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): October 11, 2022

JAGUAR HEALTH, INC.

(Exact name of registrant as specified in its charter)

001-36714

(Commission File Number)

Delaware (State or other jurisdiction of incorporation)

> 200 Pine Street, Suite 400 San Francisco, California

(Address of principal executive offices)

94104 (Zip Code)

46-2956775 (IRS Employer Identification No.)

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 \Box

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. \Box

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 October 11, 2022, Jaguar Health, Inc., a Delaware corporation (the "Company"), entered into an Amended and Restated License and Services Agreement (the "Amended License Agreement") with SynWorld Technologies Corporation, a corporation duly incorporated under the laws of Canada ("Licensee"), C&E Telecom, LTD, a company organized under the laws of the British Virgin Islands ("Licensee Guarantor"), and Tao Wang ("Parent"), which agreement amended and restated in its entirety the License and Services Agreement, dated as of June 28, 2022, by and among the same parties, as amended by the First Amendment to the License and Services Agreement (the "Amendment"), dated as of August 18, 2022, by and between Licensor and Licensee (the "Original License Agreement"). A copy of the Original License Agreement is attached as Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission (the "SEC") on June 29, 2022, and a copy of the Amendment is attached as Exhibit 10.2 to the Company's Current Report on Form 8-K filed with the SEC on August 23, 2022.

Pursuant to the Original License Agreement, (i) the Company (A) granted Licensee an exclusive license to commercialize a canine-specific pharmaceutical product utilizing crofelemer as its active drug substance, which product is marketed in the United States under the trademark Canalevia® and Canalevia-CA1 ("Product"), for the treatment, prevention or amelioration of diarrhea in dogs (the "Licensed Indication") in the People's Republic of China, excluding Hong Kong (the "Licensee Territory"), and (B) engaged Licensee as a service provider to prepare, submit and obtain regulatory approval of the Product for the Licensed Indication in the Licensee Territory on behalf of the Company (the "Services") and (ii) Licensee (A) agreed to pay the Company a license fee (the "License Fee") equal to \$5 million, which fee is payable in monthly installments during the initial two-year term of the Original License Agreement, and (B) committed to purchasing up to \$5 million worth of unregistered shares of common stock of the Company ("Common Stock") over the initial two-year term of the Original License agreement (the "Subscription Shares"). As consideration for the Services to be provided by Licensee under the Original License Agreement, the Company would pay Licensee a service fee (the "Service Fee") of up to \$5 million, payable in monthly installments in the form of unregistered shares of Common Stock over the initial two-year term of the Original License Agreement (the "Subscription Shares"). As consideration for the Service Shares"). The price per Service Share would be equal to the Minimum Price (as defined under Nasdaq Listing Rule 5635(d)) of the Common Stock at the time of such issuance, provided that such price shall in no event be less than (A) \$0.25 per share, with respect to such shares that are issued prior to the six-month anniversary of the effective date of the Amendment, and (B) \$0.31 per share, with respect to such shares that are issued on or after the six-month anniversary of the effective date of the Amendme

The Amended License Agreement, among other things, (i) removes (A) Licensee's commitment to purchase the Subscription Shares and (B) the Floor Price that the issuance of the Service Shares is subject to, such that the Service Shares will be issued at a price per share equal to the Minimum Price at the time of such issuance, and (ii) provides the Company with the discretion to elect to pay for the Licensee's Services either in cash or in the Service Shares in terms of each monthly installment.

In addition, the Amended License Agreement (i) provides the Company with a unilateral right to cause the parties to the Amended License Agreement to suspend their respective obligations under the Amended License Agreement without terminating such agreement, and (ii) acknowledges that (A) the License Fee due and payable by Licensee for September 2022, (B) the obligation of Licensee to purchase the Subscription Shares for September 2022, and (C) the Service Fee due and payable by the Company for September 2022 are all waived in full.

Consistent with the terms of the Original License Agreement, under no circumstances will the number of shares of Common Stock issued by the Company under the Amended License Agreement (i) exceed 19.99% of the total shares outstanding of the Company or (ii) result in the total number of shares of Common Stock held by Licensee and its affiliates exceeding 19.99% of total shares outstanding of the Company at any given time, in each case unless stockholder approval is obtained.

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 exhibit is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibit

Exhibit No.	Description
<u>10.1</u>	Amended and Restated License and Services Agreement, dated October 11, 2022, by and among Jaguar Health, Inc., SynWorld
	Technologies Corporation, C&E Telecom, LTD and Tao Wang.
104	Cover Page Interactive Data File (embedded within the inline XBRL document)

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

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

Date: October 14, 2022

AMENDED AND RESTATED LICENSE AND SERVICES AGREEMENT

This AMENDED AND RESTATED LICENSE AND SERVICES AGREEMENT (this "Agreement") is entered into as of October 11, 2022 (the "Restatement Date") by and among Jaguar Health, Inc., a Delaware corporation ("Licensor"), SynWorld Technologies Corporation, a corporation duly incorporated under the laws of Canada ("Licensee"), solely for purposes of Sections 9.4 (Representations and Warranties of Licensee, Licensee Guarantor and Parent), 10.3 (Indemnification by Licensee Guarantor and Parent) and 13.13 (Guaranty), C&E Telecom, LTD, a company organized under the laws of the British Virgin Islands ("Licensee Guarantor"), and, solely for purposes of Sections 9.4 (Representations and Warranties of Licensee, Licensee Guarantor and Parent) and 10.3 (Indemnification by Licensee Guarantor and Parent), Tao Wang, an individual ("Parent"). Licensor and Licensee and, solely for purposes of Article 10 (Indemnification; Liability; Insurance), Licensee Guarantor and Parent are referred to in this Agreement individually as a "Party" and collectively as the "Parties."

RECITALS

WHEREAS, Licensor has certain intellectual property rights with respect to Crofelemer and the Product;

WHEREAS, the Parties previously entered into that certain License and Services Agreement, dated as of June 28, 2022 (the "Effective Date"), as amended by that certain First Amendment to the License and Services Agreement, dated as of August 18, 2022, by and between Licensor and Licensee (the "Original Agreement"), pursuant to which Licensee (i) granted to Licensee certain licenses to significantly improve and/or expand the scope of Licensor's intellectual property rights, including in respect of the Product, and to commercialize the Product and (ii) engaged Licensee to obtain regulatory approval for the Product to treat all forms of diarrhea in dogs in the Licensee Territory, in each case pursuant to the terms and conditions of the Original Agreement; and

WHEREAS, the Parties desire to amend and restate the Original Agreement in its entirety as of the Restatement Date.

AGREEMENT

NOW, THEREFORE, in consideration of the foregoing and other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the Parties hereby agree that the Original Agreement is hereby amended and restated in its entirety as follows:

1. **DEFINITIONS**

"Affiliate" means, with respect to a Party, any person or entity that directly or indirectly, through one or more intermediates, controls, is controlled by, or is under common control with such Party. For the purpose of this definition, "control" means the direct or indirect ownership of: (i) fifty percent (50%) or more of the capital stock or share capital entitled to vote for the election of directors of the entity (or such lesser percentage which is the maximum allowed to be owned by a foreign corporation in a particular jurisdiction), (ii) fifty percent (50%) or more of the equity or voting interest of the entity (or such lesser percentage which is the maximum allowed to be owned by a foreign corporation in a particular jurisdiction), or (iii) status as a general partner in any partnership; in each case, whereby such person or entity controls or has the right to control the board of directors or equivalent governing body of a corporation or other entity. An entity will be an Affiliate for purposes of this Agreement only so long as it satisfies the definition set forth herein. "Bankruptcy Code" means the U.S. Bankruptcy Code (in the United States of America), 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 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 Effective Date and end on December 31 of the year in which the 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.

"CFIUS" has the meaning set forth in <u>Section 9.3(h)</u>.

"Claims" has the meaning set forth in <u>Section 10.1</u>.

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

"Collaboration Manager" has the meaning set forth in Section 3.1.

"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 6.1.

"Common Stock" means shares of voting common stock, par value \$0.0001 per share, of the Licensor.

"Confidential Information" means all information disclosed, directly or indirectly, by the Disclosing Party to the Receiving Party during the Term or prior to the Effective Date that is identified as confidential or is customarily regarded as confidential within the pharmaceutical industry, whether disclosed in electronic, tangible, oral or visual form. To the extent practical, Confidential Information shall be disclosed in tangible form and marked "Confidential." The existence of this Agreement and the terms hereof shall be deemed to be "Confidential Information" of each Party. Confidential Information shall not include such information that: (1) was or becomes generally available to the public other than as a result of an unauthorized disclosure by the Receiving Party or any of Receiving Party's Affiliates, employees, agents or representatives; (2) was or becomes available to the Receiving Party or any of Receiving Party's Affiliates, employees, agents or representatives; (2) was or becomes available to the Receiving Party's Affiliates, employees, agents or representatives; (2) was or becomes available to the Receiving Party's Affiliates, employees, agents or representatives; (2) was or becomes available to the Receiving Party's Affiliates, employees, agents or representatives; (2) was or becomes available to the Receiving Party's Affiliates, employees, agents or representatives; (2) was or becomes available to the Receiving Party's Affiliates, employees, agents or representatives; (2) was or becomes available to the Receiving Party's Affiliates, employees, agents or representatives; (3) has been disclosed to the Receiving Party without restrictions or other protection against public disclosure; provided that such source was not known by the Receiving Party or its Affiliates to be bound by any agreement to keep such information confidential or otherwise prohibited from transmitting the information by a contractual, legal or fiduciary obligation. Information that is otherwise Confidential Information and consi

"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.

"Deliverables" has the meaning set forth in Section 5.3.

"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.

"Disclosing Party" has the meaning set forth in Section 11.1(a).

"Dispute" has the meaning set forth in Section 13.4.

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

"European Union" means, at any particular time, all countries that are then officially recognized as member states of the European Union or members of the European Economic Area.

"Exchange Act" means the U.S. Securities Exchange Act of 1934, as amended, and the rules and regulations promulgated thereunder.

"Exchange Cap" means the maximum number of shares of Common Stock that could be issued to Licensee without violating The Nasdaq Capital Market rules related to the aggregation of offerings under Nasdaq Listing Rule 5635(d), if applicable.

"Generic Product" means, with respect to the Product, any product that is approved, or is sought to be approved, under an Abbreviated New Drug Application, 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, under the same Regulatory Approval Application for the 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 for current good clinical practice, as all such standards, practices and procedures may be updated or amended from time to time.

"Governmental 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.

"Improvements" has the meaning set forth in Section 2.3.

"Indemnified Party" has the meaning set forth in Section 10.4.

"Indemnifying Party" has the meaning set forth in Section 10.4.

"Indication" means any disease, symptom, syndrome and medical condition 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.

"Infringement" has the meaning set forth in Section 8.2(a).

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

"Launch Date" means the earlier of (i) the date on which Licensee commences its Commercialization efforts of the Product to customers after Regulatory Approvals have been obtained in the Licensee Territory or (ii) thirty (30) days from the date that Regulatory Approvals for the Product have been obtained in the Licensee Territory.

"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.

"Licensed Indication" means the treatment, prevention, or amelioration of diarrhea in dogs.

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

"Licensed Know-How" means all Information (including regulatory data, files, approvals and other documentation) owned or Controlled by Licensor or any of its Affiliates before or on the Effective Date or at any time during the Term, in each case, that is (a) generally not known and (b) useful to the Commercialization of the Product for the Licensed Indication in the Licensee Territory, but excluding any Information to the extent described in any published Licensed Patent.

"Licensed Patents" means any Patent that: (a) covers the Product or its Commercialization for the Licensed Indication in the Licensee Territory, (b) is owned or Controlled by Licensor or any of its Affiliates and (c) is issued or filed before or on the Effective Date or at any time during the Term, but excluding any Licensee Arising Patents. The Licensed Patents existing as of the Effective Date are set forth in Exhibit A hereto.

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

"Licensee Arising Know-How" means all Information (including regulatory data, files, approvals and other documentation) owned or Controlled by Licensee to the extent derived from Licensee's activities under this Agreement that is useful for the Development or Commercialization of Crofelemer and/or the Product, but excluding any Information derived from the performance of the Services.

"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 or Commercialization of Crofelemer and/or the Product, but excluding any Information derived from the performance of the Services.

"Licensee Indemnitees" has the meaning set forth in Section 10.1.

"Licensee Territory" means the People's Republic of China, excluding Hong Kong; provided that the Licensee Territory may be expanded, as mutually agreed upon by the Parties, and as evidenced in a written amendment to this Agreement.

"Licensor Indemnitees" has the meaning set forth in Section 10.2.

"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 B hereto.

"Liens" has the meaning set forth in Section 9.2(a).

"Major Market Countries" means each of the Licensee Territory, the United States, the countries in the European Union, and the United Kingdom.

"Manufacturing Cost Price" means, with respect to the Product provided by Licensor to Licensee, the actual costs and expenses borne by Licensor to acquire the Product from Third Party manufacturers, including, without limitation, transportation to Licensee, plus a markup of fifteen percent (15%).

"Maximum Service Fee Amount" means, with respect to each Service Payment Date, the maximum amount in cash to be paid by Licensor to Licensee or the maximum dollar value of Service Shares to be issued by Licensor to Licensee, as the case may be, on such Service Payment Date as specified in Exhibit C hereto.

"Minimum Price" means, with respect to a given date, the lower of: (i) the closing price (as reflected on Nasdaq.com) immediately preceding such date or (ii) the average closing price of the Common Stock (as reflected on Nasdaq.com) for the five (5) trading days immediately preceding such date.

"Net Profits" means the Net Sales of the Product less (i) the Manufacturing Cost Price for such Product, (ii) the applicable costs for Commercialization as well as an allocation of Overhead based on the time, expenses, and resources devoted to the Product-related activities, and (iii) any customary and reasonable costs incurred in connection with the sale of the Product.

"Net Sales" means, with respect to any given period, all revenues without limitation from the sale of Product, also called gross sales, by Licensee and its Affiliates to Third Parties, less deductions for normal and customary trade, quantity and cash discounts and sales returns and allowances. For purposes of determining Net Sales, the Product 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 or its Affiliates in connection therewith.

"OFAC" has the meaning set forth in Section 9.3(h).

"**Overhead**" means all customary and usual operating expenses directly related to the Product incurred by and in support of the particular manufacturing cost centers, purchasing department and quality assurance operations specifically related to the 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.

"Personnel" means employees, agents and other personnel of Licensee, its Affiliates or any subcontractors engaged to perform the Services.

"Pharmacovigilance Agreement" has the meaning set forth in Section 5.7.

"Profit-Sharing Report" has the meaning set forth in Section 7.2.

"Product" means a canine-specific pharmaceutical product for the Licensed Indication that utilizes Crofelemer as its active drug substance marketed in the United States under the Trademark Canalevia®, Canalevia-CA1 and Canalevia CA-2.

"**Product Labeling**" means, with respect to the Product: (a) the Regulatory Authority-approved full prescribing information for the 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 the Product in such country or other jurisdiction.

"Pro Rata Percentage" means (a) with respect to Licensee, forty percent (40%) and (b) with respect to Licensor, sixty percent (60%), subject to adjustment pursuant to <u>Section 5.5(c)</u>.

"Publication" has the meaning set forth in Section 11.4.

"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 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 Effective Date, and the last Calendar Quarter ends on the last day of the Term.

"Monthly License Fee" has the meaning set forth in Section 7.1.

"Monthly Service Fee" means the fee for the Services to be paid either in cash or in unregistered, restricted shares of Common Stock (the "Service Shares"), at the sole discretion of Licensor, in the amounts and according to the schedule set forth in <u>Exhibit C</u> hereto.

"OFAC" has the meaning set forth in Section 9.3(h).

"Receiving Party" has the meaning set forth in Section 11.1(a).

"**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 the 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.

"Regulatory Expenses" has the meaning set forth in Section 5.1(a).

"**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 Commercialize the Product in a particular country or jurisdiction.

"Reimbursement Cap" means Two Million Dollars (US\$2,000,000).

"Reimbursement Shares" has the meaning set forth in Section 5.5(c).

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

"SDN List" has the meaning set forth in Section 9.3(h).

"Securities Act" means the Securities Act of 1933, as amended, and the rules and regulations promulgated thereunder.

"Service Payment Date" has the meaning set forth in Section 5.5(a).

"Service Share Amount" means, for each Service Payment Date, a number of Service Shares determined by dividing the Maximum Service Fee Amount for such Service Payment Date by the Minimum Price on such Service Payment Date.

"Service Shares" has the meaning set forth in the defined term "Monthly Service Fee."

"Services" has the meaning set forth in Section 5.1(a).

"Shares" means collectively, the Service Shares and the Reimbursement Shares.

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

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

"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.

"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 an exclusive (even as to Licensor), non-transferable, non-sublicensable license under the Licensed IP and the Licensor Trademarks for Licensee to Commercialize the Product for the Licensed Indication in the Licensee Territory; *provided, however*, for the avoidance of doubt, nothing in this Agreement grants Licensee the right to manufacture or have manufactured the Product for Commercialization or any other purpose, as set forth in <u>Section 4.1</u> hereof (*Supply of Product*).

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 <u>Section 12.3</u> (*Effect of Termination*)), transferable license under the Licensee Arising IP to Develop or Commercialize any product for any Indication anywhere in the world (other than, with respect to Commercialization, the Product for the Licensed Indication in the Licensee Territory). Licensor and its Affiliates shall have the right to sublicense the rights granted to it under this <u>Section 2.2</u> 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 No Implied Licenses. Except as explicitly set forth in this Agreement, neither Party will be deemed to have granted to 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. GOVERNANCE

3.1 Collaboration Management. Each of the Parties shall appoint a single representative to act as that Party's collaboration manager (each, a "Collaboration Manager").

3.2 Roles and Responsibilities. The role of the Collaboration Manager is to act as a point of contact between the Parties to assure a successful collaboration. The Collaboration Managers shall develop the strategies for and oversee the Commercialization of the Product in the Licensee Territory. In particular, the Collaboration Managers shall: (a) develop the Commercialization Plan; (b) review, discuss and implement all registration and regulatory activities in the Licensee Territory with respect to the Product; and (c) 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.

3.3 Substitutions. Each Party may change its designated Collaboration Manager from time to time upon written notice to the other Party. Any Collaboration Manager may designate a substitute to temporarily perform the functions of that Collaboration Manager by written notice to the other Party.

4. MANUFACTURING AND SUPPLY

4.1 Supply of Product. Licensor shall be responsible for the supply of Product to Licensee at the Manufacturing Cost Price in accordance with U.S. Current Good Manufacturing Practices. All Product supplied under this Agreement will be delivered FOB Licensor's designated warehouse located in the United States of America. Under no circumstance shall Licensee have the right or obligation to manufacture Crofelemer or Product.

4.2 Responsibilities of Collaboration Managers. Prior to the anticipated Launch Date of the Product in the Licensee Territory, the Collaboration Managers shall agree on the quantities of Product that Licensor shall supply and such other terms and conditions as they consider necessary or desirable to carry out the purposes of the foregoing. If Licensor is unable to meet such supply schedule at any time, the Collaboration Managers shall discuss in good faith as to the cause(s) of such failure and confer on a resolution.

5. ENGAGEMENT FOR SERVICES

5.1 Scope of Services.

(a) Licensee shall prepare, submit and obtain all Regulatory Approvals for the Product in the Licensee Territory on behalf of, and in the name of, Licensor (the "Services"). Licensee shall perform the Services in accordance with the terms of this Agreement. During the Initial Term, Licensee shall be solely responsible for all fees and expenses incurred by or on behalf of Licensee with respect to the performance of the Services (collectively, "Regulatory Expenses"), subject to the Parties' election for Licensor to reimbursement Regulatory Expenses up to the Reimbursement Cap in accordance with <u>Section 5.5(c)</u> (*Reimbursement of Regulatory Expenses*).

(b) Upon reasonable request from Licensee and as reasonably appropriate, Licensor shall compile all necessary data, documents and Regulatory Approvals for the Product in the U.S. Licensee shall be responsible for any formatting or translations required by Regulatory Authorities in the Licensee Territory, which formatting or translations Licensor shall have the right to review and edit.

(c) To the extent applicable, Licensee shall, if requested to do so by Licensor, represent Licensor in customs declaration, and satisfying and completing any and all quality supervision, inspection and quarantine requirements and formalities relating to the product under Chinese law free of any charge to Licensor.

(d) If and when Regulatory Approvals for the Product are secured, Licensee shall maintain and renew the Regulatory Approvals in the Licensee Territory and pay all user fees and other costs required to obtain and maintain such Regulatory Approvals during the Initial Term.

(e) Licensee shall keep Licensor informed of developments relating to the Services and shall promptly notify Licensor in writing of any action or decision by any Regulatory Authority in the Licensee Territory regarding the Services. Licensee shall provide Licensor for review and approval all draft Regulatory Materials as soon as practicable in advance of their intended date of submission to a Regulatory Authority in the Licensee Territory. Use of such Regulatory Materials may not be implemented until Licensor approval has been obtained. Once per Quarter, Licensee shall provide the Collaboration Managers with a written report that sets forth (i) a summary and timeline for all ongoing and planned Regulatory Activities, (ii) a summary of all material and substantive interactions with applicable Regulatory Authorities for the Product in the Licensee Territory and (iii) updates on key milestones relating thereto.

(f) Licensee hereby agrees, upon request, to provide copies of all Regulatory Materials, Regulatory Approvals and all corresponding documentation to Licensor as soon as practicable after Licensee's submission to Regulatory Authorities, including English translations thereof prepared by a Third Party translation service mutually agreed upon between the Parties.

5.2 Subcontracting; Personnel. Licensee may subcontract the Services to any Third Party, and Licensee shall engage qualified and experienced Personnel to perform the Services, and shall remain responsible for performance and/or breach of this Agreement by Personnel. Licensee shall be solely responsible for all employer obligations toward Personnel under Applicable Laws, including compensation, payroll taxes and benefits. Prior to performing any Services and/or receiving Confidential Information of Licensor, all Personnel must (a) be subject to, and bound by, confidentiality obligations consistent with the terms of this Agreement, and (b) assign and otherwise effectively vest in Licensee any and all rights that such Personnel might otherwise have in the results of their work.

5.3 Ownership. As between Licensor and Licensee, all rights, title and interest to all Regulatory Approvals, reports, data, technical information, original works of authorship and all other information, furnished by or on behalf of Licensor, or developed or provided by Licensee or Personnel in connection with the Services under this Agreement, including all related data, materials, and other work product (collectively, the "**Deliverables**"), are "works made for hire" for Licensor under applicable copyright law and are the exclusive property of Licensor. To the extent any Deliverables do not qualify as a "work made for hire," Licensee hereby assigns to Licensor all right, title and interest in such Deliverables, including all related intellectual property rights. At Licensor's request and expense, Licensee will sign documents and take any other action reasonably necessary to perfect or otherwise protect Licensor's rights in the Deliverables. Licensee will not incorporate any Third Party intellectual property into a Deliverable without Licensor's express written consent.

5.4 Cooperation. Licensor shall provide reasonable cooperation to Licensee with respect to obtaining Regulatory Approval for the Product. Licensor hereby grants to Licensee a right of reference to all Regulatory Materials filed by or on behalf of Licensor in the Licensor Territory or Licensee Territory, which right of reference Licensee may use for the sole purpose of performing the Services. Licensor shall promptly submit any necessary notices or authorizations to Regulatory Authorities that are necessary to effect such rights of reference.

5.5 Payment Terms.

(a) As consideration for the Services, Licensor shall initiate payment to Licensee of a Monthly Service Fee on the second to last Business Day of the applicable calendar month (except for the initial Monthly Service Fee, which shall be paid within three (3) Business Days of the Effective Date) (each such date, a "Service Payment Date") with delivery of such Monthly Service Fee to occur no later than the second Business Day immediately following the end of the applicable calendar month; *provided, however*, in no event shall the cumulative number of Shares issued to Licensee (i) exceed the Exchange Cap or (ii) result in Licensee, together with its Affiliates and any other person or entity whose holdings would be aggregated with Licensee for purposes of Section 13(d) of the Exchange Act, beneficially owning more than 19.99% of the issued and outstanding Common Stock, unless stockholder approval is obtained.

(b) **Service Payment Notice**. On each Service Payment Date, Licensor shall provide notice (by telephone or electronic mail) to Licensee of (i) whether the Monthly Service Fee for the applicable month will be paid in cash or in the Service Shares, which election will be at Licensor's sole discretion, (ii) in the event of payment in cash, the actual amount of payment, and (iii) in the event of payment in the Service Shares, (A) the Minimum Price on such Service Payment Date and (B) the Service Share Amount.

(c) **Reimbursement of Regulatory Expenses**. Upon mutual agreement of Licensor and Licensee, Licensor shall have the option, at any time during the Initial Term, to reimburse Licensee for all Regulatory Expenses up to, but not exceeding, the Reimbursement Cap, with all Regulatory Expenses in excess of the Reimbursement Cap and any additional fees and expenses incurred thereafter for maintaining the Regulatory Approvals to be borne by Licensee shall provide Licensor with an invoice for such amount, along with documentation evidencing the actual payment made by Licensee with respect to the Regulatory Expenses. Licensor shall pay such invoice in cash or through the issuance of unregistered, restricted shares of Common Stock of Licensor (the "**Reimbursement Shares**") to Licensee (based on the Minimum Price at the time of such election) within thirty (30) days of receipt of the invoice and accompanying documents; *provided, however*, in no event shall the cumulative number of Shares issued to Licensee (i) exceed the Exchange Cap or (ii) result in Licensee, together with its Affiliates and any other person or entity whose holdings would be aggregated with Licensee for purposes of Section 13(d) of the Exchange Act, beneficially owning more than 19.99% of the issued and outstanding Common Stock, unless stockholder approval is obtained. If Licensor has reimbursed Licensee for Regulatory Expenses incurred during the Initial Term as provided in this <u>Section 5.5(c)</u>, each Party's Pro Rata Percentage of the Net Profits of the Product shall be adjusted to, with respect to Licensee, twenty percent (20%) and, with respect to Licensee, eighty percent (80%).

(d) **Payment through the Issuance of Shares**. In the event Licensor elects to pay (i) the Monthly Service Fee in form of the Service Shares, and/or (ii) the invoice for the Regulatory Expenses in the form of the Reimbursement Shares:

(i) The Shares shall be deemed fully vested, fully earned, not subject to forfeiture or rescission, free of any contingencies and fully paid for, as of the issuance date, and Licensee shall be deemed to hold all investment risk therewith on such issuance date. Notwithstanding the foregoing, the Shares will be unregistered and bear the restrictive legend set forth in <u>Section 5.8</u> (*Restrictive Legend*). Licensor shall have no obligation to register the Shares.

(ii) To facilitate the payment of Shares, Licensor shall open an account with its transfer agent and authorize the issuance of the Shares in book entry form with the transfer agent. Licensor shall pay for any transfer agent and/or legal related costs that Licensee might incur in the process of removing the trading restrictions from the Shares, which includes but is not limited to, Licensor providing a legal opinion for the Shares, provided the Shares meet the requirements under the Securities Act for the removal of the restrictive legend described in <u>Section 5.8</u> (*Restrictive Legend*).

5.6 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 Commercialization or Regulatory Approval of the Product.

5.7 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 Product in the Licensee Territory, the Parties shall define and finalize the actions that the Parties shall employ with respect to the Product 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.

5.8 Restrictive Legend. Each instrument evidencing the Shares which Licensee may acquire hereunder shall be imprinted with a legend substantially in the following form:

"THE SECURITIES REPRESENTED BY THIS CERTIFICATE HAVE NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933, AS AMENDED (THE "ACT") OR APPLICABLE STATE SECURITIES LAWS. THE SECURITIES MAY NOT BE OFFERED FOR SALE, SOLD, TRANSFERRED OR ASSIGNED IN THE ABSENCE OF (A) AN EFFECTIVE REGISTRATION STATEMENT FOR THE SECURITIES UNDER THE ACT OR (B) AN OPINION OF COUNSEL, IN FORM REASONABLY ACCEPTABLE TO THE COMPANY, THAT REGISTRATION IS NOT REQUIRED UNDER THE ACT."

5.9 Legend Removal. Licensor shall remove all restrictive legends from any Shares within ten (10) Business Days of Licensee's valid request made pursuant to Rule 144 of the Securities Act, or following the effective date of a registration statement filed by Licensor covering the resale of such Shares (this in no way obligates Licensor to file a registration statement).

6. COMMERCIALIZATION

6.1 Commercialization Plan. The Commercialization of the Product in the Licensee Territory shall be conducted pursuant to a strategy and plan (the "Commercialization Plan"), which the Collaboration Managers shall develop. The Commercialization Plan shall include, with respect to the Licensee Territory, a high-level overview of:

- (a) general strategies for the promoting, detailing, marketing and distributing of the Product;
- (b) pre-Launch Date Commercialization activities and the expected Launch Date;
- (c) the nature of promotional activities anticipated;

(d) (i) summary-level peak market forecasts and 24-month written rolling sales forecasts for the Product in the Licensee Territory, updated quarterly and (ii) performance criteria for such sales forecasts (to be established by the Collaboration Managers two (2) years after the Launch Date of the Product in the Licensee Territory); and

(e) projections of annual Net Profits for the Product.

6.2 Commercialization Diligence. Following receipt of Regulatory Approval of the Product in the Licensee Territory, Licensee shall Commercialize the Product for the Licensee Indication in the Licensee Territory in accordance with the Commercialization Plan.

6.3 Responsibility for Commercialization in the Licensee Territory. Subject to the terms and conditions of this <u>Article 6</u>, Licensee shall have sole control over and decision-making authority for, at its cost and expense, implementing the Commercialization Plan for the Product in the Licensee Territory. Licensee shall, with respect to the Product 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, if any, 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 Product in the Licensee Territory.

6.4 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 the Product, including via internet or mail order, into the Licensor Territory.

(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 the Product, including via internet or mail order, into the Licensee Territory.

7. COMPENSATION

7.1 Monthly License Fee. As consideration for the license granted hereunder, Licensee shall make non-refundable cash payments in the amounts and in accordance with the schedule set forth in <u>Exhibit D</u> (the "Monthly License Fee") to Licensor. Licensee shall pay the Monthly License Fee no later than the last Business Day prior to the end of the applicable calendar month (except for the initial Monthly License Fee, which shall be paid within three (3) Business Days of the Effective Date). The maximum aggregate amount payable by Licensee pursuant to this <u>Section 7.1</u> is Five Million Dollars (\$5,000,000). For clarity, (i) following the Initial Term, no further Monthly License Fee shall be payable by Licensee and (ii) a breach of this <u>Section 7.1</u> shall constitute a material breach of this Agreement for which the remedies of <u>Section 12.2(b)</u> (*Termination for Material Breach*) shall be available to Licensor.

7.2 Profit-Sharing. Each Party shall be entitled to receive its Pro Rata Percentage, subject to adjustment as provided in <u>Section 5.5(c)</u> (*Reimbursement of Regulatory Expenses*), of aggregate Net Profits from sales of the Product in the Licensee Territory, on a quarterly basis. Within sixty (30) days after each Quarter commencing with the Quarter upon which the Launch Date occurs, Licensee shall furnish consolidated profit statements that show Net Sales and Net Profits of the Product for such Calendar Year, together with an itemized analysis of the deductions from gross to Net Sales and number of units sold (less damaged, rejected, recalled or returned product), as well as the components of each of the foregoing and calculations performed to calculate such Net Sales and Net Profits (the "**Profit-Sharing Report**"). Concurrent with the delivery of the Profit-Sharing Report, Licensee shall remit payment to Licensor of Licensor's Pro Rata Percentage of aggregate Net Profits from sales of the Product in the Licensee Territory.

7.3 Currency; Exchange Rate. All payments to be made by Licensee to Licensor under this Agreement, except for payments through issuance of Shares, shall be made in Dollars by bank wire transfer in immediately available funds to a bank account designated by written notice from Licensor. For the purpose of calculating any such sums due, Licensee shall convert any amount expressed in a foreign currency into Dollar equivalents using its standard conversion methodology consistent with the International Financial Reporting Standards as issued by the International Accounting Standards Board.

7.4 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, the successor thereto (if any), or the highest rate allowable by applicable Law, whichever is less.

7.5 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**. Each Party agrees to cooperate with the other Party and to use reasonable efforts to reduce or eliminate tax withholding or similar obligations in respect of the Monthly License Fee and Monthly Service Fee made by such Party under this Agreement, as applicable. 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.

7.6 Financial Records and Audits. Licensee shall maintain complete and accurate records in sufficient detail to permit Licensor to confirm the accuracy of 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 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. 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 reports furnished by Licensee or the 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 7.4 (*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 13.4 (*Referral of Disputes to Parties Executive Officers*). If such audit reveals any overpayment, such amount shall be creditable against future payments due under this Agreement (or promptly refunded to Licensee, if there is no future 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.

8. INTELLECTUAL PROPERTY MATTERS

8.1 Patent Prosecutions.

(a) Licensed Patents.

(1) Licensor shall have the 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 <u>Article 8</u>, "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 Governmental 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 Governmental 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.

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

(c) **Cooperation in Prosecution**. Each Party shall provide the other Party all reasonable assistance and cooperation in the patent prosecution efforts provided above in this <u>Section 8.1</u>, including providing any necessary powers of attorney and executing any other required documents or instruments for such prosecution.

8.2 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 Licensee Patents against such Infringement, 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; Expense and Recoveries**. Upon request of the Party bringing the action under <u>Section 8.2(b)</u> (*Enforcement Right*), the other Party will reasonably cooperate with such enforcing Party. The non-enforcing Party shall have the right to be represented in such matter by counsel of its own choice and at its own expense. Any and all recoveries resulting from such enforcement action shall first be applied to reimburse each Party's costs and expenses in connection therewith, and any remaining recoveries 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 and Net Profits subject to the profit share payment by Licensee to Licensor under <u>Section 7.2</u> (*Profit-Sharing*).

8.3 Trademarks.

(a) **Coordination**. Licensee will notify Licensor of the Trademarks and trade dress it intends to use on the Product in the Licensee Territory. If in its sole discretion the Licensee chooses to utilize the Licensor's Trademark, such utilization will be coordinated by the Collaboration Managers.

9. REPRESENTATION AND WARRANTIES; COVENANTS

9.1 Representations and Warranties of Each Party. Each Party represents and warrants to the other Party as of the Effective Date and the Restatement 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.

9.2 Representations and Warranties of Licensor. Licensor represents and warrants to Licensee as of the Restatement 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 Effective Date, Licensor has not received any written notice from any Third Party asserting or alleging that any research or development of the Product by or on behalf of Licensor prior to the 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 the Product and/or the Licensed IP by or against Licensor or any of its Affiliates in or before any Governmental Authority;

(d) Licensed Patents. (i) Exhibit A includes all Patents that are owned by or licensed to Licensor or its Affiliates as of the Effective Date and are reasonably necessary for or directly related to Licensor in the Commercialization of the 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".

9.3 Representations and Warranties of Licensee. Licensee hereby represents and warrants as of the Restatement Date and as of each Service Payment Date and each date on which Licensee receives the Reimbursement Shares that:

(a) it is an "accredited investor" as that term is defined in Rule 501(a) of Regulation D under the Securities Act and Licensee shall promptly notify Licensor of any changes to its status as an "accredited investor";

(b) neither Licensee, nor any person or entity with whom Licensee shares beneficial ownership of the Shares, is subject to any of the "Bad Actor" disqualifications described in Rule 506(d)(1)(i)-(viii) of the Securities Act;

(c) Licensee is acquiring the Shares for investment for Licensee's own account, and not with a view to, or for resale in connection with, any distribution thereof, and Licensee has no present intention of selling or distributing any of the Shares;

(d) Licensee has had an opportunity to discuss Licensor's business, management and financial affairs with Licensor's management and to obtain any additional information which Licensee has deemed necessary or appropriate for deciding whether or not to acquire the Shares, including an opportunity to receive, review and understand the information set forth in Licensor's financial statements, capitalization and other business information as Licensee deems prudent;

(e) Licensee has such knowledge and experience in financial and business matters, including investments in other emerging growth companies that such individual or entity is capable of evaluating the merits and risks of the investment in the Shares and it is able to bear the economic risk of such investment;

(f) Licensee acknowledges and agrees that the Shares must be held indefinitely unless it is subsequently registered under the Securities Act or an exemption from such registration is available, and Licensee has been advised or is aware of the provisions of Rule 144 promulgated under the Securities Act as in effect from time to time, which permits limited resale of securities purchased in a private placement subject to the satisfaction of certain conditions, including, among other things: the availability of certain current public information about Licensor and the resale occurring following the required holding period under Rule 144;

(g) Licensee acknowledges that: (i) Licensor is a U.S.-based issuer, (ii) that any Shares issued to Licensee hereunder shall be issued in the United States; (iii) that Licensor is not an authority on the securities laws of other countries, (iv) that Licensor is not, in any way, advising Licensee with respect to the Shares nor the securities laws of the People's Republic of China, and (v) it is solely Licensee's responsibility to seek and obtain appropriate and necessary advice from a professional expert in the securities laws, tax laws and all other laws of the People's Republic of China applicable to the issuance of the Shares to Licensee and applicable to Licensee's ability to receive, and realize value from, the Shares;

(h) neither Licensee, any of its affiliates or beneficial owners, nor any person for whom Licensee is acting as agent or nominee, (i) appears on the list of Specially Designated Nationals and Blocked Persons ("SDN List") maintained by the Office of Foreign Assets Control of the U.S. Treasury Department ("OFAC"), the list of Foreign Sanctions Evaders maintained by OFAC, or any other lists of restricted parties maintained by the U.S. Government, nor are they otherwise a party with which any entity is prohibited to deal under the laws of the United States, (ii) is directly or indirectly owned, individually or in aggregate, 50% or more by one or more persons on the SDN List, (iii) is a senior foreign political figure or any immediate family member or close associate of a senior foreign political figure or (iv) is identified as a terrorist organization on any other relevant lists maintained by governmental authorities. Licensee further represents and warrants that the monies used to pay the Monthly License Fee are not derived from, invested for the benefit of, or related in any way to, and that no monies or dividends received as a result of the investment in the Shares shall be provided to or for the benefit of, the governments of, or persons within, any country (A) under a U.S. embargo enforced by OFAC, (B) that has been designated as a "noncooperative country or territory" by the Financial Action Task Force or (C) that has been designated by the U.S. Secretary of the Treasury as a "primary money laundering concern." Licensee further represents and warrants that this Agreement and any related transactions are not designed or intended to evade or circumvent any applicable regulations related to or oversight by the Committee on Foreign Investment in the United States ("CFIUS"). Licensee further represents and warrants that it: (1) has conducted thorough due diligence with respect to all of its beneficial owners, (2) has established the identities of all beneficial owners and the source of each of the beneficial owner's funds and (3) shall retain evidence of any such identities, any such source of funds and any such due diligence. Licensee further represents and warrants that Licensee does not know or have any reason to suspect that (x) the monies used to pay the Monthly License Fee have been or will be derived from or related to any illegal activities, including money laundering activities, or any such monies were, or will be, directly or indirectly derived from activities that may contravene federal, state or international laws and regulations, including antimoney laundering laws and regulations, and (y) the proceeds from Licensee's investment in the Shares will be used to finance any illegal activities;

(i) Licensee is aware that the anti-manipulation rules of Regulation M under the Exchange Act may apply to sales of the Shares and other activities with respect to the Common Stock by the Licensee; and

(j) Licensee, together with its Affiliates and any other person or entity whose holdings would be aggregated with Licensee for purposes of Section 13(d) of the Exchange Act, will not, after giving effect to any Shares issued or issuable on such date, beneficially own more than 19.99% of the issued and outstanding Common Stock as of such date.

If at any time during the Term, the representations and warranties set forth in this <u>Section 9.3</u> cease to be true, Licensee shall promptly so notify Licensor in writing.

9.4 Representations and Warranties of Licensee, Licensee Guarantor and Parent.

(a) Each of Licensee, Licensee Guarantor and Parent hereby represents and warrants that it has, and shall continue to have at all times, the available funds and/or capital commitments and financial ability necessary to timely fulfill Licensee's obligations hereunder.

(b) Licensee Guarantor hereby represents and warrants as of the Restatement Date and as of each Service Payment Date and each date on which Licensee receives the Reimbursement Shares that neither Licensee Guarantor nor any of its affiliates or beneficial owners, nor any person for whom Licensee Guarantor is acting as agent or nominee, (i) appears on the SDN List maintained by OFAC, the list of Foreign Sanctions Evaders maintained by OFAC, or any other lists of restricted parties maintained by the U.S. Government, nor are they otherwise a party with which any entity is prohibited to deal under the laws of the United States, (ii) is directly or indirectly owned, individually or in aggregate, 50% or more by one or more persons on the SDN List, (iii) is a senior foreign political figure or any immediate family member or close associate of a senior foreign political figure or (iv) is identified as a terrorist organization on any other relevant lists maintained by governmental authorities. Licensee Guarantor further represents and warrants that the monies used to pay the Monthly License Fee are not derived from, invested for the benefit of, or related in any way to, and that no monies or dividends received as a result of the investment in the Shares shall be provided to or for the benefit of, the governments of, or persons within, any country (A) under a U.S. embargo enforced by OFAC, (B) that has been designated as a "non-cooperative country or territory" by the Financial Action Task Force or (C) that has been designated by the U.S. Secretary of the Treasury as a "primary money laundering concern." Licensee Guarantor further represents and warrants that this Agreement and any related transactions are not designed or intended to evade or circumvent any applicable regulations related to or oversight by CFIUS. Licensee Guarantor further represents and warrants that it: (1) has conducted thorough due diligence with respect to all of its beneficial owners, (2) has established the identities of all beneficial owners and the source of each of the beneficial owner's funds and (3) shall retain evidence of any such identities, any such source of funds and any such due diligence. Licensee Guarantor further represents and warrants that Licensee Guarantor does not know or have any reason to suspect that (x) the monies used to pay the Monthly License Fee have been or will be derived from or related to any illegal activities, including money laundering activities, or any such monies were, or will be, directly or indirectly derived from activities that may contravene federal, state or international laws and regulations, including anti-money laundering laws and regulations, and (y) the proceeds from Licensee's investment in the Shares will be used to finance any illegal activities.

(c) Parent hereby represents and warrants as of the Restatement Date and as of each Service Payment Date and each date on which Licensee receives the Reimbursement Shares that neither Parent nor any of its affiliates or beneficial owners, nor any person for whom Parent is acting as agent or nominee, (i) appears on the SDN List maintained by OFAC, the list of Foreign Sanctions Evaders maintained by OFAC, or any other lists of restricted parties maintained by the U.S. Government, nor are they otherwise a party with which any entity is prohibited to deal under the laws of the United States, (ii) is directly or indirectly owned, individually or in aggregate, 50% or more by one or more persons on the SDN List, (iii) is a senior foreign political figure or any immediate family member or close associate of a senior foreign political figure or (iv) is identified as a terrorist organization on any other relevant lists maintained by governmental authorities. Parent further represents and warrants that the monies used to pay the Monthly License Fee are not derived from, invested for the benefit of, or related in any way to, and that no monies or dividends received as a result of the investment in the Shares shall be provided to or for the benefit of, the governments of, or persons within, any country (A) under a U.S. embargo enforced by OFAC, (B) that has been designated as a "non-cooperative country or territory" by the Financial Action Task Force or (C) that has been designated by the U.S. Secretary of the Treasury as a "primary money laundering concern." Parent further represents and warrants that this Agreement and any related transactions are not designed or intended to evade or circumvent any applicable regulations related to or oversight by CFIUS. Parent further represents and warrants that Licensee Guarantor does not know or have any reason to suspect that (x) the monies used to pay the Monthly License Fee have been or will be derived from or related to any illegal activities, including money laundering, or any such monies were, or will be, directly or indirectly derived from activities that may contravene federal, state or international laws and regulations, including anti-money laundering laws and regulations, and (y) the proceeds from Licensee's investment in the Shares will be used to finance any illegal activities.

9.5 Disclaimer. EXCEPT AS EXPRESSLY STATED IN THIS <u>ARTICLE 9</u>, (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.

9.6 Covenants.

(a) **Compliance with Law**. 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 or entity 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.

(b) No Short Sales. No short sales shall be permitted by Licensee or its Affiliates during the period commencing on the Effective Date and continuing through the termination of this Agreement.

(c) Share Ownership Disclosure. Upon the written or oral request of Licensor, Licensee shall, within one (1) Business Day confirm orally and in writing to Licensor the number of shares of Common Stock then beneficially owned by Licensee, together with Licensee's Affiliates and any other person or entity whose holdings would be aggregated with Licensee for purposes of Section 13(d) of the Exchange Act.

(d) Lock-Up. Without prejudice and in addition to any other transfer restrictions specified in this Agreement, Licensee agrees not to sell, transfer, loan, grant any option for the purchase of, or otherwise dispose of (collectively, a "Transfer") any Shares acquired by Licensee pursuant to this Agreement until after the 90-day period following the date of such acquisition.

10. INDEMNIFICATION; LIABILITY; INSURANCE

10.1 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 claim, suit, action or other legal proceeding brought by a Third Party (collectively, "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 or Commercialization of Crofelemer and/or the Product by or on behalf of Licensor or any of its Affiliates or licensees prior to the Effective Date; except in each case, to the extent such Claims result from the activities set forth in Section 10.2 (Indemnification by Licensee) for which Licensee is obligated to indemnify Licensor Indemnitees.

10.2 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; (c) the Commercialization of the Product by or on behalf of Licensee or any of its Affiliates or sublicensees after the Effective Date and (d) the performance of the Services by or on behalf of Licensee or any of its Affiliates or sublicensees after the Effective Date; except in each case, to the extent such Claims result from the activities set forth in <u>Section 10.1</u> (*Indemnification by Licensor*) for which Licensor is obligated to indemnify Licensee Indemnitees.

10.3 Indemnification by Licensee Guarantor and Parent. Licensee Guarantor and Parent shall indemnify and hold Licensor Indemnitees harmless from and against any Claims against them arising or resulting from the breach of any warranties or representations made by Licensee Guarantor and Parent to Licensor under this Agreement; except to the extent such Claims result from the activities set forth in <u>Section 10.1</u> (*Indemnification by Licensor*) for which Licensor is obligated to indemnify Licensee Indemnitees.

10.4 Indemnification Procedure. If a Party is seeking indemnification under <u>Section 10.1</u> (*Indemnification by Licensor*), <u>10.2</u> (*Indemnification by Licensee Guarantor and Parent*) (the "Indemnified Party"), it shall inform the Party or Parties from which it is seeking indemnification (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 Indemnifying 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 Indemnifying Party shall have the right to participate, at its own expense and with counsel of its choice, in the defense of any Section 10.1 (*Indemnifying Party's written consent, which consent shall not be unreasonably withheld or delayed.* If the Parties cannot agree as to the application of <u>Section 10.1</u> (*Indemnification by Licensor*), <u>10.2</u> (*Indemnification by Licensee Guarantor and Parent*) to any Claim, pending resolution of the dispute pursuant to <u>Section 13.4</u> (*Referral of Disputes to Parties Executive Officers*), the Parties may conduct separate defenses of such Claims, with each Party retaining the right to claim indemnification by *Licensee* (*Indemnification by Licensee*) or <u>10.3</u> (*Indemnification to Party*), the Parties may conduct separate defenses of such Claims, with each Party retaining the right to claim indemnification by *Licensee* (*Indemnification by Licensee*) or <u>10.3</u> (*Indemnification and Parent*) upon resolution of the underlying Claim.

10.5 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 <u>Article 10</u>. 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.

10.6 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 <u>SECTION 10.6</u> IS INTENDED TO OR SHALL LIMIT OR RESTRICT THE INDEMNIFICATION RIGHTS OR OBLIGATIONS OF ANY PARTY UNDER <u>SECTION 10.1</u> (*INDEMNIFICATION BY LICENSOR*), <u>10.2</u> (*INDEMNIFICATION BY LICENSEE*) OR <u>10.3</u> (*INDEMNIFICATION BY LICENSOR*), <u>10.2</u> (*INDEMNIFICATION BY LICENSEE*) OR <u>10.3</u> (*INDEMNIFICATION BY LICENSEE* GUARANTOR AND PARENT), OR DAMAGES AVAILABLE FOR A PARTY'S BREACH OF CONFIDENTIALITY OBLIGATIONS IN <u>ARTICLE 11</u> (*CONFIDENTIALITY; PUBLICATION*).

10.7 Insurance. Licensee shall cooperate with Licensor to procure and maintain insurance, including product liability insurance, at Licensee's sole cost and expense, in a manner adequate to cover Licensee obligations hereunder and consistent with normal business practices of prudent companies similarly situated at all times during which the Product is being commercially distributed or sold by Licensee hereunder. Licensee shall name Licensor and its 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 <u>Article 10</u>. Licensee shall provide Licensor with written evidence of such 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.

11. CONFIDENTIALITY; PUBLICATION

11.1 Duty of Confidence. Subject to the other provisions of this <u>Article 11</u>:

(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 for 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.

11.2 Exceptions. The foregoing obligations in <u>Section 11.1</u> (*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.

11.3 Authorized Disclosures. Notwithstanding the obligations set forth in <u>Sections 11.1</u> (*Duty of Confidence*) and <u>11.5</u> (*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 <u>Section 11.3</u> shall remain otherwise subject to the confidentiality and non-use provisions of this <u>Article 11</u>, 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 Information.

11.4 Technical Publication. The Parties shall ensure that all publications, and other forms of public disclosure such as abstracts and presentations, of activities carried out under this Agreement or otherwise relating to the Product in the Licensee Territory (each of the foregoing, a "**Publication**") comply with the strategy established by the Collaboration Managers.

11.5 Security Exchange Disclosures. Subject to <u>Section 11.3</u> (*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 <u>Section 11.5</u>. 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 <u>Section 11.5</u>. 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 from the Securities Exchange Commission (or equivalent foreign agency) as represented by the redacted version reviewed by the other Party.

11.6 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 <u>Sections 11.3</u> (*Authorized Disclosures*) and <u>11.5</u> (*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.

12. TERM AND TERMINATION; SUSPENSION

12.1 Term. The term of this Agreement shall commence upon the Effective Date and, unless earlier terminated pursuant to this <u>Article 12</u>, shall expire upon the second anniversary of the Effective Date (the "Initial Term"). The Term will be automatically be extended for successive two (2)-year terms ("Renewal Term") and remain in effect until (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 Crofelemer in any Major Market Country; and (ii) the initiation of sales of a Generic Product with respect to the Product in the Licensee Territory. The "Term" shall consist of the Initial Term and any Renewal Terms. Upon the expiration of this Agreement, all rights and licenses granted hereunder shall terminate, provided that the license granted by Licensee to Licensor under <u>Section 2.2</u> (*Licensee Grant to Licensor*) for the Product in the Licensee Territory shall continue and become fully-paid, perpetual and irrevocable.

12.2 Termination.

(a) **Termination for Failure to Pay Monthly Service Fee**. If Licensor fails to pay the Monthly Service Fee, then Licensee shall have the right, in its sole discretion to terminate this Agreement effective on ninety (90) days' written notice of termination to Licensor.

(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, licenses of rights to "intellectual property" as defined under Article 101(35A) of the Bankruptcy Code.

(d) **Termination for Lack of Regulatory Approval or Failure to Commercialize**. In the event that Licensee (i) does not obtain Regulatory Approval for the Product in the Licensee Territory prior to the fourth (4th) anniversary of the Effective Date or (ii) fails to achieve sales of Product in the Licensee Territory that equals or exceeds seventy-five percent (75%) of the sales forecast set forth in the Commercialization Plan in any Calendar Year and does not "cure" within sixty (60) days of notification from the Licensor, then, in each case, Licensor may terminate this Agreement by providing ninety (90) days' prior written notice thereof to Licensee.

(e) **Termination for Failure to Initiate Regulatory Approval Process.** In the event that Licensee does not conduct activities necessary or useful or otherwise requested or required by a Regulatory Authority in support of obtaining Regulatory Approval during the Initial Term in a manner that Licensor would normally take in its reasonable business discretion to accomplish a similar objective, Licensor may terminate this Agreement by providing ninety (90) days' prior written notice thereof to Licensee. For clarity, Licensor shall have the right to terminate under this Section 12.2(e) where Licensee fails to initiate and engage in communications with Regulatory Authorities in the Licensee Territory during the Initial Term.

(f) Unilateral Termination by Licensor. Notwithstanding any other provision of this Agreement, Licensor may terminate this Agreement in its entirety by providing ninety (90) days' prior written notice to Licensee.

(g) Mutual Termination. The Parties may mutually agree to terminate this Agreement at any time for any or no reason.

12.3 Effect of Termination.

(a) **Return or Destruction of Confidential Information**. Upon the termination of this Agreement for any reason, each Party shall promptly return or (at the other Party's election) destroy and irretrievably erase 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 for archival purposes and shall continue to comply with the terms of <u>Article 11</u> (*Confidentiality; Publication*) in respect of the same.

(b) **Termination by Licensee for Failure to Pay Monthly Service Fee, for Material Breach, or for Insolvency**. If this Agreement is terminated by Licensee pursuant to <u>Section 12.2(a)</u> (*Termination for Failure to Pay Monthly Service Fee*), <u>Section 12.2(b)</u> (*Termination for Material Breach*), or <u>Section 12.2(c)</u> (*Termination for Insolvency*), then, in addition to the consequences set forth in <u>Section 12.3(a)</u> (*Return or Destruction of Confidential Information*), (1) the license 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 shall immediately be due and payable. For clarity, any payment obligations arising in the calendar month when this Agreement is terminated and all payment obligations due and payable or arising under this Agreement following the date of termination shall be terminated and deemed null and void.

(c) Termination by Licensor for Material Breach, for Insolvency, for Lack of Regulatory Approval or Failure to Commercialize, or for Failure to Initiate Regulatory Process, or Mutual Termination. If this Agreement is terminated by Licensor under Section 12.2(b) (*Termination for Material Breach*), Section 12.2(c) (*Termination for Insolvency*), Section 12.2(d) (*Termination for Lack of Regulatory Approval or Failure to Commercialize*), or Section 12.2(e) (*Termination for Failure to Initiate Regulatory Approval Process*), or as mutually agreed to by the Parties under Section 12.2(g) (*Mutual Termination*), then, in addition to the consequences set forth in Section 12.3(a) (*Return or Destruction of Confidential Information*), (1) the license granted by Licensor to Licensee under the Licensed IP and all rights relating thereto shall terminate; (2) all amounts outstanding at the date of termination shall immediately be due and payable; (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 and Commercialize the Product 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 the Product, including but not limited to Regulatory Materials and related data of the Product, in each case to the extent such information and data are included in the Licensee Arising IP. For clarity, any payment obligations arising in the calendar month when this Agreement is terminated and all payment obligations due and payable or arising under this Agreement following the date of termination shall be termination shall be terminated and deemed null and void.

(d) **Unilateral Termination by Licensor**. If this Agreement is terminated by Licensor pursuant to <u>Section 12.2(f)</u> (Unilateral Termination By Licensor), then, in addition to the consequences set forth in <u>Section 12.3(c)</u> (Termination by Licensor for Material Breach, for Insolvency or Lack of Regulatory Approval or Failure to Commercialize, or for Failure to Initiate Regulatory Process, or Mutual Termination), Licensor shall, within ninety (90) days of such termination, remit payment to Licensee in an amount equal to one hundred twenty-five percent (125%) of the Regulatory Expenses incurred up through the date of receipt of the termination notice delivered by Licensor to Licensee pursuant to <u>Section 12.2(f)</u> (Unilateral Termination By Licensor).

12.4 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 <u>Articles 1</u> (*Definitions*), <u>10</u> (*Indemnification; Liability; Insurance*) and <u>13</u> (*Miscellaneous*), and <u>Sections 7.4</u> (*Late Payments*), <u>7.6</u> (*Financial Records and Audits*), <u>8.1(b)</u> (*Licensee Patents*), <u>8.1(c)</u> (*Cooperation in Prosecution*), <u>11.1</u> (*Duty of Confidence*), <u>11.2</u> (*Exceptions*), <u>11.3</u> (*Authorized Disclosures*), <u>11.5</u> (*Security Exchange Disclosures*), <u>12.1</u> (*Term*), and <u>12.3</u> (*Effect of Termination*) and this <u>Section 12.4</u> shall survive the expiration or termination of this Agreement for any reason.

12.5 Suspension. Licensor may, at its sole discretion, suspend its obligations under this Agreement except those under <u>Article 11</u> (*Confidentiality; Publication*), without terminating this Agreement, by providing written notice to Licensee at least three (3) days prior to the date on which Licensor wishes to suspend (the "Suspension Date"). Licensee shall suspend any performance under this Agreement related to Licensor's obligations that are suspended after the Suspension Date until receipt of written notice from Licensor to resume performance.

13. MISCELLANEOUS

13.1 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 each of Licensor, Licensee and Licensee Guarantor 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.

13.2 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.

13.3 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.

13.4 Referral of Disputes to Parties Executive Officers. In the event of any disputes, controversies or differences between the Parties arising out of, in relation to, or in connection with this Agreement, including any alleged failure to perform, or breach, of this Agreement, or any issue relating to the validity, construction, interpretation, enforceability, breach, performance, application, suspension, or termination of this Agreement a ("Dispute"), then upon the written request of either Party, the Dispute shall be first submitted to the Executive Officers of each Party for attempted resolution by good faith negotiations within thirty (30) days. If the Dispute is not resolved within sixty (60) days following the written request for amicable resolution, then either Party may then initiate dispute resolution under Section 13.5 (*Arbitration of Claims*).

13.5 Arbitration of Claims. If the Parties do not fully settle a Dispute pursuant to <u>Section 13.4</u> (*Referral of Disputes to Parties Executive Officers*) and a Party wishes to pursue the matter, each such Dispute shall be finally settled under the Rules of Arbitration of the International Chamber of Commerce by three (3) arbitrators. Each Party shall appoint one (1) 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 (2) arbitrators appoint the third arbitrator within thirty (30) days of the arbitrators fail to appoint the third arbitrator within thirty (30) days of the arbitrator shall be made by the President of the arbitrators, the appointment of the third arbitrator shall be made by the President of the ICC International Court of Arbitrators, the appointment of the third arbitrator shall be made by the President of the ICC International Court of Arbitrators.

(a) The place, or legal seat, of the arbitration shall be San Francisco, California, and the language of the arbitration shall be English.

(b) In addition to the Rules of Arbitration of the International Chamber of Commerce, 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 10.6 (*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.

13.6 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 California, without giving effect to any choice of law or conflict of law provision or rule (whether of the State of California or any other jurisdiction) that would cause the application of the laws of any jurisdiction other than the State of California. The Parties agree to exclude the application to this Agreement of the United Nations Convention on Contracts for the International Sale of Goods.

13.7 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.

13.8 Entire Agreement; Modification; Waiver. This Agreement, including the Exhibits, the Pharmacovigilance Agreement (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 (including the Original Agreement, which is hereby amended, restated and replaced by the version signed by the Parties as of the Restatement Date). 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.

13.9 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. 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.

13.10 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.

13.11 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 <u>Section 13.11</u>.

13.12 English Language and Mutual Drafting. This Agreement shall be written and executed in, and all other communications under or in connection with this Agreement shall be in, the English language. Any translation into any other language shall not be an official version thereof, and in the event of any conflict in interpretation between the English version and such translation, the English version shall control. This Agreement is the mutual product of the parties hereto, and each provision hereof has been subject to the mutual consultation, negotiation, and agreement of each of the parties, and shall not be construed for or against any party hereto.

13.13 Guaranty. Licensee Guarantor irrevocably guarantees the performance of all financial obligations of Licensee under the provisions of this Agreement. This is a guarantee of payment and performance of payment obligations, and not of collection, and Licensee Guarantor acknowledges and agrees that this guarantee is full and unconditional, and no release or extinguishments of Licensee's applicable liabilities (other than in accordance with the terms of this Agreement), whether by decree in any bankruptcy proceeding or otherwise, will affect the continuing validity and enforceability of this guarantee. If and each time that Licensee fails to make any payment when it is due under or pursuant to this Agreement, Licensee Guarantor must at Licensor's request (without requiring Licensor first to take steps against Licensee) pay directly to Licensor the relevant amount as if it were the principal obligor in respect of that amount.

13.14 Waiver of Payments for September 2022. Notwithstanding anything to the contrary in this Agreement, (i) Licensor hereby acknowledges and agrees that (A) the Monthly License Fee due and payable by Licensee for September 2022 and (B) the obligation of Licensee to subscribe for and purchase the Subscription Shares (as defined in the Original Agreement) for September 2022, as provided in the Original Agreement, are waived in full, and (ii) Licensee hereby acknowledges and agrees that the Monthly Service Fee due and payable by Licensor for September 2022 is waived in full.

[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 Restatement Date.

LICENSOR:

JAGUAR HEALTH, INC.

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

LICENSEE:

SynWorld Technologies Corporation

By: <u>/s/ Tao Wang</u> Name: Tao Wang Title: CEO

LICENSEE GUARANTOR:

C&E TELECOM, LTD

By: /s/ Tao Wang Name: Tao Wang Title: General Manager

PARENT:

/s/ Tao Wang Tao Wang

[Signature Page to License and Services Agreement]

EXHIBIT A

Licensed Patents

[Attached]

[Exhibit A to License and Services Agreement]

<u>EXHIBIT B</u>

Licensor Trademarks

[Attached]

[Exhibit B to License and Services Agreement]

EXHIBIT C

Monthly Service Fee

Period	Maximum Service Fee Amount (US\$) ¹
June 2022	150,000
July 2022	166,666.66
August 2022	166,666.66
September 2022	166,666.67 ²
October 2022	166,666.66
November 2022	166,666.66
December 2022	166,666.67
January 2023	166,666.66
February 2023	166,666.66
March 2023	166,666.67
April 2023	166,666.66
May 2023	166,666.66
June 2023	166,666.67
July 2023	250,000
August 2023	250,000
September 2023	250,000
October 2023	250,000
November 2023	250,000
December 2023	250,000
January 2024	450,000
February 2024	450,000
March 2024	450,000
Total	5,000,000 ³

1. Dollar amounts set forth in the table are maximum amounts only and the exact amount in cash payable or dollar value of shares issuable for any given period shall be provided in the Service Payment Notice provided pursuant to <u>Section 5.5(b)</u> of the Agreement.

2. The Monthly Service Fee for September 2022 is waived in full pursuant to Section 13.14 of the Agreement.

3. The total amount of the Monthly Service Fees for all the months shall decrease by an amount equal to the Monthly Service Fee for September 2022, pursuant to Section 13.14 of the Agreement.

[Exhibit C to License and Services Agreement]

EXHIBIT D

Monthly License Fee

Period	Monthly License Fee (US\$)
June 2022	150,000
July 2022	166,666.66
August 2022	166,666.66
September 2022	166,666.67 ¹
October 2022	166,666.66
November 2022	166,666.66
December 2022	166,666.67
January 2023	166,666.66
February 2023	166,666.66
March 2023	166,666.67
April 2023	166,666.66
May 2023	166,666.66
June 2023	166,666.67
July 2023	250,000
August 2023	250,000
September 2023	250,000
October 2023	250,000
November 2023	250,000
December 2023	250,000
January 2024	450,000
February 2024	450,000
March 2024	450,000
Total	5,000,000 ²

1. The Monthly License Fee for September 2022 is waived in full pursuant to Section 13.14 of the Agreement.

2. The total amount of the Monthly Licensee Fees for all the months shall decrease by an amount equal to the Monthly License Fee for September 2022, pursuant to Section 13.14 of the Agreement.

[Exhibit D to License and Services Agreement]