

**MEMORANDUM OF UNDERSTANDING
BETWEEN
MEDICINES PATENT POOL AND FERRING INTERNATIONAL CENTER S.A.**

This Memorandum of Understanding (“MOU”) is made as of December 21, 2023, by and between Ferring International Center S.A. (“Ferring”), whose corporate headquarters is located at Chemin de la Vergognausaz 50, 1162 Saint-Prex Switzerland, and Medicines Patent Pool Foundation (“MPP”), whose corporate headquarters is located at Rue de Varembe 7, Geneva 1202, Switzerland. MPP and Ferring will be referred to individually as a “Party” and collectively as “Parties” to this MOU.

Background

Ferring is a research-driven, specialty biopharmaceutical group committed to helping people build healthy families and live better lives. Ferring has a strong interest in women's health and is dedicated to identifying, developing and marketing innovative products in the fields of obstetrical care and gynecology, among others. Ferring has developed and commercialized a proprietary ICH zone IV stable formulation of carbetocin product (“HSC”) for the prevention of post-partum hemorrhage (“PPH”), packaged in ampoules exclusively for use by and in the Public Sector of Target Countries (other capitalized terms defined below). Ferring is committed to making HSC accessible to women suffering or at risk of suffering of PPH. Towards that end, Ferring is collaborating with the World Health Organization (“WHO”) and Unitaid in the implementation of a randomized controlled trial, entitled ‘Heat-stable carbetocin for the treatment of postpartum hemorrhage: a phase III, randomized, double-blind, active-controlled, multi-country, multi-centre, non-inferiority trial’ (“Treatment Trial”) arranged and coordinated by the UNDP/UNFPA/UNICEF/WHO/World Bank Special Programme of Research, Development and Research Training in Human Reproduction (“WHO/HRP”) and for the purpose of inter alia further expanding access to HSC for the treatment of PPH in the Public Sector of Target Countries (defined below).

The Treatment Trial will evaluate whether HSC is safe and non-inferior to oxytocin when used for the treatment of PPH in women who receive HSC for prevention of PPH. The Parties furthermore acknowledge the execution by Ferring on December 16, 2013 of an agreement with WHO and Merck Sharpe & Dohme Corp (“Merck”) in order to collaborate in the further development of HSC, including the subsequent amendments to that agreement (noting that through an amendment, effective January 12, 2021, Merck withdrew as a party to that agreement and the agreement is continuing as between WHO and Ferring). The aforesaid agreement and its amendments are hereinafter jointly referred to as the “Existing Agreement”. The above-mentioned collaboration between Ferring, Unitaid and WHO and this MOU and its Annexes are without prejudice to the terms and conditions of the Existing Agreement and in particular any rights of, and commitments made by Ferring to, WHO and Merck, except as WHO, Merck and Ferring may otherwise agree in writing, through an amendment to the Existing Agreement executed by the duly authorized representatives of WHO, Merck and Ferring (“as applicable”).

MPP is a non-profit organization with a mission to improve the health of people living in low- and middle-income countries by increasing access to quality, safe, efficacious and affordable medicines by facilitating access to intellectual property to allow for the rapid development and manufacturing of these medicines.

Ferring and MPP wish to collaborate for the purpose of facilitating a limited license to Ferring’s intellectual property on HSC to MPP for the purpose of ensuring long-term equitable access to HSC by women suffering, or at-risk of suffering from PPH in Target Countries. This MOU memorializes the terms and conditions under which an in-license, including a right to sublicense, will be granted by Ferring to MPP.

- 1. Term and Termination.** This MOU shall become effective on the date of last signature by either Party (“Effective Date”) and shall remain in effect until the later of the expiration, lapse or invalidation of the last remaining patent licensed by Ferring to MPP pursuant to this MOU (“Term”), unless terminated

sooner by either Party as set forth below. It may be modified by mutual written consent of the Parties (provided always that the terms and conditions of the Existing Agreement and in particular any rights of, and commitments made by Ferring to, WHO and Merck shall not be prejudiced).

- a) This MOU may be terminated by either Party with immediate effect by written notice to the other Party in the event of the other Party is in material breach of this MOU and/or the license and sublicense agreements executed pursuant to this MOU (as applicable to the Party), and where such breach is capable of remedy, such other Party fails to remedy such breach within thirty (30) days of written notice requiring such breach to be remedied.
- b) This MOU shall automatically terminate in the event any of the following conditions occur: (i) the grant agreement between Unitaid and HRP is terminated prior to the completion of the Treatment Trial; or (ii) if a Party voluntarily commences any action or seeks any relief by liquidation, reorganization (other than for corporate reorganization), dissolution or similar act under any bankruptcy, insolvency or similar law or otherwise seeks any arrangement between or with its creditors or if a proceeding is commenced or an order, judgment or decree is entered seeking its liquidation, reorganization or dissolution or any other relief under any bankruptcy, insolvency or similar law or an arrangement is made with respect to its debts or business by its creditors with or without its consent.
- c) All provisions of this MOU intended to survive expiration or prior termination of the MOU including, without limitation, Section 3 (Confidentiality), Section 4 (Press Releases and Other Communications), and Section 6 (Governing Law) shall so survive.

2. Description of Proposed Collaboration.

- a) If and when each of the following criteria are met, the Parties agree to execute the License Agreement (attached hereto as Annexure A), to cover the Public Sector in the Target Countries:
 - i) HSC for the treatment of PPH is included in the relevant WHO guidelines on PPH; and
 - ii) at least one Stringent Regulatory Authority (defined in the License Agreement) has approved an extension of the HSC product label to include the treatment of PPH; and
 - iii) Ferring and/or its authorized distributors receive confirmed orders of at least ten (10) million ampoules (in aggregate and less any returns) of HSC for use in prevention and treatment of PPH (“Field”) in the Public Sector of the Target Countries as calculated on a rolling twelve (12) month basis during the Term, and as evidenced in writing by order reports provided by Ferring to MPP on a quarterly basis, which details the monthly orders.
 - (1) MPP acknowledges that Ferring uses an authorized third-party distributor to distribute HSC packaged in ampoules to the Public Sector of the Target Countries (except India) and the data from such countries shall be based on reports provided by Ferring’s authorized distributor. Ferring supplies HSC directly in India and MPP acknowledges that the data provided by Ferring for orders of HSC packaged in ampoules for the Public Sector in India shall be from reports provided by a Ferring affiliate in India.
 - (2) The Parties shall have quarterly business meetings to review and discuss the order reports, to evaluate then-current market conditions, Ferring’s forecasts, and assess trends or performance towards the demand threshold set forth above.

- (3) The records provided directly by Ferring and/or its third-party authorized distributor in support of its calculation of the demand threshold set forth in Section 2a)iii) above may be subject to an audit by MPP upon reasonable advance written notice to Ferring, during Ferring's normal business hours and at mutually agreed upon times. The audit shall be subject to a mutually agreed upon confidentiality agreement and any applicable laws pertaining to confidentiality of personal data that may be contained in such records. The audit shall be performed by MPP's external auditors (provided that such external auditors shall be a reputable international firm of accountants). The audits may occur no more than once every twenty-four (24) months during the Term. The audits shall be limited to a conclusion of whether or not the calculation of the volume threshold reported during the previous twenty-four (24) month period was accurate. This conclusion shall be used solely for the purpose of determining whether the criterion for in-licensing as set forth in Section 2a)iii) above has been met and, if not, what adjustment is necessary to correct the calculations for the purpose of determining whether the criterion in Section 2a)iii) above is met. The audits shall be conducted at MPP's sole cost and expense.
- b) Once the criteria in Section 2a) above are met, the Parties shall memorialize in writing, their agreement that the criteria have been met and shall promptly execute the License Agreement in furtherance thereof.
- c) MPP will identify appropriate generic manufacturing or other partners that have the R&D, manufacturing and/or commercial capabilities to produce and supply the Licensed Product (defined in the License Agreement), in accordance with the terms of the License Agreement, and will provide to Ferring such list of potential sublicensees for approval, prior to executing any sublicense agreements with such firms.
- d) The terms of this MOU and any License Agreement (including any applicable sublicense agreements) executed in connection herewith are limited to the Public Sector of Target Countries.
- i) "Public Sector" is defined as a government, or a department or agency thereof, or a non-profit non-governmental organization or other entity recognized by the government, procuring and/or distributing reproductive health products for and/or in the Target Countries, including WHO and any other organization within the United Nations system.
- ii) "Target Country(ies)" is/are defined as: (a) low-income and lower middle-income countries; and (b) upper middle-income countries, if and to the extent such upper middle-income countries have an elevated incidence of maternal mortality, defined as being greater than 140 per 100,000 live births, and such countries fulfil one of the following additional criteria: (i) capability to maintain cold chain is an issue; or (ii) the normal commercial price for HSC would constitute an impediment to access in the Public Sector (it being understood that low income, lower-middle income and upper-middle income countries will be determined based on then-current World Bank classifications).

A list of the Target Countries will be established, based on the criteria set out above, and will be included as an exhibit/schedule to the executed License Agreement. Ferring and the MPP will agree on an appropriate mechanism to update this list on a regular basis, as set forth in the License Agreement.

- e) Any license granted under the License Agreement will be a non-exclusive, non-transferable, royalty-free license for sales in the Public Sector of the Target Countries and will cover the Field. This MOU shall not be construed as a waiver of any Ferring rights anywhere in the world, nor shall

it be construed as a grant of rights to MPP or any other party to use any Ferring intellectual property rights anywhere in the world for any purpose other than as explicitly provided in this MOU and the License Agreement. Requests for sublicenses pursuant to the License Agreement shall be submitted to Ferring and shall require Ferring's written approval (not to be unreasonably withheld) and the License Agreement to be executed prior to any such sublicense being granted.

- f) The Parties acknowledge and agree that this MOU and the License Agreement attached hereto, will be at all times without prejudice to the terms and conditions of the Existing Agreement.
- g) For the avoidance of doubt, the commitments of MPP and Ferring set out in this MOU are subject to final approval by Unitaid of its investment in research by WHO/HRP to expand access to HSC for the treatment of PPH (the "HRP Project") and execution of a grant agreement between Unitaid and WHO/HRP for funding of the HRP Project, which includes the implementation of the Treatment Trial. Neither MPP nor Ferring will be required to fulfil the commitments set out in this MOU in the event that, for any reason the grant agreement between Unitaid and HRP for funding of the HRP Project is not executed.

3. Confidentiality.

- a) During the course of this MOU, the Parties (each a "Disclosing Party") may make available to each other (each a "Receiving Party") certain Confidential Information (as hereinafter defined) or one Party may otherwise learn of Confidential Information belonging to the other Party. For purposes of this Section, "Confidential Information" means any and all confidential or proprietary information regarding a Party or its business, including, without limitation, all products, patents, trademarks, copyrights, trade secrets, processes, techniques, scientific information, computer programs, databases, software, services, research, development, inventions, financial, purchasing, accounting, marketing, fundraising and other information, whenever conceived, originated, discovered or developed, concerning any aspect of its business, whether or not in written or tangible form; provided, however, that the term "Confidential Information" shall not include information (i) which is or becomes generally available to the public on a non-confidential basis, including from a third party provided that such third party is not in breach of an obligation of confidentiality with respect to such information, (ii) which was independently developed by a Party not otherwise in violation or breach of this MOU or any other obligation of one Party to the other, or (iii) which was rightfully known to the Receiving Party prior to entering into this MOU.
- b) Any Confidential Information disclosed by the Disclosing Party to the Receiving Party in connection with this MOU shall be used solely and exclusively by the Receiving Party in a manner consistent with the rights granted hereunder and for the purposes of this MOU; shall be maintained in strict confidence by the Receiving Party; and shall not be further used, relied upon or disclosed to a third-party without the prior written consent of the Disclosing Party. Notwithstanding the foregoing, the Receiving Party may disclose such Confidential Information to its employees and third-parties who are bound by confidentiality obligations no less restrictive than those set forth herein and need to know such Confidential Information solely to perform the Receiving Party's obligations and/or exercise the Receiving Party's rights under or in connection with this MOU. Notwithstanding the foregoing, the Receiving Party shall not be in violation of this subsection in the event that: (i) the Receiving Party is legally compelled to disclose any of the Confidential Information, provided however that such Receiving Party notifies the Disclosing Party of the requested disclosure within sufficient time to enable the Disclosing Party to seek an appropriate protective order or other remedy with respect to narrowing the scope of such required disclosure; or (ii) MPP discloses any order report or data received from Ferring under Section 2a)iii) to a third party on a need-to-know basis, and who is bound by confidentiality obligations no less restrictive than those contained in this MOU.

- c) Within thirty (30) days after any expiration or termination of this MOU, Receiving Party shall destroy (and certify to the Disclosing Party such destruction) or return all Confidential Information provided by the Disclosing Party except as otherwise set forth in this MOU. One copy of the Disclosing Party's Confidential Information may be retained in the Receiving Party's files solely for archival purposes as a means of determining any continuing or surviving obligations under this MOU.
 - d) Notwithstanding any of the terms set forth in this Section 3, the Parties acknowledge and agree that Ferring may share a copy of this MOU and License Agreement (and form sublicense) with Unitaid and WHO prior to and upon execution in order to enable: (i) Unitaid to confirm that this MOU and License Agreement (and form sublicense) are in accordance with the principles set out in any agreement between Ferring and Unitaid; and (ii) WHO to confirm that this MOU and License Agreement (and form sublicense) are without prejudice to the terms and conditions of the Existing Agreement and in particular any rights of, and commitments made by Ferring to WHO and Merck.
 - e) The obligations of this Section 3 shall survive the expiration or termination of this MOU.
4. **Press Release and Other Communications.** The signature of this MOU may be announced through a press release (joint or individual) agreed to by the Parties. Ferring acknowledges that this MOU, in accordance with MPP policy, will be made publicly available on MPP's website and by other appropriate means. Ferring further agrees that MPP may periodically publish updates on the order reports or data received from Ferring under Section 2a)iii) subject to Ferring's prior approval, such approval not to be unreasonably withheld.
5. **Severability.** If, for any reason, any part of this MOU is held to be invalid or unenforceable, that ruling shall not impair the operation of such other parts of this MOU as may remain otherwise valid and enforceable.
6. **Governing Law.** This MOU shall be governed by the laws of Switzerland, excluding any rules of conflicts of laws that would apply the substantive laws of any other jurisdiction. The Parties agree that all disputes arising in connection with this MOU shall be commenced or referred to and finally resolved by the courts in Geneva, Switzerland. For the avoidance of doubt, nothing contained in this MOU shall be construed as a waiver of any of the privileges and immunities enjoyed by WHO, or Unitaid and/or HRP under national or international law, and/or as submitting WHO, Unitaid and/or HRP to any national court jurisdiction.

Signed and acknowledged by authorized representatives of the Parties:

FERRING INTERNATIONAL CENTER S.A.

FERRING INTERNATIONAL CENTER S.A.

DocuSigned by:
Per Falk
F26A26564088424...
 Signature
 Per Falk

 Name
 President

 Title
 12/21/2023

 Date

DocuSigned by:
Dominic Moorhead
80C87FC35F14447...
 Signature
 Dominic Moorhead

 Name
 Chief Financial Officer

 Title
 12/21/2023

 Date

**THE MEDICINES PATENT POOL
FOUNDATION**

DocuSigned by:
Charles Gore
4713D0F59C13482...
 Signature
 Charles Gore

 Name
 Executive Director

 Title
 12/22/2023

 Date

Annexure A

LICENSE AGREEMENT

This license agreement (this “**Agreement**”) is made on the last date of signature below (the “**Effective Date**”), by and between Ferring International Center S.A. (“**Ferring**”), whose corporate headquarters is located at Chemin de la Vergognausaz 50, 1162 Saint-Prex Switzerland, and Medicines Patent Pool Foundation (“**MPP**”), whose corporate headquarters is located at Rue de Varembe 7, Geneva 1202, Switzerland. MPP and Ferring will be referred to individually as a “**Party**” and collectively as “**Parties**” to this Agreement.

Recitals

WHEREAS, MPP is a non-profit organisation with a mission to improve the health of people living in the developing world by increasing access to quality, safe efficacious and affordable medicines by facilitating access to intellectual property on these medicines;

WHEREAS, Ferring owns certain rights, title and interest in and/or has the right to sublicense the Licensed Patents (as defined below);

WHEREAS, MPP desires to obtain a license from Ferring under the Licensed Patents solely to allow it to grant sublicenses of the Licensed Patents to various third parties for the use, development and sale of the Licensed Product in the Field in the Territory (as these terms are defined below);

WHEREAS, Ferring is willing to grant such a license subject to and in accordance with the terms of this Agreement; and

NOW THEREFORE, in consideration of the covenants and obligations expressed in this Agreement, and intending to be legally bound, the Parties agree as follows:

1. DEFINITIONS

For the purposes of this Agreement, including the preamble and schedules:

- a) “**Affiliate**” shall mean any corporation, firm, partnership or other entity which is directly or indirectly controlled by, in control of, or under common control with such party. For the purposes of this definition, “**control**” shall mean the ability of any corporation, firm, partnership or other entity, whether through ownership of shares or otherwise, to influence or direct the affairs of a party in accordance with the wishes of such corporation, firm, partnership or other entity.
- b) “**Agreement Quarter**” shall mean any period of three months ending on the last day of March or June or September or December.
- c) “**Business Day**” shall mean a day (other than a Saturday or Sunday) on which the banks are open for normal business in Switzerland.
- d) “**Confidential Information**” has the meaning given to such term in Section 7 below.
- e) “**Exploit**” shall mean to research, develop, make, have made, offer for sale, sell, have sold, import, export or otherwise exploit, or transfer possession of a product.
- f) “**Field**” shall mean the use of the Licensed Product for the prevention and treatment of post-partum haemorrhage(ing) (“**PPH**”).
- g) “**Good Distribution Practice**” or “**GDP**” shall mean all applicable then-current good distribution

practice standards that promote the safety and integrity of the pharmaceutical supply chain, or in any similar set of laws, regulations, rules, or practices that are applicable in countries where development activities are or will be carried out under this Agreement or in parts of the Territory in which Licensed Product will be sold, including WHO's good storage and distribution practices for medical products.

- h) **“Good Manufacturing Practice”** or **“GMP”** shall mean all applicable then-current principles and guidelines of good manufacturing practice for medicinal products for human use as set forth in the laws, regulations, rules, or practices that are applicable in countries where the Licensed Product is or will be manufactured under this Agreement or areas of the Territory in which the Licensed Product is or will be sold, including WHO good manufacturing practices for pharmaceutical products.
- i) **“Know-How”** shall mean any and all confidential and proprietary information and materials, discoveries, processes, protocols, formulas, molecular constructs, reagents, assays, improvements, compositions of matter (including compounds), formulations, and findings, techniques, technology, trade secrets, inventions, methods, know-how, data and results (including pharmacological, toxicological and clinical data and results), analytical and quality control data and results, regulatory documents, and other information, in each case, patentable or otherwise, and including any copyrights therein.
- j) **“Letter of Indemnity”** shall mean a letter of indemnity in the form set out in Schedule 4 hereto.
- k) **“Licensed Know-How”** shall mean all Know-How that (a) is owned or controlled by Ferring and/or its Affiliates as of the Effective Date and (b) is reasonably necessary in the development or manufacture of the Licensed Product as reasonably determined by Ferring.
- l) **“Licensed Patents”** shall mean those patents and patent applications (as set forth in Schedule 1) covering the Licensed Product, and any additions, divisions, continuation, continuation-in-part, substitutions, and reissues claiming priority thereto, as well as any re-examinations, extensions, registrations, patent term extensions, supplemental protection certificates, renewals and the like with respect to any of the foregoing and foreign equivalents thereof.
- m) **“Licensed Product”** shall mean a pharmaceutical product containing the ICH zone IV stable formulation of 100mcg/mL carbetocin for intramuscular administration, packaged in ampoules.
- n) **“Private Sector”** shall mean any entity, sector or market that is not the Public Sector.
- o) **“Public Sector”** shall mean a government, or a department or agency thereof, or a non-profit non-governmental organization or other entity recognized by the government, procuring and/or distributing reproductive health products for and/or in the Target Countries, including WHO and any other organization within the United Nations system.
- p) **“Stringent Regulatory Authority”** means any of the regulatory agencies which is: (a) a member of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH), being the European Commission, the US Food and Drug Administration and the Ministry of Health, Labour and Welfare of Japan also represented by the Pharmaceuticals and Medical Devices Agency (as before 23 October 2015); or (b) an ICH observer, being the European Free Trade Association, as represented by Swissmedic, and Health Canada (as before 23 October 2015); or (c) a regulatory authority associated with an ICH member through a legally-binding, mutual recognition agreement, including Australia, Iceland, Liechtenstein and Norway (as before 23 October 2015).
- q) **“Sublicense”** means a license agreement in the form set out in Schedule 3 hereto.
- r) **“Sublicensee”** means a third party, which in the opinion of MPP and Ferring (acting reasonably) has demonstrated willingness and capacity to:
 - (1) manufacture and distribute the Licensed Product in a manner consistent with:

- (i) GDP and GMP; and
 - (ii) World Health Organization ("**WHO**") pre-qualification standards or the standards of any Stringent Regulatory Authority; and
 - (2) make the Licensed Product widely available at terms that will facilitate access to Licensed Product for use in the Field within the Territory, and
 - (3) that has entered into a Sublicense.
- s) "**Target Countries**" shall mean:
- (1) low-income and lower middle-income countries; and
 - (2) upper middle-income countries, if and to the extent such upper middle-income countries have an elevated incidence of maternal mortality, defined as being greater than 140 per 100,000 live births, and such countries fulfil one of the following additional criteria:
 - (i) capability to maintain cold chain is an issue; or
 - (ii) the normal commercial price for HSC would constitute an impediment to access in the Public Sector; and
 - (3) as identified in Schedule 2 hereto (it being understood that low income, lower-middle income and upper-middle income countries will be determined based on then-current World Bank classifications).
- t) "**Territory**" shall mean the Public Sector of the Target Countries set forth in Schedule 2 hereto.
- u) "**Trade Dress Guidance**" has the meaning given to such term in the Sublicense.
- v) "**WIPO Mediation Rules**" shall mean the mediation rules adopted by the World Intellectual Property Organization from time to time.

2. GRANT OF LICENSE

2.1. Subject to the terms and conditions of this Agreement, Ferring hereby grants to MPP a non-exclusive, non-transferable, royalty-free license under the Licensed Patents and Licensed Know-How to enter into Sublicenses with Sublicensees solely to Exploit the Licensed Product and solely for use in the Field in the Territory. No rights are hereby granted for any other purpose and MPP agrees that it will not use the Licensed Patents and/or Licensed Know-How itself or grant sublicenses: (i) to entities other than Sublicensees; and/or (ii) other than in the form of the Sublicense.

3. SUBLICENSE

3.1. The Parties intend that MPP will identify potential manufacturers of pharmaceutical products with a view to enter into Sublicenses. Upon identification of such a manufacturer, in each case, MPP shall provide notice to Ferring of the identity of the manufacturer (including the name, address, principal place of business, list of affiliated entities) and provide Ferring with (i) the information contemplated by Section 3.2, (ii) the complete development, manufacturing and commercialization plans proposed by the manufacturer, including without limitation the proposed supply chain of the Licensed Product; and (iii) any additional information that may be at the time reasonably requested by Ferring to enable Ferring to evaluate a proposed Sublicensee.

3.2. MPP shall only enter into Sublicenses with entities that have produced reasonable evidence demonstrating their intent and capability to: (i) comply with applicable laws relating to corruption (including but not limited to: anti-bribery laws and the U.S. Foreign Corrupt Practices Act and the UK Bribery Act), where certification to this effect, absent other contrary evidence, shall constitute reasonable evidence under this Section 3.2; (ii) manufacture and distribute Licensed Product in a manner consistent with GDP and GMP, and either WHO pre-qualification standards or the standards of any Stringent Regulatory Authority; and (iii) make the Licensed Product available in the Territory at terms that will facilitate access to the Licensed Product solely for use in the Field within the Territory.

- 3.3. MPP shall not enter into a Sublicense with a party without Ferring's prior written consent with respect to that party. Ferring's consent shall not be withheld, except as reasonably based upon the Sublicensee requirements set forth in this Section 3 not being met. Ferring's consent shall be understood as granted unless otherwise notified by Ferring in writing within thirty (30) days of MPP's initial written notice to Ferring pursuant to this Section 3.3. Ferring's consent to a Sublicense pursuant to this Section 3.3 shall not waive or derogate from any other obligation of MPP under this Agreement. If Ferring reasonably objects to a Sublicense being granted pursuant to this Section 3.3, the Parties shall discuss in good faith Ferring's concerns and any potential mitigations necessary to address Ferring's concerns and if not appropriately mitigated as reasonably determined by Ferring, such sublicense shall not be granted.
- 3.4. MPP shall not grant sublicenses other than in the form of the Sublicense (after receiving Ferring's prior written consent as set forth above).
- 3.5. MPP shall cause the Sublicensees to purchase and maintain appropriate product liability insurance as per the terms of the Sublicense.
- 3.6. MPP acknowledges that the number of Sublicenses entered into with Sublicensees pursuant to this Agreement must be commensurate to the need for Licensed Product for use in the Field in the Territory or in specific Target Countries within the Territory.
- 3.7. MPP shall ensure that at the same time as any Sublicense is entered into, the relevant Sublicensee shall also execute a Letter of Indemnity and that within five (5) Business Days of the execution of such Sublicense, a fully executed copy of the relevant Sublicense and two originals of the relevant Letter of Indemnity shall be provided to Ferring.
- 3.8. For the avoidance of doubt, nothing in this Agreement shall be construed as a waiver of, or prevent Ferring from exercising, any rights it may have in connection with any acts or omissions by a Sublicensee that does not comply with this Agreement or the Sublicense.
- 3.9. MPP and Ferring together commit to meet and review on an annual basis the operational elements of this Agreement and will work in good faith to ensure effective use of the resources of both Parties and any amendments that need to be made to this Agreement.
- 3.10. Following the Effective Date, Ferring shall assemble a discrete data package related to the Licensed Know-How. A Sublicensee shall submit any request for access to the data package to MPP in writing. MPP shall collect relevant access information, as determined by Ferring, from such Sublicensee to enable access to the data package and submit such information to Ferring, following which Ferring shall make the data package available to such Sublicensee. MPP acknowledges that such data package is and shall be treated by MPP and each Sublicensee as Ferring's Confidential Information. Ferring shall not be required to provide any technical support or technical assistance to a Sublicensee for any reason.

4. MONITORING AND COMPLIANCE

- 4.1. MPP agrees that it shall provide such assistance as Ferring reasonably requires to enable Ferring to exercise its rights under this Agreement and any Sublicense.
- 4.2. MPP agrees to monitor the compliance with each Sublicense by each Sublicensee, including but not limited to by:
 - 4.2.1. Using reasonable endeavours to ensure that Sublicensees provide reports to MPP in accordance with the Sublicense, and reviewing with all reasonable skill and care any such reports;
 - 4.2.2. within thirty (30) days following the end of each Agreement Quarter, reporting to Ferring which Sublicensees (if any) have not complied with their reporting obligations under the Sublicense and what action MPP has taken to facilitate compliance of such Sublicensees;

- 4.2.3. within thirty (30) days following the end of each Agreement Quarter, sending to Ferring a copy of any reports provided to MPP under the Sublicense;
- 4.2.4. fully exercising the audit right set out in the Sublicense at MPP's own cost as soon as MPP has reasonable cause to believe (and/or as soon as Ferring has notified MPP that Ferring has reasonable cause to believe) an audit is necessary (including without limitation where such a party has reasonable grounds for suspecting non-compliance with the Sublicense); and
- 4.2.5. assessing with all reasonable skill and care whether any requests for prior written approval for trademarks, service marks, trade dress (where applicable), symbols, devices, company names or domain names provided to MPP by Sublicensees under the Sublicense comply with the Trade Dress Guidance, and submitting to Ferring for written approval, those (and only those) requests which MPP considers meet the criteria provided in the Trade Dress Guidance. Ferring shall respond to any request for approval within thirty (30) days of receipt by Ferring of all the relevant documentation necessary to consider the Licensees' request.
- 4.3. Ferring agrees to treat any information of Sublicensees provided to it under this Section 4 as Confidential Information and the confidentiality obligations of the Sublicense shall apply, *mutatis mutandis*, to Ferring with respect to such information.
- 4.4. Where the Sublicense requires the Sublicensee to obtain approval from Ferring, MPP shall facilitate the provision of such approval in accordance with the Sublicense.
- 4.5. If MPP becomes aware of any act or omission of a Sublicensee which constitutes a breach of the relevant Sublicense, MPP shall immediately notify Ferring and (i) if the breach is capable of correction and does not give rise to an immediate right of termination under the Sublicense, direct the relevant Sublicensee in writing to cure the breach, with a copy of that writing to Ferring; and (ii) if the breach remains uncured at the end of the specified period, or if there are otherwise grounds for termination under the relevant Sublicense, and in each case if so requested by Ferring, procure the termination of the relevant Sublicense in accordance with its terms.
- 4.6. MPP agrees to exercise the rights of Ferring as granted under any Sublicense only as requested in writing by Ferring. For the avoidance of doubt, this shall not affect Ferring exercising its rights directly under any Sublicense.
- 4.7. MPP's obligations under this Section 4 constitutes direct, primary and unconditional obligations of MPP and shall not require Ferring to first take any steps against any Sublicensee or any other person.
- 4.8. Ferring shall provide MPP the Trade Dress Guidance and shall keep it up to date, and any additional new and/or future Ferring trade dress as soon as practicable after Ferring considers such information no longer to be confidential.
- 4.9. Ferring does not grant any rights to MPP or Sublicensees under this Agreement to use or register any trademark, service mark, trade dress, symbol, device, company name or domain name (or any confusingly similar trademark, service mark, trade dress, symbol, device, company name or domain name) that is used or registered by Ferring and/or its Affiliates. MPP shall require that Sublicensees do not use or seek to register (or, where it is possible to do so, apply to use or register) any trademark, service mark, trade dress (where applicable), symbol, device, company name or domain name in relation to any Licensed Product or any of their packaging (whether external, intermediate or internal) or promotional material which incorporates or is identical with or confusingly similar to any trademark, service mark, trade dress, symbol, device, company name or domain name used or registered by Ferring and/or its Affiliates anywhere in the world.

5. COMPLIANCE WITH APPLICABLE LAWS

- 5.1. MPP shall comply fully at all times with all applicable laws and regulations, including but not limited to applicable anti-corruption laws, of the territories in which MPP conducts business with Ferring and/or grants Sublicenses.
- 5.2. Ferring shall be entitled to terminate this Agreement immediately on written notice to MPP if MPP fails to perform its obligations in accordance with this Section 5. MPP shall have no claim against Ferring or any of Ferring's Affiliates for compensation for any loss of whatever nature by virtue of the termination of this Agreement in accordance with this Section 5. To the extent (and only to the extent) that applicable law provides for any such compensation to be paid to MPP upon the termination of this Agreement, MPP hereby expressly agrees to waive (to the extent possible under applicable law) or repay to Ferring any such compensation or indemnity.
- 5.3. The responsibilities of the Parties for reporting of adverse drug experiences related to the Licensed Product to regulatory authorities in the Territory shall be performed in accordance with local laws and regulations as applicable to such Party. The responsibilities of the Parties for safety related or Licensed Product related inquiries shall be performed in accordance with local laws and regulations as applicable to such Party. MPP hereby undertakes to: (a) monitor the activities and duties of the Sublicensees with respect to pharmacovigilance obligations set out in the Sublicense, and (b) otherwise ensure compliance by the Sublicensees with such terms.
- 5.4. MPP represents that neither MPP nor, to the knowledge of MPP, any Affiliate, director, officer, or employee of MPP, is a sanctioned entity or sanctions target.

6. INDEMNIFICATION AND LIMITATION OF LIABILITY

- 6.1. MPP shall be primarily liable for any breach of a Sublicense by any Sublicensee and shall indemnify Ferring and its Affiliates, and each of their respective officers, directors, shareholders, representatives, agents, employees, successors and assigns (collectively, the "**Ferring Indemnitees**") in respect of any and all liabilities, costs, damages and expenses (including, but not limited to, legal costs) ("**Losses**") incurred by Ferring Indemnitees arising out of, or in connection with (a) any breach by MPP or a Sublicensee of the terms and conditions of this Agreement, (b) any negligence or willful misconduct by or on behalf of MPP or a Sublicensee, (c) any breach of a Sublicense by MPP or a Sublicensee, provided that the indemnification obligation established in this Section shall not apply to the extent such Losses arise out of negligence or wilful misconduct by Ferring, its Affiliates and their respective officers, directors, shareholders, representatives, agents, employees, successors and assigns. Where Ferring exercises its rights under this Section 6.1, Ferring shall: (i) provide MPP with prompt written notice of such claims, (ii) grant MPP the right to control the defence or negotiation of settlement of such claims (except to the extent such claims relate to the validity or enforcement of Licensed Patents or Licensed Know-How) and (iii) reasonably cooperate with MPP in defending any claims.
- 6.2. NOTWITHSTANDING ANY OTHER PROVISION OF THIS AGREEMENT, MPP ACKNOWLEDGES AND AGREES THAT (I) THE FERRING LICENSED PATENTS AND LICENSED KNOW-HOW ARE LICENSED TO MPP "AS IS" AND (II) FERRING DOES NOT GIVE ANY REPRESENTATIONS OR WARRANTIES, EXPRESS OR IMPLIED, REGARDING THE LICENSED PRODUCT, THE FERRING LICENSED PATENTS, LICENSED KNOW-HOW OR ANY OTHER MATTER, INCLUDING, WITHOUT LIMITATION, WARRANTIES OF NON-INFRINGEMENT.
- 6.3. NOTWITHSTANDING ANYTHING IN THIS AGREEMENT OR OTHERWISE, IN RECOGNITION OF THE HUMANITARIAN NATURE OF THIS AGREEMENT AND THE LACK OF ANY ROYALTY TO FERRING OR OTHER PAYMENTS TO FERRING UNDER THIS AGREEMENT, FERRING WILL NOT HAVE ANY LIABILITY TO MPP OR THE SUBLICENSEES FOR ANY INDIRECT, SPECIAL, CONSEQUENTIAL, PUNITIVE, EXEMPLARY OR INCIDENTAL DAMAGES RELATED TO THIS AGREEMENT UNDER CONTRACT, NEGLIGENCE, STRICT

LIABILITY OR OTHER LEGAL OR EQUITABLE THEORY. IN PARTICULAR, AND WITHOUT LIMITING THE FOREGOING, FERRING WILL HAVE NO LIABILITY IN THE EVENT THE FERRING LICENSED PATENTS OR LICENSED KNOW-HOW ARE INVALID OR UNENFORCEABLE, OR IN THE EVENT THE EXERCISE BY MPP OF ITS RIGHTS UNDER THIS AGREEMENT OR A SUBLICENSEE UNDER THE RELEVANT SUBLICENSE AGREEMENT INFRINGES THE INTELLECTUAL PROPERTY RIGHTS OF ANY THIRD PARTY.

7. CONFIDENTIALITY

- 7.1. During the course of this Agreement, the Parties (each a “**Disclosing Party**”) may make available to the other Party (each a “**Receiving Party**”) certain Confidential Information (as hereinafter defined) or one Party may otherwise learn of Confidential Information belonging to the other Party. For purposes of this Agreement, “**Confidential Information**” means any and all confidential or proprietary information regarding a Party or its business, including, without limitation, all products, patents, trademarks, copyrights, trade secrets, processes, techniques, scientific information, computer programs, databases, software, services, research, development, inventions, financial, purchasing, accounting, marketing, fundraising and other information, whenever conceived, originated, discovered or developed, concerning any aspect of its business, whether or not in written or tangible form; provided, however, that the term “Confidential Information” shall not include information (i) which is or becomes generally available to the public on a non-confidential basis, including from a third party provided that such third party is not in breach of an obligation of confidentiality with respect to such information, (ii) which was independently developed by a Party not otherwise in violation or breach of this Agreement or any other obligation of one Party to the other, or (iii) which was rightfully known to the Receiving Party prior to entering into this Agreement.
- 7.2. Any Confidential Information disclosed by the Disclosing Party to the Receiving Party in connection with this Agreement shall be used solely and exclusively by the Receiving Party in a manner consistent with the rights granted hereunder and for the purposes of this Agreement; shall be maintained in strict confidence by the Receiving Party; and shall not be further used, relied upon or disclosed to a third-party without the prior written consent of the Disclosing Party. Notwithstanding the foregoing, the Receiving Party may disclose such Confidential Information to its employees and third parties who are bound by confidentiality obligations no less restrictive than those set forth herein and need to know such Confidential Information solely to perform the Receiving Party’s obligations and/or exercise the Receiving Party’s rights under or in connection with this Agreement. Notwithstanding the foregoing, the Receiving Party shall not be in violation of this subsection in the event that the Receiving Party is legally compelled to disclose any of the Confidential Information, provided however that such Receiving Party notifies the Disclosing Party of the requested disclosure within sufficient time to enable the Disclosing Party to seek an appropriate protective order or other remedy with respect to narrowing the scope of such required disclosure.
- 7.3. Within thirty (30) days after any expiration or termination of this Agreement, Receiving Party shall destroy (and certify to the Disclosing Party such destruction) or return all Confidential Information provided by the Disclosing Party except as otherwise set forth in this Agreement. One copy of the Disclosing Party’s Confidential Information may be retained in the Receiving Party’s files solely for archival purposes as a means of determining any continuing or surviving obligations under this Agreement. The confidentiality obligations under this Agreement shall survive the termination or expiration of this Agreement.

8. PUBLICITY

Each Party shall seek each other’s previous written approval of any press release or public announcement concerning the grant, scope or terms of this License prior to such press release or other publication being made. Following an initial announcement, neither Party shall be required to seek the other Party’s consent to reactive statements, provided such statements are accurate and not misleading.

9. TERM AND TERMINATION

- 9.1. The term of this Agreement shall commence on the Effective Date and expire upon the later of the expiration, lapse or invalidation of the last remaining Licensed Patent (unless terminated earlier in accordance with its terms) (“Term”). Either Party may terminate this Agreement with immediate effect by written notice to the other Party if the other Party:
- 9.1.1. commits a material breach of this Agreement (including but not limited to MPP’s failure to terminate a Sublicense due to the Sublicensee’s material breach of the Sublicense), and where such breach is capable of remedy, such other Party fails to remedy such breach within thirty (30) days of written notice requiring such breach to be remedied; or
 - 9.1.2. voluntarily commences any action or seeks any relief by liquidation, reorganization (other than for corporate reorganization), dissolution or similar act under any bankruptcy, insolvency or similar law or otherwise seeks any arrangement between or with its creditors or if a proceeding is commenced or an order, judgment or decree is entered seeking its liquidation, reorganization or dissolution or any other relief under any bankruptcy, insolvency or similar law or an arrangement is made with respect to its debts or business by its creditors with or without its consent.
- 9.2. Upon the expiry of this Agreement, or in the event that this Agreement is terminated earlier in accordance with its terms, MPP shall ensure that any Sublicenses already granted shall be immediately terminated in accordance with their terms (if that Sublicensee is in breach of the Sublicense) or converted (by way of MPP, Ferring and the relevant Sublicensee entering into a novation agreement transferring the rights and obligations of MPP under the Sublicense to Ferring) into a license between Ferring and the relevant Sublicensee(s) under the same terms and conditions of the Sublicense if that Sublicensee is not in breach of the Sublicense, and/or if the Sublicense has not otherwise been terminated earlier or expired. Notwithstanding anything in the foregoing, such conversion shall only occur if this Agreement is terminated earlier in accordance with its terms. Ferring shall not be required to convert a Sublicense into a license agreement between Ferring and the Sublicensee in the event this Agreement expires. This Section 9.2 shall survive any termination of this Agreement.

10. ASSIGNMENT

- 10.1. Ferring may assign this Agreement and/or any of its rights and obligations under this Agreement to its Affiliate or to a Third-Party in the context of a sale of all or substantially all assets related to Ferring’s ICH zone IV stable formulation of 100mcg/mL carbetocin for intramuscular administration, packaged in ampoules, with prior notice to MPP. MPP may not assign all or any part of its rights, or delegate all or any part of its obligations, under this Agreement without Ferring’s prior written consent.
- 10.2. This Agreement shall be binding upon and inure to the benefit of the Parties and their successors and permitted assignees. For the avoidance of doubt, any successor or permitted assignee shall not be permitted to amend this Agreement unless in accordance with Section 11.2 of this Agreement.

11. MISCELLANEOUS

- 11.1. This Agreement sets forth the entire agreement between the Parties and supersedes all prior agreements, arrangements and understandings, oral or written, between the Parties with respect to the subject matter hereof.
- 11.2. This Agreement may only be amended in writing signed by duly authorised representatives of each Party. For the avoidance of doubt, and notwithstanding the rights of MPP pursuant to the Sublicense, MPP shall not amend the Sublicense without Ferring’s express consent in writing.
- 11.3. The rights of each Party under this Agreement: (a) may be exercised as often as necessary; (b) except as otherwise expressly provided in this Agreement, are cumulative and not exclusive of rights and remedies provided by law; and (c) may be waived only in writing and specifically. Delay in exercising or non-exercise of any such right is not a waiver of that right.

11.4. This Agreement may be executed in counterparts, which taken together shall constitute one and the same agreement, and any Party (including any duly authorised representative of a Party) may enter into this agreement by executing a counterpart.

11.5. A person who is not a Party may not enforce any of the terms of this Agreement.

12. GOVERNING LAW AND JURISDICTION

12.1. This Agreement and any non-contractual obligations arising out of or in connection with it shall be governed by the laws of Switzerland without regard to its conflict of laws principles.

12.2. Any dispute between the Parties relating to this Agreement will first be submitted in writing by one Party to the other Party's senior executive who shall (unless otherwise notified in writing), promptly meet and confer in an effort to resolve such dispute. In the event the executives are unable to resolve any dispute within thirty (30) days after submission to them, then, such disputes shall be referred to mediation in accordance with the WIPO Mediation Rules. The place of mediation shall be Geneva, Switzerland. The language to be used in the mediation shall be English.

12.3. In the event that the dispute remains outstanding after sixty (60) days from the date when it was first discussed (in any manner) between the Parties, either Party may commence court proceedings.

12.4. The courts in Geneva shall have exclusive jurisdiction to settle any dispute arising out of or in connection with this Agreement (including a dispute relating to any non-contractual obligations arising out of or in connection with this Agreement) and the Parties submit to the exclusive jurisdiction of the courts in Geneva.

12.5. Without prejudice to any of the foregoing in relation to MPP, nothing in this Section 12 shall prevent or restrict Ferring from electing to bring proceedings in relation to patent infringement or from applying for injunctive relief in any country at any time.

[Signature page follows]

IN WITNESS WHEREOF the Parties, through their duly authorised representatives, have executed this Agreement.

Signed for and on behalf of:
FERRING INTERNATIONAL CENTER S.A.

.....
Signature

.....
Name

.....
Title

.....
Date

Signed for and on behalf of:
FERRING INTERNATIONAL CENTER S.A.

.....
Signature

.....
Name

.....
Title

.....
Date

Signed for and on behalf of:
THE MEDICINES PATENT POOL FOUNDATION

.....
Signature

.....
Name

.....
Title

.....
Date

SCHEDULE 1
LIST OF PATENTS

Country	Filed Date	Application Number	Grant Date	Patent No.
United Arab Emirates	2011-09-29	328/2013	2020-06-23	2421
Albania	2011-09-29	11776530.5	2017-06-14	2621468
Albania	2011-09-29	17169328.6	2021-11-03	3222272
Argentina	2011-09-29	20110103594		
Argentina	2011-09-29	20200102711		
Austria	2011-09-29	11776530.5	2017-06-14	2621468
Austria	2011-09-29	17169328.6	2021-11-03	3222272
Australia	2011-09-29	2011309762	2014-10-30	2011309762
Belgium	2011-09-29	11776530.5	2017-06-14	2621468
Belgium	2011-09-29	17169328.6	2021-11-03	3222272
Bulgaria	2011-09-29	11776530.5	2017-06-14	2621468
Bulgaria	2011-09-29	17169328.6	2021-11-03	3222272
Brazil	2011-09-29	112013007362-4	2021-06-25	112013007362-4
Brazil	2011-09-29	BR122021001119-2		
Canada	2011-09-29	2,812,510		
Switzerland	2011-09-29	11776530.5	2017-06-14	2621468
Switzerland	2011-09-29	17169328.6	2021-11-03	3222272
Cyprus (Republic of)	2011-09-29	11776530.5	2017-06-14	2621468
Cyprus (Republic of)	2011-09-29	17169328.6	2021-11-03	3222272
Czechia	2011-09-29	11776530.5	2017-06-14	2621468
Czechia	2011-09-29	17169328.6	2021-11-03	3222272
Germany (Federal Republic of)	2011-09-29	11776530.5	2017-06-14	2621468
Germany (Federal Republic of)	2011-09-29	17169328.6	2021-11-03	3222272
Denmark	2011-09-29	11776530.5	2017-06-14	2621468
Denmark	2011-09-29	17169328.6	2021-11-03	3222272
Algeria	2011-09-29	130183		
Estonia	2011-09-29	11776530.5	2017-06-14	2621468
Estonia	2011-09-29	17169328.6	2021-11-03	3222272
Egypt	2011-09-29	504/2013		
Egypt	2011-09-29	D2 PCT 504/2013		
European Patent	2011-09-29	11776530.5	2017-06-14	2621468
European Patent	2011-09-29	17169328.6	2021-11-03	3222272
European Patent	2011-09-29	21192651.4		
Spain	2011-09-29	11776530.5	2017-06-14	2621468

Spain	2011-09-29	17169328.6	2021-11-03	3222272
Finland	2011-09-29	11776530.5	2017-06-14	2621468
Finland	2011-09-29	17169328.6	2021-11-03	3222272
France	2011-09-29	11776530.5	2017-06-14	2621468
France	2011-09-29	17169328.6	2021-11-03	3222272
United Kingdom	2011-09-29	11776530.5	2017-06-14	2621468
United Kingdom	2011-09-29	17169328.6	2021-11-03	3222272
Greece	2011-09-29	11776530.5	2017-06-14	2621468
Greece	2011-09-29	17169328.6	2021-11-03	3222272
Hong Kong	2011-09-29	18103960.0	2022-06-10	HK1244442
Hong Kong	2011-09-29	42022053728.6		
Croatia	2011-09-29	11776530.5	2017-06-14	2621468
Croatia	2011-09-29	17169328.6	2021-11-03	3222272
Hungary	2011-09-29	11776530.5	2017-06-14	2621468
Hungary	2011-09-29	17169328.6	2021-11-03	3222272
Ireland (Republic of)	2011-09-29	11776530.5	2017-06-14	2621468
Ireland (Republic of)	2011-09-29	17169328.6	2021-11-03	3222272
Israel	2011-09-29	225238	2018-11-01	225238
Israel	2011-09-29	245328	2022-07-02	245328
India	2011-09-29	2471/DELNP/2013	2022-01-27	387567
Iceland	2011-09-29	11776530.5	2017-06-14	2621468
Iceland	2011-09-29	17169328.6	2021-11-03	3222272
Italy	2011-09-29	11776530.5	2017-06-14	2621468
Italy	2011-09-29	17169328.6	2021-11-03	3222272
Jordan	2011-09-28	297/2011	2020-01-26	3400
Jordan	2011-09-28	103/2018	2022-06-27	3968
Japan	2011-09-29	2013-530810	2016-11-11	6038797
Korea, Republic of (KR)	2011-09-29	10-2013-7010256	2018-11-09	10-1919119
Kuwait	2011-09-29	105/2011		
Lithuania	2011-09-29	11776530.5	2017-06-14	2621468
Lithuania	2011-09-29	17169328.6	2021-11-03	3222272
Luxembourg	2011-09-29	11776530.5	2017-06-14	2621468
Luxembourg	2011-09-29	17169328.6	2021-11-03	3222272
Latvia	2011-09-29	11776530.5	2017-06-14	2621468
Latvia	2011-09-29	17169328.6	2021-11-03	3222272
Morocco	2011-09-29	11776530.5	2017-05-18	2621468
Monaco	2011-09-29	11776530.5	2017-06-14	2621468
Monaco	2011-09-29	17169328.6	2021-11-03	3222272
North Macedonia	2011-09-29	11776530.5	2017-06-14	2621468
North Macedonia	2011-09-29	17169328.6	2021-11-03	3222272
Malta	2011-09-29	11776530.5	2017-06-14	2621468
Malta	2011-09-29	17169328.6	2021-11-03	3222272
Mexico	2011-09-29	MX/a/2013/003365	2017-12-15	352949

Mexico	2011-09-29	MX/a/2016/014747	2022-09-02	395271
Netherlands	2011-09-29	11776530.5	2017-06-14	2621468
Netherlands	2011-09-29	17169328.6	2021-11-03	3222272
Norway	2011-09-29	11776530.5	2017-06-14	2621468
Norway	2011-09-29	17169328.6	2021-11-03	3222272
New Zealand	2011-09-29	608163	2014-03-04	608163
Poland	2011-09-29	11776530.5	2017-06-14	2621468
Poland	2011-09-29	17169328.6	2021-11-03	3222272
Portugal	2011-09-29	11776530.5	2017-06-14	2621468
Portugal	2011-09-29	17169328.6	2021-11-03	3222272
Romania	2011-09-29	11776530.5	2017-06-14	2621468
Romania	2011-09-29	17169328.6	2021-11-03	3222272
Serbia	2011-09-29	11776530.5	2017-06-14	2621468
Serbia	2011-09-29	17169328.6	2021-11-03	3222272
Russian Federation	2011-09-29	2013112666	2016-12-10	2604690
Saudi Arabia	40817	111320809		
Sweden	2011-09-29	11776530.5	2017-06-14	2621468
Sweden	2011-09-29	17169328.6	2021-11-03	3222272
Slovenia	2011-09-29	11776530.5	2017-06-14	2621468
Slovenia	2011-09-29	17169328.6	2021-11-03	3222272
Slovak Republic	2011-09-29	11776530.5	2017-06-14	2621468
Slovak Republic	2011-09-29	17169328.6	2021-11-03	3222272
San Marino	2011-09-29	11776530.5	2017-06-14	2621468
San Marino	2011-09-29	17169328.6	2021-11-03	3222272
Turkey	2011-09-29	11776530.5	2017-06-14	2621468
Turkey	2011-09-29	17169328.6	2021-11-03	3222272
Taiwan	2011-09-29	100135257	2016-05-11	1532507
United States of America	2011-09-29	13/824,132	2017-02-14	9,566,311
United States of America	2022-07-12	17/863,319		
South Africa	2011-09-29	2013/01991	2013-11-27	2013/01991

SCHEDULE 2**LIST OF COUNTRIES FORMING THE TARGET COUNTRIES**

Below is the initial list of Target Countries. The Parties shall consult at least every three years [(starting in INSERT CALENDAR YEAR)] in order to update and include in or delete from the then-current version of Schedule 2 any country, territory or area that, as relevant: (1) has been or ceases to be classified as low income or lower-middle income by the World Bank, or (2) has been or ceases to be classified as upper middle income by the World Bank and meets or ceases to meet the criteria set out in Section 1)(s)(2) of this Agreement. As part of the aforementioned consultation between the Parties, to the extent that a country, territory or area is to be deleted from the then-current version of Schedule 2, and Sublicensee has sold the Licensed Product in such country, territory or area in compliance with the terms and conditions of the Sublicence, the Parties shall consider and agree on a case-by-case basis, in good faith, on a transition plan for the continued sale of the Licensed Product and any limitations thereto, in such country, territory or area, as appropriate.

Any update of the list included in this Schedule 2 shall be added to this Agreement via a signed written amendment and shall replace the preceding list. All references to Schedule 2 shall be deemed to refer to the then-current version of this Schedule.

1	Afghanistan	31	Guinea	61	Philippines
2	Algeria	32	Guinea-Bissau	62	Rwanda
3	Angola	33	Guyana	63	Samoa
4	Bangladesh	34	Haiti	64	Sao Tomé & Príncipe
5	Belize	35	Honduras	65	Senegal
6	Benin	36	India	66	Sierra Leone
7	Bhutan	37	Indonesia	67	Solomon Is
8	Bolivia	38	Iran	68	Somalia
9	Botswana	39	Kenya	69	South Africa
10	Burkina Faso	40	Kiribati	70	South Sudan
11	Burundi	41	Kyrgyzstan	71	Sri Lanka
12	Cambodia	42	Lao People's DR	72	Sudan
13	Cameroon	43	Lesotho	73	Swaziland / Eswatini
14	Cape Verde	44	Liberia	74	Syrian Arab Rep
15	Central African Republic	45	Madagascar	75	Tajikistan
16	Chad	46	Malawi	76	Tanzania
17	Comoros	47	Mali	77	Timor-Leste
18	Congo Brazzaville	48	Mauritania	78	Togo
19	Cote d'Ivoire	49	Micronesia	79	Tunisia
20	Djibouti	50	Mongolia	80	Uganda
21	DR of Korea	51	Morocco	81	Ukraine
22	DRC	52	Mozambique	82	Uzbekistan
23	Egypt	53	Myanmar	83	Vanuatu
24	El Salvador	54	Namibia	84	Vietnam
25	Equatorial Guinea	55	Nepal	85	West Bank/Gaza
26	Eritrea	56	Nicaragua	86	Yemen
27	Ethiopia	57	Niger	87	Zambia
28	Gabon	58	Nigeria	88	Zimbabwe

29	Gambia	59	Pakistan		
30	Ghana	60	Papua New Guinea		

SCHEDULE 3

FORM OF SUBLICENSE

LICENSE AGREEMENT

THIS LICENSE AGREEMENT (this “**Agreement**”) is made as of _____ (the “**Effective Date**”) by and between **THE MEDICINES PATENT POOL FOUNDATION**, a non-profit foundation registered under the laws of Switzerland, and having a principal place of business at Rue de Varembé 7, CH-1202 Geneva (the “**Licensor**”); and [**NAME OF SUBLICENSEE**], a company incorporated under the laws of [*Licensee country of incorporation*] and having its registered office at [*Licensee address*] (the “**Licensee**”), with Licensor and Licensee each individually referred to as a “**Party**” and collectively referred to as the “**Parties**”.

WITNESSETH THAT:

WHEREAS the Licensor has been granted by Ferring (as defined below) the right to sublicense the Licensed Patents and Licensed Know-How solely for the sale and development of the Licensed Product and solely for use in the Field in the Territory (as these terms are defined below);

WHEREAS the Licensee desires to obtain a license from the Licensor to use the aforesaid Licensed Patents and Licensed Know-How and the Licensor is willing to grant to the Licensee such a license in accordance with the terms and subject to the conditions of this Agreement;

WHEREAS the intent of this Agreement is to provide access to the Licensed Patents and Licensed Know-How (and therefore facilitate access to the Licensed Product for patients in resource-limited jurisdictions), and not to create any non-patent-related barriers where Licensed Patents (as defined below) do not exist; and

NOW THEREFORE in consideration of the covenants and obligations expressed in this Agreement, and intending to be legally bound, the Parties agree as follows:

1 DEFINITIONS

- 1.1 “**Affiliate**” shall mean any corporation, firm, partnership or other entity which is directly or indirectly controlled by, in control of, or under common control with such entity. For the purposes of this definition, “**control**” shall mean the ability of any corporation, firm, partnership or other entity, whether through ownership of shares or otherwise, to influence or direct the affairs of a party in accordance with the wishes of such corporation, firm, partnership or other entity.
- 1.2 “**Adverse Event**” shall mean any untoward medical occurrence in a patient or clinical trial subject administered a Licensed Product and which does not necessarily have a causal relationship with this treatment. An Adverse Event can therefore be any unfavourable and unintended sign (e.g. an abnormal laboratory finding), symptom or disease temporally associated with the use of a Licensed Product. For a marketed Licensed Product, this can also include lack of efficacy, and adverse events associated with circumstances of overdose, medication errors, abuse or misuse. In addition to the foregoing, in the context of clinical trials an Adverse Event will also mean events associated with and/or possibly attributable to the clinical trial protocol design or clinical trial procedures.
- 1.3 “**Agreement Quarter**” shall mean any period of three months ending on the last day

of March or June or September or December.

- 1.4 “**Approval Date**” shall mean the date on which the Licensed Product first receives the relevant regulatory approval(s) in a Target Country within the Territory by a Relevant Regulatory Authority.
- 1.5 “**Approved Public Market Procurement**” shall have the meaning given to it in Section 2.3.
- 1.6 “**Business Day**” shall mean a day (other than a Saturday or Sunday) on which the banks are open for normal business in Switzerland.
- 1.7 “**Confidential Information**” shall mean any and all confidential or proprietary information regarding a party or its business, including, without limitation, all products, patents, trademarks, copyrights, trade secrets, processes, techniques, scientific information, computer programs, databases, software, services, research, development, inventions, financial, purchasing, accounting, marketing, fundraising and other information, whenever conceived, originated, discovered or developed, concerning any aspect of its business, whether or not in written or tangible form.
- 1.8 “**Effective Date**” shall mean the last date of signature of this Agreement.
- 1.9 “**Event of Force Majeure**” shall have the meaning given in Section 15.
- 1.10 “**Exploit**” shall mean to research, develop, make, have made, offer for sale, sell, have sold, import, export or otherwise exploit, or transfer possession of a product.
- 1.11 “**Ferring**” shall mean Ferring International Center S.A. and/or its Affiliates, as the context admits.
- 1.12 “**Field**” shall mean the use of the Licensed Product for the prevention and treatment of post-partum haemorrhage(ing) (“**PPH**”).
- 1.13 “**Good Distribution Practice**” or “**GDP**” shall mean all applicable then-current good distribution practice standards that promote the safety and integrity of the pharmaceutical supply chain, or in any similar set of laws, regulations, rules, or practices that are applicable in countries where development activities are or will be carried out under this Agreement or in parts of the Territory in which the Licensed Product will be sold, including WHO’s good storage and distribution practices for medical products.
- 1.14 “**Good Manufacturing Practice**” or “**GMP**” shall mean all applicable then-current principles and guidelines of good manufacturing practice for medicinal products for human use as set forth in the laws, regulations, rules, or practices that are applicable in countries where the Licensed Product is or will be manufactured under this Agreement or areas of the Territory in which the Licensed Products are or will be sold, including WHO’s good manufacturing practices for pharmaceutical products..
- 1.15 “**Head License**” shall mean the Licensor’s agreement with Ferring dated [INSERT DATE] (as subsequently amended and restated) under which its right to license the Licensed Patents and Licensed Know-How is derived.
- 1.16 “**Improvement**” shall mean any new or improved process, any new or improved manufacturing techniques, or any further invention which relate to the manufacture or

formulation of the Licensed Product or incorporate or are based on the Licensed Patents and/or the Licensed Know-How.

- 1.17 “**Improvement Patents**” shall mean any patents or patent applications which generically or specifically claim any Improvements which are developed by the Licensee, or to which the Licensee otherwise has the right to grant licenses, now or in the future.
- 1.18 “**Know-How**” shall mean any and all confidential and proprietary information and materials, discoveries, processes, protocols, formulas, molecular constructs, reagents, assays, improvements, compositions of matter (including compounds), formulations, and findings, techniques, technology, trade secrets, inventions, methods, know-how, data and results (including pharmacological, toxicological and clinical data and results), analytical and quality control data and results, regulatory documents, and other information, in each case, patentable or otherwise, and including any copyrights therein.
- 1.19 “**Licensee Trademarks**” shall have the meaning given in Section 9.1.
- 1.20 “**Licensed Know-How**” shall mean all Know-How that (a) is owned or controlled by Ferring and/or its Affiliates as of the Effective Date and (b) is reasonably necessary in the development or manufacture of the Licensed Product as reasonably determined by Ferring.
- 1.21 “**Licensed Patent(s)**” shall mean those patents and patent applications (as set forth in Appendix B) covering the Licensed Product, and any additions, divisions, continuation, continuation-in-part, substitutions, and reissues claiming priority thereto, as well as any re-examinations, extensions, registrations, patent term extensions, supplemental protection certificates, renewals and the like with respect to any of the foregoing and foreign equivalents thereof.
- 1.22 “**Licensed Product**” shall mean a pharmaceutical product containing the ICH zone IV stable formulation of 100mcg/mL carbetocin for intramuscular administration, packaged in ampoules.
- 1.23 “**Net Sales Value**” shall mean gross sale price charged by the Licensee (or any person acting on its behalf) to its customers multiplied by the number of units sold less value of the sales taxes, returned/rejected Licensed Product, clearing and forwarding, freight and insurance charges.
- 1.24 “**OFAC**” shall have the meaning given in the definition of “Sanctions Target” in this Agreement.
- 1.25 “**Private Sector**” shall mean any entity, sector or market that is not the Public Sector.
- 1.26 “**Public Sector**” shall mean a government, or a department or agency thereof, or a non-profit non-governmental organization or other entity recognized by the government, procuring and/or distributing reproductive health products for and/or in the Target Countries, including WHO and any other organization within the United Nations system.
- 1.27 “**Relevant Regulatory Authority**” shall mean, in relation to a particular Target Country in the Territory, the local regulatory authority having jurisdiction over the

manufacture and/or commercialisation of the Licensed Product in that Target Country.

- 1.28 **“Reporting Guidance”** shall mean the guidance on reporting as required in Sections 3.7 and 10.2 of this Agreement on, inter alia, development timelines, regulatory activities, manufacturing and sales of Licensed Product, that will be issued by Licensor to Licensee, and as may be amended from time to time.
- 1.29 **“Sanctions”** shall have the meaning given in the definition of “Sanctions Target”.
- 1.30 **“Sanctions Authorities”** shall have the meaning given in the definition of “Sanctions Target”.
- 1.31 **“Sanctions Target”** shall mean an individual or entity that is, or is owned or controlled by, an individual or entity which is: (i) the target of any sanctions administered or enforced by the U.S. Department of Treasury’s Office of foreign Assets Control (“OFAC”), Her Majesty’s Treasury, the United Nations Security Council, the European Union or other relevant sanctions authority (together, the “Sanctions Authorities”) (collectively “Sanctions”); or (ii) located, organized or resident in a country or territory that is the target of country-wide or territory-wide Sanctions (which, at the date of this License, includes without limitation Cuba, Iran, Dem. Rep. Korea, Sudan and Syrian Arab Republic) or (iii) listed on OFAC’s List of Specially Designated Nationals and Blocked Persons or any equivalent list of parties designated by the European Union, or the United Kingdom.
- 1.32 **“Stringent Regulatory Authority”** means any of the regulatory agencies which is: (a) a member of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH), being the European Commission, the US Food and Drug Administration and the Ministry of Health, Labour and Welfare of Japan also represented by the Pharmaceuticals and Medical Devices Agency (as before 23 October 2015); or (b) an ICH observer, being the European Free Trade Association, as represented by Swissmedic, and Health Canada (as before 23 October 2015); or (c) a regulatory authority associated with an ICH member through a legally-binding, mutual recognition agreement, including Australia, Iceland, Liechtenstein and Norway (as before 23 October 2015).
- 1.33 **“Target Countries”** shall mean:
- (1) low-income and lower middle-income countries; and
 - (2) upper middle-income countries, if and to the extent such upper middle-income countries have an elevated incidence of maternal mortality, defined as being greater than 140 per 100,000 live births, and such countries fulfil one of the following additional criteria:
 - (i) capability to maintain cold chain is an issue; or
 - (ii) the normal commercial price for HSC would constitute an impediment to access in the Public Sector; and
 - (3) as identified in Appendix A hereto (it being understood that low income, lower-middle income and upper-middle income countries will be determined based on then-current World Bank classifications during the Term of this Agreement).
- 1.34 **“Term”** shall have the meaning given in Section 12.
- 1.35 **“Territory”** shall mean the Public Sector of the Target Countries set forth in Appendix A.

- 1.36 “**Third-Party(ies)**” shall mean any party other than a Party to this Agreement.
- 1.37 “**Trade Dress Guidance**” shall mean guidance on trade dress, elaborating the requirements in Sections 7 and 9 of this Agreement, issued by the Licensor and Ferring, as amended from time to time.
- 1.38 “**WHO**” means the World Health Organization.
- 1.39 “**WHO Expert Review Panel**” means the independent advisory body of technical experts coordinated by WHO to assess the quality risks associated with the use of finished pharmaceutical products that are neither WHO-prequalified nor have been approved by a Stringent Regulatory Authority, wherein such assessment results are used to inform procurement decisions relating to (time-limited) procurement of the assessed finished pharmaceutical products.
- 1.40 “**WIPO Mediation Rules**” means the mediation rules adopted by the World Intellectual Property Organization from time to time.
- 1.41 References to “this Agreement” shall mean this license agreement and shall include the Appendices.
- 1.42 References to “Sections” and “Appendices” are references to sections and appendices of and to this Agreement and references to sub-sections or paragraphs are, unless otherwise stated, references to sub-sections or paragraphs of the Sections or Appendices in which the reference appears.
- 1.43 Unless the context otherwise requires, the singular shall include the plural and vice versa and the masculine includes the feminine and neuter genders and vice versa.
- 1.44 The headings and sub-headings used in this Agreement are for convenience only and shall not affect the construction or the interpretation of this Agreement.

2 GRANT OF LICENSE

- 2.1 Subject to the terms and conditions of this Agreement and to the extent to which the Licensor has the right to grant a license in respect of the Licensed Patents and the Licensed Know-How, the Licensor hereby grants to the Licensee a non-exclusive, non-sublicensable, non-transferable, royalty-free license under the Licensed Patents and Licensed Know-How solely to Exploit the Licensed Product and solely for use in the Field in the Territory.
- 2.2 Notwithstanding anything contained in this Agreement, nothing in this Agreement shall be construed to prevent the Licensee from engaging in any activities that would not infringe a Licensed Patent granted and in force, including, without limitation, where a country has issued a compulsory license on a Licensed Patent.
- 2.3 The Licensee shall only supply Licensed Product pursuant to and in accordance with this Agreement for use in the Territory and pursuant to a procurement process of any Public Sector entity in or for the benefit of the Target Countries, only if the supply contemplated by that procurement is approved in writing by the Licensor, with such approval to be provided no later than five (5) Business Days after receipt of the request for approval, unless the Licensor has expressly indicated that approval is not granted (an “**Approved Public Market Procurement**”).
- 2.4 Other than as set forth in Section 2.1, no rights are granted to the Licensee under this

Agreement to Exploit the Licensed Product inside or outside the Target Countries. Notwithstanding any other provision of this Sublicense Agreement, Ferring and MPP make no representation or warranty of non-infringement or any representation or warranty that the Licensed Patent Rights or Licensed Know-How is suitable for any purpose for which it may be used by the Licensee.

- 2.5 The Licensee's license to have manufactured by a Third-Party, Licensed Product in accordance with Section 2.1 shall be limited solely to manufacture on behalf of the Licensee of Licensed Product for supply to the Licensee. Section 2.1 shall not be construed as conferring any right for a Third-Party to manufacture Licensed Product for supply to any party other than the Licensee (as applicable). Such Third-Party manufacturer must be approved in writing by the Licensor prior to engaging in any development or manufacturing activities on behalf of Licensee.
- 2.6 For the avoidance of doubt, this Agreement confers no rights on the Licensee to sublicense its rights hereunder, which is expressly prohibited. The Licensee shall procure that any Third-Party manufacturer shall comply with the terms of this Agreement as if it was the Licensee, and the Licensee shall remain fully liable for the acts or omissions of such Third-Party manufacturer.
- 2.7 The Licensee shall, acting in compliance with this Agreement and all applicable laws and regulations, use its best endeavours to maximize access to the Licensed Product for use in the Field in the Territory.
- 2.8 It is expressly acknowledged by the Licensee that this Agreement confers no intellectual property rights whatsoever on the Licensee other than those expressly granted in Section 2.1 for the Term of this Agreement. Without prejudice to the generality of the foregoing, other than as expressly granted in Section 2.1, no license is granted to the Licensee:
 - (a) to perform any acts or omissions which infringe any rights (including, but not limited to, patent and/or intellectual property rights) of the Licensor, Ferring and/or any of their Affiliates and/or their sublicensees within or outside the Target Countries;
 - (b) to perform any acts or omissions which infringe any rights of any Third-Party (including, without limitation, Ferring) within or outside the Target Countries; or
 - (c) in relation to the Licensed Patents and Licensed Know-How, to Exploit the Licensed Product where such Licensed Product would be supplied directly or indirectly to (i) the Private Sector within or outside the Target Countries or (ii) the Public Sector outside the Target Countries, or (iii) for use outside the Field within our outside the Territory and/or for any indication or patient population other than as set forth on the Licensed Product's approved label.
- 2.9 Nothing in this Agreement shall be deemed to constitute a license for the Licensee to manufacture, import, use or supply any active ingredient other than those identified in the Licensed Know-How.
- 2.10 Notwithstanding the Effective Date of this Agreement, the Licensee undertakes not to sell or offer for sale a Licensed Product in a Target Country in the Territory prior to (i) the relevant Approval Date for that Licensed Product for that Target Country and (ii) WHO prequalification or approval by a Stringent Regulatory Authority (or, as a

provisional measure, the review of the Licensed Product by a WHO Expert Review Panel and a notification of no-objection from that WHO Expert Review Panel for time-limited use of the Licensed Product).

- 2.11 Where this Agreement requires the Licensee to obtain approval from Ferring, the Licensee shall request such approval through the Licensor.

3 COMMERCIALISATION AND REGISTRATION

- 3.1 As of the Effective Date and subject always to Ferring's retained rights to the Licensed Patents and Licensed Know-How (and that of its licensees), the Licensee shall have full control, responsibility (financial and otherwise) and authority over development, registration, importation, manufacture and commercialisation of the Licensed Product to be sold or supplied by the Licensee in the Territory under this Agreement.
- 3.2 Upon the Licensee's written request to Licensor and submission of relevant access information requested by Licensor, Ferring shall make available to Licensee, on a confidential basis, a discrete data package related to the Licensed Know-How. Ferring shall not be required to provide any technical support or technical assistance to the Licensee for any reason.
- 3.3 Licensee agrees that it will manufacture and distribute the Licensed Product in a manner consistent with the following standards as applicable: (i) WHO pre-qualification standards or the standards of any Stringent Regulatory Authority (unless, as a provisional measure, the Licensed Product has been reviewed by a WHO Expert Review Panel and a notification of no-objection has been issued from that WHO Expert Review Panel for time-limited use of the Licensed Product); and (ii) GMP and GDP.
- 3.4 The Licensee will obtain from the relevant authorities in the Target Countries and maintain in force, as appropriate, all health registrations, permissions, consents and regulatory authorizations relating to the importation, manufacture and sale of the Licensed Product which are necessary to enable the Licensed Product to be sold or supplied in the Territory in accordance with this Agreement.
- 3.5 Licensee shall file for (i) regulatory approval of the Licensed Product before at least one Relevant Regulatory Authority or (ii) WHO pre-qualification of the Licensed Product or approval by a Stringent Regulatory Authority no later than thirty-six (36) months from the Effective Date.
- 3.6 If the Licensee sells, supplies or otherwise disposes of any Licensed Product in the Target Countries but has not obtained: (i) the necessary approvals from the Relevant Regulatory Authority and (ii) WHO pre-qualification or approval by a Stringent Regulatory Authority (or, as a provisional measure, a notification of no-objection has not been issued by a WHO Expert Review Panel for time-limited use of the Licensed Product), the Licensor shall be entitled to immediately terminate this Agreement by providing written notice to the Licensee.
- 3.7 Within ten (10) Business Days following the end of each Agreement Quarter, the Licensee shall provide the Licensor with a quarterly written report on the status of development of, and any planned, as well as any filed and/or obtained, regulatory filing, and/or submissions for WHO prequalification and/or WHO Expert Review Panel review regarding the Licensed Product in relation to that Agreement Quarter. Such reporting shall be made in accordance with the Reporting Guidance issued by the Licensor and should cover (a) status of development of the Licensed Product, (b) regulatory filing plan for the Licensed Product, and (c) a list of countries for which such

regulatory approvals or authorizations have been filed and/or obtained for the Licensed Product. The Parties agree to confer on a quarterly basis regarding such reports and also review development and filing status of the Licensed Product. Licensor shall provide Ferring with a copy of the reports produced pursuant to this Section 3.7 in accordance with the Head License. For avoidance of doubt, Ferring and the Licensor agree that information contained in quarterly and other such reports shall be treated as Confidential Information.

- 3.8 If upon review of a Licensee's regulatory filing plan (per Section 3.7), Ferring reasonably determines that such regulatory filing plan prejudices or could prejudice Ferring's contractual obligations to register and supply Ferring's ICH zone IV stable carbetocin product in the Territory, Ferring shall, no later than thirty (30) Business Days of receiving such report from Licensor, provide written notification to Licensor, including any reasonable requests for modification to such regulatory filing plan. Licensor shall in turn, provide written notice of such request for modification to Licensee no later than thirty (30) Business Days of receiving such request for modification from Ferring, to ensure that the requested modifications are promptly implemented by Licensee. Upon receipt, Licensee agrees to make the requested modifications to its regulatory filing plans and shall send an updated regulatory filing plan to Licensor for Ferring's review and approval. Such approval shall be deemed provided if Ferring does not provide its disapproval of the submitted updated regulatory filing plan to Licensor within thirty (30) Business Days of its receipt from Licensor.
- 3.9 The Licensee will manufacture and sell the Licensed Product in accordance with all laws and regulations relevant to the manufacture and sale of the Licensed Product for use in the Field in the Territory and in accordance with good industry practice.

4 SUPPLY, DISTRIBUTION AND LABELLING

- 4.1 The Licensee shall be solely responsible for providing its own clinical, promotional and commercial infrastructure to support the manufacture and sale of the Licensed Product in the Territory. The Licensee agrees, where applicable and to the extent that it is able: (a) to not seek; and (b) to waive, regulatory exclusivity in the Target Countries in relation to any data relating to the Licensed Product.
- 4.2 The Licensee shall be solely responsible for the distribution of all Licensed Product to be sold in the Territory under this Agreement.

5 EXCHANGE OF INFORMATION AND CONFIDENTIALITY

- 5.1 Any Confidential Information disclosed by a Party, or Ferring and/or Ferring's Affiliates (the "**Disclosing Party**") to the other Party, or Ferring and/or Ferring's Affiliates (the "**Receiving Party**") in connection with this Agreement shall be used solely and exclusively by the Receiving Party in a manner consistent with the rights granted hereunder and for the purposes of this Agreement; shall be maintained in strict confidence by the Receiving Party; and shall not be further used, relied upon or disclosed to a Third-Party without the prior written consent of the Disclosing Party. Notwithstanding the foregoing, the Receiving Party may disclose such Confidential Information to its employees and Third-Parties who are bound by confidentiality obligations no less restrictive than those set forth herein and need to know such Confidential Information solely to perform the Receiving Party's obligations and/or exercise the Receiving Party's rights under or in connection with this Agreement. This confidentiality obligation shall not apply to such information which:
- (a) the Receiving Party can prove, by written records and to the reasonable satisfaction of the Disclosing Party, is or has become a matter of public knowledge other than through any breach by or at the instigation of the

Receiving Party, or any of its Affiliates, of this Agreement;

- (b) is already legitimately in the possession of the Receiving Party;
 - (c) is disclosed to the Receiving Party by a Third-Party (other than Ferring and/or its Affiliates) having the right to do so;
 - (d) is subsequently and independently developed by employees of the Receiving Party or its Affiliates who had no knowledge of the Confidential Information disclosed; or
 - (e) in the case of the Licensor, is required to be disclosed to Ferring under the terms of the Head License.
- 5.2 The Parties shall ensure that no unauthorized use or disclosure is made by others to whom access to such Confidential Information is granted, by binding such persons on like terms to this Agreement which are enforceable by each of the Licensor and Ferring.
- 5.3 All Confidential Information shall remain the property of the Disclosing Party. In the event that a court or other legal or administrative tribunal of competent jurisdiction, directly or through an appointed master, trustee or receiver, assumes partial or complete control over the assets of a Party to this Agreement, based on the insolvency or bankruptcy of such Party (or based on any other analogous or similar status of that party under foreign laws), the bankrupt or insolvent Party shall promptly notify the court or other tribunal:
- (a) that Confidential Information remains the property of the Disclosing Party; and
 - (b) of the confidentiality obligations under this Agreement.
- 5.4 In addition, the bankrupt or insolvent Party shall, to the extent permitted by law, take all steps necessary or desirable to maintain the confidentiality of such Confidential Information and to ensure that the court, other tribunal or appointee maintains such information in confidence in accordance with the terms of this Agreement.
- 5.5 Prior to submitting for written or oral publication any manuscript, abstract or the like which includes data or other information generated and provided under the terms of (including but not limited to Licensed Know-How), or in relation to, this Agreement or relating to Licensed Product, the Licensee shall provide a copy of such intended publication to Ferring and give Ferring at least thirty (30) days to review the proposed submission and provide its comments to the submission. Licensee shall take into account Ferring's reasonable comments in connection therewith and delete any Ferring Confidential Information before proceeding to publication.
- 5.6 Nothing in this Agreement shall be construed as preventing or in any way inhibiting the Receiving Party from complying with statutory and regulatory requirements relating to, or arising out of, its rights and obligations under this Agreement if in the reasonable opinion of the Receiving Party's counsel, such disclosure is necessary for such compliance; provided however that such Receiving Party notifies the Disclosing Party of the requested disclosure within sufficient time to enable the Disclosing Party to seek an appropriate protective order or other remedy with respect to narrowing the scope of such required disclosure.
- 5.7 Within thirty (30) days after any expiration or termination of this Agreement, Receiving Party shall destroy (and certify to the Disclosing Party such destruction)

or return all Confidential Information provided by the Disclosing Party except as otherwise set forth in this Agreement. One copy of the Disclosing Party's Confidential Information may be retained in the Receiving Party's files solely for archival purposes as a means of determining any continuing or surviving obligations under this Agreement. The confidentiality obligations under this Agreement shall survive the termination or expiration of this Agreement.

6 ADVERSE EXPERIENCE REPORTING

6.1 The responsibilities of the Parties for reporting of adverse drug experiences related to the Licensed Product to regulatory authorities in the Target Countries shall be performed in accordance with local laws and regulations. The responsibilities of the Parties for safety related or Licensed Product related inquiries shall be performed in accordance with local laws and regulations.

6.2 Without prejudice to Section 6.1:

- (a) Licensee undertakes that it will maintain until the termination or expiration of this Agreement (or, as applicable, until the rights and obligations intended to survive termination of this Agreement have been fulfilled), pharmacovigilance and risk management systems, procedures and documentation needed to perform and comply with its regulatory obligations and its related obligations under this Agreement.
- (b) Licensee undertakes that it will ensure that it will comply with all applicable laws and regulations regarding the Licensed Product in the Target Countries including without limitation those laws and regulations relating to risk management, drug safety and pharmacovigilance.
- (c) Licensee will hold and maintain a safety database regarding the Licensed Product sold in the Territory.
- (d) Licensee will be responsible for fulfilling all pharmacovigilance activities in accordance with the local regulations and requirements for the Licensed Product in the Target Countries (this includes but is not limited to collating Adverse Events and expedited and periodic reporting to regulatory agencies in the Target Countries, literature review, performing safety evaluation and signal detection on all available Adverse Events, etc.).
- (e) Licensee shall provide Licensor and Ferring with a report containing information regarding Adverse Events which are associated with the Licensed Product, and which have been received by Licensee, from both spontaneous reporting and clinical trial sources. Such report shall be provided annually and otherwise on reasonable request by the Licensor and/or Ferring.
- (f) Licensee shall notify the Licensor and Ferring forthwith of the receipt of an enquiry from a regulatory authority in the Target Countries relating to the Licensed Product that concerns any safety issue. If Licensee becomes aware of action that may or will be or has been taken by a regulatory authority for a safety reason connected with the Licensed Product, it shall immediately and in any event no later than twenty-four (24) hours after receiving such notice from a regulatory authority notify Licensor and Ferring in writing (including, but not limited to email communications) with available details regarding the same.
- (g) Notwithstanding Section 19, notices to be provided pursuant to this Section 6

shall, in addition, also be sent to:

FERRING Pharmaceuticals A/S
Department: Global Pharmacovigilance
Address: Amager Strandvej 405, 2770 Kastrup, Denmark
E-Mail: DK0-PV-COBS@ferring.com

or such person as shall be nominated by Ferring in writing from time to time.

7 NON-DIVERSION

7.1 Save as provided under this Agreement, and to the extent that such restrictions comply with applicable law, the Licensee shall not, directly or indirectly, sell or supply Licensed Product outside the Territory, or sell or supply Licensed Product to any Third-Party that the Licensee knows, believes or ought reasonably to suspect will sell or supply Licensed Product outside the Territory.

7.2 The Licensee shall ensure that packaging (whether external, intermediate or internal), data sheets and promotional materials for the Licensed Product to be sold or otherwise supplied by the Licensee under this Agreement shall carry clear statements in bold type that:

- (a) the Licensed Product has been manufactured under a license from the Licensor; and
- (b) any other statements stipulated in the Trade Dress Guidance.

These obligations are further elaborated in the Trade Dress Guidance.

7.3 The Licensee agrees that any Licensed Product sold pursuant to this Agreement will be visually differentiated from any ICH zone IV stable carbetocin product or other product sold by Ferring in a manner further elaborated under the Trade Dress Guidance. Licensee will submit trade dress documents required by the Trade Dress Guidance to Licensor (through the designated trade dress portal of the Licensor) for the Licensor's and Ferring's approval. Licensee agrees not to manufacture batches of Licensed Product or to sell Licensed Product pursuant to this Agreement until the Licensor and Ferring have approved the brand name, packaging and presentation of the trial batches, such approval will not be unreasonably withheld, delayed or conditioned. Once Licensor and Ferring have approved the brand name, packaging and presentation of the trial batches (i) the Licensor agrees not to make any additional requests for differentiation (except as provided in Section 7.4 below), and (ii) the Licensee agrees only to sell Licensed Product that conforms to the brand name, packaging and presentation of the trial batch approved by the Licensor and Ferring pursuant to this Section 7.3.

7.4 Without prejudice to Section 7.3, Licensee agrees to comply with such additional requirements for differentiation of the packaging of Licensed Product as Ferring may reasonably request and agrees to use its reasonable endeavours to ensure timely registration of the variation with all Relevant Regulatory Authorities as they may require.

7.5 The Licensee shall give written notice, of the restrictions contained in this Section 7 to any Third-Party to which it sells the Licensed Product, prior to any sale of the Licensed Product to such Third-Party, and the Licensee shall use its best endeavours, without prejudice to any other provision of this Agreement, to ensure that such Third-Party(ies) will undertake to abide by the restrictions contained in this Section 7 and will assist

the Licensor and Ferring in securing compliance with this Section 7 and the restrictions which it contemplates.

8 INTELLECTUAL PROPERTY

- 8.1 If at any time during the term of this Agreement the Licensee and/or its Affiliates (or any of their employees, agents, or other persons acting under its authority) makes, develops, conceives, acquires, reduces to practice, becomes entitled to or secures control over any Improvement it shall communicate such Improvement to Licensor and Ferring in full together with all available information concerning the mode of working and using the same. Licensor and Ferring shall treat this information as Confidential Information.
- 8.2 Licensee hereby grants to Licensor and Ferring a perpetual, irrevocable, worldwide, royalty free, non-exclusive license to use any Improvement, Improvement Patent and related know-how (and shall promptly execute such document as Ferring may reasonably request accordingly). Licensor shall not sub-license such rights to any Third-Party, provided, however, that should Licensor desire to sub-license any such rights, Licensee and Licensor agree to enter into good-faith negotiations regarding such sub-license. Ferring shall be entitled to grant sub-licenses (without further right to sub-license) under such license only to its Affiliates and/or contract manufacturers, distributors and service providers solely for use in connection with their engagement of commercialising Ferring products.
- 8.3 In the event that Licensee develops a new formulation of the Licensed Product, Licensee will grant to Ferring an option and right of first refusal to negotiate further mechanisms to make the new formulation available in countries outside the Target Countries, including but not limited to licensing or purchase of such new formulations by Ferring.
- 8.4 The Licensee shall have no rights in relation to the conduct of any matter relating to the Licensed Patents, including the filing, prosecution and maintenance thereof.
- 8.5 If any suit or claim by a Third-Party is instituted against the Licensor or the Licensee for patent infringement involving the Licensed Product, the Party sued shall promptly notify the other Party and Ferring in writing. Ferring shall have the right, but not the obligation, to defend or to conduct its defence of such suit or claim at its own expense. The Licensee shall assist Ferring and co-operate in any such litigation at Ferring's request and expense.
- 8.6 Ferring (and in no circumstances the Licensee) shall be entitled to bring infringement action against a Third-Party at its own expense. To the extent Ferring decides not to bring any such infringement action, Ferring shall not be liable to the Licensee in any respect for such decision. The Licensee shall assist Ferring and co-operate in any such litigation at Ferring's request without expense to the Licensee.

9 TRADEMARKS AND NON-PROPRIETARY NAMES

- 9.1 Subject always to Sections 9.2 and 9.3, the Licensee, at its expense, shall be responsible for the selection, registration and maintenance of all trademarks which it employs in connection with the Licensed Product ("**Licensee Trademarks**") to be sold by the Licensee in the Territory under this Agreement and shall own and control the Licensee Trademarks. Nothing in this Agreement shall be construed as a grant of rights, by license or otherwise, to the Licensor to use or register the Licensee Trademarks for any purpose. Further, nothing in this Agreement shall be construed as a grant of rights, by license or otherwise, to the Licensee to use or register any trademark service mark, trade dress, symbol, device, company name or domain name which is identical with or

confusingly similar to any trademark, trade dress, symbol, device, company name or domain name which is used or registered by the Licensor, Ferring, and/or any of their Affiliates anywhere in the world for any purpose.

- 9.2 The Licensee shall not use or seek to register (or, where it is possible to do so, apply to use or register) any trademark, service mark, trade dress (where applicable), symbol, device, company name or domain name in relation to any Licensed Product or any of their packaging (whether external, intermediate or internal) or promotional material which incorporates or is identical with or confusingly similar to any trademark, service mark, trade dress, symbol, device, company name or domain name used or registered by the Licensor, Ferring and/or any of their Affiliates anywhere in the world. This Section shall be without prejudice to any legal rights the Licensee may have in relation to the use of a trademark, service mark, trade dress, symbol, device, company name or domain name which is identical with or confusingly similar to any trademark, service mark, trade dress, symbol, device, company name or domain name used by the Licensor, Ferring and/or any of their Affiliates anywhere in the world where that use by the Licensee would not infringe the rights of the Licensor, Ferring and/or any of their Affiliates. If the Licensor and/or Ferring become aware that the Licensee is in breach of this Section 9.2, the Licensee shall immediately stop any such use and withdraw any such trademark application and/or registration upon request by the Licensor and/or Ferring.
- 9.3 The Licensee shall obtain the prior written approval in accordance with the procedures set out in the Trade Dress Guidance, such approval not to be unreasonably withheld or conditioned, of the Licensor and Ferring for all trademark, service mark, trade dress (where applicable), symbols, devices, company names or domain names which the Licensee proposes to use in relation to the Licensed Product or any of their packaging (whether external, intermediate or internal) or promotional material before seeking to register any such trademarks, before offering to sell, selling or otherwise disposing of any Licensed Product, and before applying for government or relevant regulatory authorization to do so. The Licensor and Ferring shall respond to any request for approval from the Licensee within thirty (30) days of receipt by Ferring (from the Licensor) of all the relevant documentation necessary to consider the Licensee's request, with an approval or a written statement of why the request is not being approved by Ferring. For the avoidance of doubt, the Trade Dress Guidance does not limit in any way the Licensor and/or Ferring's right to refuse to provide approval under this Section 9.3, and the basis of Ferring's refusal to provide approval under this Section 9.3 shall not be limited to breaches of Section 9.2.
- 9.4 For the avoidance of doubt, any approval provided by the Licensor and/or Ferring under Section 9.3 is not to be interpreted as acquiescence by the Licensor and/or Ferring that any packaging and/or labelling complies with any local legal or regulatory requirements, which remains the Licensee's responsibility.
- 9.5 If Licensee wishes to use the Ferring name (or use of the Ferring name is required by a local regulatory authority or for any other reason) on packaging or in promotional materials, a request for prior written approval will be made through the Trade Dress Guidance submission process in accordance with Section 9.3.

10 STATEMENTS AND REMITTANCES

- 10.1 At all times the Licensee shall, to the extent permitted by law, keep, and shall require its Affiliates and any Third-Party manufacturers and Third-Parties making sales on its behalf, to keep complete and accurate records for at least seven (7) years of all quantities of the Licensed Product manufactured and/or sold under the licenses granted by this Agreement, together with that information contemplated by Section 10.2. The

Licensor and Ferring shall each have the right (and the Licensee shall procure such right), at its expense, through a certified public accountant or like person appointed by it, to examine such records during regular business hours during the Term of this Agreement and for one (1) year after its termination or expiry; provided, however, that such examination shall not take place more often than twice in any calendar year and shall not cover such records for more than the preceding two (2) calendar years and provided further that such accountant or like person shall report to Ferring only as to:

- (a) the accuracy of the manufacturing and sales of the Licensee (and/or its Affiliates and/or its Third-Party manufacturers contemplated by this Agreement) in relation to such manufacture and sales;
- (b) the appropriateness of quantities of Licensed Product imported, exported or manufactured pursuant to this Agreement by reference to what quantities of Licensed Product would reasonably be required to meet demand for actual sales made and sales forecasted by the Licensee;
- (c) verification that all sales and other supplies of Licensed Product made by the Licensee have been made in the Territory and otherwise in accordance with Section 7; and
- (d) verification that all sales and other supplies of Licensed Product made by Third-Party manufacturers contemplated by this Agreement have been made to the Licensee in accordance with this Agreement.

10.2 Within ten (10) Business Days following the end of each Agreement Quarter, the Licensee shall provide the Licensor with a quarterly written report of all Licensed Product (in terms of smallest units and patient packs for each formulation) sold or supplied by the Licensee under this Agreement during such Agreement Quarter. Such accounting shall be made in accordance with the Reporting Guidance issued by the Licensor and show smallest unit, pack size, gross sales and Net Sales Value in US Dollars on a Product-by-Product, country-by-country, month-by-month and purchaser-by-purchaser basis. Such a statement shall include copies of the relevant Public Sector procurement documentation in relation to which Approved Public Market Procurement the relevant Licensed Product were supplied.

11 SANCTIONS

- 11.1 The Parties acknowledge that a number of organizations and countries including the United Nations, the United States, the United Kingdom and the European Union have adopted sanctions legislation relating to the Territory and/or entities and individuals which or who are resident or operate in the Territory and that such sanctions are varied or amended from time to time.
- 11.2 The Licensee represents and warrants to Licensor and Ferring that (a) neither the Licensee nor, to the knowledge of the Licensee, any Affiliate, director, officer, employee of the Licensee, is a Sanctions Target, or (b) that it has obtained a license or other authorization from OFAC and/or any other relevant Sanctions Authorities in relation to such an entity which is a Sanctions Target.
- 11.3 The Licensee represents and covenants that, prior to, directly or indirectly:
 - (a) making the Licensed Patents or any Licensed Product available to, or contracting for Licensed Product manufacture with any Sanctions Target; or

- (b) making the Licensed Patents or any Licensed Product available to a country or territory that is the target of country-wide or territory-wide Sanctions;

it will obtain a license or other authorization, either directly or through MPP, from OFAC and/or any other relevant Sanctions Authorities.

- 11.4 In the event that performance of this Agreement by either Party or the Head Licensee would (or might) in the reasonable opinion of the Licensor and/or Ferring breach any Sanctions, any applicable export control regime or other similar applicable laws of any jurisdiction (whether or not such Sanctions, controls or laws were in existence as of the Effective Date of this Agreement and whether or not there have been any other changes in circumstance from those that existed as of the Effective Date of this Agreement), the Licensor shall be entitled to suspend the operation of such provisions of the Agreement (including any payment or supply provisions) which require or permit performance by either or both Parties; provided that, in the reasonable opinion of the Licensor and/or Ferring, such performance would result in a breach of any such Sanctions, controls or laws until, in the reasonable discretion of Ferring and Licensor, such time as all necessary approvals or licenses have been obtained to enable the Agreement to continue in a lawful and compliant manner. Notwithstanding any provision of this Agreement, neither the Licensor or Ferring shall be obliged to pay any compensation to the Licensee or otherwise indemnify the Licensee in respect of any losses or costs which that the Licensee may suffer or incur as a result of such suspension and/or termination.

12 TERM AND TERMINATION

- 12.1 This Agreement shall be deemed to come into effect on the Effective Date and shall continue thereafter subject to the further provisions of this Section 12.2.
- 12.2 Unless otherwise terminated, this Agreement shall expire upon the expiration, lapse or invalidation of the last remaining Licensed Patents.
- 12.3 Save as otherwise provided in this Agreement, if the Licensee breaches any provision of this Agreement and if such breach (i) is material and incapable of correction; or (ii) is capable of correction but is not corrected within sixty (60) days after receiving written notice with respect to such default, the Licensor shall have the right to terminate this Agreement with immediate effect by giving written notice to the party in default.
- 12.4 If:
- (a) Licensor becomes aware of an actual or threatened claim that Licensee's use of the Licensed Patents in any Target Country infringes the intellectual property rights of a Third-Party; or
 - (b) Licensor receives notice from Ferring that Ferring's right to grant licenses of the Licensed Patents is challenged,

Licensor shall (and Ferring shall be entitled to) notify the Licensee in writing, detailing the nature of such claim or challenge. Licensee shall, within ten (10) Business Days of receipt of such notice, and without prejudice to any of the Licensee's other obligations or liabilities under this Agreement or the Licensor's rights (including without limitation under Section 12.5), elect to:

- (i) suspend the terms of this License in respect of the relevant Licensed Patent until such issue is resolved; or
- (ii) confirm in writing that it will indemnify Licensor and Ferring against any Losses (as defined in Section 14.5) incurred by Licensor and/or Ferring in connection with Licensee's continued use of such Licensed Patent pursuant to this License.

If Licensee does not so notify Licensor within ten (10) Business Days of Licensor's initial notice, the license shall be deemed suspended pending resolution of the issue.

12.5 The Licensor may terminate this Agreement, either in whole or in relation to a particular Licensed Patent with immediate effect by notice in writing to the Licensee if:

- (a) the Licensee breaches any of the provisions of Section 7;
- (b) it is determined that the Licensee's use of the Licensed Patents infringes the intellectual property rights of a Third-Party;
- (c) Ferring's right to grant licenses of the Licensed Patents expires or is terminated;
- (d) Ferring or Licensor receives a Third-Party claim or demand for royalty payments relating to sales of the Licensed Product by the Licensee, unless the Licensee agrees to satisfy the claim should such a claim or demand become payable;
- (e) the legal or beneficial ownership or control of the Licensee and/or any of its Affiliates changes in such a manner as Ferring shall in its sole discretion consider significant;
- (f) Licensee repeatedly fails to comply with or to timely provide Licensor with any report or statement such as those contained in Section 10.2 of this Agreement;

12.6 The provisions of Sections 12.5(a), 12.5(b) and 12.5(d) are without prejudice to the Licensor's or Ferring's rights to claim all damage and loss suffered by the Licensor, Ferring and/or any of their Affiliates arising out of, or in relation to, the event giving rise to termination. In respect of such damage or loss under Sections 12.5(a), 12.5(b) and/or 12.5(d) the Licensee hereby agrees to indemnify the Licensor and Ferring subject to the Licensor and Ferring (each of which shall be entitled to conduct the defense of such claims against them) taking reasonable account of the Licensee's input in the conduct of the claim to which such loss or damage relates. For the avoidance of doubt, the provisions of Section 27.3 apply to any dispute between the Parties, or between Ferring and the Licensee, in relation to the indemnities given under this Section 12.6.

12.7 Any Party may terminate this Agreement with immediate effect by providing a written termination notice to the other Party if, at any time, the other Party shall compound or make arrangements with its creditors or be adjudicated bankrupt or have a receiver appointed over all or any part of its assets or go into liquidation (whether voluntary or otherwise) otherwise than as part of a bona fide amalgamation or reconstruction without insolvency or suffer any insolvency event or analogous process under foreign laws.

12.8 Any change in the legal or beneficial ownership or control of the Licensee shall be immediately notified in writing to the Licensor and Ferring by the Licensee. For the

purposes of this Section 12.8, “control” shall mean the ability of a person, entity or corporation to ensure, whether through ownership of shares or otherwise, that the affairs of a party are conducted in accordance with the wishes of such person, entity or corporation.

- 12.9 If Licensee fails to file for (i) regulatory approval of the Licensed Product before at least one Relevant Regulatory Authority or (ii) WHO pre-qualification of the Licensed Product or approval by Stringent Regulatory Authority within thirty-six (36) months from the Effective Date, Licensor shall have the right to terminate this Agreement with immediate effect by giving written notice to the Licensee.
- 12.10 If, in the reasonable opinion of the Licensor, the Licensee fails to promote access to the Licensed Product for use in the Field in the Territory in accordance with this Agreement, the Licensor shall give notice to the Licensee requiring it to cure such failure. If in the opinion of the Licensor, the Licensee fails to report reasonable progress within one hundred and eighty (180) days after receiving written notice with respect to the default, the Licensor shall have the right to terminate this Agreement with immediate effect by giving written notice to the Licensee. Without limitation to the generality of this Section 12.10 in exercising its reasonable opinion, the Licensor shall take into account the period within which the Relevant Regulatory Authorities provide the necessary approvals, normal development lead time for the Licensed Product, and progress reported by Licensee in its quarterly reports provided under Section 3.7.
- 12.11 Unless notice to the contrary is given by Ferring, this Agreement shall terminate immediately in the event that the Head License is terminated or expires. This Agreement shall be converted into a license between Ferring and the Licensee, provided that Licensee is not in breach of this Agreement, this Agreement has not expired or otherwise been earlier terminated; and that Ferring has notified both the Licensor and Licensee of such conversion.
- 12.12 Licensee may terminate this Agreement at any time by providing thirty (30) days written notice to Licensor.

13 RIGHTS AND DUTIES UPON TERMINATION OR EXPIRY

- 13.1 Upon early termination of this Agreement, the Parties will cooperate with one another to provide for an orderly wind-down of the transactions contemplated in this Agreement. All rights and licenses granted by Licensor to Licensee under this Agreement shall immediately terminate as of the effective date of termination or expiration, and Licensee and its Affiliates, and any Third-Party manufacturers must immediately cease all use of Licensed Know-How and Licensed Patents and all marketing, sales, supply or distribution of the Licensed Product, except to the extent permitted in Section 13.2.
- 13.2 Upon early termination of this Agreement in accordance with Sections 12.5(e), 12.7, 12.9, 12.11 and/or 12.12, the Licensee shall immediately notify the Licensor and Ferring of the amount of Licensed Product the Licensee then has available to it and, provided that such amount is, in the opinion of Ferring, reasonable in all the circumstances, the Licensee may be permitted to sell that amount of Licensed Product for use in the Field in the Territory upon Ferring’s written approval (such approval not to be unreasonably withheld). This provision shall only apply to the extent that such termination would deprive Licensee of legal rights with respect to Licensed Product.
- 13.3 Notwithstanding anything in the foregoing, Licensee shall ensure that neither it nor its Affiliates, and/or any Third Parties acting on its behalf or in its interests sell off, supply or otherwise distribute any Licensed Product in or to i) the Private Sector of any country

within or outside the Target Countries or ii) otherwise outside the Territory upon termination or expiry of this Agreement.

- 13.4 Termination or expiry of this Agreement shall not affect those provisions of this Agreement which are expressed or intended to survive the termination or expiration of this Agreement in particular, but without limitation, Sections 5, 10, 14.5, 14.6 and 14.7 and the relevant provisions of this Section 13. In addition, any other provisions required to interpret and enforce the parties' rights and obligations under this Agreement shall also survive, but only to the extent that such survival is required for the full observation and performance of this Agreement by the Parties.
- 13.5 Termination of this Agreement in accordance with the provisions hereof shall not limit remedies which may be otherwise available in law or equity and shall be without prejudice to any rights that any person may have pursuant to this Agreement for antecedent breaches.

14 WARRANTIES AND INDEMNITIES

- 14.1 Each of the Parties warrants that, to the best of its knowledge and belief:
- (a) it has power to execute and deliver this Agreement and to perform its obligations under it and has taken all action necessary to authorise such execution and delivery and the performance of such obligations; and
 - (b) this Agreement constitutes legal, valid and binding obligations of that Party in accordance with its terms.
- 14.2 Nothing in this Agreement shall be construed as a warranty that (a) the information set out in Appendix B accurately reflects the status of Ferring's patents and patent applications relating to the Licensed Product, (b) any of the Licensed Patents are valid or enforceable or (c) their exercise does not infringe any patent rights of any Third-Parties.
- 14.3 The Licensee acknowledges that, in entering into this Agreement, the Licensee has independently evaluated any information supplied by the Licensor and Ferring (including, but not limited to, such information related to the Licensed Product), as well as the viability of this Agreement, before making its decision to enter into this Agreement and to undertake the commitments and obligations set forth herein.
- 14.4 The Licensee acknowledges that the Licensor and Ferring do not in any way endorse the use of any Licensed Product sold or manufactured by the Licensee.
- 14.5 In accordance with and in furtherance of the Letter of Indemnity to be executed by Licensee and Ferring as required under the Head License, the Licensee hereby agrees to indemnify the Licensor, Ferring, their Affiliates and their respective officers, directors, shareholders, representatives, agents, employees, successors and assigns (each an "**Indemnified Person**") against any and all suits, claims (whether or not successful, compromised or settled), actions, demands, proceedings, judgements, liabilities, expenses and/or losses, including reasonable legal expense and attorneys' fees ("**Losses**"), that arise in connection with (i) the Licensee's breach of this Agreement; or (ii) the Licensee's exercise of its rights pursuant to this Agreement (including for the avoidance of doubt any product liability claim relating to the Licensed Product manufactured by or on behalf of Licensee pursuant to this Agreement), provided that the indemnification obligation established in this Section shall not apply to the extent such Losses arise out of negligence or wilful misconduct by Ferring, its Affiliates and their respective officers, directors, shareholders,

representatives, agents, employees, successors and assigns. Ferring shall, or shall procure that the Indemnified Person shall, provide Licensee with prompt written notice of such claims. Subject to Sections 8.5 and 12.6, the Indemnified Person and Licensee will agree on the appropriate party to assume control of the defense or negotiation of settlement and will agree to make available all reasonable assistance in defending any claims.

- 14.6 Section 14.5 may be enforced, by each Indemnified Person against the Licensee.
- 14.7 Immediately upon the first administration of a Licensed Product to a human in accordance with this Agreement, and for a period of ten (10) years after the expiration or earlier termination of this Agreement, the Licensee shall obtain and/or maintain, at its sole cost and expense, product liability insurance in amounts which are reasonable and customary in the pharmaceutical industry of the countries in which the Licensed Product is manufactured, distributed and sold (as relevant), subject always to a minimum limit equivalent to U.S.\$10,000,000 per occurrence (or claim) and in the aggregate annually. Such product liability insurance shall insure against all liability, including product liability, personal liability, physical injury or property damage. The Licensee shall provide written proof of the existence of such insurance to the Licensor and Ferring upon request from either therefor and shall monitor such policy on a monthly basis to ensure that any cover is revised to take account of any currency fluctuations.

15 FORCE MAJEURE

If the performance of any part of this Agreement by any Party, or of any obligation under this Agreement (other than those provisions which in any respect concern the payment under any indemnity or otherwise under this Agreement) is prevented, restricted, interfered with or delayed by reason of any cause beyond the reasonable control of the Party liable to perform (an “**Event of Force Majeure**”), unless conclusive evidence to the contrary is provided, the Party so affected shall, upon giving written notice to the other Party, be excused from such performance to the extent of such prevention, restriction, interference or delay, provided that the affected Party shall use its reasonable endeavours to avoid or remove such causes of non-performance and shall continue performance with the utmost dispatch whenever such causes are removed. If the Event of Force Majeure continues for a period of more than six months, any Party not prevented, restricted, interfered with or delayed or otherwise in terms of performance may terminate this Agreement by providing a written termination notice to the other Party.

16 THIRD-PARTY RIGHTS

- 16.1 Except for Ferring and Ferring’s Affiliates or as otherwise expressly provided under this Agreement, a person who is not a party to this Agreement shall not have any rights to enforce any term of this Agreement.
- 16.2 Ferring and/or any of its Affiliates have the right to enforce and rely on the terms of this Agreement. The Licensee expressly agrees that Ferring or any of its Affiliates shall be entitled to enforce any of the provisions of this Agreement as if they were named as a party to this Agreement in place of the Licensor.
- 16.3 The rights of the Licensor under this Agreement shall be applicable to Ferring to the same extent as for the Licensor and the Licensor shall exercise such rights on behalf of Ferring if so requested by Ferring.

17 SEVERABILITY

- 17.1 In the event that any portion of this Agreement is or is held by any court or tribunal of competent jurisdiction to be illegal, void, unenforceable or ineffective, the remaining

portions hereof shall remain in full force and effect.

- 17.2 If any of the terms or provisions of this Agreement are in conflict with any applicable statute or rule of law, then such terms or provisions shall be deemed inoperative to the extent that they may conflict therewith and shall be deemed to be modified to the minimum extent necessary to procure conformity with such statute or rule of law.
- 17.3 In the event that the terms and conditions of this Agreement are materially altered as a result of Sections 17.1 or 17.2, the Parties and Ferring will seek to renegotiate the terms and conditions of this Agreement to resolve any inequities. If the Parties cannot reach an agreement, they agree to submit their dispute to mediation in accordance with Section 27.3 of this Agreement. In the event that the dispute remains unresolved, either Party may terminate this Agreement by providing a written termination notice to the other Party.

18 ENTIRE AGREEMENT

- 18.1 This Agreement constitutes the entire agreement between the Parties relating to the subject matter hereof and supersedes all previous writings and understandings between the Parties relating to the transactions contemplated by this Agreement.
- 18.2 Subject to Section 18.3, each Party acknowledges that in entering into this Agreement it has not relied on any representation, warranty, collateral contract or other assurance (except those set out in this Agreement) made by or on behalf of any other Party before the date of this Agreement. Each Party waives all rights and remedies which, but for this Section, might otherwise be available to it in respect of any such representation, warranty, collateral contract or other assurance.
- 18.3 Nothing in this Section 18 limits or excludes any liability for fraud.

19 NOTICES

- 19.1 Any notice, document or other communication required to be given or served under, or in connection with, this Agreement: (a) shall be in writing; (b) shall be in the English language; and (c) shall be: (i) delivered personally; (ii) sent by commercial courier; sent by pre-paid post; or (iii) sent by airmail, requiring signature on delivery.
- 19.2 The addresses for delivery of a notice or other communication are as follows:
- (a) to the Licensor at:
- Rue de Varembé 7
CH-1202 Geneva
Switzerland,
e-mail: office@medicinespatentpool.org,
- marked for the attention of General Counsel,
- (b) to the Licensee at:
- [*Licensee address*],
- marked for the attention of [*Licensee contact*],
- (c) to Ferring at:
- Ferring International Center S.A.,

Chemin de la Vergognausaz 50,
1162 Saint-Prex Switzerland

marked for the attention of General Counsel.

- 19.3 If a notice or other communication has been properly sent or delivered in accordance with this Section 19, it will be deemed to have been received as follows: (a) if delivered personally, at the time of delivery; (b) if sent by commercial courier, on the date and at the time of signature of the courier's delivery receipt; (c) if sent by pre-paid post, 9.00 a.m. on the second Business Day after posting; or (d) if sent by airmail, 9.00 a.m. on the fifth Business Day after posting.
- 19.4 The provisions of this Section 19 shall not apply to the service of any proceedings or other documents in any legal action.
- 19.5 Any notice, document or other communication required to be given or served under, or in connection with, this Agreement shall be validly given if sent by e-mail.

20 ASSIGNMENT AND SUB-CONTRACTING

- 20.1 Neither this Agreement nor any interest arising out of or under this Agreement shall be assignable by the Licensor or the Licensee.
- 20.2 Save as expressly set out in Section 2, and subject to those Sections, neither the Licensor nor the Licensee shall be entitled to subcontract any of its rights or obligations under this Agreement.

21 NO COMPENSATION

To the extent that such exclusion is permitted by applicable law, no compensation, whether for loss of profit or any other reason whatsoever, shall be payable by any Party arising from any lawful amendment or lawful termination or expiry of this Agreement.

22 COSTS

Each Party shall pay the costs and expenses incurred by it in connection with the entering into this Agreement.

23 AMENDMENTS

The Parties agree that any amendment of this Agreement shall not be effective unless set out in writing, expressed to amend this Agreement and signed by authorized representatives of: (a) each of the Parties; and (b) Ferring. Notwithstanding the aforesaid, the Licensor (pursuant to approval from Ferring) shall have the right to amend Appendix B of this Agreement at any time without the Licensee's consent in order to include additional patents in that appendix.

24 WAIVER

The rights of each Party under this Agreement: (a) may be exercised as often as necessary; (b) are cumulative and not exclusive of rights or remedies provided by law; and (c) may be waived only in writing and specifically. Delay in exercising or non-exercise of any such right is not a waiver of that right.

25 NO PARTNERSHIP OR AGENCY

Nothing in this Agreement shall be deemed to constitute a partnership between the Parties (or between either Party and Ferring), nor constitute either Party as the agent of the other Party (or either Party as the agent of Ferring or Ferring as the agent of either Party).

26 EXECUTION IN COUNTERPARTS

This Agreement may be executed in any number of counterparts, each of which shall be deemed

an original but all of which together shall constitute one and the same instrument.

27 GOVERNING LAW AND JURISDICTION

- 27.1 This Agreement and any non-contractual obligations arising out of or in connection with it shall be governed by Swiss law.
- 27.2 Subject to Section 27.3, the Swiss courts shall have exclusive jurisdiction to settle any dispute arising out of or in connection with this Agreement (including a dispute relating to any non-contractual obligations arising out of or in connection with this Agreement) and the parties submit to the exclusive jurisdiction of the Swiss courts.
- 27.3 The Parties agree that in the event of a dispute they shall submit such dispute to mediation in accordance with the WIPO Mediation Rules. In the event that the dispute remains outstanding after sixty (60) days from the date when it was first discussed (in any manner) between the parties, either Party may commence court proceedings. The foregoing however shall not prevent any person from seeking and obtaining injunctive relief at any time.
- 27.4 The Parties waive any objection to the Geneva, Switzerland courts on the grounds that they are an inconvenient or inappropriate forum to settle any such dispute.
- 27.5 Without prejudice to the foregoing in relation to the Licensee, nothing in this Section 27 shall prevent or restrict Ferring from electing to bring proceedings in relation to patent infringement or from applying for injunctive relief in any country outside Switzerland, to which election the Licensor and the Licensee hereby agree.

IN WITNESS WHEREOF the Parties, through their duly authorized representatives, have executed this Agreement.

SIGNATORIES

For and on behalf of THE MEDICINES PATENT POOL FOUNDATION

Signature:

Name (Printed) :

Position:

Date:

For and on behalf of [INSERT NAME OF LICENSEE]

Signature:

Name (Printed):

Position:

Date:

APPENDIX A

LIST OF COUNTRIES FORMING THE TARGET COUNTRIES

Below is the initial list of Target Countries. Licensor and Ferring shall consult at least every three years [(starting in INSERT CALENDAR YEAR)] in order to update and include in or delete from the then-current version of Appendix A, any country, territory or area that, as relevant: (1) has been or ceases to be classified as low income or lower-middle income by the World Bank, or (2) has been or ceases to be classified as upper middle income by the World Bank and meets or ceases to meet the criteria set out in Section 1.33 of this Agreement. As part of the aforementioned consultation between Licensor and Ferring, to the extent that a country, territory or area is to be deleted from the then-current version of Schedule 2, and Licensee has sold the Licensed Product in such country, territory or area in compliance with the terms and conditions of the Agreement, Licensor and Ferring shall consider and agree on a case-by-case basis, in good faith, on a transition plan for the continued sale of the Licensed Product and any limitations thereto, in such country, territory or area, as appropriate.

Any update of the list included in this Appendix A shall be added to this Agreement via a signed written amendment and shall replace the preceding list. All references to Appendix A shall be deemed to refer to the then-current version of this Schedule.

[LIST TO BE INSERTED]

APPENDIX B
LICENSED PATENTS

Country	Filed Date	Application Number	Grant Date	Patent No.
United Arab Emirates	2011-09-29	328/2013	2020-06-23	2421
Albania	2011-09-29	11776530.5	2017-06-14	2621468
Albania	2011-09-29	17169328.6	2021-11-03	3222272
Argentina	2011-09-29	20110103594		
Argentina	2011-09-29	20200102711		
Austria	2011-09-29	11776530.5	2017-06-14	2621468
Austria	2011-09-29	17169328.6	2021-11-03	3222272
Australia	2011-09-29	2011309762	2014-10-30	2011309762
Belgium	2011-09-29	11776530.5	2017-06-14	2621468
Belgium	2011-09-29	17169328.6	2021-11-03	3222272
Bulgaria	2011-09-29	11776530.5	2017-06-14	2621468
Bulgaria	2011-09-29	17169328.6	2021-11-03	3222272
Brazil	2011-09-29	112013007362-4	2021-06-25	112013007362-4
Brazil	2011-09-29	BR122021001119-2		
Canada	2011-09-29	2,812,510		
Switzerland	2011-09-29	11776530.5	2017-06-14	2621468
Switzerland	2011-09-29	17169328.6	2021-11-03	3222272
Cyprus (Republic of)	2011-09-29	11776530.5	2017-06-14	2621468
Cyprus (Republic of)	2011-09-29	17169328.6	2021-11-03	3222272
Czechia	2011-09-29	11776530.5	2017-06-14	2621468
Czechia	2011-09-29	17169328.6	2021-11-03	3222272
Germany (Federal Republic of)	2011-09-29	11776530.5	2017-06-14	2621468
Germany (Federal Republic of)	2011-09-29	17169328.6	2021-11-03	3222272
Denmark	2011-09-29	11776530.5	2017-06-14	2621468
Denmark	2011-09-29	17169328.6	2021-11-03	3222272
Algeria	2011-09-29	130183		
Estonia	2011-09-29	11776530.5	2017-06-14	2621468
Estonia	2011-09-29	17169328.6	2021-11-03	3222272
Egypt	2011-09-29	504/2013		
Egypt	2011-09-29	D2 PCT 504/2013		
European Patent	2011-09-29	11776530.5	2017-06-14	2621468
European Patent	2011-09-29	17169328.6	2021-11-03	3222272
European Patent	2011-09-29	21192651.4		
Spain	2011-09-29	11776530.5	2017-06-14	2621468
Spain	2011-09-29	17169328.6	2021-11-03	3222272

Finland	2011-09-29	11776530.5	2017-06-14	2621468
Finland	2011-09-29	17169328.6	2021-11-03	3222272
France	2011-09-29	11776530.5	2017-06-14	2621468
France	2011-09-29	17169328.6	2021-11-03	3222272
United Kingdom	2011-09-29	11776530.5	2017-06-14	2621468
United Kingdom	2011-09-29	17169328.6	2021-11-03	3222272
Greece	2011-09-29	11776530.5	2017-06-14	2621468
Greece	2011-09-29	17169328.6	2021-11-03	3222272
Hong Kong	2011-09-29	18103960.0	2022-06-10	HK1244442
Hong Kong	2011-09-29	42022053728.6		
Croatia	2011-09-29	11776530.5	2017-06-14	2621468
Croatia	2011-09-29	17169328.6	2021-11-03	3222272
Hungary	2011-09-29	11776530.5	2017-06-14	2621468
Hungary	2011-09-29	17169328.6	2021-11-03	3222272
Ireland (Republic of)	2011-09-29	11776530.5	2017-06-14	2621468
Ireland (Republic of)	2011-09-29	17169328.6	2021-11-03	3222272
Israel	2011-09-29	225238	2018-11-01	225238
Israel	2011-09-29	245328	2022-07-02	245328
India	2011-09-29	2471/DELNP/2013	2022-01-27	387567
Iceland	2011-09-29	11776530.5	2017-06-14	2621468
Iceland	2011-09-29	17169328.6	2021-11-03	3222272
Italy	2011-09-29	11776530.5	2017-06-14	2621468
Italy	2011-09-29	17169328.6	2021-11-03	3222272
Jordan	2011-09-28	297/2011	2020-01-26	3400
Jordan	2011-09-28	103/2018	2022-06-27	3968
Japan	2011-09-29	2013-530810	2016-11-11	6038797
Korea, Republic of (KR)	2011-09-29	10-2013-7010256	2018-11-09	10-1919119
Kuwait	2011-09-29	105/2011		
Lithuania	2011-09-29	11776530.5	2017-06-14	2621468
Lithuania	2011-09-29	17169328.6	2021-11-03	3222272
Luxembourg	2011-09-29	11776530.5	2017-06-14	2621468
Luxembourg	2011-09-29	17169328.6	2021-11-03	3222272
Latvia	2011-09-29	11776530.5	2017-06-14	2621468
Latvia	2011-09-29	17169328.6	2021-11-03	3222272
Morocco	2011-09-29	11776530.5	2017-05-18	2621468
Monaco	2011-09-29	11776530.5	2017-06-14	2621468
Monaco	2011-09-29	17169328.6	2021-11-03	3222272
North Macedonia	2011-09-29	11776530.5	2017-06-14	2621468
North Macedonia	2011-09-29	17169328.6	2021-11-03	3222272
Malta	2011-09-29	11776530.5	2017-06-14	2621468
Malta	2011-09-29	17169328.6	2021-11-03	3222272
Mexico	2011-09-29	MX/a/2013/003365	2017-12-15	352949
Mexico	2011-09-29	MX/a/2016/014747	2022-09-02	395271

Netherlands	2011-09-29	11776530.5	2017-06-14	2621468
Netherlands	2011-09-29	17169328.6	2021-11-03	3222272
Norway	2011-09-29	11776530.5	2017-06-14	2621468
Norway	2011-09-29	17169328.6	2021-11-03	3222272
New Zealand	2011-09-29	608163	2014-03-04	608163
Poland	2011-09-29	11776530.5	2017-06-14	2621468
Poland	2011-09-29	17169328.6	2021-11-03	3222272
Portugal	2011-09-29	11776530.5	2017-06-14	2621468
Portugal	2011-09-29	17169328.6	2021-11-03	3222272
Romania	2011-09-29	11776530.5	2017-06-14	2621468
Romania	2011-09-29	17169328.6	2021-11-03	3222272
Serbia	2011-09-29	11776530.5	2017-06-14	2621468
Serbia	2011-09-29	17169328.6	2021-11-03	3222272
Russian Federation	2011-09-29	2013112666	2016-12-10	2604690
Saudi Arabia	40817	111320809		
Sweden	2011-09-29	11776530.5	2017-06-14	2621468
Sweden	2011-09-29	17169328.6	2021-11-03	3222272
Slovenia	2011-09-29	11776530.5	2017-06-14	2621468
Slovenia	2011-09-29	17169328.6	2021-11-03	3222272
Slovak Republic	2011-09-29	11776530.5	2017-06-14	2621468
Slovak Republic	2011-09-29	17169328.6	2021-11-03	3222272
San Marino	2011-09-29	11776530.5	2017-06-14	2621468
San Marino	2011-09-29	17169328.6	2021-11-03	3222272
Turkey	2011-09-29	11776530.5	2017-06-14	2621468
Turkey	2011-09-29	17169328.6	2021-11-03	3222272
Taiwan	2011-09-29	100135257	2016-05-11	1532507
United States of America	2011-09-29	13/824,132	2017-02-14	9,566,311
United States of America	2022-07-12	17/863,319		
South Africa	2011-09-29	2013/01991	2013-11-27	2013/01991

SCHEDULE 4

FORM OF LETTER OF INDEMNITY

[ON THE LETTERHEAD OF THE LICENSEE¹]

To: **Ferring International Center S.A.**
Chemin de la Vergognausaz 50,
1162 Saint-Prex, Switzerland

Date: [●]

Re: Letter of indemnity regarding the License Agreement between the Medicines Patent Pool Foundation and [insert name of the Licensee] dated [insert date]

We refer to the license agreement between the Medicines Patent Pool Foundation and ourselves, [insert name of the Licensee] (the “**Licensee**”) dated [insert date] (the “**License Agreement**”) under which the Licensee was granted a license relating to the Licensed Patents (as such term is defined under the License Agreement).

It is noted that **Ferring International Center S.A** and or its Affiliates (together “**Ferring**”) own the rights, title and interest in and/or is the licensor of the Patents.

Unless the contrary intention appears, a word or expression used in this letter shall have the same meaning as given to that word or expression under the License Agreement.

The Licensee hereby agrees that:

- (a) notwithstanding anything contained in the License Agreement, it does not have a right to sublicense under the License Agreement; and
- (b) it shall be responsible for and undertakes to indemnify Ferring and its Affiliates (as stated here and in accordance with the additional indemnification terms set forth in the Sublicense) in respect of any and all liability, costs, damages and expenses (including, but not limited to, legal costs) (“**Losses**”) incurred by Ferring and/or its Affiliates arising out of, or in connection with: (i) any breach of the License Agreement by the Licensee or any of its Affiliates; and/or (ii) the Licensee’s exercise of its rights pursuant to the License Agreement (including for the avoidance of doubt any product liability claim relating to the Licensed Product manufactured by or on behalf of Licensee pursuant to this Agreement), provided that the indemnification obligation established in this Letter of Indemnity shall not apply to the extent such Losses arise out of negligence or wilful misconduct by Ferring and/or its Affiliates.

This letter and any non-contractual obligations arising out or in connection with it shall be governed by and construed in accordance with Swiss law and the courts in Geneva shall have exclusive jurisdiction to settle any dispute arising out of or in connection with this letter (including a dispute relating to any non-contractual obligations arising out of or in connection with this letter) and the parties submit to the exclusive jurisdiction of the courts in Geneva.

This letter shall be executed and take effect as a deed and may be executed in any number of counterparts.

Please acknowledge your agreement to the above by executing the enclosed copy of this letter as a deed and returning a copy to the Licensee at its address above.

¹ Note: To include Licensee’s registered address.

Yours faithfully

EXECUTED as a DEED² by)
[NAME OF LICENSEE])
acting by:)
in the presence of:) Director

Witness's signature:

Name:

Address:

.....

We acknowledge our agreement to the above:

.....
EXECUTED as a DEED by)
FERRING INTERNATIONAL S.A.)
acting by:)
in the presence of:) Director

Witness's signature:

Name:

Address:

.....

² Note: To be executed in a way that is binding upon the Licensee.