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): **July 19, 2022**

JAGUAR HEALTH, INC.

(Exact name of registrant as specified in its charter)

Delaware	**001-36714**	**46-2956775**
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

200 Pine Street, Suite 400 **San Francisco, California** (Address of principal executive offices)	**94104** (Zip Code)

Registrant's telephone number, including area code: **(415) 371-8300**

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 (*see* General Instruction A.2. below):

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

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

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

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

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

Emerging growth company ☐

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

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, Par Value $0.0001 Per Share	JAGX	The NASDAQ Capital Market

Item 1.01 Entry into a Material Definitive Agreement.

On July 19, 2022, Napo Pharmaceuticals, Inc. ("Napo Pharma"), the wholly-owned subsidiary of Jaguar Health, Inc. ("Jaguar"), entered into an amended and restated license agreement (the "Amended License Agreement") with Napo Therapeutics S.p.A. (f/k/a Napo EU S.p.A.), an Italy law joint stock company and majority-owned subsidiary of Napo Pharma ("Napo Thera"), which agreement amended and restated in its entirety the License Agreement, dated August 18, 2021, by and between Napo Pharma and Napo Thera, as amended (the "Original License Agreement"). A copy of the Original License Agreement is attached as Ex. 10.1 to Jaguar's Current Report on Form 8-K filed with the Securities and Exchange Commission on August 24, 2021.

Pursuant to the Original License Agreement, Napo Pharma granted Napo Thera (i) an exclusive license to develop, commercialize and manufacture pharmaceutical products utilizing crofelemer or lechlemer as its active drug substance (collectively, "Products") in Europe for short bowel syndrome with intestinal failure, HIV-related diarrhea, and symptomatic relief and treatment in patients with congenital diarrheal disorders and (ii) options to licenses to develop, commercialize and manufacture Products in Europe for additional indications. The Original License Agreement provided that Napo Pharma would have sole control over all manufacturing activities for CMC, clinical and commercial supply of Products in Europe for all licensed indications; provided, however, that Napo Thera would be entitled to utilize its license to manufacture such Products only to the extent that Napo Pharma was unable to supply. The Amended License Agreement modifies, among other things, Napo Thera's rights to manufacture finished Products for certain licensed indications. Pursuant to the Amended License Agreement, Napo Thera will now be able to use a mutually acceptable, third party contract manufacturer to manufacture (i) commercial supply of finished Products for certain licensed indications involving intestinal failure (e.g., short bowel syndrome with intestinal failure and symptomatic relief and treatment in patients with congenital diarrheal disorders) (collectively, "IFD Indications") at any time following receipt of regulatory approval such Product and (ii) commercial scale batches of Products as required in order to validate a process to obtain regulatory approval in Europe. Napo Thera will, consistent with the terms Original License Agreement, still be entitled to utilize its license to manufacture Products for licensed indications other than IFD Indications, but only to the extent that Napo Pharma is unable to supply Product.

The foregoing summary of the Amended License Agreement does not purport to be complete and is subject to, and qualified in its entirety by, the Amended License Agreement attached as Exhibit 10.1 to this Current Report on Form 8-K, which is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits

Exhibit No.	Description
10.1#	Amended and Restated License Agreement, dated July 19, 2022, by and between Napo Pharmaceuticals, Inc. and Napo Therapeutics S.p.A.
104	Cover Page Interactive Data File (embedded with the inline XBRL document)

Portions of this exhibit have been omitted pursuant to Item 601 of Regulation S-K promulgated under the Securities Act because the information (i) is not material and (ii) would be competitively harmful if publicly disclosed.

SIGNATURES

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

JAGUAR HEALTH, INC.

By: /s/ Lisa A. Conte
Name: Lisa A. Conte
Title: President and Chief Executive Officer

Date: July 20, 2022

Exhibit 10.1

Execution Version

CERTAIN INFORMATION MARKED AS [****] HAS BEEN EXCLUDED FROM THIS EXHIBIT BECAUSE IT IS BOTH (I) NOT MATERIAL AND (II) WOULD BE COMPETITIVELY HARMFUL IF PUBLICLY DISCLOSED.

AMENDED AND RESTATED LICENSE AGREEMENT

This AMENDED AND RESTATED LICENSE AGREEMENT (this "**Agreement**") is made effective as of July 19, 2022 (the "**Effective Date**") by and between Napo Pharmaceuticals, Inc., a Delaware corporation ("**Licensor**"), and Napo Therapeutics S.p.A. (f/k/a Napo EU S.p.A.), an Italy law joint stock company ("**Licensee**"). Licensor and Licensee are referred to in this Agreement individually as a "**Party**" and collectively as the "**Parties**."

RECITALS

WHEREAS, the Parties have previously executed that certain License Agreement (the "**Original Agreement**") dated as of August 18, 2021 (the "**Original Agreement Effective Date**"), as amended by that certain First Amendment to the License Agreement dated October 21, 2021 and as further amended by that certain Second Amendment to the License Agreement dated November 18, 2021, pursuant to which Licensee obtained from Licensor, and Licensor granted to Licensee, certain licenses under the Licensed IP (as defined below) to develop, commercialize and manufacture the Products (as defined below); and

WHEREAS, the Parties wish to amend and restate, and supersede, the Original Agreement to set forth the Party's respective rights and obligations relating to the subject of the Original Agreement.

AGREEMENT

NOW, THEREFORE, in consideration of the foregoing and upon the terms and conditions set forth below, the Parties agree as follows:

1. DEFINITIONS

"**Accounting Standards**" means internationally recognized accounting principles (including IFRS, U.S. GAAP, and the like), in each case, as generally and consistently applied by the applicable Party.

"**Arbitration Standards**" has the meaning set forth in Section 15.4.

"**Bankruptcy Code**" means, as applicable, the U.S. Bankruptcy Code (in the United States of America) or Legge Fallimentare / Codice della Crisi d'Impresa e dell'Insolvenza (in Italy), as amended from time to time, and the rules and regulations and guidelines promulgated thereunder, or any applicable bankruptcy laws of any other country or competent Governmental Authority, as amended from time to time, and the rules and regulations and guidelines promulgated thereunder.

"**Business Day**" means any day other than a Saturday, Sunday or any day on which banks located in the United States of America or Italy are authorized or obligated to close.

"**Calendar Year**" means each successive period of twelve (12) calendar months commencing on January 1 and ending on December 31, except that the first Calendar Year of the Term shall commence on the Original Agreement Effective Date and end on December 31 of the year in which the Original Agreement Effective Date occurs and the last Calendar Year of the Term shall commence on January 1 of the year in which the Term ends and end on the last day of the Term.

"**Claim**" has the meaning set forth in Section 15.4.

"**CMC**" means the chemistry, Manufacturing and controls of Product.

"**Clinical Study**" means any study conducted in humans (healthy volunteers or patients) according to a set protocol and meeting the requirements of GCP.

"**Combined Company**" means the Dragon SPAC following the consummation of the Merger.

"**Commercialization**", "**Commercialize**" or "**Commercializing**" means, with respect to a given product, all activities undertaken before or after obtaining Regulatory Approvals relating to the pre-launch, launch, promotion, detailing, medical education and medical liaison activities, branding, marketing, advertising, pricing, reimbursement, offering for sale, sale and distribution of such product, including product support, life cycle management, patient support, customer support, the booking of sales, safety monitoring, sampling, shipping, handling, warehousing, logistics management and invoicing activities. "Commercialization" excludes any Development or Manufacture of such product.

"**Commercialization Plan**" has the meaning set forth in Section 8.1.

"**Control**" or "**Controlled**" means, with respect to any material, Information, or intellectual property right, that a Party (a) owns or (b) has a license or other right (other than a license granted to such Party under this Agreement) to use, assign or grant a license or other right to or under such material, Information, or intellectual property right, and, in each case, has the ability to grant to the other Party access, a license or a sublicense (as applicable) to the foregoing on the terms and conditions set forth in this Agreement without violating the terms of any then-existing agreement or other arrangement with any Third Party.

"**Crofelemer**" means, oligomeric proanthocyanidin (OPC) containing catechin, epicatechin, gallocatechin, and epigallocatechin randomly sequenced in chain lengths ranging from n=3 to n=30 with an average molecular weight of approximately 2000 daltons, including any Improvements thereto.

"**Develop**", "**Developing**" or "**Development**" means, with respect to a given product, all activities that are necessary or useful to obtain, support or maintain Regulatory Approval (other than to obtain any pricing or reimbursement approvals) of such product in any particular country or jurisdiction in the Licensee Territory, including any such activities relating to preparing and conducting pre-clinical studies, non-clinical studies and Clinical Studies and regulatory activities (e.g., preparing, filing and obtaining regulatory applications). "Develop" or "Development" excludes the Commercialization and the Manufacture of such product.

"**Development Plan**" has the meaning set forth in Section 5.1.

"**Direct Labor and Benefits**" means that portion of basic wages, labor and related payroll taxes and employee benefits spent specifically in production and quality control of the Product, which are directly related to the Products and allocated to the Manufacturing and supply of the Products.

"**Dollar**" means U.S. dollars, and "$" shall be interpreted accordingly.

"**Dragon SPAC**" means Dragon SPAC S.p.A., an incorporated Italian joint stock company having its registered office in Milan (Italy), via M. Barozzi, no. 2, registration number with the Register of Enterprises of Milan-Monza-Brianza-Lodi 11764390966.

"**EEA**" means the European Economic Area established by the EEA Agreement entered into force on 1 January 1994**,** which unites the EU member states and the three European Free Trade Associate states (Iceland, Liechtenstein, and Norway) into an Internal Market governed by the same basic rules.

"**EMA**" means the European Medicines Agency or any successor entity.

"**EU Supplier**" means a mutually acceptable, Third Party contract manufacturer selected by the Parties that has all necessary licenses, permits or approvals from Regulatory Authorities with respect to the Manufacture of Products under GMP that are intended to be Commercialized in the Licensee Territory.

"**Finished Product**" means a Product manufactured, tested and released and suitably labelled and packaged for distribution to Clinical Study sites and/or for Commercialization needs in the respective country in the Licensee Territory.

"**FFDCA**" means the United States Federal Food, Drug, and Cosmetic Act, as amended from time to time, together with any rules, regulations and requirements promulgated thereunder (including all additions, supplements, extensions, and modifications thereto).

"**Generic Product**" means, with respect to a Product, any product that is approved, or is sought to be approved, under an Abbreviated New Drug Application as defined in the FFDCA or any corresponding foreign application in the Licensee Territory, and in reliance, in whole or in part, on the prior approval (or on safety or efficacy data submitted in support of the prior approval) of such Product as determined by the applicable Regulatory Authority. A product licensed or produced by Licensee or any of its Affiliates or Sublicensees, under the same Regulatory Approval Application for a Product (i.e., an authorized generic product) will not constitute a Generic Product.

"**Good Clinical Practices**" or "**GCP**" means the international ethical and scientific quality standard for the design, conduct, performance, monitoring, auditing, recording, analyses and reporting of clinical trials as set out in the latest guidelines entitled "Guidance for Industry E6" "Guideline for Good Clinical Practice", and all applicable equivalent regulatory requirements imposed, adopted and promulgated by the applicable Regulatory Authority in territories within the Licensee Territory but outside the EEA for current good clinical practice, as all such standards, practices and procedures may be updated or amended from time to time.

"**Good Manufacturing Practices**" or "**GMP**" means the applicable regulatory standards and requirements for current good manufacturing practices promulgated by the EMA under Directive 2003/94/EC, including any applicable and binding guidance documents published, and applicable equivalent regulatory requirements of a Regulatory Authority in territories outside the EEA for good manufacturing practice, as all such standards, requirements and guidance may be updated or amended from time to time.

"**Government Authority**" means any federal, national, state, provincial or local government, or political subdivision thereof, or any multinational organization or any authority, agency or commission entitled to exercise any administrative, executive, judicial, legislative, police, regulatory or taxing authority or power, any court or tribunal (or any department, bureau or division thereof, or any governmental arbitrator or arbitral body) with jurisdiction over the Parties and the activities contemplated under this Agreement.

"**IFD Indications**" or "**Intestinal Failure Disorders**" has the meaning set forth in Section 6.2(a).

"**IFD Product Supply and Technology Transfer Agreement**" has the meaning set forth in Section 6.2(a).

"**Improvements**" has the meaning set forth in Section 2.4.

"**Indication**" means any human diseases, symptoms, syndromes and medical conditions that can be diagnosed, treated, prevented or ameliorated.

"**Information**" means any data, results, approvals, technology, or information, in any tangible or intangible form, including know-how, trade secrets, practices, techniques, methods, processes, inventions, ideas, drawings, developments, specifications, formulations, formulae, materials or compositions of matter of any type or kind (patentable or otherwise), software, algorithms, marketing reports, expertise, technology, test data (including pharmacological, biological, chemical, biochemical, clinical test data and data resulting from pre-clinical and nonclinical studies), stability data and other study data and procedures.

"**Joint Inventions**" has the meaning set forth in Section 10.1.

"**Joint Patents**" has the meaning set forth in Section 10.1.

"**JSC**" has the meaning set forth in Section 4.1(a).

"**Laws**" means all applicable laws, statutes, rules, regulations, ordinances and other pronouncements having the effect of law of any federal, national, multinational, state, provincial, county, city or other political subdivision, domestic or foreign, anywhere in the world.

"**Lechlemer**" or "**NP300**" means an oral botanical drug extracted and purified from the plant species *Croton lechleri* containing sixty percent (60%) to eighty percent (80%) proanthocyanidins that range in size from monomers to higher polymers and other botanical constituents, none of which have known toxicities, including any Improvements thereto.

"**Licensed Indications**" means each of the following Indications for a Product: (a) the Tier A Indications and (b) the Indications added to this Agreement through the exercise of an Option.

"**Licensed IP**" means, collectively, the Licensed Patents and the Licensed Know-How.

"**Licensed Know-How**" means all Information owned or Controlled by Licensor or any of its Affiliates before or on the Original Agreement Effective Date or at any time during the Term, in each case, that is (a) is generally not known and (b) useful to the Development, Manufacture or Commercialization of a Product, but excluding any Information to the extent described in any published Licensed Patent.

"**Licensed Patents**" means collectively the Tier A Patents, the Tier B Patents for which Licensee has exercised its Tier B Option in accordance with Section 3 and Tier C Patents for which Licensee has exercised its Tier C Option in accordance with Section 3.

"**Licensee Arising IP**" means, collectively, Licensee Arising Patents and Licensee Arising Know-How.

"**Licensee Arising Know-How**" means all Information owned or Controlled by Licensee to the extent derived from Licensee's activities under this Agreement that is useful for the Development, Manufacture or Commercialization of Crofelemer or Lechlemer.

"**Licensee Arising Patents**" all Patents owned or Controlled by Licensee to the extent derived from Licensee's activities under this Agreement that is useful for the Development, Manufacture or Commercialization of Crofelemer or Lechlemer, but excluding any Joint Patents.

"**Licensee Territory**" means, collectively, all the countries set forth in Exhibit C.

"**Licensee Trademarks**" has the meaning set forth in Section 10.5(c) (*Licensee Trademarks*).

"**Licensor Cost of Goods Sold**" means the actual costs of Licensor for the Manufacture of Crofelemer, Lechlemer, or the finished dosage of any Product, as applicable, including in-process testing, labelling, and packaging, which shall be comprised of: (i) the actual cost of Direct Labor and Benefits incurred by Licensor, (ii) Overhead (solely to the extent allocable to the Product, Crofelemer or Lechlemer) incurred by Licensor, and (iii) payments actually made by Licensor to Third Parties for the Manufacture of the finished dosage of the Product, the bulk Product, or Crofelemer or Lechlemer used for the Manufacture of Product, as the case may be, and with respect to clauses (i) and (ii), as determined in accordance with Accounting Standards used consistently for all of Licensor's products.

"**Licensor Territory**" means worldwide other than the Licensee Territory.

"**Licensor Trademarks**" means the Trademarks Controlled by Licensor or its Affiliates, whether registered or unregistered in any country in the Licensee Territory that are set forth in Exhibit D hereto.

"**Manufacture**" and "**Manufacturing**" means, with respect to a given product, all activities related to the production, manufacture, formulation, processing, filling, finishing, packaging, labeling, handling and holding of any such product, or any intermediate thereof, including formulation development, process development, process qualification and validation, scale-up, pre-clinical, non-clinical, clinical and commercial manufacture (including manufacture of pre-clinical, non-clinical or Clinical Study material (including placebo and active controls)), analytic development, product characterization, stability testing, quality assurance, quality control and release testing. "Manufacture" excludes any Development or Commercialization of such product.

"**Merger**" means the merger by way of absorption (*fusione per incorporazione*) of Napo EU into Dragon SPAC pursuant to the Master Agreement.

"**Master Agreement**" means the Master Agreement to be entered by and among Dragon SPAC, Napo Pharmaceuticals, Inc., Napo EU and Joshua Mailman.

"**Net Sales**" means, with respect to any given period, the gross amount invoiced by Licensee and its Affiliates and Sublicensees for the sale of Products to Third Parties (other than Sublicensees) (the "**Invoiced Sales**") less deductions for:

a. normal and customary trade, quantity and cash discounts and sales returns and allowances, including (i) those granted on account of price adjustments, billing errors, rejected goods, damaged goods and returns, (ii) administrative and other fees and reimbursements and similar payments to wholesalers and other distributors, buying groups, pharmacy benefit management organizations, health care insurance carriers and other institutions, (iii) allowances, rebates and fees paid to distributors, and (iv) chargebacks;

b. freight, postage, shipping and insurance expenses to the extent that such items are included in the Invoiced Sales;

c. customs and excise duties and other duties related to the sales to the extent that such items are included in the Invoiced Sales;

d. rebates and similar payments made with respect to sales paid for by any governmental or regulatory authority such as, by way of illustration and not in limitation of the parties' rights hereunder Federal or state Medicaid, Medicare or similar state program or equivalent foreign governmental program;

e. sales and other taxes and duties directly related to the sale or delivery of Products (but not including taxes assessed against the income derived from such sale);

f. any other similar and customary deductions that are consistent with GAAP, or in the case of non-United States sales, other applicable accounting standards;

g. distribution expenses to the extent that such items are included in the Invoiced Sales; and

h. any such invoiced amounts that are not collected by Licensee or its Affiliates or Sublicensees.

Any of the deductions listed above that involves a payment by Licensee or its Affiliates or Sublicensees shall be taken as a deduction in the Quarter in which the payment is accrued by such entity. Deductions pursuant to subsection (h) above shall be taken in the Quarter in which such sales are no longer recorded as a receivable. For purposes of determining Net Sales, Products shall be deemed to be sold when invoiced and a "sale" shall not include transfers or dispositions for charitable, promotional, pre-clinical, clinical, regulatory or governmental purposes to the extent no amount is received by Licensee, its Affiliates, or Sublicensees in connection therewith.

For purposes of calculating Net Sales, sales between or among Licensee, its Affiliates and its Sublicensees shall be excluded from the computation of Net Sales, but sales by Licensee, its Affiliates or its Sublicensees to Third Parties (other than Sublicensees) shall be included in the computation of Net Sales.

If Licensee should, in a given country during a given accounting period, sell a Product that contains one or more active ingredients in addition to Crofelemer or Lechlemer (which may be either combined in a single formulation or bundled with separate formulations but sold as one product), Net Sales for such combination product will be calculated by multiplying actual Net Sales of such combination product by the fraction A/(A+B) where A is the average total invoice price of a Product if sold separately (for the same dosage strength) in such period, and B is the average total invoice price of such other active ingredient or ingredients in the product, if sold separately (for the same dosage strength) in such period. If, on a country-by-country basis, either a Product, on the one hand, or such other active ingredient or ingredients in the combination product, on the other hand, is, or both of the foregoing are, not sold separately in said country, Net Sales for the purpose of determining royalties of a Product shall be determined by the respective chief financial officers of the Parties in good faith and in a manner consistent with the intent of this Agreement, *provided* that any matters in dispute with respect thereto shall be ultimately and finally reasonably determined by the Chief Financial Officer of Licensor.

"**Non-IFD Product Supply Agreement**" has the meaning set forth in Section 6.2(b).

"**Non-IFD Product Technology Transfer Agreement**" has the meaning set forth in Section 6.3(c).

"**Option**" means the Tier B Option or the Tier C Option and together, the "**Options**".

"**Option Exercise Period**" means the period beginning on the Original Agreement Effective Date and expiring on the earlier of (i) June 30, 2023 and (ii) the twenty-four-month anniversary of the consummation of a Qualifying Merger.

"**Other Committees**" has the meaning set forth in Section 4.1(b).

"**Overhead**" means all customary and usual operating expenses directly related to a Product incurred by and in support of the particular manufacturing cost centers, purchasing department and quality assurance operations specifically related to such Product (including labor, related payroll taxes and employee benefits), depreciation, general taxes, rent, repairs and maintenance, supplies, utilities and factory administrative expense.

"**Patents**" means any and all (a) patent applications and issued patents, including, all national, regional, and international patents and patent applications; provisionals; continuations; divisionals; continuations-in-part; continued prosecution applications; reissues, renewals, substitutions, reexaminations, and revivals thereof; (b) patents that have issued or in the future issue from the foregoing patent applications, including utility models, petty patents and design patents and certificates of invention; and (c) extensions (including pediatric exclusivity, patent term extension and supplementary patent certificate) or restorations of the patents described above by existing or future extension or restoration mechanisms.

"**Pharmacovigilance Agreement**" has the meaning set forth in Section 7.7.

"**Private Placement**" means the private placement of equity securities by Dragon SPAC.

"**Products**" means collectively the Tier A Products, Tier B Products and Tier C Products.

"**Product Labeling**" means, with respect to a Product: (a) the Regulatory Authority-approved full prescribing information for such Product for a country or other jurisdiction, including any required patient information; and (b) all labels and other written, printed, or graphic matter upon a container, wrapper or any package insert utilized with or for such Product in such country or other jurisdiction.

"**Proposed Arbitrators**" has the meaning set forth in Section 15.4.

"**Qualifying Merger**" means a merger or consolidation of Licensee with or into another person or entity or similar corporate transaction.

"**Quarter**" means each successive period of three (3) calendar months commencing on January 1, April 1, July 1 and October 1, except that the first Quarter of the Term commences on the Original Agreement Effective Date and ends on the day immediately before the first to occur of January 1, April 1, July 1 or October 1 after the Original Agreement Effective Date, and the last Calendar Quarter ends on the last day of the Term.

"**Regulatory Approval**" means, with respect to a particular country and product, a marketing authorization granted by the applicable Regulatory Authority in such country for such product, including, where applicable, (a) pricing or reimbursement approval in such country or other jurisdiction, (b) pre- and post-approval marketing authorizations (including any prerequisite Manufacturing approval or authorization related thereto) and (c) approval of Product Labeling.

"**Regulatory Approval Application**" means an application to the applicable Regulatory Authority for approval to Commercialize a Product in a particular jurisdiction in the Licensee Territory.

"**Regulatory Authority**" means, with respect to a particular country or jurisdiction, any applicable Governmental Authority involved in granting Regulatory Approvals of pharmaceutical products in such country or jurisdiction (e.g., EMA).

"**Regulatory Materials**" means Regulatory Approval Applications, investigational new drug applications, clinical trial applications, submissions, notifications, communications, correspondence, registrations, Regulatory Approvals or other filings made to, received from or otherwise conducted with a Regulatory Authority to Develop, Manufacture or Commercialize a Product in a particular country or jurisdiction.

"**ROFN License**" has the meaning set forth in Section 3.2.

"**ROFN Notice**" has the meaning set forth in Section 3.2(a).

"**ROFN Period**" has the meaning set forth in Section 3.2(b).

"**ROFN Proposal**" has the meaning set forth in Section 3.2(b).

"**SEC Reports**" means collectively all reports, schedules, forms, statements and other documents filed by Jaguar Health, Inc., parent of the Licensor, under the Securities Act of 1933, as amended, and the Securities Exchange Act of 1934, as amended, including pursuant to Section 13(a) or 15(d) thereof, including the exhibits thereto and documents incorporated by reference therein.

"**Sole Inventions**" has the meaning set forth in Section 10.1.

"**Sublicensee**" means any entity to which a sublicense is validly granted pursuant to Section 2.3.

"**Subscription Agreement**" means that certain subscription agreement, dated June 1, 2021, by and among Licensee, Licensor and Joshua Mailman.

"**Third Party**" means any person other than a Party or an affiliate of a Party.

"**Tier A Indications**" means, collectively, the Indications set forth under the heading "Tier A" in Exhibit B.

"**Tier A Patents**" means the Patents that: (a) cover any Tier A Product or its Development, Manufacture or Commercialization in the Licensee Territory; (b) are owned or Controlled by Licensor or any of its Affiliates; and (c) are issued or filed before or on the Original Agreement Effective Date or at any time during the Term, but excluding any Licensee Arising Patents. The Tier A Patents existing as of the Original Agreement Effective Date are set forth under the heading "Tier A" in Exhibit A.

"**Tier A Product**" means a pharmaceutical product that utilizes Crofelemer or Lechlemer as its active drug substance, alone or in combination with another active pharmaceutical ingredient and indicated for any Tier A Indications.

"**Tier B Indications**" means, collectively, the Indications set forth under the heading "Tier B" in Exhibit B.

"**Tier B Option**" has the meaning set forth in Section 3.1(a).

"**Tier B Patents**" means, the Patents that: (a) cover any Tier B Product or its Development, Manufacture or Commercialization in the Licensee Territory; (b) are owned or Controlled by Licensor or any of its Affiliates; and (c) are issued or filed before or on the Original Agreement Effective Date or at any time during the Term, but excluding any Licensee Arising Patents. The Tier B Patents existing as of the Original Agreement Effective Date are set forth under the heading "Tier B" in Exhibit A.

"**Tier B Product**" means a pharmaceutical product that utilizes Crofelemer or Lechlemer as its active drug substance, alone or in combination with another active pharmaceutical ingredient and indicated for any Tier B Indications.

"**Tier C Indications**" means, collectively, the Indications set forth under the heading "Tier C" in Exhibit B.

"**Tier C Option**" has the meaning set forth in Section 3.1(a).

"**Tier C Patents**" means, the Patents that: (a) cover any Tier C Product or its Development, Manufacture or Commercialization in the Licensee Territory; (b) are owned or Controlled by Licensor or any of its Affiliates; and (c) are issued or filed before or on the Original Agreement Effective Date or at any time during the Term, but excluding any Licensee Arising Patents. The Tier C Patents existing as of the Original Agreement Effective Date are set forth under the heading "Tier C" in Exhibit A.

"**Tier C Product**" means a pharmaceutical product that utilizes Crofelemer or Lechlemer as its active drug substance, alone or in combination with another active pharmaceutical ingredient and indicated for any Tier C Indications.

"**Tier 1 Territory**" means, collectively, the European Union, Switzerland and the United Kingdom.

"**Trademark**" means any word, name, symbol, color, designation or device or any combination thereof that functions as a source identifier, including any trademark, trade dress, brand mark, service mark, trade name, brand name, logo, business symbol or domain names, whether or not registered.

"**Transfer Price**" means, with respect to a Product, Crofelemer or Lechlemer, as applicable, provided by Licensor to Licensee, the price Licensee shall pay for such Product, Crofelemer or Lechlemer, which price shall equal the Licensor Cost of Goods Sold plus ten percent (10%).

"**Upfront Payment**" has the meaning set forth in Section 9.1.

"**Upfront Payment Deadline**" has the meaning set forth in Section 9.1.

"**Valid Claim**" means a claim of (a) any issued and unexpired patent whose validity, enforceability, or patentability has not been affected by any of the following: (i) irretrievable lapse, abandonment, revocation, dedication to the public, or disclaimer; or (ii) a holding, finding, or decision of invalidity, unenforceability, or non-patentability; or (b) a pending patent application that is filed and prosecuted in good faith and no more than ten (10) years have elapsed from its earliest priority date.

2. LICENSE

2.1 Licensor Grant to Licensee. Subject to the terms and conditions of this Agreement, Licensor hereby grants to Licensee:

(a) an exclusive (even as to Licensor), perpetual (subject to the termination rights of the Parties set forth in Section 14.3), non-transferable license, with right to grant and authorize sublicenses solely as permitted under Section 2.3, under the Licensed IP and the Licensor Trademarks for Licensee to Develop and Commercialize Products in the Licensee Territory; and

(b) a non-exclusive, non-transferable license, with right to grant and authorize sublicenses (to a contract manufacturer only) solely as permitted under Section 2.3, under the Licensed IP for Licensee to Manufacture or have Manufactured Products for Commercialization in the Licensee Territory, including the right to Manufacture Crofelemer and Lechlemer; *provided*, *however*, that during the Term, Licensee shall only be entitled to utilize its license to Manufacture or have Manufactured Products to the extent provided in Section 6.3.

For the avoidance of doubt, the Combined Company shall assume the rights and obligations of this Agreement, including but not limited to the licenses granted under this Section 2.1, without any additional consent or waiver by Licensor.

2.2 Licensee Grant to Licensor. Subject to the terms and conditions of this Agreement, Licensee hereby grants to Licensor an exclusive (even as to Licensee), perpetual (subject to the termination rights of the Parties set forth in Section 14.3) license under the Licensee Arising IP to Develop, Manufacture or Commercialize (a) Products anywhere in the world outside of the Licensee Territory and (b) any products for any Indications (other than the Licensed Indications) anywhere in the world (including the Licensee Territory). Licensor and its Affiliates shall have the right to sublicense the rights granted to it under this Section 2.2 to any Third Party; *provided*, *that*, in each such case, Licensor shall be responsible for any such Third Party as if Licensor were exercising such sublicensed rights itself under this Agreement.

2.3 Sublicense. Licensee may sublicense the rights granted to it under Section 2.1 to Third Parties with Licensor's prior written consent in each and every case, which consent by Licensor shall not be unreasonably withheld, delayed or conditioned; *provided*, that Licensee shall remain responsible for any acts or omissions of its Affiliates and Sublicensees with respect to this Agreement as if they were Licensee's own acts or omissions.

2.4 No Implied Licenses. Except as explicitly set forth in this Agreement, neither Party will be deemed to have granted the other Party any license or other right to any intellectual property of such Party, whether by estoppel, implication or otherwise. Licensee acknowledges and agrees that as between Licensee and Licensor, except for the license granted under this Agreement, Licensor retains all right, title and interest in and to the Licensed Patents, including all improvements and enhancements to the Licensed Patents made or created by Licensee pursuant to this Agreement or made or created by or on behalf of Licensor during the Term (collectively, "**Improvements**").

3. OPTIONS AND RIGHT OF FIRST NEGOTIATION.

3.1 Options.

(a) **Grant of Options**. Licensor hereby grants to Licensee during the applicable Option Exercise Period exclusive options to obtain the licenses to the Tier B Patents and Tier C Patents, as applicable, to Develop and Commercialize, pursuant to the terms of this Agreement, (i) Tier B Products (the "**Tier B Option**") and (ii) Tier C Products (the "**Tier C Option**").

(b) **Option Exercise**. Licensee will have the right to exercise each Option, in its sole discretion, by (i) providing to Licensor written notice ("**Option Exercise Notice**") and (ii) making the payment to Licensor set forth in Section 9.2, in each case prior to the expiration of the Option Exercise Period. Upon exercise of an Option in accordance with this Section 3.1(b), (x) the definition of Licensed Indications hereunder is hereby automatically deemed to be amended to include, as applicable, such Tier B Indications and/or Tier C Indications and (y) the definition of Licensed Patents hereunder is hereby automatically deemed to be amended to include, as applicable, such Tier B Patents and/or Tier C Patents, in each case ((x) and (y)) without any further action by either Party.

3.2 Right of First Negotiation. If the Option Exercise Period expires without exercise by Licensee of either or both Options pursuant to Section 3.1(b), then until the earlier of (i) June 30, 2024 and (ii) the three-year anniversary of the consummation of the Qualifying Merger, Licensor shall grant Licensee a right of first negotiation to license the Tier B Patents and Tier C Patents, as applicable, on substantially the same terms as this Agreement to Develop, Commercialize and Manufacture the Tier B Products and/or Tier C Products in Europe (the "**ROFN License**"). The exclusive negotiating period will last for sixty (60) days, subject to each Party's obligation to negotiate in good faith the terms of such license. The mechanics of the right of first negotiation are as follows:

(a) If Licensor or its Affiliates intends to enter into discussions or negotiations with a Third Party with respect to the ROFN License, Licensor shall provide written notice to Licensee of its intention to Licensee (the "**ROFN Notice**").

(b) Licensee shall have thirty (30) days after receipt of the ROFN Notice to provide written notice to Licensor of its interest in entering into negotiations for the ROFN License together with an initial term sheet, including proposed financial terms, for the ROFN License (a "**ROFN Proposal**"). If Licensee provides a ROFN Proposal, then for a period of sixty (60) days from Licensor's receipt of the ROFN Proposal ("**ROFN Period**"), Licensee or its Affiliate will have the exclusive right to negotiate terms in which it will obtain the ROFN License from Licensor or its Affiliate. Such Parties shall negotiate in good faith the terms for the ROFN License. If, at the end of the ROFN Period, such Parties are unable to reach agreement on the ROFN License, Licensor shall have no further obligation to Licensee concerning the ROFN License pursuant to this Section 3.2; *provided*, that Licensor shall not, within sixty (60) days of the end of the ROFN Period, offer to grant the ROFN License to a Third Party on more favorable terms, taken as a whole, than those last offered to Licensor during the ROFN Period without first offering those terms to Licensee, which Licensee shall have thirty (30) days to accept or reject. For clarity, if Licensee does not provide Licensor with a ROFN Proposal during the initial thirty (30) day period, Licensor shall have no further obligation to Licensee concerning the ROFN License thereafter.

4. GOVERNANCE.

4.1 Joint Steering Committee.

(a) **Formation and Responsibilities**. Within sixty (60) days after the Original Agreement Effective Date, the Parties shall establish a joint steering committee (the "**JSC**") for the overall coordination and oversight of the Parties' activities under this Agreement. The JSC shall have review, discussion or comment responsibilities for certain matters, and decision-making authority for certain matters, as specified in Sections 4.1(b) and 4.1(c), respectively. The JSC has only the powers expressly assigned to it in Sections 4.1(b) and 4.1(c) and elsewhere in this Agreement. Notwithstanding anything to the contrary set forth in this Agreement, the JSC has no power to interpret, amend, modify or waive compliance with this Agreement.

(b) **Review and Discussion Only**. The responsibilities of the JSC are to review, discuss or comment on the following matters (which responsibilities, for clarity, do not include any decision-making authority and are not subject to a vote by the JSC):

(1) to provide oversight, direction and consulting on technical issues related to the Development and Commercialization of a Product in the Licensee Territory;

(2) to review and discuss the filing and maintenance of all Licensee Trademarks to be used with respect to the Commercialization of a Product in the Licensee Territory;

(3) to review and discuss Development and regulatory update reports provided by Licensee to the JSC for the Licensee Territory pursuant Section 5.5 (*Development and Regulatory Updates*);

(4) to appoint any other operating committees (collectively, the "**Other Committees**"), consisting of equal numbers of appropriately qualified members appointed by each Party, from time to time as it deems fit during the Term;

(5) to attempt to resolve, in a timely manner, issues presented to it by, and disputes within the Other Committees; and

(6) to perform such other functions as appropriate to further the purposes of this Agreement, as expressly set forth in this Agreement or as mutually determined by the Parties in writing.

(c) **Review and Approval**. The responsibilities of the JSC are to review and approve the following matters:

(1) to review, discuss and approve the Development Plan and the Commercialization Plan;

(2) periodically (no less often than annually) review and serve as a forum for discussing the Development Plan and the Commercialization Plan, and review, discuss and approve amendments thereto;

(3) to review, discuss and agree on any Regulatory Material filed by or on behalf of Licensee in the Licensee Territory;

(4) to review, discuss, agree on and coordinate the Parties' Commercialization activities among the Licensor Territory and the Licensee Territory as contemplated by Section 8.5; and

(5) to review, discuss, agree on and coordinate the Parties' scientific presentation and publication strategy relating to a Product in the Licensee Territory and the Licensor Territory, which shall be implemented as provided in Section 13.4 (*Technical Publication*).

(d) **Members**. Each Party shall initially appoint three (3) representatives to the JSC, each of whom will be an officer, employee or key scientific or clinical advisor of such Party having sufficient experience and/or seniority within the applicable Party to make decisions arising within the scope of the JSC's responsibilities. The JSC may change its size from time to time by mutual consent of its members, and each Party may replace its representatives at any time upon written notice to the other Party; *provided*, *however*, that the JSC will at all times consist of equal numbers of members appointed by each Party. If a JSC representative from either Party is unable to attend or participate in a meeting of the JSC, the Party who designated such representative may designate an appropriately qualified substitute representative for the meeting. The JSC will have a chairperson, who will be elected, on an annual basis, alternatively by Licensor or Licensee, with Licensor electing the initial chairperson. The role of the chairperson is to convene and preside at all meetings of the JSC and to ensure the preparation of meeting minutes, but the chairperson has no additional powers or rights beyond those held by other JSC representatives.

(e) **Meetings**. The JSC shall meet at least two (2) times per Calendar Year during the Term unless the Parties mutually agree in writing to a different frequency for such meetings. Either Party may also call a special meeting of the JSC (by videoconference or teleconference) upon at least ten (10) Business Days' prior written notice to the other Party if such Party reasonably believes that a significant matter must be addressed before the next regularly scheduled meeting, and such Party shall provide the JSC materials reasonably adequate to enable an informed discussion by its members no later than ten (10) Business Days before the special meeting. The JSC may meet in person, by videoconference or by teleconference, *provided*, *however*, at least one (1) meeting per Calendar Year occurs in person at a mutually agreeable location. Each Party shall pay for its own expenses relating to such meetings. As appropriate, other employee representatives of the Parties or their respective Affiliates may attend JSC meetings as non-voting observers or presenters. The chairperson of the JSC shall prepare reasonably detailed written minutes of all JSC meetings that reflect and include all material decisions made at such meetings.

(f) **Decision Making**.

(1) Decisions to be made by the JSC pursuant to Section 4.1(c) will be made by consensus pursuant to a unanimous vote, with each Party having one (1) vote representing the views of its members.

(2) If the JSC fails to reach consensus on any of the matters set forth in Section 4.1(c) for a period in excess of sixty (60) days, then Licensor may cast the deciding vote for the JSC to the extent the disputed issue might reasonably be expected to (i) affect any regulatory activities in the Licensor Territory or (ii) have a material adverse effect on the Development of any products or Manufacture or Commercialization thereof in the Licensor Territory.

(3) Each Party retains the rights, powers, and discretion granted to it under this Agreement and neither Party shall delegate to or vest in any such rights, powers, or discretion in the JSC unless such delegation or vesting of rights is expressly provided for in this Agreement or the Parties expressly so agree in writing.

4.2 Good Faith. In conducting themselves on the JSC or any Other Committees, all representatives of each Party shall consider reasonably and in good faith all input received from the other Party.

4.3 Scope of Governance. Without limiting the Parties' obligations under Article 12 (Confidentiality; Publication), the Parties agree not to share or discuss at the JSC any strategic or commercially sensitive Information beyond the scope of the collaboration contemplated by this Agreement.

4.4 Alliance Managers. Each of the Parties shall appoint a single employee to act as that Party's "**Alliance Manager**". The role of the Alliance Manager is to act as a point of contact between the Parties to assure a successful collaboration. The Alliance Managers may attend all JSC meetings and support the chairperson of the JSC in the discharge of their responsibilities. Alliance Managers shall be non-voting participants in such JSC meetings, unless they are also appointed members of the JSC; *provided*, *however*, that an Alliance Manager may bring any matter to the attention of the JSC if such Alliance Manager reasonably believes that such matter warrants such attention. Each Party may change its designated Alliance Manager from time to time upon written notice to the other Party. Any Alliance Manager may designate a substitute to temporarily perform the functions of that Alliance Manager by written notice to the other Party. Each Alliance Manager will also: (i) coordinate cooperative efforts and communications between the Parties; and (ii) take responsibility for ensuring that governance activities, such as the conduct of required JSC meetings and production of meeting minutes, occur as set forth in this Agreement, and that relevant action items resulting from such meetings are appropriately carried out or otherwise addressed.

5. PRODUCT DEVELOPMENT.

5.1 Licensee Responsibility. Within ninety (90) days following the Original Agreement Effective Date, Licensee shall prepare for review and approval by the JSC, a written development plan setting forth in reasonable detail the Development activities to be performed with respect to a Product (including but not limited to the CMC development activities that are required to be performed to obtain Regulatory Approval in the Licensee Territory), risks and anticipated timelines for such Development activities, including a budget with respect thereto (the "**Development Plan**"). Licensee will be responsible, at its sole cost and expense, for all Development activities for Products in the Licensee Territory, and shall perform such activities in accordance with the Development Plan.

5.2 Updates; Amendments. The JSC shall review the Development Plan at least annually for the purpose of considering appropriate amendments thereto. In addition, either Party, through its representatives on the JSC, may propose amendments to the Development Plan at any time.

5.3 Development Diligence and Responsibilities. Licensee shall conduct Development activities under this Agreement in accordance with the Development Plan and in a good scientific manner and comply in all material respects with applicable Laws. In particular, Licensee shall:

(a) communicate with one or more regulatory authorities in at least one country in Tier 1 Territory (e.g., EMA, SwissMedic, MHRA, etc.) within six (6) months of the Original Agreement Effective Date; and

(b) initiate a Clinical Trial in support of the Product for SBS within six (6) months of the achievement of the milestone event set forth in Section 9.3(a).

5.4 Data Exchange and Use. Promptly after the Original Agreement Effective Date, Licensor shall disclose and make available to Licensee all Licensed Know-How that is necessary for Licensee to perform its obligations or exercise its rights under this Agreement. Licensee shall reimburse Licensor for any reasonable out-of-pocket costs directly incurred by Licensor with respect to such transfer within thirty (30) days of its receipt of an invoice from Licensor for such costs.

5.5 Development and Regulatory Updates. Once per Quarter, Licensee shall provide the JSC with a written report that sets forth (a) a summary and timeline for all ongoing and planned pre-clinical studies and Clinical Studies for the Products set forth in the Development Plan, (b) a summary of all material and substantive interactions with applicable Regulatory Authorities for the Products in the Licensee Territory and (c) updates on key milestones relating thereto.

5.6 Development Records. During the Term, Licensee shall maintain complete, current and accurate records of all Development activities conducted by it hereunder, and all data and other Information resulting from such activities. Such records will fully and properly reflect all work done and results achieved in the performance of the Development activities in good scientific manner appropriate for regulatory and patent purposes. Licensee shall document all pre-clinical studies and Clinical Studies conducted pursuant to this Agreement in formal written study records according to applicable Law.

6. MANUFACTURING AND SUPPLY

6.1 CMC and Clinical Supply. Unless otherwise set forth in the Development Plan, Licensor shall, either directly or through an Affiliate or licensee, have sole responsibility for (a) CMC development and industrialization of the Manufacture of clinical supplies of Product and (b) the Manufacture of all of Licensee's requirements for Product for use in Development in the Licensee Territory, which Licensor shall supply to Licensee at the Transfer Price.

6.2 Manufacture and Commercial Supply.

(a) **IFD Indications**. The Parties shall negotiate with an EU Supplier in good faith with respect to commercial supply of the Finished Products for Licensed Indications involving intestinal failure disorders (e.g., SBS, SBS-IF, CDD, etc.) (collectively, "**IFD Indications**" or "**Intestinal Failure Disorders**") in the Licensee Territory, and shall execute such supply agreement (the "**IFD Product Supply and Technology Transfer Agreement**") as soon as reasonably practicable after the EU Supplier is identified by the Parties and, in any event, within the prescribed time period required by applicable Law to obtain all Regulatory Approvals for any such Products. The IFD Product Supply and Technology Transfer Agreement shall set forth customary supply terms as mutually agreed to by the Parties and EU Supplier. The Parties agree to include in the IFD Product Supply and Technology Transfer Agreement that (a) Licensor shall effect a full transfer to EU Supplier and/or Licensee of all Licensed Know-How relating to the then-current specifications and process for the Manufacture of the Finished Products for Intestinal Failure Disorders, (b) EU Supplier shall supply to Licensee the Finished Products for Intestinal Failure Disorders in such quantities as Licensee may order in accordance with the terms and conditions of such agreement, and (c) Licensor shall supply Crofelemer to EU Supplier and/or Licensee at the Transfer Price to enable EU Supplier to Manufacture the Finished Products for Intestinal Failure Disorders to be used for qualification, validation and Commercialization in the Licensee Territory. The IFD Product Supply and Technology Transfer Agreement shall also set forth provisions with respect to an appropriate plan to provide reasonable assurances of continuity of supply of Crofelemer from Licensor, including adequate rights or remedies to which Licensee may be entitled for Licensor's inability to supply when such failure is caused by or results from reasons within the reasonable control of Licensor that which Licensor is unable to justify.

(b) **Licensed Indications other than IFD Indications**. Licensor shall, either directly or through an Affiliate or licensee, have sole responsibility for Manufacturing activities for commercial supply of the Products for Licensed Indications other than IFD Indications in the Licensee Territory at the Transfer Price in accordance with the Supply Agreement. Within twelve (12) months prior to the anticipated completion of a clinical trial in support of registration of a Product in the Licensee Territory for any Licensed Indication other than for an IFD Indication, the Parties shall commence negotiations for a manufacture and commercial supply agreement of such Products to Licensee (the "**Non-IFD Supply Agreement**"), which agreement shall also cover the quality aspects for the commercial supply of such Products.

6.3 Manufacture License.

(a) **Manufacture of Product for IFD Indications**. Subject to the terms and conditions of this Agreement, Licensee shall be entitled to utilize its license to Manufacture or have Manufactured a Finished Product for Licensed Indications involving IFD Indications (i) only to the extent such Manufacturing activities are for commercial scale batches of Products as required in order to validate a process to obtain Regulatory Approvals in the Licensee Territory and (ii) for Commercialization in a country in the Licensee Territory at any time following receipt of Regulatory Approval for a Product for such IFD Indication in such country in the Licensee Territory.

(b) **Manufacture of Product for Licensed Indications other than IFD Indications**. Subject to the terms and conditions of this Agreement, Licensee shall only be entitled to utilize its license to Manufacture or have Manufactured a Product for Licensed Indications other than IFD Indications to the extent that Licensor is unable to supply (i) such Product for use in Development in the Licensee Territory as provided in Section 6.1 or (ii) such Product for Commercialization in the Licensee Territory as determined in accordance with the Supply Agreement.

(c) **Non-IFD Product Technology Transfer Agreement**. The Parties shall, within sixty (60) days of Licensee's written request following satisfaction of the conditions in Section 6.3(b), enter into a technology transfer agreement ("**Non-IFD Product Technology Transfer Agreement**") in order to enable the Licensee to Manufacture such Product for the Licensee Territory. Licensee shall reimburse Licensor for any reasonable out-of-pocket costs directly incurred by Licensor with respect to such transfer within thirty (30) days of its receipt of an invoice from Licensor for such costs.

7. REGULATORY MATTERS

7.1 Regulatory Responsibilities in the Licensee Territory. Commencing on the Original Agreement Effective Date, Licensee will be the "sponsor" of and take the lead and have sole responsibility for preparing, filing, obtaining and maintaining Regulatory Approvals for the Products in the Licensee Territory and conducting all associated regulatory activities for the Products in the Licensee Territory, subject to JSC approval as required under Section 4.1(c)(3).

7.2 Development Breach by Licensee. A breach of Licensee's obligation to Develop the Products shall include, but is not limited to, the failure of Licensee to (a) comply with its obligations under Section 5.3(a) or Section 5.3(b) or (b) initiate a clinical assessment in support of a conditional regulatory approval pathway with the EMA within eighteen (18) months of the consummation of the Qualifying Merger. For the avoidance of doubt, a breach of this Section 7.2 shall constitute a material breach of this Agreement for which the remedies of Section 14.3(c) (*Termination by Licensor for Material Breach, Insolvency or Failure to Develop or Commercialize*) shall be available to Licensor.

7.3 Commercial Updates. Licensee shall keep Licensor informed at JSC meetings of regulatory developments relating to the Products in the Licensee Territory and shall promptly notify Licensor in writing of any action or decision by any Regulatory Authority in the Licensee Territory regarding the Product. Licensee shall provide Licensor for review and comment all draft Regulatory Materials as soon as practicable in advance of their intended date of submission to a Regulatory Authority in the Licensee Territory, and shall consider any comments thereto provided by Licensor, to the extent reasonable and practicable.

7.4 Regulatory Costs. Licensee shall be solely responsible for all regulatory costs incurred by or on behalf of Licensee with respect to preparing, filing, obtaining and maintaining Regulatory Approval for the Products from the Regulatory Authorities in the Licensee Territory. Licensee shall be responsible for all costs and activities associated with specialized formulation for SBS-IF.

7.5 Right of Reference to Regulatory Materials. Licensee hereby (a) grants to Licensor a right of reference to all Regulatory Materials filed by or on behalf of Licensee in the Licensee Territory, which right of reference Licensor may use for the sole purpose of seeking, obtaining and maintaining Regulatory Approvals and Developing and Commercializing (i) the Products in the Licensor Territory and (ii) product for any Indications other than the Licensed Indications anywhere in the world (including the Licensee Territory) and (b) agrees to provide copies of such Regulatory Materials, Regulatory Approvals and all corresponding documentation to Licensor as soon as practicable after Licensee's submission to Regulatory Authorities. Licensee shall promptly submit any necessary notices or authorizations to Regulatory Authorities that are necessary to effect such rights of reference. Licensee shall support Licensor, as reasonably requested by Licensor, in obtaining Regulatory Approvals in Licensor's Territory, including providing necessary documents or other materials required by Laws to obtain Regulatory Approval in Licensor's Territory.

7.6 Notification of Threatened Action. Each Party shall immediately notify the other Party of any information it receives regarding any threatened or pending action, inspection or communication by or from any Regulatory Authority, which may affect the Development, Commercialization or Regulatory Approval of Product.

7.7 Adverse Event Reporting and Safety Data Exchange. No later than one hundred eighty (180) days following the submission of the first Regulatory Approval Application for the Products in any country in the Licensee Territory, the Parties shall define and finalize the actions that the Parties shall employ with respect to the Products to protect patients and promote their well-being in a written pharmacovigilance agreement (the "**Pharmacovigilance Agreement**"). In the event of any inconsistency between the provisions of the Pharmacovigilance Agreement and the provisions of this Agreement, the wording of the Pharmacovigilance Agreement shall govern any and all patient safety matters and this Agreement shall govern all other matters.

8. COMMERCIALIZATION

8.1 Commercialization Diligence. The Commercialization of the Products in the Licensee Territory shall be conducted pursuant to a comprehensive plan (the "**Commercialization Plan**"), which Licensee shall develop and propose to the JSC within sixty (60) days of completion of a pivotal clinical trial, or a similar clinical study prescribed by the Regulatory Authorities, in support of registration of the Products in the Licensee Territory for any Indication. Following receipt of Regulatory Approval of the Products in a country in the Licensee Territory, Licensee shall Commercialize the Products in such country in accordance with the Commercialization Plan. Within six (6) months of receipt of Regulatory Approval in any country in the Licensee Territory, Licensee shall commence sales of Products within such country.

8.2 Updates; Amendments. The JSC shall review the Commercialization Plan at least annually, and shall make amendments thereto with respect to the Commercialization of the Product. In addition, either Party, through its representatives on the JSC, may propose amendments to the Commercialization Plan at any time.

8.3 Responsibility for Commercialization in the Licensee Territory. Subject to the terms and conditions of this Article 8 (*Commercialization*), Licensee shall have sole control over and decision-making authority in, at its cost and expense, implementing the JSC-approved Commercialization Plan for the Products in the Licensee Territory. Licensee shall, with respect to the Products in the Licensee Territory, have full ownership of and control over: (a) developing the strategy for, and negotiating with applicable Governmental Authorities regarding, the price and reimbursement status of the Product; (b) marketing and promotion; (c) booking sales, and distribution and performance of related services; (d) handling all aspects of order processing, invoicing and collection, inventory and receivables; (e) providing customer support, including handling medical queries, and performing other related functions; and (f) conforming its practices and procedures to applicable Laws relating to the marketing, detailing and promotion of the Products in the Licensee Territory.

8.4 Cross-Territorial Restrictions.

(a) **Licensee Restrictions**. As permitted by Law, Licensee shall not, and shall ensure that its Affiliates will not, either directly or indirectly, knowingly promote, market, distribute, import, sell or have sold any Product, including via internet or mail order, into the Licensor Territory. As to the Licensor Territory, Licensee shall not, and shall ensure that its Affiliates will not: (i) establish or maintain any branch, warehouse or distribution facility for any Product in the Licensor Territory, (ii) engage in any advertising or promotional activities relating to any Product that are directed primarily to customers or other purchasers or users of such Product located in the Licensor Territory, (iii) solicit orders for such Product from any prospective purchaser located in the Licensor Territory, (iv) sell or distribute any such Product to any person in the Licensee Territory who it knows intends to sell such Product in the Licensor Territory or (v) deliver or tender (or cause to be delivered or tendered) any Product into a country in the Licensor Territory. If Licensee receives any order from a prospective purchaser located in the Licensor Territory, then Licensee shall immediately refer that order to Licensor, and Licensee shall not accept any such orders.

(b) **Licensor Restrictions**. As permitted by Law, Licensor shall not, and shall ensure that its Affiliates will not, either directly or indirectly, knowingly promote, market, distribute, import, sell or have sold any Product, including via internet or mail order, into countries in the Licensee Territory. As to such countries in the Licensee Territory, Licensor shall not, and shall ensure that its Affiliates will not: (i) establish or maintain any branch, warehouse or distribution facility for any Product in such countries for the sale of such Product in such country, (ii) engage in any advertising or promotional activities relating to any Product that are directed primarily to customers or other purchasers or users of such Product located in such countries, (iii) solicit orders from any prospective purchaser located in such countries, (iv) sell or distribute any Product to any person in the Licensor Territory who it knows intends to sell any Product in such countries or (v) deliver or tender (or cause to be delivered or tendered) any Product into a country in the Licensee Territory. If Licensor receives any order from a prospective purchaser located in the Licensee Territory, then Licensor shall immediately refer that order to Licensee, and Licensor shall not accept any such orders.

8.5 Territorial Coordination. The Parties shall, where appropriate, coordinate their Commercialization activities among the Licensor Territory and the Licensee Territory, through the JSC, which coordination may include implementation of a global branding strategy and/or development and execution of a commercial launch and pre-launch plan for Product.

8.6 Reports. Licensee shall update the JSC at each regularly scheduled JSC meeting regarding its Commercialization activities with respect to the Products in the Licensee Territory. Each such update will be in a form to be agreed by the JSC and will summarize Licensee's significant Commercialization activities with respect to the Products in the Licensee Territory pursuant to this Agreement, covering subject matter at a level of detail reasonably requested by Licensor.

9. COMPENSATION

9.1 Upfront Payment. As consideration for the licenses and Options granted hereunder, Licensee shall make a non-refundable upfront cash payment in an amount equal to Ten Million Dollars ($10,000,000) (the "**Upfront Payment**") to Licensor. The Upfront Payment shall be payable in accordance with the following schedule:

Amount	**Deadline** (the "**Upfront Payment Deadline**")
Thirty-Three Percent (33%) of gross proceeds received in the Private Placement	No later than the earlier of (a) sixty (60) days following the consummation of a Qualifying Merger or (b) December 15, 2021.
Remaining balance of the Upfront Payment	No later than the earlier of (a) the twelve (12)-month anniversary of the consummation of a Qualifying Merger or (b) within sixty (60) days of when Licensee receives more than Twenty Million Dollars ($20,000,000) from a business combination with Dragon SPAC and/or private placement proceeds directly into the Combined Company (inclusive of the €8,830,000 received by Dragon SPAC from Napo pursuant to the Subscription Agreement, with the Dollar-equivalent of such amount calculated using the exchange rate as of the date of the Subscription Agreement).

9.2 Payment Upon Option Exercise. On an Option-by-Option basis, upon Licensee's exercise of an Option in accordance with this Agreement, Licensee shall make the applicable non-refundable payment set forth in the table below (each, an "**Option Exercise Fee**") within three (3) days of the Licensee's delivery of the Option Exercise Notice for such Option:

Option	**Option Exercise Fee**
Tier B Option	Fifteen Million Dollars ($15,000,000)
Tier C Option	Twenty-Five Million Dollars ($25,000,000)

9.3 Milestone Payments. Licensee shall pay Licensor the following one-time milestone payments within thirty (30) days after the first of the occurrence of a "Milestone Event" as set forth in the tables below. Each milestone payment set forth in this Section 9.3 is payable only once (i.e., the first time the milestone event is achieved for a Product) and is non-refundable once paid.

Milestone Event	**Milestone Due**
(a) Licensor's delivery to Licensee of a highly concentrated liquid or lyophilized drug product suitable for administration in a Clinical Study for SBS	Two Million Five Hundred Thousand Dollars ($2,500,000)
(b) Licensee exercises Tier B Option and NDA Approval for CTD for Crofelemer in the U.S. is received	Five Million Dollars ($5,000,000)
(c) Licensee exercises Tier B Option and Regulatory Approval for CTD for Crofelemer is received in any country in the Tier 1 Territory	Five Million Dollars ($5,000,000)

9.4 Royalty Payments.

(a) **Royalty Rate**. As further consideration for the licenses and Options granted hereunder, Licensee shall make royalty payments to Licensor on Net Sales of Products in each country in the Licensee Territory, as calculated by multiplying the applicable royalty rate by the corresponding amount of incremental Net Sales in such country, as follows:

Annual Net Sales of Products in the Applicable Country	**Royalty Rate**
For that portion of annual Net Sales up to One Hundred Million Dollars ($100,000,000)	Twelve Percent (12%)
For that portion of annual Net Sales greater than One Hundred Million Dollars ($100,000,000) but less than Five Hundred Million Dollars ($500,000,000)	Fifteen Percent (15%)
For that portion of annual Net Sales equal to or greater than Five Hundred Million Dollars ($500,000,000)	Eighteen Percent (18%)

(b) **Royalty Term**. Licensee's obligation to pay royalties pursuant to this Section 9.4 (*Royalty Payments*) shall commence, on a country-by-country and Product-by-Product basis, upon the First Commercial Sale of such Product in such country and shall continue until the latest of (i) the expiration of the last-to-expire Valid Claim included in the Licensed Patents or Licensee Arising Patents, in each case, that claims the composition of matter, manufacture, use or sale of such Product in such country; (ii) the initiation of sales of a Generic Product with respect to such Product in such country; and (iii) the twentieth (20th) anniversary of the First Commercial Sale of such Product in such country (the "**Royalty Term**").

(c) **Royalty Reduction**. If a Product is generating Net Sales in a country in the Territory during the Royalty Term in such country at a time when the composition of matter, manufacture, use or sale of such Product is not covered by a Valid Claim included in the Licensed Patents in such country, then the royalty rate applicable to Net Sales of such Product in such country shall be reduced by fifty percent (50%) for the remainder of the Royalty Term in such country in respect of such Product.

9.5 Royalty Reports and Payment. Within forty-five (45) days after each Quarter commencing with the Quarter during which the First Commercial Sale of a Product is made anywhere in the Licensee Territory, Licensee shall provide Licensor with a report (the "**Royalty Report**") that contains the amount of Net Sales of Product in each country or other jurisdiction in the Licensee Territory during the applicable Quarter and calculation of the amount of royalties due on such Net Sales for such Quarter, on a Product-by-Product and country-by-country basis. Concurrent with the delivery of the Royalty Report, Licensee shall pay in Dollars all royalties owed with respect to Net Sales for such Quarter.

9.6 Currency; Exchange Rate. All payments to be made by Licensee to Licensor under this Agreement shall be made in Dollars by bank wire transfer in immediately available funds to a bank account designated by written notice from Licensor.

9.7 Late Payments. If Licensor does not receive payment of any sum due to it on or before the due date therefor, simple interest shall thereafter accrue on the sum due to Licensor from the due date until the date of payment at a rate per annum (but with interest accruing on a daily basis) equal to the London Interbank Offered Rate ("**LIBOR**"), the successor thereto (if any), or the highest rate allowable by applicable Law, whichever is less.

9.8 Taxes.

(a) **Taxes on Income**. Each Party shall pay all taxes imposed on its share of income arising directly or indirectly from the efforts of, or the receipt of any payment by, such Party under this Agreement.

(b) **Tax Cooperation**. Licensee agrees to cooperate with Licensor and to use reasonable efforts to reduce or eliminate tax withholding or similar obligations in respect of the Upfront Payment, milestones, royalties and other payments made by Licensee to Licensor under this Agreement. Licensor shall provide Licensee with any tax forms that may be reasonably necessary in order for Licensee not to withhold tax or to withhold tax at a reduced rate under an applicable bilateral income tax treaty a reasonable time prior to the date the applicable payment is due. Licensee shall provide Licensor with reasonable assistance to enable the recovery, as permitted by Law, of withholding taxes, value added taxes or similar obligations resulting from payments made under this Agreement, such recovery to be for the benefit of Licensor.

9.9 Financial Records and Audits. Licensee shall maintain complete and accurate records in sufficient detail to permit Licensor to confirm the accuracy of royalty payments under this Agreement. Upon reasonable prior notice, such records shall be open for examination during regular business hours for a period beginning on the Original Agreement Effective Date until five (5) years from the termination or expiry of this Agreement, at Licensor's expense, not more often than once each Calendar Year, by an independent certified public accounting firm selected by Licensor, and for the sole purpose of verifying the accuracy of the royalty reports furnished by Licensee under this Agreement or any royalty payments made, or required to be made, by Licensee under this Agreement. Any such accounting firm shall not disclose Licensee's Confidential Information to Licensor, except to the extent such disclosure is necessary to verify the accuracy of the royalty reports furnished by Licensee or the royalty payments under this Agreement. If such audit reveals any underpayment, Licensee shall pay such amount within thirty (30) days after the date of the accountant's report, plus interest (as set forth in Section 9.7 (*Late Payments*)) from the original due date (unless challenged in good faith by Licensee, in which case any dispute with respect thereto shall be resolved in accordance with Section 15.4 (*Arbitration of Claims*)). If such audit reveals any overpayment, such amount shall be creditable against future royalty payments due under this Agreement (or promptly refunded to Licensee, if there is no future royalty payment due). Licensor shall bear the full cost of such audit unless such audit reveals an underpayment by Licensee of more than five percent (5%) of the amount actually due for the audited time period, in which case Licensee shall reimburse Licensor for the costs for such audit.

10. INTELLECTUAL PROPERTY MATTERS

10.1 Ownership of Inventions. Each Party shall solely own any Inventions made solely by it and/or its Affiliates' employees, agents, or independent contractors ("**Sole Inventions**"). The Parties shall jointly own any Inventions that are made jointly by employees, agents, or independent contractors of one Party and its Affiliates together with by employees, agents, or independent contractors of the other Party and its Affiliates ("**Joint Inventions**"). For clarity, the determination of which Party "made" a particular Invention shall be made, with respect to patentable Inventions, in accordance with the rules of inventorship under U.S. patent laws. All Patents claiming patentable Joint Inventions shall be referred to herein as "**Joint Patents**." Except to the extent either Party is restricted by the licenses granted to the other Party under this Agreement, each Party shall be entitled to practice, license, assign and otherwise exploit the Joint Inventions and Joint Patents without the duty of accounting to or seeking consent from the other Party.

10.2 Disclosure of Inventions.

(a) Each Party shall promptly disclose to the other Party all Joint Inventions, including any invention disclosures, or other similar documents, submitted to it by its employees, agents or independent contractors describing such Joint Inventions, and shall promptly respond to any reasonable request from the other Party for additional information relating to such Joint Inventions.

(b) Promptly following the provision of the report in Section 9.5 (*Royalty Reports and Payment*), Licensee shall disclose to Licensor all Sole Inventions (including any invention disclosures, or other similar documents, submitted to it by its employees, agents or independent contractors describing such Sole Inventions) made by it and/or its Affiliates in the preceding Quarter and shall promptly respond to any reasonable request from Licensor for additional information relating to such Sole Inventions.

10.3 Patent Prosecutions.

(a) **Licensed Patents**.

(1) Licensor shall have the first right to, and shall use reasonable endeavors to, file, prosecute and maintain all Licensed Patents in the Licensee Territory, at Licensor's own cost and expense. For the purpose of this Article 10 (*Intellectual Property Rights*), "prosecution" shall include any post-grant proceeding including patent interference proceeding, opposition proceeding and reexamination.

(2) Licensor shall consult with Licensee and keep Licensee reasonably informed of the status of the Licensed Patents in the Licensee Territory and shall promptly provide Licensee with all material correspondence received from any Government Authority in connection therewith. In addition, Licensor shall use reasonable endeavors to provide Licensee with drafts of all proposed material filings and correspondence to any Government Authority with respect to the Licensed Patents in the Licensee Territory for Licensee's review and comment prior to the submission of such proposed filings and correspondences. Licensor shall confer with Licensee and consider in good faith Licensee's comments prior to submitting such filings and correspondences, but, for the avoidance of doubt, shall decide (in its absolute discretion) whether to adopt any of Licensee's comments.

(3) Licensor shall notify Licensee of any decision to cease prosecution and/or maintenance of, or not to continue to pay the expenses of prosecution and/or maintenance of, any Licensed Patents in the Licensee Territory at least forty-five (45) days prior to any filing or payment due date, or any other due date that requires action, in connection with such Licensed Patent. If Licensor makes such a decision to cease prosecution and/or maintenance of, or not to continue to pay the expenses of prosecution and/or maintenance of, any Licensed Patents in the Licensee Territory, Licensor shall permit Licensee, at its discretion and at its sole expense, to continue prosecution or maintenance of such Licensed Patent. Licensee's prosecution or maintenance of such Licensed Patent shall not change the Parties' respective rights and obligations under this Agreement with respect to such Licensed Patent other than those expressly set forth in this Section 10.3(a)(3).

(b) **Joint Patents**.

(1) Licensee shall have the first right in its sole discretion to file, prosecute and maintain any Joint Patents in the Licensee Territory, at Licensee's own cost and expense.

(2) Licensee shall consult with Licensor and keep Licensor reasonably informed of the status of the Joint Patents in the Licensee Territory and shall promptly provide Licensor with material correspondences received from patent authorities in connection therewith. In addition, Licensee shall promptly provide Licensor with drafts of all proposed material filings and correspondences to the patent authorities with respect to the Joint Patents in the Licensee Territory for Licensor's review and comment prior to the submission of such proposed filings and correspondences. Licensee shall confer with Licensor and consider in good faith Licensor's comments prior to submitting such filings and correspondences.

(3) Licensee shall notify Licensor of any decision to cease prosecution and/or maintenance of, or not to continue to pay the expenses of prosecution and/or maintenance of, any Joint Patents in the Licensee Territory at least forty-five (45) days prior to any filing or payment due date, or any other due date that requires action, in connection with such Joint Patent. If Licensee makes such a decision to cease prosecution and/or maintenance of, or not to continue to pay the expenses of prosecution and/or maintenance of, any Joint Patents in the Licensee Territory, Licensee shall permit Licensor, at its discretion and expense, to continue prosecution or maintenance of such Joint Patent. Licensor's prosecution or maintenance of such Joint Patent shall not change the Parties' respective rights and obligations under this Agreement with respect to such Joint Patent other than as expressly set forth in this Section 10.3(b)(3).

(c) **Licensee Patents**. Licensee shall have the sole right to file, prosecute and maintain the Licensee Patents in the Licensee Territory, at Licensee's cost and expense.

(d) **Cooperation in Prosecution**. Each Party shall provide the other Party all reasonable assistance and cooperation in the patent prosecution efforts provided above in this Section 10.3 (Patent Prosecution), including providing any necessary powers of attorney and executing any other required documents or instruments for such prosecution.

10.4 Patent Enforcement.

(a) **Notification**. Each Party shall promptly notify the other party if it becomes aware of any alleged or threatened infringement by a Third Party of any of the Licensed Patents ("**Infringement**").

(b) **Enforcement Right**. Licensee shall have the first right to bring and control any legal action in connection with any Infringement in the Licensee Territory at its own expense and as it reasonably determines appropriate. If Licensee decides not to enforce the Licensed Patents against such Infringement or does not bring such legal action or otherwise take commercially reasonable action to abate such Infringement before the earlier of: (i) sixty (60) days after the notice provided pursuant to Section 10.4(a)(*Notification*), or (ii) ten (10) Business Days before the time limit (if any) set forth in applicable Law for the filing of such legal action (provided that notice of infringement has been provided pursuant to Section 10.4(a)(*Notification*) prior to such time limit), then Licensor shall have the right to bring and control any legal action in connection with such Infringement in the Licensee Territory at its own expense as it reasonably determines appropriate.

(c) **Cooperation**. At the request and expense of the Party bringing the action under Section 10.4(b) (*Enforcement Right*) above, the other Party shall provide reasonable assistance in connection therewith, including by executing reasonably appropriate documents, cooperating in discovery and joining as a plaintiff party to the action if required by applicable Law to pursue such action. In connection with any such proceeding, the enforcing Party shall keep the other Party reasonably informed of the status and progress of such enforcement action, and shall reasonably consider the other Party's comment on any such efforts. The non-enforcing Party shall be entitled to separate representation in such matter by counsel of its own choice and at its own expense, but such Party shall at all times cooperate fully with the enforcing Party.

(d) **Expense and Recoveries**. The enforcing Party shall be solely responsible for the cost and expenses incurred in connection with the enforcement action under Section 10.4(b) (*Enforcement Right*). If such Party recovers monetary damages from any Third Party in such enforcement action brought against an Infringement, such recovery shall be allocated first to the reimbursement of any expenses incurred by the Parties in such enforcement action, and any remaining amounts shall be retained by the enforcing Party, *provided* that, if Licensee is the enforcing Party, such remaining amounts shall be included in the Net Sales subject to the royalty payment by Licensee to Licensor under Section 9.4 (*Royalty Payments*).

10.5 Trademarks.

(a) **Coordination**. Licensee will notify Licensor of the Trademarks and trade dress it intends to use on Products in the Licensee Territory.

(b) **Licensor Trademarks**. In any country in the Licensee Territory where a Licensor Trademark is registered and Licensee in its sole discretion elects to use such Licensor Trademark:

(1) Licensee shall comply strictly with the directions provided to Licensee by Licensor regarding the form and manner of the application of such Licensor Trademark. Apart from such Licensor Trademark, no other Trademark or logo of the Licensor may be affixed to, or used in connection with, the Products in such country. Upon advance written notice to Licensor, Licensee may register the Licensor Trademarks in any applicable country(ies) in the Licensee Territory in Licensor's name. In connection with Licensee's use of the Licensor Trademarks, Licensee shall comply with all applicable Laws.

(2) Licensee shall ensure that all Products sold by Licensee carrying the Licensor Trademark and all related quotations, specifications, descriptive literature and other materials carrying the Licensor Trademark, will be marked with the appropriate trademark notices in accordance with Licensor's instructions.

(3) Licensee agrees that it shall not, directly or indirectly: (A) take, omit to take, or permit any action which is intended to dilute the Licensor Trademark or tarnish or bring into disrepute the reputation of or goodwill associated with the Licensor Trademark or Licensor, or which is intended to invalidate or jeopardize any registration of the Licensor Trademark; or (B) apply for, or obtain, or assist any person or entity in applying for or obtaining any registration of the Licensor Trademark, or any Trademark, service mark, trade name, or other indicia confusingly similar to the Licensor Trademark in any country in the Licensee Territory.

(4) Licensee may prepare, file, prosecute and maintain the Licensor Trademarks in the Licensee Territory in the name of Licensor, and Licensee may enforce and defend the Licensor Trademarks in the Licensee Territory, in each case, in its discretion and at its sole cost and expense.

(c) **Licensee Trademarks**. In any countries in the Licensee Territory where a Licensor Trademark is not registered or Licensee in its sole discretion elects not to use a Licensor Trademark, Licensee will be responsible, at its sole cost, for selecting, filing and maintaining its own Trademarks for use in relation to the Commercialization of Products in such country (the "**Licensee Trademarks**") and shall have sole discretion with respect to its choice of Licensee Trademarks, subject only to review and discussion at the JSC and Licensee's obligations under Section 10.5(b) (*Licensor Trademarks*). Licensee shall consider in good faith any reasonable comments provided by Licensor in connection with Licensee's choice of such trademarks and trade dress. Licensee shall own all right, title, and interest in and to any such Licensee Trademarks and assumes full responsibility, at its sole expense, for any infringement of its Licensee Trademarks by a Third Party.

10.6 Common Interest. All information exchanged between the Parties' representatives pursuant to this Article 10 (*Intellectual Property Rights*) regarding the preparation, filing, Prosecution, maintenance, or enforcement of Patents and Trademarks will be the disclosing Party's Confidential Information. In addition, the Parties acknowledge and agree that, with regard to such preparation, filing, prosecution, maintenance, and enforcement of the Licensed Patents and Trademarks, the interests of the Parties as licensor and licensee are to obtain the strongest patent and Trademark protection possible, and as such, are aligned and are legal in nature. The Parties agree and acknowledge that they have not waived, and nothing in this Agreement constitutes a waiver of, any legal privilege concerning such Patents, including privilege under the common interest doctrine and similar or related doctrines.

11. REPRESENTATION AND WARRANTIES; COVENANTS

11.1 Representations and Warranties of Each Party. Each Party represents and warrants to the other Party as of the Original Agreement Effective Date that:

(a) it has the full right, power and authority to enter into this Agreement, to perform its obligations hereunder; and

(b) this Agreement has been duly executed by it and is legally binding upon it, enforceable in accordance with its terms, and does not conflict with any agreement, instrument or understanding, oral or written, to which it is a party or by which it may be bound, nor violate any material law or regulation of any court, governmental body or administrative or other agency having jurisdiction over it.

11.2 Representations and Warranties of Licensor. Licensor represents and warrants to Licensee as of the Original Agreement Effective Date that:

(a) **Title; Encumbrances**. Licensor solely owns the entire right, title and interest in and to the Licensed IP, free and clear from any mortgages, pledges, liens, security interests, conditional and installment sale agreement, encumbrances, charges or claim of any kind (collectively, "**Liens**"), except for Liens issued to lenders in connection with secured borrowings by Licensor or its Affiliates, and it has the right to grant the licenses to Licensee as purported to be granted pursuant to this Agreement, and Licensor has not previously granted any license or rights under the Licensed IP that is inconsistent with the license granted to Licensee hereunder;

(b) **Notice of Infringement**. In the three (3) years prior to the Original Agreement Effective Date, Licensor has not received any written notice from any Third Party asserting or alleging that any research or development of any Product by or on behalf of Licensor prior to the Original Agreement Effective Date infringed or misappropriated the intellectual property rights of such Third Party;

(c) **No Proceeding**. There are no pending, and to Licensor's knowledge, no threatened, adverse actions, suits, claims, interferences or formal governmental investigations involving any Product and/or the Licensed IP by or against Licensor or any of its Affiliates in or before any Government Authority;

(d) **Licensed Patents**. (i) Exhibit A includes all Patents that are owned by or licensed to Licensor or its Affiliates as of the Original Agreement Effective Date and are reasonably necessary for or directly related to Licensor in the research, Development, Manufacture, use, and/or Commercialization of Crofelemer, Lechlemer and/or Product; (ii) none of the Licensed Patents are subject to any pending, or to Licensor's knowledge, threatened, re-examination, opposition, interference or litigation proceedings; and (iii) to Licensor's knowledge, there are no acts or omissions of Licensor that would (A) constitute inequitable conduct, fraud or misrepresentation with respect to any Licensed Patents, or (B) render any Licensed Patents invalid or unenforceable in whole or in part; and

(e) **Licensor Trademarks and Trademark Applications**. Licensor makes no representations or warranties regarding any Licensor Trademarks, which are being licensed "AS IS, WHERE IS".

11.3 Disclaimer. EXCEPT AS EXPRESSLY STATED IN THIS ARTICLE 11 (REPRESENTATIONS AND WARRANTIES; COVENANTS), (A) NO REPRESENTATION, CONDITION OR WARRANTY WHATSOEVER IS MADE OR GIVEN BY OR ON BEHALF OF LICENSOR OR LICENSEE; AND (B) ALL OTHER CONDITIONS AND WARRANTIES WHETHER ARISING BY OPERATION OF LAW OR OTHERWISE ARE HEREBY EXPRESSLY EXCLUDED, INCLUDING ANY CONDITIONS AND WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE OR NON-INFRINGEMENT.

11.4 Covenants. Each Party covenants that in performing its obligations or exercising its rights under this Agreement: (a) it shall comply with all applicable Laws, industry guidance and codes of practice; and (b) it shall not employ or engage any Person who has been debarred or disqualified by any Regulatory Authority or, to its knowledge, is the subject of debarment or disqualification proceedings by any Regulatory Authority.

12. INDEMNIFICATION; LIABILITY; INSURANCE

12.1 Indemnification by Licensor. Licensor shall indemnify and hold Licensee, its Affiliates, and their respective officers, directors, agents and employees ("**Licensee Indemnitees**") harmless from and against any Claims against them arising or resulting from: (a) the negligence or willful misconduct of any of the Licensor Indemnitees; (b) the breach of this Agreement by Licensor, including any warranties or representations made by Licensor to Licensee under this Agreement; or (c) the Development, Manufacture or Commercialization of Crofelemer, Lechlemer and/or any Product by or on behalf of Licensor or any of its Affiliates or licensees prior to the Original Agreement Effective Date; except in each case, to the extent such Claims result from the activities set forth in Section 12.2 (*Indemnification by Licensee*) for which Licensee is obligated to indemnify Licensor Indemnitees.

12.2 Indemnification by Licensee. Licensee shall indemnify and hold Licensor, its Affiliates and their respective trustees, officers, directors, agents and employees ("**Licensor Indemnitees**") harmless from and against any Claims against them arising or resulting from: (a) the negligence or willful misconduct of any of the Licensee Indemnitees; (b) the breach of this Agreement by Licensee, including any warranties or representations made by Licensee to Licensor under this Agreement; or (c) the Development, Manufacture or Commercialization of Crofelemer, Lechlemer and/or any Product by or on behalf of Licensee or any of its Affiliates or sublicensees after the Original Agreement Effective Date; except in each case, to the extent such Claims result from the activities set forth in Section 12.1 (*Indemnification by Licensor*) for which Licensor is obligated to indemnify Licensee Indemnitees.

12.3 Indemnification Procedure. If either Party is seeking indemnification under Sections 12.1 (*Indemnification by Licensor*) or 12.2 (*Indemnification by Licensee*) (the "**Indemnified Party**"), it shall inform the other Party (the "**Indemnifying Party**") of the Claim giving rise to the obligation to indemnify pursuant to such Section as soon as reasonably practicable after receiving notice of the Claim. The Indemnifying Party shall have the right to assume the defense of any such Claim for which it is obligated to indemnify the Indemnified Party. The Indemnified Party shall cooperate with the Indemnifying Party and the Indemnifying Party's insurer as the Indemnifying Party may reasonably request, and at the Indemnifying Party's cost and expense. The Indemnified Party shall have the right to participate, at its own expense and with counsel of its choice, in the defense of any Claim that has been assumed by the Indemnifying Party. Neither Party shall have the obligation to indemnify the other Party in connection with any settlement made without the Indemnifying Party's written consent, which consent shall not be unreasonably withheld or delayed. If the Parties cannot agree as to the application of Section 12.1 (*Indemnification by Licensor*) or 12.2 (*Indemnification by Licensee*) to any Claim, pending resolution of the dispute pursuant to Section 15.4 (*Arbitration and Claims*), the Parties may conduct separate defenses of such Claims, with each Party retaining the right to claim indemnification from the other Party in accordance with Section 12.1 (*Indemnification by Licensor*) or 12.2 (*Indemnification by Licensee*) upon resolution of the underlying Claim.

12.4 Mitigation of Loss. Each Indemnified Party shall take and shall procure that its Affiliates take all such reasonable steps and action as are reasonably necessary or as the Indemnifying Party may reasonably require in order to mitigate any Claims (or potential losses or damages) under this Article 12 (*Indemnification; Liability; Insurance*). Nothing in this Agreement shall or shall be deemed to relieve any Party of any common law or other duty to mitigate any losses incurred by it.

12.5 Limitation of Liability. NEITHER PARTY SHALL BE LIABLE TO THE OTHER FOR ANY SPECIAL, CONSEQUENTIAL, INCIDENTAL, PUNITIVE, OR INDIRECT DAMAGES (INCLUDING CONSEQUENTIAL OR INCIDENTAL LOSS OF PROFIT, LOSS OF OPPORTUNITY OR LOSS OF USE) ARISING FROM OR RELATING TO ANY BREACH OF THIS AGREEMENT, REGARDLESS OF ANY NOTICE OF THE POSSIBILITY OF SUCH DAMAGES. NOTWITHSTANDING THE FOREGOING, NOTHING IN THIS SECTION 12.5 (*LIMITATION OF LIABILITY*) IS INTENDED TO OR SHALL LIMIT OR RESTRICT THE INDEMNIFICATION RIGHTS OR OBLIGATIONS OF ANY PARTY UNDER SECTION 12.1 (*INDEMNIFICATION BY LICENSOR*) OR 12.2 (*INDEMNIFICATION BY LICENSEE*), OR DAMAGES AVAILABLE FOR A PARTY'S BREACH OF CONFIDENTIALITY OBLIGATIONS IN ARTICLE 13 (*CONFIDENTIALITY; PUBLICATION*).

12.6 Insurance. Licensee shall procure maintain insurance, including product liability insurance, or shall self-insure, in each case in a manner adequate to cover its obligations hereunder and consistent with normal business practices of prudent companies similarly situated at all times during which any Product is being clinically tested or commercially distributed or sold by Licensee hereunder. Licensee shall procure insurance or self-insure at its own expense. Licensee shall name Licensor and its subsidiaries and affiliates as an additional insured on each such policy. Such insurance does not create a limit of Licensee's liability with respect to its indemnification obligations under this Article 12 (*Indemnification; Liability; Insurance*). Licensee shall provide Licensor with written evidence of such insurance or self-insurance upon request. In the event of any notice of cancellation or non-renewal of such insurance, Licensee will take all necessary steps to ensure continuity of coverage and provide to Licensor written disclosure thirty (30) days in advance of such cancellation or non-renewal.

13. CONFIDENTIALITY; PUBLICATION

13.1 Duty of Confidence. Subject to the other provisions of this Article 13 (*Confidentiality; Publication*):

(a) all Confidential Information disclosed by a Party (the "**Disclosing Party**") or its Affiliates under this Agreement shall be maintained in confidence and otherwise safeguarded by the recipient Party (the "**Receiving Party**"), in the same manner and with the same protection as such Receiving Party maintains its own confidential information;

(b) the Receiving Party may only use any such Confidential Information for the purposes of performing its obligations or exercising its rights under this Agreement;

(c) the Receiving Party may disclose Confidential Information of the other Party to: (i) its Affiliates and sublicensees; and (ii) employees, directors, agents, contractors, consultants and advisers of the Receiving Party and its Affiliates and sublicensees, (iii) to such Party's directors, attorneys, independent accountants or financial advisors for the sole purpose of enabling such directors, attorneys, independent accountants or financial advisors to provide advice to such Party, in each case to the extent reasonably necessary for the purposes of, and for those matters undertaken pursuant to, this Agreement; provided that such Persons are bound to maintain the confidentiality of, and non-use obligations in respect of, the Confidential Information in a manner consistent with the confidentiality provisions of this Agreement; and

(d) the Receiving Party may disclose Confidential Information of the other Party to actual or potential investors, acquirers, collaborators, licensees, sublicensees and other financial or commercial partners solely for the purpose of evaluating or carrying out an actual or potential investment, acquisition, collaboration or licensing or sublicensing arrangement in connection with the Receiving Party; *provided* that such Persons are bound to maintain the confidentiality of, and non-use obligations in respect of, the Confidential Information in a manner consistent with the confidentiality provisions of this Agreement, provided that the duration may be shorter if consistent with applicable industry norms.

13.2 Exceptions. The foregoing obligations in Section 13.1 (*Duty of Confidence*) shall not apply to the extent that the Receiving Party can demonstrate that such Confidential Information:

(a) is known by the Receiving Party at the time of its receipt without an obligation of confidentiality, and not through a prior disclosure by the Disclosing Party, as documented by the Receiving Party's business records;

(b) is in the public domain before its receipt from the Disclosing Party, or thereafter enters the public domain through no fault of the Receiving Party;

(c) is subsequently disclosed to the Receiving Party by a Third Party who may lawfully do so and is not under an obligation of confidentiality to the Disclosing Party; or

(d) is developed by the Receiving Party independently and without use of, or reference to, any Confidential Information received from the Disclosing Party, as documented by the Receiving Party's business records.

Any combination of features or disclosures shall not be deemed to fall within the foregoing exclusions merely because individual features are published or available to the general public or in the rightful possession of the Receiving Party unless the combination itself and principle of operation are published or available to the general public or in the rightful possession of the Receiving Party.

13.3 Authorized Disclosures. Notwithstanding the obligations set forth in Sections 13.1 (*Duty of Confidence*) and 13.5 (*Security Exchange Disclosures*), a Party may disclose the other Party's Confidential Information to the extent such disclosure is required by Law, judicial or administrative process, *provided* that in such event the Receiving Party shall promptly inform the Disclosing Party of such required disclosure and provide the Disclosing Party an opportunity to challenge or limit the disclosure obligations. Confidential Information that is disclosed pursuant to this Section 13.3 (*Authorized Disclosures*) shall remain otherwise subject to the confidentiality and non-use provisions of this Article 13 (*Confidentiality; Publication*), and the Receiving Party disclosing Confidential Information pursuant to Law or court order shall take all steps reasonably necessary, including seeking of confidential treatment or a protective order to ensure the continued confidential treatment of such Confidential Information.

13.4 Technical Publication. The Parties shall ensure that all publications, and other forms of public disclosure such as abstracts and presentations, of results of studies carried out under this Agreement or otherwise relating to any Product in the Licensee Territory and the Licensor Territory (each of the foregoing, a "**Publication**") comply with the strategy established by the JSC pursuant to Section 4.1(c)(5). Neither Party nor their Affiliates shall submit for publication, publish or present a Publication without the opportunity for prior review and comment by the other Party, except to the extent required by Laws. A Party seeking, or whose Affiliate is seeking, to submit, publish or present a Publication shall provide the JSC with a written copy of the Publication for an opportunity to approve, review and comment on the proposed Publication at least thirty (30) days before its intended submission for publication or presentation. The JSC shall provide the Party seeking, or whose Affiliate is seeking, to publish or present with its comments in writing, if any, within thirty (30) days after receipt of such proposed Publication. The Party seeking, or whose Affiliate is seeking, to publish or present shall consider in good faith any comments thereto provided by the JSC and shall comply with the JSC's request to remove any and all of such other Party's Confidential Information from the proposed Publication. In addition, the Party seeking, or whose Affiliate is seeking, to publish or present shall delay the submission for a period of up to thirty (30) days if the non-publishing Party on the JSC can demonstrate reasonable need for such delay to prepare and file a patent application for which it has prosecution control pursuant to this Agreement. For clarity, a Party seeking to publish or present a Publication shall not have the right to publish or present such Publication without the JSC's written approval. The Party seeking, or whose Affiliate is seeking, to publish or present shall provide the other Party a copy of the manuscript, abstract or presentation at the time of the submission or presentation, as applicable. Each Party agrees to acknowledge the contributions of the other Party and its Affiliates and their employees in all Publications, as scientifically appropriate.

13.5 Security Exchange Disclosures. Subject to Section 13.3 (*Authorized Disclosures*) above, neither Party shall disclose the terms of this Agreement without the prior written consent of the other Party (which shall not be unreasonably withheld or delayed) except as may be required by applicable Law in accordance with the requirements of this Section 13.5 (*Security Exchange Disclosures*). A Party may disclose the terms of this Agreement in securities filings with the Securities Exchange Commission (or equivalent foreign agency) to the extent required by applicable Law after complying with the procedure set forth in this Section 13.5 (*Security Exchange Disclosures*). In such event, the Party seeking such disclosure shall prepare a draft confidential treatment request and redacted version of this Agreement to request confidential treatment for this Agreement, and the other Party agrees to promptly (and in any event, no less than five (5) days after receipt of such confidential treatment request and proposed redactions) give its input in a reasonable manner in order to allow the Party seeking disclosure to file its request within the time lines proscribed by applicable Law. The Party seeking such disclosure shall exercise reasonable endeavors to obtain confidential treatment of the Agreement from the Securities Exchange Commission (or equivalent foreign agency) as represented by the redacted version reviewed by the other Party.

13.6 Press Release and Use of Names. Each Party shall not make any public announcement concerning the entry into this Agreement without the prior written consent of the other Party. Each Party shall have the right to use the other Party's name and logo in presentations, the company's website, collateral materials, corporate overviews and other public disclosures contemplated by Sections 13.3 (*Authorized Disclosures*) and 13.5 (*Security Exchange Disclosures*), in each case only to describe the licensing relationship. Any other use by a Party of the other Party's name and logo shall be subject to such other Party's prior written consent.

14. TERM, CANCELLATION AND TERMINATION

14.1 Term. The term of this Agreement shall commence upon the Original Agreement Effective Date and, unless earlier terminated pursuant to this Article 14 (*Term, Cancellation and Termination*), shall remain in effect, on a Product-by-Product and country-by-country basis, until the expiration of the Royalty Term for such Product in such country and expires in its entirety upon the expiration of the Royalty Term for the last Product in the last country in the Licensee Territory (the "**Term**"). Upon the expiration (but not earlier termination) of the Royalty Term for a particular Product in a particular country, (a) provided that all outstanding amounts under Article 9 (*Compensation*) have been paid by Licensee, the license granted by Licensor to Licensee under Section 2.1 (*Licensor Grant to Licensee*) for such Product in such country shall continue and become fully-paid, royalty-free, perpetual and irrevocable and (b) the license granted by Licensee to Licensor under Section 2.2 (*Licensee Grant to Licensor*) for such Product in such country shall continue and become fully-paid, royalty-free, perpetual and irrevocable.

14.2 Termination.

(a) **Termination for Failure to Make Upfront Payment**. If Licensee fails to make the Upfront Payment on or before the Upfront Payment Deadline, then Licensor shall have the right, in its sole discretion to terminate this Agreement effective on written notice of termination to Licensee.

(b) **Termination for Material Breach**. If either Party believes that the other is in breach of its material obligations hereunder, then the non-breaching Party may deliver notice of such breach to the other Party, and the allegedly breaching Party shall have sixty (60) days from such notice to dispute or cure such breach. If the allegedly breaching Party fails to cure, or fails to dispute, that breach within such time period, then the Party originally delivering the notice of breach may terminate this Agreement effective on written notice of termination to the other Party.

(c) **Termination for Insolvency**. Subject to the applicable Bankruptcy Code in any country, each Party may terminate this Agreement in its entirety upon immediate written notice if the other Party (i) applies for or consents to the appointment of, or the taking of possession by, a receiver, custodian, trustee or liquidator of itself or of all or a substantial part of its property, (ii) makes a general assignment for the benefit of its creditors, (iii) commences a voluntary case under the Bankruptcy Code of any country, (iv) files a petition seeking to take advantage of any Laws relating to bankruptcy, insolvency, reorganization, winding-up, or composition or readjustment of debts, (v) fails to controvert in a timely and appropriate manner, or acquiesce in writing to, any petition filed against it in any involuntary case under the Bankruptcy Code of any country, (vi) takes any corporate action to effect any of the foregoing, (vii) has a proceeding or case commenced against it in any court of competent jurisdiction, seeking (A) its liquidation, reorganization, dissolution or winding-up, or the composition or readjustment of its debts, (B) the appointment of a trustee, receiver, custodian, liquidator or the like of all or any substantial part of its assets, or (C) similar relief under the Bankruptcy Code of any country, or an order, judgment or decree approving any of the foregoing is entered, and, in each case (A) through (C), such proceeding or case continues unstayed for a period of sixty (60) days, or (viii) has an order for relief against it entered in an involuntary case under the Bankruptcy Code of any country. All rights and licenses granted under or pursuant to this Agreement by each Party to the other Party, as applicable, are and shall otherwise be deemed to be, for purposes of Section 365(n) of the Title 11, United States Code, as amended (the "**US Bankruptcy Code**"), licenses of rights to "intellectual property" as defined under Article 101(35A) of the US Bankruptcy Code.

(d) **Termination for Failure to Develop or Commercialize**. In the event that Licensee (i) does not perform Development activities for a Product in any country in accordance with the Development Plan or (ii) fails to Commercialize a Product in any country in the Licensee Territory in accordance with the Commercialization Plan, then Licensor may provide written notice of such non-performance or failure to Licensee. If Licensee fails to cure such non-performance or failure within ninety (90) days after receipt of such notice, Licensor may terminate this Agreement with respect to such country and such Product by providing thirty (30) days' prior written notice thereof to Licensee.

14.3 Effect of Termination.

(a) Upon the termination of this Agreement for any reason, each Party shall promptly return all embodiments of the other Party's Confidential Information which are in its power, possession, custody or control; *provided*, that each Party may retain one copy of such Confidential Information for the sole purpose of performing any continuing obligations hereunder or exercising any continuing rights hereunder or for archival purposes and shall continue to comply with the terms of Article 13 (*Confidentiality; Publication*) in respect of the same.

(b) **Termination for Failure to Make Upfront Payment**. If this Agreement is terminated by Licensor pursuant to Section 14.2(a) (*Termination for Failure to Make Upfront Payment*), then, in addition to the consequences set forth in Section 14.3(a), (1) the licenses granted by Licensor to Licensee under the Licensed IP and all rights relating thereto shall terminate; and (2) all amounts outstanding at the date of termination other than the Upfront Payment shall immediately be due and payable to Licensor by Licensee.

(c) **Termination by Licensor for Material Breach, Insolvency or Failure to Develop or Commercialize**. If this Agreement is terminated by Licensor under Section 14.2(a) (*Termination for Material Breach*), Section 14.2(c) (*Termination for Insolvency*), or Section 14.2(d) (*Termination for Failure to Develop or Commercialize*), then, in addition to the consequences set forth in Section 14.3(a), (1) the licenses granted by Licensor to Licensee under the Licensed IP and all rights relating thereto shall terminate for all Licensed Indications, except HIV-related diarrhea to the extent that, as of the effective date of termination, Licensee either (A) has received Regulatory Approval for the Product for the HIV-related diarrhea Indication in at least one country in the Tier 1 Territory or (B) has submitted a Regulatory Approval Application for the Product for the HIV-related diarrhea Indication in at least one country in the Tier 1 Territory; (2) all amounts outstanding at the date of termination shall immediately be due and payable to Licensor by Licensee; (3) Licensee shall grant to Licensor a fully paid up, perpetual, sublicenseable, nonexclusive license, under Licensee Arising IP and Licensee Trademarks, for Licensor to Develop, Manufacture and Commercialize Products or any other products anywhere in the world, and (4) at Licensor's request and expense, Licensee shall transfer to Licensor all information and data relating to Crofelemer, Lechlemer and/or Product, including but not limited to Regulatory Materials and related data from clinical trials or preclinical testing of Crofelemer, Lechlemer and/or Product, in each case to the extent such information and data are included in the Licensee Arising IP.

14.4 Survival. Expiration or termination of this Agreement shall not relieve the Parties of any obligation accruing prior to such expiration or termination. Without limiting the foregoing, the provisions of Articles 1 (*Definitions*), 12 (*Indemnification; Liability; Insurance*) and 15 (*Miscellaneous*), and Sections 9.7 (*Late Payments*), 9.9 (*Financial Records and Audits*), 10.1 (*Ownership of Inventions*), 10.3(b) (*Joint Patents*), 10.3(c) (*Licensee Patents*), 10.3(d) (*Cooperation in Prosecution*), 13.1 (*Duty of Confidence*), 13.2 (*Exceptions*), 13.3 (*Authorized Disclosures*), 13.5 (*Security Exchange Disclosures*), 14.1 (*Term*), 14.3 (*Effect of Termination*), and 14.4 (*Survival*) shall survive the expiration or termination of this Agreement for any reason.

15. MISCELLANEOUS

15.1 Notices. Unless otherwise provided in this Agreement, all notices permitted or required under this Agreement shall be in writing and shall be delivered personally, sent by facsimile with a hard copy confirmation of receipt, or sent by express delivery service to the address provided by one Party to the other Party from time to time. Notices shall be effective upon receipt in the case of personal delivery, on the date of the hard copy confirmation of receipt in the case of delivery by facsimile or on the date the notice is delivered to the applicable address in the case of delivery by express overnight service.

15.2 Successors and Assigns. This Agreement or any of the severable rights and obligations inuring to the benefit of or to be performed by Licensor hereunder may be assigned by Licensor to a Third Party, including its affiliates, in whole or in part, without the need to obtain Licensee's consent thereto. Licensee may not assign its rights or obligations under this Agreement or delegate its duties hereunder without the prior written consent of Licensor.

15.3 Independent Contractors. In performing this Agreement, each of the Parties will operate as, and have the status of, an independent contractor. This Agreement does not create any agency, employment, partnership, joint venture, franchise or other similar or special relationship between the Parties. Neither Party will have the right or authority to assume or create any obligations or to make any representations, warranties or commitments on behalf of the other Party or its affiliates, whether express or implied, or to bind the other Party or its affiliates in any respect whatsoever.

15.4 Arbitration of Claims. All disputes arising out of or in connection with this Agreement, including its validity or a breach thereof, as well as all questions of arbitrability, shall be finally settled under the Rules of Arbitration of the International Chamber of Commerce ("**ICC Rules**") by three arbitrators. Each Party shall appoint one arbitrator. If a Party fails to appoint an arbitrator within thirty (30) days of the commencement of the arbitration, such appointment shall be made by the President of the ICC International Court of Arbitration. The two arbitrators appointed in accordance with the preceding sentences shall appoint the third arbitrator, who shall be the chairperson of the tribunal. If the two arbitrators fail to appoint the third arbitrator within thirty (30) days of the appointment of the second of the arbitrators, the appointment of the third arbitrator shall be made by the President of the ICC International Court of Arbitration.

(a) The place, or legal seat, of the arbitration shall be New York, New York, and the language of the arbitration shall be English.

(b) In addition to the ICC Rules, the Parties agree that the arbitration shall be conducted in accordance with the IBA Rules on the Taking of Evidence in International Arbitration, as current on the date of the commencement of any arbitration.

(c) Subject to Section 12.5 (*Limitation of Liability*) above, the arbitrators shall have the power to grant any interim or provisional measures that they deem appropriate, including but not limited to injunctive relief and specific performance, and any interim or provisional measures that the arbitrators order may be specifically enforced by any court of competent jurisdiction as a final award. Nothing herein, however, shall authorize the arbitrators to act as *amiable compositeurs* or to proceed *ex aequo et bono*, and the arbitrators shall have no authority to exercise rights of *jura novit curia*. Each party hereto retains the right to seek interim measures from a judicial authority, and any such request shall not be deemed incompatible with the agreement to arbitrate or a waiver of the right to arbitrate.

(d) The arbitrators may award to the prevailing Party, if any, as determined by the arbitrators, its costs and expenses, including reasonable attorneys' fees. Judgment upon any award rendered by the arbitrators may be entered in any court of competent jurisdiction.

No information concerning an arbitration, beyond the names of the parties and the relief requested, may be unilaterally disclosed to a third party by any party unless required by law. Any documentary or other evidence given by a party or witness in the arbitration shall be treated as confidential by any party whose access to such evidence arises exclusively as a result of its participation in the arbitration, and shall not be disclosed to any third party (other than a witness or expert), except as may be required by law. Any party who commences any judicial proceeding in connection with an arbitration initiated hereunder shall endeavor to have the judicial record of any such proceeding sealed to the extent permitted by law.

15.5 Governing Law; Venue. This Agreement shall be construed and enforced in accordance with, and all questions concerning the construction, validity, interpretation and performance of this Agreement shall be governed by, the internal laws of the State of New York, without giving effect to any choice of law or conflict of law provision or rule (whether of the State of New York or any other jurisdiction) that would cause the application of the laws of any jurisdiction other than the State of New York.

15.6 Severability. If any provision of this Agreement or portion thereof is determined by a court of competent jurisdiction, or declared under any law, rule or regulation of any government having jurisdiction over the Parties hereto, to be invalid, illegal or otherwise unenforceable, then such provision will, to the extent permitted by the court or government not be voided but will instead be construed to give effect to its intent to the maximum extent permissible under applicable law and the remainder of this Agreement will remain in full force and effect according to its terms.

15.7 Entire Agreement; Modification; Waiver. This Agreement, including the Exhibits, together with the IFD Product Supply and Technology Transfer Agreement, the Non-IFD Product Supply Agreement, the Non-IFD Product Technology Transfer Agreement, the Pharmacovigilance Agreement (each when executed) and any other documents delivered pursuant hereto or thereto constitute the entire agreement of the Parties concerning the subject matter hereof and supersedes any and all prior or contemporaneous, written or oral negotiations, correspondence, understandings and agreements, between the Parties respecting the subject matter of this Agreement. The Parties acknowledge and agree that this Agreement amends, restates, supersedes and replaces the Original Agreement in its entirety. No supplement, modification or amendment to this Agreement shall be binding unless evidenced by a writing signed by an authorized officer of each Party. No waiver of any of the provisions of this Agreement shall be deemed, or shall constitute, a waiver of any other provision, whether or not similar, nor shall any waiver constitute a continuing waiver. No waiver shall be binding unless executed in writing by the Party making the waiver.

15.8 Execution; Counterparts. This Agreement shall not be binding in whole or in part upon the Parties unless and until duly executed by or on behalf of both Parties hereto, in which event this Agreement shall be effective as of the Effective Date. This Agreement may be executed in counterparts, each of which shall be deemed to be an original instrument enforceable in accordance with its terms and all of which shall constitute but one and the same agreement of the Parties.

15.9 Further Assurances. Each Party shall do and perform, or cause to be done and performed, all such further acts and things, and shall execute and deliver all such other agreements, certificates, instruments and documents, as the other Party may reasonably request in order to carry out the intent and accomplish the purposes of this Agreement and the consummation of the transactions contemplated hereby.

15.10 Waiver of Jury Trial. Each Party hereby waives to the fullest extent permitted by applicable Law, any right it may have to a trial by jury in respect to any litigation directly or indirectly arising out of, under or in connection with this Agreement. Each Party (a) certifies that no representative, agent or attorney of any other party has represented, expressly or otherwise, that such other party would not, in the event of litigation, seek to enforce that foregoing waiver, and (b) acknowledges that it and the other Parties have been induced to enter into this Agreement, as applicable, by, among other things, the mutual waivers and certifications in this Section 15.10.

[Remainder of page intentionally left blank; signature page follows]

IN WITNESS WHEREOF, the Parties hereto have caused this Agreement to be executed by their duly authorized officers or representatives as of the Effective Date.

LICENSOR:

NAPO PHARMACEUTICALS, INC.

By: /s/ Lisa A. Conte
Name: Lisa A. Conte
Title: President& CEO

LICENSEE:

NAPO THERAPEUTICS S.P.A

By: /s/ Massimo Mineo
Name: Massimo Mineo
Title: CEO

[Signature Page to Amended and Restated License Agreement]

EXHIBIT A

Licensed Patents

Number	Country	Title	Application Number	Application Date	Grant Date	Expiration Date	Status
[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]

EXHIBIT B

Indications

Tier A

1. Short bowel syndrome ("**SBS**") and intestinal failure ("**IF**" and, together with SBS, "**SBS-IF**")
2. HIV-related diarrhea
3. Symptomatic relief and treatment in patients with congenital diarrheal disorders ("**CDDs**")

Tier B

4. Cancer therapy-related diarrhea ("**CTD**")

Tier C

5. Irritable bowel syndrome ("**IBS**")
6. Functional/idiopathic diarrhea
7. Inflammatory diarrhea, including acute and/or long-hauler Covid-related diarrhea ("**COVID-Related Diarrhea**")
8. Symptomatic relief and treatment in patients with inflammatory bowel disease ("**IBD**")
9. All other potential Indications for Crofelemer or Lechlemer, such as acute infectious diarrhea from pathogens

EXHIBIT C

Licensee Territory

European Union
United Kingdom
Switzerland
Norway
Sweden
Liechtenstein
Iceland
Croatia
Albania
Andorra
Armenia
Bosnia and Herzegovina
Vatican City
Kosovo
Moldova
Monaco
Montenegro
North Macedonia
San Marino
Serbia
Turkey
Ukraine

EXHIBIT D

Licensor Trademarks

None