

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**  
Washington, D.C. 20549

**FORM 6-K**

**REPORT OF FOREIGN PRIVATE ISSUER  
PURSUANT TO RULE 13A-16 OR 15D-16 UNDER THE  
SECURITIES EXCHANGE ACT OF 1934**  
Dated December 30, 2020  
Commission File Number 001-36421

**AURINIA PHARMACEUTICALS INC.**  
(Exact name of Registrant as specified in its charter)

N/A  
(Translation of Registrant's Name)  
#1203-4464 Markham Street  
Victoria, British Columbia  
V8Z7X8  
(250) 708-4272  
(Address and telephone number of registrant's principal executive offices)

Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F.  
Form 20-F  Form 40-F

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b) (1):

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b) (7):

Indicate by check mark whether by furnishing the information contained in this Form, the registrant is also thereby furnishing the information to the Commission pursuant to Rule 12g3-2(b) under the Securities Exchange Act of 1934.

Yes  No

This Form 6-K is hereby filed and incorporated by reference in the registrant's Registration Statement on Form F-10 (File No. 333-238785).

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**SIGNATURES**

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

Dated: December 30, 2020

**Aurinia Pharmaceuticals Inc.**

*By: /s/ Joseph Miller*

Name: Joseph Miller

Title: Chief Financial Officer

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## EXHIBIT INDEX

Exhibit	Description of Exhibit
<a href="#">99.1</a>	Material Change Report - Dated December 29, 2020 - Collaboration and license agreement with Otsuka Pharmaceutical Co., Ltd
<a href="#">99.2</a>	Otsuka-Aurinia Collaboration License Agreement

Exhibit 99.1 included with this report on Form 6-K is hereby incorporated by reference as exhibits to the Registration Statement on Form F-10 of Aurinia Pharmaceuticals Inc. (File No. 333-238785), as amended or supplemented.

**FORM 51-102F3**  
**Material Change Report**

Exhibit 99.1

**Item 1 Name and Address of Company**

Aurinia Pharmaceuticals Inc. (the "**Company**")  
#1203-4464 Markham Street  
Victoria, BC V8Z 7X8  
Canada

**Item 2 Date of Material Change**

December 17, 2020

**Item 3 News Release**

A news release was issued and disseminated by the Company through Business News Wire on December 17, 2020.

**Item 4 Summary of Material Change**

On December 17, 2020, the Company announced that it has entered into a collaboration and license agreement with Otsuka Pharmaceutical Co., Ltd. (Otsuka) for the development and commercialization of oral voclosporin for the treatment of Lupus Nephritis (LN) in the European Union (EU), Japan, as well as the United Kingdom, Russia, Switzerland, Norway, Belarus, Iceland, Liechtenstein and Ukraine.

**Item 5 Full Description of Material Change**

On December 17, 2020, the Company announced that it has entered into a collaboration and license agreement with Otsuka for the development and commercialization of oral voclosporin for the treatment of LN in the EU, Japan, as well as the United Kingdom, Russia, Switzerland, Norway, Belarus, Iceland, Liechtenstein and Ukraine.

As part of the agreement, Aurinia will receive an upfront cash payment of US\$50 million and has the potential to receive up to US\$50 million in regulatory and reimbursement milestone payments. Aurinia will receive tiered royalties ranging from 10 to 20 percent (dependent on achievement of sale milestones) on net sales upon commercialization, along with additional milestone payments based on the attainment of certain annual sales by Otsuka.

Voclosporin is a novel, investigational, orally administered treatment developed to treat patients with LN, a chronic, progressive inflammation of the kidneys that is one of the most serious complications of the autoimmune disease systemic lupus erythematosus (SLE).

The agreement leverages Otsuka's well-recognized expertise in rare kidney diseases to underscore Aurinia's commitment to expanding global access to voclosporin for the treatment of LN. Otsuka expects to file a marketing authorization application (MAA) with the European Medicines Agency (EMA) in Q2 2021 and will also manage the filing of voclosporin for LN with Pharmaceuticals Medical Devices Agency (PDMA) in Japan at a later date. Voclosporin is currently under review with the U.S. Food and Drug Administration (FDA) with an assigned Prescription Drug User Fee Act (PDUFA) target action date of January 22, 2021.

**Item 5.2 Disclosure of Restructuring Transactions**

Not applicable.

**Item 6 Reliance on subsection 7.1(2) of National Instrument 51-102**

Not applicable.

**Item 7 Omitted Information**

No significant facts remain confidential in, and no information has been omitted from, this report.

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**FORM 51-102F3**  
**Material Change Report**

Exhibit 99.1

**Item 8 Executive Officer**

For further information, please contact:

Mr. Joseph M. Miller, Chief Financial Officer  
240-291-6917  
jmillier@auriniapharma.com

**Item 9 Date of Report**

December 29, 2020

**Forward-Looking Statements**

*Certain statements made in this material change report may constitute forward-looking information within the meaning of applicable Canadian securities law and forward-looking statements within the meaning of applicable United States securities law. These forward-looking statements or information include but are not limited to statements or information with respect to: the Company receiving up to US\$50 million in regulatory and reimbursement milestone payments; the Company receiving tiered royalties ranging from 10 to 20 percent (dependent on achievement of sale milestones) and additional milestone payments based on annual sales by Otsuka; the Company filing an MAA with the EMA in Q2 2021; plans for the filing of voclosporin for LN with PDMA in Japan at a later date; and the Company's anticipated PDUFA date of January 22, 2021. It is possible that such results or conclusions may change based on further analyses of these data. Words such as "anticipate", "will", "believe", "estimate", "expect", "intend", "target", "plan", "goals", "objectives", "may" and other similar words and expressions, identify forward-looking statements. We have made numerous assumptions about the forward-looking statements and information contained herein, including among other things, assumptions about: the regulatory and reimbursement milestones will be achieved and the milestones payments made; and the FDA will not alter the PDUFA date; Aurinia will be able to obtain all necessary regulatory approvals for commercialization of voclosporin for use in LN on terms that are acceptable to it and that are commercially viable including approval of marketing authorization applications and new drug approvals, as well as favourable product labeling; and that Aurinia's intellectual property rights are valid and do not infringe the intellectual property rights of other parties. Even though the management of Aurinia believes that the assumptions made, and the expectations represented by such statements or information are reasonable, there can be no assurance that the forward-looking information will prove to be accurate.*

*Forward-looking information by its nature is based on assumptions and involve known and unknown risks, uncertainties and other factors which may cause the actual results, performance or achievements of Aurinia to be materially different from any future results, performance or achievements expressed or implied by such forward-looking information. Should one or more of these risks and uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those described in forward-looking statements or information. Such risks, uncertainties and other factors include, among others, the following: Aurinia may not be able to obtain necessary regulatory approvals for commercialization of voclosporin in a timely fashion, or at all; the regulatory, reimbursement and sales milestones may not be achieved. Although we have attempted to identify factors that would cause actual actions, events or results to differ materially from those described in forward-looking statements and information, there may be other factors that cause actual results, performances, achievements or events to not be as anticipated, estimated or intended. Also, many of the factors are beyond our control. There can be no assurance that forward-looking statements or information will prove to be accurate, as actual results and future events could differ materially from those anticipated in such statements. Accordingly, you should not place undue reliance on forward-looking statements or information.*

*Except as required by law, Aurinia will not update forward-looking information. All forward-looking information contained in this material change report is qualified by this cautionary statement. Additional information related to Aurinia, including a detailed list of the risks and uncertainties affecting Aurinia and its business can be found in Aurinia's most recent Annual Information Form available by accessing the Canadian Securities Administrators' System for Electronic Document Analysis and Retrieval (SEDAR) website at [www.sedar.com](http://www.sedar.com) or the U.S. Securities and Exchange Commission's Electronic Document Gathering and Retrieval System (EDGAR) website at [www.sec.gov/edgar](http://www.sec.gov/edgar).*

**COLLABORATION AND LICENSE Agreement**  
**by and between**  
**AURINIA PHARMACEUTICALS INC.**  
**and**  
**OTSUKA PHARMACEUTICAL CO., LTD.**  
**DECEMBER 17, 2020**

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**List of Exhibits:**

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**Exhibit 1.45: Chemical Structure of VCS**

**Exhibit 6.3: Commercialization Plan**

**Exhibit 6.4: Commercialization Reports**

**Exhibit 10.5(a): Product Marks**

**Exhibit 11.3(a): Existing Aurinia Patents**



## COLLABORATION AND LICENSE Agreement

**This Collaboration and License Agreement** (this “**Agreement**”) is entered into as of December 17, 2020 (the “**Effective Date**”), by and between **Aurinia Pharmaceuticals Inc.**, a corporation organized and existing under the laws of Canada, having an address at 1203-4464 Markham Street, Victoria, BC V8Z 7X8 Canada (“**Aurinia**”) and **Otsuka Pharmaceutical Co., Ltd.**, a corporation organized and existing under the laws of Japan, having an address at 2-9, Kanda Tsukasa-machi, Chiyoda-ku, Tokyo 101-8535, Japan (“**Otsuka**”). Aurinia and Otsuka may be referred to herein individually as a “**Party**” or collectively as the “**Parties**.”

### Recitals

**Whereas**, Aurinia, a biopharmaceutical company, is developing its proprietary investigational drug known as Voclosporin (“**VCS**”) for the treatment of lupus nephritis, and owns or controls certain patents, know-how and other intellectual property relating to VCS;

**Whereas**, Otsuka (itself and through its Affiliates) has expertise in the development and commercialization of biopharmaceutical products and is interested in obtaining an exclusive license to Develop, Package, Commercialize and conduct Medical Affairs for Products in the Otsuka Territory (as such terms are defined below);

**Whereas**, Otsuka and Aurinia desire to establish a collaboration to Develop, Manufacture, Commercialize and conduct Medical Affairs for Products, under which Aurinia will continue to have primary responsibility for the conduct of the global development program for VCS and will Manufacture and supply Products to Otsuka for the Otsuka Territory, and Otsuka will obtain the exclusive license to Develop, Package, Commercialize and conduct Medical Affairs for Products in the Otsuka Territory, all on the terms and conditions set forth in this Agreement; and

**Whereas**, Otsuka and Aurinia intend that Aurinia will have the benefit of work product arising or exploited in the collaboration for Products in the Aurinia Territory and, except for the Product in the Otsuka Territory, for all other pharmaceutical products containing the Compound as an active ingredient worldwide (including in the Otsuka Territory).

### Agreement

**Now, Therefore**, in consideration of the foregoing premises and the mutual covenants contained herein, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, Aurinia and Otsuka hereby agree as follows:

#### 1. DEFINITIONS

- 1.1 “**52-Week Limitation**” means a limitation on the dosing or treatment duration of the Product to a period of 52 weeks or less.
- 1.2 “**Acquirer**” has the meaning set forth in Section 1.50.
- 1.3 “**Acquirer Competing Product**” has the meaning set forth in Section 2.9(c).
- 1.4 “**Additional Development**” has the meaning set forth in Section 4.2(a).

**1.5 “Additional Development Proposal”** has the meaning set forth in Section 4.2(a).

**1.6 “Additional Indication”** means any indication for the Product other than the Initial Indication.

**1.7 “Affiliate”** means, with respect to either Party, any entity that, directly or indirectly through one or more intermediaries, controls, is controlled by or is under common control with such Party, but for only so long as such control exists. As used in this Section 1.7, “control” means (a) to possess, directly or indirectly, the power to direct the management or policies of an entity, whether through ownership of voting securities, by contract relating to voting rights or corporate governance; or (b) direct or indirect beneficial ownership of more than fifty percent (50%) (or such lesser percentage which is the maximum allowed to be owned by a foreign corporation in a particular jurisdiction) of the voting share capital or other equity interest in such entity.

**1.8 “Agreed Development”** means: (i) the Initial Development; (ii) any Additional Development with respect to which both Parties have agreed to a regulatory milestone in accordance with Section 4.2(c); (iii) Global Additional Development agreed-to by both Parties in accordance with Section 4.2(e)(i); and (iv) Global Additional Development the compensation for which both Parties have agreed to in accordance with Section 4.2(e)(iii).

**1.9 “Alliance Managers”** has the meaning set forth in Section 3.7.

**1.10 “Allocated Reasonably”** means, with respect to any Aurinia costs to be shared between the Parties (other than costs to be allocated pursuant to Section 2.8(j)), that the costs will be allocated between the Otsuka Territory and the Aurinia Territory (and, if such costs apply to Aurinia Domain Products, between Products and Aurinia Doman Products) based on the ratio between (i) the number of units of Product sold in the Otsuka Territory and (ii) the number of units of Product sold in the Aurinia Territory (and the number of units of Aurinia Domain Products sold worldwide, if applicable); provided that if there are no sales of Product in one or the other Party’s Territory, or if the sales of Product have or will commence at different times in the Territories and are or will ramp up at different times and rates, the Parties shall discuss in good faith and agree on a reasonable allocation based on the anticipated relative market share of worldwide Product sales in each Party’s respective Territory (using sales data provided by IQVIA or a similar Third Party provider agreed upon by the Parties). All of the foregoing shall be determined in accordance with U.S. Generally Accepted Accounting Principles consistently applied in Aurinia financial statements. With respect to costs to be Allocated Reasonably pursuant to Section 2.8(j), the costs will be allocated between the Otsuka Territory and the Aurinia Territory and between Products and Aurinia Doman Products based on Net Sales revenue rather than on the number of units sold.

**1.11 “Applicable Laws”** means the applicable provisions of any and all national, supranational, regional, state and local laws, treaties, statutes, rules, regulations, administrative codes, guidance, ordinances, judgments, decrees, directives, injunctions, orders, permits, approvals (including Regulatory Approvals) of or from any court, Regulatory Authority or other Governmental Authority having jurisdiction over the subject item, including, as applicable, cGLP, cGCP and cGMP.

1.12 “**Audited Party**” has the meaning set forth in Section 9.5.

1.13 “**Auditing Party**” has the meaning set forth in Section 9.5.

1.14 “**Auditor**” has the meaning set forth in Section 9.5.

1.15 “**Aurinia Data**” has the meaning set forth in Section 10.1(a).

1.16 “**Aurinia Domain Product**” means any pharmaceutical product containing the Compound as an active ingredient in a form other than the Oral Form.

1.17 “**Aurinia Indemnitee**” has the meaning set forth in Section 12.2.

1.18 “**Aurinia Initial Development**” has the meaning set forth in Section 4.1(a).

1.19 “**Aurinia Know-How**” means all Know-How that Aurinia or its Affiliates Control as of the Effective Date or during the Term (including Aurinia Sole Inventions and Aurinia Data that Aurinia or its Affiliates Control but excluding Aurinia’s interest in Joint Inventions) that is necessary or reasonably useful for the Development, Packaging, Commercialization and Medical Affairs for the Product in the Field in the Otsuka Territory.

1.20 “**Aurinia Patents**” means all Patents that Aurinia or its Affiliates Control as of the Effective Date or during the Term (including all Patents Controlled by Aurinia or its Affiliates that claim any Aurinia Sole Inventions but excluding Aurinia’s interest in Joint Patents) that (a) Cover the Development, Packaging, Commercialization, or Medical Affairs for the Product in the Field in the Otsuka Territory or (b) are necessary or reasonably useful for the Development, Packaging, Commercialization, or Medical Affairs for the Product in the Field in the Otsuka Territory.

1.21 “**Aurinia Sole Inventions**” has the meaning set forth in Section 10.1(b)(ii).

1.22 “**Aurinia Technology**” means Aurinia KnowHow and Aurinia Patents.

1.23 “**Aurinia Territory**” means the world outside the Otsuka Territory.

1.24 “**Aurinia Territory Additional Development**” has the meaning set forth in Section 4.2.

1.25 “**Bulk Product**” means, unless otherwise agreed between the Parties, finished Product in gelcaps in bulk (not packaged) quantities ready for storage or shipment to a facility to enable the primary and secondary Packaging of finished Product.

1.26 “**Business Day**” means any day (other than a Saturday or Sunday) on which the banks in Tokyo, Japan, London, England, New York, New York and Vancouver, Canada are open for business.

1.27 “**Calendar Quarter**” means each respective period of three (3) consecutive months ending on March 31, June 30, September 30, and December 31; provided that (a) the first Calendar Quarter of the Term shall begin on the Effective Date and end on the first to occur of March 31, June 30, September 30 or December 31 thereafter and the last Calendar Quarter of the

Term shall end on the last day of the Term, and (b) the first Calendar Quarter of a Royalty Term for a Product shall begin on the First Commercial Sale of such Product in the Otsuka Territory and end on the first to occur of March 31, June 30, September 30 or December 31 thereafter and the last Calendar Quarter of a Royalty Term for a Product shall end on the last day of such Royalty Term.

**1.28 “Calendar Year”** means each respective period of twelve (12) consecutive months ending on December 31; provided that (a) the first Calendar Year of the Term shall begin on the Effective Date and end on the first December 31 thereafter and the last Calendar Year of the Term shall end on the last day of the Term, and (b) the first Calendar Year of a Royalty Term for a Product shall begin on the First Commercial Sale of such Product in the Otsuka Territory and end on the first December 31 thereafter and the last Calendar Year of a Royalty Term for a Product shall end on the last day of such Royalty Term.

**1.29 “cGCP”** means all current good clinical practice standards for the design, conduct, performance, monitoring, auditing, recording, analyses and reporting of clinical trials, including, as applicable: (a) ICH Harmonized Tripartite Guideline for Good Clinical Practice (CPMP/ICH/135/95); (b) FDA regulations and guidelines for good clinical practice, as promulgated by the FDA 21 CFR Parts 50, 54, 56 and 312; (c) European Commission Directive 2001/20/EC, brought into law by European Commission Directive 2005/28/EC, and related guidelines; and (d) any amendments, updates or clarifications with respect to any of the foregoing and any equivalents thereto in the country in which Clinical Trials of the Product are conducted.

**1.30 “cGLP”** means all current good laboratory practice standards, including, as applicable: (a) FDA regulations and guidelines for good laboratory practice, as promulgated by the FDA under 21 CFR Part 58; (b) European Commission Directive 2004/10/EC relating to the application of the principles of good laboratory practices; and (c) any amendments, updates or clarifications with respect to any of the foregoing and any equivalents thereto in the country in which Non-Clinical Studies of the Compound or Clinical Trials of the Product are conducted.

**1.31 “cGMP”** means all applicable current good manufacturing practices, including, as applicable: (a) the applicable part of quality assurance to ensure that products are consistently produced and controlled in accordance with the quality standards appropriate for their intended use, as defined in European Commission Directive 2003/94/EC laying down the principles and guidelines of good manufacturing practice; (b) the principles detailed in the U.S. Current Good Manufacturing Practices, 21 CFR Parts 210 and 211; (c) the Rules Governing Medicinal Products in the European Community, Volume IV Good Manufacturing Practice for Medicinal Products; (d) the principles detailed in the ICH Q7A guidelines; (e) the guidelines of good manufacturing control and quality control based on the requirements of the Pharmaceuticals and Medical Devices Act of Japan; and (f) any amendments, updates or clarifications with respect to any of the foregoing and any equivalents thereto in the country in which the Compound, any Clinical Samples or any Product is Manufactured.

**1.32 “Clinical Samples”** has the meaning set forth in Section 7.2.

**1.33 “Clinical Supply Agreement”** set forth in Section 7.2.

**1.34** “**Clinical Trial**” means a human clinical study involving the Product.

**1.35** “**CMC**” has the meaning set forth in Section 4.1.

**1.36** “**CMO**” means Third Party contract manufacturer for the supply of Compound, Clinical Samples, Bulk Product or Semi-Finished Product or any component thereof for the Otsuka Territory.

**1.37** “**CMO Agreement(s)**” means, as of the Effective Date, those agreements listed in Exhibit 1.37, and after the Effective Date, any agreement between Aurinia and a CMO for the supply of Compound, Clinical Samples, Product or any component thereof for the Otsuka Territory.

**1.38** “**Commercial Supply Agreement**” set forth in Section 7.2.

**1.39** “**Commercialization**” means the conduct of all activities undertaken before and after Regulatory Approval directed to marketing, promoting, distributing (including importing, exporting, transporting, customs clearance, warehousing, invoicing, handling and delivering Products to customers), offering to sell, selling or having sold (including receiving, accepting and filling Product orders) of a Product in the Field, including sales force efforts, detailing, advertising, market research, market access (including pricing and reimbursement activities), and interacting with Regulatory Authorities regarding any of the foregoing, in each case as pertains to the Product, including seeking any required Pricing or Reimbursement Approval, but excluding Medical Affairs Activities and activities directed to the Manufacture (including Packaging) and Development of a Product and interacting with Regulatory Authorities regarding Regulatory Approvals. For clarity, Commercialization includes all Regulatory Activities related to obtaining Pricing or Reimbursement Approval. The terms “**Commercialize**” and “**Commercializing**” have correlative meanings.

**1.40** “**Commercialization Plan**” has the meaning set forth in Section 6.3.

**1.41** “**Commercially Reasonable Efforts**” means, with respect to the achievement of an objective related to the Compound or the Product, including the Development, Manufacture and Packaging of the Compound or the Development, Manufacture, Packaging and Commercialization of the Product by a Party, those commercially reasonable efforts and resources consistent with the usual practices that an entity in the pharmaceutical industry of similar size and similar resources to the relevant Party would typically devote to the development and commercialization of a pharmaceutical product of similar market potential, profit potential, and strategic value and at a similar stage of development or product life to the Compound or Product, based on conditions then prevailing and taking into account all relevant factors, including issues of safety and efficacy, anticipated or actual product labeling, the competitiveness of alternative Third Party products in the marketplace, the nature and extent of expected and actual market exclusivity (including Patent coverage and regulatory exclusivity), the expected likelihood of regulatory approval, the expected and actual reimbursability and pricing, regulatory status, including anticipated or approved labeling and anticipated or approved post-approval requirements, the present and future market and commercial potential, including competitive market conditions and potential profitability, and other relevant scientific, technical, legal, medical and commercial factors. Such efforts shall be at least as great as a similar entity

would apply to its own products (including internally developed, acquired and in-licensed products) as provided above, but the existence of such own products shall not be a consideration used to reduce the efforts applicable to the Compound or Product.

**1.42 “Committee”** means the Europe JCC, the Japan JCC, and each subcommittee established by either Local JCC, including the subcommittees listed in [Section 3.1\(r\)](#).

**1.43 “Competing Product”** means any small molecule pharmaceutical product for which the primary mechanism of action is calcineurin inhibition. Competing Product includes any pharmaceutical product containing the Compound as an active ingredient (other than the Product Commercialized by or on behalf of Otsuka in the Otsuka Territory as permitted by this Agreement). Competing Product includes any generic version of a Product including a Generic Product and any Design-Around Product.

**1.44 “Competitive Activities”** has the meaning set forth in [Section 2.9\(a\)](#).

**1.45 “Compound”** means Aurinia’s proprietary calcineurin inhibitor (referred to by Aurinia as VCS), having the chemical structure set forth in [Exhibit 1.45](#).

**1.46 “Compound Invention”** has the meaning set forth in [Section 10.1\(b\)\(i\)](#).

**1.47 “Compound Invention Patents”** has the meaning set forth in [Section 10.1\(b\)\(i\)](#).

**1.48 “Confidential Information”** means, subject to the exceptions in [Section 13.2](#), all confidential or proprietary information or data, including Know-How and other proprietary scientific, pre-clinical, clinical, regulatory, manufacturing, marketing, financial, commercial or intellectual property information or data that is generated by or on behalf of or for the benefit of a Party (including by such Party’s Representatives on behalf of or for the benefit of such Party) or in respect of which one Party owes a duty of confidentiality to a Third Party (including information disclosed prior to the Effective Date pursuant to the Confidentiality Agreement), in each case which one Party or any of its Representatives or a Third Party on behalf of such Party has supplied or otherwise made available to the other Party or its Representatives pursuant to this Agreement, whether made available orally, in writing, or in electronic form, or learned by the other Party or its Representatives pursuant to this Agreement, including information comprising or relating to concepts, discoveries, inventions, data, designs or formulae in relation to this Agreement. All Aurinia Technology will be deemed Aurinia’s Confidential Information (and Otsuka will be deemed the receiving Party with respect thereto), all Otsuka Technology will be deemed Otsuka’s Confidential Information (and Aurinia will be deemed the receiving Party with respect thereto), and all Joint Technology will be deemed both Parties’ Confidential Information (and both Parties will be deemed the receiving Parties with respect thereto).

**1.49 “Confidentiality Agreement”** means that certain Confidentiality Agreement between Aurinia and Otsuka dated as of August 4, 2019.

**1.50 “Control” or “Controlled”** means, with respect to any Know-How, Patents or other intellectual property rights, the legal authority or right (whether by ownership, license or otherwise but without taking into account any rights granted by one Party to the other Party pursuant to this Agreement) of a Party to grant access, a license or a sublicense of or under such Know-How, Patents or other intellectual property rights to the other Party, or to otherwise



disclose proprietary or trade secret information to the other Party, without breaching the terms of any agreement with a Third Party, or misappropriating the proprietary or trade secret information of a Third Party. Any intellectual property right that is licensed to or acquired by a Party relating to Product after the Effective Date and that would otherwise be considered to be under the Control of such Party will be deemed to be under the "Control" of such Party for the purposes of this Agreement unless, (a) the application of such definition in the context of any licenses or sublicenses granted to the non-granting Party under this Agreement would require the granting Party to make any additional royalty or other payments to a Third Party in connection with such license or sublicense grants, and (b) the non-granting Party provides written notification to the granting Party indicating that it does not agree to reimburse the granting Party for such additional royalty or other payments due to such Third Party. Notwithstanding the foregoing, no Patent, Know-How, or other intellectual property right will be "Controlled" by either Party hereunder if such Patent, Know-How, or other intellectual property right is owned or in-licensed by a Third Party that becomes an Affiliate of such Party after the Effective Date as a result of such Party being acquired by such Third Party, whether by merger, stock purchase, or purchase of assets (such Third Party, an "**Acquirer**"); provided that prior to the date of such transaction, neither such Party nor any of its Affiliates had any rights to any such Patent, Know-How, or other intellectual property right owned or in-licensed by the Acquirer. Notwithstanding the foregoing, any such Patent, Know-How, or other intellectual property right that is owned or in-licensed by an Acquirer and that is necessary for or used following the date of such transaction by such Acquirer or acquired Party or its Representatives in connection with the Development, Manufacture, or Commercialization of the Product will be "Controlled" by such Acquirer (as an Affiliate) or acquired Party for purposes of this Agreement.

**1.51 "Cost of Goods"** means, with respect to Bulk Product, Semi-Finished Product or Clinical Samples, as applicable, supplied to Otsuka pursuant to this Agreement and the Supply Agreements, and without duplication:

(a) to the extent Bulk Products, Semi-Finished Products or Clinical Samples, as applicable, are Manufactured by Aurinia or its Affiliates, Aurinia's or such Affiliate's fully-burdened cost, calculated on a per unit basis, of all direct materials, labor and indirect labor reasonably allocated to the Manufacture of the applicable Product or Clinical Samples and the fully-allocated Manufacturing overhead directly attributable and reasonably allocated to the Manufacture of the applicable Product or Clinical Samples, including Aurinia's or its Affiliate's:

(i) direct material costs (the actual costs incurred in Manufacturing the applicable Product or Clinical Samples or purchasing materials for the Manufacture of the applicable Product or Clinical Samples, including freight-in costs, value-added, sales and excise taxes imposed thereon (provided that Aurinia and its Affiliate will use commercially reasonable efforts to avoid or minimize such taxes), customs duty and other charges levied by Government Authorities, and all costs of packaging components for the applicable Product or Clinical Samples);

(ii) direct and reasonably allocated indirect labor costs incurred in Manufacturing the applicable Product or Clinical Samples or purchasing materials for the Manufacture of the applicable Product or Clinical Samples;

(iii) costs (including direct and reasonably allocated indirect labor and out-of-pocket costs) of testing, quality assurance and quality control activities for the applicable Product or Clinical Samples;

(iv) storage, packaging, shipping and importing costs for the applicable Product or Clinical Samples; and

(v) indirect charges and overhead (including depreciation and lease expenses) that are reasonably allocated to Manufacturing the applicable Product or Clinical Samples, including those reasonably allocated to any of the foregoing activities; and

(b) to the extent Bulk Products, Semi-Finished Products or Clinical Samples, as applicable, are Manufactured by CMOs: the actual out-of-pocket unit costs paid by Aurinia to such CMOs for the Manufacture and supply of the applicable Product or Clinical Samples, without mark-up, including freight-in costs, value-added, sales and excise taxes imposed thereon (provided that Aurinia will use commercially reasonable efforts to avoid or minimize such taxes), customs duty and other charges levied by Government Authorities.

(c) All of the foregoing shall be determined in accordance with U.S. Generally Accepted Accounting Principles consistently applied in Aurinia financial statements.

Notwithstanding the foregoing, to the extent Bulk Product, Semi-Finished Product or Clinical Samples is Manufactured by Aurinia or its Affiliates, (A) Cost of Goods shall not include any margin or mark-up, whether for profit for inter-company supply, intra-company transfer pricing or otherwise, and (B) Cost of Goods shall not include any costs to be shared by Otsuka pursuant to Section 7.4 or 7.5. For clarity, to the extent Otsuka is obligated to share costs pursuant to Section 7.4 or 7.5, such costs will be paid in accordance with Section 7.4 or 7.5 and shall not be included in Cost of Goods.

**1.46 “Cover,” “Covering” or “Covers”** means as to a compound or product, a Patent, that, in the absence of a license granted under, or ownership of, such Patent, the making, using, selling, offering for sale or importation of such compound or product would infringe any Valid Claim of such Patent or, as to a pending claim included in such Patent, the making, using, selling, offering for sale or importation of such compound or product would infringe such Patent if such pending claim were to issue in an issued patent without modification, in each case, without regard to the validity or enforceability of such Patent.

**1.47 “Data”** means any and all: (i) data pertaining to the Development of any Product; and (ii) real-world data and the resulting real-world evidence (as defined by FDA at the following: <https://www.fda.gov/science-research/science-and-research-special-topics/real-world-evidence>, or as defined by any other Regulatory Authority) pertaining to Product; in each case that is generated by or on behalf of Aurinia, Otsuka, their respective Affiliates, licensees and Sublicensees, including scientific, technical, test, and research data, clinical pharmacology data, non-clinical data, clinical data, clinical study reports, and submissions performed in furtherance of or made in association with an IND or an MAA or contained in any Regulatory Documentation with respect to any Product.

**1.48 “Debarred”** has the meaning set forth in Section 11.1(b).

**1.49** “**Default Notice**” has the meaning set forth in Section 14.2.

**1.50** “**Design-Around Product**” means, on a Product-by-Product and country-by-country basis, any pharmaceutical product in Oral Form (other than a Product) sold by a Third Party that (a) has the Compound as the sole active pharmaceutical ingredient, and (b) has obtained Regulatory Approval through a regulatory pathway similar to the pathway under Section 505(b)(2) of the FDCA; (c) such approval is for one or more indications for which the Product has received Regulatory Approval; and (d) such pharmaceutical product was not Developed, Manufactured, Packaged or Commercialized by Otsuka or any of its Affiliates or Sublicensees.

**1.51** “**Development**” means all research and development activities for the Compound and any Product in the Field that are directed to obtaining Regulatory Approval(s) of the Product and lifecycle management for the Product in any country in the world, including all Non-Clinical Studies and Clinical Trials of the Product; toxicology, pharmacokinetic and pharmacological studies; statistical analyses; assay development; protocol design and development; the preparation, filing and prosecution of any Regulatory Documentation, including Regulatory Approvals for the Product; development activities directed to label expansion and/or obtaining Regulatory Approval for one or more Additional Indications for the Product; Clinical Trials or other development activities conducted after receipt of Regulatory Approval that were mandated by the applicable Regulatory Authority as a condition of such Regulatory Approval (such as pediatric investigation plan studies required by the EMA, and post-marketing studies and observational studies if required by any Regulatory Authority to maintain Regulatory Approval for a Product); and all regulatory affairs related to any of the foregoing, in each case as pertains to the Product. For clarity, Development includes all Regulatory Activities related to obtaining Regulatory Approval(s) of the Product and lifecycle management for the Product. The terms “**Develop**” and “**Developing**” have correlative meanings.

**1.52** “**Disputed Matter**” has the meaning set forth in Section 15.2.

**1.53** “**Distribution End Date**” has the meaning set forth in Section 14.6(k).

**1.54** “**Drug Master File**” means any (a) drug master file filed with the FDA, (b) active substance master file (ASMF) filed with the EMA, and (c) equivalent filing in other countries in the Otsuka Territory, in each case containing data and information related to Manufacture of the Compound or the Product.

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

**1.56** “**Europe**” means, collectively, Territory-A and Territory-B.

**1.57** “**Europe JCC**” has the meaning set forth in Section 3.1.

**1.58** “**European Pricing and Reimbursement Approval**” means the first Pricing or Reimbursement Approval for the first Product for the Initial Indication by the applicable Regulatory Authority in at least three of the Major European Countries.

**1.59 “Executive Officers”** means the Chief Executive Officer of Aurinia and the Chief Executive Officer of Otsuka or OPEL, or in each case a designee who is a direct report to the Chief Executive Officer or who has requisite decision-making authority.

**1.60 “Existing Aurinia Patents”** has the meaning set forth in Section 11.3(a).

**1.61 “Expanded Territory Negotiation Right”** has the meaning set forth in Section 2.6.

**1.62 “Extended Royalty Term”** has the meaning set forth in Section 8.4(d)(i).

**1.63 “FDA”** means the U.S. Food and Drug Administration or any successor thereto.

**1.64 “FFDCA”** means the United States Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 *et seq.*, as amended from time to time, together with any rules, regulations and requirements promulgated thereunder (including all additions, supplements, extensions, and modifications thereto).

**1.65 “Field”** means use of the Product for the treatment and prevention of any and all diseases, conditions and indications in humans.

**1.66 “First Approved SmPC”** means the SmPC approved as part of the first Regulatory Approval by EMA of the first Product for the Initial Indication.

**1.67 “First Commercial Sale”** means, on a Product-by-Product and country-by-country basis, the first sale of such Product under this Agreement by Otsuka, its Affiliates or its Sublicensees to a Third Party for end use or consumption in the Field in such country, after such Product has been granted Regulatory Approval and, where applicable, Pricing or Reimbursement Approval, for distribution, marketing, and sale; provided that a First Commercial Sale excludes any sale of a Product (a) for use in a Non-Clinical Study, Clinical Trial or other Development activity or (b) for compassionate use, named-patient use, or expanded access, indigent or other patient access programs if transferred by Otsuka without consideration or for consideration equal to or less than the Cost of Goods.

**1.68 “FTE Rate”** means with respect to Aurinia personnel, an initial rate of [hourly rate redacted] per person per hour. Thereafter, the FTE Rate shall be changed annually on a Calendar Year basis to reflect any year-to-year percentage increase or decrease (as the case may be) in the Consumer Price Index for All Urban Consumers for the U.S., as published by the U.S. Department of Labor, Bureau of Labor Statistics (“CPI”) based on the change in the CPI from the most recent applicable index available as of the Effective Date to the most recent applicable index available as of the date of the calculation of such revised FTE Rate).

**1.69 “Generic Product”** means, on a Product-by-Product and country-by-country basis in the Otsuka Territory, any small molecule pharmaceutical product in Oral Form (other than a Product) sold by a Third Party that (a) has the Compound as the sole active pharmaceutical ingredient, and (b) has obtained Regulatory Approval through a regulatory pathway similar to the pathway under Section 505(j) of the FFDCA; and (c) such approval is for one or more indications for which the Product has received Regulatory Approval; and (d) such

pharmaceutical product was not Developed, Manufactured, Packaged or Commercialized by Otsuka or any of its Affiliates or Sublicensees.

**1.70** “**Global Additional Development**” has the meaning set forth in Section 4.2(a).

**1.71** “**Global Brand Plan**” has the meaning set forth in Section 6.6.

**1.72** “**Global Manufacturing IP Agreement**” has the meaning set forth in Section 2.8.

**1.73** “**Global Medical Affairs Plan**” has the meaning set forth in Section 6.8(a).

**1.74** “**Global Third Party IP Agreement**” has the meaning set forth in Section 2.8.

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

**1.76** “**Government Official**” has the meaning set forth in Section 11.2(c).

**1.77** “**ICH**” means the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use.

**1.78** “**IND**” means an investigational new drug application, clinical trial application or equivalent application filed with the applicable Regulatory Authority, which application is required to commence human clinical trials in the applicable country.

**1.79** “**Indemnified Party**” has the meaning set forth in Section 12.3.

**1.80** “**Indemnifying Party**” has the meaning set forth in Section 12.3.

**1.81** “**Indemnitee**” has the meaning set forth in Section 12.3.

**1.82** “**Induction Limitation**” means a limitation to treatment with or use of the Product to induction of remission.

**1.83** “**Infringement Action**” has the meaning set forth in Section 10.3(c).

**1.84** “**Initial Development**” means the Aurinia Initial Development and the Otsuka Initial Development.

**1.85** “**Initial Indication**” means lupus nephritis.

**1.86** “**Initial Royalty Term**” has the meaning set forth in Section 8.4(c).

**1.87** “**Injunctive Relief**” has the meaning set forth in Section 15.5.

**1.88 “Invalidation Proceeding”** has the meaning set forth in Section 10.3(a).

**1.89 “Inventions”** means all inventions, whether or not patentable, that are discovered, made, conceived, developed or otherwise created by or on behalf of a Party or its Affiliate, licensee or Sublicensee (as applicable) in the course of conducting activities under this Agreement. For clarity, Inventions do not include any inventions within Know-How existing as of the Effective Date or any inventions discovered, made, conceived, developed or otherwise created outside the scope of this Agreement and in either case, without use or knowledge of or reference to the other Party’s Confidential Information.

**1.90 “Investigator-Initiated Trial”** means a Clinical Trial of Product sponsored and conducted by an investigator.

**1.91 “Japan JCC”** has the meaning set forth in Section 3.1.

**1.92 “JNDA”** means an application filed with the PMDA for approval to market and sell a Product in Japan.

**1.93 “Joint Inventions”** has the meaning set forth in Section 10.1(b)(iii).

**1.94 “Joint Patents”** has the meaning set forth in Section 10.1(b)(iii).

**1.95 “Joint Technology”** means Joint Inventions and Joint Patents.

**1.96 “Know-How”** means all technical information, know-how and data, including inventions, discoveries, trade secrets, intellectual property, specifications, instructions, processes, formulae, compositions of matter, cells, cell lines, assays, animal models and other physical, biological, or chemical materials, expertise and other technology applicable to, development, registration, use or marketing or to methods of assaying or testing them, and including all biological, chemical, pharmacological, biochemical, toxicological, pharmaceutical, physical and analytical, safety, non-clinical and clinical data, regulatory documents, Data, Regulatory Filings, instructions, expertise and other information relevant to the Development or Commercialization of the Compound or Products. Know-How excludes Patents and Trademarks.

**1.97 “Knowledge”** means, with respect to a Party, the actual knowledge of such Party’s executives in positions of Senior Vice President, Executive Vice President or C-level officers, without any inquiry or investigation.

**1.98 “Launch Countries”** has the meaning set forth in Section 6.3.

**1.99 “Launch Sequence”** has the meaning set forth in Section 6.3.

**1.100 “Limitation”** means the 52-Week Limitation or the Induction Limitation.

**1.101 “Local JCCs”** has the meaning set forth in Section 3.1.

**1.102 “Local Medical Affairs Plan”** has the meaning set forth in Section 6.8(a).

**1.103** “**Losses**” means any and all liabilities, expenses, damages, costs, fees, expenses and losses, including any damages for product liability, personal injury or property damage, and including reasonable legal expenses and attorneys’ fees.

**1.104** “**MAA**” means a marketing authorization application or equivalent application for approval to market and sell a product filed with the applicable Regulatory Authority in any country or jurisdiction, including a JNDA, and all amendments and supplements thereto. For clarity, MAA does not include any application for Pricing or Reimbursement Approval.

**1.105** “**Major European Countries**” means France, Germany, Italy, Spain, and the United Kingdom.

**1.106** “**Mandatory Recall**” has the meaning set forth in [Section 5.6](#).

**1.107** “**Manufacturing**” or “**Manufacture**” means, as applicable, all activities associated with the production, manufacture, process of formulating, processing, purifying, filling, finishing, packaging, labeling, testing, quality assurance, shipping, importing and storage of the Compound or Product (including Clinical Samples, Bulk Product or Semi-Finished Product), as applicable, and any part or component thereof, including purchasing, shipping of raw materials and components, process development, process validation, stability testing, manufacturing scale-up, pre-clinical, clinical and commercial manufacture and analytical development, product characterization, quality assurance and quality control development, testing and release, but excluding for the avoidance of doubt Developing and Commercializing.

**1.108** “**Medical Affairs**” or “**Medical Affairs Activities**” means activities designed to ensure or improve appropriate medical use of, conduct medical education of, or further medical training regarding, the Product, including by way of example: (a) the activities of medical science liaisons; (b) grants to support continuing medical education, symposia, or Third Party research related to a Product; (c) development, publication and dissemination of publications relating to a Product; (d) medical information services provided in response to inquiries communicated via sales representatives or received by letter, phone call or email; (e) advisory board meetings, international advisory board activities or other consultant programs, including the engagement of key opinion leaders (KOL) and key external experts (KEE) and health care professionals in individual or group advisory or consulting arrangements; (f) post-marketing data generation; (g) evaluation of applications for support of investigator initiated research or investigator initiated clinical trials; (h) health economics and outcomes research (HEOR); (i) activities performed in connection with patient registries; and (j) disease awareness activities, in each case ((a) through (j)) as pertains to the Product.

**1.109** “**Medical Affairs Subcommittee**” has the meaning set forth in [Section 3.1\(r\)](#).

**1.110** “**Net Sales**” means, with respect to any Product, the gross amounts invoiced for sales of Product by Otsuka and its Affiliates and Sublicensees (each, a “**Seller**”) to Third Parties, less the following deductions to the extent included in the gross invoiced sales price for such Product or otherwise directly paid or incurred by the Seller or allowed and taken with respect to the sale or other disposition of such Product:

(a) normal and customary trade, cash and quantity discounts actually allowed and properly taken with respect to sales of such Product;

(b) amounts actually repaid or credited upon returns, rejections, defects, price adjustments, billing errors, or trial prescriptions, including amounts repaid, discounted or credited by reason of risk sharing schemes with respect to the Product with any Governmental Authority or Pricing Authority;

(c) rebates (including mandatory rebates), clawbacks, discounts or chargebacks paid, granted or credited to any Governmental Authority or Pricing Authority, including its agencies, reimbursers and purchasers, or to any Third Party payor, administrator, purchaser, including trade customer, or contractee, including managed health care organizations and pharmacy benefit managers (or equivalents thereof), and including those requested by any Governmental Authority or Pricing Authority any time after the actual sale of a Product;

(d) costs of freight, carrier insurance, and other transportation charges paid to wholesalers or otherwise related to the distribution of such Product;

(e) taxes, tariffs, duties, excises and other governmental charges (including any value added tax, sales tax, consumption tax or similar tax, other than any taxes based on income) levied or imposed with respect to the sale, transportation, delivery, use, exportation, or importation of such Product or measured by the billing amount for such Product; and

(f) discounts paid under any Governmental Authority-legislated or Seller-sponsored discount prescription drug programs or reductions or coupon and voucher programs.

In addition, the Parties will discuss in good faith amendments to the foregoing deductions that may be permitted to be taken as appropriate on a country-by-country or region-by-region basis in accordance with generally accepted accounting principles consistently applied by a Seller.

Notwithstanding the above, the following shall not be included in the computation of Net Sales: the sale, distribution or supply of Product: (a) as promotional or other samples, for use in Non-Clinical Studies or Clinical Trials, or for use in any test or studies reasonably necessary to comply with any Applicable Laws or as is otherwise normal and customary in the industry; or (b) for compassionate use, named-patient use, or expanded access, indigent or other patient access programs; in each case so long as Seller does not receive payment for such Product.

Except as set forth in the preceding paragraph, any transaction, disposition, or other dealing involving Products between Seller and Third Party that is made at less than fair market value is deemed to have been made at fair market value, and the fair market value of the transaction, disposition, or other dealing will be added to and deemed part of the Net Sales and will be included in the calculation of royalties under this Agreement.

No discount, rebate, chargeback, credit or the like shall apply disproportionately to Product when compared to the other products of Otsuka or its Affiliate or Sublicensee, as applicable.

Otsuka shall not sell any Product in combination with, as part of a bundle or risk sharing scheme with, or as a combination therapy with other products, or offer packaged arrangements to customers that include a Product, in such a manner as to disproportionately discount the selling price of the Product.



Upon any sale or other disposition of any Product for any consideration other than exclusively monetary consideration on bona fide arms'-length terms, or if the Product is sold with other products, then for purposes of calculating Net Sales under this Agreement, such Product shall be deemed to be sold exclusively for money at the average sales price of the relevant Product in arm's length transactions during the applicable reporting period generally achieved for such Product in the country in which such sale or other disposition occurred when such Product is sold alone and not with other products (average sales price to be measured as the aggregate Product Net Sales divided by the aggregate number of units sold in such country).

In no event will any particular amount identified above be deducted more than once in calculating Net Sales. Sales of a Product between Otsuka and its Affiliates or Sublicensees for resale shall be excluded from the computation of Net Sales, but the subsequent resale of such Product to a Third Party by such Affiliates or Sublicensees shall be included within the computation of Net Sales.

**1.111** “**Non-Breaching Party**” has the meaning set forth in [Section 14.2](#).

**1.112** “**Non-Clinical Study**” means a study, including a pre-clinical or non-clinical study, involving the Compound or the Product in vitro or in animals (not humans).

**1.113** “**OPEL**” means Otsuka Pharmaceutical Europe Ltd., an Affiliate of Otsuka.

**1.114** “**Oral Form**” means a finished dosage form that is delivered to the gastrointestinal tract after delivery through the mouth, in any dosage strength. Specifically, an Oral Form includes gelcaps, tablets, forms that dissolve in the mouth and liquids suitable only for delivery through the mouth but does not include any other form, including forms delivered by parenteral administration (including by way of injection, inhalation, transdermal delivery) or transmucosal (other than sublingual) delivery, or topical delivery.

**1.115** “**Other Aurinia Licensee**” means any licensee or sublicensee of Aurinia (other than Otsuka or any of its Affiliates) to which a license or a sublicense under the Aurinia Technology is granted by Aurinia, on or after the Effective Date, for the Development or Commercialization of Product in the Field for all or any portion of the Aurinia Territory beyond the mere right to purchase Products from Aurinia, including any Third Party that is granted co-promotion rights, but excluding wholesalers, distributors, contract research organizations, contract manufacturing organizations and other similar entities. In no event shall Otsuka or any of its Affiliates be deemed an Other Aurinia Licensee.

**1.116** “**Other Covered Party**” has the meaning set forth in [Section 11.2\(c\)](#).

**1.117** “**Otsuka Initial Development**” has the meaning set forth in [Section 4.1\(b\)](#).

**1.118** “**Otsuka Data**” has the meaning set forth in [Section 10.1\(a\)](#).

**1.119** “**Otsuka Indemnitee**” has the meaning set forth in [Section 12.1](#).

**1.120** “**Otsuka Know-How**” means all Know-How: that Otsuka or its Affiliates Control after the Effective Date or during the Term; that is generated, discovered, made, conceived, developed or otherwise created in the course of conducting activities under this Agreement

(including Otsuka Sole Inventions and Otsuka Data that Otsuka or its Affiliates Control but excluding Otsuka's interest in Joint Inventions); and that is necessary or reasonably useful for the Development, Manufacture, Packaging, Commercialization and Medical Affairs for the Product or any Aurinia Domain Product.

**1.121 "Otsuka Patents"** means all Patents that Otsuka or its Affiliates Control after the Effective Date or during the Term that claim any Otsuka Know-How and that Cover the Development, Manufacture, Packaging, Commercialization and Medical Affairs for the Product or any Aurinia Domain Product anywhere in the world, but excluding Otsuka's interest in Joint Patents.

**1.122 "Otsuka Sole Inventions"** has the meaning set forth in [Section 10.1\(b\)\(ii\)](#).

**1.123 "Otsuka Technology"** means Otsuka Know-How and Otsuka Patents.

**1.124 "Otsuka Territory"** means, collectively, Territory-A, Territory-B, and Japan. If Otsuka exercises the Expanded Territory Negotiation Right and the Parties agree on an amendment to this Agreement as provided in [Section 2.6](#), then the Otsuka Territory shall include the country(ies) or region(s) that are the subject of such amendment.

**1.125 "Otsuka Territory Additional Development"** has the meaning set forth in [Section 4.2\(a\)](#).

**1.126 "Otsuka Territory-Specific Brand Plan"** has the meaning set forth in [Section 6.6](#).

**1.127 "Otsuka Territory Third Party IP Agreement"** has the meaning set forth in [Section 2.8](#).

**1.128 "Package," "Packaged" or "Packaging"** means placing Clinical Samples, Bulk Product or Semi-Finished Product into primary (if applicable) and secondary packaging and preparing and utilizing labeling (including the Regulatory Authority-approved Product labeling) for such packaging, including written, printed or graphic matter upon a container, wrapper or any package insert or outsert utilized with or for Clinical Samples or Product, for purposes of producing Clinical Samples or Product in its finished form, ready for commercial sale to the market, promotional sampling or use in any Clinical Trial, as the case may be.

**1.129 "Patents"** means (a) all patents and patent applications in any country or jurisdiction, (b) all patent applications filed either from such patents or patent applications or from an application claiming priority from any of these, including divisionals, continuations, continuations-in-part, provisionals, converted provisionals, and continued prosecution applications, (c) any and all patents that have issued or in the future issue from the foregoing patent applications, and (d) any and all substitutions, renewals, registrations, confirmations, extensions, or restorations, including revalidations, reissues, and re-examinations (including any supplementary protection certificates and the like) of the foregoing patents or patent applications.

**1.130 "Payment Forms"** means two copies of Form 3 (Application Form for Income Tax Convention) or any form substituted therefor by a Governmental Authority in Japan, which,

at the time Aurinia provides such form to Otsuka, must be currently effective (un-expired), completed and signed.

**1.131 “Pharmacovigilance Agreement”** has the meaning set forth in [Section 5.5\(a\)](#).

**1.132 “Pharmacovigilance Committee”** or **“PVC”** has the meaning set forth in [Section 5.5\(a\)](#).

**1.133 “Phase 2 Clinical Trial”** means a human clinical trial, the principal purpose of which is to explore a variety of doses, dose response, and duration of effect, and to generate evidence of clinical safety, effectiveness and dose ranging for a particular indication or indications in a target patient population, consistent with the requirements of U.S. 21 C.F.R. § 312.21(b) or (for a trial conducted outside the U.S.) its equivalents in the applicable non-U.S. jurisdictions

**1.134 “Phase 3 Clinical Trial”** means a human clinical trial, the principal purpose of which is to establish that the product is safe and efficacious for its indicated use, define contraindications, warnings, precautions and adverse reactions that are associated with the product in the dosage range to be prescribed, to support the filing of an application for Regulatory Approval for such product, consistent with the requirements of U.S. 21 C.F.R. §312.21(c) or (for a trial conducted outside the U.S.) its equivalents in the applicable non-U.S. jurisdictions.

**1.135 “PMDA”** means the Japanese Pharmaceuticals and Medical Devices Agency or any successor thereto.

**1.136 “Pricing Authority”** means any Governmental Authority (including the National Institute of Clinical Excellence and the Scottish Medicines Consortium in the United Kingdom; the Institute for Quality and Efficiency in Healthcare in Germany; the Technical Scientific Commission in Italy; the Directorate of Pharmacy and Healthcare Products in Spain; and the National Union of Health Insurance Funds and the National Authority of Health in France) or non-Governmental Authority (including “Sick Funds” in Germany) with the authority to control, approve, recommend or otherwise determine pricing and reimbursement of pharmaceutical products, including those with authority to enter into risk sharing schemes and/or to impose retroactive price reductions, discounts, or rebates.

**1.137 “Pricing or Reimbursement Approval”** means, with respect to a Product, and as applicable: (a) the approval, agreement, determination or decision establishing prices that can be charged for such Product in regulatory jurisdictions where the applicable Governmental Authorities (including Pricing Authorities) approve or determine the price of pharmaceutical products, or (b) the approval, agreement, determination or decision establishing the prices at which such Product will be reimbursed in regulatory jurisdictions where the applicable Governmental Authority (including Pricing Authority) approves, determines or recommends the reimbursement or use of pharmaceutical products, including, in Germany, the reimbursement price established under Arzneimittelmarktneuordnungsgesetz (or AMNOG).

**1.138 “Privacy Laws”** means all Applicable Laws with respect to the collection, use, transfer, storage, deletion, processing (both by computer and manually), combination, or other use of subject or patient or other personal data.

1.139 “**Product**” means any pharmaceutical product containing the Compound as an active ingredient in the Oral Form.

1.140 “**Product Infringement**” has the meaning set forth in Section 10.3(a).

1.141 “**Product Mark Infringement**” has the meaning set forth in Section 10.5(c).

1.142 “**Product Marks**” has the meaning set forth in Section 10.5(a).

1.143 “**Product Materials**” has the meaning set forth in Section 6.10.

1.144 “**Professional Requirements**” means: (a) the codes and standards of the European Accreditation Council for Continuing Medical Education (EACCME) and the European Federation of Pharmaceutical Industries and Associations (EFPIA); (b) the codes of the Prescription Medicines Code of Practice Authority (PMCPA) and the Association of the British Pharmaceutical Industry (ABPI); and (c) all other national and international pharmaceutical industry codes of practice in and for the countries in the Otsuka Territory; as any of the foregoing may be amended or replaced from time-to-time.

1.145 “**Prosecution**” has the meaning set forth in Section 10.2. The term “**Prosecute**” has correlative meaning.

1.146 “**Quality Agreement**” has the meaning set forth in Section 7.2.

1.147 “**Recall Decision-Makers**” has the meaning set forth in Section 5.6.

1.148 “**Regulatory Activities**” means any and all regulatory affairs related to (a) Development (including MAA pre-submission meetings with EMA, meetings and discussions with rapporteurs or co-rapporteurs and other regulatory affairs activities directed to obtaining Regulatory Approvals of Products), including interactions with Regulatory Authorities regarding Regulatory Approvals and other Regulatory Filings and (b) Commercialization, including Pricing or Reimbursement Approval, including interactions with Pricing Authorities.

1.149 “**Regulatory Approval**” means any and all approvals, licenses, registrations, permits, notifications and authorizations (or waivers) of any Regulatory Authority that are necessary for the marketing and sale of a pharmaceutical product in a country or jurisdiction, including approval of any MAA but excluding any Pricing or Reimbursement Approval.

1.150 “**Regulatory Authority**” means any Governmental Authority or Pricing Authority that has responsibility or authority in its applicable jurisdiction over the testing, development, manufacture, use, storage, import, transport, promotion, marketing, distribution, offer for sale, sale, pricing or reimbursement of pharmaceutical products, including the FDA, the EMA, the Medicines and Healthcare products Regulatory Agency (MHRA), Swissmedic, and the PMDA .

1.151 “**Regulatory Documentation**” means all (a) Regulatory Filings, and (b) reports and material correspondence and communications submitted to or received from any Regulatory Authority (including minutes and contact reports relating to substantive communications,

conversations or meetings with any Regulatory Authority), and all supporting documents with respect thereto, relating to the Compound or the Product in the Field.

**1.152 “Regulatory Exclusivity”** means exclusive marketing rights or data exclusivity rights conferred by any Regulatory Authority with respect to a Product in a country in the Otsuka Territory, excluding any Patent right, but including new chemical entity data exclusivity and pediatric exclusivity rights.

**1.153 “Regulatory Filing”** means any applications (including INDs and MAAs), filings, submissions, approvals (including Regulatory Approvals), licenses, registrations, permits, notifications, and authorizations (or waivers) with respect to the Development, Manufacture or Commercialization of any Product made to any Regulatory Authority in a given country.

**1.154 “Regulatory Meeting”** has the meaning set forth in [Section 5.3\(a\)](#).

**1.155 “Removal Condition”** means modification of the First Approved SmPC to remove both Limitations (if both Limitations were included in the First Approved SmPC) or the Limitation (if only one Limitation was included in the First Approved SmPC).

**1.156 “Representatives”** means, in respect of a Party, such Party’s Affiliates and the consultants, contractors, subcontractors, employees, directors, officers and agents of either of such Party and such Party’s Affiliates, excluding any CMO.

**1.157 “Responsible Party”** has the meaning set forth in [Section 10.3\(e\)](#).

**1.158 “Right of Reference”** means the authority to rely upon, and otherwise use, an investigation for the purpose of obtaining a Regulatory Approval, including the ability to make available the underlying raw data from the investigation for audit by a Regulatory Authority, if necessary.

**1.159 “Royalty Report”** has the meaning set forth in [Section 9.1](#).

**1.160 “Rules”** has the meaning set forth in [Section 15.4](#).

**1.161 “Safety Data”** means Data and information related to any adverse drug experiences and serious adverse drug experiences pertaining to the Compound or Products as such Data and information are reportable to Regulatory Authorities. Safety Data includes Data and other Product information related to “adverse events,” “adverse drug reactions” and “unexpected adverse drug reactions” as defined in the ICH Harmonised Tripartite Guideline for Clinical Safety Data Management: Definitions and Standards for Expedited Reporting.

**1.162 “Securities Authority”** has the meaning set forth in [Section 13.5](#).

**1.163 “Seller”** has the meaning set forth in [Section 1.110](#).

**1.164 “Semi-Finished Product”** means Product in primary packaging (e.g., blister packs) ready for storage or shipment to a facility to enable the secondary Packaging of finished Product.

**1.165 “SmPC”** means Summary of Product Characteristics.

**1.166** “**Sublicensee**” means, with respect to a Party, a Third Party to whom such Party grants a sublicense under the licenses granted under [Article 2](#), beyond the mere right to purchase Products from such Party, including any Third Party that is granted co-promotion rights, but excluding wholesalers, distributors, contract research organizations, contract manufacturing organizations and other similar entities. For clarity, Sublicensee does not include any entity that purchases Products from such Party or such Party’s Affiliate (even if such entity conducts sales-related activities, such as marketing and promotion, with respect to such purchased Products) provided such entity does not receive a license or right from such Party to conduct Development or prosecute or enforce Aurinia Technology, Otsuka Technology or Product Marks. In no event shall a Party or any of its Affiliates be deemed a Sublicensee of the other Party.

**1.167** “**Sued Party**” has the meaning set forth in [Section 10.4](#).

**1.168** “**Supply Agreement**” means a Clinical Supply Agreement or a Commercial Supply Agreement, as further set forth in [Section 7.2](#).

**1.169** “**Supporting Party**” has the meaning set out in [Section 10.3\(e\)](#).

**1.170** “**Term**” has the meaning set forth in [Section 14.1](#).

**1.171** “**Terminated Country**” has the meaning set forth in [Section 14.6\(b\)](#).

**1.172** “**Territory ROFN Notice**” has the meaning set forth in [Section 2.6](#).

**1.173** “**Territory**” means, with respect to Aurinia, the Aurinia Territory and, with respect to Otsuka, the Otsuka Territory.

**1.174** “**Territory-A**” means the twenty-seven (27) member states of the European Union as of the Effective Date.

**1.175** “**Territory-B**” means Belarus, Iceland, Lichtenstein, Norway, Russia, Switzerland, Ukraine and United Kingdom.

**1.176** “**Third Party**” means any entity other than Aurinia or Otsuka or an Affiliate of Aurinia or Otsuka.

**1.177** “**Third Party Claims**” means claims, demands, actions or other proceedings in each case brought by any Third Party.

**1.178** “**Third Party Infringement Suit**” has the meaning set forth in [Section 10.4](#).

**1.179** “**Third Party IP**” has the meaning set forth in [Section 2.8](#).

**1.180** “**Trademark**” means any trademark, trade name, service mark, service name, brand, domain name, trade dress, logo, slogan or other indicia of origin or ownership, in any language, including the goodwill and activities associated with each of the foregoing.

**1.181** “**Trademark Infringement Suit**” has the meaning set forth in [Section 10.5\(d\)](#).

**1.182** “**Transition Activities**” has the meaning set forth in [Section 14.6\(j\)](#).

**1.183** “U.S.” means the United States of America, including its territories and possessions (including Puerto Rico).

**1.184** “Valid Claim” means a claim of an issued and unexpired patent that has not been revoked or held unenforceable, unpatentable or invalid by a decision of a court or other governmental agency of competent jurisdiction that is not appealable or has not been appealed within the time allowed for appeal, and that has not been surrendered, abandoned, disclaimed, denied or admitted to be invalid or unenforceable through reissue, re-examination, disclaimer or otherwise.

**1.185** “Voclosporin Manufacturing Trade Secrets” [definition of Aurinia trade secrets redacted]

**1.186** “Voluntary Recall” has the meaning set forth in Section 5.6.

## **2. LICENSES; RIGHTS; EXCLUSIVITY**

### **2.1 License Grants to Otsuka**

**(a) License.** Subject to the terms and conditions of this Agreement, including Aurinia’s retained rights under Section 2.3, Aurinia hereby grants to Otsuka, during the Term, an exclusive (even as to Aurinia and its Affiliates, except as expressly set forth herein), royalty-bearing, transferable (solely as provided in Section 16.5), license, with the right to grant sublicenses solely as provided in Section 2.1(b), under the Aurinia Technology, the Product Marks and Aurinia’s interest in Joint Technology to:

**(i)** use, Develop, have Developed, Commercialize and conduct Medical Affairs for the Products in the Field in the Otsuka Territory, and

**(ii)** Package and have Packaged the Products for use in the Field in the Otsuka Territory.

**(b) Sublicense Rights.** Otsuka shall have the right to grant sublicenses under the license granted in Section 2.1(a), to the following Sublicensees:

**(i)** any Affiliate without Aurinia’s express prior written consent and without providing any written notice to Aurinia, provided that such sublicense will terminate if such Sublicensee no longer qualifies as an Affiliate of Otsuka;

**(ii)** any Third Party with the prior written consent of Aurinia, which consent shall not be unreasonably withheld. Otsuka will provide prior written notice to Aurinia identifying Otsuka’s intention to grant such sublicense, the purpose of such sublicense, the identity of the Third Party to whom Otsuka intends to grant such sublicense, the scope or purpose of such sublicense and the terms on which such sublicense would be granted. Otsuka shall provide Aurinia with data and information and assist Aurinia to conduct other due diligence relating to such sublicense as reasonably requested by Aurinia.

**(c)** Each Sublicensee will hold its rights contingent on the rights licensed to Otsuka under the terms of this Agreement. All sublicenses granted to Third Parties under the

license granted in Section 2.1(a) shall be in writing and all sublicenses (to Third Parties and Affiliates) shall be subject to, and consistent with, the terms and conditions of this Agreement, and shall require that the Sublicensee shall comply with the terms of this Agreement that are applicable to such sublicense with only those differences necessary to reflect the scope and purpose of the sublicense, including, to the extent applicable, Sections 2.5 (No Implied Licenses; Negative Covenant), 2.7 (Disclosure of Know-How), 2.9 (Exclusivity), if the Sublicensee has rights to perform Development, 4.3 (Summary Development Reports), 4.5 (Development Records), 5.8 (No Harmful Actions), 9.5 (Records; Audit), 10.1 (Ownership of Intellectual Property), (and, if the Sublicensee has rights to prosecute or enforce Aurinia Technology, Otsuka Technology or Product Marks, as applicable, the rest of Section 10 (Intellectual Property)), 11.5, (Disclaimer), 12.5 (Limitation of Liability), and 13 (Confidentiality) all as if the Sublicensee were Otsuka hereunder. Except as provided in this Section 2.1(c), no sublicense shall be further sublicensable or assignable except with the prior written consent of Aurinia, which consent shall not be unreasonably withheld. For clarity, if in the performance of obligations and exercise of rights under this Agreement in Europe, as contemplated under Section 16.6, OPEL grants a sublicense to its Affiliate or a Third Party, such sublicense shall be treated as a sublicense by Otsuka (and will be subject to the terms of this Section 2.1(b) as if Otsuka were granting such sublicense) and shall not be deemed a further sublicense by Otsuka. Notwithstanding any sublicense, Otsuka shall remain primarily liable to Aurinia for the performance by the Sublicensee of all of Otsuka's obligations under, and Otsuka's compliance with all provisions of, this Agreement. A breach by a Sublicensee of the terms of this Agreement shall be deemed to be a breach by Otsuka.

## 2.2 License Grants to Aurinia

**(a) License.** Subject to the terms and conditions of this Agreement, including Otsuka's retained rights under Section 2.3, Otsuka hereby grants to Aurinia:

**(i)** an exclusive (even as to Otsuka and its Affiliates, except as expressly set forth herein), transferable (solely as provided in Section 16.5), perpetual, irrevocable and royalty-free license (subject to Section 14.6(d)), with the right to grant sublicenses solely as provided in Section 2.2(b), under the Otsuka Technology and Otsuka's interest in Joint Technology to use, Develop, have Developed, Manufacture, have Manufactured (including Package), Commercialize, and conduct Medical Affairs for (A) the Products in the Aurinia Territory and (B) the Aurinia Domain Products worldwide; and

**(ii)** a non-exclusive, transferable (solely as provided in Section 16.5) and royalty-free license, during the Term to perform its obligations under this Agreement.

**(b) Sublicense Rights.** Aurinia shall have the right to grant sublicenses through multiple tiers under the license granted in Section 2.2(a) to the following Sublicensees: any Affiliate of Aurinia or any Third Party. Aurinia will provide written notice to Otsuka prior to or promptly after granting a sublicense to a Third Party, indicating the identity of the Third Party sublicensee and the scope and purpose of such sublicense. All sublicenses granted to Third Parties under the license granted in Section 2.2(a) shall be in writing and all sublicenses (to Third Parties and Affiliates) shall be subject to, and consistent with, the terms and conditions of this Agreement, and shall require that the Sublicensee shall comply with the terms of this Agreement that are applicable to such sublicense with only those differences necessary to reflect the scope



and purpose of the sublicense, including, to the extent applicable, Sections 2.5 (No Implied Licenses; Negative Covenant), 2.7 (Disclosure of Know-How), 2.9 (Exclusivity), 4.3 (Summary Development Reports), 4.5 (Development Records), 5.8 (No Harmful Actions), 10.1 (Ownership of Intellectual Property), (and, if the Sublicensee has rights to prosecute or enforce Aurinia Technology, Otsuka Technology or Product Marks, as applicable, the rest of Section 10 (Intellectual Property)) 11.5 (Disclaimer), 12.5 (Limitation of Liability), and 13 (Confidentiality) all as if the Sublicensee were Aurinia hereunder. Notwithstanding any sublicense, Aurinia shall remain primarily liable to Otsuka for the performance by the Sublicensee of all of Aurinia's obligations under, and Aurinia's compliance with all provisions of, this Agreement.

### **2.3 Retained Rights**

. Any rights not expressly granted to Otsuka by Aurinia are hereby retained by Aurinia and any rights not expressly granted to Aurinia by Otsuka are hereby retained by Otsuka. For clarity, subject to Section 2.9, (a) Aurinia hereby retains (i) the right under Aurinia Technology, Regulatory Documentation, and Product Marks to exercise its rights and perform its obligations under this Agreement, including the right to Develop, have Developed, Manufacture, and have Manufactured and Package the Compound and Products in the Otsuka Territory for the purpose of obtaining and maintaining Regulatory Approval and Commercializing Products in the Aurinia Territory, (ii) all rights to practice, and to grant licenses under, the Aurinia Technology and Regulatory Documentation outside of the scope of the license granted to Otsuka in Section 2.1, including (A) the exclusive (except with respect to Packaging) right to Manufacture and have Manufactured the Compound and Products anywhere in the world, (B) the exclusive right to Develop, have Developed, Commercialize, have Commercialized and conduct Medical Affairs for the Products in the Aurinia Territory, and (C) the exclusive right to practice the Aurinia Patents and Aurinia Know-How with respect to all compounds and products other than Compound and Products, including the right to develop, have developed, manufacture, have manufactured, commercialize, have commercialized, conduct medical affairs for and otherwise exploit Aurinia Domain Products worldwide, and (iii) the non-exclusive right to perform Medical Affairs Activities in the Otsuka Territory; in accordance with Section 6.8; and (b) Otsuka hereby retains (i) the right under Otsuka Technology to exercise its rights and perform its obligations under this Agreement, and (ii) subject to Section 2.9, all rights to practice, and to grant licenses under, the Otsuka Technology outside of the scope of the license granted to Aurinia in Section 2.2, including the exclusive right to practice the Otsuka Patents and Otsuka Know-How with respect to compounds and products other than Compound and Products.

### **2.4 Access to Sublicensee Work Product**

. Without limiting Otsuka's obligations under Section 2.1(b) and Aurinia's obligations under Section 2.2(b):

(i) Otsuka shall ensure that it Controls any intellectual property rights relating to the Product (including its use and Packaging (and Manufacturing if Otsuka obtains rights to Manufacture)) arising from the enjoyment by a Sublicensee of the sublicense granted in Section 2.1(b) so that Aurinia and its Sublicensees may access and exploit such intellectual property rights as Otsuka Technology on the terms set out in Section 2.2.

(ii) Otsuka shall ensure that it Controls any Data, Regulatory Documentation, Regulatory Approvals, Product Materials, and information regarding Medical Affairs referred to in Section 6.8 arising from the enjoyment by a Sublicensee of the sublicense granted in Section 2.1(b) so that Aurinia and its Sublicensees may access and exploit such Data and Regulatory Documentation and Regulatory Approvals as Otsuka Data, Otsuka's Regulatory Documentation and Regulatory Approvals on the terms set out herein.

(iii) Aurinia shall use commercially reasonable efforts to Control any intellectual property rights relating to the Product (including its use and Manufacture) arising from the enjoyment by its Sublicensees of the sublicense granted in Section 2.2(b) or from licenses or sublicenses granted to Other Aurinia Licensees so that Otsuka, its Affiliates and its Sublicensees may access and exploit such intellectual property rights as Aurinia Technology on the terms set out in Section 2.1.

(iv) Aurinia shall use commercially reasonable efforts to Control any Data, Regulatory Documentation, Regulatory Approvals, Product Materials, and information regarding Medical Affairs referred to in Section 6.8 arising from the enjoyment by any Sublicensees of the sublicense granted in Section 2.2(b) or from any licenses or sublicenses granted to Other Aurinia Licensees so that Otsuka, its Affiliates and its Sublicensees may access and exploit such Data, Regulatory Documentation, Regulatory Approvals, Product Materials, and Medical Affairs information as Data, Regulatory Documentation, Regulatory Approvals, Product Materials, and Medical Affairs information of Aurinia on the terms set out in Section 2.1.

(v) In any license with a Sublicensee of Aurinia or with any Other Aurinia Licensee, Aurinia shall not give such Sublicensee or Other Aurinia Licensee access (or a Right of Reference) to Otsuka Data or Otsuka's Regulatory Documentation and Regulatory Approvals unless such Sublicensee or Other Aurinia Licensee, as applicable, agrees to give Otsuka and its Sublicensees access (or a Right of Reference) to such Aurinia Sublicensee's or Other Aurinia Licensee's Data, Regulatory Documentation and Regulatory Approvals on the terms set out herein.

(vi) If an Aurinia Sublicensee or Other Aurinia Licensee restricts the sharing of its Know-How with Otsuka or its Affiliates or Sublicensees to exclude any Know-How regarding Commercialization or Medical Affairs, then Aurinia will not share the equivalent Otsuka Know-How regarding Commercialization or Medical Affairs with such Sublicensee or Other Aurinia Licensee, as applicable.

(vii) Nothing in this Agreement gives Otsuka or its Sublicensees any rights to Aurinia Know-How regarding any Aurinia Domain Product.

(viii) Nothing in this Agreement gives Otsuka or its Sublicensees any rights to Aurinia Technology regarding the Manufacture of Product, other than Packaging-related activities. Nothing in this Agreement shall oblige Aurinia to disclose or grant any rights to the Voclosporin Manufacturing Trade Secrets, except as set forth in Section 5.3(b).

(ix) Notwithstanding anything else in this Agreement, each Party shall exchange Safety Data regarding the Compound and Product as required by any Regulatory Authority and as otherwise set out in the Pharmacovigilance Agreement.

## 2.5 No Implied Licenses; Negative Covenant

. Except as set forth in this Agreement, neither Party shall acquire any license or other intellectual property interest, by implication or otherwise, under or to any Patents, Know-How or other intellectual property owned or controlled by the other Party. Neither Party shall, nor shall it permit any of its Affiliates, licensees or sublicensees to, practice any Patents or Know-How licensed to it by the other Party outside the scope of the licenses granted to it under this Agreement.

## 2.6 Negotiation Right

. Subject to the terms and conditions of this Agreement, Aurinia hereby grants Otsuka a right of negotiation to obtain an exclusive license under Aurinia Technology to Develop or Commercialize the Products in the Field in one or more countries or regions not then included in the Otsuka Territory, excluding the U.S. and Canada (the “**Expanded Territory Negotiation Right**”) on the terms set out in this Section. If Aurinia intends to grant an exclusive license under Aurinia Technology to Develop or Commercialize the Products in the Field (other than on early access/named-patient programs basis) in any country or region not then included in the Otsuka Territory, excluding the U.S. and Canada, and, as a result of such grant, any such Third Party would be an Other Aurinia Licensee, Aurinia shall promptly notify Otsuka in writing of such intent (the “**Territory ROFN Notice**”) and, if Otsuka wishes to exercise the Expanded Territory Negotiation Right for one or more such countries or regions, it shall notify Aurinia in writing within **[time period redacted]** of receipt of the Territory ROFN Notice from Aurinia. If Otsuka notifies Aurinia in writing of Otsuka’s desire to exercise the Expanded Territory Negotiation Right within such period, the Parties shall negotiate in good faith, for a period up to **[time period redacted]** after Otsuka provides such notice (or such longer time period as the Parties may agree upon), to enter into an amendment to this Agreement to add such country or region on financial and other terms to be agreed between the Parties. If Otsuka fails to exercise the Expanded Territory Negotiation Right or notifies Aurinia in writing that it will not exercise the Expanded Territory Negotiation Right with respect to all or any of such countries or regions, in either case within the **[time period redacted]** period above, or if the Parties fail to reach agreement on an amendment to this Agreement during such **[time period redacted]** (or longer) negotiation period, Otsuka shall have no rights under this Section 2.6 with respect to such countries or regions and no rights or license to Develop or Commercialize the Compound or any Product in such countries or regions.

## 2.7 Disclosure of Know-How

(a) For as long as Otsuka is conducting any Agreed Development or any Otsuka Territory Additional Development hereunder, to the extent in the Control of Aurinia, Aurinia shall disclose and make available to Otsuka, in its original form (or where available, in electronic form), without translation, all such Aurinia Know-How necessary or reasonably useful for such Development (i) that was not previously provided to Otsuka, promptly after the Effective Date, and (ii) for the first six months following the Effective Date, promptly after the generation, receipt, development or making of such Aurinia Know-How; and (iii) that comes into existence more than six months after the Effective Date, promptly upon request by Otsuka.

(b) For as long as Otsuka is conducting any Agreed Development or any Otsuka Territory Additional Development hereunder, Otsuka shall and shall cause its Affiliates to, at no cost to Aurinia, disclose and make available to Aurinia, in its original form (or in electronic form where available), without translation, any Otsuka Know-How necessary or reasonably useful for Aurinia's Development of the Product in the Aurinia Territory and Aurinia Domain Products worldwide (i) for the first six months following the Effective Date, promptly after the generation, receipt, development or making of such Otsuka Know-How, and (ii) that comes into existence more than six months after the Effective Date, promptly upon request by Aurinia.

(c) Each of the Europe JCC and the Japan JCC shall establish a mechanism for the reciprocal disclosure of Know-How within its respective area of responsibility.

(d) Except for Agreed Development and as otherwise set out in this Agreement, nothing in this Section 2.7 obliges Aurinia to disclose to Otsuka any Voclosporin Manufacturing Trade Secrets or any Know-How arising from development of any Product or Aurinia Domain Product by or on behalf of Aurinia. For clarity, as of the Effective Date, Know-How arising from Agreed Development may be Aurinia Know-How for the purposes of this Section 2.7. However, except to the extent necessary for Otsuka to perform activities under this Agreement and subject to Section 4.2(e)(iii), Otsuka does not obtain rights to exploit the Know-How arising from Global Additional Development unless the Parties have agreed to pursue it together as contemplated by Section 4.2(e)(i); or agreed on a regulatory milestone in accordance with Section 4.2(c) or agreed on the payment to be made by Otsuka in connection with its opt-in right in accordance with Section 4.2(e)(iii) and covenants to limit the use same pursuant to such Section 4.2(e)(iii).

(e) Except as expressly set out in this Agreement, nothing in this Agreement will obligate Aurinia to create any new materials or documentation (i.e., requiring additional analysis, formatting, or other efforts not previously performed) or deliver any materials or documentation that is not in the Control of Aurinia.

## **2.8 Third Party IP Agreements**

(a) [Provisions relating to treatment of third party IP agreements redacted]

## **2.9 Exclusivity**

(a) On a country-by-country basis in the Otsuka Territory, during the period from the Effective Date until the expiration of the Initial Royalty Term in such country, except as permitted by this Agreement, each Party shall not (and shall cause its Affiliates that are exercising Commercialization rights under this Agreement and its Sublicensees, except as set forth in Section 2.9(d) below, to not), itself or with or through its Affiliates or a Third Party, market, promote, distribute, sell, offer to sell or otherwise commercialize any Competing Product: (i) for the Initial Indication; and (ii) for any other indication for which the Product has received Regulatory Approval (or, prior to that time, for one or more of the same indication(s) for which a Product is being Developed hereunder in a Phase 2 Clinical Trial or later stage of

Development) for the Otsuka Territory. Any activities that would violate the terms of this Section (a) shall be referred to herein as a “**Competitive Activities.**”

(b) From the Effective Date until the expiration of the last to expire Initial Royalty Term in any country in the Otsuka Territory, except as permitted by this Agreement, Otsuka shall not (and shall cause its Affiliates that are exercising Commercialization rights under this Agreement and its Sublicensees, except as set forth in Section 2.9(d) below, to not), itself or with or through its Affiliates or a Third Party, market, promote, distribute, sell, offer to sell or otherwise commercialize in the Aurinia Territory: (i) any pharmaceutical product that contains the Compound; or (ii) any Competing Product for the Initial Indication or for any other indication for which the Product or any Aurinia Domain Product has received Regulatory Approval in the Aurinia Territory.

(c) Notwithstanding the foregoing, if a Competing Product is owned or controlled (including internally developed, acquired and in-licensed products) by an Acquirer of a Party prior to the closing of the transaction in which such Party is acquired, and provided such Competing Product was not owned or controlled by such Acquirer by virtue of a license or other right granted by a Party (such product, an “**Acquirer Competing Product**”), then the Acquirer’s Competitive Activities conducted with respect to such Acquirer Competing Product shall not be subject to the restrictions in this Section 2.9. The Acquirer and its Affiliates (including the acquired Party) shall (i) establish and enforce internal processes, policies, procedures, systems and safeguards (including firewalls) to ensure that such Competitive Activities do not use, incorporate or reference, and are not based on or covered by, (A) Aurinia Technology, Joint Technology or other Confidential Information of Aurinia (if such transaction involves Otsuka) or (B) Otsuka Technology, Joint Technology or other Confidential Information of Otsuka (if such transaction involves Aurinia), and (ii) conduct the Competitive Activities independently of the activities under this Agreement, including by ensuring that (A) no personnel of the Acquirer or any of its Affiliates (including such Party) who perform any Competitive Activities have access to any Confidential Information of the other Party, and (B) no Confidential Information of the other Party is shared with personnel of the Acquirer or any of its Affiliates (excluding the acquired Party) who perform any Competitive Activities or is otherwise shared for use (intentionally or unintentionally) or used in connection with Competitive Activities.

(d) Notwithstanding the above, the terms of this Section 2.9 shall not apply with respect to any generic product that is a Competing Product (other than a Generic Product) if such generic product is being marketed, promoted, distributed, sold or otherwise commercialized by a Party’s Sublicensee at the time such Party and such Sublicensee enter into a sublicense agreement.

### 3. GOVERNANCE

#### 3.1 Joint Collaboration Committees; Responsibilities

. Within thirty (30) days after the Effective Date, the Parties shall establish a joint collaboration committee for Europe (the “**Europe JCC**”) and a joint collaboration committee for Japan (the “**Japan JCC**”) (the Europe JCC and the Japan JCC, collectively, the “**Local JCCs**”). Each Local JCC shall be composed of an equal number of up to three (3) senior officers of each Party to discuss and oversee the Development, Commercialization, Medical Affairs, Regulatory

Activities and intellectual property activities related to the Product in the Otsuka Territory. Each of the Europe JCC and the Japan JCC shall act as a joint consultative body and, to the extent expressly provided herein, a joint decision-making body. The Europe JCC, with respect to Europe, the Japan JCC, with respect to Japan, and Local JCCs (jointly), with respect to the Otsuka Territory and, where applicable, the Aurinia Territory, shall:

( a ) provide a forum for discussion of the Development of the Compound and Products in the Otsuka Territory and in the Aurinia Territory and with respect to the Aurinia Domain Product, where applicable, including sharing of Development Data in accordance with Section 2.7;

( b ) review the status, progress, results and reports of each Party's Development activities respecting any Agreed Development, and any Otsuka Territory Additional Development including any Non-Clinical Studies, Clinical Trials and Investigator-Initiated Trials supported by Otsuka and consented to by Aurinia pursuant to Section 4.2(g) including:

( i ) reviewing and approving the protocols and statistical analysis plans and any other important trial design issues for Clinical Trials (and any amendments thereto) for Clinical Trials for Agreed Development and any Otsuka Territory Additional Development, including any Non-Clinical Study of the Compound or the Product, and any Investigator-Initiated Trials supported by Otsuka, in each case, once permitted pursuant to the terms of Section 4.2(g), and monitoring the progress of such Clinical Trials;

( ii ) reviewing Data resulting from such Clinical Trials; and

( iii ) determining progression to submission of Regulatory Filings and reviewing the draft Regulatory Filings and all Regulatory Documentation and all Regulatory Activities, including in furtherance of obtaining and maintaining Regulatory Approvals;

( c ) review Additional Development Proposals, and approve any development plan and budget for mutually agreed-to Global Additional Development and approve any development plan for Otsuka Territory Additional Development, once permitted pursuant to the terms of Section 4.2;

( d ) review, discuss and monitor worldwide regulatory actions and pharmacovigilance and safety matters, unless the Local JCCs establish and delegate such matters to a regulatory subcommittee or to the Pharmacovigilance Committee;

( e ) review and discuss the Global Brand Plan and review, discuss and approve any Otsuka Territory-Specific Brand Plan pursuant to Section 6.6;

( f ) review, discuss and agree on the Commercialization Plans for each of Europe and Japan, and any matters related thereto, including amendments thereto;

( g ) provide a forum for and facilitate communications and coordination between the Parties with respect to the Commercialization of Products in the Otsuka Territory and the Aurinia Territory;

- (h) on an annual basis, review Otsuka's sales forecasts for Product;
- (i) review and discuss the Launch Sequence and amendments and updates thereto, in each case, to be prepared by Otsuka;
- (j) review and discuss Otsuka's decision not to launch (or to significantly delay the launch of) or not to Commercialize any Product for the Field in any country in the Otsuka Territory, and the portion of the initial Commercialization Plan or any amendment or update thereto that contemplates not launching or Commercializing a Product in such country;
- (k) review and discuss the major findings of Otsuka's market research with respect to any Product in the Otsuka Territory;
- (l) receive and discuss reports of Otsuka's Commercialization of the Product made pursuant to Section 6.4;
- (m) review, discuss and approve list price ranges for Product for Europe and the pricing and reimbursement strategy for Product for Europe, including its potential impact on international reference pricing;
- (n) review, discuss and agree on any applications for Pricing or Reimbursement Approvals and their prosecutions in Europe;
- (o) review and approve any unitary Trademark for the Otsuka Territory or any alternative Trademark, local language Trademark, or additional Trademark proposed by Otsuka pursuant to Section 10.5(a);
- (p) review and discuss a global publication strategy developed pursuant to Section 13.4 and the publication and dissemination of any publication regarding the Compound or Product or any Clinical Trial;
- (q) review and discuss the Global Medical Affairs Plan, and agree to the Local Medical Affairs Plan, including proposed amendments thereto, unless the Local JCCs delegate such functions to the Medical Affairs Subcommittee;
- (r) establish additional joint subcommittees as deemed necessary or advisable to further the purposes of this Agreement, provided that, promptly after the Effective Date, the JCC shall establish (A) a Manufacturing and Supply Subcommittee to review and discuss matters pertaining to the Manufacture and supply of Bulk Product and Semi-Finished Product for the Otsuka Territory, including manufacturing and supply strategy, supply performance and Cost of Goods, and periodic review of worldwide order forecasts for the Product to avoid supply shortage and the treatment of Otsuka's supply requirements relative to those of Aurinia and Other Aurinia Licensees, (B) a Quality Subcommittee to deal with quality issues as they arise, (C) a Medical Affairs Subcommittee (the "**Medical Affairs Subcommittee**"), and (D) a Pharmacovigilance Committee;
- (s) discuss in good faith any action or intended action by a Party referred to the JCC pursuant to Section 5.8 or otherwise that could reasonably be expected to have a

material adverse effect on obtaining or maintaining Regulatory Approval of any Product in the other Party's Territory or Commercialization of any Product in the other Party's Territory;

(t) resolve any disputed matter submitted to it by any joint subcommittee established by JCC; and

(u) perform such other functions as appropriate to further the purposes of this Agreement, as expressly set forth in this Agreement or allocated to it by the Parties' written agreement, but excluding, for clarity, those matters expressly excluded from the purview of the JCC, including those matters strictly reserved to the sole discretion of a Party.

### 3.2 Executive Meeting

(a) . Each Party shall designate an appropriate senior executive officer (e.g., CEO or his or her designee) to meet once a year to discuss strategic issues and other issues that either Party deems important to maintain a successful partnership and collaboration.

### 3.3 Committee Membership and Meetings

(a) **Committee Members.** Each of the Local JCC's representatives shall have appropriate knowledge and expertise and sufficient seniority within the applicable Party to make decisions arising within the scope of the applicable Committee's responsibilities. Each Party may replace its representatives on any Committee upon written notice to the other Party. The chairperson of each Local JCC meeting shall alternate between the representative appointed by Aurinia from among its members to act as chairperson and the representative appointed by Otsuka from among its members to act as chairperson. The chairperson shall prepare and circulate agendas to Committee members at least seven (7) days before each Committee meeting and shall direct the preparation of reasonably detailed minutes for each Committee meeting, which shall be approved by the chairperson and circulated to Committee members within thirty (30) days of such meeting. The initial members of the JCC shall be determined by the Parties promptly following the Effective Date.

(b) **Meetings.** Each Committee shall hold meetings at such times as it elects to do so, provided that, unless the Parties mutually agree otherwise, meetings of the Local JCCs shall be held at least once every three (3) months until receipt of the first Regulatory Approval of the first Product for the Initial Indication in Europe and Japan (and, if applicable, during any period in which Development activities respecting any mutually agreed-upon Additional Development hereunder, and Otsuka Territory Additional Development, including any Non-Clinical Studies, Clinical Trials and Investigator-Initiated Trials supported by Otsuka and consented to by Aurinia pursuant to Section 4.2(g) are being conducted), and thereafter the Local JCCs shall meet at least every six (6) months. The Europe JCC and Japan JCC may meet jointly if the Parties intend to discuss matters applicable throughout the Otsuka Territory. Committee meetings will be held by teleconference or videoconference, or in-person if agreed by the Parties. In-person Committee meetings, if any, shall be held at locations alternately selected by each Party. Each Party shall be responsible for all of its own expenses of participating in Committee meetings. No action taken at any meeting of a Committee shall be effective unless at least one (1) representative of each Party is participating. In addition, upon written notice to the other Party, either Party may request that a special *ad hoc* meeting of a Local JCC be convened to



address matters that cannot reasonably be postponed until the following scheduled meeting of such Local JCC. Such ad hoc meeting shall be convened at such time as may be mutually agreed by the Parties, but no later than twenty (20) days following the notification date of request that such meeting be held.

**(c) Non-Member Attendance.** Each Party may from time to time invite a reasonable number of participants, in addition to its representatives, to attend Committee meetings in a nonvoting capacity; provided that if either Party intends to have any Third Party (including any Third Party Representative) attend such a meeting, such Party shall provide reasonable prior written notice to the other Party and obtain the other Party's approval for such Third Party to attend such meeting, which approval shall not be unreasonably withheld. Such Party shall ensure that such Third Party is bound by written confidentiality and non-use obligations consistent with the terms of this Agreement.

### **3.4 Decision-Making**

**(a)** All decisions of each Committee shall be made by unanimous vote, with each Party's representatives collectively having one (1) vote. If after reasonable discussion and good faith consideration of each Party's view on a particular matter before a Committee, the representatives of the Parties cannot reach an agreement as to such matter within fifteen (15) Business Days (or such longer period as such representatives mutually agree upon) after such matter was brought to such Committee for resolution, then either Party at any time may refer such issue to the Executive Officers for resolution.

**(b)** If the Executive Officers cannot resolve such matter within fifteen (15) Business Days (or such longer period as such Executive Officers mutually agree upon) after such matter has been referred to them, then:

**(i)** Aurinia shall have the final decision-making authority with respect to: (A) the Global Brand Plan, subject to Section 6.6; (B) Manufacture (excluding Packaging) of Products for the Otsuka Territory, provided that Aurinia's final decision-making authority with respect to any such Manufacturing decision shall be subject to and limited by the terms of the Supply Agreements and Quality Agreements for Product; (C) the conduct of any Non-Clinical Study of the Compound or the Product, the conduct or sponsorship of any Clinical Trials and the support or supply of Product in the Field to any Investigator-Initiated Trials, to the extent such Non-Clinical Studies, Clinical Trials or Investigator-Initiated Trials require the consent of Aurinia in accordance with Section 4.2(g); (D) the consent to the filing or prosecution of any patent application for an Invention as set forth in Section 10.1(a); (E) the global publication strategy and the publication, consent to publication or dissemination of publications as set forth in Section 13.4; and (F) the interpretation, in light of Aurinia's global pharmacovigilance data, of adverse events in the Aurinia Territory and in the Otsuka Territory (including as pertains to any Aurinia Domain Product) of which Aurinia becomes aware in compliance with the Pharmacovigilance Agreement and Applicable Law.

**(ii)** Otsuka shall have the final decision-making authority with respect to; (A) pricing for Product for Europe, including list price ranges and pricing and reimbursement strategy; (B) Commercialization of Products in the Otsuka Territory, provided that such Commercialization is consistent with the Global Brand Plan or, if applicable, the Otsuka

Territory-Specific Brand Plan, including matters related to obtaining or maintaining Pricing or Reimbursement Approvals (including applications for Pricing or Reimbursement Approvals and their prosecutions in Europe) but excluding approval of any alternative or additional Product Marks for the Otsuka Territory; (C) Medical Affairs for the Otsuka Territory, provided that such Medical Affairs Activities are consistent with the Local Medical Affairs Plan; (D) Otsuka Initial Development and all Regulatory Activities in the Otsuka Territory; (E) Otsuka Territory Additional Development except to the extent such Development includes any Non-Clinical Study of the Compound or the Product, the conduct or sponsorship of any Clinical Trials and the support or supply of Product to any Investigator-Initiated Trials that, in each case, require the consent of Aurinia in accordance with Section 4.2(g); (F) local pharmacovigilance in the Otsuka Territory in compliance with the Pharmacovigilance Agreement and Applicable Law; and (G) Packaging of Products for the Otsuka Territory; unless, in each case of (B) through (F) above, in Aurinia's reasonable judgment, such Commercialization, Medical Affairs, Otsuka Initial Development or Otsuka Territory Additional Development is likely to have a material adverse effect on obtaining or maintaining Regulatory Approval of any Product in the Aurinia Territory or Commercialization of any Product in the Aurinia Territory.

**(iii)** The following matters are subject to the mutual agreement of both Parties, and shall not be subject to referral to the Executive Officers, expert determination, arbitration or any other form of external dispute resolution and are not subject to Aurinia's or Otsuka's decision-making authority pursuant to sub-clause (i) or (ii) of this Section 3.4(b): (A) the decision whether or not to pursue together any Global Additional Development in accordance with Section 4.2(e)(i), or to agree on a regulatory milestone in accordance with Section 4.2(c) or to agree on the payment to be made by Otsuka in connection with its opt-in right in accordance with Section 4.2(e)(iii); (B) the Aurinia Initial Development, and (C) approval of (x) any development plan and budget for agreed-to Global Additional Development, or (y) any alternative or additional Product Marks for the Otsuka Territory. In addition, the approval of any Otsuka Territory-Specific Brand Plan shall be subject to mutual agreement of the Parties after referral to the Executive Officers, and shall not be subject to expert determination, arbitration or any other form of external dispute resolution and are not subject to Aurinia's or Otsuka's decision-making authority pursuant to sub-clause (i) or (ii) of this Section 3.4(b).

**(iv)** Aurinia shall have sole decision-making authority in its sole discretion with respect to the following matters without any obligation to inform a Committee (except as set out below), or submit any such matter to the Executive Officers, expert determination, arbitration or any other form of external dispute resolution and are not subject to Aurinia's or Otsuka's decision-making authority pursuant to sub-clause (i) or (ii) of this Section 3.4(b): (A) Commercialization of Products in the Aurinia Territory (subject to Section 3.1(g) with respect to any discussions at the JCC) and Commercialization of Aurinia Domain Products worldwide, including matters related to pricing or obtaining or maintaining Pricing or Reimbursement Approvals for Products in the Aurinia Territory and with respect to Aurinia Domain Products worldwide; (B) Clinical Trials and other Development (other than agreed-to Global Additional Development) for the Product in the Aurinia Territory (subject to Section 3.1(a) with respect to a forum for discussion at the JCC) and clinical trials and other development of Aurinia Domain Products; and (C) clinical trials of Aurinia Domain Products that are ongoing or planned as of the Effective Date and Clinical Trials of Product in the Aurinia Territory that are ongoing or planned as of the Effective Date other than Clinical Trials to be conducted as part of

Aurinia Initial Development (which are subject to mutual agreement of both Parties in accordance with Section 3.4(b)(iii)).

(v) If a Committee decision cannot be resolved by the Executive Officers in accordance with this Section 3.4(b) and none of Sections 3.4(b)(i), 3.4(b)(ii), 3.4(b)(iii), and 3.4(b)(iv) apply to such decision, then the decision may be referred by either Party to be resolved by expert determination in accordance with Section 15.3. In addition, if a Party overrules the other Party's final decision-making authority pursuant to Section 3.4(b)(ii) based on a determination that, in such Party's reasonable judgment, a decision by the other Party is likely to have a material adverse effect, and if the other Party disputes such determination of a likely material adverse effect, such dispute shall be resolved by expert determination in accordance with Section 15.3.

(vi) In the event that Aurinia notifies in good faith Otsuka as a result of discussions pursuant to Section 3.1(s) or otherwise that any action that Otsuka is taking or intends to take is likely to have a material adverse effect on obtaining or maintaining Regulatory Approval of any Product in the Aurinia Territory or Commercialization of any Product in the Aurinia Territory, and Aurinia refers such issue to the Executive Officers for resolution, and if the decision cannot be resolved by the Executive Officers in accordance with Section 3.4(b), commences and diligently pursues an expert determination in accordance with Section 15.3, then Otsuka shall not take such action until such Disputed Matter is resolved by the Executive Officers in accordance with Section 3.4(b) or absent such resolution, an expert determination in accordance with Section 15.3 concludes that such action will not cause such material adverse effect.

### **3.5 Limitations on Authority; Consideration**

. Each Committee shall have only such powers as are expressly assigned to it in this Agreement, and such powers shall be subject to the terms and conditions of this Agreement. Without limiting the generality of the foregoing, (a) no Committee will have the power to amend this Agreement, (b) no decision of a Committee may be in contravention of any terms and conditions of this Agreement, (c) neither any Committee nor either Party (in the exercise of its final decision-making authority pursuant to Section 3.4(b)) will have the authority to (i) amend or modify, or waive compliance with this Agreement or any Supply Agreement, Quality Agreement or Pharmacovigilance Agreement, or (ii) obligate either Party to violate Applicable Law, the requirements of any Regulatory Authority or any agreement with any Third Party, and (d) Aurinia will not have the right to overrule Otsuka's final decision-making authority on the basis of material adverse effect if that would cause Otsuka to violate or be unable to comply with Applicable Law in the Otsuka Territory. The Party with final decision-making authority pursuant to Section 3.4(b) shall make all such decisions only after giving reasonable consideration to the other Party's comments (through its JCC members or Senior Officer, as applicable) on such matters.

### **3.6 Discontinuation of Committees**

. The activities to be performed by each Committee shall solely relate to governance under this Agreement, and are not intended to be or involve the delivery of services. Each Committee shall continue to exist until the Parties mutually agree to disband such Committee. Upon the Parties'

agreement to disband a Committee, such Committee shall have no further obligations under this Agreement and, thereafter, each Party shall designate a contact person for the exchange of information under this Agreement or such exchange of information shall be made through Alliance Managers, and decisions of such Committee shall be decisions as between the Parties, subject to the other terms and conditions of this Agreement.

### **3.7 Alliance Managers**

. Promptly after the Effective Date, each Party shall appoint one or two individuals, who shall be employees of such Party having appropriate qualifications and experience, one of whom will act as the alliance manager for such Party with respect to Europe and one of whom will act as the alliance manager for such Party with respect to Japan (collectively the “**Alliance Managers**”). If a Party appoints one individual, such individual shall be the Alliance Manager for both Europe and Japan. The Alliance Managers shall be responsible for coordinating and managing processes and interfacing between the Parties with respect to their respective regions on a day-to-day basis throughout the Term. Each Alliance Manager shall be permitted to attend meetings of the applicable Local JCC, as well as joint meetings of the Local JCCs and other Committees as appropriate, in each case as non-voting participants. The Alliance Managers shall be the primary contact for the Parties regarding the activities contemplated by this Agreement and shall facilitate all such activities hereunder. Each Party may replace either of its Alliance Managers with an alternative representative at any time with prior written notice to the other Party. Any Alliance Manager may designate a substitute to temporarily perform the functions of that Alliance Manager. Each Alliance Manager shall be charged with creating and maintaining a collaborative work environment within each applicable Local JCC and other Committees. Each Party shall bear its own costs of its Alliance Managers.

### **3.8 Working Language**

(a) . Except as otherwise expressly set out in this Agreement, the working language of this Agreement and the dispute resolution processes set out herein shall be English. The language of the JCC shall be Japanese and English and Otsuka shall make available to the JCC and any committees appropriate translation to English as may be required. The JCC shall cause complete and accurate minutes of all JCC and committee meetings to be kept in English. Aurinia’s Initial Development and other assistance and support to be provided under this Agreement shall be in English. When Otsuka is providing information to Aurinia that must be considered in a timely way, such as top-line data derived from Clinical Trials, Otsuka shall translate same or where necessary, summaries of same, into English and share same with Aurinia.

## **4. DEVELOPMENT**

### **4.1 Initial Regulatory Approval of the Initial Indication**

(a) Aurinia shall be responsible for: the conduct of all chemistry, manufacturing, and controls (“**CMC**”) activities and Non-Clinical Studies necessary for conducting Regulatory Activities and obtaining initial Regulatory Approvals of the Product for the Initial Indication in all countries in the Otsuka Territory; preparing the filing dossiers for the MAA(s) for the Product for the Initial Indication in Territory-A with Otsuka as set out in Section

5.1(a); and the conduct of any pediatric investigation plan study required by the EMA (the “**Aurinia Initial Development**”).

(b) Otsuka shall be responsible for the conduct of all Development activities (other than those described in Section 4.1(a) necessary to obtain any and all Regulatory Approvals of the Product for the Initial Indication in each country in the Otsuka Territory, including a Phase 3 Clinical Trial for the Initial Indication in Japan (the “**Otsuka Initial Development**”).

(c) Aurinia shall obtain Otsuka’s prior written approval, such approval not to be unreasonably withheld, of any changes to the design of any pediatric investigation plan study Aurinia is required or otherwise intends to conduct for the Aurinia Initial Development.

(d) Otsuka shall submit to the JCC any plan for the Otsuka Initial Development prior to initiation.

#### 4.2 Additional Development

(a) **Additional Development Generally.** If either Party proposes to conduct additional Development work on a Product for the Field beyond the Initial Development, including the pursuit of an Additional Indication or label expansion, but excluding Clinical Trials that are ongoing or planned as of the Effective Date, including AURORA 2 (“**Additional Development**”) (i) for the benefit of both the Aurinia Territory and the Otsuka Territory, including any multi-regional Clinical Trial designed or intended to obtain or optimize Regulatory Approval in both (A) the U.S. and (B) Territory-A and/or Japan (“**Global Additional Development**”) or (ii) solely for the benefit of the Otsuka Territory or any country or region in the Otsuka Territory (“**Otsuka Territory Additional Development**”), then the proposing Party shall provide the other Party with a written proposal of such Additional Development, including a synopsis of the Development activities related to such Additional Development, the potential role of the non-Proposing Party with respect to such Additional Development, the timeline for such Additional Development, the proposed Clinical Trial protocols or designs, if applicable, the estimated costs associated with such Additional Development, and, in the case of Global Additional Development, the proposed cost allocation between the Otsuka Territory and the Aurinia Territory (the “**Additional Development Proposal**”).

(b) Within thirty (30) days of receipt of the Additional Development Proposal, the Local JCCs (at a joint meeting of the Europe JCC and the Japan JCC) shall meet to review the Additional Development Proposal and to permit the non-proposing Party an opportunity to ask questions and request additional information from the proposing Party related to the Additional Development Proposal, including whether such Proposal is reasonably likely to have a material adverse effect on obtaining or maintaining Regulatory Approval of any Product or Commercializing any Product, in either case, in the non-proposing Party’s Territory.

(c) If the Additional Development Proposal is for Global Additional Development that includes Development of the Product for the Field for an Additional Indication in the Otsuka Territory, the Parties also shall negotiate in good faith to agree, prior to initiation of such Additional Development, upon one regulatory milestone payment to be made by Otsuka

based upon achievement of first Regulatory Approval in the Otsuka Territory of the first Product for such Additional Indication.

(d) Nothing in this Agreement will obligate either Party to agree to conduct or participate in any Additional Development, which agreement may be withheld in each Party's sole discretion.

**(e) Global Additional Development.**

(i) If the Parties mutually agree to pursue Global Additional Development, including mutual agreement on a development plan and the cost allocation between the Otsuka Territory and the Aurinia Territory taking into account the respective value of such Development (including, with respect to an Additional Indication, the anticipated market value of such Additional Indication using sales data provided by IQVIA or similar Third Party provider agreed upon by the Parties) to each Party's Territory, then the Parties shall prepare and submit the development plan and budget for such mutually agreed Global Additional Development for review and approval by the Local JCCs (with neither Party having final decision-making authority in accordance with the terms of Section 3.4(b)(iii)). Such development plan shall include an allocation between the Parties of internal and out-of-pocket costs (based on the mutually agreed cost allocation between the Otsuka Territory and the Aurinia Territory) and responsibilities with respect to such Global Additional Development.

(ii) If the Parties do not mutually agree to pursue Global Additional Development, Aurinia may pursue such Global Additional Development, at its cost and expense, for the sole purpose of obtaining Regulatory Approval and Commercializing the Product in the Aurinia Territory, and, subject to Otsuka's rights under Section 4.2(e)(iii), such Development shall be Aurinia Territory Additional Development hereunder.

(iii) If Aurinia elects to pursue Global Additional Development in accordance with this Section 4.2(e), it shall provide Development reports and Data to Otsuka related to such Global Additional Development in accordance with Section 4.3, and Otsuka shall have the right, at any time prior to MAA filing in the U.S. with respect to such Global Additional Development, to opt-in with respect to such Global Additional Development upon payment to Aurinia of an amount, to be agreed upon by each Party after good faith negotiations, to compensate Aurinia for conducting such Global Additional Development at risk. Unless and until Otsuka elects to opt-in with respect to such Global Additional Development that Aurinia conducts at its cost and expense and the Parties have agreed on the compensation for same: (i) Otsuka shall not have the right to use or reference the Data and Know-How generated from such Global Additional Development except to satisfy any reporting obligations with Regulatory Authorities in the Otsuka Territory or to obtain or maintain Regulatory Approvals of the Product in the Otsuka Territory for the Initial Indication or for any Additional Indication the Parties have mutually agreed to pursue or Otsuka has pursued as Otsuka Territory Additional Development; and (ii) Otsuka shall not file for any Regulatory Approval or label expansion of or Commercialize the Product for any indication that was the subject of such Global Additional Development or take any action that could reasonably be expected to cause the Product to be used in or for such indication. For clarity, Aurinia shall only have the right to pursue Global Additional Development for the purpose of obtaining Regulatory Approval and Commercializing

the Product in the Aurinia Territory, and Aurinia shall not have the right to seek to obtain Regulatory Approval of the Product for any Additional Indication in the Otsuka Territory.

**(f) Otsuka Territory Additional Development.** Otsuka shall have the right to conduct Otsuka Territory Additional Development: (i) subject to Aurinia's right to consent to Non-Clinical Studies, Clinical Trials and Investigator-Initiated Trials of Product in accordance with Section 4.2(g), and (ii) unless, in Aurinia's reasonable judgment, such Otsuka Territory Additional Development is likely to have a material adverse effect on obtaining or maintaining Regulatory Approval of any Product in the Aurinia Territory or Commercialization of any Product in the Aurinia Territory. If Otsuka plans to conduct Otsuka Territory Additional Development, it shall prepare a development plan for such Otsuka Territory Additional Development and shall provide such development plan to the Europe JCC or Japan JCC, as applicable (or the Local JCCs if such Otsuka Territory Additional Development includes both Japan and one or more countries or regions in Europe) for approval in accordance with Section 3.4(b)(ii). Otsuka shall conduct such Otsuka Territory Additional Development in accordance with such development plan, at its cost and expense, and shall provide Development reports related to such Additional Development in accordance with Section 4.3. For clarity, Aurinia shall not have the right to pursue any Otsuka Territory Additional Development.

**(g) Non-Clinical Studies and Clinical Trials by Otsuka.** Except for Clinical Trials that are part of any Agreed Development, Otsuka shall not, except with the prior written consent of Aurinia, which consent may be given or withheld in Aurinia's sole discretion:

**(i)** conduct, support or supply Product to any Non-Clinical Study of the Compound or the Product;

**(ii)** conduct or sponsor or supply any Clinical Trials of Product; provided that if Aurinia is conducting a Clinical Trial of Product in any country in the Aurinia Territory for an Additional Indication, Otsuka shall have the right to conduct Clinical Trials of the Product in the Otsuka Territory for the same Additional Indication without the consent of Aurinia under this Section 4.2(g), but subject to submission and consideration by the JCC pursuant to Section 3.1 and the decision-making process set out in Section 3.4. For clarity, Aurinia consent will not be required for Otsuka to conduct Clinical Trials that are part of Otsuka Initial Development or any other Agreed Development); and

**(iii)** support (including by providing financial support or Product to) any Investigator-Initiated Trials of Product.

Any Non-Clinical Studies, Clinical Trials and Investigator-Initiated Trials of Product permitted pursuant to this Section 4.2(g) shall be "Otsuka Territory Additional Development" hereunder.

**(h) Aurinia Territory Additional Development.** Aurinia shall have the right, at its cost and expense, to conduct Additional Development solely for the benefit of the Aurinia Territory or one or more countries or regions in the Aurinia Territory ("**Aurinia Territory Additional Development**") in its sole discretion. Aurinia's sole obligations under this Agreement with respect to such Aurinia Territory Additional Development shall be that, if Aurinia (or its Affiliate or licensee) conducts Aurinia Territory Additional Development, Aurinia shall comply with the terms of Section 4.3 with respect to such Additional Development.

### 4.3 Summary Development Reports

At each regularly scheduled meeting of the Europe JCC (with respect to Agreed Development, and any Otsuka Territory Additional Development, specific to Europe) and the Japan JCC (with respect to Agreed Development, and any Otsuka Territory Additional Development, specific to Japan) and at each joint meeting of the Local JCCs (with respect to Agreed Development or Otsuka Territory Additional Development in both Japan and Europe, and with respect to Agreed Development in the Aurinia Territory and any Aurinia Territory Additional Development), each Party shall provide an update (by means of a slide presentation or otherwise) summarizing its Development activities for the Products, including the results of such activities and the status of each pending and proposed Regulatory Filing, since the last such update. In addition, after the completion of any Clinical Trial or other study of the Product, the Party responsible for the conduct of such Clinical Trial or study shall promptly provide the other Party (but in no event more than ten (10) days following receipt) with top-line results of such Clinical Trial or study. Further, each Party will promptly provide written notice to the other Party, through the Local JCCs or Alliance Managers, of any significant Development events (*e.g.*, Clinical Trial initiation or completion, clinical holds, receipt of Regulatory Approvals) that the reporting Party reasonably believes may affect the Development or Commercialization activities of the Product in the other Party's Territory or otherwise may be of interest to the other Party.

### 4.4 Compliance; Development Efforts, Support

( a ) Each Party shall perform, and each will ensure that its Affiliates, licensees and Sublicensees (as applicable), and Representatives perform, all Development activities under this Agreement in a good scientific manner, in accordance with cGLP, cGCP, and cGMP, as applicable, and in compliance with all Applicable Laws.

( b ) Aurinia, at its own cost and expense, shall use Commercially Reasonable Efforts to perform the Aurinia Initial Development. Otsuka, at its own cost and expense, shall use Commercially Reasonable Efforts to perform the Otsuka Initial Development.

( c ) Otsuka, at its own cost and expense, shall use Commercially Reasonable Efforts to obtain and maintain Regulatory Approval and Pricing and Reimbursement Approval (where required) for the Product for the Initial Indication in the Field in each country in the Otsuka Territory.

( d ) Aurinia shall use Commercially Reasonable Efforts to perform the activities allocated to Aurinia under each development plan for any Agreed Development.

( e ) Otsuka shall use Commercially Reasonable Efforts to perform the activities allocated to Otsuka under each development plan for any Agreed Development.

( f ) Each Party shall use Commercially Reasonable Efforts to provide all assistance reasonably requested by the performing Party in connection with the performing Party's Development obligations hereunder. For all such assistance requested by the performing Party and provided by the assisting Party, the performing Party shall reimburse the assisting Party's reasonable out-of-pocket costs incurred in connection with providing such assistance.



#### **4.5 Development Records**

Each Party and its Affiliates will maintain written or electronic records, in sufficient detail, in a good scientific manner (in accordance with cGLP, cGCP, and cGMP, as applicable), and appropriate for regulatory and patent purposes, and that are complete and accurate in all material respects and reflect all Development work performed and results achieved, in each case, by or on behalf of such Party and its Affiliates, licensees, or Sublicensees (as applicable) under this Agreement. Each Party shall document all Clinical Trials and other studies of Product in formal written study reports according to Applicable Laws and national and international guidelines (e.g., ICH, cGCP, cGLP, and cGMP).

#### **4.6 Subcontractors for Development**

Each Party may perform any of its Development activities under this Agreement through one or more Sublicensees as permitted under Section 2.1(b) or through one or more Representatives, provided that, with respect to Representatives: (a) such Party remains responsible for the Development work allocated to, and payment to, such Representatives as if it had done such work itself; (b) each Third Party Representative undertakes in writing obligations of confidentiality and non-use regarding Confidential Information that are substantially the same as those undertaken by the Parties pursuant to Article 13 (and a reasonable term with respect to the duration of such obligations); (c) each Third Party Representative that may develop intellectual property in the course of performing any Development work agrees in writing to assign all such intellectual property to such Party (or, in the event such assignment is not feasible, to provide joint ownership of or a license to such intellectual property with the right to sublicense to the other Party as contemplated in this Agreement); and (d) each Third Party Representative agrees in writing to bound by terms for the benefit of the delegating Party to allow such Party to comply with the terms of Sections 2.7 (Disclosure of Know-How), 4.3 (Summary Development Reports), and 4.5 (Development Records). Each Party may also subcontract work on terms other than those set forth in this Section 4.6 with the prior approval of the Europe JCC, the Japan JCC or the Local JCCs, as applicable.

### **5. REGULATORY ACTIVITIES**

#### **5.1 Regulatory Responsibilities**

##### **(a) Territory-A.**

(i) Otsuka shall be responsible for all Regulatory Activities related to Products in Territory-A, subject to the remainder of this sub-clause (a) and Section 4.1(a), Section 5.2 and Section 5.3.

(ii) Aurinia shall be responsible for preparing the filing dossiers for the MAA(s) for the Product for the Initial Indication in Territory-A, based on the US existing version of the NDA for the Product prepared by Aurinia, in close consultation with Otsuka; provided that, if the Parties fail to agree on a plan for filing for the regulatory dossiers, Otsuka may assume responsibility for same. Subject to Section 3.4, Otsuka will have final decision-making authority over all Regulatory Activities for the Product for the Initial Indication in Territory-A, including the content and strategy with respect to such filing dossiers.

(iii) Otsuka will file the MAA for the Product for the Initial Indication (and any material amendment or update thereto) in Territory-A in the name of Otsuka or its Affiliate, and Otsuka or its Affiliate will be the holder and official applicant thereof.

(iv) Prior to receipt of the first Regulatory Approval from EMA for the Product for the Initial Indication in Territory-A, the Parties shall collaborate and work closely together, through the Europe JCC (or any regulatory subcommittee to which the Europe JCC may delegate such authority), to communicate with and coordinate responses to questions, comments and other correspondence from the EMA and any other Regulatory Authority regarding the MAA for the Product for the Initial Indication in Territory-A, and the Parties shall participate jointly (unless the Parties agree that Otsuka or its Affiliate will solely participate) in meetings with the EMA and any other Regulatory Authorities in Territory-A regarding such MAA.

(v) Following receipt of the first Regulatory Approval from EMA for the Product for the Initial Indication in Territory-A, Otsuka will be responsible, directly or through its Affiliates or Sublicensees, for maintaining the MAA and for preparing, filing and maintaining all other Regulatory Filings for Products in Territory-A.

(vi) The Parties will pursue Regulatory Approval for the Initial Indication in Territory-A using the EMA's centralized authorization procedure. If the milestone event for the first Regulatory Approval by EMA of the first Product for the Initial Indication set out in Section 8.2(a) (milestone event (1)) is not considered achieved because the First Approved SmPC contains one or more Limitations, then, until the date that is [time period redacted] after the first Regulatory Approval by EMA of the first Product for the Initial Indication, Otsuka will use Commercially Reasonable Efforts (taking into consideration that regulatory exclusivity will begin to run from the first approval) to perform Regulatory Activities (which, for purposes of this Section 5.1(a)(vi), includes engagement of KOLs) to achieve the Removal Condition. For clarity, Otsuka shall not be obliged pursuant to this Section 5.1(a)(vi) to conduct any Non-Clinical Studies or Clinical Trials.

**(b) Territory-B and Japan.**

(i) Otsuka shall be responsible for all Regulatory Activities related to Products in Territory-B in consultation with Aurinia, including the responsibility for preparing filing dossiers for the MAA for the Product for the Initial Indication in each country in Territory-B, subject to Section 5.2 and Section 5.3.

(ii) As soon as practically possible after Effective Date, Otsuka and Aurinia shall agree on the contents of the PMDA consultation meeting relating to the JNDA for the Product for the Initial Indication and shall jointly prepare materials for such meeting (subject to Otsuka's final decision-making authority regarding such materials). The Parties will then jointly participate in such meeting if Aurinia wishes to participate in such meeting. If Aurinia requires an interpreter for its attendees at such PMDA consultation meeting, Aurinia shall retain, at its cost and expense, an interpreter who can provide simultaneous interpretation. At Aurinia's request, Otsuka shall provide support for finding and selecting an appropriate interpreter.

(iii) Following such PMDA consultation meeting and until receipt of the first Regulatory Approval for the Product for the Initial Indication in Japan, the Parties shall collaborate and work closely together, through the Japan JCC (or any regulatory subcommittee to which the Japan JCC may delegate such authority), to communicate with and coordinate responses to questions, comments and other correspondence from the PMDA and any other Regulatory Authority regarding the JNDA for the Product for the Initial Indication in Japan.

(iv) Otsuka shall be responsible for all Regulatory Activities related to Products in Japan, including the responsibility for preparing the filing dossier for the JNDA for the Product for the Initial Indication in Japan, subject to Section 5.2 and Section 5.3.

(v) Otsuka or its Affiliates shall be the holder of all MAAs for Products in Territory-B and Otsuka shall be the holder of each JNDA for Products in Japan.

**(c) Aurinia Assistance and Documentation.**

(i) At Otsuka's request, Aurinia shall support and reasonably cooperate with Otsuka in the conduct of Otsuka's Regulatory Activities forming a part of the Agreed Development and any Otsuka Territory Additional Development in the Otsuka Territory, including providing all assistance reasonably requested by Otsuka or its Affiliate in connection with preparation and filing of Regulatory Documentation and communications with Regulatory Authorities in the Otsuka Territory. Otsuka will reimburse Aurinia its reasonable out-of-pocket costs incurred in connection with providing such assistance.

(ii) Without limiting the foregoing, as soon as practicable following the Effective Date, Aurinia shall, at no cost to Otsuka: (i) provide access to Otsuka or its Affiliate (as designated by Otsuka) all Regulatory Filings submitted to Regulatory Authorities in the Otsuka Territory relating to the Products that are in Aurinia's name or possession or Control, other than INDs relating to Clinical Trials of Product sponsored by Aurinia and planned or ongoing as of the Effective Date or to be conducted by or on behalf of Aurinia under this Agreement, including Aurinia Territory Additional Development; and (ii) provide to Otsuka (x) all Aurinia Data and other Aurinia Know-How, documents and information in Aurinia's Control and (y) copies, in electronic form, of all Regulatory Documentation in the Otsuka Territory relating to the Products that are in Aurinia's name or possession or Control, in each case, ((i) and (ii)), as may be necessary or reasonably useful for Otsuka to submit Regulatory Filings and obtain and maintain Regulatory Approvals for Products in the Otsuka Territory, and otherwise for Otsuka to fulfill its regulatory responsibilities hereunder. To the extent that any of the foregoing are Voclosporin Manufacturing Trade Secrets, the terms of Section 5.3(b) will apply in lieu of the terms of this Section 5.1(c).

(iii) Aurinia shall provide assistance to Otsuka as set out in this Agreement, including the assistance and support of Aurinia referred to in Sections 2.7, 4.4(f), 5.1(c)(i) and (ii), 5.3(b), 6.5(b) and 7.5(c). Otsuka will bear the out-of-pocket expenses incurred by Aurinia in providing all such assistance, including the reasonable out-of-pocket costs incurred with Aurinia's CMOs in the provision of support for Regulatory Activities pursuant to Sections 5.1, 5.2 and 5.3. After: (A) receipt of the first Regulatory Approval from EMA for the Product for the Initial Indication, in respect of assistance with respect to Europe; and (B) first Regulatory Approval of the first Product for the Initial Indication in Japan with respect to Japan, Aurinia will

continue to use Commercially Reasonable Efforts (without an obligation to hire additional personnel) to provide the assistance contemplated by this Agreement, provided that if such assistance in the aggregate exceeds [time period redacted] in any one Calendar Year period, Aurinia shall have the option of invoicing Otsuka for such assistance in excess of such [time period redacted] at the FTE Rate, and Otsuka shall pay such payments within thirty (30) days of the receipt of such invoice.

**(d) CMC Variations.** To the extent any variations to the CMC section of any Regulatory Filing for the Product in any jurisdiction in the Otsuka Territory are required to conform with a variation required solely for Packaging Product in and for the Otsuka Territory, whether initiated by either Party or to comply with Applicable Laws or any requirement of a Regulatory Authority, Otsuka shall be responsible for the associated fees for any such variations.

## **5.2 Regulatory Documentation Sharing**

Each Party shall promptly provide to the other Party, at no cost to the other Party, copies of all material Regulatory Documentation for the Product prepared, submitted or received by such Party and Controlled by such Party and, in respect of Agreed Development or Otsuka Territory Additional Development, the other Party shall have the right to review and comment on drafts of Regulatory Filings or responses to other material Regulatory Documentation, provided that such review and comment shall not delay the submission of any such Regulatory Filings or responses. For clarity, for purposes of this Section 5.2, material Regulatory Documentation means, (a) with respect to Regulatory Filings for the Otsuka Territory, material sections of MAA filing dossiers (specifically, with respect to the JNDA filing dossier, Modules 1.8. 2.5.1 and 2.5.6), (b) with respect to Regulatory Filings for the Aurinia Territory, the U.S. NDA filing dossier for the Product and all other Regulatory Filings submitted by or on behalf of Aurinia to the FDA in connection with seeking, obtaining or maintaining Regulatory Approval of the Product in the U.S., (c) any and all Regulatory Documentation received or required to be submitted by or on behalf of Aurinia in the Otsuka Territory, including as a result of Aurinia's Development and Manufacturing activities in the Otsuka Territory, and (d) other Regulatory Documentation received by a Party from any Regulatory Authority in its Territory that is necessary or reasonably useful for the other Party to obtain and maintain Regulatory Approvals for Products in such other Party's Territory or Aurinia Domain Product worldwide; but in each case excluding Voclosporin Manufacturing Trade Secrets except as provided in Section 5.3(b).

## **5.3 Regulatory Authority Meetings; Drug Master File**

**(a) Regulatory Meetings.** Otsuka shall provide Aurinia with reasonable advance notice (or as much advance notice as practicable under the circumstances) of all formal meetings (including formal in-person, teleconference or videoconference meetings) with any Regulatory Authority in the Otsuka Territory pertaining to the Compound or any Product (each, a "**Regulatory Meeting**"). Otsuka shall be solely responsible for communications with Regulatory Authorities in the Otsuka Territory regarding the Product in connection with performing its regulatory responsibilities set forth in this Article 5 and in no event will Aurinia unilaterally or independently communicate with any Regulatory Authority (including the EMA or PMDA) regarding the Product in any country or jurisdiction in the Otsuka Territory, except as required by Applicable Laws, including with respect to any safety issue, or as contemplated in Section 5.3(b). To the extent not restricted or prohibited by Applicable Law or a Regulatory Authority,

Aurinia shall have the right to participate in all Regulatory Meetings for the Product in the Otsuka Territory at Aurinia's cost and expense; provided that Otsuka shall not be obligated to change or re-schedule any Regulatory Meeting in order to accommodate the schedule of Aurinia's representatives and if attendance by Aurinia representatives is not permitted by such Regulatory Authority, then no Aurinia representative shall be permitted to attend such Regulatory Meeting. If Aurinia Representative(s) are not able to attend any Regulatory Meeting, Aurinia's Representatives may participate in the preparation for the Regulatory Meeting and in the post-meeting debrief. If Otsuka requests Aurinia's participation in any Regulatory Meeting, then the appropriate representatives of Aurinia (as requested by Otsuka) shall attend such meeting at Otsuka's cost and expense; provided that, if such Regulatory Meeting relates to the Manufacture of the Compound or Product (including any Bulk Product or Semi-Finished Product supplied to Otsuka hereunder or under any Supply Agreement), then Aurinia's attendance at such meeting shall be at Aurinia's cost and expense. If Aurinia requires an interpreter for its representatives attending any Regulatory Meeting, Aurinia shall retain, at its cost and expense, an interpreter who can provide simultaneous interpretation. At Aurinia's request, Otsuka shall provide support for finding and selecting an appropriate interpreter.

**(b) Drug Master File.** Notwithstanding anything to the contrary in this Agreement, where required in order to obtain a Regulatory Approval for the Product in a country in the Otsuka Territory, including where required for filing any IND for the Product or conducting any Clinical Trial in the Otsuka Territory, Aurinia shall be responsible (itself or through its CMO(s)) for (i) preparing the Drug Master File and any CMC regulatory information not covered by a Drug Master File, in each case in the applicable format required by Regulatory Authorities in the Otsuka Territory, (ii) providing the closed part of the Drug Master File for the Compound and all CMC regulatory information for the Compound not covered by or submitted as part of such Drug Master File, as appropriate, directly to the applicable Regulatory Authority in the Otsuka Territory, and to the extent not applicable in a country in the Otsuka Territory, making other arrangements for the submission of such Compound information to the appropriate Regulatory Authority; (iii) notwithstanding Section 5.3(a), communicating with Regulatory Authorities in the Otsuka Territory regarding such Drug Master File and CMC regulatory documentation for the Compound. **[Exceptions from Aurinia's requirement to provide information redacted.]**

#### **5.4 Rights of Reference**

Each Party hereby grants to the other Party and its Affiliates (as well as to the other Party's and its Affiliates' and licensees and Sublicensees, as applicable, when and if designated by the other Party from time to time) a non-exclusive, non-transferable right to rely upon and reference all information and data (including all CMC information as well as Data made, collected or otherwise generated in the conduct of any Clinical Trials or early access/named-patient programs for the Products) included in or used in support of any Regulatory Filing, Drug Master File or other Regulatory Documentation owned or Controlled by the granting Party that relates to the Compound or any Product as may be necessary or reasonably useful for the grantee-Party's Territory. The grantee-Party (and its Affiliates and licensees and Sublicensees) may use such rights of reference solely for the purposes of seeking, obtaining and maintaining Regulatory Approvals and Commercializing Products in its Territory and otherwise performing its obligations under this Agreement. The granting Party shall, if requested by the other Party, provide a signed statement that the other Party may rely upon, and the Regulatory Authority may

access, in support of the other Party's application for Regulatory Approvals for Products in its Territory, and any underlying data or information submitted by such Party to the Regulatory Authority with respect to any Regulatory Filing, Drug Master File or other Regulatory Documentation owned or Controlled by such Party or its Affiliates, (as applicable) that relates to the Compound or any Product as may be necessary or reasonably useful for the grantee-Party's Territory. In addition, upon request of either Party (on behalf of itself or an Affiliate, licensee or Sublicensee), the other Party shall obtain and provide to the requesting Party certificates or other formal or official attestations concerning the regulatory status of the Products in the Otsuka Territory or the Aurinia Territory, as applicable.

## 5.5 Pharmacovigilance

(a) **Pharmacovigilance Committee.** The JCC shall establish a joint pharmacovigilance subcommittee (the "**Pharmacovigilance Committee**" or "**PVC**") at an appropriate time, but in any event prior to the earlier of (i) the First Commercial Sale of the first Product in the Otsuka Territory, or (ii) Otsuka's conduct of any Development activities related to the Product. In addition to any other matters that the JCC may delegate to the PVC, the PVC shall provide a forum for the Parties to discuss, share information, issue escalation and resolution of safety topics regarding the Product and other pharmacovigilance matters worldwide in accordance with a Pharmacovigilance Committee Charter to be agreed upon by the members of the PVC.

(b) **Safety Management Plan.** At least sixty (60) days (or such other time period agreed by the Parties) in advance of the start of any Development activities by Otsuka in any country in the Otsuka Territory, the Parties (under the guidance of their respective pharmacovigilance departments, or equivalent thereof) will enter into a written Safety Management Plan setting forth the study specific safety information handling as outlined in the specific Clinical Trial protocol. All procedures and responsibilities set forth in the Safety Management Plan shall be in accordance with, and will enable the Parties to fulfill, local, national and international regulatory reporting obligations under Applicable Laws (including to the extent applicable, obligations contained in ICH guidelines).

(c) **Pharmacovigilance Agreement.** At least twelve (12) months (or such other time period agreed by the Parties) in advance of any Regulatory Approval in any country in the Otsuka Territory, the Parties (under the guidance of their respective pharmacovigilance departments, or equivalent thereof) will enter into a written pharmacovigilance agreement setting forth the worldwide pharmacovigilance procedures for and responsibilities of the Parties with respect to the Compound and Products, such as Safety Data sharing, adverse events reporting and safety signal and risk management (the "**Pharmacovigilance Agreement**"), which agreement shall be amended by the Parties from time to time as necessary to comply with any changes in Applicable Laws or guidance received from Regulatory Authorities. Such Pharmacovigilance Agreement will provide for the receipt, investigation, recording, communication, and exchange by the Parties of information that a Party becomes aware of in the Otsuka Territory and globally concerning adverse events in or involving a research subject or, in the case of Non-Clinical Studies, an animal in a toxicology study, and the seriousness thereof, and other Safety Data, including any such information and other Safety Data received by either Party from a Third Party (subject to receipt of any required consents from such Third Party). All procedures and responsibilities set forth in the Pharmacovigilance Agreement shall be in accordance with, and

enable the Parties to fulfill, local, national and international regulatory reporting obligations under Applicable Laws (including to the extent applicable, obligations contained in ICH guidelines). Subject to compliance with Applicable Law, each Party hereby agrees to comply with its respective obligations under the Pharmacovigilance Agreement (as the Parties may agree to modify it from time to time) and to cause its Affiliates and licensees and Sublicensees (as applicable) to comply with such obligations. It is understood that each Party and its Affiliates and licensees and Sublicensees (as applicable) will have the right to disclose Safety Data if such disclosure is reasonably necessary to comply with Applicable Laws and Regulatory Authority regulations and requirements in its Territory. After the execution of the Pharmacovigilance Agreement, the Parties' sole obligations with respect to pharmacovigilance procedures for and responsibilities with respect to the Compound and Products, such as Safety Data sharing, adverse events reporting and safety signal and risk management, shall be as set out in the Pharmacovigilance Agreement. Once executed, the Pharmacovigilance Agreement shall supersede and replace the terms of this Agreement applicable to pharmacovigilance, all as may be further described in the Pharmacovigilance Agreement.

**(d) Responsibilities; Global Safety Database.** In each case in accordance with, and subject to (once executed), the Pharmacovigilance Agreement:

**(i)** Aurinia will own all of the Safety Data, and the Pharmacovigilance Agreement will include provisions requiring the establishment of a global safety database for the Products that will be owned and maintained by Aurinia;

**(ii)** Aurinia shall be responsible, at its cost and expense, for pharmacovigilance with respect to the Products in the Aurinia Territory and shall be responsible for the collection, assessment, and safety reporting of individual case safety reports to Regulatory Authorities, and generating aggregated report(s), risk management plan and responses to any requests from Regulatory Authorities, with respect to Products in the Aurinia Territory, and for sharing such information with Otsuka for its compliance with regulatory requirements in the Otsuka Territory, in each case subject to and in compliance with Applicable Law and the Pharmacovigilance Agreement;

**(iii)** Aurinia shall own and shall maintain, at its cost and expense, the company core data sheet (CCDS) for the Product for so long as the Compound or any Product is under Development or Commercialization by the Parties hereunder;

**(iv) [Terms for cost-sharing redacted]**

**(v)** Each Party shall submit the Safety Data and other information from its Territory necessary to populate the global safety database at its own cost and expense.

**(vi)** Otsuka shall be responsible, at its cost and expense, for pharmacovigilance with respect to the Products in the Otsuka Territory and shall be responsible for the collection, assessment, and safety reporting of individual case safety reports to Regulatory Authorities, and submitting aggregated report(s), risk management plan and responses to any requests from Regulatory Authorities, with respect to Products in the Otsuka Territory, and for sharing such information with Aurinia for its compliance with regulatory requirements in the

Aurinia Territory, in each case subject to and in compliance with Applicable Law and the Pharmacovigilance Agreement.

(vii) Aurinia shall be responsible for the interpretation, in light of Aurinia's global pharmacovigilance data, of adverse events in the Otsuka Territory of which Aurinia becomes aware, including adverse events reported to Aurinia by Otsuka.

(viii) Subject to all of the foregoing, in the Otsuka Territory, Otsuka, in collaboration with Aurinia's PV department, shall be responsible for local medical surveillance, risk management, medical literature review and monitoring within the Otsuka Territory, and responses to the appropriate Regulatory Authorities within the Otsuka Territory. Otsuka shall provide an English-translated copy of the final responses to Regulatory Authorities to Aurinia. Through the Pharmacovigilance Committee, the Parties will consult, communicate, and cooperate with each other with respect to the foregoing. In addition, for purposes of Otsuka's compliance with regulatory requirements, Aurinia shall support Otsuka by providing information, such as surveillance and literature search information, reasonably requested by Otsuka. Aurinia will ensure that each Party, its Affiliates, Other Aurinia Licensees and Sublicensees are able to access the data, if necessary indirectly, from the global safety database in order to meet legal and regulatory obligations.

(ix) In addition, prior to the execution of the Pharmacovigilance Agreement, the each Party will promptly forward to the Party responsible for handling and reporting to applicable Regulatory Authorities all reports received by such non-regulatory responsible Party of adverse drug events, pregnancy reports, and any other information concerning the safety and benefit-risk profile that are or may be associated with the Products, and comply with the terms of Sections 5.5(a), 5.5(b) and 5.5(d).

## 5.6 Recalls

Each Party will notify the other Party promptly following the first Party's determination that any event, incident, or circumstance has occurred that may result in the need for a recall, withdrawal or correction (including the dissemination of relevant information) of the Product. To the extent possible, such Party will include in such notice the reasoning behind such determination, and any supporting facts. The Parties shall cooperate to gather information required to assess and discuss the situation. If a recall, withdrawal or correction (including the dissemination of relevant information) of any Product in a Party's Territory is mandated by a Regulatory Authority, or if a Regulatory Authority requires or advises a Party or its Affiliates or licensees or Sublicensees (as applicable) to disseminate a "Dear Healthcare Provider" letter or its equivalent regarding use of any Product in such Party's Territory (any such recall, withdrawal, correction, or dissemination of information shall be referred to herein as a "**Mandatory Recall**") or if a recall, withdrawal or correction of a Product in a Party's Territory is deemed advisable by either Party ("**Voluntary Recall**"), such Party shall so notify the other Party immediately and promptly confirm such notice in writing. Otsuka will initiate, control and manage any Mandatory Recall in the Otsuka Territory, as mandated by the applicable Regulatory Authority, and any Voluntary Recall in the Otsuka Territory that Otsuka deems advisable in its sole discretion, in each case in compliance with Applicable Law. If Aurinia notifies Otsuka that Aurinia deems it advisable to implement a Voluntary Recall in the Otsuka Territory, then promptly after Aurinia provides such notice, each Party's quality, safety, compliance, or regulatory affairs personnel with authority to make



product recall decisions on behalf of such Party (the “**Recall Decision-Makers**”) will discuss and attempt to agree on whether or not to implement such Voluntary Recall in the Otsuka Territory, and if the Parties’ Recall Decision-Makers fail to agree within a reasonably appropriate time period (depending upon the circumstances), Otsuka will have the right to decide whether or not to implement such Voluntary Recall in the Otsuka Territory; provided that if Aurinia’s Recall Decision-Makers determine, and provide information to Otsuka’s Recall Decision-Makers supporting such determination, that a Voluntary Recall should be carried out in the Otsuka Territory for health or safety reasons or other “for cause” reasons (such as the commencement or requirement to commence a Mandatory Recall in the Aurinia Territory) and if Otsuka nonetheless decides not to implement such Voluntary Recall in the Otsuka Territory, Otsuka shall indemnify and hold harmless Aurinia from and against any Losses that may result thereafter from Otsuka’s failure to implement such Voluntary Recall despite Aurinia’s determination that such Voluntary Recall should be carried out in the Otsuka Territory. In connection with any Mandatory Recall in the Otsuka Territory or any Voluntary Recall that Otsuka’s undertakes in the Otsuka Territory, Aurinia shall provide Otsuka with such assistance as may be reasonably requested by Otsuka and in any Voluntary Recall or Mandatory Recall, each Party shall conduct such activities in coordination and collaboration with the other Party, in a manner that enables both Parties to comply with all Applicable Laws and requests and mandates from any Regulatory as expeditiously as possible. **[Terms for cost-sharing redacted.]**

### **5.7 Data Security**

During the Term, each Party will maintain (and, as applicable, cause its Affiliates to maintain) environmental, safety, and facility procedures, data security procedures, and other safeguards against the disclosure, destruction, loss, or alteration of the other Party’s Know-How in the possession of such Party or its Affiliates, including procedures to ensure compliance with Privacy Laws, that are no less rigorous than those maintained by such Party (or any of its Affiliates) for its own Know-How of a similar nature. In addition, each Party has implemented and will continue to implement during the Term appropriate controls to comply with Privacy Laws and maintain data privacy of its own Know-How, including for detecting, responding to, and reporting potential breaches in accordance with Applicable Law. Without limiting the foregoing, each Party will put in place a “business continuity plan” to be implemented in the event of a catastrophic data loss of its primary databases.

### **5.8 No Harmful Actions**

If a Party believes that the other Party is taking or intends to take any action with respect to a Product that could reasonably be expected to have a material adverse effect on obtaining or maintaining Regulatory Approval of any Product in either Party’s Territory or Commercialization of any Product in either Party’s Territory, then such Party may bring the matter to the attention of the Local JCCs and the Parties shall discuss in good faith to resolve such concern.

### **5.9 Notification of Threatened Action**

Each Party shall notify the other Party within twenty-four (24) hours of any information it receives regarding any threatened or pending action, inspection or communication by any

Regulatory Authority, which may affect the safety or efficacy claims of any Product or the continued Development or Commercialization of any Product. Upon receipt of such information, the Parties shall promptly consult with each other in an effort to arrive at a mutually acceptable procedure for taking appropriate action.

## **6. COMMERCIALIZATION AND MEDICAL AFFAIRS**

### **6.1 Commercialization in General**

Subject to the terms and conditions of this Agreement, and the Commercialization Plan as modified pursuant hereto, Otsuka shall have the sole right and responsibility for, and full control and discretion over, all aspects of the Commercialization of Products in the Field in the Otsuka Territory, including with respect to each Product: (a) developing and executing a commercial launch and pre-launch plan, (b) negotiating with Governmental Authorities and Pricing Authorities regarding Pricing or Reimbursement Approvals; (c) marketing, advertising and promotion; (d) distribution and performance of related services; (e) handling order processing, invoicing and collection, inventory and receivables; (f) determining pricing and terms of sale of Product (subject to Section 3.1(m)); (g) providing customer support, including handling medical queries, and performing related functions; and (h) conforming its practices and procedures to applicable Professional Requirements and Applicable Laws relating to Commercialization and the marketing, detailing and promotion of Products in the Field in the Otsuka Territory. Otsuka shall bear all costs and expenses incurred in connection with such Commercialization activities in the Otsuka Territory. For clarity, Otsuka or its Affiliates will book the sales of all Products in the Otsuka Territory.

### **6.2 Commercialization Efforts**

Otsuka, directly or through its Affiliates or Sublicensees, will use Commercially Reasonable Efforts to Commercialize the Product in Japan and at least each of the Major European Countries and to achieve First Commercial Sale as promptly as practicable after receipt of Regulatory Approval and Pricing and Reimbursement Approval (if applicable) for the Product in Japan and each of the Major European Countries, and, in addition, after achieving First Commercial Sale in such country, Commercialize such Product in such country in the Territory in accordance with the Commercialization Plan.

### **6.3 Commercialization Plan**

At least twelve (12) months prior to the anticipated First Commercial Sale of a Product in each of Japan and Europe (or, if the anticipated First Commercial Sale will be earlier than twelve (12) months after the Effective Date, then no later than six (6) months after the Effective Date), Otsuka shall prepare and present to the Japan JCC and the Europe JCC, respectively, for review and discussion a Commercialization plan for Products (each a “**Commercialization Plan**”) with respect to Japan and with respect to the countries in Europe in which Otsuka expects to launch the Product, including at a minimum, the Major European Countries (all of such expected countries, the “**Launch Countries**”), including timelines reflecting potential date ranges for First Commercial Sale following receipt of Regulatory Approval and Pricing and Reimbursement Approval (if applicable) in the Launch Countries (the “**Launch Sequence**”). Each initial Commercialization Plan will be a two-year high-level strategic and tactical plan for

Commercialization in the initial Launch Countries and in Japan, as applicable, and shall contain at a minimum the elements set out in Exhibit 6.3. At least six (6) months prior to the anticipated First Commercial Sale of a Product in each of the Launch Countries and Japan, Otsuka shall prepare and present to the Europe JCC and the Japan JCC, respectively, for review and discussion an amended Commercialization Plan that will include an update to the initial two-year high-level strategic and tactical plan, and general descriptions with respect to the upcoming Calendar Year. On an annual basis thereafter, Otsuka shall prepare and present to the Europe JCC and the Japan JCC, respectively, for review and discussion an update to each Commercialization Plan, including with respect to any new Launch Countries. Each Party will have the right to propose through the JCC any additions or changes to the Commercialization Plan.

#### **6.4 Commercialization Reports**

Commencing with the meeting of the Europe JCC and the Japan JCC at which Otsuka presents the first amended Commercialization Plan for Europe and Japan, respectively, pursuant to Section 6.3 (i.e., at least six (6) months prior to the applicable anticipated First Commercial Sale) and thereafter, Otsuka shall present to the Europe JCC or the Japan JCC, as applicable, following each applicable reporting period set forth in clause (a) and clause (b) of this Section 6.4, a summary in reasonable detail (by means of a slide presentation or otherwise) of (a) key Commercialization activities (including, to the extent applicable, the elements set out in Exhibit 6.4) and progress under each Commercialization Plan for each of the Major European Countries and for Japan, and any other country in the Otsuka Territory in which Commercialization activities are taking place, respectively, on a Calendar Year basis, and (b) following the First Commercial Sale of a Product in any of the Major European Countries and in Japan, sales performance for each Product for each of the Major European Countries and for Japan, respectively, on a Calendar Quarter basis.

#### **6.5 Pricing or Reimbursement Approvals**

(a) Subject to the terms and conditions of this Agreement, Otsuka shall have the sole right and responsibility for, and full control and discretion over, obtaining and maintaining Pricing or Reimbursement Approvals in the Otsuka Territory, including with respect to any payor and pricing studies related thereto, and including all submissions, communications, meetings and other dealings with Regulatory Authorities (including with respect to NHI price listing in Japan), Pricing Authorities, payors, and other Third Parties relating to pricing and reimbursement of Products in the Otsuka Territory. Otsuka shall keep Aurinia timely informed on the status of any application for Pricing and Reimbursement Approval or material updates to an existing Pricing and Reimbursement Approval in the Otsuka Territory, including any discussion with a Regulatory Authority with respect to such material matters.

(b) At Otsuka's request, Aurinia shall provide support to Otsuka with regard to seeking, obtaining and maintaining Pricing or Reimbursement Approvals for the Products in the Otsuka Territory, including providing to Otsuka all Data and other Know-How that is necessary or reasonably useful for meetings with Regulatory Authorities or Pricing Authorities or for the preparation and filing of submissions to obtain and maintain Pricing or Reimbursement Approvals, at no cost to Otsuka. In addition, at Otsuka's request, Aurinia shall attend any meeting with a Regulatory Authority, payor, or other Third Parties relating to pricing and

reimbursement of Products in the Otsuka Territory, and Otsuka shall reimburse Aurinia for its out-of-pocket expenses incurred to attend such meeting.

## **6.6 Brand Plans**

As soon as practicable, but in any event no later than six (6) months after the Effective Date, Aurinia shall prepare, and present to the Local JCCs for joint review and discussion in accordance with Section 3.4, a global brand plan with global branding strategy (including global key positioning and messaging strategy) for the Products throughout the world (“**Global Brand Plan**”). Aurinia may update the Global Brand Plan from time to time and will submit updates and amendments to the Global Brand Plan to the Local JCCs for joint review and discussion in accordance with Section 3.4. The Global Brand Plan shall at all times conform to Professional Requirements and Applicable Laws (including compliance requirements) with adjustments necessary to comply with local Applicable Laws and Professional Requirements in the Otsuka Territory. Otsuka will Commercialize the Products in a manner consistent with the then-current version of the Global Brand Plan. Notwithstanding the foregoing, if the Parties mutually agree in accordance with Section 3.4(b)(iii) or otherwise upon a Product brand strategy that is specific to the Otsuka Territory, including any Product positioning or messaging that is inconsistent with the Global Brand Plan (“**Otsuka Territory-Specific Brand Plan**”), then Otsuka will Commercialize the Products in a manner consistent with the Otsuka Territory-Specific Brand Plan, as may be updated or amended from time to time by Otsuka and mutually agreed-to in accordance with Section 3.4(b)(iii). The Parties will strive to have any Otsuka Territory-Specific Brand Plan be consistent with the Global Brand Plan, except where necessary or advisable to be different. Any Otsuka Territory-Specific Brand Plan shall at all times conform to Professional Requirements and Applicable Laws (including compliance requirements) in the Otsuka Territory.

## **6.7 Subcontractors for Commercialization**

Otsuka may perform any of its Commercialization obligations under this Agreement through one or more Sublicensees as permitted under Section 2.1(b) or through one or more distributors, wholesalers or Representatives, provided that, with respect to distributors, wholesalers and Representatives: (a) Otsuka remains responsible for the Commercialization work allocated to, and payment to, such distributors, wholesalers or Representatives as if it had done such work itself; (b) each distributor, wholesaler or Third Party Representative undertakes in writing obligations of confidentiality and non-use regarding Confidential Information that are substantially the same as those undertaken by the Parties pursuant to Article 13 (and a reasonable term with respect to the duration of such obligations); and (c) each Third Party Representative that may develop intellectual property in the course of performing any Commercialization work agrees in writing to assign all such intellectual property to Otsuka (or, in the event such assignment is not feasible, to provide joint ownership of or a license to such intellectual property with the right to sublicense to the other Party as contemplated in this Agreement).

## **6.8 Medical Affairs Activities.**

(a) **Medical Affairs Plans.** At such time as the Parties agree, Aurinia will prepare a reasonably detailed, annual plan for global Medical Affairs (the “**Global Medical Affairs Plan**”), and Otsuka will prepare one or more reasonably detailed, annual plan(s) for Medical Affairs in the Otsuka Territory or in any country or region in the Otsuka Territory (the

“**Local Medical Affairs Plan**”). The Local Medical Affairs Plan and, to the extent the Global Medical Affairs Plan will include any Medical Affairs Activities in the Otsuka Territory (including any conventions, seminars and interaction with KOLs and the like, including medical professional organizations and associations in the Otsuka Territory), the Global Medical Affairs Plan, shall at all times conform to Professional Requirements and Applicable Laws (including compliance requirements) in the Otsuka Territory. In order to ensure consistency between the Global Medical Affairs Plan and the Local Medical Affairs Plan(s) and coordination and alignment between the Parties with respect to Medical Affairs to be conducted by Aurinia in the Otsuka Territory pursuant to the Global Medical Affairs Plan and the Medical Affairs to be conducted by Otsuka in the Otsuka Territory pursuant to the Local Medical Affairs Plan(s), the Global Medical Affairs Plan and the Local Medical Affairs Plan(s), and any amendments or updates thereto, will be reviewed and discussed jointly by the Medical Affairs Subcommittee and the Local JCCs (jointly).

**(b) Medical Affairs Activities; Coordination.** Otsuka shall, at its cost and expense, lead and conduct all Medical Affairs Activities in the Otsuka Territory in accordance with the Local Medical Affairs Plan(s). Aurinia shall, at its cost and expense, conduct all Medical Affairs Activities in the Aurinia Territory and shall have the right, but not the obligation, to also conduct Medical Affairs Activities in the Otsuka Territory in global support of the Product in accordance with the Global Medical Affairs Plan (including with respect to conventions, seminars and interaction with KOLs and the like) (and in all cases in accordance with Professional Requirements and Applicable Laws in the Otsuka Territory) Neither Party shall undertake Medical Affairs Activities in the other Party’s Territory without prior coordination with the other Party, through the Medical Affairs Subcommittee or otherwise, except (i) in accordance with or as contemplated by the Global Medical Affairs Plan (including with respect to conventions and seminars and the like) or (ii) as agreed through the Medical Affairs Subcommittee or otherwise; provided that, unless contemplated by the Global Medical Affairs Plan, Otsuka shall not, with respect to Product, present at conventions or conduct seminars in the Aurinia Territory or invite KOLs from the Aurinia Territory to the Otsuka Territory, in each case without prior consent of Aurinia, which consent shall not be unreasonably withheld. Each Party will conduct all Medical Affairs in a professional and ethical business manner and in compliance with all Professional Requirements and Applicable Laws. Each Party will provide the other Party with reasonable cooperation, support, and assistance with respect to preparing such Party’s Medical Affairs plan, and conducting activities under each such plan, in order to coordinate Medical Affairs in the Otsuka Territory and the Aurinia Territory. In addition, each Party will provide to the Local JCCs (in a joint meeting) an annual update and will provide to the Medical Affairs Subcommittee (when requested by the Medical Affairs Subcommittee) an update (in each case by means of a slide presentation or otherwise) summarizing its Medical Affairs Activities and progress under the Global Medical Affairs Plan (with respect to Aurinia) and Local Medical Affairs Plan(s) (with respect to Otsuka).

**(c) Advisory Panels.** To the extent practicable, each Party shall give the other Party written notice at least thirty (30) days in advance of any international level advisory panel meetings and related events with key opinion leaders with respect to the Products in the Otsuka Territory and the Aurinia Territory (for clarity, excluding any generally applicable international conferences or congresses, such as the World Congress of Nephrology) that are held, sponsored or attended by either Party or its Affiliate or licensee or Sublicensee (as

applicable), and each Party shall have the right to attend and participate in such meetings, at the attending Party's cost and expense.

### **6.9 Standards of Conduct; Compliance**

Otsuka will perform, or will ensure that each of its Affiliates, Sublicensees (as applicable), and Representatives perform, all Commercialization activities in a professional and ethical business manner and in compliance with Applicable Laws, applicable Professional Requirements and the Commercialization Plan.

### **6.10 Product Materials**

Otsuka shall, at its cost and expense, prepare, develop, produce or otherwise obtain, and utilize sales, promotional, advertising, marketing, website, educational (including medical education and medical information) materials, and training materials ("**Product Materials**") to support its Commercialization activities and Medical Affairs in the Otsuka Territory. From time to time, and in any event upon Otsuka's request, Aurinia shall share with Otsuka samples of Product Materials (including English translations, if available) Controlled by Aurinia and which are used by Aurinia, its Affiliates or Other Aurinia Licensees in connection with the Commercialization of the Products and Medical Affairs in the Aurinia Territory to enable Otsuka to align its Product Materials with the Global Brand Plan and Global Medical Affairs Plan. From time to time, and in any event upon Aurinia's request, Otsuka shall share with Aurinia samples of Product Materials (including English translations, if available) Controlled by Otsuka and which are used by Otsuka, its Affiliates or Sublicensees in connection with the Commercialization of the Products and Medical Affairs in the Otsuka Territory.

### **6.11 Diversion**

(a) Each Party hereby covenants and agrees that it and its Affiliates shall not, and it will contractually obligate its licensees and Sublicensees (as applicable) not to, directly or indirectly, promote, market, distribute, import, sell, have sold, deliver or tender (or cause to be delivered or tendered) any Product, including via the Internet or mail order, to any Third Party or to any address (including any Internet Protocol address or the like) for the other Party's Territory.

(b) Neither Party shall engage, nor permit its Affiliates, licensees and Sublicensees (as applicable) to engage, in any advertising or promotional activities relating to any Product for use directed primarily to customers or other buyers or users of such Product located in or shipping to the other Party's Territory, or solicit orders from any prospective purchaser located in the other Party's Territory. If a Party or its Affiliates, licensees or Sublicensees (as applicable) receives any order for a Product for use from a prospective purchaser located in the other Party's Territory, such Party shall immediately refer that order to such other Party and shall not accept such order.

(c) Upon the written request of either Party, the Parties shall meet and in good faith endeavor to reach further agreement on means of avoiding, correcting or abating off-label uses of the Product or any Aurinia Domain Product (for an indication for which one or the other product obtains Regulatory Approval) and addressing the consequences of such uses in a fair and reasonable manner, including incorporating in detail the issues contemplated in this Section 6.11

and any other matters necessary or useful to discourage or prevent use in the other Party's Territory.

## 7. MANUFACTURE AND SUPPLY

### 7.1 General

Subject to the terms and conditions of each Supply Agreement, Aurinia will Manufacture and supply, itself or through a CMO in compliance with all Applicable Laws, including cGMP, all Clinical Samples, Compound and Products for use in the Development and Commercialization of Products in the Otsuka Territory under this Agreement. Notwithstanding the foregoing, neither Aurinia nor any of its Affiliates will have the right to Manufacture directly (rather than through a CMO) Product or Clinical Samples for supply to the Otsuka Territory unless Aurinia's or its Affiliate's Cost of Goods to Manufacture Product or Clinical Samples plus Otsuka's share of the other Manufacturing costs referred to in Section 7.4(b) in the aggregate will be less than the Cost of Goods for Manufacture of Product or Clinical Samples by CMOs plus Otsuka's share of the other Manufacturing costs referred to in Section 7.4(a) in the aggregate. Aurinia will supply to Otsuka or its Affiliates for Commercialization in the Otsuka Territory either Semi-Finished Product or Bulk Product, in each case as specified by Otsuka from time to time. Aurinia will supply to Otsuka or its Affiliates for Development in the Otsuka Territory Semi-Finished Product and Clinical Samples in the same primary packaging (e.g., blister packs) as such Semi-Finished Product. Otsuka shall be responsible, at its cost and expense, for Packaging Products for Development and Commercialization in the Otsuka Territory. Subject to Section 7.7 and the terms and conditions of each Supply Agreement (including supply failure provisions), Otsuka shall purchase 100% of its demand for Clinical Samples, Compound and Product exclusively from Aurinia.

### 7.2 Supply and Quality Agreements

As soon as practicable, but in any event in advance of Otsuka initiating any Clinical Trial or other studies of Product in the Otsuka Territory, the Parties will agree upon and enter into a clinical supply agreement on reasonable and customary terms for the supply of Bulk Product or Semi-Finished Products and their matching placebo (collectively, "**Clinical Samples**") by Aurinia to Otsuka for use in such Development (a "**Clinical Supply Agreement**"), and reasonably in advance of the First Commercial Sale of the first Product in the Otsuka Territory, the Parties will agree upon and enter into a commercial supply agreement on reasonable and customary terms for supply of Bulk Product or Semi-Finished Product by Aurinia to Otsuka for use in Commercialization in the Otsuka Territory (a "**Commercial Supply Agreement**"). Each Supply Agreement will be consistent with any applicable CMO Agreement, and will contain reasonable and customary terms for clinical supply or commercial supply, as applicable, and will include shipment and delivery terms on a FCA Origin (Incoterms 2020) basis. Without limiting the foregoing, the Commercial Supply Agreement will include the following terms, unless the Parties agree otherwise: forecasting and ordering terms; criteria regarding manufacturing capacity, quantity, timeliness of delivery, quality and cost; specifications (including shelf life requirements); provisions relating to safety stock, and failure to supply (including appropriate remedies in the event of a failure to supply); acknowledgement of the sensitive and proprietary nature of the Voclosporin Manufacturing Trade Secrets and procedures for the protection of same, including through authorized manufacturers; shortage allocation terms; change control

provisions; warranties; acceptance and rejection procedures; provisions relating to audits and inspections; and an arbitration provision consistent with the terms of this Agreement, including with respect to tolling. **[Terms of cost sharing redacted.]** The Product supplied under any Supply Agreement shall be the Product supplied under Aurinia's CMO Agreement. In addition to, or as part of, each Supply Agreement, the Parties will agree upon and enter into one or more quality technical agreements (each, a "**Quality Agreement**") containing reasonable and customary terms and conditions regarding quality assurance, quality control and compliance with cGMP and cGCP (as applicable). After the execution of the Supply Agreement(s), and Quality Agreement, the Parties' sole obligations with respect to Manufacture and supply of Clinical Samples and Product shall be further set out in the Supply Agreements and Quality Agreements and, once executed, the terms of the applicable Supply Agreement and the terms of the applicable Quality Agreement shall supersede and replace the terms of this Agreement applicable to Manufacture and supply of Clinical Samples and Product, all as may be further described in the Supply Agreements and Quality Agreements.

### 7.3 Supply Price

Aurinia shall Manufacture and supply to Otsuka all Bulk Product, Semi-Finished Product and Clinical Samples in accordance with each Supply Agreement and Quality Agreement at a supply price equal to the Cost of Goods for such Product and Clinical Samples plus, solely with respect to Product or Clinical Samples Manufactured by CMOs, a **[percentage redacted]** markup on the Cost of Goods (and, for clarity, there will be no markup on Cost of Goods if Aurinia or its Affiliate Manufactures Product or Clinical Samples). If, in any Calendar Year after the Effective Date, the Cost of Goods, whether for Product or Clinical Samples Manufactured by Aurinia or its Affiliate or for Product or Clinical Samples Manufactured by a CMO, will increase by **[percentage redacted]** or more over the Cost of Goods in the preceding Calendar Year, Aurinia shall provide prompt written notice to Otsuka of such increase, including a reasonably detailed description of the reason for such increase, and the Parties shall discuss options for addressing such increase and managing the supply price for Product or Clinical Samples, as applicable. If Product, Clinical Samples or Compound is Manufactured by any CMO(s), Aurinia shall not amend its agreement(s) with such CMO(s), including any amendment to the price paid by Aurinia to such CMO(s), without first consulting with Otsuka.

### 7.4 Other Manufacturing Costs

(a) To the extent Bulk Product or Semi-Finished Product or Clinical Samples is Manufactured by a CMO and Aurinia is required to pay to such CMO any charges that are directly attributable or allocated to Manufacture of such Bulk Product or Semi-Finished Product or Clinical Samples, as opposed to any other product, the Parties shall share such charges, to the extent not included in Cost of Goods, Allocated Reasonably: **[Specified costs redacted.]**

(b) To the extent Bulk Product or Semi-Finished Product is Manufactured by Aurinia or its Affiliates directly (rather than through a CMO), the Parties shall share the following costs, to the extent directly attributable or allocated to Manufacture of such Bulk product or Semi-Finished Product or Clinical Samples, as opposed to any other product, and not included in Cost of Goods, Allocated Reasonably: **[Specified costs redacted]**



## 7.5 Other Product Costs

(a) At Otsuka's request and, if applicable, as required by any Regulatory Authority in the Otsuka Territory, or if Aurinia is otherwise required by any Regulatory Authority to conduct any activities to supply Product to Otsuka for the Otsuka Territory or ensure that the Product supplied for the Otsuka Territory can be sold in the Otsuka Territory, for example, validation, stability testing and any other specific testing of Clinical Samples, Bulk Product and Semi-Finished Product Manufactured and supplied by or on behalf of Aurinia hereunder and under each Supply Agreement, Aurinia shall, through a CMO or Third Party Representative, conduct such activities, and to the extent not included in Cost of Goods, Otsuka will reimburse Aurinia for the actual out-of-pocket costs paid by Aurinia to the CMO for such activities plus a **[percentage redacted]** markup within thirty (30) days of receipt of an invoice and supporting documentation, which supporting documentation shall include copies of Third Party contracts (if not previously provided) and invoices reflecting the out-of-pocket costs paid by Aurinia. If such activities are applicable to both the Otsuka Territory and the Aurinia Territory, the foregoing charges shall be Allocated Reasonably.

(b) Otsuka will reimburse Aurinia for the actual out-of-pocket costs paid by Aurinia for storage, quality assurance and quality control activities (if performed by a Third Party), and CMO charges for inspections or audits of a CMO (if the CMO charges separately for inspections or audits) in each case for Product for the Otsuka Territory plus a **[percentage redacted]** markup within thirty (30) days of receipt of an invoice and supporting documentation, which supporting documentation shall include copies of Third Party contracts (if not previously provided) and invoices reflecting the out-of-pocket costs paid by Aurinia. If such activities are applicable to both the Otsuka Territory and the Aurinia Territory, the foregoing charges shall be Allocated Reasonably.

(c) In addition, at Otsuka's request, Aurinia will provide one or more technology transfer(s) to Otsuka or its designee of information (including test methods for Clinical Sample QA/QC) necessary or reasonably useful to support Otsuka's Packaging activities, including information relating to packaging processes and analytical methods and stability testing of the Products in furtherance of Packaging, and including providing reasonable assistance to Otsuka or its designee in connection therewith upon Otsuka's request.

## 7.6 CMO Agreements and Audits and Inspections

(a) **By or on Behalf of Otsuka.** Prior to entering into any CMO Agreement after the Effective Date, Aurinia shall: consult with Otsuka on the selection of and discussions with prospective CMOs; take Otsuka's comments into consideration in good faith; and use commercially reasonable efforts (without a requirement to make additional payment) to obtain rights to allow Otsuka to participate in Aurinia's audits under such CMO Agreement. Aurinia retains the exclusive right to negotiate with such prospective CMO and no Otsuka consent to such CMO Agreement is required. In addition, Aurinia will use commercially reasonable efforts (without a requirement to make additional payment) to allow Otsuka to participate in Aurinia's audits of the CMOs identified in Exhibit 1.37. Prior to entering into any agreement with a Third Party for the primary Packaging of Product, Otsuka will consult with Aurinia on the selection of and discussions with prospective contract manufacturing organizations for primary Packaging and take Aurinia's comments into consideration in good faith with respect to same. Otsuka

retains the exclusive right to negotiate with such contract manufacturing organization and no Aurinia consent to any agreement with such contract manufacturing organization is required.

**(b) By Governmental Authority.** If any Governmental Authority carries out or gives notice to either Party of its intention to carry out any inspection or audit of Aurinia or any of its Affiliates or CMOs or Third Party laboratories in relation to Manufacture or testing of Clinical Samples, Compound or Product for the Otsuka Territory, the applicable Party shall promptly notify the other Party thereof and if Aurinia has the right to have its licensees present at any such inspection or audit, Aurinia shall use commercially reasonable efforts to enforce such right so that Otsuka may be present at any such inspection or audit to the extent related to the Manufacture or testing of Clinical Samples, Compound or Product for the Otsuka Territory. Additional details, including relating to findings and responses to critical issues from such inspections or audits, will be discussed by the Parties and set forth in the Supply Agreements and Quality Agreements.

## **7.7 Transfer of Manufacturing**

**(a)** At any time after the expiration of the last to expire Initial Royalty Term in any country in the Otsuka Territory, on twelve (12) months' written notice to Otsuka, Aurinia may, at its expense, transfer to Otsuka the ability to Manufacture or acquire Products from a CMO on terms no less favorable to Otsuka in the aggregate than the terms of any Supply Agreement then in effect. Upon such transfer, (a) Aurinia shall have no further obligation for the supply of Product, (b) neither Party shall have any further obligations under Sections 2.4 (Access to Sublicensee Work Product), 2.6 (Negotiation Right), 2.7 (Disclosure of Know-How), 2.8 (Third Party IP Agreements) (only with respect to any Third Party IP identified after such transfer), 3.1 (Joint Collaboration Committees; Responsibilities), 3.2 (Executive Meeting), Article 4 (Development), Article 5 (Regulatory Activities), Article 6 (Commercialization and Medical Affairs), and Article 7 (Manufacture and Supply), in each case except to the extent any such Sections survive termination or expiration of this Agreement as provided in Section 14.8) and (c) the royalty payable to Aurinia hereunder pursuant to Section 8.4(d)(i) shall be reduced as set out therein.

## **8. FINANCIAL PROVISIONS**

### **8.1 Upfront Payment**

Following the Effective Date, in partial consideration of the license and rights granted to Otsuka hereunder, Otsuka shall make a one-time, non-refundable, noncreditable upfront payment to Aurinia of fifty million U.S. Dollars (\$50,000,000) within five (5) Business Days of Otsuka's receipt of an invoice and Payment Forms from Aurinia.

### **8.2 Regulatory Milestone Payments.**

**(a) Regulatory Milestones.** In partial consideration of the license and rights granted to Otsuka hereunder, subject to the remainder of this Section 8.2, Otsuka shall pay to Aurinia the one-time, non-refundable, non-creditable payments set forth in the tables below upon the first achievement of the applicable milestone event (whether by Otsuka or its Affiliate or Sublicensee). The milestone payments set forth in the tables below shall be paid only once with respect to each milestone event regardless of the number of Products to achieve such milestone

event or the number of times a Product achieves such milestone event. In respect of the first table, only one of the following scenarios as set out in columns A, B or C shall apply. For clarity, if the Removal Condition is achieved after [time period redacted] of First EMA Approval, no milestone payments will be due for milestone event (4) or milestone event (5).

<b>Milestone Events For Europe</b>	<b>A</b>	<b>B</b>	<b>C</b>
	<b>Regulatory Approval without Limitations, then European Pricing and Reimbursement Approval</b>	<b>Regulatory Approval with Limitations, then Removal Condition achieved, then European Pricing and Reimbursement Approval</b>	<b>Regulatory Approval with Limitations, then European Pricing and Reimbursement Approval, then Removal Condition achieved</b>
(1) Upon first Regulatory Approval by EMA of the first Product for the Initial Indication, “ <b>First EMA Approval</b> ” provided that the First Approved SmPC does not contain a Limitation:	\$30,000,000		
(3) If milestone event (1) is achieved, upon European Pricing and Reimbursement Approval:	\$10,000,000		
(2) If the First Approved SmPC includes one or both Limitations, then, unless Otsuka terminates this Agreement with respect to Europe in accordance with <u>Section 14.4(c)</u> , upon expiration of the time period set forth in <u>Section 14.4(c)</u> :		\$15,000,000	

<p>(4) If milestone event (2) is achieved and the Removal Condition is achieved before European Pricing and Reimbursement Approval, upon achievement of the Removal Condition:</p>		<p>If Removal Condition achieved within <b>[time period redacted]</b> of First EMA Approval: \$15,000,000 or If Removal Condition achieved after <b>[time period redacted]</b> and on or before <b>[time period redacted]</b> of First EMA Approval: \$7,500,000</p>	
<p>(5) If milestone event (2) is achieved and the Removal Condition is achieved before European Pricing and Reimbursement Approval, upon European Pricing and Reimbursement Approval:</p>		<p>If Removal Condition achieved within <b>[time period redacted]</b> of First EMA Approval: \$10,000,000 or If Removal Condition achieved after <b>[time period redacted]</b> and on or before <b>[time period redacted]</b> of First EMA Approval: \$5,000,000</p>	
<p>(2) If the First Approved SmPC includes one or both Limitations, then, unless Otsuka terminates this Agreement with respect to Europe in accordance with <u>Section 14.4(c)</u>, upon expiration of the time period set forth in <u>Section 14.4(c)</u>:</p>			<p>\$15,000,000</p>
<p>(5) If milestone event (2) is achieved and European Pricing and Reimbursement Approval is achieved before achievement of the Removal Condition, upon European Pricing and Reimbursement Approval:</p>			<p>\$5,000,000</p>

(4) If milestone event (2) is achieved and European Pricing and Reimbursement Approval is achieved before achievement of the Removal Condition, upon achievement of the Removal Condition:			<p>If Removal Condition achieved within <b>[time period redacted]</b> of First EMA Approval: \$20,000,000</p> <p>or</p> <p>If Removal Condition achieved after <b>[time period redacted]</b> and on or before <b>[time period redacted]</b> of First EMA Approval: \$7,500,000</p>
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<b>Milestone Events</b>	<b>Milestone Payment (U.S. Dollars)</b>
(5) Upon first Regulatory Approval of the first Product for the Initial Indication in Japan	\$10,000,000
(6) Upon first Regulatory Approval in the Otsuka Territory of the first Product for an Additional Indication	One Milestone Payment to be negotiated by the Parties prior to initiation of Development pursuant to Section 4.2(c)

**(b) Notice and Payment.** Otsuka shall provide Aurinia written notice within **[time period redacted]** Business Days after the achievement of any milestone event set forth in this [Section 8.2](#) by or on behalf of Otsuka or its Affiliates (or, within **[time period redacted]** Business Days after Otsuka’s receipt of notification of such achievement by or on behalf of its Sublicensees). Aurinia shall send Otsuka an invoice (and, if there has been any change (amendment) to a Payment Form previously submitted, or if a previously submitted Payment Form has expired, updated Payment Forms) for the applicable milestone payment following receipt of such written notice, and Otsuka shall pay Aurinia the milestone payment within **thirty (30)** days after receipt of such invoice (and Payment Forms, if applicable).

**8.3 Commercial Milestones Payments**

**(a) Net Sales Milestones in Europe.** In partial consideration of the license and rights granted to Otsuka hereunder, Otsuka shall pay to Aurinia the one-time, non-refundable, non-creditable payments set forth in the table below when the applicable aggregate amount of Net Sales of all Products in Europe in a single Calendar Year (whether by or on behalf of Otsuka or its Affiliates or Sublicensees) first reach the value set forth below. For the avoidance of doubt, each payment in this [Section 8.3\(a\)](#) shall be payable once only, regardless of the number of times such milestone event is subsequently achieved.

<b>Aggregate Net Sales of all Products in Europe in a single Calendar Year</b>	<b>Milestone Payment (U.S. Dollars)</b>
Equal or exceed [Financial threshold redacted]	[Payment amount redacted]
Equal or exceed [Financial threshold redacted]	[Payment amount redacted]
Equal or exceed [Financial threshold redacted]	[Payment amount redacted]

**(b) Net Sales Milestones in Japan.** In partial consideration of the license and rights granted to Otsuka hereunder, Otsuka shall pay to Aurinia the one-time, non-refundable, non-creditable payments set forth in the table below when the applicable aggregate amount of Net Sales of all Products in Japan in a single Calendar Year (whether by or on behalf of Otsuka or its Affiliates or Sublicensees) first reach the value set forth below. For the avoidance of doubt, each payment in this Section 8.3(b) shall be payable once only, regardless of the number of times such milestone event is subsequently achieved.

<b>Aggregate Net Sales of all Products in Japan in a single Calendar Year</b>	<b>Milestone Payment (U.S. Dollars)</b>
Equal or exceed [Financial threshold redacted]	[Payment amount redacted]
Equal or exceed [Financial threshold redacted]	[Payment amount redacted]
Equal or exceed [Financial threshold redacted]	[Payment amount redacted]

**(c) Notice and Payment.** Otsuka shall provide Aurinia written notice within [time period redacted] days after the Calendar Quarter in which any Net Sales milestone event in Section 8.3(a) or Section 8.3(b) is achieved by or on behalf of Otsuka or its Affiliates (or, within [time period redacted] days after the Calendar Quarter in which Otsuka is notified of such achievement by or on behalf of its Sublicensees). Aurinia shall send Otsuka an invoice (and, if there has been any change (amendment) to a Payment Form previously submitted, or if a previously submitted Payment Form has expired, updated Payment Forms) for the applicable milestone payment following receipt of such written notice, and Otsuka shall pay Aurinia the milestone payment within thirty (30) days after receipt of such invoice (and Payment Forms, if applicable).

**8.4 Royalty Payments.**

**(a) Royalty Rates in Europe.** In partial consideration of the license and rights granted to Otsuka hereunder, subject to the other terms of this Section 8.4, during the Initial Royalty Term, Otsuka shall make quarterly non-refundable, non-creditable royalty payments to Aurinia on the Net Sales of all Products sold in Europe in a Calendar Year on a tiered basis at the applicable incremental royalty rate set forth below.

<b>Portion of Aggregate Net Sales of all Products in Europe in a Calendar Year</b>	<b>Royalty Rate</b>
Portion less than or equal to <b>[Financial threshold redacted]</b>	12%
Portion greater than <b>[Financial threshold redacted]</b> and less than or equal to <b>[Financial threshold redacted]</b>	<b>[percentage redacted]</b>
Portion greater than <b>[Financial threshold redacted]</b> and less than or equal to <b>[Financial threshold redacted]</b>	<b>[percentage redacted]</b>
Portion greater than <b>[Financial threshold redacted]</b>	20%

**(b) Royalty Rates in Japan.** In partial consideration of the license and rights granted to Otsuka hereunder, subject to the other terms of this [Section 8.4](#), during the Initial Royalty Term, Otsuka shall make quarterly non-refundable, non-creditable royalty payments to Aurinia on the Net Sales of all Products sold in Japan in a Calendar Year on a tiered basis at the applicable incremental royalty rate set forth below.

<b>Portion of Aggregate Net Sales of all Products in Japan in a Calendar Year</b>	<b>Royalty Rate</b>
Portion less than or equal to <b>[Financial threshold redacted]</b>	10%
Portion greater than <b>[Financial threshold redacted]</b> and less than or equal to <b>[Financial threshold redacted]</b>	<b>[percentage redacted]</b>
Portion greater than <b>[Financial threshold redacted]</b> and less than or equal to <b>[Financial threshold redacted]</b>	<b>percentage redacted]</b>
Portion greater than <b>[Financial threshold redacted]</b>	18%

**(c) Initial Royalty Term.** The royalties set forth in [Section 8.4\(a\)](#) and [Section 8.4\(b\)](#) shall be paid on a Product-by-Product and country-by-country basis in the Otsuka Territory from the First Commercial Sale of such Product in such country by or on behalf of Otsuka or its Affiliates or Sublicensees, until the latest of (i) expiration of the last to expire Valid Claim (including any patent term extension available and granted for such claim) of the Aurinia Patents or the Joint Patents that Cover the composition of matter of such Product or method of using such Product in such country; (ii) the expiration of any Regulatory Exclusivity covering such Product in such country; or (iii) the twelfth (12<sup>th</sup>) anniversary of the First Commercial Sale of the first Product to launch in such country (the “**Initial Royalty Term**”).

**(d) Reductions.**

**(i)** On a Product-by-Product and country-by-country basis in Europe and Japan, upon expiration of the Initial Royalty Term for such Product in such country, the royalty rate payable by Otsuka to Aurinia hereunder will be **[percentage redacted]** of Net Sales of such Product in such country without reduction for the remainder of the Term, except as follows: if Aurinia elects to transfer to Otsuka the ability to Manufacture or acquire Products from a CMO pursuant to [Section 7.7](#), then, upon such transfer, the foregoing royalty rate payable by Otsuka to Aurinia hereunder will be **[Provisions relating to reductions in applicable royalty rates redacted.]**

(ii) On a Product-by-Product and country-by-country basis during the Initial Royalty Term, in no event will the royalty rate that otherwise would be due and payable by Otsuka to Aurinia for a Product in a country in a Calendar Quarter pursuant to Sections 8.4(a) and 8.4(b) be reduced under the cumulative effect of Sections 8.4(d)(ii), 8.4(d)(iii), 8.4(d)(iv) and 8.4(d)(v) to less than **[percentage redacted]** in any country in Europe and **[percentage redacted]** in Japan.

## **9. PAYMENT; RECORDS; AUDITS**

### **9.1 Reports; Payment**

Royalty payments due to Aurinia under Section 8.4 shall be calculated and reported for each Calendar Quarter. Within thirty (30) days after the end of each Calendar Quarter during the Initial Royalty Term and the Extended Royalty Term, Otsuka will provide to Aurinia a written report (each, a “**Royalty Report**”) setting forth in sufficient detail to enable amounts owed or payable hereunder to be determined (a) the gross sales of the Products sold by Otsuka and its Affiliates and Sublicensees in each in country in Europe and in Japan in such Calendar Quarter; (b) the aggregate Net Sales of all Products sold by Otsuka and its Affiliates and Sublicensees in each country in Europe and in Japan in such Calendar Quarter and the itemized deductions from gross sales; (c) the exchange rates used to calculate the royalties payable in U.S. Dollars in accordance with Section 9.2; (d) any withholding taxes required to be made from such royalties, (e) any adjustments to royalties in accordance with Section 8.4(d), (f) any other information necessary to enable royalties owed or payable to be determined; and (g) the royalties payable. Upon or after receipt of the Royalty Report, Aurinia shall send Otsuka an invoice (and, if there has been any change (amendment) to a Payment Form previously submitted, or if a previously submitted Payment Form has expired, updated Payment Forms) for the royalties payable and, within **[time period redacted]** Business Days of receipt of such invoice (and Payment Form, if applicable), Otsuka shall pay the associated royalties. The information contained in each Royalty Report shall be the Confidential Information of both Parties.

### **9.2 Exchange Rate; Manner and Place of Payment**

All payments hereunder shall be payable in U.S. Dollars and all references to Dollars and “\$” herein shall refer to U.S. Dollars. When conversion of Net Sales from any currency other than U.S. Dollars is required, such conversion shall be calculated as of the last day of the Calendar Quarter prior to the payment due date using a standard conversion method consistent with GAAP using a widely accepted source of published exchange such as published by OANDA.com or any substitute agreed-to between the Parties. All payments owed under this Agreement shall be made by wire transfer in immediately available funds to a bank and account designated in writing by Aurinia, unless otherwise specified in writing by Aurinia.

### **9.3 No Set-Off**

Otsuka shall in no case be entitled to set off or otherwise withhold or adjust any payment due to Aurinia under this Agreement in view of claims, whether justified or unjustified, that Otsuka may have against Aurinia for any reason.



#### 9.4 Taxes

Each Party shall be solely responsible for the payment of all taxes imposed on its share of income arising directly or indirectly from the activities of the Parties under this Agreement. The Parties agree to cooperate with one another and use commercially reasonable efforts to avoid or reduce tax withholding or similar obligations in respect of the payments made by Otsuka to Aurinia under this Agreement. To the extent Otsuka is required by Applicable Laws to deduct and withhold taxes on any payment to Aurinia, Otsuka shall pay such taxes to the proper Governmental Authority in a timely manner and promptly transmit to Aurinia an official tax certificate or other evidence of such payment. Otsuka shall have the right to deduct any such tax, levy or charge actually paid from payment due to Aurinia. Aurinia shall provide Otsuka any tax forms that may be reasonably necessary in order for Otsuka to not withhold tax or to withhold tax at a reduced rate under an applicable bilateral income tax treaty, to the extent legally able to do so. Aurinia shall use commercially reasonable efforts to provide any such tax forms to Otsuka in advance of the due date. Each Party agrees to assist the other Party in claiming exemption from such deductions or withholdings under double taxation or similar agreement or treaty from time to time in force and in minimizing the amount required to be so withheld or deducted.

#### 9.5 Records; Audit

Each Party shall maintain complete and accurate books and records in sufficient detail in relation to this Agreement to permit the other Party to confirm the accuracy of the amount of the Cost of Goods, achievement of milestones, the amount of royalties and other payments under this Agreement and any Supply Agreement. Each Party will keep such books and records for at least seven (7) years following the Calendar Year to which they pertain. Upon reasonable prior notice, each Party (the “**Auditing Party**”) shall have the right to inspect and audit such books and records of the other Party (the “**Audited Party**”) during regular business hours at such place or places where such records are customarily kept by an independent certified public accountant (the “**Auditor**”) selected by the Auditing Party and reasonably acceptable to the Audited Party for the sole purpose of verifying for the Auditing Party the accuracy of the financial reports, statements or invoices furnished by the Audited Party pursuant to this Agreement or of any payments made, or required to be made, by or to the Audited Party pursuant to this Agreement. Before beginning its audit, the Auditor shall execute an undertaking acceptable to each Party by which the Auditor agrees to keep confidential all information reviewed during the audit. Such audits may occur no more often than once each Calendar Year and not more frequently than once with respect to records covering any specific period of time. Each Party shall only be entitled to audit the books and records from the three (3) Calendar Years prior to the Calendar Year in which the audit request is made. Such Auditor shall not disclose the Audited Party’s Confidential Information to the Auditing Party, except to the extent such disclosure is necessary to verify the accuracy of the financial reports, statements or invoices furnished by the Audited Party or the amount of payments to or by the Audited Party under this Agreement. In the event that the final result of the audit reveals an undisputed underpayment or overpayment, the underpaid or overpaid amount shall be settled within thirty (30) days after the Auditor’s report. The Auditing Party shall bear the full cost of such audit unless such audit reveals an overpayment to, or an underpayment by, the Audited Party that resulted from a discrepancy in the financial report, statement or invoice provided by the Audited Party for the audited period, which underpayment or overpayment was more than five percent (5%) of the amount set forth in

such report, in which case the Audited Party shall reimburse the Auditing Party for the costs for such audit.

## 9.6 Late Payments

In the event that any payment due under this Agreement is not paid when due in accordance with the applicable provisions of this Agreement (including any underpayments of royalties found during an audit under [Section 9.5](#), simple interest shall thereafter accrue on the sum due from the due date until the date of payment at a per-annum rate of five percent (5%); provided that, in no event shall such rate exceed the maximum annual interest rate allowed by Applicable Law.

## 10. INTELLECTUAL PROPERTY

### 10.1 Ownership

(a) **Data.** All Data generated in connection with the Development or Commercialization of any Product conducted by or on behalf of Aurinia and its Affiliates and Other Aurinia Licensees (the “**Aurinia Data**”) shall, as between the Parties, be the sole and exclusive property of Aurinia. All Data generated in connection with the Development or Commercialization of any Product conducted by or on behalf of Otsuka or its Affiliates or Sublicensees (the “**Otsuka Data**”) shall, as between the Parties, be the sole and exclusive property of Otsuka. For clarity, each Party shall have access and right to use and reference the other Party’s Data as and to the extent set forth in this Agreement. To the extent a patentable Invention Controlled by a Party is supported by any Data owned by the other Party, the Party Controlling such Invention shall have the right, upon the other Party’s prior written consent (not to be unreasonably withheld), to use and disclose such Data owned by the other Party in its patent applications to support such Invention. **[Restriction on patent application redacted]**

(b) **Inventions.** Inventorship of any Inventions will be determined in accordance with the standards of inventorship under applicable patent laws. Ownership of Inventions will be allocated as provided in this [Section 10.1\(b\)](#) and the Parties will work together to resolve any issues regarding inventorship or ownership of Inventions.

(i) Aurinia shall solely own all Inventions that solely and specifically relate to the composition, manufacture or use of the Compound (“**Compound Inventions**”) and all Patents that solely claim Compound Inventions (“**Compound Invention Patents**”). All Compound Inventions are included in Aurinia Know-How and all Compound Invention Patents are included in Aurinia Patents and, in each case, are licensed to Otsuka under [Section 2.1](#). To the extent any Compound Invention is made by Otsuka, whether solely or jointly with Aurinia, Otsuka shall, and hereby does, assign to Aurinia, without additional consideration, all of its right, title and interest in such Compound Invention.

(ii) Aurinia shall solely own all Inventions discovered, made, conceived, developed or otherwise created solely by Aurinia’s Representatives (“**Aurinia Sole Inventions**”) and, except for Compound Inventions, Otsuka shall solely own all Inventions discovered, made, conceived, developed or otherwise created solely by Otsuka’s Representatives (“**Otsuka Sole Inventions**”).

(iii) Except for Compound Inventions, the Parties shall jointly own, and shall have an equal, undivided interest in, any Inventions that are made jointly by the Representatives of one Party together with the Representatives of the other Party (“**Joint Inventions**”). All Patents claiming Joint Inventions shall be referred to herein as “**Joint Patents**.” Except as otherwise set out in this Agreement, each Party shall be entitled to practice, license, assign and otherwise exploit its interest under the Joint Inventions and Joint Patents without the duty of accounting or seeking consent from the other Party. Each Party shall grant, on the terms set out in Article 2, an exclusive license of such granting Party’s interest in Joint Inventions and Joint Patents on the terms set out therein. Each Party will grant and hereby does grant all permissions, consents and waivers with respect to, and all licenses under, Joint Inventions and Joint Patents, throughout the world, necessary to provide the other Party with such rights of use and exploitation of the Joint Inventions and Joint Patents permitted hereby, and will execute documents as necessary to accomplish the foregoing.

(c) **Employee Assignment.** Each Party shall ensure that all of its employees, directors, officers and agents who are acting under its or its Affiliates’ authority in the performance of this Agreement assign to such Party under a binding written agreement all Know-How and Patents discovered, made, conceived, developed or otherwise created by such Representative as a result of such Representative’s performance of this Agreement. In the case of all other Representatives acting in the performance of a Party’s obligations under this Agreement, such as clinical investigators or non-employees working for non-profit institutions, the Party that engages such Third Party shall use commercially reasonable efforts to ensure that such Third Party is also so obligated to assign under such an agreement, unless otherwise approved by the Parties.

## 10.2 Patent Prosecution and Maintenance

### (a) Aurinia Patents.

(i) Aurinia shall have the first right, but not the obligation, to control the preparation, filing, prosecution and maintenance (including any interferences, reissue proceedings, reexaminations, inter partes review, patent term extensions, applications for supplementary protection certificates and oppositions (“**Prosecution**”) of the Aurinia Patents worldwide. Aurinia shall keep Otsuka informed of material progress with regard to Prosecution of Aurinia Patents in the Otsuka Territory and shall provide Otsuka (or have provided to Otsuka) all filings and material correspondence related thereto for the Otsuka Territory within a reasonable time after the receipt or prior to the filing of such documents, to allow Otsuka and its patent counsel to be able to review and provide comments to Aurinia and its patent counsel regarding the filing and contents of such application, amendment, submission, response or other documents, including the content, timing and jurisdiction of the filing of Aurinia Patents in the Otsuka Territory provided that such review and comment shall not delay the Prosecution. Aurinia shall consult with, and consider in good faith the comments, requests and suggestions of, Otsuka with respect to Prosecution of Aurinia Patents in the Otsuka Territory.

(ii) Aurinia shall not, without the prior written consent of Otsuka, abandon, forfeit or otherwise cease the Prosecution of any of the Existing Aurinia Patents in the Otsuka Territory; provided that Otsuka’s consent shall not be unreasonably withheld if Aurinia has, and informs Otsuka of, a reasonable strategic reason for ceasing the Prosecution of an

Existing Aurinia Patent in the Otsuka Territory. In the event that Otsuka provides consent pursuant to the preceding sentence with respect to any Existing Aurinia Patent or Aurinia fails to file or desires to abandon, forfeit or otherwise cease Prosecution of any other Aurinia Patent in any country in the Otsuka Territory, Aurinia shall provide reasonable prior written notice to Otsuka of such intention (which notice shall, to the extent possible, be given at least ninety (90) days before such Patent would become abandoned or forfeited). If Aurinia fails to file or ceases the Prosecution of any of the Aurinia Patents in the Otsuka Territory in accordance with the foregoing, other than for a reasonable strategic reason, Otsuka may, upon written notice to Aurinia, elect to assume Prosecution of such Aurinia Patent in such country in the Otsuka Territory. If Otsuka elects to assume Prosecution of such Aurinia Patent in such country in the Otsuka Territory, Otsuka shall Prosecute such Aurinia Patent in such country at its cost and expense in the name of Aurinia; provided that thereafter such Aurinia Patent shall not be included in the Aurinia Patents for purposes of Section 8.4(c) and shall no longer provide a basis for royalty payments under this Agreement. If Otsuka does not elect to assume Prosecution of such Aurinia Patent in such country in the Otsuka Territory, Aurinia will have the right to cease the Prosecution of such Aurinia Patent in such country.

(iii) Aurinia shall bear all costs and expenses in connection with Prosecution of Aurinia Patents worldwide, except to the extent Otsuka will bear such costs in accordance with Section 10.2(a)(ii).

**(b) Otsuka Patents.**

(i) Except as otherwise set forth in this Section 10.2(b), Otsuka shall have the first right, in its discretion, to control the Prosecution of all Otsuka Patents worldwide. Otsuka shall keep Aurinia informed of material progress with regard to Prosecution of Otsuka Patents in the Aurinia Territory and shall provide Aurinia (or have provided to Aurinia) all filings and material correspondence related thereto, within a reasonable time after the receipt or prior to the filing of such documents, to allow Aurinia and its patent counsel to be able to review and provide comments to Otsuka and its patent counsel regarding the filing and contents of such application, amendment, submission, response or other documents, including the content, timing and jurisdiction of the filing of Otsuka Patents in the Aurinia Territory provided that such review and comment shall not delay the Prosecution. Otsuka shall consult with, and consider in good faith the comments, requests and suggestions of, Aurinia with respect to Prosecution of Otsuka Patents.

(ii) In the event that Otsuka fails to file or desires to abandon, forfeit or otherwise cease Prosecution of any Otsuka Patent in any country in the Aurinia Territory or the Otsuka Territory, Otsuka shall provide reasonable prior written notice to Aurinia of such intention (which notice shall, to the extent possible, be given at least ninety (90) days before such Patent would become abandoned or forfeited). If Otsuka fails to file or ceases the Prosecution of any Otsuka Patents in a country in the Aurinia Territory or the Otsuka Territory other than for a reasonable strategic reason, Aurinia may, upon written notice to Otsuka, elect to assume Prosecution of such Otsuka Patent in such country and, in that event, Aurinia shall Prosecute such Otsuka Patent in such country at its cost and expense in the name of Otsuka. If Aurinia does not elect to assume Prosecution of such Otsuka Patent in such country, Otsuka will have the right to cease the Prosecution of such Otsuka Patent in such country.

(iii) Otsuka shall bear all costs and expenses in connection with Prosecution of Otsuka Patents worldwide, except to the extent Aurinia will bear such costs in accordance with Section 10.2(b)(ii).

**(c) Joint Patents.**

(i) Aurinia shall have the first right, but not the obligation, to Prosecute Joint Patents using patent counsel mutually agreed to by the Parties. Aurinia shall keep Otsuka informed of material progress with regard to Prosecution of Joint Patents worldwide and shall provide Otsuka (or have provided to Otsuka) all filings and material correspondence related thereto within a reasonable time after the receipt or prior to the filing of such documents to allow Otsuka and its patent counsel to be able to review and provide comments to Aurinia and its patent counsel regarding the filing and contents of such application, amendment, submission, response or other documents, including the content, timing and jurisdiction of the filing of Joint Patents in any country in the world provided that such review and comment shall not delay the Prosecution. Aurinia shall consult with, and consider in good faith the comments, requests and suggestions of, Otsuka with respect to Prosecution of Joint Patents worldwide.

(ii) In the event that Aurinia fails to file or desires to abandon, forfeit or otherwise cease Prosecution of any Joint Patent in any country, Aurinia shall provide reasonable prior written notice to Otsuka of such intention (which notice shall, to the extent possible, be given at least ninety (90) days before such Patent would become abandoned or forfeited). In such case, Otsuka may, upon written notice to Aurinia, elect to assume Prosecution of such Joint Patent in such country and, in that event, (A) Aurinia shall assign all of its right, title and interest in and to such Joint Patent in such country to Otsuka at no cost to Otsuka, and (B) Otsuka shall Prosecute such Joint Patent in such country at its cost and expense. Aurinia shall execute such documents and perform such acts, at no cost to Otsuka, as may be necessary to allow Otsuka to continue the Prosecution of such Joint Patent in such country. Any such assignment shall be completed in a timely manner to allow Otsuka to continue Prosecution of such Joint Patent and any such Patent so assigned shall cease to be either a Joint Patent or an Otsuka Patent. If Otsuka does not elect to assume Prosecution of such Joint Patent in such country, Aurinia will have the right to cease the Prosecution of such Joint Patent in such country.

(iii) Subject to Section 10.2(c)(ii), each Party shall bear fifty percent (50%) of all costs and expenses in connection with Prosecution of Joint Patents worldwide.

**(d) Cooperation.** Each Party agrees to cooperate fully in the Prosecution of Patents under this Section 10.2 and in the obtaining and maintenance of any patent term extensions, supplementary protection certificates and their equivalent with respect thereto, respectively, at its cost and expense (except as expressly set forth otherwise in this Article 10). Such cooperation includes (i) executing all papers and instruments, or requiring its Representatives, to execute such papers and instruments, so as enable the other Party to apply for and to prosecute patent applications in any country as permitted by this Section 10.2, and (ii) promptly informing the other Party of any matters coming to such Party's attention that may affect the preparation, filing, prosecution or maintenance of any such patent application and the obtaining of any patent term extensions, supplementary protection certificates and their equivalent.

### 10.3 Patent Enforcement

(a) **Notice.** Each Party shall promptly notify the other Party of any known, suspected, alleged or threatened infringement or misappropriation by a Third Party of any of the Aurinia Technology, Joint Technology, or Otsuka Technology by reason of the making, using, offering to sell, selling or importing of any Product or Competing Product other than a Product or Aurinia Domain Product, in each case permitted by this Agreement (“**Product Infringement**”) or any declaratory judgment, opposition, or similar action alleging the invalidity or unenforceability of any Aurinia Patents, Joint Patents or Otsuka Patents (“**Invalidation Proceeding**”), in each case anywhere in the world, of which such Party becomes aware.

(b) **Invalidation Proceedings.** Aurinia shall have the first right, but not the obligation, to defend any Invalidation Proceeding in the Otsuka Territory respecting the Aurinia Patents and Aurinia shall have the first right, but not the obligation, to defend any Invalidation Proceeding anywhere in the world respecting the Joint Patents. Otsuka shall have the first right, but not the obligation, to defend any Invalidation Proceeding in the Aurinia Territory respecting the Otsuka Patents. If the Party with the first right to defend in accordance with the foregoing does not inform the other Party that it intends to defend such an Invalidation Proceeding **within thirty (30) days** after a request from the other Party, and does not provide commercially reasonable reasons why such Party does not intend to defend such Invalidation Proceeding, then the following shall apply: (i) with respect any Invalidation Proceeding respecting Aurinia Patents in the Otsuka Territory, Otsuka will have the second right, but not the obligation, to defend such Invalidation Proceeding; (ii) with respect to any Invalidation Proceeding respecting Joint Patents anywhere in the world, Otsuka will have the second right, but not the obligation to defend such Invalidation Proceeding; and (iii) with respect any Invalidation Proceeding respecting Otsuka Patents in the Aurinia Territory, Aurinia will have the second right, but not the obligation, to defend such Invalidation Proceeding. Notwithstanding the foregoing, Aurinia shall have the sole right, but not the obligation, to defend any Invalidation Proceeding in the Aurinia Territory respecting the Aurinia Patents and Otsuka shall have the sole right, but not the obligation, to defend any Invalidation Proceeding in the Otsuka Territory respecting the Otsuka Patents.

(c) **Otsuka Enforcement Right.** Otsuka shall have the first right, but not the obligation, to take any reasonable measures it deems appropriate with respect to any Product Infringement in the Otsuka Territory. Such measures may include (i) initiating or prosecuting an infringement suit or action (“**Infringement Action**”) in the Otsuka Territory, or (ii) subject to Section 2.1(b)(ii), granting adequate rights and licenses to such Third Party necessary to render continued Product Infringement in the Otsuka Territory non-infringing. Notwithstanding the foregoing, if Otsuka does not inform Aurinia that it intends to either initiate an Infringement Action in the Otsuka Territory or grant adequate rights and licenses to such Third Party within ninety (90) days after Otsuka’s receipt of a notice of a Product Infringement pursuant to Section 10.3(a) and does not provide Aurinia commercially reasonable reasons why Otsuka does not intend to initiate such Infringement Action or grant such rights or licenses within such 90-day period, then Aurinia will have the second right, but not the obligation, to initiate an Infringement Action, but solely with respect to any Aurinia Technology or Joint Technology.

(d) **Aurinia Enforcement Right.** Aurinia shall have the sole right, but not the obligation, to take any measures it deems appropriate with respect to any Product Infringement in the Aurinia Territory respecting any Aurinia Technology or Joint Technology. Aurinia shall have

the first right, but not the obligation, to take any reasonable measures it deems appropriate with respect to any Product Infringement in the Aurinia Territory respecting any Otsuka Technology (“**Otsuka Technology Product Infringement**”). If Aurinia does not inform Otsuka that it intends to take measures with respect to any Otsuka Technology Product Infringement in the Aurinia Territory within ninety (90) days after Aurinia’s receipt of a notice of such Otsuka Technology Product Infringement pursuant to Section 10.3(a) and does not provide Otsuka commercially reasonable reasons why Aurinia does not intend to initiate such measures within such 90-day period, then Otsuka will have the second right, but not the obligation, to initiate measures with respect to any Otsuka Technology Product Infringement in the Aurinia Territory. For clarity, Aurinia shall have the sole right, but not the obligation, to take any measures it deems appropriate with respect to any known, suspected, alleged or threatened infringement or misappropriation by a Third Party of any of the Aurinia Technology or Joint Technology by reason of the making, using, offering to sell, selling or importing of any Aurinia Domain Product.

**(e) Collaboration.** The Party initiating any Infringement Action or defending any Invalidation Proceeding under Section 10.3(b), Section 10.3(c) or Section 10.3(d) (such Party, the “**Responsible Party**”) shall have the right to control the initiation and prosecution of such Infringement Action, or the defense of any Invalidation Proceeding, including the right to select counsel therefor, at its cost and expense. The other Party (the “**Supporting Party**”) shall be entitled to separate representation in any Infringement Action or Invalidation Proceeding by counsel of its own choice. If requested by the Responsible Party, the Supporting Party shall join as a party to such Infringement Action and will execute and cause its Affiliates to execute all documents, including registration of exclusive license, necessary for the Responsible Party to initiate, prosecute, maintain or defend such Infringement Action. In addition, at the Responsible Party’s request, the Supporting Party shall provide reasonable assistance to the Responsible Party in connection with an Infringement Action or Invalidation Proceeding at no charge to the Responsible Party except for reimbursement by the Responsible Party of reasonable out-of-pocket costs incurred by the Supporting Party in rendering such assistance. The Responsible Party shall keep the Supporting Party regularly informed of the status and progress of such Infringement Action or Invalidation Proceeding. In respect of any Invalidation Proceeding, the Responsible Party shall provide the Supporting Party and its counsel with an opportunity to consult with the Responsible Party and its counsel regarding the defense of such Invalidation Proceeding (including reviewing the contents of any correspondence, legal papers or other documents related thereto), and the Responsible Party shall take into account reasonable requests of the Supporting Party regarding such defense, including, where the Responsible Party is Otsuka, taking into account Aurinia’s global patent strategy. In no event shall the Responsible Party settle any Infringement Action or Invalidation Proceeding or take any other action that materially adversely affects the other Party’s rights or interests and, for clarity, the Responsible Party may not admit invalidity or unenforceability of any Patent Controlled by the other Party or any Joint Patent without the express prior written consent of the other Party.

**(f) Recoveries.** If a Responsible Party recovers monetary damages in an Infringement Action, such recovery shall be allocated first to the reimbursement of any expenses incurred by the Responsible Party in connection with such Infringement Action, second to the reimbursement of any expenses incurred by the other Party in connection with such Infringement Action, and any remaining amounts shall be retained by the Responsible Party provided that, **[treatment of recovery redacted]**.

#### 10.4 Infringement of Third Party Patents or Know-How

If a Third Party sues a Party (the “**Sued Party**”) alleging that the Sued Party’s, or its Affiliate’s or Sublicensee’s, Development, Manufacture or Commercialization of a Product in the Otsuka Territory infringes or will infringe such Third Party’s Patents or misappropriates or will misappropriate such Third Party’s Know-How (“**Third Party Infringement Suit**”), then the Sued Party shall promptly notify the other Party of such Third Party Infringement Suit. The Parties shall promptly meet to consider the appropriate course of action and may, if appropriate, agree on and enter into a “common interest agreement” wherein the Parties agree to their shared, mutual interest in the outcome of such Third Party Infringement Suit. Absent such agreement, the Sued Party shall defend the Third Party Infringement Suit; provided that Section 10.3 shall govern the right of Otsuka to assert a counterclaim of infringement of any Aurinia Patents, Joint Patents or Otsuka Patents. At the Sued Party’s request, the other Party will provide reasonable assistance to the Sued Party in connection with the Sued Party’s defense of any such Third Party Infringement Suit. If the other Party has not joined in such Third Party Infringement Suit, the Sued Party will keep the other Party reasonably informed on a Calendar Quarter basis prior to and during the pendency of such Third Party Infringement Suit. The Sued Party will not enter into any settlement of any Third Party Infringement Suit that is instituted or threatened to be instituted against the other Party without the other Party’s prior written consent, which will not be unreasonably withheld; except that, such consent will not be required if such settlement includes a release of all liability in favor of the other Party. Further, the Sued Party shall not settle or compromise any Third Party Infringement Suit, or knowingly take any other action in the course thereof, in a manner that materially adversely affects the other Party’s rights or interests, without the prior written consent of such other Party, such consent not to be unreasonably withheld. If, as part of a settlement or compromise of a Third Party Infringement Suit, the Sued Party enters into an agreement with a Third Party to obtain a license under or otherwise acquire rights to Third Party IP, the acquisition of rights under such agreement will be governed by the terms of Section 2.8.

#### 10.5 Trademarks

(a) **Product Marks.** Aurinia shall use Commercially Reasonable Efforts to develop and adopt Trademarks to be used for the Products (the “**Product Marks**”); provided that Aurinia shall consult with Otsuka regarding the development of, and shall use Commercially Reasonable Efforts to obtain and maintain, a unitary Product Mark for use worldwide. If Aurinia is unable to obtain or maintain a unitary Product Mark for use worldwide, Otsuka may propose a unitary Trademark to be used for the Products throughout the Otsuka Territory, and if Aurinia is unable to obtain or maintain any other Product Marks in any country in the Otsuka Territory, Otsuka may propose country-specific Trademarks in the Otsuka Territory. The Parties shall discuss at the Local JCCs (or, as applicable, the Europe JCC, Japan JCC or any subcommittee to which the Local JCCs may delegate such discussion) any unitary Trademark proposed by Otsuka for the Otsuka Territory or other Trademarks as may be available for registration and marketing of the Product in any country in the Otsuka Territory. In addition, if Otsuka believes that any Product Marks are not appropriate for one or more countries in the Otsuka Territory, whether due to linguistic reasons, any notice (including rejection or refusal) by a Regulatory Authority, market research showing that the Product Marks are not appropriate for commercial use in a country, or otherwise, Otsuka may propose and the Parties shall discuss at the Local JCCs (or, as applicable, the Europe JCC, the Japan JCC or any subcommittee to which the Local JCCs may



delegate such discussion) an alternative Trademark for Products in such country(ies) in the Otsuka Territory, which shall not be confusingly similar to any other Otsuka mark. In addition, Otsuka may propose and the Parties shall discuss at the Local JCCs (or, as applicable, the Europe JCC, the Japan JCC or any subcommittee to which the Local JCCs may delegate such discussion) Trademarks in local languages in the Otsuka Territory (including a katakana Trademark, which is a Japanese notation of a Trademark to be used for Products in Japan) and any additional Trademarks (e.g., logos and slogans) to be used in the Commercialization of Products in one or more country(ies) in the Otsuka Territory. Any such unitary Trademark for the Otsuka Territory or alternative Trademark, local language Trademark, or additional Trademark that is approved by the Local JCCs in accordance with Section 3.4 shall be a Product Mark. Otsuka shall use the Product Marks in the Otsuka Territory in a manner consistent with trademark usage guidelines provided by Aurinia to Otsuka from time to time. As of the Effective Date, the existing Product Marks or candidates for Product Marks are set out in Exhibit 10.5(a). The Product Marks shall appear on all Product packaging, labels and inserts and other materials which Otsuka uses for the Commercialization of the Product, in such form, location and manner as shall be approved by the JCC. Consistent with Otsuka's exclusive right to Product Marks under Section 2.1(a), Otsuka shall use Product Marks in a manner consistent with this Agreement, including the Global Brand Plan or the Otsuka Territory-Specific Brand Plan, as applicable, and for no other purpose. Subject to the foregoing: (a) Otsuka shall not use any other marks that are confusingly similar to any Product Mark, (b) all rights in each of the Product Marks shall remain at all times the sole property of Aurinia, and all use of such Product Marks shall inure to the benefit of Aurinia, and (c) Otsuka agrees not to contest or attack Aurinia's ownership of the Product Marks.

**(b) Prosecution.** Aurinia shall own the Product Marks throughout the world and all goodwill in the Product Marks shall accrue to Aurinia. Aurinia shall be responsible, at its cost and expense, for the filing, prosecution, registration and maintenance (including the defense of opposition proceeding and equivalent proceeding) of the Product Marks on a timely basis in the Otsuka Territory; provided that, from the date of the first Regulatory Approval of the first Product in Europe, in respect of Europe, and from the date of the first Regulatory Approval of the first Product in Japan, in respect of Japan, as applicable, Otsuka will thereafter bear the reasonable costs incurred by Aurinia for the filing, prosecution, registration and maintenance (including the defense of opposition proceeding and equivalent proceeding) of the Product Marks that are approved by the applicable Regulatory Authority for use with the Product in Europe and Japan, respectively, and reimburse to Aurinia such costs and expenses within sixty (60) days after receipt of invoices therefor from Aurinia. Aurinia shall keep Otsuka informed of material progress with regard to the prosecution, registration, and maintenance (including the defense of opposition proceeding and equivalent proceeding) of Product Marks in the Otsuka Territory, including content, timing and jurisdiction of the filing of Product Marks in the Otsuka Territory, sufficiently in advance for Otsuka to be able to review any material documents, and Aurinia shall consult with, and consider in good faith the comments, requests and suggestions of, Otsuka with respect to strategies for filing and prosecuting Product Marks in the Otsuka Territory.

**(c) Enforcement.** During the Term, each Party will promptly notify the other Party in writing of any known or suspected infringement or unauthorized use or misappropriation by a Third Party of any Product Marks in the Otsuka Territory ("**Product Mark Infringement**"). Otsuka shall have the first right, but not the obligation, to take any reasonable measures it deems appropriate with respect to any Product Mark Infringement, at its cost and expense, including

initiating or prosecuting an infringement, misappropriation or other appropriate suit or action to enforce the Product Marks in the Otsuka Territory. Notwithstanding the foregoing, if Otsuka does not inform Aurinia that it intends to initiate a suit or take other action against Product Mark Infringement within ninety (90) days after Otsuka's receipt of a notice of such Product Mark Infringement and does not provide Aurinia commercially reasonable reasons why Otsuka does not intend to initiate such suit or take such other action within such period, then Aurinia will have the second right, but not the obligation, to initiate a suit or take other action against such Product Mark Infringement. If requested by the Party that initiates suit or takes other action against Product Mark Infringement (the "**Enforcing Party**"), the other Party shall join as a party to such suit or action and will execute and cause its Affiliates to execute all documents necessary for the Enforcing Party to initiate and maintain such suit or action. In addition, at the Enforcing Party's request, the other Party shall provide reasonable assistance to the Enforcing Party in connection with such suit or action at no charge to the Enforcing Party except for reimbursement by the Enforcing Party of reasonable out-of-pocket costs incurred by the other Party in rendering such assistance.

(d) **Defense** If a Third Party brings suit alleging that a Sued Party's, or its Affiliate's or Sublicensee's, Development, manufacture or Commercialization of a Product in the Otsuka Territory infringes or will infringe such Third Party's Trademarks ("**Trademark Infringement Suit**"), then the Sued Party shall promptly notify the other Party of such Trademark Infringement Suit and Otsuka shall be responsible, at its cost and expense, for the defense of such Trademark Infringement Suit. At Otsuka's request and expense, Aurinia will provide reasonable assistance in connection with Otsuka's defense of such Trademark Infringement Suit and Otsuka will keep Aurinia reasonably informed on a Calendar Quarter basis prior to and during the pendency of such Trademark Infringement Suit. Otsuka will not enter into any settlement of any Trademark Infringement Suit that is instituted or threatened to be instituted against Aurinia without Aurinia's prior written consent, which will not be unreasonably withheld; *except that*, such consent will not be required if such settlement includes a release of all liability in favor of Aurinia. Further, Otsuka shall not settle or compromise any Trademark Infringement Suit, or knowingly take any other action in the course thereof, in a manner that materially adversely affects Aurinia's rights or interests, without Aurinia's prior written consent.

## 11. REPRESENTATIONS AND WARRANTIES

### 11.1 Mutual Representations and Warranties

(a) Each Party represents and warrants to the other Party that, as of the Effective Date: (i) it is duly organized, validly existing, and in good standing under the laws of its jurisdiction of incorporation or formation; (ii) has full corporate or other power and authority to execute and deliver this Agreement and to carry out its obligations hereunder, and the person or persons executing this Agreement on its behalf has been duly authorized to do so by all requisite corporate action; (iii) this Agreement is legally binding upon it and enforceable in accordance with its terms; (iv) the execution, delivery and performance of this Agreement by it will not constitute a default under or conflict with any agreement, instrument or understanding, oral or written, to which it is a party or by which it may be bound; and (v) it has the right to grant the licenses granted by it under this Agreement.

(b) Each Party represents and warrants to the other Party that, as of the Effective Date, it is not debarred, disqualified or the subject of a conviction under Section 306 of the FFDCA, or comparable laws in any country or jurisdiction other than the U.S. (“**Debarred**”), and it does not employ or use the services of any person who is Debarred in connection with any activities relating to the Compound or any Product.

## 11.2 Mutual Covenants

(a) Each Party covenants that it shall use commercially reasonable efforts to not use, in any capacity in connection with activities under this Agreement or relating to the Compound or any Product, any person who has been Debarred. If either Party becomes aware that it or any person or entity used in any capacity by it or its Affiliate in the performance of activities under this Agreement or relating to the Compound or any Product is Debarred or is subject to any action, suit, claim, investigation or legal or administrative proceeding (whether pending or threatened) pursuant to which it may be Debarred, such Party shall immediately notify the other Party in writing and such Party shall cease employing, contracting with, or retaining any such person to perform any such activities.

(b) Each Party covenants that, in the performance of its obligations under this Agreement, such Party shall, and shall cause its Affiliates, licensees, Sublicensees and Representatives to, comply with all Applicable Laws, including the European General Data Protection Regulation (Regulation (EU) 2016/679) and all other applicable data protection legislation and Privacy Laws, and all applicable anti-corruption laws, including the Foreign Corrupt Practices Act of 1977 and the Bribery Act 2010, as amended from time to time.

(c) Each Party covenants that it will not in the future offer, promise, pay, authorize, or give, money or anything of value, directly or indirectly, to any Government Official or Other Covered Party for the purpose, pertaining to this Agreement, of: (i) influencing any act or decision of the Government Official or Other Covered Party; (ii) inducing the Government Official or Other Covered Party to do or omit to do an act in violation of a lawful duty; (iii) securing any improper advantage; or (iv) inducing the Government Official or Other Covered Party to influence the act or decision of a government or government instrumentality, in order to obtain or retain business, or direct business to, any person or entity, in each case in any way related to this Agreement. For purposes of the foregoing, “**Government Official**” means any official, officer, employee, or representative of: (A) any federal, state, provincial, administrative division, county, or municipal government or any department or agency thereof; (B) any public international organization or any department or agency thereof; or (C) any company or other entity owned or controlled by any government or Governmental Authority, and “**Other Covered Party**” means any political party or party official, or any candidate for political office.

## 11.3 Aurinia Representations and Warranties

Aurinia represents and warrants to Otsuka that, except as disclosed in writing to Otsuka, as of the Effective Date:

(a) Exhibit 11.3(a) sets forth a complete and accurate list of the Aurinia Patents for the Otsuka Territory Controlled or owned, either solely or jointly, or in-licensed by Aurinia and its Affiliates (the “**Existing Aurinia Patents**”) and indicates, for each Existing

Aurinia Patent, whether such Patent is owned solely or jointly by Aurinia or licensed by Aurinia from a Third Party and if so, identifies the co-owner or the licensor or sublicensor from which such Patent is licensed;

**(b)** the Existing Aurinia Patents have been filed, maintained and are being Prosecuted in the Otsuka Territory maintained in a manner consistent with Aurinia's standard practice, no official final deadlines with respect to prosecution thereof have been missed, and all applicable fees have been paid on or before the due date for payment;

**(c)** Aurinia has obtained the assignment of all interests and all rights of any and all Third Parties who are named as inventors with respect to the subject matter of the Existing Aurinia Patents in the Territory and there are no claims or assertions in writing received by Aurinia regarding inventorship with respect to any Existing Aurinia Patents alleging that additional or alternative inventors ought to be listed and to Aurinia's Knowledge, the inventors listed are correct;

**(d)** Aurinia has the right to grant all rights and licenses it purports to grant to Otsuka with respect to the Aurinia Technology under this Agreement, free and clear of any rights therein granted by Aurinia or its Affiliates to any Third Party, and neither any license, option or other right granted (whether existing or purported to be terminated) by Aurinia or its Affiliates to any Third Party, nor any license or other right granted by any Third Party to Aurinia or its Affiliates conflicts with the rights and licenses granted to Otsuka hereunder;

**(e)** Aurinia has not granted any lien, security interest to any Third Party under the Aurinia Technology that would conflict with the rights granted to Otsuka hereunder;

**(f)** no claim or action has been brought or, to Aurinia's Knowledge, threatened by any Third Party alleging that the use of the Aurinia Technology, or the Development or Manufacture of the Compound or any Product infringes or misappropriates, or would infringe of misappropriate, any Patent, Know-How or other intellectual property right of any Third Party;

**(g)** other than routine patent prosecutions, no litigation or other claim or action has been brought or is pending or, to Aurinia's Knowledge, threatened that seeks to invalidate or challenge the enforceability of any of the Existing Aurinia Patents in the Otsuka Territory; no Third Party has challenged in writing, or, to the Knowledge of Aurinia, has threatened to challenge, Aurinia's right to use and license the Aurinia Know-How in the Otsuka Territory; and there are no judgments or settlements against Aurinia or any of its Affiliates, or any pending or, to Aurinia's Knowledge, threatened claims or litigation against Aurinia or any of its Affiliates relating to the transactions contemplated by this Agreement;

**(h)** no Existing Aurinia Patent is the subject of any interference, opposition, cancellation or other protest proceeding;

**(i)** other than routine patent prosecutions, Aurinia is not the subject of any Patent proceeding in respect of any Existing Aurinia Patent, and it is not aware of any pending or threatened action, suit, proceeding, or claim by a Third Party challenging Aurinia's ownership rights in, or the validity or scope of, any Existing Aurinia Patent;

(j) to Aurinia's Knowledge, no Third Party is infringing or misappropriating or has infringed or misappropriated the Aurinia Technology in the Otsuka Territory;

(k) there are no claims or litigation pending or, to the Knowledge of Aurinia, threatened alleging, and Aurinia otherwise has no Knowledge that the Development, Manufacture, or Commercialization of the Compound and Products in the manner contemplated herein as of the Effective Date, infringes, misappropriates or violates or would infringe, misappropriate or violate any Patent, Know-How or other intellectual property right of any Third Party in the Otsuka Territory;

(l) there are no investigations, inquiries, actions, or other proceedings of which Aurinia has notice, or, to Aurinia's Knowledge, threatened by any Regulatory Authority or other Governmental Authority in the Otsuka Territory with respect to the Compound or any Product arising from any fault by Aurinia or its Affiliate or a Third Party acting on behalf of Aurinia or its Affiliate in the discovery or Development of the Compound, and Aurinia has not received written notice threatening any such investigation, inquiry, action, or other proceeding;

(m) Aurinia has provided Otsuka with complete and accurate copies of all INDs and other Regulatory Filings held by Aurinia for the Product in the Otsuka Territory and all Regulatory Documentation filed by or on behalf of Aurinia with respect to the Product in the Otsuka Territory;

(n) Aurinia has not received any written notice from any Regulatory Authority or other Governmental Authority commencing or threatening withdrawal of any active IND or other Regulatory Filing held by Aurinia with respect to the Product;

(o) there are no licensees or sublicensees of Aurinia to which a license or a sublicense under the Aurinia Technology has been granted by Aurinia and is in effect as of the Effective Date for the Development or Commercialization of Product in the Field in the Territory;

(p) to Aurinia's Knowledge, Aurinia and its Third Party Representatives acting on its behalf have conducted all Development and Manufacturing of the Compound and Product prior to the Effective Date in compliance in all material respects with all Applicable Laws, including cGLP, cGCP and cGMP, as applicable; and

(q) to Aurinia's Knowledge, Aurinia has not withheld from Otsuka: (i) any study reports from past or ongoing Non-Clinical Studies and Clinical Trials referenced in the NDA; or (ii) any Regulatory Documentation, including briefing documents and meeting minutes, made prior to the filing of the NDA or any written communications with the FDA after the filing of the NDA; that are necessary or material for the evaluation of the safety or efficacy of the Product.

#### **11.4 Otsuka Representations and Warranties**

Otsuka represents and warrants to Aurinia that, as of the Effective Date to Otsuka's Knowledge, Otsuka owns or Controls no Know-How or Patents that would be infringed or misappropriated by the making, using, offering to sell, selling or importing of the Product worldwide or any Aurinia Domain Product worldwide.

## 11.5 Disclaimer

EXCEPT AS EXPRESSLY SET FORTH HEREIN, THE INTELLECTUAL PROPERTY RIGHTS PROVIDED BY AURINIA ARE PROVIDED “AS IS” AND WITHOUT WARRANTY. EXCEPT AS EXPRESSLY SET FORTH HEREIN, EACH OF THE PARTIES EXPRESSLY DISCLAIMS ANY AND ALL WARRANTIES OF ANY KIND, EXPRESS OR IMPLIED, INCLUDING THE WARRANTIES OF DESIGN, MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, VALIDITY, OR ENFORCEABILITY OF THEIR RESPECTIVE INTELLECTUAL PROPERTY RIGHTS, AND NONINFRINGEMENT OF THE INTELLECTUAL PROPERTY RIGHTS OF THIRD PARTIES, ARISING FROM A COURSE OF DEALING, USAGE, OR TRADE PRACTICES, IN ALL CASES WITH RESPECT THERETO. EACH PARTY HEREBY DISCLAIMS ANY REPRESENTATION OR WARRANTY THAT THE DEVELOPMENT, MANUFACTURE OR COMMERCIALIZATION OF ANY PRODUCT PURSUANT TO THIS AGREEMENT SHALL BE SUCCESSFUL OR THAT ANY PARTICULAR SALES LEVEL WITH RESPECT TO ANY LICENSED PRODUCT SHALL BE ACHIEVED.

## 12. INDEMNIFICATION

### 12.1 Indemnification by Aurinia

Aurinia shall defend, indemnify and hold harmless Otsuka and its Representatives (each, an “**Otsuka Indemnitee**”) from and against any and all Losses to which any Otsuka Indemnitee may become subject as a result of any Third Party Claims to the extent such Third Party Claims arise out of: (a) the Development, Manufacture, use, handling, storage, Commercialization, Medical Affairs or other disposition of the Compound or the Product by or on behalf of Aurinia or its Affiliates or its or their respective licensees or Sublicensees (other than Otsuka and its Affiliates, or its or their respective Sublicensees), including before and after the Effective Date, (b) the negligence or willful misconduct of any Aurinia Indemnitee, or (c) the breach by Aurinia of any provisions of this Agreement; except, in each case (a)-(c), to the extent such Third Party Claims arise out of any activities for which Otsuka is obligated to indemnify the Aurinia Indemnitee under Section 12.2.

### 12.2 Indemnification by Otsuka

Otsuka shall defend, indemnify and hold harmless Aurinia and its Representatives (each, an “**Aurinia Indemnitee**”) from and against any and all Losses to which any Aurinia Indemnitee may become subject as a result of any Third Party Claims to the extent such Third Party Claims arise out of: (a) the Development, manufacture, use, handling, storage, Commercialization, Medical Affairs or other disposition of the Product by or on behalf of Otsuka or its Affiliates or its or their respective Sublicensees, (b) the negligence or willful misconduct of any Otsuka Indemnitee, or (c) the breach by Otsuka of any provisions of this Agreement; except, in each case (a)-(c), to the extent such Third Party Claims arise out of any activities for which Aurinia is obligated to indemnify the Otsuka Indemnitee under Section 12.1.

### 12.3 Procedure

In the event of a Third Party Claim against any Otsuka Indemnitee or Aurinia Indemnitee (individually, an “**Indemnitee**”), the Party seeking indemnification under this Article 12 (the

“**Indemnified Party**”) shall promptly notify the other Party (the “**Indemnifying Party**”) in writing of such Third Party Claim; provided that any failure or delay in providing such notice will not relieve the Indemnifying Party of its indemnification obligation, except to the extent it is actually prejudiced by such failure or delay. The Indemnitee will reasonably cooperate with the Indemnifying Party and may, at its option, be represented in such action or proceeding at its cost and expense. The Indemnifying Party will have the right to assume and control the defense of the Third Party Claim at its own expense with counsel selected by the Indemnifying Party and reasonably acceptable to the Indemnified Party. If the Indemnifying Party does not assume the defense of the Third Party Claim pursuant to this Section 12.3, then the Indemnified Party may defend the Third Party Claim but will have no obligation to do so. Each Party will promptly furnish to the other Party copies of all papers and official documents received in respect of any Third Party Claims. The Indemnified Party will not settle or compromise the Third Party Claim without the prior written consent of the Indemnifying Party, which consent will not be unreasonably withheld, and the Indemnifying Party will not settle or compromise the Third Party Claim in any manner which would have an adverse effect on the Indemnified Party’s interests (including any rights under this Agreement or the scope, validity, or enforceability of any Patents, Confidential Information, or other rights licensed by either Party to the other Party hereunder), without the prior written consent of the Indemnified Party.

#### **12.4 Insurance**

Each Party, at its own expense, shall maintain commercial general liability insurance and product liability and other appropriate insurance, in amounts consistent with sound business practice and reasonable in light of its obligations under this Agreement. Each Party shall maintain such insurance for the period commencing promptly after the Effective Date until three (3) years after the Term of this Agreement. Each Party shall provide a certificate of insurance evidencing such coverage to the other Party upon request. It is understood that such insurance shall not be construed to create any limit of either Party’s obligations or liabilities with respect to its indemnification obligations under this Agreement.

#### **12.5 Limitation of Liability**

NEITHER PARTY SHALL BE LIABLE TO THE OTHER PARTY FOR ANY SPECIAL, INCIDENTAL, CONSEQUENTIAL OR PUNITIVE DAMAGES, INCLUDING LOST PROFITS, ARISING OUT OF THIS AGREEMENT OR THE EXERCISE OF RIGHTS OR PERFORMANCE OR FAILURE TO PERFORM HEREUNDER, REGARDLESS OF ANY NOTICE OF SUCH DAMAGES, EXCEPT AS A RESULT OF A PARTY’S WILLFUL MISCONDUCT OR INTENTIONAL BREACH OF THIS AGREEMENT, INCLUDING AN INTENTIONAL BREACH OF SECTION 2.9 (EXCLUSIVITY), OR A PARTY’S BREACH OF ARTICLE 13 (CONFIDENTIALITY) OR THE EXCLUSIVITY TERMS OR SCOPE OF THE LICENSES GRANTED IN ARTICLE 2. NOTHING IN THIS SECTION 12.5 IS INTENDED TO LIMIT OR RESTRICT THE INDEMNIFICATION RIGHTS OR OBLIGATIONS OF EITHER PARTY.

## 13. CONFIDENTIALITY

### 13.1 Confidential Information

Except to the extent expressly authorized by this Agreement or otherwise agreed in writing by the Parties, the Parties agree that, during the Term and for seven (7) years thereafter, the receiving Party shall keep confidential and shall not publish or otherwise disclose and shall not use for any purpose other than as expressly provided for in this Agreement any Confidential Information of the other Party, and both Parties shall keep confidential and, subject to this Article 13, shall not publish or otherwise disclose the terms of this Agreement. Each Party may use the other Party's Confidential Information only to the extent required to accomplish the purposes of this Agreement, including exercising its rights or performing its obligations under this Agreement. Each Party will use at least the same standard of care as it uses to protect proprietary or confidential information of its own (but no less than reasonable care) to ensure that its Representatives do not disclose or make any unauthorized use of the Confidential Information of the other Party. Each Party will promptly notify the other upon discovery of any unauthorized use or disclosure of the Confidential Information of the other Party.

### 13.2 Exceptions

The obligations of confidentiality and restriction on use under Section 13.1 will not apply to any portion of Confidential Information of the disclosing Party that the receiving Party can prove by competent written evidence: (a) is now, or hereafter becomes, through no act or failure to act on the part of the receiving Party, generally known or available to the public; (b) is known by the receiving Party at the time of receiving such information, other than by previous disclosure of the disclosing Party, or its Representatives; (c) is lawfully furnished to the receiving Party without restriction by a Third Party who has no obligation of confidentiality or limitations on use with respect thereto, as a matter of right; or (d) is independently discovered or developed by the receiving Party without the use of or reference to Confidential Information belonging to the disclosing Party.

### 13.3 Authorized Disclosure

Each Party may disclose Confidential Information belonging to the other Party as expressly permitted by this Agreement or if and to the extent such disclosure is reasonably necessary in the following instances:

- (a) Prosecuting Patents as permitted by this Agreement;
- (b) Regulatory Filings for Products that such Party has a license or right to Develop and Commercialize hereunder;
- (c) prosecuting or defending litigation as permitted by this Agreement;
- (d) complying with applicable court orders or Applicable Laws; and
- (e) disclosure to its Representatives, and to its actual and prospective licensees and Sublicensees and contract manufacturing organizations, in each case on a need-to-know basis in connection with the Development, Manufacture and Commercialization of the



Compound and Products and performance of Medical Affairs and other rights and obligations in accordance with the terms of this Agreement, in each case under written obligations of confidentiality and non-use at least as stringent as those herein and for a duration that is reasonable in the circumstances; and

(f) disclosure to potential and actual investors, acquirors, licensees, Sublicensees and other financial or collaboration partners solely for the purpose of evaluating or carrying out an actual or potential investment, acquisition or collaboration, in each case under written obligations of confidentiality and non-use at least as stringent as those herein and for a duration that is reasonable in the circumstances, provided that the disclosing Party redacts the financial terms and other provisions of this Agreement that are not reasonably required to be disclosed in connection with such potential investment, acquisition or collaboration.

Notwithstanding the foregoing, in the event a Party is required to make a disclosure of the other Party's Confidential Information pursuant to Section 13.3(c) or Section 13.3(d), it will, except where impracticable, give reasonable advance notice to the other Party of such disclosure and use efforts to secure confidential treatment of such Confidential Information at least as diligent as such Party would use to protect its own confidential information, but in no event less than reasonable efforts. In any event, the Parties agree to take all reasonable action to avoid to the greatest extent possible disclosure of Confidential Information hereunder. Any information disclosed pursuant to Section 13.3(c) or Section 13.3(d) shall remain Confidential Information and subject to the restrictions set forth in this Agreement, including the foregoing provisions of this Article 13.

#### **13.4 Publications**

Aurinia shall prepare, and present to the Local JCCs for joint review and discussion in accordance with Section 3.4, a global publication strategy pursuant to which the Parties may publish Data or other key results achieved in connection with Development of the Compound and Products, with the goal of protecting the Parties' ability to obtain Patents with respect to such activities, as applicable, and to position the Products for Regulatory Approval and successful Commercialization in the Parties' respective Territories. Aurinia may update the global publication strategy from time to time and will submit updates and amendments to the global publication strategy to the Local JCCs for joint review and discussion in accordance with Section 3.4. The Parties may publish such Data and other key results consistent with such global publication strategy in accordance with the terms of this Section 13.4. If either Party or its Representatives wishes to publish or present to any Third Party research results, Data, or other clinical information or key results, in each case related to the Compound or the Products, then such Party will deliver to the other Party a copy of the proposed written publication or an outline of an oral presentation as soon as practicable prior to submission for publication or presentation. The reviewing Party will have the right to (i) propose modifications to the publication or presentation for Patent reasons, trade secret reasons, confidentiality reasons, or business reasons, including reasons relating to the pricing or reimbursement of a Product, and the publishing Party shall remove all Confidential Information of the reviewing Party if requested by the reviewing Party, or (ii) request a reasonable delay in publication or presentation in order to protect patentable information. If the reviewing Party requests a delay to protect patentable information, then the publishing Party will delay submission or presentation for a period not to exceed ninety (90) days to enable Patent applications protecting each Party's rights in such information to be

filed in accordance with the terms of this Agreement. If the reviewing Party reasonably requests modifications to the publication or presentation to prevent disclosure of trade secret or proprietary business information, then the publishing Party will edit such publication to prevent the disclosure of such information prior to submission of the publication or presentation. For as long as the JCC remains in place, the JCC shall be responsible for overseeing and facilitating the Parties' communications and activities with respect to publications and presentations under this Section 13.4. Notwithstanding the foregoing, except as required by Applicable Law or a Securities Authority, Otsuka shall not publish, consent to the publication, or disseminate any publication regarding the Development of the Compound and Products, including publication of data and key results, without the prior written consent of Aurinia, which consent shall not be unreasonably withheld.

### **13.5 Publicity; Public Disclosures**

It is understood that each Party may desire or be required to issue press releases relating to this Agreement or activities hereunder. The Parties agree to consult with each other reasonably and in good faith with respect to the text and timing of such press releases and to obtain the consent of the other Party prior to the issuance thereof, provided that such other Party may not unreasonably withhold, condition or delay such consent, and that either Party may issue such press releases or make such disclosures (including the filing of this Agreement) to the United States Securities and Exchange Commission or similar regulatory agency in any country other than the U.S. or of any stock exchange or listing entity ("**Securities Authority**") as it determines, based on advice of counsel, to be reasonably necessary to comply with Applicable Laws, including laws or regulations of a Securities Authority, or for appropriate market disclosure. Each Party shall provide the other Party with advance notice of legally required disclosures to the extent practicable. The Parties will consult with each other on the provisions of this Agreement to be redacted in any filings made by a Party with a Securities Authority or as otherwise required by Applicable Laws; provided that each Party shall have the right to make any such filing as it reasonably determines necessary under Applicable Laws. In addition, following the initial press releases announcing this Agreement, either Party shall be free to disclose, without the other Party's prior written consent, the existence of this Agreement, the identity of the other Party and those terms of this Agreement which have already been publicly disclosed in accordance herewith.

### **13.6 Prior Confidentiality Agreement**

As of the Effective Date, the terms of this Article 13 shall supersede the Confidentiality Agreement and any other prior non-disclosure, secrecy or confidentiality agreement between the Parties (or their Affiliates) relating to the subject matter of this Agreement. Any information disclosed pursuant to the Confidentiality Agreement or any other such prior agreement shall be deemed Confidential Information for purposes of this Agreement.

### **13.7 Equitable Relief**

Given the nature of the Confidential Information and the competitive damage that a Party would suffer upon unauthorized disclosure, use or transfer of its Confidential Information to any Third Party, the Parties agree that monetary damages may not be a sufficient remedy for any breach of this Article 13. Therefore, in addition to all other remedies, a Party shall be entitled to seek

specific performance and injunctive and other equitable relief as a remedy for any breach or threatened breach of this Article 13.

### 13.8 Voclosporin Manufacturing Trade Secrets

[Provisions relating to treatment of Voclosporin Manufacturing Trade Secrets redacted.]

## 14. TERM AND TERMINATION

### 14.1 Term

This Agreement shall commence on the Effective Date and, unless terminated earlier as provided in this Article 14, shall continue on a country-by-country basis in the Otsuka Territory until Otsuka, its Affiliates and Sublicensees are no longer Commercializing any Product in such country (the “Term”).

### 14.2 Termination for Material Breach

(a) If either Party (the “**Non-Breaching Party**”) believes that the other Party (the “**Breaching Party**”) is in material breach of any of its obligations under this Agreement, then the Non-Breaching Party may deliver written notice of such material breach to the Breaching Party specifying the nature of the breach (a “**Default Notice**”). The Breaching Party shall have ninety (90) days (or thirty (30) days in the event of a payment breach) from the receipt of the Default Notice to cure such breach or to dispute the allegation of breach; provided that if any breach other than a payment breach is not reasonably curable within such ninety (90) day period and if the Breaching Party is making a bona fide effort to cure such breach, then such termination shall be delayed for a time period to be agreed by both Parties, not to exceed an additional ninety (90) days, in order to permit the Breaching Party a reasonable period of time to cure such breach. If the Breaching Party fails to cure such breach within the applicable cure period, then the Non-Breaching Party may terminate this Agreement in its entirety by giving the Breaching Party written notice of termination, which termination shall be effective immediately upon the Breaching Party’s receipt of such notice of termination.

(b) If the Breaching Party disputes in good faith the existence or materiality of a breach specified in a Default Notice [exception redacted] or disputes any allegation that the Breaching Party failed to cure or remedy such breach [exception redacted], and the Breaching Party commences (by filing a request for arbitration and paying the required filing fee) and pursues arbitration in good faith in accordance with Article 15 during the applicable cure period above,, then the Non-Breaching Party shall not have the right to terminate this Agreement under this Section 14.2 unless and until an arbitral panel, in accordance with Article 15, has determined that the Breaching Party has materially breached this Agreement. Upon a determination by an arbitral panel that the Breaching Party is in material breach of the Agreement, the Non-Breaching Party may terminate this Agreement by giving the Breaching Party written notice of termination, which termination shall be effective immediately upon the Breaching Party’s receipt of such notice of termination. For clarity, except as otherwise set out herein, during the pendency of such dispute, the applicable cure period will be tolled, all the terms of this Agreement will remain in effect, and the Parties will continue to perform all of their respective obligations hereunder.

### 14.3 Termination for Bankruptcy

. Each Party shall have the right to terminate this Agreement in its entirety immediately upon written notice to the other Party if such other Party makes a general assignment for the benefit of creditors, files an insolvency petition in bankruptcy, petitions for or acquiesces in the appointment of any receiver, trustee or similar officer to liquidate or conserve its business or any substantial part of its assets, commences under the laws of any jurisdiction any proceeding involving its insolvency, bankruptcy, reorganization, adjustment of debt, dissolution, liquidation or any other similar proceeding for the release of financially distressed debtors or becomes a party to any proceeding or action of the type described above and such proceeding is not dismissed within sixty (60) days after the commencement thereof. The Parties acknowledge and agree that a Party may, from time-to-time, make changes in its corporate structure, including *inter alia* changes in the shareholdings of Affiliates, and such changes will not constitute a case of bankruptcy under this [Section 14.3](#).

### 14.4 Termination by Otsuka

**(a) For Convenience.** Otsuka shall have the right to terminate this Agreement in its entirety or on a country-by-country basis at any time for any or no reason upon six (6) months' prior written notice to Aurinia.

**(b) For Safety.** Otsuka shall have the right to terminate this Agreement in its entirety immediately upon written notice to Aurinia if: (i) Otsuka reasonably determines, based upon additional information that becomes available or an analysis of the existing information at any time (including based upon preclinical safety data, such as data from animal toxicology studies, or the observation of serious adverse effects in humans after a Product has been administered to humans, such as during a Clinical Trial or after the First Commercial Sale), that it would be incompatible with the welfare of patients to continue to Develop or Commercialize such Product; (ii) substantially all ongoing Clinical Trials of a Product are ordered or required to be terminated by one or more Regulatory Authorities in the Otsuka Territory; or (iii) any Regulatory Approval for a Product in the Aurinia Territory or the Otsuka Territory is withdrawn.

**(c) Due to SmPC Limitations.** Otsuka shall have the right to terminate this Agreement with respect to Europe upon written notice to Aurinia at any time within **[time period redacted]** of the date of the first Regulatory Approval by EMA of the first Product for the Initial Indication, if any section of the First Approved SmPC includes a 52-Week Limitation or an Induction Limitation, or both. Solely for the purposes of determining the effects of termination under [Section 14.6](#), the consequences of termination in the event of termination pursuant to this [Section 14.4\(c\)](#) shall be as if the Agreement were terminated by Otsuka pursuant to [Section 14.4\(a\)](#).

### 14.5 Termination by Aurinia

**(a) Patent Challenge.** Aurinia shall have the right to terminate this Agreement in its entirety upon written notice to Otsuka, if Otsuka or any of its Affiliates or Sublicensees directly, or indirectly through any Third Party, commences any interference or opposition proceeding with respect to, challenges the validity or enforceability of, or opposes any extension of or the grant of a supplementary protection certificate with respect to, any Aurinia

Patent or a Joint Patent (“**Patent Challenge**”); provided that Aurinia shall not have the right to terminate this Agreement if (i) such Patent Challenge is brought by a Sublicensee and, within sixty (60) days after Otsuka’s receipt of Aurinia’s written notice of termination, the Patent Challenge is withdrawn or dismissed, or Otsuka terminates its sublicense agreement with such Sublicensee, or Otsuka has given notice of termination to such Sublicensee and enforces such termination, or (ii) such Patent Challenge is brought by an Affiliate of Otsuka that is not a subsidiary of Otsuka and, within sixty (60) days after Otsuka’s receipt of Aurinia’s written notice of termination, the Patent Challenge is withdrawn or dismissed.

**(b) Keeping Whole.** If Otsuka terminates this Agreement pursuant to Section 14.4(a) (for convenience) or if Aurinia terminates this Agreement pursuant to Section 14.5(c) on a country-by-country basis in respect of:

**(i)** Russia, then Aurinia may terminate this Agreement for Belarus and Ukraine;

**(ii)** at least three of the Major European Countries, then Aurinia may terminate this Agreement for the rest of such countries and any remaining countries in Territory-A;

**(iii)** an aggregate of ten or more countries in Territory-A, then Aurinia may terminate this Agreement for the rest of Territory-A; provided that this subclause (iii) shall not apply in the case of termination of such countries by Aurinia pursuant to Section 14.5(c); or

**(iv)** Territory-A, (or if Aurinia terminates this Agreement for Territory-A pursuant to this Section 14.5(b)), then Aurinia may terminate this Agreement for Norway, Switzerland and United Kingdom.

**(c) Failure to Develop and Commercialize in Certain Countries.** At any time more than [time period redacted] after the first Regulatory Approval from EMA for the Product for the Initial Indication in Territory-A, on a country-by-country basis in respect of any country(ies) in the Otsuka Territory other than Japan and the Major European Countries, if there is no Regulatory Approval in such country or country(ies) and Otsuka is not making material efforts to Develop and Commercialize the Product in such country(ies), other than due to an event for which Otsuka claims the benefit of Section 16.11, Force Majeure, then Aurinia shall have the right to deliver a notice to Otsuka with the effect of a Default Notice pursuant to Section 14.2, and if Otsuka does not make Commercially Reasonable Efforts to Develop and Commercialize the Product in such country(ies) within the period for same pursuant to Section 14.2, Aurinia may terminate this Agreement with respect to such country(ies), all as if terminated for Otsuka’s material breach under Section 14.2.

#### **14.6 Effects of Termination**

Upon expiration or earlier termination of this Agreement, the following will apply:

**(a) General.** The Parties acknowledge and agree that, under every scenario for early termination of this Agreement or expiry of the Term, the Parties intend to ensure that the Product is available to patients in the Otsuka Territory at all times and that patients who were being treated with such Product(s) prior to expiry or termination or who desire access to such

Product(s) can continue to have access to such Product(s) after expiry or termination and that the Parties shall cooperate to return to Aurinia the Product and all rights in the Product and the related program so that Aurinia may continue the Development, Manufacture and Commercialization of the Product in the Otsuka Territory quickly and with as little disruption as is reasonably possible. In furtherance thereof, the Parties have agreed on the consequences of termination set out in this Section 14.6.

**(b) Partial Early Termination.** If this Agreement is terminated only with respect to a particular country, then the terms of this Section 14.6 shall apply only to the terminated country (the “**Terminated Country**”) and such Terminated Country shall be included in the Aurinia Territory.

**(c) Licenses to Otsuka.** All licenses granted by Aurinia to Otsuka hereunder will automatically terminate, including all sublicenses granted by Otsuka to any Sublicensee, subject to Section 14.6(f), except to the extent necessary or reasonably useful for Otsuka to perform Transition Activities pursuant to Section 14.6(j) or to sell Products post-termination pursuant to Section 14.6(j).

**(d) Licenses to Aurinia.**

**(i)** The license grant to Aurinia under Section 2.2(a)(i) shall remain perpetual, irrevocable and royalty-free, and the license grant to Aurinia under Section 2.2(a)(ii) will automatically terminate, including all sublicenses granted by Aurinia to any Sublicensee.

**(ii)** If Aurinia terminates this Agreement in its entirety pursuant to Section 14.2 (where Otsuka is the Breaching Party), Section 14.3 (where Otsuka is the Party subject to the bankruptcy or other proceedings as described therein), or Section 14.5(a) (for Patent Challenge), or if Otsuka terminates this Agreement in its entirety or on a country-by-country basis pursuant to Section 14.4 (for convenience or safety reasons), or if Aurinia terminates this Agreement on a country-by-country basis pursuant to Section 14.5(b) or 14.5(c), and, if Aurinia exercises its option to expand the license under Section 2.2(a)(i) to include rights to Products in the Otsuka Territory pursuant to Section 14.6(d)(iii), the license grant to Aurinia under Section 2.2(a)(i) shall become worldwide (if this Agreement is terminated in its entirety) or shall be expanded to include the Terminated Country(ies) (if this Agreement is terminated on a country-by-country basis).

**(iii)** At Aurinia’s option, which Aurinia shall exercise by giving written notice to Otsuka within thirty (30) days after notice of termination, the license under Section 2.2(a)(i) shall be expanded to include the rights to Products in the Otsuka Territory, effective as of the effective date of termination.

**(iv)** If Otsuka terminates this Agreement in its entirety pursuant to Section 14.2 (where Aurinia is the Breaching Party) or Section 14.3 (where Aurinia is the Party subject to the bankruptcy or other proceedings as described therein) and if Aurinia exercises its option to expand the license under Section 2.2(a)(i) to include rights to Products in the Otsuka Territory pursuant to Section 14.6(d)(iii), then Aurinia shall pay royalties of [percentage redacted] on Net Sales of the Products in the Otsuka Territory until the last day of the month in which the total royalties paid by Aurinia to Otsuka pursuant to this Section 14.6(d)(iv) equal

**[multiplier redacted]** the total internal and out-of-pocket costs incurred by or on behalf of Otsuka in connection with the Development of Products prior to the effective date of termination (with the definition of Net Sales in Section 1.110 and the terms of Article 9 applying *mutatis mutandis*).

(v) If Otsuka terminates this Agreement in its entirety pursuant to Section 14.2 (where Aurinia is the Breaching Party) or Section 14.3 (where Aurinia is the Party subject to the bankruptcy or other proceedings as described therein) and if Aurinia does not exercise its option to expand the license under Section 2.2(a)(i) pursuant to Section 14.6(d)(iii), then Aurinia shall not, itself or with or through an Affiliate or Third Party, Commercialize any Products in the Otsuka Territory.

(e) **Rights of Reference.** The right of reference granted to Otsuka pursuant to Section 5.4 will terminate. The right of reference granted to Aurinia pursuant to Section 5.4 will survive and, if the license grant to Aurinia under Section 2.2(a)(i) is expanded to include the Otsuka Territory or a Terminated Country pursuant to Section 14.6(d)(iii), will extend to the Otsuka Territory or the Terminated Country.

(f) **Sublicenses.** If this Agreement is terminated prior to expiration, at each Sublicensee's written request to Aurinia, Aurinia shall grant to such Sublicensee a direct license, provided that such Sublicensee (i) is not then in default of its sublicense agreement, (ii) agrees in writing to comply with the terms of this Agreement to the extent applicable to the rights originally sublicensed to such Sublicensee by Otsuka, and (iii) agrees to pay directly to Aurinia such Sublicensee's payments under such sublicense agreement. The scope of such direct license shall be no less than the scope of the license granted herein and sublicensed to such Sublicensee, and Aurinia shall have no obligation to perform any task for such Sublicensee beyond the obligations owed to Otsuka hereunder.

(g) **Assignments.** As soon as practicable after the effective date of expiration or termination, or in accordance with timelines set forth in any transition plan for Transition Activities that the Parties agree upon pursuant to Section 14.6(j) (if applicable), unless Aurinia informs Otsuka that Aurinia will not (itself or with or through its Affiliates or any Third Party) continue Development or Commercialization of the Products in the Otsuka Territory (e.g., if this Agreement is terminated for safety reasons pursuant to Section 14.4(b)), Otsuka shall transfer and assign to Aurinia or its designee (i) all Regulatory Filings, Regulatory Approvals, Pricing or Reimbursement Approvals and other Regulatory Documentation (including pharmacovigilance files and documentation), in each case that are Controlled by Otsuka or its Affiliate, (ii) all of Otsuka's rights, title, and interests in and to (to the extent that they are owned by Otsuka or its Affiliates) all Product Marks and all domain names associated with the Product Marks (if any), and (iii) any Clinical Trial agreements (subject to Section (1)), at Aurinia's option, distribution agreements, confidentiality and other agreements (in each case to the extent assignable and not cancelled) to which Otsuka or its Affiliate is a party, in each case, that are necessary or reasonably useful for the Development or Commercialization of the Products. Such transfers and assignments shall be at no cost to Aurinia unless Otsuka terminates this Agreement in its entirety pursuant to Section 14.2 (where Aurinia is the Breaching Party) or Section 14.3 (where Aurinia is the Party subject to the bankruptcy or other proceedings as described therein), in which case Aurinia shall pay Otsuka's reasonable internal costs calculated using the same methodology as Otsuka used to calculate such expenses in its most recently audited financial statements prior to

the expiry or termination date and reimburse Otsuka for its out-of-pocket costs incurred in connection with such transfers and assignments, in each case within thirty (30) days of receipt of an invoice therefor from Otsuka.

**(h) Disclosure.** At the time Otsuka makes the assignments pursuant to Section (g), Otsuka shall disclose to Aurinia, to the extent not previously disclosed, (i) Data and other Otsuka Know-How (to the extent in Otsuka's Control) that are necessary or reasonably useful for the Development or Commercialization of the Products and (ii) all documents that are Controlled by Otsuka and in its possession or that Otsuka is able to obtain using commercially reasonable efforts, and that embody the foregoing or that embody any of the items assigned pursuant to Section (g).

**(i) Certain Post-Termination Activities.** Except with respect to the Transition Activities and other activities of Otsuka contemplated by this Section 14.6 (including Section 14.6(k)), Otsuka shall promptly cease Developing, Packaging, Commercializing and conducting Medical Affairs and Regulatory Activities for the Products in the Terminated Countries. For a period of two years after such termination, Otsuka shall not destroy any documentation pertaining to the Product or Compound without the prior written consent of Aurinia.

**(j) Transition Activities.**

**(i)** The Parties wish to provide a mechanism to ensure that, assuming the Product is available to patients in the Terminated Countries in the Otsuka Territory as of the effective date of expiration or termination, patients who were being treated with Product(s) prior to such expiration or termination or who desire access to Product(s) can continue to have access to such Product(s) while the responsibilities for Product(s) in such Terminated Countries in the Otsuka Territory are transitioned from Otsuka to Aurinia or its designee.

**(ii)** As such, Aurinia may request Otsuka to perform transition activities with respect to Product(s) in such Terminated Countries in the Otsuka Territory that are necessary or reasonably useful to (i) transition Commercialization activities (if any) to Aurinia, including transitioning distribution responsibilities to Aurinia or its designee, to avoid any shortage of Product(s) and minimize disruption to sales in such countries, (ii) provide patients with continued access to Product(s) (if applicable), (iii) enable Aurinia or its designee to assume and execute the responsibilities under all Regulatory Approvals and ongoing Clinical Trials for Product(s), and (iv) ensure long-term continuity of supply of Product(s) in such Terminated Country(ies); (collectively, the "**Transition Activities**").

**(iii)** If, within forty-five (45) days after the effective date of expiration or termination, Aurinia provides a written request to Otsuka to perform Transition Activities with respect to Product(s) and Terminated Country(ies) in the Otsuka Territory, then the Parties will mutually agree on a transition plan for Otsuka to perform such Transition Activities, including transition dates, and, to the extent permitted under Applicable Law, Otsuka or its Affiliate will conduct such Transition Activities in accordance with such plan, but in no event for longer than one year following the effective date of expiration or termination. In addition, the Parties will establish a transition committee consisting of at least each Party's Alliance Managers, and up to two (2) additional representatives from each Party who are from other relevant functional groups



to facilitate a smooth transition, and the Parties will mutually agree on talking points and a communication plan to customers, physicians, Regulatory Authorities, patient advocacy groups, and Clinical Trial investigators, in each case only if applicable at the time of expiration or termination, and Otsuka will make such communications to such applicable entities in accordance with the mutually agreed talking points. As part of the Transition Activities, Otsuka will cooperate with all reasonable requests of Aurinia relating to the transition of activities relating to the Product to Aurinia or its designee and, at Aurinia's request, Otsuka shall provide Aurinia with reasonable assistance with any inquiries and correspondence with Regulatory Authorities regarding the Product.

(iv) Aurinia shall pay Otsuka's internal costs calculated using the same methodology as Otsuka used to calculate such expenses for Product in its most recently audited financial statements prior to the expiry or termination date and shall reimburse Otsuka for its out-of-pocket costs incurred in connection with performance of the Transition Activities within thirty (30) days of receipt of an invoice therefor from Otsuka. Except as set forth in Section 14.6(k) (with respect to Inventory Sell-Off), Aurinia will own all revenue derived from the Products after the effective date of termination and Otsuka will remit to Aurinia all such revenues received by Otsuka in the performance of the Transition Activities no later than the forty-fifth (45<sup>th</sup>) day following the end of the month in which such revenue was received.

(k) **Distribution and Sale of Inventory.** In order to avoid any shortage of Product(s) in the Terminated Country(ies) in the Otsuka Territory, if Aurinia requests that Otsuka perform Transition Activities in accordance with the terms hereof, Aurinia shall continue to Manufacture and supply Otsuka such Product(s) according to the terms and conditions of the applicable Supply Agreement (to the extent Otsuka's then-existing inventory of such Product(s) is insufficient to fulfill sales of Product(s) in such Terminated Country(ies)) and Otsuka or its Affiliates or Sublicensees shall continue to distribute such Product(s) in such country(ies). If Aurinia does not request Otsuka to perform Transition Activities in accordance with the terms hereof, Otsuka shall have the right to sell-off its inventory of Product(s) ("**Inventory Sell-Off**"), all at prices and on terms determined in the ordinary course of business prior to expiry or termination, until the earlier of (i) such time as Aurinia or its designee is able to assume responsibility for distribution of Product(s) in such country(ies) or (ii) the dates on which the Regulatory Approvals for Product(s) in the Terminated Country(ies) in the Otsuka Territory are transferred and assigned to Aurinia or its designee (or such other date as may be permitted under Applicable Law, such as the implementation date proposed by mutual agreement of Aurinia and Otsuka and agreed upon by the EMA for Territory-A) (the earlier of (i) or (ii), the "**Distribution End Date**"). In the event of Inventory Sell-Off (as opposed to distribution as part of the Transition Activities), Otsuka shall retain all revenues from sales of such inventory of Product(s) through the Distribution End Date, provided that Otsuka shall continue to pay royalties (and any applicable commercial milestones) due on such Net Sales pursuant to Section 8.4. As soon as practicable following the Distribution End Date (in the event of Inventory Sell-Off) or as soon as practicable following completion of Transition Activities, if applicable, Otsuka shall, as instructed by Aurinia in writing, either destroy or deliver to Aurinia all of Otsuka's and its Affiliates' remaining inventory of Product(s), and Aurinia shall reimburse Otsuka for such inventory (with a remaining shelf life of 18 months) at a price equal to the supply price paid by Otsuka to acquire such inventory from Aurinia. For clarity, Otsuka shall have no obligation to recover any Product(s) sold to customers, including wholesalers and distributors, prior to the Distribution End Date or prior to completion of the Transition Activities.

**(l) Clinical Trials.** If this Agreement is terminated in whole or in part while any Clinical Trial of the Product sponsored by Otsuka or its Affiliate or Sublicensee is being conducted in the Otsuka Territory, unless Otsuka terminates this Agreement in its entirety pursuant Section 14.4(b) (for safety reasons):

**(i)** Otsuka shall and shall cause its Affiliates and Sublicensees to undertake one of the following, as requested in writing by Aurinia within thirty (30) days after the effective date of termination (or in the case of Otsuka's termination for convenience pursuant to Section 14.4(a), within thirty (30) days after notice of termination): (A) complete such Clinical Trial; (B) wind down such Clinical Trial in accordance with Applicable Law and the requirements of applicable institutional review board(s); or (C) transfer sponsorship and management of such Clinical Trial to Aurinia and continue to conduct such Clinical Trial for up to six (6) months to enable such transfer to be completed without interruption of such Clinical Trial; and

**(ii)** if Otsuka is bearing all or any of the costs of a Clinical Trial not completed at the time of notice of such termination, Otsuka will remain liable for such costs of such Clinical Trial to completion of the Clinical Trial (including, if applicable, completion of such Clinical Trial after transfer of sponsorship to Aurinia) or, if applicable, to completion of wind down of the Clinical Trial; provided that, if Otsuka terminates this Agreement in its entirety pursuant to Section 14.2 (where Aurinia is the Breaching Party) or Section 14.3 (where Aurinia is the Party subject to the bankruptcy or other proceedings as described therein), Aurinia shall bear all costs of all Clinical Trials not completed at the time of notice of such termination until completion of such Clinical Trials (and including, if applicable, all costs in connection with transfer of sponsorship of such Clinical Trials to Aurinia) or, if applicable, to completion of wind down of such Clinical Trials.

#### **14.7 Confidential Information**

Upon expiration or termination of this Agreement in its entirety, except to the extent that a Party obtains or retains the right to use the other Party's Confidential Information (including to perform its obligations or exercise its rights that survive the termination or expiration of this Agreement) and except as set forth in Section 14.6(i), each Party shall promptly return to the other Party, or delete or destroy, all relevant records and materials in such Party's possession or control containing Confidential Information of the other Party; provided that such Party may keep one copy of such materials for archival purposes only subject to continuing confidentiality obligations.

#### **14.8 Survival; Accrued Rights**

The obligations and rights of the Parties under the following provisions of this Agreement shall survive expiration or termination of this Agreement: Sections 2.3 (Retained Rights), 2.4(vii), 2.4(viii), 2.5 (No Implied Licenses; Negative Covenant), 4.5 (Development Records) 10.1(a) and (b) (Ownership of Data and Inventions), 10.2(c) and (d) (Prosecution of Joint Patents), 10.3 (Patent Enforcement) (solely with respect to Joint Patents), 11.5 (Disclaimer), 14.6 (Effects of Termination), 14.7 (Confidential Information), 14.8 (Survival; Accrued Rights), 16.1 (Governing Law), 16.2 (Entire Agreement; Modification), 16.3 (Relationship Between the Parties), 16.4 (Non-Waiver), 16.5 (Assignment), 16.7 (Severability) (solely with respect to other surviving

provisions), 16.9 (No Solicitation), 16.10 (Notices), and 16.12 (Interpretation) (to the extent applicable to other surviving provisions), and Articles 1 (Definitions) (to the extent applicable to other surviving provisions), 9 (Payments, Records, Audits) (to the extent applicable to a payment that accrued prior to expiration or termination), 12 (Indemnification), 13 (Confidentiality), and 15 (Dispute Resolution). In any event, expiration or termination of this Agreement will not relieve the Parties of any liability that accrued hereunder prior to the effective date of such expiration or termination nor preclude either Party from pursuing all rights and remedies it may have hereunder or at law or in equity with respect to any breach of this Agreement, nor prejudice either Party's right to obtain performance of any obligation that accrued hereunder prior to the effective date of such expiration or termination (including the rights to receive reimbursement for costs incurred prior to the effective date of such termination and payments accrued or due prior to the effective date of such termination).

#### **14.9 Rights in Bankruptcy**

All rights and licenses granted under or pursuant to this Agreement by one Party to the other Party are, and will otherwise be deemed to be, for purposes of Section 365(n) of the U.S. Bankruptcy Code or comparable provision of applicable bankruptcy or insolvency laws in countries other than the U.S., licenses of right to "intellectual property" as defined under Section 101 of the U.S. Bankruptcy Code or comparable provision of applicable bankruptcy or insolvency laws. The Parties agree that a Party that is a licensee of such rights under this Agreement will retain and may fully exercise all of its rights and elections under the U.S. Bankruptcy Code or comparable provision of applicable bankruptcy or insolvency laws. The Parties further agree that, in the event of the commencement of a bankruptcy proceeding by or against a Party to this Agreement under the U.S. Bankruptcy Code or comparable provision of applicable bankruptcy or insolvency laws, the other Party will be entitled to a complete duplicate of (or complete access to, as appropriate) any such intellectual property and all embodiments of such intellectual property, and the same, if not already in its possession, will be promptly delivered to it (a) upon any such commencement of a bankruptcy or insolvency proceeding upon its written request therefor, unless the bankrupt Party elects to continue to perform all of its obligations under this Agreement, or (b) if not delivered under clause (a) above, following the rejection of this Agreement by or on behalf of the bankrupt Party upon written request therefor by the other Party.

### **15. DISPUTE RESOLUTION**

#### **15.1 Objective**

The Parties recognize that disputes as to matters arising under or relating to this Agreement or either Party's rights and obligations hereunder may arise from time to time. It is the objective of the Parties to establish procedures to facilitate the resolution of such disputes in an expedient manner by mutual cooperation and without resort to litigation. To accomplish this objective, the Parties agree to follow the procedures set forth in this [Article 15](#) to resolve any such dispute if and when it arises.

## 15.2 Executive Negotiation

The Parties will try to settle any dispute, controversy or claim that arises out of, or relates to, any provision of this Agreement, including any alleged material breach of this Agreement, but excluding any disagreement of the JCC (which is subject to [Section 3.4](#) and, if applicable, [Section 15.3](#)) (“**Disputed Matter**”) by first referring the Disputed Matter to the Executive Officers. Either Party may initiate such informal dispute resolution by sending written notice of the Disputed Matter to the other Party, and, within twenty (20) days after such notice, the Executive Officers of the Parties will meet (in person or by teleconference or videoconference) for attempted resolution by good faith negotiations. If the Executive Officers (or their respective designees) are unable to resolve such dispute within thirty (30) days of their first meeting for such negotiations (or such longer period as such Executive Officers, either Party may seek to have such dispute resolved in accordance with [Section 15.4](#) below.

## 15.3 Expert Determination

If a Committee decision cannot be resolved by the Executive Officers in accordance with [Section 3.4\(b\)](#) and none of [Sections 3.4\(b\)\(i\)](#), [3.4\(b\)\(ii\)](#), [3.4\(b\)\(iii\)](#), and [3.4\(b\)\(iv\)](#) apply to such decision, or if a Party exercises its final decision-making authority or overrules the other Party’s final decision-making authority pursuant to [Section 3.4\(b\)](#) based on a determination that, in such Party’s reasonable judgment, a decision by the other Party is likely to have a material adverse effect as provided in [Section 3.4\(b\)](#), and if the other Party disputes such determination of a likely material adverse effect, the Parties shall resolve such dispute as follows: The Parties shall agree upon a single independent expert, which expert shall have at least fifteen (15) years of relevant expertise and experience in the pharmaceutical industry. If the Parties are unable to agree upon a single expert within ten (10) Business Days, then Aurinia and Otsuka will each select one expert and the Parties’ two selected experts will, within ten (10) Business Days after selection of both Parties’ experts, jointly select a third expert who will be the sole appointed expert. If the Parties’ experts are unable to agree on the sole expert within such second ten (10)-Business Day period, then the International Chamber of Commerce shall appoint such expert in accordance with the Rules. The Parties shall cooperate fully in the expeditious conduct of the expert determination and, if the expert or either Party requests oral testimony, the Parties shall provide the expert with a written report, including supporting documentation, in connection with such Party’s oral testimony. Within thirty (30) days after the appointment of the expert or the conclusion of oral testimony (if applicable), each Party shall submit one proposal to the expert. The expert shall accept only one of the proposals submitted by the Parties (without making any changes to such proposal) and shall render such proposal as the expert’s final decision. The expert’s decision shall be final and binding on the Parties. For clarity, the expert shall not have the authority to render any decision other than selecting one of the proposals submitted by a Party, and the expert shall act as an expert and not as an arbitrator. The Parties shall share equally the costs of the expert determination, regardless of the outcome of the determination.

## 15.4 Dispute Resolution

(a) If the Parties are unable to resolve a Disputed Matter using the process described in [Section 15.2](#) and [Section 15.3](#) does not apply, then a Party seeking further resolution of the Disputed Matter shall submit the Disputed Matter to resolution by final and binding arbitration.

If a Party decides to institute arbitration proceedings, it will give written notice of such decision to the other Party.

**(b)** The seat, or legal place, of arbitration shall be New York, New York. The arbitration shall be administered by the International Chamber of Commerce pursuant to its ICC International Arbitration Rules then in effect as determined in accordance herewith (the "Rules"), except as otherwise provided herein and applying the substantive law specified in Section 16.1. The language of the arbitration shall be English.

**(c)** Except as otherwise set out in this Section 15.3 and in Section 15.5, the arbitration will be conducted by a panel of three (3) arbitrators appointed in accordance with the Rules; provided that each Party will, within thirty (30) days after the institution of the arbitration proceedings, appoint an arbitrator, and such arbitrators will together, within thirty (30) days, select a third (3rd) arbitrator as the chairperson of the arbitration panel. Within 10 (ten) Business Days of initiation of arbitration, the Parties shall reach agreement upon and thereafter follow procedures directed at assuring that the arbitration will be concluded and the award rendered within no more than one year from the date the arbitrators are confirmed. Failing such agreement, the arbitrator(s) will design and the Parties will follow procedures directed at meeting such a time schedule. Each arbitrator must have at least twenty (20) years of business or legal experience in the pharmaceutical industry. If the two (2) initial arbitrators are unable to select a third (3rd) arbitrator within such thirty (30) day period, the third (3rd) arbitrator will be appointed in accordance with the Rules.

**(d)** Notwithstanding Section 15.4(b), if the Disputed Matter involves the dispute of a Default Notice for any default other than a determination of an alleged failure to use Commercially Reasonable Efforts to Develop or Commercialize the Product, the Non-Breaching Party may elect on notice to the Breaching Party to apply the ICC Expedited Procedure Provisions to the Arbitration and, if such election is made, the number of arbitrators shall be one and the period for the rendering of the final award shall be six months from the date of the case management conference.

**(e)** The Parties agree that any dispute concerning the propriety of the commencement of the arbitration or the scope and applicability of the agreement to arbitrate shall be determined by the arbitrators.

**(f)** No panel of arbitrators will have the power to award damages excluded pursuant to Section 12.5.

**(g)** During the pendency of a dispute, the Parties will share equally any administrative costs of the arbitration, including any initial or other deposits and fees of the arbitration and the fees and costs of the arbitrators.

**(h)** The losing Party, as determined by the panel of arbitrators, will pay all of the ICC administrative costs (including the filing fee), and the attorneys' fees, expert or witness fees, and any other fees and costs of the other Party and the arbitrators will be directed to provide for payment or reimbursement of such fees and costs by the losing Party. If the panel of arbitrators determines that there is no losing Party, the Parties will each bear or pay one-half of

the ICC administrative costs and their own attorneys' fees, expert or witness fees, and any other fees and costs, and the arbitrators' award will so provide.

(i) Except as may be required by Applicable Law, neither a Party nor any arbitrator may disclose the existence, content or results of any arbitration hereunder without the prior written consent of both Parties, unless to protect or pursue a legal right.

(j) The arbitral award shall be final and binding on the Parties and the Parties shall carry out the award without delay. Judgment on the award so rendered may be entered in any court of competent jurisdiction.

### **15.5 Injunctive Relief**

Notwithstanding the terms of and procedures set forth in Section 15.4:

(a) any applications, motions or orders to show cause seeking temporary restraining orders, preliminary injunctions or other similar preliminary or temporary legal or equitable relief ("**Injunctive Relief**") concerning a Disputed Matter (including, but not limited to, Disputed Matters arising out of a potential or actual breach of intellectual property rights or the confidentiality and non-use provisions in Article 13) may immediately be brought in the first instance for hearing and resolution in and by a court of competent jurisdiction; and

(b) alternatively, a Party seeking Injunctive Relief concerning a Disputed Matter (including, but not limited to, Disputed Matters arising out of a potential or actual breach of intellectual property rights or the confidentiality and non-use provisions in Article 13, or arising out of any action that the other Party is taking or intends to take which could reasonably be expected to have a material adverse effect on obtaining or maintaining Regulatory Approval of any Product in the first Party's Territory or Commercialization of any Product in the first Party's Territory), then the Party making such allegation may immediately, without invocation or exhaustion of the procedures set forth in Section 15.4, seek Injunctive Relief in accordance with the ICC emergency arbitration procedures then in effect and applying the substantive law specified in Section 16.1.

(c) In either event ((a) or (b)), once the Injunctive Relief proceedings have been conducted and a decision rendered thereon by the court or arbitral forum, the Parties will, if the Disputed Matter is not finally resolved by the Injunctive Relief, proceed to resolve the Disputed Matter in accordance with the terms of Section 15.4.

## **16. GENERAL PROVISIONS**

### **16.1 Governing Law**

This Agreement, and all questions regarding the validity, interpretation, breach or performance of this Agreement, and the respective rights of the Parties hereunder, shall be governed by, and construed and enforced in accordance with, the laws of the State of New York, United States, without reference to its conflicts of law principles.

## **16.2 Entire Agreement; Modification**

This Agreement, including the exhibits, is both a final expression of the Parties' agreement and a complete and exclusive statement with respect to all of its terms. This Agreement supersedes all prior and contemporaneous agreements and communications, whether oral, written or otherwise, concerning any and all matters contained herein. This Agreement may only be modified or supplemented in a writing expressly stated for such purpose and signed by the Parties to this Agreement.

## **16.3 Relationship Between the Parties**

The Parties' relationship, as established by this Agreement, is solely that of independent contractors. This Agreement does not create any partnership, joint venture or similar business relationship between the Parties. Neither Party is a legal representative of the other Party, and neither Party can assume or create any obligation, representation, warranty or guarantee, express or implied, on behalf of the other Party for any purpose whatsoever.

## **16.4 Non-Waiver**

The failure or delay of a Party to insist upon strict performance of any provision of this Agreement or to exercise any right arising out of this Agreement shall neither impair that provision or right nor constitute a waiver of that provision or right, in whole or in part, in that instance or in any other instance. Any waiver by a Party of a particular provision or right shall be in writing, shall be as to a particular matter and, if applicable, for a particular period of time and shall be signed by such Party.

## **16.5 Assignment**

Except as expressly provided hereunder, neither this Agreement nor any rights or obligations hereunder may be assigned or otherwise transferred by either Party without the prior written consent of the other Party; provided that, either Party may assign or otherwise transfer this Agreement and its rights and obligations hereunder without the other Party's consent (a) to an Affiliate or (b) in connection with the transfer or sale of all or substantially all of the business or assets of such Party to which this Agreement relates, whether by merger, consolidation, sale of stock, sale of assets or otherwise. The rights and obligations of the Parties under this Agreement shall be binding upon and inure to the benefit of the successors and permitted assigns of the Parties specified above, and the name of a Party appearing herein will be deemed to include the name of such Party's successors and permitted assigns to the extent necessary to carry out the intent of this Section 16.5. Any assignment not in accordance with this Section 16.5 shall be null and void.

## **16.6 Performance by Affiliates**

Notwithstanding anything to the contrary set forth herein, either Party will have the right to perform any or all of its obligations and exercise any or all of its rights under this Agreement through any Affiliate. The Parties acknowledge and agree that Otsuka may perform obligations (including Regulatory Activities) and exercise rights under this Agreement in Europe through its Affiliate, OPEL. Each Party hereby guarantees the performance by its Affiliates of such Party's

obligations under this Agreement, and will cause its Affiliates to comply with the provisions of this Agreement in connection with such performance.

#### **16.7 Severability**

If, for any reason, any part of this Agreement is adjudicated invalid, unenforceable or illegal by a court of competent jurisdiction, such adjudication shall not, to the extent feasible, affect or impair, in whole or in part, the validity, enforceability, or legality of any remaining portions of this Agreement. All remaining portions shall remain in full force and effect as if the original Agreement had been executed without the invalidated, unenforceable or illegal part.

#### **16.8 Language**

Each Party will provide the Other Party with all documents regarding the Regulatory Filings in the providing Party's Territory in their original format, without translation. If English-translation versions of such documents are available, the providing Party will also provide such translated versions.

#### **16.9 No Solicitation**

During the Term and for **[time period redacted]** thereafter, neither Party nor its Affiliates shall, directly or indirectly, solicit for employment in such Party's or its Affiliates' operations, any employee of the other Party or the other Party's Affiliate who was materially involved in Development, Manufacturing or Commercialization activities related to the Product in the **[time period redacted]** period preceding the date of solicitation. For clarity, the preceding sentence shall not prohibit or restrict either Party or its Affiliates from discussing employment with, making an offer of employment to, or hiring any employee of the other Party or the other Party's Affiliates in connection with general solicitations of employment not specifically targeted at employees of the other Party or the other Party's Affiliates, including responses to general advertisements.

#### **16.10 Notices**

Any notice or other communication required under this Agreement shall be in writing, shall refer specifically to this Agreement, and shall be deemed given only if (a) delivered by hand, (b) sent by internationally recognized overnight delivery service, or (c) sent by email if confirmed by the recipient, or (d) sent by registered or certified mail, addressed to the Parties at their respective addresses specified below or to such other address as a Party may specify in accordance with this Section 16.10. Such notice shall be deemed to have been given as of the date delivered, if delivered by hand or by email, or on the second Business Day (at the place of delivery) after deposit with an internationally recognized overnight delivery service. This Section 16.10 is not intended to govern the day-to-day business communications between the Parties in performing their obligations under this Agreement.

If to Otsuka, notices must be addressed to:

Otsuka Pharmaceuticals, Co. Ltd.  
Shinagawa Grand Central Tower,  
2-16-4 Konan, Minato-ku,



Tokyo, 108-8242 Japan,  
Attention: Director, Pharmaceutical Division

With a copy to (which will not constitute notice for purposes of this Agreement):

Otsuka Pharmaceutical Co., Ltd.  
Shinagawa Grand Central Tower  
2-16-4 Konan, Minato-ku  
Tokyo, 108-8242 Japan  
Attn: Director, Global Business Development  
Email: **[Email address redacted]**

Otsuka Pharmaceutical Co., Ltd.  
Shinagawa Grand Central Tower  
2-16-4 Konan, Minato-ku  
Tokyo, 108-8242 Japan  
Attn: Director, Legal Affairs Department  
Email: **[Email address redacted]**

Otsuka Pharmaceutical Europe Ltd.  
Gallions, Wexham Springs, Framewood Road.  
Wexham SL3 6PJ, United Kingdom  
Attn: General Counsel, Otsuka Pharmaceutical Europe Ltd.  
Email: **[Email address redacted]**

If to Aurinia, notices must be addressed to:

Aurinia Pharmaceuticals Inc.  
#1203-4464 Markham St.  
Victoria, BC  
Canada  
V8Z 7X8  
Attn: Michael Martin, Chief Business Officer  
Email: **[Email address redacted]**

Aurinia Pharmaceuticals Inc.  
#1203-4464 Markham St.  
Victoria, BC  
Canada  
V8Z 7X8  
Attn: Stephen Robertson, Executive Vice President, General Counsel, Corporate Secretary & Chief Compliance Officer  
Email: **[Email address redacted]**

With a copy to (which will not constitute notice for purposes of this Agreement):

Farris LLP  
2500 – 700 West Georgia Street

Vancouver, BC  
Canada  
V7Y 1B3  
Canada  
Attn: James Hatton, QC  
Email: [Email address redacted]

#### **16.11 Force Majeure**

Each Party shall be excused from liability for the failure or delay in performance of any obligation under this Agreement by reason of any event beyond such Party's reasonable control including acts of God, fire, flood, explosion, earthquake, pandemic, disease, or other natural forces, war, civil unrest, acts of terrorism, accident, destruction or other casualty, any lack or failure of transportation facilities, any lack or failure of supply of raw materials, or any other event similar to those enumerated above. Such excuse from liability shall be effective only: to the extent and duration of the event(s) causing the failure or delay in performance and provided that the affected Party has not caused such event(s) to occur; provided that the affected Party shall have given notice to the other Party of failure or delay in performance due to force majeure within ten (10) days after its occurrence; and while the affected Party makes commercially reasonable efforts to avoid or remove such cause of non-performance. In no event shall any Party be required to prevent or settle any labor disturbance or dispute. If such force majeure persists for a period of one year or more, the Party whose performance is not prevented may terminate this Agreement by delivering written notice to the other Party. Solely for the purposes of determining the effects of termination under Section 14.6, the consequences of termination in the event of termination pursuant to this Section 16.11 shall be as if the Agreement were terminated pursuant to Section 14.2 and the affected Party were the Breaching Party thereunder.

#### **16.12 Interpretation**

The headings of clauses contained in this Agreement preceding the text of the sections, subsections and paragraphs hereof are inserted solely for convenience and ease of reference only and shall not constitute any part of this Agreement, or have any effect on its interpretation or construction. All references in this Agreement to the singular shall include the plural where applicable. Unless otherwise specified, references in this Agreement to any Article shall include all Sections, subsections and paragraphs in such Article, references to any Section shall include all subsections and paragraphs in such Section, and references in this Agreement to any subsection shall include all paragraphs in such subsection. The word "including" and similar words means including without limitation. The word "or" means "and/or" unless the context dictates otherwise because the subject of the conjunction are mutually exclusive. The words "herein," "hereof" and "hereunder" and other words of similar import refer to this Agreement as a whole and not to any particular Section or other subdivision. The words "sole discretion" mean discretion that may be exercised arbitrarily and without regard to satisfying a standard of good faith, fair dealing or any other standard provided for in this Agreement or elsewhere. The words "not to be unreasonably withheld" or the like means "not to be unreasonably withheld, conditioned or delayed". The Parties have used defined terms in the grant of rights to Otsuka and elsewhere throughout this Agreement to specify the rights to be exercised by Otsuka with respect to "Product" in the Otsuka Territory (for example, Develop, Commercialize and the like), and when the same terms are used to grant or define rights for Aurinia for the Product in the Aurinia

Territory or Aurinia Domain Product worldwide, such terms should be interpreted broadly to encompass the grant of rights to Aurinia described in the recitals of this Agreement. Unless specifically and expressly provided for to the contrary in this Agreement, a Party who has an obligation or right to take an action under this Agreement shall be solely responsible for any and all expenses associated with such action. All references to days in this Agreement mean calendar days, unless otherwise specified. Ambiguities and uncertainties in this Agreement, if any, shall not be interpreted against either Party, irrespective of which Party may be deemed to have caused the ambiguity or uncertainty to exist. This Agreement has been prepared in the English language and the English language shall control its interpretation. In addition, all notices required or permitted to be given hereunder, and all written, electronic, oral or other communications between the Parties regarding this Agreement shall be in the English language.

### **16.13 Counterparts; Electronic Signatures**

This Agreement may be executed in any number of counterparts, each of which shall be an original, but all of which together shall constitute one instrument. This Agreement may be executed and delivered electronically and upon such delivery such electronic signature will be deemed to have the same effect as if the original signature had been delivered to the other Party.

**{Signature Page Follows}**

**In Witness Whereof**, the Parties hereto have caused this Collaboration and License Agreement to be executed and entered into by their duly authorized representatives as of the Effective Date.

**Aurinia Pharmaceuticals Inc.**

By: (signed) Michael R. Martin

Name: Michael R. Martin

Title: Chief Business Officer

**Otsuka Pharmaceutical Co., Ltd.**

By: (signed) Makoto Inoue

Name: Makoto Inoue

Title: President and Representative Director

**Aurinia Pharmaceuticals Inc.**

By: (signed) Stephen Robertson

Name: Stephen Robertson

Title: Executive Vice President, General Counsel, Corporate Secretary & Chief Compliance Officer

**Otsuka Pharmaceutical Co., Ltd.**

By: (signed) Tetsuya Tachikawa

Name: Tetsuya Tachikawa

Title: Senior Vice President and Global Head of Business Development

[Signature Page to Collaboration and License Agreement]

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**Exhibit 1.37**

**CMO Agreement(s)**

**[List of CMO Agreements redacted]**

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**Exhibit 1.45**

**Chemical Structure of VCS**

[Chemical structure chart of VCS redacted]

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### Exhibit 6.3

#### **Commercialization Plan**

The Commercialization Plan shall be consistent with the other terms of this Agreement and shall set forth:

- the comprehensive Commercialization strategy for the Product, including the market development, marketing, sales, supply and distribution strategy for the Product, expected product profile/value label as driver, resource allocation requirements, specific Commercialization objectives including projected milestones and activities to be performed over each period (including all anticipated Post-Regulatory Approval Clinical Trials)
  - demographics and market dynamics, market strategies, a marketing plan (including advertising, detailing forecasts, samples and sales forecasts)
  - planned key marketing and promotional activities for each Product, positioning of each Product by Otsuka's or its Affiliate's sales representatives, key messaging
  - plans to obtain pricing & reimbursement coverage for the Product, including considerations related to order of launches in various countries (e.g., reference pricing, etc.), and any health economics / outcomes research strategies
  - a timeline for all of the forgoing activities, including the estimated launch date(s)
  - a sales and marketing expense forecast (including at least three years of estimated sales and marketing expenses)
  - sales forecasts for each Product
-

## **Exhibit 6.4**

### **Commercialization Reports**

A report of progress under the Commercialization Plan and, to the extent applicable at the time of the report:

- Sales force sizing, deployment and call patterns and insights
  - Market research – findings from work conducted and/or design of planned studies
  - Any market analysis conducted to understand HCP or patient/consumer populations, segments, etc.
  - Development and/or deployment/use of promotional materials (whether targeted at healthcare professionals or consumers/patients)
  - Key campaigns and initiatives being conducted within the commercial and/or medical affairs team
  - Any key medical meetings/conferences or trade shows
  - Interactions with medical professional organizations and associations on matters such as guidelines and recommendations for treatment of diseases for which the Product is or could be used
  - Any activities being conducted with and/or planned with disease / patient advocacy organizations
  - Any consumer / patient focused campaign (to the extent permitted in the countries in question)
  - Any activities related to establishing patient services & support
  - Interaction with pricing and reimbursement authorities (at any relevant level of government)
  - Any key developments and interactions related to wholesaling and distribution channels
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**Exhibit 10.5(a)**

**Product Marks**

**[List of Product Marks redacted]**

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**Exhibit 11.3(a)**

**Existing Aurinia Patents**

**[List of existing Aurinia Patents redacted]**