction laws or regulations applicable in the Territory or Switzerland (the "Anti-Corruption and Sanction Laws");

(iv) the respective Party, its Affiliates, and, to its knowledge, any agent or other person acting on behalf of the respective Party or any of its Affiliates have conducted their businesses in compliance with such Anti-Corruption and Sanction Laws, and have instituted and will maintain during the Term of this Agreement policies and procedures designed to ensure, and which are reasonably expected to continue to ensure, continued compliance therewith;

(v) each Party represents and warrants that except in the case of its disclosure to the other Party in writing prior to the signing of this Agreement, (1) no significant shareholders (>25.0% shareholding), members of senior management team, members of the Board of Directors, or key individuals who will be responsible for the provision of goods / services, are currently or have been in the past two years a Government Official; (2) it is not aware of any immediate relatives (e.g., spouse, parents, children or siblings) of the persons listed in the previous subsection (1) having a public or private role which involves making decisions that could affect either Party's interests; (3) it does not have any other interest which directly or indirectly conflicts with its proper and ethical performance of this Agreement; and (4) it shall maintain arm's length relations with all third parties with which it deals for or on behalf of it in performance of this Agreement. Each Party shall inform the other Party in writing at the earliest possible opportunity of any conflict of interest as described in this clause that arises during the performance of this Agreement;

(vi) each Party represents and warrants it will not make any payment or transfer of value, directly or indirectly, to a Government Official or to any other person while knowing that all or some portion of the payment will be offered to the person for purposes of influencing the person's action or having any other influence on any person to do or omit to do any act in violation of the person's lawful duties, influencing an act or decision of the person's in his or her official capacity, inducing the person to use his or her influence with the government, or influencing the person to assist the other Party in obtaining or retaining business or in securing any improper business advantage or benefit;

(h) it does not have in effect, and after the Effective Date it shall not enter into any oral or written agreement or arrangement that would conflict with its obligations under this Agreement;

(i) it shall not, and shall cause its Affiliates and permitted Sublicensees not to, without the other Party's prior written consent, use any funding from any Governmental Authority to perform any activities under this Agreement in the Territory.

(j) each Party covenants to the other, as of the Effective Date and during the Term of this Agreement, that it shall be solely responsible for, and shall ensure the payment of, any compensation or remuneration for its employees or contractors performing activities in connection with this Agreement that is legally sufficient under Applicable Laws to compensate, remunerate and award such employees or contractors for their contributions to the Catalyst Inventions, Santhera Inventions and Joint Inventions, as applicable.

10.2 Clarification Regarding Field. As per the Execution Date, Santhera's Development of the Compound and the Product was focused mainly on the Initial Indication. Santhera is willing to grant a license in the Field as per Section 2.1 (Grant to Catalyst), but does not represent and warrant that the Compound or Product or Licensed Intellectual Property can be Developed or Commercialized for any Additional Indication.

10.3 Due Diligence. Catalyst acknowledges and confirms (a) it has conducted its own investigation and analysis of (i) the Licensed Intellectual Property and other proprietary rights of Third Parties as such rights relate to the Commercialization and Development of the Product in the Field in the Territory, and (ii) the potential infringement thereof, (b) understands the complexity and uncertainties associated with possible claims of infringement of Patent Rights or other proprietary rights of Third Parties, particularly those relating to pharmaceutical products, and (c) acknowledges and agrees that it is, subject to any claim it may have against Santhera for a misrepresentation or breach of warranty or otherwise under this Agreement, solely responsible for the risks of such claims. Catalyst acknowledges and agrees that it has received access to all requested information relating to the Licensed Intellectual Property and the Product and all its questions in relation thereto have been answered to its satisfaction in the course of its due diligence related to the transactions contemplated by this Agreement.

10.4 Disclaimers. EXCEPT FOR THE EXPRESS WARRANTIES SET FORTH HEREIN, NEITHER PARTY MAKES ANY REPRESENTATIONS OR WARRANTIES, EXPRESS OR IMPLIED, RELATING TO THE SUBJECT MATTER OF THIS AGREEMENT, AND EACH PARTY SPECIFICALLY DISCLAIMS ANY OTHER WARRANTIES RELATING TO THE SUBJECT MATTER OF THIS AGREEMENT, INCLUDING ANY WARRANTY OF VALIDITY OF LICENSED INTELLECTUAL PROPERTY, OR OF QUALITY, MERCHANTABILITY, OR FITNESS OF THE COMPOUND OR PRODUCT FOR A PARTICULAR USE. NOTHING IN THIS AGREEMENT SHALL BE CONSTRUED AS A WARRANTY OR REPRESENTATION BY SANTHERA THAT THE COMPOUND OR PRODUCT, OR THE PRACTICE OR USE OF THE LICENSED INTELLECTUAL PROPERTY WILL NOT INFRINGE THE INTELLECTUAL PROPERTY RIGHTS OF ANY THIRD PARTY.

11. **Confidentiality**

11.1 Obligations of Confidentiality and Non-Use. Each Receiving Party agrees that it shall keep confidential and shall not publish or otherwise disclose, and will take all reasonable steps to prevent disclosure of, Confidential Information of the Disclosing Party and will not use any Confidential Information of the Disclosing Party except to the extent permitted by this Agreement in connection with the performance of its obligations or exercise of its rights hereunder or otherwise agreed to in writing. Joint Inventions shall be deemed Confidential Information of both Parties. No provision of this Agreement shall be construed to preclude disclosure of Confidential Information to the extent required to be disclosed by Applicable Laws or by any rule or regulation of any court, stock exchanges or other Governmental Authority with competent jurisdiction; provided that the Receiving Party shall notify the Disclosing Party as soon as reasonably possible and whenever legally permissible and the Receiving Party shall, if requested by the Disclosing Party, use reasonable good faith efforts, at the expense of the Disclosing Party, to assist in seeking a protective order (or equivalent) with respect to such disclosure or otherwise take reasonable steps to avoid making such disclosure, and the Receiving Party shall furnish only that portion of the Confidential Information which it is advised by counsel is legally required whether or not a protective order or other similar order is obtained by the Disclosing Party. In addition, (a) the obligations of confidentiality set forth herein shall not be construed to prevent use or disclosure of, or reference to, such information as reasonably necessary to enforce the terms of this Agreement (whether in court, arbitration or otherwise), provided that the Party shall use reasonable good faith efforts to obtain confidential treatment in connection with any such disclosure of the Confidential Information of the other Party, and (b) either Party may disclose the Confidential Information of the other Party as reasonably necessary, under reasonable and customary written obligations of confidentiality, to actual or potential investors, acquirers (of the company or of assets related to this Agreement), permitted Sublicensees, contractors and others on a need to know basis, (c) a Receiving Party may use and disclose the Confidential Information of the Disclosing Party as reasonably necessary to obtain or maintain any Regulatory Approval and to conduct Development and Commercialization activities, including to conduct non-clinical studies and clinical trials and for pricing approvals, provided, that such activities are otherwise consistent with the Receiving Party's rights and obligations under this Agreement and that the Receiving Party shall take all reasonable steps to limit disclosure of the Confidential Information outside such regulatory agency and to otherwise maintain the confidentiality of the Confidential Information.

11.2 Confidentiality of Agreement. Except as permitted by this Section 11 (Confidentiality), neither Party shall disclose any financial terms or conditions of this Agreement or of the ReveraGen Agreement, without the prior written consent of the other Party; provided, however, that Santhera may disclose this Agreement and documents regarding reporting of royalties, audit rights, and patent prosecution relating to this Agreement or regarding its performance (including reports on milestones and any payments) to the Originator to the extent required for Santhera to comply with its obligations under the ReveraGen Agreement. Notwithstanding the foregoing, either Party may disclose the terms of this Agreement to the extent required by applicable statute, rule or regulation of any court or other Governmental Authority with competent jurisdiction or by applicable rules of the U.S. Securities and Exchange Commission or similar regulatory agency in any country other than the U.S. or of any stock exchange or listing entity ("Securities Authority") as it determines, based on advice of counsel, to be reasonably necessary to comply with Applicable Laws, including laws or regulations of a Securities Authority, or for appropriate market disclosure. Each Party shall provide the other Party with advance notice of such disclosures to the extent practicable and shall use reasonable efforts to submit to the other Party a draft of such public disclosure for review and comment by the other Party. The Parties will consult with each other on the provisions of this Agreement to be redacted in any filings made by a Party with a Securities Authority or as otherwise required by Applicable Laws; provided that each Party shall have the right to make any such filing as it reasonably determines to be necessary under Applicable Laws provided such Party shall use reasonable efforts to obtain confidential treatment of any information concerning this Agreement that such other Party requests be kept confidential, and shall only disclose Confidential Information which it is advised by counsel is legally required to be disclosed. No such notice shall be required under this Section 11.2 if the substance of the description of or reference to this Agreement contained in the proposed filing has been included in any previous filing made by the either Party hereunder or otherwise approved by the other Party.

11.3 Publicity. The Parties intend to issue a press release upon execution and delivery of this Agreement in a form reasonably acceptable to each of them. Thereafter, Santhera and Catalyst shall be free to use the information set forth in such press release or other publicly disclosed information in future public announcements or disclosures. Neither Party shall issue any other public announcement, press release, or other public disclosure regarding this Agreement or its subject matter, except (a) with the other Party's prior written consent, which shall not be unreasonably withheld, conditioned, or delayed, (b) for any such disclosure that is, in the opinion of the disclosing Party's counsel, required by Applicable Laws or the rules of a stock exchange on which the securities of the disclosing Party are listed, or (c) as provided in Section 11.2. Moreover, neither Party shall have any right to use the name, trademark, trade name or logo of the other Party or its employees without the prior express written permission of the other Party, except as may be required by the Applicable Laws or stock exchange regulations. Each Party acknowledges that, subject to this Section 11.3, the Party's Affiliates may issue a press release in relation to activities under this Agreement.

11.4 Scientific Publications. Each Party recognizes that the publication, such as by public oral presentation, manuscript or abstract, of the results of Development activities, including clinical trials, with respect to the Compound or Products may be beneficial to both Parties provided such publications are subject to reasonable controls to protect Confidential Information of each Party. Accordingly, each Party will have the right to review and comment on any scientific material proposed for publication or public oral or visual presentation by the other Party that relates to data developed as part of the Development of the Compound or Products (whether in or outside the Territory and including investigator-initiated trial data) or includes Confidential Information of such Party. Before any such material is submitted for publication, each Party will deliver a complete copy to the other Party at least [***] prior to submitting the material to a publisher or initiating any other disclosure. Such other Party will review any such material and give its comments to the Party within [***] of the delivery of such material to such other Party. With respect to public oral presentation materials and abstracts, each Party will make reasonable efforts to expedite review of such materials and abstracts, and will return such items as soon as practicable to the other Party with appropriate comments, if any, but in no event later than [***] from the date of delivery to such Party. Each Party will comply with the other Party's request to delete references to such other Party's Confidential Information in any such material. In addition, if any such publication contains patentable subject matter, then at the non-publishing Party's request, the publishing Party will either delete the patentable subject matter from such publication or delay any submission for publication or other public disclosure for a period of up to an additional [***] so that appropriate patent applications may be prepared and filed. For clarity, these limitations, other than with respect to confidential data, do not apply to investor presentations or materials presented by Catalyst or Santhera.

11.5 Equitable Relief. Each Party acknowledges that its breach of this Section 11 (Confidentiality) would cause irreparable harm to the other Party, which cannot be reasonably or adequately compensated in damages in an action at law. By reasons thereof, each Party agrees that the other Party shall be entitled, in addition to any other remedies it may have under this Agreement or otherwise, to preliminary and permanent injunctive and other equitable relief to prevent or curtail any actual or threatened breach of the obligations relating to Confidential Information set forth in this Section 11 (Confidentiality) by the other Party.

12. **Indemnification; Liability; Insurance**

12.1 Catalyst Indemnification. Catalyst shall indemnify, defend and hold Santhera, its Affiliates, and their respective officers, directors, employees and agents ("Santhera Indemnitees") harmless from and against any and all harm, liability, damage, loss and expense (including reasonable attorneys' fees and expenses of litigation) ("Loss") as a result of any Third Party claim, demand, action, or judgment, to the extent arising out of or relating to (a) the Development, Manufacture or Commercialization of the Product in the Territory by Catalyst, its Affiliates or Third Parties on behalf of Catalyst or its Affiliates; (b) any breach by Catalyst of this Agreement; or (c) the gross negligence or willful misconduct of any Catalyst Indemnitee (as hereinafter defined) relating to the Commercialization of the Product, provided, however, that the foregoing indemnity shall not apply to the extent that such Loss arose out of any of the matters for which Santhera is obligated to indemnify the Catalyst Indemnitees pursuant to Section 12.1 (Santhera Indemnification).

12.1 Santhera Indemnification. Santhera shall indemnify, defend and hold Catalyst, its Affiliates, and their respective officers, directors, employees and agents ("Catalyst Indemnitees") harmless from and against any and all Loss as a result of any Third Party claim, demand, action, or judgment, to the extent arising out of or relating to (a) the Development, Manufacture or Supply or Commercialization of the Product by Santhera, its Affiliates or Third Parties on behalf of Santhera or its Affiliates; (b) any breach by Santhera of this Agreement; or (c) the gross negligence or willful misconduct of any Santhera Indemnitee; provided, however, that the foregoing indemnity shall not apply to the extent that such Loss arose out of any of the matters for which Catalyst is obligated to indemnify the Santhera Indemnitees pursuant to Section 12.1 (Catalyst Indemnification).

12.2 LIMITATION ON LIABILITY. IN NO EVENT WILL EITHER PARTY BE LIABLE TO THE OTHER UNDER THIS AGREEMENT FOR ANY INDIRECT, SPECIAL, EXEMPLARY, PUNITIVE, INCIDENTAL OR CONSEQUENTIAL DAMAGES, INCLUDING LOST PROFITS AND LOST REVENUES.

12.3 Claims Procedures. A Party entitled to be indemnified by the other Party (an "Indemnified Party") pursuant to Section 12.1 (Catalyst Indemnification) or Section 12.1 (Santhera Indemnification) hereof shall give written notice to the other Party (the "Indemnifying Party") promptly after such Indemnified Party has actual knowledge of any threatened or asserted claim as to which indemnity may be sought, and shall permit the Indemnifying Party to assume the defense of any such claim or any litigation resulting therefrom, provided that:

(a) the Indemnified Party may participate in such defense at such Indemnified Party's expense;

(b) the failure of any Indemnified Party to give notice as provided herein shall not relieve the Indemnifying Party of its obligations under this Agreement to the extent that such failure to give notice did not result in prejudice to the Indemnifying Party or the Indemnifying Party's insurer;

(c) the Indemnifying Party, in the defense of any such claim or litigation, shall not, except with the approval of the Indemnified Party (which approval shall not be unreasonably withheld or delayed), consent to entry of any judgment or enter into any settlement which, (i) would result in injunctive or other non-monetary relief being imposed against the Indemnified Party; or (ii) does not include the giving (as an unconditional term thereof) by the claimant or plaintiff to such Indemnified Party of a release from all liability in respect to such claim or litigation; or (iii) includes an admission of liability; and

(d) the Indemnified Party shall furnish such information regarding itself or the claim in question as the Indemnifying Party may reasonably request in writing, and shall be reasonably required in connection with the defense of such claim or litigation resulting therefrom.

12.4 Insurance. Each Party shall obtain and maintain comprehensive general liability insurance customary in the industry for companies of similar size conducting similar business.

13. **Governing Law; Dispute Resolution**

13.1 Governing Law. This Agreement shall be governed by and construed in accordance with the laws of the State of New York, U.S. without regard to its conflict of laws rules and to the Convention on the International Sale of Goods.

13.2 Referral to Executives. If a Dispute cannot be resolved by good faith negotiations, it shall be referred, by written notice from either Party to the other, to the CEOs of the Parties for resolution. The CEOs or their respective designees (with similar authority to resolve such Dispute) shall negotiate in good faith to resolve such dispute through discussions promptly following such written notice. If the CEOs cannot resolve the dispute within [***] of such written notice, or either Party concludes that the matter will not be so resolved, then the Dispute shall be resolved as provided in Section 13.3 (Arbitration).

13.3 Arbitration. Subject to Section 13.4 (Disputes Relating to Patents and Trademarks and Equitable Relief), any Dispute arising out of or in connection with this Agreement or the enforcement of any provision of this Agreement, if not resolved by the CEOs pursuant to Section 13.2 (Referral to Executives), shall be finally resolved by binding arbitration administered by the ICC pursuant to the Rules of Arbitration of the ICC in force on the date on which a request for arbitration is submitted in accordance with those Rules. Judgment on the arbitration award may be entered in any court having jurisdiction thereof. The arbitration shall be conducted by a one or three arbitrators who shall have experience with respect to the matter(s) to be arbitrated. In case of three arbitrators, one shall be nominated by Catalyst, one shall be nominated by Santhera, and the third arbitrator, who shall serve as a chair, shall be nominated by the two party-nominated arbitrators. The place of arbitration shall be New York (New York, U.S.A.). The language of the proceedings shall be English. Either Party may apply to the arbitrator(s) for interim injunctive relief until the arbitration award is rendered or the controversy is otherwise resolved. Nothing contained herein shall be construed to permit the arbitrator(s) to award punitive, exemplary or similar damages. Each Party shall bear an equal share of the arbitrators' fees and any administrative fees of arbitration. Except to the extent necessary to confirm, challenge, or enforce an award or as may be required by Applicable Laws, neither a Party nor an arbitrator may disclose the existence, content, or results of an arbitration without the prior written consent of both Parties. The Parties further agree that any payments made pursuant to this Agreement pending resolution of the dispute shall be refunded if the arbitrator determines that such payments are not due.

13.4 Disputes Relating to Patents and Trademarks and Equitable Relief. Any Dispute relating to (a) either (i) the scope, validity, enforceability or infringement of any Patent Rights; or (ii) any Trademarks, shall in each case be submitted to a court of competent jurisdiction in the territory in which such Patent Rights or Trademark rights were granted or arose, or (b) the need to seek urgent preliminary (including injunctive) relief (e.g., in the event of a potential or actual breach of the provisions in Section 2.7 (Non-Compete During the Term) or the confidentiality and non-use provisions in Section 11 (Confidentiality)) need not be resolved through the procedure described in Section 13.3 (Arbitration), but may be immediately brought in any court of competent jurisdiction in order to preserve the status quo during the resolution of any dispute under Section 13.3 (Arbitration).

13.5 Attorneys' Fees. If any action or proceeding relating to this Agreement or the enforcement of any provision of this Agreement is brought against any Party hereto, the prevailing Party shall be entitled to recover reasonable attorneys' fees, costs and disbursements (in addition to any other relief to which the prevailing Party may be entitled).

14. **General Provisions**

14.1 Force Majeure. Except with regard to obligations to pay money, neither Party shall be held liable or responsible to the other Party or be deemed to have defaulted under or breached this Agreement for failure or delay in fulfilling or performing any term of this Agreement when such failure or delay is caused by Force Majeure. The non-performing Party shall notify the other Party of such Force Majeure by giving written notice to the other Party stating the nature of the event, its anticipated duration, and any action being taken to avoid or minimize its effect. The suspension of performance shall be of no greater scope and no longer duration than necessary to resolve such Force Majeure event and the non-performing Party shall use diligent efforts to remedy its inability to perform. If a condition constituting Force Majeure exists for more than [***], the Parties shall meet to negotiate a mutually satisfactory solution to the problem.

14.2 Amendment and Waiver. The terms and conditions of this Agreement may not be amended or modified, except in a writing signed by both Parties. No provision of or right under this Agreement shall be deemed to have been waived by any act or acquiescence on the part of any Party, its agents or employees, except by an instrument in writing signed by an authorized officer of such Party. No waiver by either Party of any breach of this Agreement by any other Party shall be effective as to any other breach, whether of the same or any other term or condition and whether occurring before or after the date of such waiver.

14.3 Independent Contractors. Each Party represents that it is acting on its own behalf as an independent contractor and is not acting as an agent for or on behalf of any Third Party. This Agreement and the relations hereby established by and between Santhera and Catalyst do not constitute a partnership, joint venture, agency or contract of employment between them. Neither Party shall be responsible for acts or omissions of the other Party or the other Party's agents or Affiliates or Sublicensees.

14.4 Assignment. No Party shall sell, assign or transfer its rights or obligations under this Agreement to any Third Party or to an Affiliate without the prior written consent of the other Party, except that (a) Santhera is entitled to assign the right to receive any payments under this Agreement from Catalyst (including milestone and other payments) to a Third Party without Catalyst's consent, and (b) each Party may sell, assign or transfer its rights and obligations under this Agreement without the other Party's consent to (i) a Third Party successor to substantially all of the relevant Party's business or assets relating to the Compound or Products (whether by merger, sale of stock, sale of assets or other transaction), or (ii) to an Affiliate. Any purported assignment of this Agreement in breach of this Section 14.4 (Assignment) shall be null and void. Subject to the foregoing, this Agreement will be binding on and inure to the benefit of the Parties and their respective successors and permitted assigns.

14.5 No Set-Off. Unless otherwise provided herein (including in Section 2.9(b) (ReveraGen Agreement) and in Section 6.11(f) (Recall)) or agreed in writing, payments to be made under this Agreement shall be made in full without any set-off or other similar rights.

14.6 Notices. All communications hereunder shall be in writing, in English and shall be deemed to have been duly given upon receipt by the addressee at the addresses set forth below, or such other address as either Party may specify by notice sent in accordance with this Section 14.6 (Notices). Receipt may be sufficiently established by confirmation of delivery by an internationally recognized courier service, such as Federal Express, DHL or UPS.

If to Catalyst:

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

with a copy to:

Akerman LLP
201 East Las Olas Blvd., 18th Floor
Fort Lauderdale, FL 33301
USA
Attention: Philip B. Schwartz, Esq.
Email: philip.schwartz@akerman.com

and

Cooley LLP
1700 Seventh Avenue, Suite 1900
Seattle, WA 98101
USA
Attention: Alison Freeman Gleason, Esq.
Email: afreemangleason@cooley.com

If to Santhera:

Santhera Pharmaceuticals (Schweiz) AG
Attn: Group General Counsel
Hohenrainstrasse 24
4133 Pratteln
Switzerland
Email: oliver.strub@santhera.com

with a copy to:

Schellenberg Wittmer AG
Attn.: Philipp Groz
Löwenstrasse 19
8001 Zürich
Switzerland
Email: philipp.groz@swlegal.ch

A copy of any notice under this Agreement shall be sent to the receiving Party by email, however, such email is neither a requirement for a proper notice, nor is it a sufficient notice. However, for communications at a day-to-day, operational level, correspondence by email shall be sufficient.

14.7 Severability. In the event any provision of this Agreement shall for any reason be held to be invalid, illegal or unenforceable in any respect, such invalidity, illegality or unenforceability shall not affect any other term or provision hereof. The Parties agree that they will negotiate in good faith or will permit a court or arbitrator to replace any provision hereof so held invalid, illegal or unenforceable with a valid provision which is as similar as possible in substance to the invalid, illegal or unenforceable provision.

14.8 No Presumption. In construing the terms of this Agreement, the Parties agree that no presumption shall exist or be implied against the Party which drafted such terms.

14.9 Word Meanings. Words such as herein, hereinafter, hereof and hereunder refer to this Agreement as a whole and not merely to a Section or paragraph in which such words appear, unless the context otherwise requires. The singular shall include the plural, and each masculine, feminine and neuter reference shall include and refer also to the others, unless the context otherwise requires. The word "or" is used in the inclusive sense typically associated with the phrase "and/or." The words "include," "includes" and "including" shall be deemed to be followed by the phrase "without limitation" and shall not be construed to limit any general statement which it follows to the specific or similar items or matters immediately following it. The word "will" shall be construed to have the same meaning and effect as the word "shall." All references herein to Sections or Exhibits shall be construed to refer to Sections and Exhibits of this Agreement, and references to this Agreement include all Exhibits hereto.

14.10 Language. This Agreement is in the English language only, which language will be controlling in all respects, and all versions hereof in any other language will be for accommodation only and will not be binding upon the Parties. All correspondence, documents and any other oral or written matters in connection with this Agreement shall be in English.

14.11 Expenses. Each party bears its own costs and expenses in connection with negotiating and drafting this Agreements.

14.12 Entire Agreement. This Agreement and the Exhibits attached hereto contain the entire understanding of each of the Parties hereto with respect to the transactions and matters contemplated hereby supersedes all prior agreements and understandings relating to the subject matter hereof; and no representations, inducements, promises or agreements, whether oral or otherwise, between such Parties not contained herein or incorporated herein by reference shall be of any force or effect. Any information exchanged between the Parties under the Confidential Disclosure Agreement shall be deemed Confidential Information under this Agreement and shall be governed by the provisions of this Agreement, in particular Section 11 (Confidentiality).

14.13 Further Assurances. Each Party shall and shall use all reasonable endeavors to procure that any necessary Third Party shall promptly execute and deliver such further documents and do such further acts as may be required for the purpose of giving full effect to this Agreement.

14.14 Counterparts. This Agreement may be executed in multiple counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. Each Party may execute this Agreement in Adobe™ Portable Document Format (PDF) sent by electronic mail or by any other electronic means. PDF or electronic signatures of authorized signatories of the Parties will be deemed to be original signatures, will be valid and binding on the Parties, and, upon delivery, will constitute due execution of this Agreement.

[signature page follows]

Santhera Pharmaceuticals (Schweiz) AG

By: /s/ Gunther Metz
Name: Gunther Metz
Title: EVP, Business Development

Date: June 19, 2023

By: /s/ Dario Eklund
Name: Dario Eklund
Title: CEO

Date: June 19, 2023

Santhera Pharmaceuticals Holding AG

By: /s/ Andrew Smith
Name: Andrew Smith
Title: CFO

Date: June 19, 2023

By: /s/ Oliver Strub
Name: Oliver Strub
Title: General Counsel

Date: June 19, 2023

Catalyst Pharmaceuticals Inc.

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

Date: June 19, 2023

Exhibits

Exhibit 1.78 – Licensed Patents

Exhibit 1.95 – Overview on Primary Packaging and Secondary Packaging

Exhibit 1.78
Licensed Patents

[***]

Exhibit 1.95
Overview on Primary Packaging and Secondary Packaging

[***]

EXHIBIT 10.2

Certain identified information has been excluded from this exhibit because it is both (i) not material, and (ii) would likely cause competitive harm to the registrant if publicly disclosed. [***] indicates that information has been redacted.

Investment Agreement

dated as of June 19, 2023

by and between

Santhera Pharmaceuticals Holding AG
Hohenrainstrasse 24
4133 Pratteln
Switzerland

(hereinafter the **Company**)

and

Catalyst Pharmaceuticals, Inc.
355 Alhambra Circle
Suite 801
Coral Gables, Florida 33134
USA

(hereinafter, the **Investor**)

(each the Company and the Investor a **Party** and together the **Parties**)

Whereas

A. The Company is a corporation organized and existing under the laws of Switzerland, registered in the Commercial Register of Canton Basel-Landschaft (the **Commercial Register**) under identification number CHE-105.388.338, with its registered office at Hohenrainstrasse 24, CH-4133 Pratteln, with a nominal share capital of CHF 1,255,884.45 (of which CHF 1,255,884.45 are registered in the Commercial Register at the date hereof), divided into 125,588,445 registered shares with a nominal value of CHF 0.01 each (each a **Share** and any such shares in the Company, the **Shares**). The Shares issued as at the date hereof are listed according to the International Reporting Standard on the SIX Swiss Exchange Ltd (the **SIX**) under ISIN CH0027148649.

B. As of the date hereof, the Company and its subsidiaries own 34,926,909 Shares in treasury (the **Treasury Shares**).

C. The Company is proposing to its 2023 annual general meeting of shareholders (the **AGM**), scheduled for June 27, 2023, a reverse share split at a ratio of 10:1 (the "**Reverse Split**"), as further set out in the invitation to the AGM available on the Company's website.

D. The Investor is a corporation organized under the laws of the State of Delaware, USA, with its principal place of business located at 355 Alhambra Circle, Suite 801, Coral Gables, Florida 33134, USA. At the date of this Investment Agreement, the Investor does not, whether directly or indirectly, own any Shares in the Company.

E. Concurrently with this Investment Agreement the Parties are entering into a License and Collaboration Agreement (the **License and Collaboration Agreement**) of even date herewith under which Santhera Pharmaceuticals (Schweiz) AG, a wholly-owned subsidiary of the Company, is granting to Investor, among other rights, the rights to develop and commercialize Vamorolone in North America.

F. The Company desires to privately place with the Investor 14,146,882 pre-Reverse Split Treasury Shares (each an **Investment Share**, collectively the **Investment Shares**), and the Investor desires to acquire the Investment Shares, in each case subject to the terms and conditions of this agreement (the **Investment Agreement**).

G. Subject to the lockup provisions contained in this Investment Agreement, the Investment Shares will be listed and freely tradable on the SIX.

Now, therefore, the Parties agree as follows:

1. Definitions

Capitalized terms used and not otherwise defined in this Investment Agreement shall have the meanings ascribed to them below:

Closing means the delivery of the Investment Shares to the Investor against payment of the aggregate Subscription Price.

Closing Date means the date on which the Closing actually occurs.

CO means the Swiss Code of Obligations of March 30, 1911, as amended.

Material Adverse Effect has the meaning of that term as set forth in the License and Collaboration Agreement

Securities Act means the United States Securities Act of 1933, as amended.

Subscription Price means a price per Investment Share equal to CHF 0.9477 pre-Reverse Split share, corresponding to the "volume weighted average closing price" of the Company's ordinary shares and the exchange rate as of the execution date of this Investment Agreement as reported on Bloomberg VWAP calculator during the ten Trading Days beginning 12 Trading Days before the execution date of this Investment Agreement and ending on the date that is two Trading Days prior to the execution date of this Investment Agreement. If applicable, the Subscription Price will be adjusted to account for the proposed Reverse Split of the Company's ordinary shares described in Recital C above.

Trading Day means any day on which the Shares are traded on SIX.

Transaction means the private placement of the Investment Shares with the Investor pursuant to this Investment Agreement.

2. Subscription and Payment by the Investor

Subject to the terms and conditions of this Investment Agreement, the Company hereby agrees to sell and transfer to the Investor, at the Closing, and the Investor hereby agrees to purchase and accept from the Company at the Closing, full legal and beneficial ownership of the Investment Shares, free and clear of any liens; at the fixed consideration per Investment Share payable by the Investor equal to the Subscription Price.

3. Conditions Precedent and Closing Date

3.1 Conditions Precedent

(a) The obligation of the Company to sell the Investment Shares to the Investor and the Investor's obligation to acquire the Investment Shares from the Company shall be subject to the satisfaction of the following conditions:

(i) the License and Collaboration Agreement has become effective;

(ii) the accuracy in all material respects (or, to the extent representations or warranties are qualified by Material Adverse Effect, in all respects when made), on the Closing Date of the representations and warranties of the Parties (unless as of a specific date therein, in which case they shall be accurate as of such date);

(iii) all governmental approvals required to effect the Closing, if any are required, have been obtained, including the HSR filing required under the License and Collaboration Agreement; and

(iv) no action shall be pending and no order or injunction of any governmental authority or arbitral tribunal shall exist which prohibits the consummation of this Investment Agreement;

(v) there has been no Material Adverse Effect with respect to the Company since the execution date of this Investment Agreement.

(b) The Closing shall occur on the Effective Date (as defined in the License and Collaboration Agreement).

(c) If the conditions precedent set forth in Section 3.1(a) have not been satisfied or have become incapable of being satisfied, or if Closing shall not have occurred, in each case within 30 calendar days after the Effective Date and other than due to the frustration of such conditions precedent or a breach of this Investment Agreement by the party seeking to terminate this Investment Agreement, each party may terminate this Investment Agreement.

3.2 Closing Actions of the Company

(a) On the Closing Date, in exchange for the performance of the closing actions by the Investor pursuant to Section 3.3, the Company shall deliver or procure the delivery of the Investment Shares to the custody account of the Investor (or, if such custody account is booked outside Switzerland, the custody account of the Swiss correspondent bank of the Investor's custodian) designated by the Investor to the Company in writing.

(b) At the Closing, the Company shall also deliver to Investor:

(i) a certificate of an officer of the Company and dated the Closing Date confirming on behalf of the Company that the conditions set forth in Section 3.1(a) have been satisfied.

(ii) a certificate of the corporate secretary of the Company certifying to Investor a true and complete copy of the Company's Articles of Association and Organizational Resolutions and a copy of the resolutions adopted by the board of directors of the Company approving the transactions contemplated by this Investment Agreement and the License and Collaboration Agreement.

(iii) The Company shall deliver to the Investor an executed W8/BEN or other appropriate tax form to support payment of the Subscription Price without required withholding.

3.3 Closing Actions of the Investor

(a) On the Closing Date, in exchange for the performance of the closing actions by the Company pursuant to Section 3.2, the Investor shall pay the aggregate Subscription Price for the Investment Shares to [***] (the **Company's Bank Account**) with value date not later than the Trading Day following the Closing Date.

(b) At the Closing, the Investor shall also deliver to Company:

(i) a certificate of an officer of the Investor and dated the Closing Date confirming on behalf of the Investor that the conditions set forth in Section 3.1(a) have been satisfied.

(ii) a certificate of the corporate secretary of the Investor certifying to Company a true and complete copy of the Certificate of Incorporation and Bylaws of the Investor and a copy of the resolutions adopted by the board of directors of the Investor approving the transactions contemplated by this Investment Agreement and by the License and Collaboration Agreement.

4. Representations

4.1 Representations of the Company

Subject to the limitations set forth in this Investment Agreement, the Company hereby represents to the Investor in the sense of article 197 CO that the following representations (*Zusicherungen*) are true and correct as of the execution date of this Investment Agreement and will be true and correct as of the Closing Date:

(a) The Company is duly incorporated, organized and validly existing under the laws of Switzerland and has the full corporate power, authority and right to carry on its business as presently being conducted and to complete the transaction contemplated by this Investment Agreement.

(b) The Company has the right and capacity to execute this Investment Agreement and has, except to the extent contemplated by this Investment Agreement, taken all actions and obtained all consents and approvals necessary to execute and perform its obligations under this Investment Agreement; (ii) this Investment Agreement constitutes valid and binding obligations of the Company, enforceable against the Company in accordance with its terms; and (iii) there are no limitations under applicable law, subject to applicable bankruptcy, reorganization, insolvency or other laws affecting the enforcement of creditors' rights in general, that would prevent the Company from entering into or performing its obligations under this Investment Agreement.

(c) The execution of, and performance by the Company of its obligations under, this Investment Agreement as contemplated by this Agreement, and the consummation of the transactions herein contemplated, do not or will not conflict with or result in a breach or violation of any of the terms or provisions of, or constitute a default under, (i) the articles of association, by-laws or other constituent documents of the Company, (ii) any applicable law, statute, rule, regulation, judgement, order, writ or decree of any government, governmental authority or agency or court, domestic or foreign, having jurisdiction over the Company or any of its subsidiaries or any of its or their assets or operations, (iii) any obligation, agreement, undertaking or condition contained in any contract, indenture, mortgage, deed of trust, loan or credit agreement, note, lease, license or other instrument to which the Company or any of its subsidiaries is a party or by which the Company or any of its subsidiaries bound or to which any of the property or assets of the Company or any its subsidiaries is subject, or (iv) any judgment, order or decree of any government, governmental authority or agency or court, domestic or foreign, having jurisdiction over the Company or any of its subsidiaries or any of its or their assets or operations.

(d) The Company has valid title to the Investment Shares.

(e) Prior to the execution date of this Investment Agreement, the board of directors of the Company has approved with all requisite required corporate formalities:

(i) the execution, delivery and performance of this Investment Agreement by the Company and the transactions contemplated herein; and

(ii) the registration of the Investor for all Investment Shares in the share register of the Company with full voting rights, subject only to the Closing occurring.

(f) No authorizations, permits or consents are required from any governmental or administrative authority or any third party (including, without limitation, any shareholders or creditors of the Company) for the consummation of the Transaction other than as set forth in this Investment Agreement.

(g) There are no actions, suits or proceedings pending or threatened in writing against the Company before any court, arbitral tribunal or governmental or administrative authority seeking to prohibit the consummation of this Investment Agreement.

(h) The Investment Shares are duly authorized, validly issued, fully paid and nonassessable, and free and clear of any liens or encumbrances except for any restrictions provided by this Investment Agreement.

(i) Neither the Company nor any person acting on behalf of the Company has offered or sold any of the Investment Shares by any form of general solicitation or general advertising. The Company has offered the Investment Shares for sale only to the Investor.

(j) The share capital of the Company as of the date hereof is as set forth on Schedule 4.1(j) to this Investment Agreement, which Schedule 4.1(j) shall also include a description of treasury shares, authorized and conditional capital, and capital range.

(k) The sale and delivery of the Investment Shares does not contravene the rules and regulations of the SIX, and the sale and delivery of the Investment Shares to the Investor will not require any filing with or approvals by the competent commercial register or the SIX.

(l) Since the date of the last audited financial statements, except as set forth on Schedule 4.1(l), there have been no events, occurrences or developments that have or could reasonably be expected to have a Material Adverse Effect on the Company's results of operations, assets, business, condition (financial or otherwise) or prospects.

(m) Immediately upon announcement of entering into the License and Collaboration Agreement and this Investment Agreement, the Company will have made public all information required to be made public by applicable law and regulation and the Company has not postponed the disclosure of any price-sensitive information (as that term is understood pursuant to art. 53 of the Listing Rules of the SIX).

(n) The sale of the Investment Shares will not constitute a violation by the Company of any applicable law prohibiting insider trading in securities or the misuse of insider information.

(o) As of the Closing Date, after giving effect to the receipt of the proceeds from the sale of the Investment Shares and the proceeds payable on the Closing Date to the Company under the License and Collaboration Agreement, the Company will be solvent and have sufficient working capital for the 12 months following the Closing Date for the operation of its business and for the business of its subsidiaries as currently conducted and intended to be conducted over such 12-month period.

4.2 Representations of the Investor

Subject to the limitations set forth in this Investment Agreement, the Investor hereby represents to the Company in the sense of article 197 CO that the following representations (*Zusicherungen*) are true and correct of the execution date of this Investment Agreement and will be true and correct as of the Closing Date:

(a) The Investor is duly incorporated, organized and validly existing under the laws of the jurisdiction of its incorporation and has the full corporate power, authority and right to carry on its business as presently being conducted.

(b) (i) the Investor has the right and capacity to execute this Investment Agreement and to perform its obligations hereunder; (ii) this Investment Agreement constitutes valid and binding obligations of the Investor, enforceable against the Investor in accordance with its terms; and (iii) there are no limitations under applicable law, subject to applicable bankruptcy, reorganization, insolvency or other laws affecting the enforcement of creditors' rights in general, and the constitutional documents of the Investor that would prevent the Investor from entering into or performing its obligations under this Investment Agreement.

(c) No authorizations, permits or consents are required from any governmental or administrative authority or any third party (including, without limitation, any shareholders or creditors of the Investor) for the consummation of the Transaction other than as set forth herein.

(d) There are no actions, suits or proceedings pending or threatened in writing against the Investor before any court, arbitral tribunal or governmental or administrative authority seeking to prohibit the consummation of this Investment Agreement.

(e) The purchase of the Investment Shares will not constitute a violation by the Investor of any applicable law prohibiting insider trading in securities or the misuse of insider information.

(f) The Investor has liquid funds available to pay the aggregate Subscription Price.

(g) The Investor is acquiring the Investment Shares in the ordinary course of its business, in its own name, for its own account and for investment purposes and not with a view to, or for offer or sale in connection with, any distribution (within the meaning of the United States securities laws) of the Investment Shares or any economic interest therein.

(h) In making the decision to invest in the Investment Shares, the Investor is able to fend for itself and has such knowledge and experience in financial or business matters that it is capable of evaluating the merits and risks of the investment in the Investment Shares. The Investor has made its own assessment, to its satisfaction, concerning legal, regulatory, tax, business and financial considerations in connection with the Transaction, has had access to and reviewed all publicly available information concerning the Company that it considers necessary or appropriate and sufficient in making an investment decision with respect to the Investment Shares, and has made such investment decision based solely upon its own judgment, due diligence and analysis. The Investor can bear the economic risk of its investment in the Investment Shares, including the complete loss of the entire aggregate Subscription Price.

(i) The Investor has satisfied itself as to the full observance of securities and other laws applicable to the Investor in connection with the Transaction.

(j) The Investor acknowledges that there may be certain consequences under U.S. and other tax laws resulting from an investment in the Shares and has satisfied itself, without limitation, concerning the effects of U.S. federal, U.S. state and U.S. local income tax laws and tax laws outside the United States concerning its investment in the Investment Shares. The Investor acknowledges that the Company is giving no assurance that it is not and will not become a “passive foreign investment company” within the meaning of Section 1297 of the U.S. Internal Revenue Code of 1986, as amended.

(k) The Investor is not purchasing the Investment Shares as a result of any advertisement, article, notice or other communication regarding the Investment Shares published in any newspaper, magazine or similar media or broadcast over television or radio or presented at any seminar or any other “general solicitation” or “general advertising” within the meaning of Rule 502(c) under the Securities Act.

(l) The Investor is an accredited investor as defined in Rule 501(a)(3) of Regulation D under the Securities Act and has not been organized for the purpose of acquiring the Investment Shares or any Shares. The Investor understands that the issuance and sale of the Investment Shares have not been and will not be registered under the Securities Act, or registered or qualified under any U.S. state securities laws, and agrees that the issuance and sale of the Investment Shares are being made in reliance on exemptions from the registration requirements of the Securities Act. The Investor acknowledges and agrees that the Investment Shares cannot be resold in the United States unless they are registered under the Securities Act or disposed of pursuant to an applicable exemption from the registration requirements of the Securities Act. The Investor is familiar with Rule 144 under the Securities Act, as presently in effect, and understands the resale limitations imposed thereby and by the Securities Act. The Investor acknowledges and agrees that no representation or warranty has been made by the Company as to the availability of Rule 144, Rule 144A or any other exemptions from registration under the Securities Act for the offer, resale, pledge or transfer of the Investment Shares.

4.3 Remedies and Limitations

(a) Each Party acknowledges that, other than as expressly provided in this Investment Agreement, the other Party has not made, and does not make, and has not relied and does not rely on, any representation or warranty, express or implied, relating to the subject matter of this Investment Agreement. The Investor acknowledges that the Company does not make any representations or warranties as to the Company's and its subsidiaries' past, current or future business, results of operations, financial position or prospects, or as to the valuation of the Shares.

(b) In the event of a breach of a representation set forth in Section 4.1 or 4.2, the Party not in breach (the **Claiming Party**) shall have the right to put the Party in breach (the **Breaching Party**) in the position in which it would have been, had no such breach occurred, within 45 SIX Trading Days. To the extent such remedy cannot be effected or is not effected within such period of time, the Breaching Party shall be liable to the Claiming Party, subject to the exclusions and limitations set forth in this Investment Agreement, for any direct loss, damage, cost or expense (but excluding indirect, punitive and consequential damages, indirect costs and expenses, or loss of profit), incurred or sustained by the Claiming Party as a result of such misrepresentation.

(c) Except in case of gross negligence or willful misconduct, the Claiming Party shall only be entitled to recover losses that exceed the equivalent of [***] in the aggregate, in which case the full amount (and not the exceeding amount only) shall be recovered, and the liability of the Breaching Party under this Investment Agreement shall not exceed the aggregate Subscription Price.

(d) The remedies of the Parties set forth in this Investment Agreement shall be in lieu of, and not in addition to, the remedies and termination rights provided for under statutory law. All other remedies, including any rights pursuant to articles 192 et seq. and 197 et seq. CO (other than article 199 and article 203 CO, but including, for avoidance of doubt, article 200 CO) and any rights of a similar nature, the right to rescind this Investment Agreement (*Wandelung*) under article 205 CO or otherwise, the right to challenge the validity of this Investment Agreement for fundamental error under articles 23 et seq. CO and any remedies under the theory of *culpa in contrahendo* shall not apply and are hereby expressly waived.

5. Covenants

5.1 Conduct of Business Pending Closing

During the period beginning on the execution date of this Investment Agreement and ending on the Closing Date, unless specifically consented to by the Investor in writing (which consent shall not be unreasonably withheld), the Company shall carry on its business in the ordinary course of business and in compliance with all applicable laws, except to the extent that such non-compliance would not have a Material Adverse Effect. Except as contemplated by this Investment Agreement, without Investor's written consent (which consent may be withheld by Investor in its sole discretion), the Company will not:

(a) voluntarily liquidate, dissolve or wind up its business and affairs, declare, set aside or pay any dividends on, or make any other distributions (whether in cash, stock or property) in respect of any of its capital stock, or effect any stock split combination of shares, recapitalization, or reclassification, except for the Reverse Split;

(b) enter into any merger, consolidation, business combination, recapitalization, liquidation, dissolution, binding share exchange or similar transaction involving the Company pursuant to which any Person or group (or the stockholders of any Person) would own, directly or indirectly, twenty-five percent (25%) or more of any class of equity securities of the Company or of the surviving entity in a merger or the resulting direct or indirect parent of the Company or such surviving entity; or

(c) authorize any of, or commit or agree to take any of, the foregoing actions.

5.2 Standstill

(a) The Investor shall not for a period of six months following the Closing of this Investment Agreement, and shall procure that no person on its behalf will, acquire, or agree to acquire, any Shares or other equity securities of the Company or any financial instruments or rights relating, in any manner whatsoever, to the Shares or any other equity securities of the Company (including financial instruments or rights providing for a cash settlement only).

(b) The Investor shall not exercise, whether directly or indirectly, its voting rights with respect to the Investment Shares for a period of three months commencing on the Closing Date of this Investment Agreement.

5.3 Lock-up

(a) The Investor shall not for a period of six months following the Closing of this Investment Agreement (the **Initial Lock-up Period**), and shall procure that no Person on its behalf will, offer, sell, contract to sell or otherwise dispose of, or publicly announce any such offer, sale, contract or disposal, whether directly or indirectly, any or all Investment Shares or enter into any swap or other arrangement that transfers to another Person, any or all of the Investment Shares or any of the economic consequences of ownership thereof or announce its intention to do any of the foregoing without the prior written consent of the Company such consent being entirely and solely in the Company's discretion.

(b) Subject to subsection (c) below, following the Initial Lock-up Period, the Investor shall not, and shall procure that no person on its behalf, will, take any action described in Section 5.3(a), without the prior written consent of the Company, except that the Investor may, without the Company's consent, sell up to 1/3 of the Investment Shares on the SIX during each month following the Initial Lock-up Period.

(c) After nine months from the Closing of this Investment Agreement, any Investment Shares still owned by the Investor shall be freely tradable and shall no longer be subject to a lock-up.

5.4 Registration as Shareholder

Subject to Article 5 of the articles of association as in effect from time to time, the Company shall register the Investor as a shareholder with voting rights with respect to the Investment Shares promptly after delivery of the Investment Shares to the custody account indicated by the Investor, in accordance with Section 3.2.

5.5 United States Limitations

The Investor agrees that if it should decide to dispose of any of the Investment Shares, it will transfer such shares in compliance with all applicable U.S. securities laws and regulations.

5.6 Other Investors

The Investor takes note that the Company may issue and/or privately place additional Investment Shares or equity-linked instruments to other investors concurrently with or subsequent to the Transaction on the same terms or on different terms as the terms of the Transaction.

5.7 Reporting

The Investor shall, and shall procure that its beneficial owners will, comply with the disclosure requirements with respect to significant shareholdings in accordance with art. 120 et seq. of the Financial Market Infrastructure Act and its implementing regulations and any other requirements applicable to the Investor by applicable laws or regulations in connection with the transactions contemplated by this Investment Agreement.

5.8 Confidentiality and Announcements

(a) The Investor hereby consents to the disclosure of information relating to the Investor and the Transaction by the Company as required by applicable laws or stock exchange regulations. The Company and the Investor will publicly announce the Transaction before the start of trading on the SIX on the Trading Day immediately following the execution date of this Investment Agreement.

(b) Until the Company and the Investor have publicly announced the Transaction, the Parties shall, and shall procure that their respective affiliates, director, officers, employees, and advisors will, keep this Investment Agreement and its content strictly confidential, subject to applicable laws.

6. Use of Proceeds

The Company shall only use the aggregate Subscription Price received by it hereunder for the purposes set forth in the License and Collaboration Agreement.

7. General Provisions

(a) Each Party shall bear all taxes incurred by or levied on it in connection with the Transaction.

(b) Each Party shall bear its own costs and expenses (including advisory and legal fees) incurred in the negotiation, preparation and completion of this Investment Agreement.

(c) Except as otherwise expressly provided in this Investment Agreement, no person other than the Parties hereto shall have any rights or benefits under this Investment Agreement, and nothing in this Investment Agreement is intended to confer on any person other than the Parties any rights, benefits or remedies.

(d) All notices, requests or other communications to be given under or in connection with this Investment Agreement shall be made in writing and delivered by registered, certified or express mail (return receipt requested), an internationally recognized courier (or by a scanned electronic copy followed by the original document), as follows:

if to the Company: to the address set forth on the cover page
Att. Oliver Strub, Group General Counsel

Email: oliver.strub@santhera.com

with a copy to: Homburger AG
Att. Daniel Häusermann
Hardstrasse 201
8005 Zurich, Switzerland

Email: daniel.haeusermann@homburger.ch

if to the Investor: to the address set forth on the cover page
Att. Brian Elsbernd, Chief Legal Officer

Email: belsbernd@catalystpharma.com

with copies to: Akerman LLP
Att. Philip B. Schwartz, Esq.
201 East Las Olas Blvd., Suite 1800
Fort Lauderdale, Florida 33301

Email: philip.schwartz@akerman.com

and

Advestra AG
Att: Daniel Raun, Esq.
Uraniastrasse 9
8001 Zurich, Switzerland

Email: daniel.raun@advestra.ch

Any notice to be given hereunder shall be given prior to the expiry of a term or deadline (if any) set forth in this Investment Agreement or by applicable law and shall be effective only if it was (i) timely and duly given in accordance with this Section 6(d) and (ii) actually received by the Party to whom it is addressed, irrespective of whether such notice was received prior to or after the expiry of the respective term or deadline (if any).

(e) This Investment Agreement constitutes the entire agreement and understanding between the Parties with respect to the subject matter hereof, and shall supersede all prior oral and written agreements and understandings of the Parties relating hereto.

(f) This Investment Agreement may only be modified or amended by a document signed by the Parties. Any provision contained in this Investment Agreement may only be waived by a document signed by the Party waiving such provision.

(g) Signatures to this Investment Agreement transmitted by facsimile, by email in “portable document format” (pdf), or by any other electronic means intended to preserve the original graphic and pictorial appearance of this Investment Agreement shall have the same effect as physical delivery of the paper document bearing original signature.

(h) Except as otherwise expressly provided in this Investment Agreement, a Party shall not assign this Investment Agreement or any rights or obligations hereunder to any third party without the prior written consent of the other Party.

(i) If the last or appointed day for the taking of any action or the expiration of any right required or granted herein shall not be a Trading Day, then such action may be taken or such right may be exercised on the next succeeding Trading Day.

(j) The Parties agree that each of them and/or their respective counsel have reviewed and had an opportunity to revise the Investment Agreement and, therefore, the rule of construction to the effect that any ambiguities are to be resolved against the drafting party shall not be employed in the interpretation of the Investment Agreement or any amendments thereto.

(k) Each and every reference to share prices and shares of Common Stock in this Investment Agreement is subject to adjustment for reverse and forward stock splits, stock dividends, stock combinations and other similar transactions of the Common Stock that occur after the date of this Investment Agreement but before the Closing Date.

(l) If any part or provision of this Investment Agreement or the application of any such part or provision to any person or circumstance shall be held to be invalid, illegal or unenforceable in any respect by any competent arbitral tribunal, court, governmental or administrative authority, (i) such invalidity, illegality or unenforceability shall not affect any other part or provision of this Investment Agreement or the application of such part or provision to any other person or circumstances, and (ii) the Parties shall endeavor to negotiate a substitute provision that best reflects the economic intentions of the Parties without being invalid, illegal or unenforceable, and shall execute all agreements and documents required for its implementation.

(m) This Investment Agreement shall be exclusively governed by and construed in accordance with the substantive laws of Switzerland, excluding its conflict of laws principles.

(n) Disputes under this Investment Agreement shall be resolved by binding arbitration conducted in the manner and at the place set forth in the applicable provision of the License and Collaboration Agreement.

[Signatures on the next page]

Executed on the date written on the cover page to this Investment Agreement.

Santhera Pharmaceuticals Holding AG

/s/ Andrew Smith
Name: Andrew Smith
Title: CFO

/s/ Oliver Strub
Name: Oliver Strub
Title: General Counsel

Executed on the date written on the cover page to this Investment Agreement.

Catalyst Pharmaceuticals, Inc.

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

SCHEDULE 4.1(j)

CAPITALIZATION

Current	Shares at CHF 0.01	After 2023 AGM at CHF0.01 - if approved	After 2023 AGM reverse split - if approved	In pct -if approved
Ordinary	125,588,445	125,588,450	12,558,845	100.0%
Capital range maximum in	—	60,411,550	6,041,155	48.1%
Authorized	46,860,687	—		0.0%
Conditional ESOP	5,034,583	5,573,000	557,300	4.4%
Conditional financing	29,888,687	55,000,000	5,500,000	43.8%
Total	**207,372,402**	**246,573,000**	**24,657,300**	**196.3%**
Treasury shares	**34,926,909**			

SCHEDULE 4.1(l)

MATERIAL CHANGES SINCE DECEMBER 31, 2022

(As per page 84 of the Company's Annual Report for 2022)

31. Events after the Reporting Date

In January 2023, the FDA formally accepted the submission of the NDA for vamorolone in DMD for review and notified that it has set the target date for its decision on the NDA to October 26, 2023. Following the acceptance of NDA submission, the Company has received USD 2.0 million milestone payment in relation to China license.

In January 2023, the Company entered into a share exchange agreement with Idorsia, pursuant to which ldorsia transferred 346,500 of its registered shares to Santhera, As consideration, Santhera delivered 5,529,016 Shares, valued at CHF 0.9043 to Idorsia and issued 2,211,607 warrants to ldorsia, each of which is exercisable for one Share at an exercise price of CHF 0.9043 at any time until January 9, 2025. The purpose of such share exchange was to obtain short-term liquidity by selling the Idorsia Shares. As of the date of issuing these consolidated financial statements, all these Idorsia Shares have been sold generating net proceeds of CHF 5.6 million

In February 2023, the Company secured a final pricing reimbursement agreement with the French authorities related to Raxone for the treatment of LHON. The newly agreed price for Raxone in France is lower than the price applied under the temporary pricing scheme, leading to a settlement payment in the amount of approximately EUR 25.4 million, with 30% due around mid-2024 and the remainder one year later. The first payment is currently expected to be covered by sales generated until mid-2024, while the majority of the second payment will be covered by sales beyond mid-2025,

In February 2023, Santhera secured additional funding through a private placement of shares and an amendment of its existing financing arrangement with funds managed by Highbridge to provide up to CHF 22.2 million, subject to certain milestones and conditions. This is intended to cover the capital requirements of the Company through to the PDUFA date in October 2023, when an FDA decision on vamorolone is expected. Concomitant with this transaction, Santhera has formed Strategy Committee focusing on evaluating all strategic options for the Company and plans to nominate Bradley Meyer for election as a new member of its Board of Directors at the Company's upcoming AGM until when he will serve as a Board Observer. In addition, Santhera issued 40 million shares, 37 million of which were transferred to treasury, in the ordinary capital increase resolved by its $ shareholders on November 29, 2022.

In March 2023, the Company announced that it has submitted a marketing authorization application (MAA) to the UK Medicines and Healthcare products Regulatory Agency (MHRA) for vamorolone for the treatment of DMD.

Exhibit 99.1

Catalyst Pharmaceuticals to License North American Rights to Vamorolone for Duchenne Muscular Dystrophy from Santhera Pharmaceuticals

June 20, 2023 at 6:00 AM EDT

Vamorolone is Currently Under Review with the FDA (PDUFA Date of October 26, 2023) for the Treatment of Duchenne Muscular Dystrophy, a Rare Neuromuscular Disease

FDA has Granted Fast Track and Orphan Drug Designation for Vamorolone to Treat Duchenne Muscular Dystrophy

Catalyst Expects to Launch Vamorolone in the U.S. Early in Q1 2024, Subject to Regulatory Approval by the PDUFA Date

Agreement to Include Commercial and Future Development Rights for Vamorolone for Additional Indications in North America and the Right of First Negotiation in Europe and Japan Should Santhera Pursue Partnership Opportunities

Transaction Also Includes a Strategic Equity Investment by Catalyst in Santhera

CORAL GABLES, Fla., June 20, 2023 (GLOBE NEWSWIRE) — Catalyst Pharmaceuticals, Inc. (“Catalyst”) (Nasdaq: CPRX), a commercial-stage biopharmaceutical company focused on in-licensing, developing, and commercializing novel medicines for patients living with rare diseases, today announced that Catalyst has entered into a definitive agreement with Santhera Pharmaceuticals Holding (“Santhera”) (SIX: SANN) under which Catalyst will enter into an exclusive North America license, manufacturing and supply agreement for Santhera’s investigational product candidate, vamorolone, a dissociative steroid currently under FDA review for the treatment of Duchenne Muscular Dystrophy (“DMD”). The licensing agreement delivers a promising complementary product to Catalyst’s growing rare neuroscience product portfolio and enables further expansion into other rare neurological diseases that address significant unmet medical needs. In addition to the North American rights, which consist of the United States, Canada, and Mexico territories, the transaction provides Catalyst the right of first negotiation for vamorolone in Europe and Japan should Santhera pursue partnership opportunities.

Vamorolone was studied for the indication of DMD, a rare neuromuscular disorder. Santhera filed a New Drug Application (“NDA”) for vamorolone, supported by clinical data from the positive pivotal Phase 2b VISION-DMD study, which met the primary endpoint with statistical significance over placebo. The vamorolone NDA has been accepted and is currently under review by the U.S. Food and Drug Administration (“FDA”) for the treatment of DMD. FDA assigned a Prescription Drug User Fee Act (“PDUFA”) target action date of October 26, 2023.

“We are extremely pleased to be entering into a partnership with Santhera on the vamorolone program and the prospect of delivering a potential therapy with a desirable profile for DMD patients,” said Patrick J. McEnany, Chairman and CEO of Catalyst. “We believe this transaction provides us with a highly complementary drug candidate with outstanding clinical data that will accelerate our offerings of effective and innovative treatment advances to people living with rare neurological disorders. If approved, vamorolone would represent an important inflection point in our long-term growth strategy, further leveraging the company as a growing leader in rare neurological diseases. Upon closing the transaction, we will be well-positioned to capitalize on the synergies of our expanded and exceptional capabilities in preparation for the launch of vamorolone, which, assuming approval of the NDA by the PDUFA date, is anticipated to occur early in 2024. We look forward to collaborating with our partners who share our commitment to providing innovative new treatment advances to patients living with rare neurological disorders.”

Mr. McEnany continued, “Vamorolone has the potential to be a differentiated treatment for DMD with a desirable profile in comparison to the current standard of care options, addressing an important unmet medical need for Duchenne patients starting at an early age. The FDA has granted vamorolone Orphan Drug, Fast Track, and Rare Pediatric Disease designations. If approved, vamorolone would further broaden our commercial portfolio with a novel asset enabling us to further build upon our growth momentum with differentiated medicines that treat rare neurological and neuromuscular disorders.”

Transaction Terms

Under the terms of the agreement, Catalyst will make a $75 million upfront payment to Santhera and a concurrent strategic equity investment of $15 million into Santhera at an investment price of CHF 0.9477, corresponding to a mutually agreed volume-weighted average price prior to signing, with the equity investment proceeds to be used by Santhera for Phase IV studies in DMD and further development of additional indications. In addition, Santhera may receive future regulatory and commercial milestone payments tied to FDA approval and calendar year sales of vamorolone, as well as commercial royalties. Furthermore, Catalyst and Santhera will enter into a Joint Steering Committee to oversee the development of vamorolone for additional indications beyond DMD.

The agreement is structured as an all-cash transaction with no financing contingencies. The transaction is expected to be completed in the third quarter of 2023, subject to customary closing conditions and regulatory clearances in the United States and does not impact Catalyst’s 2023 revenue guidance. The proposed transaction is subject to agreed terms and other closing conditions, including third-party approvals. Catalyst anticipates that upon closing of this transaction, it will be in a position to provide greater details regarding its plans and prospects for vamorolone, as well as the accounting treatment for the transaction.

Moelis & Company LLC is acting as the exclusive financial advisor to Catalyst, and Akerman LLP and Cooley LLP are acting as legal advisors to Catalyst.

About Vamorolone

Vamorolone is an investigational drug candidate with a mode of action based on binding to the same receptor as glucocorticoids but modifying its downstream activity and as such, is considered a dissociative anti-inflammatory drug [2-5]. This mechanism has shown the potential to ‘dissociate’ efficacy from steroid safety concerns and therefore vamorolone could emerge as an alternative to existing corticosteroids, the current standard of care in children and adolescent subjects with DMD. In the pivotal VISION-DMD study, vamorolone met the primary endpoint Time to Stand (TTSTAND) velocity versus placebo (p=0.002) at 24 weeks of treatment and showed a good safety and tolerability profile [1]. The most commonly reported adverse events versus placebo from the VISION-DMD study were cushingoid features, vomiting and vitamin D deficiency. Adverse events were generally of mild to moderate severity.

Vamorolone has been granted Orphan Drug status for DMD in the U.S. and in Europe and has received Fast Track and Rare Pediatric Disease designations by the U.S. FDA and Promising Innovative Medicine (PIM) status from the UK MHRA for DMD. Vamorolone is an investigational medicine and is currently not approved for use by any health authority.

References:

[1] Guglieri M et al (2022). JAMA Neurol. 2022;79(10):1005-1014.doi:10.1001/jamaneurol.2022.2480. Link.

[2] Mah JK et al (2022). JAMA Netw Open. 2022;5(1):e2144178. doi:10.1001/jamanetworkopen.2021.44178. Link.

[3] Guglieri M et al (2022) JAMA. doi:10.1001/jama.2022.4315

[4] Heier CR et al (2019). Life Science Alliance DOI: 10.26508 [5] Liu X et al (2020). Proc Natl Acad Sci USA 117:24285-24293

About Duchenne Muscular Dystrophy

DMD is a rare inherited X-chromosome-linked disease, which almost exclusively affects males. DMD is characterized by inflammation which is present at birth or shortly thereafter. Inflammation leads to fibrosis of muscle and is clinically manifested by progressive muscle degeneration and weakness. Major milestones in the disease are the loss of ambulation, the loss of self-feeding, the start of assisted ventilation, and the development of cardiomyopathy. DMD reduces life expectancy to before the fourth decade due to respiratory and/or cardiac failure. Corticosteroids are the current standard of care for the treatment of DMD.

About Santhera

Santhera Pharmaceuticals (SIX: SANN) is a Swiss specialty pharmaceutical company focused on the development and commercialization of innovative medicines for rare neuromuscular and pulmonary diseases with high unmet medical need. The company has an exclusive license for all indications worldwide to vamorolone, a dissociative steroid with novel mode of action, which was investigated in a pivotal study in patients with DMD as an alternative to standard corticosteroids. For vamorolone in the treatment of DMD, Santhera has a new drug application ("NDA") under review by the U.S. FDA, a marketing authorization application ("MAA") under review by the European Medicines Agency ("EMA") and an MAA submitted to the UK Medicines and Healthcare products Regulatory Agency ("MHRA"). The clinical stage pipeline also includes lonodelestat to treat cystic fibrosis ("CF") and other neutrophilic pulmonary diseases. Santhera out-licensed rights to its first approved product, Raxone® (idebenone), outside North America and France for the treatment of Leber's hereditary optic neuropathy ("LHON") to Chiesi Group.

For further information, please visit **www.santhera.com**.

About Catalyst Pharmaceuticals

With exceptional patient focus, Catalyst is committed to developing and commercializing innovative first-in-class medicines that address rare neurological and epileptic diseases. Catalyst's flagship U.S. commercial product is FIRDAPSE® (amifampridine) Tablets 10 mg, approved for the treatment of Lambert-Eaton myasthenic syndrome ("LEMS") for adults and for children ages six and up. In January 2023, Catalyst acquired the U.S. commercial rights to FYCOMPA® (perampanel) CIII, a prescription medicine approved in people with epilepsy aged four and older alone or with other medicines to treat partial-onset seizures with or without secondarily generalized seizures and with other medicines to treat primary generalized tonic-clonic seizures for people with epilepsy aged 12 and older. Further, Canada's national healthcare regulatory agency, Health Canada, has approved the use of FIRDAPSE® for the treatment of adult patients in Canada with LEMS. For additional information about the Company, please visit **www.catalystpharma.com**.

For Full Prescribing and Safety Information for FIRDAPSE®, please visit **www.firdapse.com**. For Full Prescribing Information, including Boxed WARNING for FYCOMPA®, please visit **www.fycompa.com**. For more information about Catalyst Pharmaceuticals, Inc., visit the Company's website at **www.catalystpharma.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 proposed agreement to license vamorolone and make the equity investment will be completed, (ii) whether the NDA for vamorolone will be approved by the PDUFA date, or at all, (iii) whether the licensing agreement, if it is completed and the NDA for vamorolone is approved by the FDA, can be successfully commercialized by Catalyst in the territory, (iv) whether if the vamorolone is commercialized by Catalyst, the results will prove to be accretive to Catalyst, (v) whether Catalyst and Santhera will successfully develop additional indications for vamorolone and obtain the ability to commercialize the product for those additional indications, (vi) whether Catalyst will, if vamorolone is commercialized by Catalyst, be successfully integrated into Catalyst's business activities, and (vii) those factors described in Catalyst's Annual Report on Form 10-K for the 2022 fiscal year, Catalyst's Quarterly Report on Form 10-Q for the first quarter of 2023, and Catalyst's other filings with the 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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