

EX-99.2 3 pharmacyte\_ex9902.htm LICENSE AGREEMENT  
Exhibit 99.2

## LICENSE AGREEMENT

This LICENSE AGREEMENT (this “**Agreement**”) is made as of April 2, 2020 (the “**Effective Date**”), between PharmaCyte Biotech, Inc., a company organized under the laws of Nevada and having an address of 23046 Avenida de la Carlota, Suite 600, Laguna Hills, CA 92653 (“**Licensee**”) and Hai Kang Life Corporation Limited, a corporation organized under the laws of Hong Kong and having an address of Units 601 - 605 Biotech Centre 1 Hong Kong Science Park, Shatin, NT, HK (Company number 0676913) (“**Licensor**”). Licensee and Licensor are referred to in this Agreement individually as a “**Party**” and collectively as the “**Parties**.”

### RECITALS

WHEREAS, Licensor developed a proprietary COVID-19 diagnostic kit and owns and/or controls all tangible or intangible know-how, trade secrets, data, information and any physical, chemical, or biological materials, inventions, or proposals for research or methods of research pertaining to the COVID-19 diagnostic kit and the development of the COVID-19 diagnostic kit;

WHEREAS, Licensee wishes to obtain from Licensor an exclusive license to develop and commercialize the COVID-19 diagnostic kit, and Licensee is willing to grant such a license, all on the terms and conditions set forth herein.

NOW, THEREFORE, in consideration of the foregoing premises and the mutual covenants contained herein, the receipt and sufficiency of which are hereby acknowledged, Licensee and Licensor hereby agree as follows:

### ARTICLE 1 DEFINITIONS

Unless the context otherwise requires, the terms in this Agreement with initial letters capitalized, shall have the meanings set forth below, or the meaning as designated in the indicated places throughout this Agreement.

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

**1.2 “Affiliate”** means, with respect to a Person, any other Person that now or in the future, directly or indirectly through one or more intermediaries controls, is controlled by, or is under common control with such Person, as applicable, but only for so long as such other Person continues to control, be controlled by, or be under common control with such first Person. For the purpose of this definition, “control” (including, with correlative meaning, the terms “controlled by” and “under the common control”) means (a) to possess, directly or indirectly, the power to direct the management or policies of a Person, whether through ownership of voting securities, by contract relating to voting rights or corporate governance, or otherwise, or (b) direct or indirect beneficial ownership of more than fifty percent (50%) (or such lesser percentage which is the maximum allowed to be owned by a foreign corporation in a particular jurisdiction) of the voting share capital or other equity interest in a Person.

**1.3 “Claims”** means all Third Party demands, claims, actions, proceedings and liability (whether criminal or civil, in contract, tort or otherwise) for losses, damages, reasonable legal costs and other reasonable expenses of any nature.

**1.4 “Commercialize” or “Commercialization”** means all activities directed to marketing, distributing, detailing, offering for sale or selling a Product (as well as importing and exporting activities in connection therewith), all activities directed to obtaining Pricing Approvals, and all activities directed to Phase 4 studies.

**1.5 “Commercially Reasonable Efforts”** means the use of reasonable, diligent, good faith efforts and resources, as normally used by a pharmaceutical company of similar size and financial standing for a product discovered or identified internally by such similarly situated company, which product is at a similar stage in its development or product life and is of similar market potential, taking into account efficacy, safety, patent and regulatory exclusivity, anticipated or approved labelling, present and future market potential, competitive market conditions, the profitability of the product in light of pricing and reimbursement issues, and other relevant factors.

**1.6 “Confidential Information”** of a Party means all Know-How, unpublished patent applications and other information and data of a financial, commercial, business, operational or technical nature of such Party that is: (a) disclosed by or on behalf of such Party or any of its Affiliates or otherwise made available to the other Party or any of its Affiliates, whether made available orally, in writing or in electronic form; or (b) learned by the other Party pursuant to this Agreement. The terms of this Agreement are the Confidential Information of both Parties.

**1.7 “Control” or “Controlled”** means, with respect to any Know-How, Patent or other intellectual property rights, that a Party has the legal authority or right (whether by ownership, license or otherwise) to grant a license, sublicense, access or other right (as applicable) under such Know-How, Patent, or other intellectual property rights to the other Party on the terms and conditions set forth herein, in each case without breaching the terms of any agreement with a Third Party, provided, that if a Party or any of its Affiliates is acquired during the Term, then the intellectual property of the acquiror of such Party or any of its Affiliates shall not be deemed Controlled by such Party or Affiliate.

**1.8 “Develop” or “Development”** means all development activities for any Product, including all pre-clinical and clinical testing and studies of any Product, distribution of Product for use in clinical trials (including placebos and comparators), statistical analyses, and the preparation, filing and prosecution of any Marketing Authorization Application for any Product, as well as all regulatory affairs related to any of the foregoing.

**1.9 “Dollar”** means U.S. dollars, and “\$” shall be interpreted accordingly.

**1.10 “EMA”** means the European Medicines Agency or any successor entity thereto.

**1.11 “Emergency Use Authorization”** means emergency use authorization pursuant to Section 564 of the Federal Food, Drug and Cosmetic Act, 21 U.S.C.A. 301 et. seq.

**1.12 “European Union”** means the European Union and its member states as of the Effective Date, which are: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, and Sweden, and each of their successors to the extent such successors occupy the same territory.

**1.13 “FDA”** means the United States Food and Drug Administration or any successor entity thereto.

**1.14 “Field”** means all human and veterinary uses, including therapeutic, prophylactic and diagnostic uses in all possible indications.

**1.15 “First Commercial Sale”** means, with respect to any Product in any country or jurisdiction in the Territory, the first arm’s length sale of such Product by Licensee, its Affiliates or Sublicensees to a Third Party for distribution, use in such country or jurisdiction after the Regulatory Approvals have been obtained for such Product in such country or jurisdiction.

**1.16 “Force Majeure Event”** means an event that is caused by or results from causes beyond the reasonable control of the affected Party, including embargoes, war, acts of war (whether war be declared or not), acts of terrorism, insurrections, riots, civil commotions, strikes, lockouts or other labor disturbances, fire, floods, earthquakes or other acts of God, or acts, omissions or delays in acting by any Government Authority.

**1.17 “Government Authority”** means any federal, national, state, provincial or local government, or political subdivision thereof, or any multinational organization or any authority, agency or commission entitled to exercise any administrative, executive, judicial, legislative, police, regulatory or taxing authority or power, any court or tribunal (or any department, bureau or division thereof, or any governmental arbitrator or arbitral body).

**1.18 “Indication”** means a separate and distinct disease or medical condition for which a separate Regulatory Approval is required. For clarity, different subpopulations of a particular human disease or medical condition (including those distinguished by phenotype, genotype, biomarker or treatment history) shall nevertheless constitute a single Indication, and different lines of therapy for a particular human disease or medical condition shall nevertheless constitute a single Indication.

**1.19 “Invention”** shall mean any process, method, improvement, composition of matter, article of manufacture, discovery or finding, patentable or otherwise, that is conceived, invented, or reduced to practice as a result of a Party exercising its rights or carrying out its obligations under this Agreement, whether directly or via its Affiliates, agents or independent contractors, including all rights, title and interest in and to the intellectual property rights therein.

**1.20 “Know-How”** means all technical information, know-how and materials, including without limitation, experimental protocols and procedures, analytical methods and tests, specifications, biological, chemical, pharmacological, toxicological, preclinical, clinical, assay, control, and other data.

**1.21 “Laboratory Developed Test”** means an in vitro diagnostic test that is designed, manufactured and used within a single laboratory for which the FDA is not enforcing any premarket review or other Regulatory Approval requirements.

**1.22 “Law”** means any federal, state, local, foreign or multinational law, statute, standard, ordinance, code, rule, regulation, resolution or promulgation, or any order by any Government Authority, or any license, franchise, permit or similar right granted under any of the foregoing, or any similar provision having the force or effect of law.

**1.23 “Licensed Know-How”** means all Know-How that is Controlled by Licensor or its Affiliates as of the Effective Date or during the term of this Agreement and relates to a Product and/or Product(s).

**1.24 “Licensed Patents”** means all Patents relating to the Product and/or Products in Licensor’s possession or Control on the Effective Date or during the term of the Agreement.

**1.25 “Licensed Technology”** means the Licensed Know-How and Licensed Patents.

**1.26 “Licensee Patents”** means all Patents generated by Licensee or its Affiliates or Sublicensees in the course of Development or Commercialization of a Product.

**1.27 “MAA” or “Marketing Authorization Application”** means an application to the appropriate Regulatory Authority for approval to market a Product (but excluding Pricing Approval) in any particular jurisdiction and all amendments and supplements thereto, including any Emergency Use Authorization filed with the FDA in the U.S.

**1.28 “MHRA”** means the Medicines and Healthcare products Regulatory Agency (MHRA) of the United Kingdom.

**1.29 “Net Sales”** means, with respect to any Product, the gross amount received by Licensee, any of its Affiliates or Sublicensees for sales or other dispositions of such Product, less the following deductions, each to the extent (i) reasonable, customary, and consistent with Licensee’s business practices, (ii) actually incurred in respect of such Product and not otherwise recovered or reimbursed to the selling party, and (iii) included in the gross invoiced sales price:

(a) freight, postage, shipping costs, and other charges, such as insurance, relating to the transportation and delivery of such Product;

(b) sales and excise taxes, customs duties, and any other governmental charges imposed upon the sale of such Product;

(c) discounts and chargebacks actually granted, allowed or incurred in connection with the sale of such Product, provided that such discounts and chargebacks, to the extent applicable to the Product and one or more other products of Licensee, its Affiliates or Sublicensees, are not allocated disproportionately to such Products compared to such other products of Licensee, its Affiliates or Sublicensees;

(d) allowances or credits actually given to customers in connection with the sale of such Product and not in excess of the selling price of such Product, in each case on account of rejection, outdating, recalls or return of such Product;

(e) rebates, reimbursements, fees or similar payments to (i) wholesalers and other distributors, pharmacies and other retailers, buying groups (including group purchasing organizations), health care insurance carriers, pharmacy benefit management companies, health maintenance organizations, Government Authorities, or other institutions or health care organizations in connection with the sale of such Product; or (ii) to patients and other Third Parties arising in connection with any program applicable to such Product, under which Licensee or its Affiliates or Sublicensees provide to low income, uninsured or other patients the opportunity to obtain pharmaceutical products at no cost or reduced cost, in each case provided that such rebates, reimbursements, fees or similar payments, to the extent applicable to the Product and one or more other products of Licensee, its Affiliates or Sublicensees, are not allocated disproportionately to such Products compared to such other products of Licensee, its Affiliates or Sublicensees; and

(f) any other charges, costs, expenses or accruals that are customarily deducted in the determination of “net sales” in accordance with the applicable selling party’s Accounting Standards.

For the avoidance of doubt, if a single item falls into more than one of the categories set forth in clauses (a)-(f) above, such item may not be deducted more than once.

Net Sales shall not include amounts (whether actually existing or deemed to exist for purposes of calculation) for (i) the transfer of Product among Licensee and its Affiliates and Sublicensees for subsequent re-sale, (ii) Product transferred at cost or for free for use in clinical trials; or (iii) Product provided at or below cost as samples or for charitable purposes.

**1.30 “North America”** means the United States and Canada, and their respective territories and possessions.

**1.31 “Patent”** means all patents, patent applications, and invention disclosures, including without limitation, any and all continuations, continuations-in-part, divisions, patents of addition, confirmations, reissues, renewals, extensions, and counterparts thereof, if applicable.

**1.32 “Person”** means any individual, partnership, limited liability company, firm, corporation, association, trust, unincorporated organization or other entity.

**1.33 “Price”** means the price per unit of Product set forth in Exhibit A.

**1.34 “Pricing Approval”** means such governmental approval, agreement, determination or decision establishing prices for a Product that can be charged and/or reimbursed in regulatory jurisdictions where the applicable Government Authorities approve or determine the price and/or reimbursement of pharmaceutical products and where such approval or determination is necessary for the commercial sale of such Product in such jurisdictions.

**1.35 “Product”** means any COVID-19 diagnostic kits, including a Laboratory Developed Test produced, Developed, Commercialized, submitted for Regulatory Approval, and/or sold in any jurisdiction in the Territory, including, without limitation any of Licensor’s existing COVID-19 diagnostic kits and any future COVID-19 diagnostic kits derived from Licensor’s COVID-19 diagnostic kits. Where applicable, Product shall additionally refer to all rights and related intellectual property rights Patent rights and Know-How related to such Product.

**1.36 “Regulatory Approval”** means all approvals, including Pricing Approvals and MAAs or Emergency Use Authorizations, that are necessary for the commercial sale of a Product in a given country or regulatory jurisdiction.

**1.37 “Regulatory Authority”** means any applicable Government Authority responsible for granting Regulatory Approvals for Product, including the FDA, the EMA, the MHRA and any corresponding national or regional regulatory authorities regulating or otherwise exercising authority with respect to activities contemplated in this Agreement.

**1.38 “Regulatory Materials”** means (a) applications for marketing approvals (including all investigational applications, Emergency Use Authorization applications, premarket notification submissions, premarket approval submissions, material labeling supplements, Regulatory Authority meeting requests, and core data sheets), registrations, licenses, authorizations, and approvals (including Regulatory Approvals), (b) correspondence and reports submitted to or received from Regulatory Authorities (including minutes and official contact reports relating to any communications with any Regulatory Authority) and all supporting documents with respect thereto, including all regulatory lists, advertising and promotion documents, adverse event files, and complaint files, and (c) data contained or relied upon in any of the foregoing, in each case ((a), (b), and (c)) relating to a Product in order to Develop, manufacture, market, sell or otherwise Commercialize a Product in a particular country or jurisdiction. “Regulatory Materials” includes any MAA, Emergency Use Authorization, or Regulatory Approval.



**1.39 “Schengen Countries”** means Austria, Belgium, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Monaco, Netherlands, Norway, Poland, Portugal, San Marino, Slovakia, Slovenia, Spain, Sweden, Switzerland, and Vatican City.

**1.40 “Sublicensee”** means a Third Party to which Licensee has granted a sublicense to research, Develop, make, have made, use, import, offer for sale, sell and otherwise Commercialize Products in the Field in any particular country in the Territory.

**1.41 “Subsidiary”** means, with respect to a Party or a Third Party, any entity that now or in the future, directly or indirectly through one or more intermediaries is controlled by such Party or Third Party, as applicable, but for only so long as such control exists. As used in this definition of “Subsidiary”, “control” means (a) to possess, directly or indirectly, the power to direct the management or policies of an entity, whether through ownership of voting securities, by contract relating to voting rights or corporate governance, or otherwise, or (b) direct or indirect beneficial ownership of more than fifty percent (50%) (or such lesser percentage which is the maximum allowed to be owned by a foreign corporation in a particular jurisdiction) of the voting share capital or other equity interest in such entity.

**1.42 “Tax” or “Taxes”** means any (a) all federal, provincial, territorial, state, municipal, local, foreign or other taxes, imposts, rates, levies, assessments and other charges in the nature of a tax (and all interest and penalties thereon and additions thereto imposed by any Government Authority), including all income, excise, franchise, gains, capital, real property, goods and services, transfer, value added, gross receipts, windfall profits, severance, ad valorem, personal property, production, sales, use, license, stamp, documentary stamp, mortgage recording, employment, payroll, social security, unemployment, disability, escheat, estimated or withholding taxes, and all customs and import duties, together with all interest, penalties and additions thereto imposed with respect to such amounts, in each case whether disputed or not; (b) any liability for the payment of any amounts of the type described in clause (a) as a result of being or having been a member of an affiliated, consolidated, combined or unitary group; and (c) any liability for the payment of any amounts as a result of being party to any tax sharing agreement or arrangement or as a result of any express or implied obligation to indemnify any other person with respect to the payment of any amounts of the type described in clause (a) or (b).

**1.43 “Territory”** means North America, the Schengen Countries, the United Kingdom, Turkey, and such other countries, if any, as may be agreed upon by the Parties.

**1.44 “Third Party”** means any Person other than a Party or an Affiliate of a Party.

**1.45 “United States” or “U.S.”** means the United States of America including its territories and possessions.

**1.46 “Valid Claim”** means, with respect to any country, a claim of an issued and unexpired Patent (as may be extended through supplementary protection certificate or patent term extension or the like) that has not been cancelled, revoked, held invalid or unenforceable by a decision of a patent office or other Government Authority of competent jurisdiction from which no appeal can be taken (or from which no appeal was taken within the allowable time period) and which claim has not been disclaimed, denied or admitted to be invalid or unenforceable through reissue, re-examination or disclaimer or otherwise.

**1.47 Additional Definitions.** The following table identifies the location of definitions set forth in various Sections of the Agreement:

Definition	Section
Additional Third Party License	4.2(c)
Agreement	PREAMBLE
Bankruptcy Code	7.2(c)
Disclosing Party	6.1(a)
Effective Date	PREAMBLE
Excluded Claim	10.7(j)
Licensor	PREAMBLE
Licensor Indemnitees	9.2
ICC	10.7(e)
Indemnified Party	9.3
Indemnifying Party	9.3
Infringement	5.4(a)
Joint Inventions	5.1
Joint Patents	5.1

Licensee

PREAMBLE

---

Definition	Section
Licensee Indemnitees	9.1
Notice of Dispute	10.7(a)
Parties	PREAMBLE
Party	PREAMBLE
Receiving Party	6.1(a)
Royalty Term	4.2(b)
Sole Inventions	5.1
Term	7.1
Transfer Tax	4.5(c)

**1.48 Interpretation.** In this Agreement, unless otherwise specified:

- (a) “includes” and “including” shall mean respectively includes and including without limitation;
- (b) words denoting the singular shall include the plural and vice versa and words denoting any gender shall include all genders;
- (c) words such as “herein”, “hereof”, and “hereunder” refer to this Agreement as a whole and not merely to the particular provision in which such words appear; and
- (d) the Exhibit and other attachments form part of the operative provision of this Agreement and references to this Agreement shall include references to the Exhibit and attachments.

## ARTICLE 2 LICENSES

**2.1 License Grant.** Subject to the terms and conditions of this Agreement, Licensor hereby grants to Licensee an exclusive (even as to Licensor), royalty-bearing and sublicenseable (including through multiple tiers in accordance with Section 2.2 (*Sublicense*)) license under the Licensed Technology to, directly or through a third party, conduct research, use, Develop, offer for sale, sell, market, distribute, import, export, and otherwise Commercialize Products in the Field in the Territory, and to make, have made, conduct research, and Develop Products in the Field both inside and outside the Territory for Commercialization, sale, and distribution in the Territory.

### 2.2 Sublicense.

(a) Licensee shall have the right to grant sublicenses under the Licensed Technology; provided that (i) the terms of such sublicense shall be no less restrictive than those set out in this Agreement; and (ii) Licensee shall remain responsible for any obligations that have been sublicensed to any Affiliate or Sublicensee and shall be responsible for any acts and omissions of its Affiliates and Sublicensees that would constitute a breach of Licensee’s obligations under this Agreement if they were Licensee’s own acts or omissions.

**2.3 No Implied Licenses; Negative Covenant.** Except as expressly set forth herein, neither Party shall acquire any license or other right or interest, by implication or otherwise, under any Know-How, Patents, trademarks, copyrights, other intellectual property of the other Party. Licensee shall not, and shall not permit any of its Affiliates or Sublicensees to, practice any Licensed Technology outside the scope of the license granted to it under this Agreement.

**2.4 Exclusivity.** Licensor will not, directly or through a third party, Develop, use, manufacture, offer for sale, sell, market, distribute, import or otherwise Commercialize any product that is a competing product to any Product(s) in the Field in the Territory during the Term.



### ARTICLE 3 DEVELOPMENT AND COMMERCIALIZATION

**3.1 General.** Subject to the terms and conditions of this Agreement, as between the Parties, Licensee shall be solely responsible for the Development and Commercialization of Products throughout the Territory, including (a) the performance of non-clinical and clinical studies on Products, (b) preparation and submission of Regulatory Materials for Products, and (c) marketing, promotion, distribution and sale of the Product. As between the Parties, Licensee shall bear all of the costs and expenses incurred in connection with the Development and Commercialization of Products in the Territory after the Effective Date.

**3.2 Technology Transfer.** With ten (10) calendar days of the Effective Date, Licensor shall disclose to Licensee all Know-How, including scientific or technical information related to the Product(s), all pre-clinical, clinical, and/or regulatory documentation, data, information, or reports related to the Product(s), and all information related to the manufacture of the Product(s) and finished form of the Product(s), that is reasonably necessary or useful for Licensee to Develop or Commercialize the Product(s) in the Territory. Any additional Know-How developed or acquired by Licensor during the term of the Agreement shall be promptly disclosed to Licensee. Licensor shall make all relevant documentation and embodiments of the Know-How Controlled by Licensor available to Licensee through electronic delivery via a mutually agreeable secure transmission method.

**3.3 Technical Assistance.** After completion of the technology transfer pursuant to Section 3.2 (*Technology Transfer*), Licensor shall use reasonable endeavors to provide Licensee with reasonable technical assistance regarding the Development of the Product, as reasonably requested by Licensee. For the avoidance of doubt, such assistance shall (unless agreed otherwise by the parties) be provided via electronic communication including, without limitation, telephone, video conference, and email.

**3.4 Diligence.** Licensee shall use Commercially Reasonable Efforts to Develop and Commercialize at least one (1) Product in the Territory. Failure to use Commercially Reasonable Efforts shall constitute a breach of Licensee's material obligations hereunder, and Licensor may, at its sole discretion, terminate this Agreement pursuant to Section 7.2(a) (*Termination for Material Breach*).

#### **3.5 Regulatory.**

(a) Licensor shall and hereby does assign to Licensee all of Licensor's entire right, title and interest in any Regulatory Materials Controlled by Licensor as of the Effective Date and any right, title, and interest in any Regulatory Materials that become Controlled by Licensor after the Effective Date.

(b) During the Term, Licensee will be solely responsible for, at its own cost and expense (except as provided herein), all regulatory matters related to the Development and Commercialization of Product in the Territory, including, without limitation, taking full responsibility for preparing and filing the relevant Regulatory Materials with the Regulatory Authorities and any recall of the Product. Licensee shall own all such Regulatory Materials. For the avoidance of doubt, the Parties acknowledge and agree that Licensor shall have no liability whatsoever in respect of any regulatory activities connected to any Product anywhere in the Territory that occur after the Effective Date.

**3.6 Manufacturing and Supply.** As between the Parties, Licensor shall be solely responsible for all aspects of the manufacturing and supply of Products for Development and Commercialization in the Territory.

**3.7 Reporting.** Licensee shall keep Licensor reasonably informed in writing as to the progress and results of its and its Affiliates' and Sublicensees' Development and Commercialization of Products under this Agreement.

(a) Within thirty (30) days after each December 31<sup>st</sup> and each June 30<sup>th</sup> during the Term prior to the First Commercial Sale of a Product in any country in the Territory, Licensee shall provide Licensor with a reasonably detailed written report that sets forth (i) a summary and timeline for all ongoing non-clinical studies and clinical studies for the Product, (ii) a summary of all material and substantive interactions with applicable Regulatory Authorities during the prior six (6)-month period with respect to the Product in the Territory, and (iii) updates on key milestones achieved in the prior six (6)-month period or anticipated to be achieved in the next six (6) months.

(b) If, based on the report provided by Licensee, Licensor reasonably believes that further detailed discussions between the Parties are required, Licensor shall promptly notify Licensee, and the Parties shall hold a meeting, no later than ninety (90) days following Licensor's receipt of the applicable report, at a mutually agreed time to discuss the Development and Commercialization of Products, either by telephone or video conference, or if mutually agreed, face-to-face.

**3.8 Subcontractors.** Licensee and its Affiliates and Sublicensees shall have the right to engage subcontractors to Develop and Commercialize Products under this Agreement, provided that any such subcontractor is bound by written obligations of confidentiality and non-use consistent with this Agreement and Licensee shall remain responsible for any obligations that have been delegated or subcontracted to any subcontractor and shall be responsible for any acts and omissions of its and its Sublicensee's subcontractors that would constitute a breach of Licensee's obligations under this Agreement if they were Licensee's own acts or omissions.

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

#### ARTICLE 4 FINANCIAL PROVISIONS

**4.1 Minimum Purchase Requirements.** In each calendar month during the Term, Licensee shall purchase from Licensor Product in a Dollar amount no less than the amounts specified in the table below:

Time Period	Minimum Purchase
1. From the Effective Date through the calendar month upon which Regulatory Approval from the FDA for the first Product is received	Six Thousand Dollars (\$6,000) per month
2. From the calendar month following the month upon which Regulatory Approval from the FDA for the first Product is received through the end of the Term	Fifty Thousand Dollars (\$50,000) per month

Licensor shall invoice Licensee for each monthly payment set forth in the table above, and Licensee shall pay to Licensor such amount within ten (10) business days after receiving such invoice. The price payable by Licensee for the Product(s) shall be the Price. Failure to make such payments when due shall be subject to Section 4.4 (*Late Payments*).

#### 4.2 Royalty Payments.

(a) **Royalty Rate.** Subject to the other terms of this Section 4.2 (*Royalty Payments*), Licensee shall make quarterly royalty payments to Licensor on a country-by-country basis, on Net Sales of Products sold by Licensee, its Affiliates and Sublicensees in each country of the Territory, in an amount equal to ten percent (10%) of Net Sales in such country.

(b) **Royalty Term.** Licensee's obligation to pay royalties pursuant to this Section 4.2 (*Royalty Payments*) shall commence upon the First Commercial Sale and shall continue, on a country-by-country and Product-by-Product basis, until the termination of this Agreement (the "**Royalty Term**").

(c) **Royalty Reduction.** If Licensee, in its sole discretion, determines that any Third Party intellectual property rights are required in order to avoid infringement of such Third Party intellectual property rights in connection with the Development or Commercialization of a Product in the Field in any given jurisdiction within the Territory, then Licensee may negotiate and obtain a license under, or otherwise pay amounts with respect to any litigation or alternative dispute resolution regarding, such Third Party's intellectual property rights (each such Third Party license or payment referred to herein as an "**Additional Third Party License**"). Any royalty amounts otherwise payable to Licensor under this Agreement with respect to Net Sales of any Product by Licensee, its Affiliates or Sublicensees in such jurisdiction will be offset by the amounts payable to Third Parties pursuant to any Additional Third Party Licenses.



(d) **Royalty Reports and Payment.** Within thirty (30) days after each calendar quarter, commencing with the calendar quarter during which the First Commercial Sale of a Product is made anywhere in the Territory, Licensee shall provide Licensor with a report showing (i) gross sales and Net Sales of Product by Licensee in the Territory and (ii) the amount of any royalties due to Licensor. Promptly after the delivery of the applicable quarterly report, Licensor shall invoice Licensee all royalties owed with respect to Net Sales for such calendar quarter, and Licensee shall pay Licensor such royalties within ten (10) business days after receiving such invoice. Failure to make such payments when due shall be subject to Section 4.4 (*Late Payments*).

**4.3 Currency; Exchange Rate.** All payments to be made by Licensee to Licensor under this Agreement shall be made in Dollars by bank wire transfer in immediately available funds to a bank account designated by written notice from Licensor. The rate of exchange to be used in computing the amount of currency equivalent in Dollars shall be the foreign exchange rate as of the invoice date provided by the Federal Reserve Bank of New York (<https://apps.newyorkfed.org/markets/autorates/fxrates/external/home>) using the 12 Noon Buying Rates provided.

**4.4 Late Payments.** If Licensor does not receive payment of any undisputed sum due to it on or before the fifteenth (15th) calendar day following the due date therefor, and Licensee fails to cure such non-payment within thirty (30) days of receiving notice of such non-payment from Licensor, then such non-payment shall constitute a breach of Licensee's material obligations hereunder, and Licensor may, at its sole discretion, terminate this Agreement pursuant to Section 7.2(a) (*Termination for Material Breach*).

#### **4.5 Taxes.**

(a) **Taxes on Income.** Except as expressly provided in this Section 4.5 (*Taxes*), each Party shall solely bear and pay all Taxes imposed on its share of income or gain arising directly or indirectly from the activities of the Parties under this Agreement.

(b) **Tax Cooperation.** The Parties agree to cooperate with one another and use Commercially Reasonable Efforts to avoid or reduce, to the extent permitted by applicable Laws, tax withholding or similar obligations in connection with royalties, milestone payments, and other payments made by Licensee to Licensor under this Agreement. To the extent Licensee is required by applicable Law to deduct or withhold Taxes on any payment to Licensor, Licensee shall (i) deduct or withhold such Taxes from the payment made to Licensor, (ii) promptly notify Licensor of such requirement, (iii) pay to the relevant authorities the full amount required to be deducted or withheld, and (iv) forward to Licensor an official receipt or other evidence of such payment and other reasonable documentation evidencing such payment reasonably requested by Licensor. To the extent that amounts are so withheld and paid to the proper taxing authority, such amounts shall be treated for all purposes of this Agreement as having been paid to the persons with respect to whom such amounts were withheld. Licensor shall provide Licensee with any Tax forms that may be reasonably necessary in order for Licensee to not withhold Tax or to withhold Tax at a reduced rate under an applicable bilateral income tax treaty. Licensor shall use Commercially Reasonable Efforts to provide any such Tax forms to Licensee at least forty-five (45) days prior to the due date for any payment for which Licensor desires that Licensee apply a reduced withholding rate. Each Party shall provide the other with reasonable assistance to enable the recovery, as permitted by applicable Laws, of withholding Taxes or similar obligations resulting from payments made under this Agreement, such recovery to be for the benefit of Licensor as the Party bearing such withholding Tax under this Section 4.5(b) (*Tax Cooperation*).

(c) **Transfer Tax.** Subject to Section 4.5(a) (*Taxes on Income*), Licensee, on the one hand, and Licensor, on the other hand, shall each bear and pay fifty percent (50%) of any transfer, stamp, value added, sales, use, or similar Taxes or obligations ("**Transfer Tax**") imposed on any transaction contemplated under this Agreement. Each Party shall cooperate with the other to file any Tax returns (as required to be filed under applicable Law) with respect to such Transfer Taxes.

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



## ARTICLE 5 INTELLECTUAL PROPERTY RIGHTS

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

### 5.2 Disclosure of Inventions.

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

(b) Promptly following the provision of the report in Section 4.2(d) (*Royalty Reports and Payment*), Licensee shall disclose to Licensor all Sole Inventions (including any invention disclosures, or other similar documents, submitted to it by its employees, agents or independent contractors describing such Sole Inventions) made by it and/or its Affiliates in the preceding quarter and shall promptly respond to any reasonable request from Licensor for additional information relating to such Sole Inventions.

### 5.3 Patent Prosecution.

#### (a) Licensed Patents and Joint Patents.

(i) Licensee shall have the first right to, and shall, in its sole discretion with regard to each Licensed Patent, Joint Patent, or invention disclosure, file, prosecute and maintain such Licensed Patents and Joint Patents in the Territory, at Licensee's own cost and expense. For the purpose of this Article 5 (*Intellectual Property Rights*), "prosecution" shall include any post-grant proceeding including patent interference proceeding, opposition proceeding and reexamination.

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

(iii) Licensee shall notify Licensor of any decision to cease prosecution and/or maintenance of, or not to continue to pay the expenses of prosecution and/or maintenance of, any Licensed Patents or Joint Patents in the Territory at least forty-five (45) days prior to any filing or payment due date, or any other due date that requires action, in connection with such Licensed Patent or Joint Patent. If Licensee makes such a decision to cease prosecution and/or maintenance of, or not to continue to pay the expenses of prosecution and/or maintenance of, any Licensed Patents or Joint Patents in the Territory, Licensee shall permit Licensor, at its discretion and at its sole expense, to continue prosecution or maintenance of such Licensed Patent or Joint Patent. Licensor's prosecution or maintenance of such Licensed Patent or Joint Patent shall not change the Parties' respective rights and obligations under this Agreement with respect to such Licensed Patent or Joint Patent other than those expressly set forth in this Section 5.3(a)(iii).

(b) **Licensee Patents.** Licensee shall have the sole right to file, prosecute and maintain the Licensee Patents in any jurisdiction worldwide, 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 Section 5.3 (*Patent Prosecution*), including providing any necessary powers of attorney and executing any other required documents or instruments for such prosecution and requiring their respective personnel, agents, consultants, contractors, and other representatives to cooperate with the preparation of and execute any documents, instruments, affidavits, assignments, declarations, and applications reasonably required by the other Party.

#### 5.4 Patent Enforcement.

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

(b) **Enforcement Right.** Licensee shall have the first right to bring and control any legal action in connection with any Infringement in the Territory at its own expense and as it reasonably determines appropriate. If Licensee decides not to enforce the Licensed Patents against such Infringement or does not bring such legal action or otherwise take commercially reasonable action to abate such Infringement before the earlier of: (i) one hundred eighty (180) days after the notice provided pursuant to Section 5.4(a) (*Notification*), or (ii) ten (10) business days before the time limit (if any) set forth in applicable Law for the filing of such legal action (provided that notice of infringement has been provided pursuant to Section 5.4(a) (*Notification*) prior to such time limit), then Licensor shall have the right to bring and control any legal action in connection with such Infringement in the Territory at its own expense as it reasonably determines appropriate.

(c) **Cooperation.** At the request and expense of the Party bringing the action under Section 5.4(b) (*Enforcement Right*) above, the other Party shall provide reasonable assistance in connection therewith, including by executing reasonably appropriate documents, cooperating in discovery and joining as a plaintiff party to the action if required by applicable Law to pursue such action. In connection with any such proceeding, the enforcing Party shall keep the other Party reasonably informed of the status and progress of such enforcement action, and shall reasonably consider the other Party's comment on any such efforts. The non-enforcing Party shall be entitled to separate representation in such matter by counsel of its own choice and at its own expense, but such Party shall at all times cooperate fully with the enforcing Party.

(d) **Expense and Recoveries.** The enforcing Party shall be solely responsible for the cost and expenses incurred in connection with the enforcement action under Section 5.4(b) (*Enforcement Right*). If such Party recovers monetary damages from any Third Party in such enforcement action brought against an Infringement, such recovery shall be allocated first to the reimbursement of any expenses incurred by the Parties in such enforcement action, and any remaining amounts shall be retained by the enforcing Party, provided that, if Licensee is the enforcing Party, such remaining amounts shall be included in the Net Sales subject to the royalty payment by Licensee to Licensor under Section 4.2 (*Royalty Payments*).

### ARTICLE 6 CONFIDENTIALITY; PUBLICATION

#### 6.1 Duty of Confidence. Subject to the other provisions of this Article 6

(*Confidentiality; Publication*):

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

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

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

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

**6.2 Exceptions.** The foregoing obligations in Section 6.1 (*Duty of Confidence*) shall not apply to the extent that the Receiving Party can demonstrate that such Confidential Information:

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

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

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

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

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

**6.3 Authorized Disclosures.** Notwithstanding the obligations set forth in Section 6.1 (*Duty of Confidence*), a Party may disclose the other Party's Confidential Information to the extent such disclosure is required by Law, judicial or administrative process, provided that in such event the Receiving Party shall promptly inform the Disclosing Party of such required disclosure and provide the Disclosing Party an opportunity to challenge or limit the disclosure obligations. Confidential Information that is disclosed pursuant to this Section 6.3 (*Authorized Disclosures*) shall remain otherwise subject to the confidentiality and non-use provisions of this Article 6 (*Confidentiality; Publication*), and the Receiving Party disclosing Confidential Information pursuant to Law or court order shall take all steps reasonably necessary, including seeking of confidential treatment or a protective order to ensure the continued confidential treatment of such Confidential Information.

**6.4 Data Publication.** Licensor shall not publish nor otherwise publicly disclose any data or results regarding any Product without the prior written consent of Licensee; provided, however, that Licensor may publish the data and results that it generates solely through the exercise of their retained right. If Licensee wishes to publish peer reviewed manuscripts disclosing any non-public results of studies carried out under this Agreement, it shall provide Licensor with the opportunity to review and comment on any proposed publication which relates to the Product at least thirty (30) days prior to its intended submission for publication. Licensee shall: (i) consider in good faith any comments thereto provided by Licensor within such thirty (30) day period; and (ii) remove any Confidential Information of Licensor identified by Licensor as part of its review.



**6.5 Press Release and Use of Names.** Each Party shall have the right to use the other Party's name and logo in presentations, the company's website, collateral materials, corporate overviews and other public disclosures contemplated by Sections 6.3 (*Authorized 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.

## ARTICLE 7 TERM AND TERMINATION

**7.1 Term.** The term of this Agreement shall commence upon the Effective Date and shall remain in effect until terminated pursuant to this Article 7 (*Term and Termination*) (the "**Term**").

### 7.2 Termination.

**(a) 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.

**(b) Termination by Licensee with Licensor's Consent.** In addition, Licensee may also terminate this Agreement with the prior written consent of Licensor (acting in its sole discretion), but such consent not to be withheld or delayed if Licensee wishes to terminate on account of demonstrable safety or efficacy concerns in respect of the Product.

**(c) Termination for Insolvency.** Either Party may immediately terminate this Agreement at any time upon written notice to the other Party if: (i) such other Party admits in writing that it is unable to pay its debts when due or (being a company) is deemed unable to pay its debts within the meaning of section 123 of the Insolvency Act 1986; (ii) a petition is filed, a resolution is passed, or an order is made, for or in connection with the winding-up of such other Party other than for the sole purpose of a scheme for a solvent amalgamation of such Party with one or more other companies or the solvent reconstruction of that Party, if not dismissed, bonded or stayed within forty-five (45) days, to the extent applicable; or (iii) an application is made to court, or an order is made, for the appointment of an administrator, or if an administrator is appointed over such other Party, if not dismissed, bonded or stayed within forty-five (45) days, to the extent applicable; or (iv) any event occurs, or proceeding is taken, with respect to such other Party in any jurisdiction to which it is subject that has an effect equivalent or similar to any of the events mentioned in this Section 7.2(c) (*Termination for Insolvency*). All rights and licenses granted under or pursuant to this Agreement by each Party to the other Party, as applicable, are and shall otherwise be deemed to be, for purposes of Section 365(n) of the Title 11, United States Code, as amended (the "**Bankruptcy Code**"), licenses of rights to "intellectual property" as defined under Article 101(35A) of the Bankruptcy Code. The Parties agree that Licensee, as a licensee of such intellectual property rights under this Agreement, shall retain and may fully exercise all of its rights and elections under the Bankruptcy Code.

**(d) Unilateral Termination by Licensee.** Licensee may unilaterally terminate this Agreement for any reason upon a 120-day written notice to Licensor.

### 7.3 Effect of Termination.

(a) Upon the termination of this Agreement for any reason:

(i) the licenses granted by Licensor to Licensee under the Licensed Technology and all rights relating thereto shall terminate;

(ii) all amounts outstanding at the date of termination shall immediately be due and payable to Licensor by Licensee; and

(iii) 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 Article 6 (*Confidentiality; Publication*) in respect of the same.



**7.4 Survival.** Expiration or termination of this Agreement shall not relieve the Parties of any obligation accruing prior to such expiration or termination. Without limiting the foregoing, the provisions of Articles 1 (*Definitions*), 9 (*Indemnification; Liability; Insurance*) and 10 (*General Provisions*), and Sections 4.5 (*Late Payments*), 4.7 (*Financial Records and Audit*), 5.1 (*Ownership of Inventions*), 5.3(b) (*Joint Patents*), 5.3(c) (*Licensee Patents*), 5.3(d) (*Cooperation in Prosecution*), 6.1 (*Duty of Confidence*), 6.2 (*Exceptions*), 6.3 (*Authorized Disclosures*), 7.1 (*Term*), 7.3 (*Effect of Termination*), 7.4 (*Survival*) and 7.5 (*Termination Not Sole Remedy*) shall survive the expiration or termination of this Agreement for any reason.

**7.5 Termination Not Sole Remedy.** Termination is not the sole remedy under this Agreement and, whether or not termination is effected and notwithstanding anything contained in this Agreement to the contrary, all other remedies shall remain available except as agreed to otherwise herein.

## **ARTICLE 8 REPRESENTATIONS AND WARRANTIES**

**8.1 Representations and Warranties of Each Party.** Each Party represents and warrants to the other Party as of the Effective Date that:

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

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

**8.2 Representations and Warranties by Licensor.** Licensor represents and warrants to Licensee as of the Effective Date that:

(a) **Title; Encumbrances.** Licensor solely owns the entire right, title and interest in and to the Licensed Technology, free and clear from any mortgages, pledges, liens, security interests, conditional and installment sale agreement, encumbrances, charges or claim of any kind, 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 Technology 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 any Product by or on behalf of Licensor prior to the Effective Date infringed or misappropriated the intellectual property rights of such Third Party;

(c) **Non-Infringement.** To Licensor's knowledge, the Development and Commercialization of any Product can be carried out in the manner reasonably contemplated as of the Effective Date in each jurisdiction in the Territory without infringing any Valid Claim granted to a Third Party;

(d) **No Debarment.**

(i) In the course of developing Products before the Effective Date, Licensor has not used any employee, consultant or contractor who (a) has been debarred by any Regulatory Authority in the United States, the European Union or China, (b) to Licensor's knowledge, has been debarred by any Regulatory Authority outside the United States, the European Union and China or (c) to Licensor's knowledge, is the subject of a debarment proceeding by any Regulatory Authority.

(ii) Neither Licensor nor any of its Affiliates, nor any of its or their respective officers, employees, or agents has made an untrue statement of material fact or fraudulent statement to the FDA or any other Regulatory Authority with respect to the Development of the Product, failed to disclose a material fact required to be disclosed to the FDA or any other Regulatory Authority with respect to the Development of the Product, or committed an act, made a statement, or failed to make a statement with respect to the Development of the Product that could reasonably be expected to provide a basis for the FDA to invoke its policy respecting "Fraud, Untrue Statements of Material Facts, Bribery, and Illegal Gratuities", set forth in 56 Fed. Reg. 46191 (September 10, 1991) and any amendments thereto or any analogous laws or policies in the Territory.



(iii) Licensor and its Affiliates (a) have complied and shall comply with all applicable Law governing bribery, money laundering, and other corrupt practices and behavior (including, as applicable, the U.S. Foreign Corrupt Practices Act and UK Bribery Act) and (b) shall not, directly or indirectly, offer, give, pay, promise to pay, or authorize the payment of any bribes, kickbacks, influence payments, or other unlawful or improper inducements to any Person in whatever form (including gifts, travel, entertainment, contributions, or anything else of value).

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

(f) **No Licensed Patents.** There are no Licensed Patents owned or controlled by Licensor or its Affiliates and neither Licensor nor any of its Affiliates has filed any Patents on or prior to the Effective Date that (i) contain any claims directed to inventions within Licensed Know-How or that otherwise claim or describe any Licensed Know-How, or (ii) are necessary for or would be infringed by the research, use, Development, sale, marketing, distribution, import, export, and/or other Commercialization of any Product;

(g) **Development and Commercialization of Products.** To Licensor's knowledge, there are no Patents, Know-How or other intellectual property owned by a Third Party and not included in the Licensed Technology that are necessary for the research, use, Development, sale, marketing, distribution, import, export and/or other Commercialization of any Product; and

(h) **Inventory.** To Licensor's knowledge, the information provided by Licensor with respect to the inventory of Product is complete and accurate. All of the Product to be provided under Section 4.1 (*Minimum Purchase Requirements*) have been manufactured, handled and stored in accordance with all applicable Laws, including the current Good Manufacturing Practice, Quality System standards set forth in 21 C.F.R. Part 820, and, as applicable, good clinical laboratory practices.

**8.3 Full Disclosure.** To Licensor's knowledge as of the Effective Date, Licensor has disclosed to Licensee and made available to Licensee for review (a) all material non-clinical and clinical reports for the Product, and (b) all other material information (including relevant correspondence with Regulatory Authorities) relating to the Product, in each of clauses (a) or (b) to the extent such reports or information are reasonably available to Licensor and pertain to the safety or efficacy of the Product.

**8.4 Disclaimer.** EXCEPT AS EXPRESSLY STATED IN THIS ARTICLE 8 (*REPRESENTATIONS AND WARRANTIES*), NO REPRESENTATION, CONDITION OR WARRANTY WHATSOEVER IS MADE OR GIVEN BY OR ON BEHALF OF LICENSEE OR LICENSOR.

## ARTICLE 9 INDEMNIFICATION; LIABILITY; INSURANCE

**9.1 Indemnification by Licensor.** Licensor shall indemnify and hold Licensee, its Affiliates, and their respective officers, directors, agents and employees ("**Licensee Indemnitees**") harmless from and against any Claims against them arising or resulting from: (a) the negligence or willful misconduct of any of the Licensor Indemnitees; (b) the breach of this Agreement by Licensor, including any warranties or representations made by Licensor to Licensee under this Agreement; or (c) the Development, manufacture or Commercialization of any 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 9.2 (*Indemnification by Licensee*) for which Licensee is obligated to indemnify Licensor Indemnitees.

**9.2 Indemnification by Licensee.** Licensee shall indemnify and hold Licensor, its Affiliates and their respective trustees, officers, directors, agents and employees ("**Licensor Indemnitees**") harmless from and against any Claims against them arising or resulting from: (a) the negligence or willful misconduct of any of the Licensee Indemnitees; (b) the breach of this Agreement by Licensee, including any warranties or representations made by Licensee to Licensor under this Agreement; or (c) the Development or Commercialization of any Product 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 Section 9.1 (*Indemnification by Licensor*) for which Licensor is obligated to indemnify Licensee Indemnitees.

**9.3 Indemnification Procedure.** If either Party is seeking indemnification under Sections 9.1 (*Indemnification by Licensor*) or 9.2 (*Indemnification by Licensee*) (the “**Indemnified Party**”), it shall inform the other Party (the “**Indemnifying Party**”) of the Claim giving rise to the obligation to indemnify pursuant to such Section as soon as reasonably practicable after receiving notice of the Claim. The Indemnifying Party shall have the right to assume the defense of any such Claim for which it is obligated to indemnify the Indemnified Party. The Indemnified Party shall cooperate with the Indemnifying Party and the Indemnifying Party’s insurer as the Indemnifying Party may reasonably request, and at the Indemnifying Party’s cost and expense. The Indemnified Party shall have the right to participate, at its own expense and with counsel of its choice, in the defense of any Claim that has been assumed by the Indemnifying Party. Neither Party shall have the obligation to indemnify the other Party in connection with any settlement made without the Indemnifying Party’s written consent, which consent shall not be unreasonably withheld or delayed. If the Parties cannot agree as to the application of Section 9.1 (*Indemnification by Licensor*) or 9.2 (*Indemnification by Licensee*) to any Claim, pending resolution of the dispute pursuant to Section 10.7 (*Dispute Resolution*), the Parties may conduct separate defenses of such Claims, with each Party retaining the right to claim indemnification from the other Party in accordance with Section 9.1 (*Indemnification by Licensor*) or 9.2 (*Indemnification by Licensee*) upon resolution of the underlying Claim.

**9.4 Mitigation of Loss.** Each Indemnified Party shall take and shall procure that its Affiliates take all such reasonable steps and action as are reasonably necessary or as the Indemnifying Party may reasonably require in order to mitigate any Claims (or potential losses or damages) under this Article 9 (*Indemnification; Liability; Insurance*). Nothing in this Agreement shall or shall be deemed to relieve any Party of any common law or other duty to mitigate any losses incurred by it.

**9.5 Limitation of Liability.** NEITHER PARTY SHALL BE LIABLE TO THE OTHER FOR ANY SPECIAL, CONSEQUENTIAL, INCIDENTAL, PUNITIVE, OR INDIRECT DAMAGES (INCLUDING CONSEQUENTIAL OR INCIDENTAL LOSS OF PROFIT, LOSS OF OPPORTUNITY OR LOSS OF USE) ARISING FROM OR RELATING TO ANY BREACH OF THIS AGREEMENT, REGARDLESS OF ANY NOTICE OF THE POSSIBILITY OF SUCH DAMAGES. NOTWITHSTANDING THE FOREGOING, NOTHING IN THIS SECTION 9.5 (*LIMITATION OF LIABILITY*) IS INTENDED TO OR SHALL LIMIT OR RESTRICT THE INDEMNIFICATION RIGHTS OR OBLIGATIONS OF ANY PARTY UNDER SECTION 9.1 (*INDEMNIFICATION BY LICENSOR*) OR 9.2 (*INDEMNIFICATION BY LICENSEE*), OR DAMAGES AVAILABLE FOR A PARTY’S OR BREACH OF CONFIDENTIALITY OBLIGATIONS IN ARTICLE 6 (*CONFIDENTIALITY; PUBLICATION*).

**9.6 Insurance.** Each Party shall procure and maintain insurance, including product liability insurance, in each case, in a manner adequate to cover its obligations hereunder and consistent with normal business practices of prudent companies similarly situated at all times during which any Product is being clinically tested or commercially distributed or sold by such Party hereunder. The Parties shall not be permitted to self-insure without the other Party’s prior written consent. Each Party shall procure insurance at its own expense. Such insurance does not create a limit of either Party’s liability with respect to its indemnification obligations under this ARTICLE 11 (*Indemnification*). Each Party shall provide the other Party with written evidence of such insurance upon request. Each Party shall provide the other Party with written notice at least thirty (30) days before the cancellation, non-renewal or material change in such insurance.

## ARTICLE 10 GENERAL PROVISIONS

**10.1 Force Majeure.** Neither Party shall be held liable to the other Party nor be deemed to have defaulted under or breached this Agreement for failure or delay in performing any obligation under this Agreement to the extent such failure or delay is caused by a Force Majeure Event. The affected Party shall notify the other Party in writing of such Force Majeure Event as soon as reasonably practical, and shall promptly undertake and continue diligently all reasonable efforts necessary to cure such Force Majeure Event.

**10.2 Assignment.** This Agreement may not be assigned or otherwise transferred, nor may any right or obligation hereunder be assigned or transferred in whole or part, by either Party without the prior written consent of the other Party. Notwithstanding the foregoing, either Party may, without consent of the other Party, assign this Agreement and its rights and obligations hereunder: (i) in whole or in part to an Affiliate of such Party, or (ii) in whole to its successor in interest to all or substantially all of the business of such Party to which this Agreement relates, whether by merger, sale of stock, sale of assets or other transaction. Any attempted assignment not in accordance with this Section 10.2 (*Assignment*) shall be null and void and of no legal effect. Any permitted successor of a Party or any permitted assignee of all of a Party’s rights under this Agreement that has also assumed all of such Party’s obligations hereunder in writing shall, upon any such succession or assignment and assumption, be deemed to be a party to this Agreement as though named herein in substitution for the assigning Party, whereupon the assigning Party shall cease to be a party to this Agreement and shall cease to have any rights or obligations under this Agreement. The terms and conditions of this Agreement shall be binding upon, and shall inure to the benefit of, the Parties and their respective successors and permitted assigns.



**10.3 Performance by Affiliates.** Each Party may discharge any obligations and exercise any right hereunder through any of its Affiliates. Each Party hereby guarantees the performance by its Affiliates of such Party's obligations under this Agreement, and shall cause its Affiliates to comply with the provisions of this Agreement in connection with such performance. Any breach by a Party's Affiliate of any of such Party's obligations under this Agreement is a breach by such Party, and the other Party may proceed directly against such Party without any obligation to first proceed against such Party's Affiliate.

**10.4 Severability.** If any one or more of the provisions contained in this Agreement is held invalid, illegal or unenforceable in any respect, the validity, legality and enforceability of the remaining provisions contained herein shall not in any way be affected or impaired thereby, unless the absence of the invalidated provision(s) adversely affects the substantive rights of the Parties. The Parties shall in such an instance use their best efforts to replace the invalid, illegal or unenforceable provision(s) with valid, legal and enforceable provision(s) which, insofar as practical, implement the purposes of this Agreement.

**10.5 Notices.** All notices which are required or permitted hereunder shall be in writing and sufficient if delivered personally, sent by facsimile or email (and promptly confirmed by personal delivery, registered or certified mail or overnight courier), sent by nationally-recognized overnight courier or sent by registered or certified mail, postage prepaid, return receipt requested, addressed as follows:

If to Licensee, to:

PharmaCyte Biotech, Inc.  
23046 Avenida de la Carlota, Suite 600  
Laguna Hills, CA 92653  
U.S.A.  
Attn: Kenneth L. Waggoner

with copies to:

Reed Smith LLP  
1901 Avenue of Stars, Suite 700  
Los Angeles, CA 90067-6078  
Attn: Michael Sanders

If to Licensor, to:

Hai Kang Life Corporation Limited  
Units 601 - 605 Biotech Centre  
1 Hong Kong Science Park,  
Shatin, NT, HK  
Attn: Professor Albert Cheung-Hoi Yu

or to such other address(es) as the Party to whom notice is to be given may have furnished to the other Party in writing in accordance herewith. Any such notice shall be deemed to have been given: (a) when delivered, if personally delivered or sent by facsimile on a business day (or if delivered or sent on a non-business day, then on the next business day); (b) on the business day after dispatch, if sent by nationally-recognized overnight courier; or (c) on the fifth (5th) business day following the date of mailing, if sent by mail.

**10.6 Governing Law.** This Agreement and any dispute or claim arising out of or in connection with it or its subject matter or formation (including non-contractual disputes or claims) shall be governed by and construed in accordance with the laws of Hong Kong Special Administrative Region of the People's Republic of China without reference to any rules of conflict of laws that would require the application of the laws of a different jurisdiction. The terms of this Agreement are intended solely for the benefit of each Party to this Agreement. Except as otherwise expressly stated in this Agreement, no one other than a Party to this Agreement may enforce any of its terms under the Contracts (Rights of Third Parties) Ordinance, Cap. 623 of the Laws of Hong Kong. Where any clause of this Agreement entitles any third party to enforce any term of this Agreement under the Contracts (Rights of Third Parties) Ordinance, the Parties to this Agreement reserve the right to vary that term or any other term of this Agreement without the consent of that third party. The United Nations Convention on Contracts for the International Sale of Goods shall not apply.





**10.7 Dispute Resolution.** If any dispute, controversy or claim arises between the Parties in relation to this Agreement or the breach thereof the Parties shall follow the following procedures in an attempt to resolve such dispute, controversy or claim:

(a) the Party claiming that such a dispute exists shall give notice in writing (“**Notice of Dispute**”) to the other Party of the nature of the dispute;

(b) within fourteen (14) days of receipt of a Notice of Dispute, designated senior executives of the Parties shall meet in person and at this meeting they shall use their reasonable endeavors to resolve the dispute (it being understood that (i) the initial designated senior executives shall be Kenneth Waggoner on behalf of Licensee, and Professor Albert Cheung-Hoi Yu on behalf of Licensor, and (ii) each Party shall be entitled to name a substitute senior executive to attend such meeting upon written notice to the other Party, provided that such senior executive is of at least comparable seniority to the executive named herein and has the authority to resolve such dispute without seeking further approval);

(c) If the designated senior executives are unable to resolve the dispute during the meeting described in (b) above or if for any reason such meeting does not take place within the period specified in (b) above, then the dispute will be referred to the Chief Executive Officer of Licensee and the Chief Executive Officer of Licensor who shall meet to discuss and seek to resolve the issue;

(d) If, within a further period of thirty (30) days, or if in any event within sixty (60) days of initial receipt of the Notice of Dispute, whichever is shorter, the dispute has not been resolved, or if, for any reason, the meeting of the Chief Executive Officer of Licensee and the Chief Executive Officer of Licensor described in (c) above has not been held within sixty (60) days of initial receipt of the Notice of Dispute, then the Parties agree that either Party may initiate binding arbitration proceedings to resolve the dispute, unless such dispute relates to an Excluded Claim; and

(e) the relevant parties shall submit their dispute to binding arbitration administered by the International Chamber of Commerce (“**ICC**”) pursuant to its arbitrations rules then in effect, and judgment on the arbitration award may be entered in any court having jurisdiction thereof. Each Party hereby expressly and irrevocably waives the right to trial by jury in any event.

(f) The arbitration shall be conducted by a panel of three arbitrators qualified in Hong Kong law and having substantial experience regarding the issues in dispute and the diagnostic/pharmaceutical business: within thirty (30) days after initiation of arbitration, each Party shall select one person to act as arbitrator and the two Party-selected arbitrators shall select a third arbitrator within thirty (30) days of their appointment. If the arbitrators selected by the Parties are unable or fail to agree upon the third arbitrator, the third arbitrator shall be appointed by ICC. The arbitrators may permit discovery (including depositions) as they deem appropriate in the circumstances of the dispute provided that the extent and scope shall be proportionate in terms of time and cost. The arbitrators shall have no power to award punitive, special, incidental or consequential damages. The arbitrator’s decision and award shall be final and binding upon all Parties. The place of arbitration shall be Hong Kong, and all proceedings and communications shall be in English.

(g) Either Party may apply to the arbitrators for interim injunctive relief until the arbitration award is rendered or the controversy is otherwise resolved. Either Party also may, without waiving any remedy under this Agreement, seek from any court having jurisdiction any injunctive or provisional relief necessary to protect the rights or property of that Party pending the arbitration award. Each Party shall bear its own costs and expenses and attorneys’ fees and an equal share of the arbitrators’ fees and any administrative fees of arbitration.

(h) Except to the extent necessary to confirm an award or as may be required by law, neither a Party nor an arbitrator may disclose the existence, content, or results of an arbitration without the prior written consent of both Parties. In no event shall an arbitration be initiated after the date when commencement of a legal or equitable proceeding based on the dispute, controversy or claim would be barred by the applicable statute of limitations under the applicable Law.

(i) The Parties agree that, in the event of a dispute over the nature or quality of performance under this Agreement, neither Party may terminate this Agreement until final resolution of the dispute through arbitration or other judicial determination. The Parties further agree that any payments made pursuant to this Agreement pending resolution of the dispute shall be refunded if an arbitrator or court determines that such payments are not due.

(j) As used in this Section, the term “**Excluded Claim**” shall mean a dispute, controversy or claim that concerns (a) the scope, validity, enforceability, inventorship or infringement of a patent, patent application, trademark (including service marks, logos, and other indicia of origin used in commerce) or copyright (including works of authorship whether or not copyrightable), in each case whether or not registered; or (b) any antitrust, anti-monopoly or competition law or regulation.

**10.8 Entire Agreement; Amendments.** This Agreement, together with the Exhibit hereto, contains the entire understanding of the Parties with respect to the subject matter hereof. Any other express or implied agreements and understandings, negotiations, writings and commitments, either oral or written, with respect to the subject matter hereof are superseded by the terms of this Agreement. The Exhibit to this Agreement is incorporated herein by reference and shall be deemed a part of this Agreement. This Agreement may be amended, or any term hereof modified, only by a written instrument duly executed by authorized representative(s) of both Parties hereto.

**10.9 Headings.** The captions to the several Articles, Sections and subsections hereof are not a part of this Agreement, but are merely for convenience to assist in locating and reading the several Articles and Sections hereof.

**10.10 Independent Contractors.** It is expressly agreed that Licensor and Licensee shall be independent contractors and that the relationship between the two Parties shall not constitute a partnership, joint venture or agency. Neither Licensor nor Licensee shall have the authority to make any statements, representations or commitments of any kind, or to take any action, which shall be binding on the other Party, without the prior written consent of the other Party.

**10.11 Waiver.** The waiver by either Party hereto of any right hereunder, or of any failure of the other Party to perform, or of any breach by the other Party, shall not be deemed a waiver of any other right hereunder or of any other breach by or failure of such other Party whether of a similar nature or otherwise.

**10.12 Cumulative Remedies.** No remedy referred to in this Agreement is intended to be exclusive, but each shall be cumulative and in addition to any other remedy referred to in this Agreement or otherwise available under law.

**10.13 Waiver of Rule of Construction.** Each Party has had the opportunity to consult with counsel in connection with the review, drafting and negotiation of this Agreement. Accordingly, the rule of construction that any ambiguity in this Agreement shall be construed against the drafting Party shall not apply.

**10.14 Business Day Requirements.** In the event that any notice or other action or omission is required to be taken by a Party under this Agreement on a day that is not a business day then such notice or other action or omission shall be deemed to be required to be taken on the next occurring business day.

**10.15 Translations.** This Agreement is in the English language only, which language shall be controlling in all respects, and all versions hereof in any other language shall be for accommodation only and shall not be binding upon the Parties.

**10.16 Counterparts.** This Agreement may be executed in two or more counterparts by original signature, facsimile or PDF files, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.

**{REMAINDER OF PAGE INTENTIONALLY LEFT BLANK}**

IN WITNESS WHEREOF, the Parties intending to be bound have caused this License Agreement to be executed by their duly authorized representatives as of the Effective Date.

**PharmaCyte Biotech, Inc.**

**Hai Kang Life Corporation Limited**

By: /s/Kenneth L. Waggoner

By: /s/ Albert Cheung-Hoi Yu

Name: Kenneth L. Waggoner

Name: Professor Albert Cheung-Hoi Yu

Title: CEO, President and General Counsel

Title: CEO

**Exhibit A**  
**Product Prices**

<b>Product</b>	<b>Price</b>
50 sample kit (C02_01_1185_150)	11,760 HKD
100 sample kit (C02_01_1185_300)	21,000 HKD