Sample Agreement 2: Public Sector Technology License


THIS AGREEMENT is effective this ______ day of ______, 20__ (“Effective Date”), by and between the Public Sector Research Centre (“PSRC”), an International Organization established according to the procedures of the Vienna Convention on the Law of Treaties, and ______________________, a corporation organized under the laws of [COUNTRY] (“COMPANY”).

WITNESSETH

WHEREAS PSRC has the rights to a newly developed technology for [USE OF TECHNOLOGY] __________________________ based on such core technology;

WHEREAS the core technology was developed in collaboration with [NAMES OF COLLABORATORS] ______________________, who have certain rights to the technology;

WHEREAS PSRC has the right to make, use, and sell and to sublicense others to make, use, and sell products arising from the technology;

WHEREAS COMPANY is engaged in [MAKING, USING, OR SELLING] __________ products such as [TYPE OF PRODUCTS] __________________________ and

WHEREAS COMPANY desires to obtain a license to make, use, and sell [PRODUCTS] __________________________ based on the core technology.

NOW, THEREFORE, the parties intending to be legally bound agree as follows:

Article I: Definitions

1.1 “Technology” means the technology for [DETAILED DEFINITION OF USE OF TECHNOLOGY] ____________________________________________.

1.2 “Licensed Product” means a product that uses the Technology.

1.3 “Exclusive Territory” means [COUNTRIES] __________________________.

1.4 “Non-exclusive Territory” means [COUNTRIES] __________________________.

Article II: Grant of License

2.1 Subject to [ANY RESTRICTIONS THAT MAY EXIST FOR PSRC IN LICENSING THE TECHNOLOGY] ________________________, PSRC grants to COMPANY on the terms and conditions herein stated:

a. An exclusive license, except as hereinabove provided, to make, use, and sell the Licensed Product in the Exclusive Territory for the purpose of [LIST OF SPECIFIC USES TO WHICH THE PRODUCT CAN BE PUT] __________________________; and

b. A nonexclusive license to sell Licensed Product in the Nonexclusive Territory,
2.2 If at any time during the period of this Agreement COMPANY desires to license the Technology in countries not heretofore included in the Agreement, PSRC agrees to negotiate with COMPANY in good faith for such extension, provided that (a) the license rights in such additional countries have not previously been licensed to others; (b) COMPANY has existing distribution capability in each of such additional countries; (c) COMPANY has manufacturing capacity to serve such additional markets; (d) COMPANY is successfully marketing the Licensed Product in the Territory; and (e) COMPANY is not in default or breach of any covenant or any obligation of this Agreement.

**Article III: KNOW-HOW**

PSRC agrees to provide COMPANY with all know-how owned or controlled by PSRC that is reasonably required for the transmission of the Technology in accordance with the schedule and conditions specified in this Article III. Such material shall include a manual outlining the Technology; identifying all materials used; and indicating a supply source, the specifications for each material and product, and the required quality control procedures. In addition, PSRC will arrange:

(a) one (1) or more visits to the facilities of COMPANY by one (1) or more technicians knowledgeable in the Technology for a total period to be determined by PSRC; and

(b) up to three (3) visits by COMPANY's staff to suitable training sites chosen by PSRC by up to two (2) COMPANY technicians fluent in English and experienced and qualified in the technology to be transferred for a total period of up to forty (40) days.

**Article IV: TECHNICIAN VISITS**

4.1 COMPANY will pay the fully allocated cost of PSRC's or, at PSRC's option, a designated agent's technicians during the visits specified in Article III, paragraph (a). COMPANY shall reimburse PSRC for the out-of-pocket expenditures incurred by the technicians and for materials used during the visits specified in Article III, paragraph (a). PSRC, through a designated agent, will use its best efforts at keeping costs to a minimum level throughout the technology transfer without sacrificing quality.

4.2 COMPANY will pay the costs of its technicians and/or staff during the visits specified in Article III, paragraphs (a) and (b) and all costs for materials and equipment used pursuant to Article III, paragraph (a).

**Article V: IMPROVEMENTS**

Should COMPANY or PSRC develop or obtain rights to additional know-how or improvements in the manufacture or composition of any of the items comprising the Technology, such know-how and/or improvements shall be licensed to the other party royalty free with the right to sublicense said improvements to others subject to:

(a) the terms and conditions of any agreements by which PSRC or COMPANY, as the case may be, obtained rights to such licensed improvements or know-how; and

(b) any sublicense granted under this Article shall incorporate terms that require the sublicensee to respect this Agreement.
Article VI: PAYMENT

6.1 COMPANY shall pay PSRC a technology transfer fee of __________ U.S. dollars ($______) to help offset PSRC’s costs and expenses. This fee shall be paid within thirty (30) days of the Effective Date.

6.2 COMPANY shall pay for the costs incurred in training COMPANY staff. Periodic expense estimates will be submitted by PSRC to COMPANY, and COMPANY shall pay PSRC seventy-five percent (75%) of the estimated amounts within ten (10) days thereof in U.S. dollars to PSRC. The balance shall be invoiced by PSRC periodically and shall be paid to PSRC under the payment terms and conditions stated above. If, at the conclusion of each stage, the amounts paid by COMPANY up to that point exceed the amount due, PSRC shall repay the excess within ten (10) days.

6.3 COMPANY shall pay PSRC a royalty of ____ percent (_%) on net sales of Licensed Products. Net sales means the gross amounts of bona fide sales to others not owned or controlled by COMPANY less cash discounts and rebates actually given, in addition to duties, returns, and free replacements. No royalties shall be payable with respect to any sale of Licensed Products that takes place between COMPANY and any company owned or controlled by COMPANY, but such royalty shall accrue upon the resale of the Licensed Products to a third party. Whenever a company owned or controlled by COMPANY itself uses the Licensed Products, royalty shall accrue on such Licensed Products. Said royalty shall be calculated by using, as a sales price, the average price at which COMPANY sold Licensed Products to third parties during the calendar quarter within which the Licensed Products were used by the company owned or controlled by COMPANY.

6.4 Royalties shall be payable each calendar quarter on the last business day of the month following the calendar quarter for the royalties covering the preceding calendar quarter. Royalties are to be paid in U.S. dollars and sent by wire transfer on or before the date due to an account specified by PSRC unless otherwise agreed in writing.

6.5 On the due date of each royalty payment, COMPANY shall furnish to PSRC a full accounting showing separately the total sales of Licensed Products to the Public Sector, the total sales of Licensed Products to the Private Sector, a calculation of the royalties payable in respect thereof, production quantities, and sales prices.

6.6 COMPANY shall maintain sufficiently detailed records and books of accounts to enable PSRC to verify the payments made to PSRC by COMPANY and the reports filed therewith. COMPANY shall permit an independent accountant, appointed by PSRC and to whom COMPANY has no reasonable objection, to inspect, at reasonable times and upon reasonable notice at the principal place of business of COMPANY, the books and records of COMPANY relating to the manufacture, use, and sale of Licensed Products. The accountant shall report to PSRC only whether the amounts reported and paid to PSRC by COMPANY are accurate and, if not, what the correct figures should be. A copy of the report shall also be supplied to COMPANY. In no event shall an examination of COMPANY’s books and records be made for a period prior to three (3) years from the date such audit is requested by PSRC. In the event the accountant reports that COMPANY has underpaid the amounts due to PSRC, then COMPANY shall bear the costs of such audit.
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Article VII: OBLIGATIONS OF COMPANY

7.1 COMPANY agrees to use its best efforts to promote diligently the sale and distribution of Licensed Products throughout the Exclusive Territory in accordance with the milestones established in Exhibit A.

7.2 COMPANY will use its best efforts to promptly establish a validated manufacturing process for Licensed Products.

7.3 Governmental Approvals

(a) The cost of obtaining governmental approval and/or registration to make, use, and sell Licensed Products in the Territory shall be borne by COMPANY. COMPANY agrees to use its best efforts to obtain such governmental approval and/or registration and shall use due diligence therein;

(b) COMPANY agrees that PSRC shall have full access to any application for governmental approval or registration and the data contained therein together with the right to use such application, data, and any subsequent approval to obtain the approval of any government of any country outside of the Territory to make, use, and/or sell Licensed Products in such country, provided that PSRC shall require that any company licensed by PSRC shall respect this Agreement; and

(c) If this Agreement is terminated under Article 11.1, COMPANY agrees, to the extent permitted by local law and/or government regulation, to assign to PSRC or to PSRC’s designee and without cost to PSRC or PSRC’s designee all governmental approvals and/or registrations owned or controlled by COMPANY for the manufacture, use, and/or sale of Licensed Products.

7.4 COMPANY agrees that it will not knowingly sell or allow the sale of any Licensed Product that it produces which sale would be outside the terms of this Agreement except with the written approval of PSRC.

7.5 COMPANY agrees to obtain the prior written approval of PSRC for any labels, containers, packaging, package inserts, or any product associated or sold with the Licensed Products. If PSRC has not responded within thirty (30) days after receipt of a request for approval, the materials shall be deemed to be approved. Upon written request by PSRC and with reasonable notice, COMPANY further agrees to print on the packaging of the Licensed Products a legend crediting PSRC and/or the Collaborators with providing the technology on which the Licensed Products are based, provided that COMPANY has no reasonable objection to the language used.

7.6 COMPANY agrees to only use, promote, or knowingly sell Licensed Products for uses consistent with the guidelines for uses of such products as published by [REGULATORY AGENCY, WHO, OR OTHERS]. A summary of these guidelines is attached hereto as Exhibit B. PSRC may update these guidelines from time to time as agencies update their guidelines. PSRC will allow COMPANY ninety (90) days from issuance of any updated guidelines to correct any of COMPANY’s promotional materials or selling practices not consistent with the updated guidelines. COMPANY agrees that, if requested by PSRC, COMPANY will communicate these guidelines to its existing and potential purchasers of the Licensed Products in a form mutually agreeable to COMPANY and PSRC.
Article VIII: GOOD MANUFACTURING PRACTICES AND QUALITY ASSURANCE

8.1 COMPANY agrees that all Licensed Products manufactured by COMPANY shall be produced in accordance with GMP prescribed under ISO 9002 and subsequent revisions. COMPANY shall comply with the additional manufacturing requirements outlined in Exhibit C herein and subsequent written directives from PSRC.

8.2 During the term of the license, COMPANY agrees to periodic quality control ("QC") testing by PSRC and/or a third party selected by PSRC and to whom COMPANY has no reasonable objection. COMPANY shall reimburse PSRC for the cost of said third-party testing. It is anticipated that QC testing will be performed on not fewer than the first three (3) batches produced and, thereafter, not fewer than one (1) batch per year. All QC testing under this paragraph 8.2 is in addition to testing required under paragraph 8.1 and/or the applicable laws and regulations of each country in the Territory where COMPANY manufactures and/or sells the Licensed Product.

8.3 COMPANY shall permit a duly authorized representative of PSRC, upon reasonable notice, to inspect the premises of COMPANY from time to time to ascertain that the provisions of this Article are being complied with by COMPANY.

8.4 COMPANY agrees to mark Licensed Products' packaging in accordance with the applicable laws of each country in the Territory where COMPANY manufactures and/or sells the Licensed Product.

8.5 In the event that COMPANY, at any time, fails to meet GMP and QC standards as provided for in this Article, COMPANY shall immediately, at the direction of PSRC or the government of any country in which COMPANY manufactures and/or sells a Licensed Product, recall all such Licensed Products not yet sold and cease further sales until such standards are met.

Article IX: CONFIDENTIALITY

9.1 COMPANY shall keep confidential and refrain from using, except under the terms of this Agreement, all know-how disclosed to it by PSRC, its employees, and its agents under this Agreement. The obligation of confidence shall not apply to:

(a) know-how that, at the time of disclosure, COMPANY can demonstrate was in the public domain;

(b) know-how that, after disclosure, becomes part of the public domain other than by COMPANY;

(c) know-how that COMPANY can show was in COMPANY's possession at the time of disclosure and was not acquired directly or indirectly from PSRC; or

(d) know-how that has been, is now, or is hereinafter furnished or made known to COMPANY by a third party as a matter of right and who did not derive the information from PSRC.
9.2 Confidential information shall not be deemed to fall within the exceptions of Article 9.1 if (1) the confidential information is specific and is merely embraced by more general information in the public domain or in COMPANY’s possession or (2) the confidential information is a combination that can be pieced together or reconstructed from multiple sources, none of which shows the whole combination, its principle of operation, and method of use.

9.3 Nothing contained in this Article shall be construed as restricting COMPANY from disclosing the know-how to others as a necessary adjunct to the manufacture, use, and sale of the Licensed Products in accordance with this Agreement.

9.4 COMPANY further agrees to take all reasonable precautions to prevent any of its personnel from divulging to any other party, except as is otherwise provided herein, any know-how furnished to COMPANY by PSRC under this Agreement.

9.5 The provisions of this Article shall survive the term of this Agreement.

Article X: HOLD HARMLESS

10.1 Except for willful misconduct by PSRC, its employees, and its agents, COMPANY agrees to hold harmless and indemnify PSRC, its employees, and its agents from the following:

(a) all product liability claims arising from the manufacture, use, or sale of the Licensed Products made by COMPANY;

(b) all medical malpractice claims in the use of Licensed Products manufactured, distributed, or sold by COMPANY; and

(c) all claims against COMPANY or PSRC for infringement arising from the manufacture, use, or sale by COMPANY of Licensed Products.

10.2 COMPANY shall, at its sole expense, assume the defense of such suit or claim. PSRC shall promptly notify COMPANY of any suit or claim against PSRC, its employees, or its agents of which PSRC is aware. COMPANY may elect to cease to manufacture, distribute, or sell the Licensed Product or obtain a license for the Licensed Product rather than defend a patent infringement suit, provided that COMPANY shall continue to be responsible with respect to any claim of infringement arising from any action of COMPANY occurring before the date of ceasing manufacture, distribution, or sale or before the date of any license.

10.3 Insofar as COMPANY has liability insurance, COMPANY agrees to instruct its insurance carrier to name PSRC as an additional insured; to issue PSRC a certificate of coverage; and to give PSRC notice of any cancellation, renewal, or changes in coverage.

10.4 The provisions of this Article shall survive the term of this Agreement, whether or not such cause of action or claim had accrued at the time of termination.
**Article XI: TERM**

11.1 This Agreement shall commence on the Effective Date and may be terminated under the following circumstances and on the following terms and conditions:

(a) If COMPANY has not successfully manufactured pilot-scale batches of at least one (1) Licensed Product in its facility within one (1) year from the Effective Date, PSRC may terminate by giving COMPANY thirty (30) days’ written notice;

(b) If COMPANY has not obtained permission, if such permission is required under [COUNTRY] law, from the Government of [COUNTRY] to sell at least one (1) Licensed Product in [COUNTRY] within ______ (__) months from the Effective Date, PSRC may terminate this Agreement by giving COMPANY thirty (30) days’ written notice;

(c) If COMPANY has not successfully completed the milestones established in Exhibit A, PSRC may terminate by giving COMPANY sixty (60) days’ written notice;

(d) COMPANY may terminate at any time by giving PSRC ninety (90) days’ written notice;

(e) If either party should at any time default or commit any breach of any covenant or any obligation of the license and should fail to remedy any default or breach within thirty (30) days after written notice thereof by the other party, the injured party may, at its sole option, terminate this license by notice in writing to such effect;

(f) If an order be made or an effective resolution be passed for the winding up of COMPANY; if there is a failure, distress, execution, or other legal process levied or enforced upon or against a substantial portion of the chattels or property of COMPANY; if a receiver is appointed for the undertaking of the property and assets of COMPANY or a substantial portion thereof; or if COMPANY shall make any assignment or composition for the benefit of its creditors or shall cease to carry on business, then PSRC may terminate by giving COMPANY thirty (30) days’ written notice;

(g) If COMPANY has not obtained permission to sell a Licensed Product from the government of any country requiring such permission within two (2) years from the date a grant was first made by PSRC to COMPANY for sales anywhere in the world for such Licensed Product, PSRC may terminate that portion of the grant giving COMPANY permission to sell said Licensed Product in those countries for which a complete application for said government permission has not been filed. This partial termination shall occur by PSRC giving COMPANY thirty (30) days’ written notice; and

(h) By mutual agreement of the parties.

11.2 UPON TERMINATION OF THIS AGREEMENT:

(a) All rights and licenses created by this Agreement shall expire, except that any sums due as royalty shall remain payable and Articles X and XI shall remain in effect. COMPANY shall return to PSRC all technical documents given to COMPANY pursuant to this Agreement, shall destroy any copies of the technical documentation supplied, shall refrain from
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further manufacture or distribution of the Licensed Products anywhere in the world, and shall assign and transfer to PSRC or to PSRC’s designee all governmental approvals and/or registrations to make, use, and/or sell Licensed Products that are owned or controlled by COMPANY to the extent permitted by local law and/or government regulation. Within thirty (30) days after termination, COMPANY shall return to PSRC all know-how; and

(b) The relationships of PSRC and COMPANY to any third parties thereafter shall be determined by mutual agreement and both parties agree to cooperate in executing and delivering such instruments of assignment or other instruments or documents as may be required to effectuate such assignments.

11.3 Unless terminated sooner, this Agreement shall remain in force and effect for ______ (__) years from the Effective Date. Thereafter, COMPANY shall retain the right to make, use, and sell Licensed Products without further obligation to PSRC hereunder except as provided under Articles IX and X.

Article XII: THIRD PARTY LICENSES
COMPANY agrees to cooperate fully with PSRC in assisting other companies or organizations selected by PSRC, and to whom COMPANY has no reasonable objection, to manufacture the Licensed Products in a country outside of the Territory and to obtain any requisite governmental approval for the manufacture, use, and sale of the Licensed Products in such country, provided that such other company or organization covenants not to manufacture, use, and/or sell Licensed Products in the Territory. In providing manufacturing and registration assistance hereunder, COMPANY shall be reimbursed its expenses, including employee time, plus ten percent (10%).

Article XIII: NOTICE
Any notice required or provided for by the terms of this Agreement shall be in writing, and all notices, reports, and payments (other than royalties) provided for hereunder shall be sent by registered mail, prepaid, or facsimile to the business address of the party to be served therewith. It is agreed that the business addresses of the parties shall be as follows:

If to COMPANY:
Facsimile:
With copies to: __________________________________
[ADDRESS]______________________________________
________________________________________
________________________________________

If to PSRC: Facsimile:
With copies to: The PSRC Organization
[ADDRESS]______________________________________
_______________________________________________
_______________________________________________
or such other addresses as either party shall have notified the other party. Any such notice, royalty, or payment shall be deemed to have been given or made on the date such letter was registered or delivered for transmission to the sender’s facsimile operator, but any assumption of actual notice or payment shall be subject to rebuttal to show that it has not actually been received.
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Article XIV: ASSIGNABILITY
This Agreement shall not be assignable or transferable by COMPANY without the written consent of PSRC, but may be assigned or transferred by PSRC without the consent of COMPANY. COMPANY may, however, assign this Agreement to any wholly owned subsidiary of COMPANY, but COMPANY assumes full responsibility to PSRC for the fulfillment of all the terms of this Agreement by the assignee.

Article XV: ENTIRE AGREEMENT
This Agreement contains the entire agreement and understanding between the parties with respect to the subject matter herein and supersedes all prior discussions and other writings, except for those specifically referred to herein. This Agreement shall not be modified except in writing.

Article XVI: ARBITRATION
This Agreement shall be governed by the law of ___________. The parties hereto undertake to settle any dispute, controversy, or claim arising under, out of, or in connection with this Agreement, including, without limitation, its formation, validity, binding effect, interpretation, performance, breach, or termination, as well as noncontractual claims, in an amicable manner. If an amicable settlement cannot be reached within 30 days for any reason, the dispute shall be referred to and finally settled by arbitration in accordance with the UNCITRAL Arbitration Rules then obtaining. The appointing authority shall be the Secretary-General of the Permanent Court of Arbitration, the number of arbitrators shall be three, and the language to be used in the arbitral proceedings shall be English. The place of arbitration shall be determined by mutual agreement, but if agreement cannot be reached the proceedings shall take place in _____________.

Either party to this Agreement may request any judicial authority to order any interim measures of protection for the preservation of its rights and interests to the extent permitted by law, including, without limitation, injunctions and measures for the conservation of such property and information that form part of the subject matter in dispute. Such requests shall not be deemed incompatible with, or as a waiver of, this agreement to arbitrate. In respect of any requests for interim measures of protection, and without limitation to proceeding in any other forum, the parties hereby consent to the exercise of jurisdiction by the judicial authorities of _____________.

In the event a party fails to proceed with arbitration, unsuccessfully challenges the arbitrator’s award, fails to comply with the arbitrator’s award, or fails to comply with any interim measure of protection issued by any competent authority, the other party shall be entitled to costs of suit, including reasonable attorney’s fees, for having to compel arbitration or defend or enforce the award or interim measure.

Article XVII: WAIVER
No waiver by either party of any provision hereof shall be deemed a waiver of any other provision hereof or of any subsequent breach by either party of the same or any other provision. None of the terms of this Agreement will be held to have been waived or altered unless such waiver or alteration is in writing and signed by both the parties hereto.
Article XVIII: WARRANTY
PSRC warrants that the Technology and the know-how associated therewith were developed by PSRC; that the Technology and know-how are owned by PSRC; and that, subject to [LIST HERE ANY RESTRICTIONS], PSRC has a worldwide, exclusive license for such Technology and know-how together with the right to sublicense others thereunder to make, use, and sell Licensed Products anywhere in the world. Nothing in this Agreement will be construed as a warranty or representation that anything made, used, sold, or otherwise disposed of under any license granted in this Agreement is or will be free from infringement of patents of third parties. Except as specifically set forth herein, PSRC makes no representations or warranties, either express or implied, arising by law or otherwise, including, but not limited to, implied warranties of merchantability or fitness for a particular purpose. In no event will PSRC, its employees, and its agents have any obligation or liability arising from tort or for loss of revenue or profit or for incidental or consequential damages.

It is the sole responsibility of COMPANY to undertake a thorough search for third party patents before selling any Licensed Product in any national market, and COMPANY agrees that PSRC, its employees, and its agents shall not have any liability for infringement of any patent as a consequence of the manufacture, use, or sale of any Licensed Product or by reason of any other use of the Technology by COMPANY.

IN WITNESS WHEREOF the parties hereto have caused these presents to be executed in duplicate by their respective duly authorized officers.

For PSRC:     For COMPANY:

By:____________________________     By:____________________________

Date:__________________________     Date:__________________________

Exhibit A

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<tr>
<th>Milestones</th>
<th>Target Date</th>
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<td>(in months from signing agreement)</td>
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<td>1. Establish a validated assembly or manufacturing process</td>
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<td>2. Conduct clinical trials of product produced in [COUNTRY]</td>
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<td>3. etc.</td>
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Exhibit B: Guidelines for Appropriate Use of Product Based on the Technology

Exhibit C: Good Manufacturing Practices for the General Release of Product Based on Technology

The following items must be completed or in place before products are released for general use:

[The Institute may specify a number of conditions depending on local considerations. Examples are listed here:

1. Review and approval by PSRC of package inserts and packaging materials

2. Inspection of manufacturing and control procedures, facilities, records, inventories, and reference samples by an PSRC consultant

3. Establishment of a system of post-market surveillance that [specify requirements] ______

4. Establishment of an introduction program to product users

5. Notification/discussion with PSRC of any change in manufacturing procedure. Pilot batches using new manufacturing procedures must pass stability testing before going into industrial production. The first two industrial batches using new manufacturing procedures must go into ongoing stability testing at room temperature (manufacturer’s warehouse). No less than one batch per year must be placed in the same program. Results are to be used to support registration and/or modify information about shelf life.

6. PSRC reserves the right to audit the manufacturer’s installations, process, and inventory, and to retain samples on a yearly basis. At any point in the distribution system, product may be tested by PSRC as part of this audit.]