

Certain information in this document, marked by [\*\*\*], has been omitted pursuant to Item 601(b)(10)(iv) of Regulation S-K under the Securities Act of 1933, as amended, because it is both (i) not material and (ii) would likely cause competitive harm to the registrant if publicly disclosed.

EXECUTION VERSION

## LICENSE AGREEMENT

This License Agreement (“Agreement”) is entered into as of August 12, 2019 (the “Effective Date”) by and between Novartis International Pharmaceutical AG, a for profit corporation with its principal place of business at Lichtstrasse 35, CH-4056 Basel, Switzerland (“Novartis”), and Pharming Group N.V., a Netherlands for profit corporation with its principal place of business at Darwinweg 24, Leiden 2333 CR, The Netherlands (“Pharming”). Novartis and Pharming are each referred to individually as a “Party” and together as the “Parties.”

### *Background*

Novartis Controls (as defined below) the Licensed Patents and the Licensed Know-How (each as defined below) relating to the Licensed Compound (as defined below). Pharming is in the business of discovering, developing and commercializing pharmaceutical products, and Pharming wishes to obtain, and Novartis wishes to grant, certain rights under the Licensed IP (as defined below) to develop, make, use and sell Licensed Products (as defined below) incorporating the Licensed Compound on the terms and subject to the conditions set forth in this Agreement.

*For good and valuable consideration, the Parties agree as follows:*

### 1. DEFINITIONS AND INTERPRETATION

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

“Accounting Standards” means, with respect to each Party, IFRS (International Financial Reporting Standards), in each case as generally and consistently applied throughout the Party’s organization. Each Party will promptly notify the other Party if such Party changes the Accounting Standards pursuant to which its records relating to this Agreement are maintained; *provided, however*, that each Party may only use internationally recognized accounting principles (*e.g.*, IFRS or US GAAP).

“Affiliate” means, with respect to a Party, any Person that controls, is controlled by, or is under common control with that Party. For the purpose of this definition, “control” will mean, direct or indirect ownership of fifty percent (50%) or more of the shares of stock entitled to vote for the election of directors, in the case of a corporation, or fifty percent (50%) or more of the equity interest in the case of any other type of legal entity, status as a general partner in any partnership, or any other arrangement whereby the entity or Person controls or has the right to control the board of directors or equivalent governing body of a corporation or other entity, or the ability to cause the direction of the management or policies of a corporation or other entity. In the case of entities organized under the laws of certain countries, the maximum percentage ownership

\* Schedules have been omitted pursuant to Item 601(a)(5) of Regulation S-K and will be furnished on a supplemental basis to the Securities and Exchange Commission upon request.

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permitted by law for a foreign investor may be less than fifty percent (50%), and in such case such lower percentage will be substituted in the preceding sentence; *provided*, that such foreign investor has the power to direct the management and policies of such entity.

“Agreement Term” has the meaning set forth in Section 11.1(a).

“Alliance Manager” has the meaning set forth in Section 3.6.

“Ancillary Agreement” has the meaning set forth in Section 5.9(b).

“ANDA” has the meaning set forth in Section 9.4(a).

“APDS” means the genetic immunodeficiency disorder in humans known as Activated Phosphoinositide 3-kinase Delta Syndrome (or Activated PI3K-Delta Syndrome). For clarity, as used in this Agreement “APDS” includes APDS/PASLI (Activated Phosphoinositide 3kinase Delta Syndrome/p110δ-activating Mutation Causing Senescent T Cells, Lymphadenopathy and Immunodeficiency).

“Applicable Law” means any federal, state, local, national, supranational or foreign law (including, common law), statute, ordinance, code, treaty, rule, regulation, judgment, order, directive, writ or decree, or any guideline, guidance document or requirement having the binding effect of law, of or from any arbitrator, court or tribunal of competent jurisdiction, any national securities exchange, automated quotation system or securities listing organization, any government or other governmental authority or agency (including Regulatory Authorities), or legislative body or commission, or any political subdivision thereof, having jurisdiction over or related to the subject item, as may be in effect from time to time, including, as applicable, GCP, GLP, and GMP.

“Auditor” has the meaning set forth in Section 8.7(b).

“Budget Cap” means the amount of [\*\*\*], as may be adjusted from time to time under Section 3.4(e) or otherwise by mutual written agreement of the Parties.

“Calendar Quarter” means the respective periods of three (3) consecutive calendar months ending on March 31, June 30, September 30, and December 31; *provided*, that the first Calendar Quarter of this Agreement shall commence on the Effective Date and end on September 30, 2019, and the last Calendar Quarter of this Agreement shall end on the date of expiration or termination of this Agreement in its entirety.

“Calendar Year” means a period of twelve (12) consecutive calendar months ending on December 31; *provided*, that the first Calendar Year of this Agreement shall commence on the Effective Date and end on December 31, 2019, and the last Calendar Year of this Agreement shall end on the date of expiration or termination of this Agreement in its entirety.

“CDZ173” means Novartis’ proprietary compound identified as CDZ173 as specifically described on Exhibit A.

“CDZ173 Material” means (a) the material identified on Exhibit D-1 and (b) any material identified on Exhibit D-2 remaining in the possession and Control of Novartis following the Completion of the Ongoing Trial and the Extension Study Transition Date.

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

“Clinical Database” has the meaning set forth in Section 5.5(b).

“CMC” means the Chemistry, Manufacturing and Control section(s) of Regulatory Filings.

“CPI” means the Consumer Price Index – Urban Wage Earners and Clerical Workers, U.S. City Average, All Items, 1982-84 = 100, published by the U.S. Department of Labor, Bureau of Labor Statistics (or its successor equivalent index).

“Combination Product” has the meaning set forth in the definition of “Net Sales.”

“Commercialize” means to manufacture, market, promote, distribute, import, export, offer to sell or sell Licensed Compound or Licensed Product, as well as conducting all associated postlaunch regulatory activities, including medical affairs oversight and post-approval studies, and any activities directed to obtaining pricing or reimbursement approvals, and “Commercialization” means commercialization activities relating to Licensed Product.

“Commercially Reasonable Efforts” means, with respect to a Party, the efforts and resources typically used by reasonable, similarly situated biotechnology or pharmaceutical companies to perform the obligation at issue, which efforts will not be less than those efforts made by such Party with respect to other products at a similar stage of development or in a similar stage of product life, with similar developmental risk profiles, of similar market and commercial potential.

“Completion of the Ongoing Trial” means the date on which the CSR is delivered to Pharming.

“Completion of Technology Transfer” means the first date upon which a Third Party contract manufacturer engaged by or on behalf of Pharming or its Affiliate in accordance with Section 6.7 and the Technology Transfer Plan manufactures [\*\*\*] in accordance with Applicable Law. As used in this Agreement, [\*\*\*]. Notwithstanding the foregoing, in the event of any failure of Pharming or its contract manufacturer to use Commercially Reasonable Efforts to complete [\*\*\*] in accordance with Section 6.7 and the Technology Transfer Plan, including the timelines set forth therein, which failure is not cured within [\*\*\*] days following delivery by Novartis to Pharming of written notice thereof, “Completion of Technology Transfer” shall be deemed to have occurred upon expiration of such [\*\*\*] day period without cure.

“Confidential Information” means all Know-How and other confidential or proprietary information and data of a financial, commercial or technical nature, including information comprising or relating to concepts, discoveries, inventions, data, designs or formulae, which the disclosing Party, its Affiliates, or its or their licensors has supplied or otherwise made available to the other Party or its Affiliates, prior to or during the Agreement Term, whether made available orally, in writing or in electronic form, pursuant to this Agreement.

“Control” or “Controlled” means, with respect to any Know-How, Patent Rights, other intellectual property rights, or any proprietary or trade secret information, the legal authority or right (whether by ownership, license or otherwise, other than by a license granted under this Agreement) of a Party or its Affiliates, to grant a license or a sublicense of or under such KnowHow, Patent Rights, or intellectual property rights to another Person, or to otherwise

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disclose such proprietary or trade secret information to another Person, without breaching the terms of any agreement with a Third Party or misappropriating the proprietary or trade secret information of a Third Party.

“Core Patents” means the Patent Rights identified on Exhibit C.

“Cover,” “Covered” or “Covering” means, with respect to a Valid Claim of a Patent Right, that, in the absence of ownership of, or a license under such Patent Right (i) with respect to a Valid Claim that is issued or granted, the practice of the subject matter of such Valid Claim would infringe such Valid Claim of such Patent right, or (ii) in the case of a Valid Claim that is pending, the practice of the subject matter of such pending Valid Claim would infringe such Valid Claim if such Valid Claim were actually issued.

“CSR” means a final clinical study report for the Ongoing Trial (including data and statistical analysis calculated in accordance with the Ongoing Trial Protocol).

“Develop” or “Development” means drug development activities, including, manufacture of the Licensed Compound or Licensed Product, test method development and stability testing, assay development and audit development, toxicology, formulation, quality assurance/quality control development, statistical analysis, pre-clinical studies, clinical studies, packaging development, regulatory affairs, and the preparation, filing, and prosecution of Regulatory Filings as necessary to obtain Regulatory Approval to market or sell a Licensed Product.

“Development Costs” means the fully-allocated Internal Costs and External Costs incurred by Novartis and its Affiliates in performing their obligations under this Agreement with respect to the Ongoing Trial and the Extension Study following the Effective Date, calculated in accordance with the Accounting Standards consistently applied.

“Development Plan” has the meaning set forth in Section 3.7(a).

“Development Report” has the meaning set forth in Section 3.7(b).

“Dispute” has the meaning set forth in Section 15.5(a).

“Effective Date” has the meaning in the preamble (*i.e.*, in the first paragraph of this Agreement).

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

“Encumbrance” means any claim, charge, equitable interest, hypothecation, lien, mortgage, pledge, option, license, assignment, power of sale, retention of title, right of pre-emption, right of first refusal or security interest of any kind.

“Existing CDA” means the Confidentiality Agreement entered into by and between [\*\*\*].

“Existing Clinical Supply” has the meaning set forth in Section 6.2(a).

“Existing INDs” means the INDs for CDZ173 filed with the FDA with IND numbers [\*\*\*].

“Extension Study” means the ongoing extension study of CDZ173 sponsored by Novartis or its Affiliate entitled, “An Open-label, Non-randomized Extension Study to Evaluate the Long Term Safety, Tolerability, Efficacy and Pharmacokinetics of CDZ173 in Patients With

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APDS/PASLI (Activated Phosphoinositide 3-kinase Delta Syndrome/p110d-activating Mutation Causing Senescent T Cells, Lymphadenopathy and Immunodeficiency)” designated by ClinicalTrials.gov Identifier: NCT02859727 and sometimes referred to by Novartis as “CDZ173X2201E01.”

“Extension Study Protocol” means the clinical trial protocol for the Extension Study as of the Effective Date, as may be amended from time to time by mutual agreement of the Parties in accordance with Section 5.2(b) or to the extent required by Applicable Law or any relevant Regulatory Authority.

“Extension Study Transition Date” means a date, not later than [\*\*\*] days following the Regulatory Filing Transfer, mutually agreed by the Parties through the Transition Committee and set forth in the Transition Plan, for the transfer of the Extension Study from Novartis to Pharming either in its entirety or on a country-by-country or trial site-by-trial site basis.

“External Costs” means all amounts paid to Third Parties (or payable to Third Parties and accrued in accordance with the Accounting Standards) by Novartis or its Affiliate and incurred in the performance of activities under this Agreement, excluding (a) capital expenditures, (b) financing costs, and (c) items included in the calculation of the FTE Rate, in each case, except as otherwise agreed in the Transition Plan.

[\*\*\*] means that certain [\*\*\*].

“FD&C Act” means the United States Federal Food, Drug, and Cosmetic Act, as amended.

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

“Field” means all prophylactic, therapeutic and diagnostic uses in humans and animals.

“Final Transfer Date” means the latest of: (a) Completion of Technology Transfer; (b) Completion of the Ongoing Trial; (c) Final Trial Transfer Date; and (d) the completion of the transfer to Pharming or its designee(s) of Licensed Know-How, Transferred Regulatory Filings and Regulatory Documentation under the Transition Plan.

“Final Trial Transfer Date” has the meaning set forth in Section 5.2(b).

“First Commercial Sale” means the first sale of a Licensed Product by Pharming, its Affiliates or a Sublicensee (for the purpose of this definition, “Sublicensees” will not include any distributors or wholesalers) to a Third Party (including a governmental authority) in a country after receipt of Regulatory Approval and Pricing and Reimbursement Approval (to the extent applicable for Commercialization) of such Licensed Product in such country.

“Force Majeure” has the meaning set forth in Section 15.6.

“FTE” means, with respect to Novartis and its Affiliates, the equivalent of a full-time individual’s work, performed by one or more individuals, at [\*\*\*] hours per year for a twelve (12) month period, performing activities pursuant to this Agreement. In the case that any fulltime personnel works partially on work pursuant to this Agreement and partially on other work in a given time period, then the full-time equivalent to be attributed to such individual’s work hereunder will be calculated based upon (a) the percentage of such individual’s total work time in such time period

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that such individual spent working under this Agreement, and (b) the percentage of a twelve (12) month period that such time period equals. Novartis and its Affiliates will track FTEs using their standard practices and normal systems and methodologies.

“FTE Rate” means the rate of [\*\*\*] per FTE per Calendar Year, which rate shall be prorated on a daily basis as necessary, and which rate is subject to annual adjustment in each Calendar Year during the Agreement Term by the percentage increase or decrease in the CPI as of December 31 of each Calendar Year, over the level of the CPI as of December 31 of the prior Calendar Year, with the first such increase to be effective on [\*\*\*]. For the avoidance of doubt, such FTE Rate shall be the fully-burdened rate and is intended to cover the cost of salaries, benefits, infrastructure costs, travel, general laboratory or office supplies, postage, insurance, training, and all other general expenses and overhead items. Notwithstanding the foregoing, for any Calendar Year during the Agreement Term that is less than a full year, the above referenced rate will be proportionately reduced to reflect such portion of such full Calendar Year.

“GCP” means the ethical, scientific, and quality standards required by the FDA or the European Commission for designing, conducting, recording, and reporting trials that involve the participation of human subjects, as set forth in FDA regulations in 21 C.F.R. Parts 11, 50, 54, 56, and 312 and related FDA guidance documents, and by the International Conference on Harmonization E6: Good Clinical Practices Consolidated Guideline, Commission Directive 2005/28/EC on good clinical practice as regards investigational medicinal products for human use, The Rules Governing Medicinal Products in the European Community, Volume 10, Clinical Trials Guidelines, or as otherwise required by Applicable Laws.

“Generic Equivalent” means, with respect to a particular Licensed Product in a country, any other product that:

- (a) has Regulatory Approval for use in such country pursuant to a regulatory process governing approval of generic products where such Regulatory Approval relied on or incorporated clinical data generated by or on behalf of either Party to this Agreement or their respective Affiliates, licensees or Sublicensees, and was obtained by a Person other than Pharming or its Affiliates or a licensee or Sublicensee thereof using an abbreviated, expedited, or other similar process; and
- (b) is not owned or licensed by Pharming or its Affiliates or a licensee or Sublicensee thereof during the Royalty Term.

“Global Safety Database” has the meaning set forth in Section 5.5(e).

“GLP” means good laboratory practice as required by the FDA under 21 C.F.R. part 58 and all applicable FDA rules, regulations, orders and guidances, and the requirements with respect to current good laboratory practices prescribed by the European Union Directive 2004/10/EC of the European Parliament and of the Council of 11 February 2004 on good laboratory practice, the OECD (Organization for Economic Cooperation and Development Council) and the ICH Guidelines, or as otherwise required by Applicable Laws.

“GMP” means good manufacturing practices and regulations as required by the FDA under provisions of 21 C.F.R. parts 210 and 211 and all applicable FDA rules, regulations, orders and guidances, and the requirements with respect to current good manufacturing practices prescribed

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by the European Union under Commission Directive 2003/94/EC laying down the principles and guidelines of good manufacturing practice in respect of medicinal products for human use and investigational medicinal products for human use and the provisions of “The Rules Governing Medicinal Products in the European Community, Volume 4, Good Manufacturing Practices,” or as otherwise required by Applicable Laws.

[\*\*\*] has the meaning set forth in Section 15.5(b).

“IND” means an application submitted to a Regulatory Authority to initiate human clinical trials, including (a) for the United States, an Investigational New Drug application or any successor application or procedure filed with the FDA pursuant to 21 C.F.R. part 312, (b) any equivalent to the application or procedure referenced in clause (a) in any country outside the United States, and (c) all supplements and amendments that may be filed with respect to (a) or (b).

“Indemnification Claim Notice” has the meaning set forth in Section 14.3(b).

“Indemnified Party” has the meaning set forth in Section 14.3(b).

“Indemnifying Party” has the meaning set forth in Section 14.3(b).

“Indication” means any disease, state or condition.

“Infringement Claim” has the meaning set forth in Section 9.7.

“Initial Transition Period” has the meaning set forth in Section 3.1(d).

“Initial Trial Budget” has the meaning set forth in Section 3.8.

“Insolvency Event” means, with respect to a Party,

- (a) such Party ceases to function as a going concern by suspending or discontinuing its business;
- (b) such Party is the subject of voluntary or involuntary bankruptcy proceedings instituted on behalf of or against such Party (except for involuntary bankruptcy proceedings that are dismissed within [\*\*\*] days);
- (c) an administrative receiver, receiver and manager, interim receiver, custodian, sequestrator, or similar officer is appointed for such Party;
- (d) a resolution to wind up such Party is passed at a meeting of the directors or shareholders of such Party;
- (e) a resolution shall have been passed by such Party or its directors to make an application for an administration order or to appoint an administrator for all of such Party’s assets; or
- (f) such Party makes any general assignment for the benefit of all of its creditors.

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“Internal Costs” means, for any period, the product obtained by multiplying (a) the actual total FTEs (or portion thereof) devoted to the performance of an activity under this Agreement during such period, by (b) the applicable FTE Rate.

“Invalidation Claim” has the meaning set forth in Section 9.5.

“Invoice” means an invoice in a form reasonably acceptable to Pharming and to Novartis.

“ICT” has the meaning set forth in Section 3.2(a).

“Joint Know-How” means Know-How that is Joint Arising IP.

“Joint Trial Plan” has the meaning set forth in Section 3.2(d).

“Know-How” means all proprietary or confidential technical information, know-how and data, including inventions (whether patentable or not), discoveries, trade secrets, specifications, instructions, processes, formulae, materials, expertise and other technology for a compound or product or to its or their manufacture, regulatory approval, pricing and reimbursement approval, development, or commercialization, or methods of assaying or testing a compound or product, and including all biological, chemical, pharmacological, biochemical, toxicological, physical and analytical, safety, quality control, manufacturing, preclinical and clinical data, instructions, processes, formulae, expertise and information, regulatory filings and copies thereof.

“Lead Product” means the Licensed Product incorporating or comprising CDZ173 Developed by Novartis and its Affiliates as of the Effective Date.

“Licensed Compound” means: (a) CDZ173; or (b) [\*\*\*] (a) and (b), in free base form or any [\*\*\*] of CDZ173 or such other compound, as applicable.

“Licensed IP” means the Licensed Know-How, the Licensed Patents, and Novartis’ interest in any Joint Arising IP.

“Licensed Know-How” means (a) the Know-How Controlled by Novartis or any of its Affiliates as of the Effective Date and identified on Exhibit B, (b) any other Know-How Controlled by Novartis or any of its Affiliates as of the Effective Date or during the period between the Effective Date and prior to or as of the Final Transfer Date, in each case, to the extent such Know-How is related to the Licensed Compound or Licensed Products and used by Novartis or its Affiliates for the Development or manufacture of the Licensed Compound or Licensed Products, and (c) Novartis’ interest in any Joint Know-How.

“Licensed Patents” means: (a) the Core Patents; (b) any other Patent Rights Controlled by Novartis or any of its Affiliates Covering: (i) the use, offer for sale, sale or import of CDZ173 and (A) used by Novartis or its Affiliates for the Development or manufacture of the Licensed Compound or Licensed Products or (B) otherwise required by Pharming or its Affiliates to Develop or Commercialize the Licensed Product, or (ii) any Licensed Know-How; (c) any of Novartis’ and its Affiliates’ interest in any Patent Rights claiming Joint Know-How, and (d) any Patent Rights claiming priority or granted from any of the foregoing in (a) to (c).

“Licensed Product” means a prophylactic, therapeutic or diagnostic product incorporating or comprising: (a) CDZ173 or (b) any other Licensed Compound.



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“Loss of Market Exclusivity” means, with respect to a Licensed Product [\*\*\*] each of the following have occurred: (a) [\*\*\*] and (b) [\*\*\*].

“MAA” means an application for the authorization to market Licensed Product in any country or group of countries outside the United States, as defined in the Applicable Laws and filed with the Regulatory Authority of a given country or group of countries.

“MAP Agreements” has the meaning set forth in Section 5.8.

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

“Manufacturing Technology” has the meaning set forth in Section 4.1.

“Milestones” means the milestones relating to Licensed Compound and Licensed Product as set forth in Sections 8.2 and 8.3.

“Milestone Payments” means the payments to be made by Pharming to Novartis upon the achievement of the corresponding Milestones as set forth in Sections 8.2 and 8.3.

“NDA” means a New Drug Application, as described in the FDA regulations, 21 C.F.R. § 314.50, submitted to the FDA.

“Net Sales” means the net sales recorded by Pharming or any of its Affiliates or Sublicensees (for the purpose of this Net Sales definition, “Sublicensees” will not include any distributors or wholesalers) for any Licensed Product sold to Third Parties other than Sublicensees, as determined by Pharming’s Accounting Standards, as consistently applied. The deductions by Pharming and its Affiliates under Pharming’s Accounting Standards to calculate the recorded net sales from gross sales may include the following:

- (a) normal trade and cash discounts;
- (b) amounts repaid or credited by reasons of defects, rejections, recalls or returns;
- (c) rebates and chargebacks to customers and Third Parties (including Medicare, Medicaid, managed healthcare and similar types of rebates);
- (d) amounts provided or credited to customers through coupons and other discount programs;
- (e) delayed ship order credits, discounts or payments related to the impact of price increases between purchase and shipping dates or retroactive price reductions;
- (f) fee for service payments to customers for any non-separable services (including compensation for maintaining agreed inventory levels and providing information); and
- (g) other reductions or specifically identifiable amounts deducted for reasons similar to those above in accordance with Pharming’s Accounting Standards.

With respect to the calculation of Net Sales:

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- (i) Net Sales only include the value charged or invoiced on the first arm's length sale to a Third Party, and sales between or among Pharming and its Affiliates, licensees and Sublicensees will be disregarded for purposes of calculating Net Sales;
  - (ii) Net Sales shall exclude (a) the transfer of reasonable and customary quantities of free samples of the Licensed Product to physicians for professional use, other than for subsequent resale, and (b) the transfer of the Licensed Product for use in clinical trials, other than for subsequent resale; and
  - (iii) if a Licensed Product is delivered to the Third Party before being invoiced (or is not invoiced), Net Sales will be calculated at the time all the revenue recognition criteria under Pharming's Accounting Standards are met.

If a Licensed Product is sold in a finished dosage form containing the Licensed Compound in combination with one or more other active ingredients (a "Combination Product"), the Net Sales of the Licensed Product for purposes of determining royalties on Licensed Products shall be determined by multiplying the [\*\*\*] by the fraction, [\*\*\*]. If such [\*\*\*] cannot be determined for both the Licensed Product and the other product(s) in combination, Net Sales for purposes of determining royalty payments shall be agreed by the Parties based on the relative value contributed by each component, such agreement not to be unreasonably withheld or delayed.

"Novartis" has the meaning set forth in the preamble.

"Novartis Collaborators" has the meaning set forth in Section 10.3(b).

"Novartis Indemnitees" has the meaning set forth in Section 14.2.

"Ongoing Trial" means the ongoing clinical trial of CDZ173 sponsored by Novartis or its Affiliate entitled, "An Open-label, Non-randomized, Within-patient Dose-finding Study Followed by a Randomized, Subject, Investigator and Sponsor-blinded Placebo Controlled Study to Assess the Efficacy and Safety of CDZ173 in Patients With APDS/PASLI" designated by ClinicalTrials.gov Identifier: NCT02435173 and sometimes referred to by Novartis as "CDZ173X2201."

"Ongoing Trial Protocol" means the clinical trial protocol for the Ongoing Trial as of the Effective Date, as may be amended from time to time by mutual agreement of the Parties in accordance with Section 5.1(b) or to the extent required by Applicable Law or any relevant Regulatory Authority.

"Patent Rights" means:

- (a) all patent applications, including any provisional patent applications, in any country or under any international treaty, convention, or jurisdiction;
- (b) any patent application claiming priority from or the benefit of such patent application in (a) or provisional application, including all divisionals, continuations, substitutions, continuations-in-part, provisionals, converted provisionals and continued prosecution applications;

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- (c) any patent that has issued or in the future issues from any of the foregoing patent applications, ((a) and (b)), including any utility model, petty patent, design patent, and certificate of invention;
  - (d) any re-examinations, reissues, additions, renewals, extensions, including patent term extensions, restorations, registrations, supplemental protection certificates, of any of the foregoing patents or patent applications ((a), (b), and (c));
  - (e) any similar rights, including so-called pipeline protection, or any importation, revalidation, confirmation or introduction patent or registration patent or patent of additions to any such foregoing patent application or patent; and
  - (f) all rights and priorities afforded under any Applicable Law with respect to any of the foregoing.

“Party” or “Parties” has the meaning set forth in the preamble.

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

“Pharmacovigilance Agreement” has the meaning set forth in Section 5.4.

“Pharming” has the meaning set forth in the preamble.

“Pharming Activities” has the meaning set forth in Section 3.2(d).

“Pharming Indemnitees” has the meaning set forth in Section 14.1.

“Pricing and Reimbursement Approval” means, with respect to a Licensed Product, the authorization or approval of reimbursement in a country or jurisdiction by the relevant Regulatory Authority, government agency, or other body responsible for such activities with respect to such Licensed Product in such country or jurisdiction under Applicable Law.

“Product Marks” has the meaning set forth in Section 9.8.

“Product Warranty” has the meaning set forth in Section 6.2(c).

“Priority Review” means a priority review of, and action upon, a human drug application by the FDA not later than six (6) months after the sixty (60) day filing date, or eight (8) months after submission, of such application to the FDA, as defined in the FD&C Act and the performance goals set forth in the applicable Prescription Drug User Fee Act commitment letter.

“Priority Review Voucher” or “PRV” means a priority review voucher issued by the United States Secretary of Health and Human Services to the sponsor of a rare pediatric disease product application or a qualifying tropical disease product application, that may be transferred and entitles the holder of such voucher to Priority Review of a single human drug application submitted under section 505(b)(1) or section 351(a) of the United States Public Health Service Act.

“PRV Consideration” has the meaning set forth in Section 5.10(a).

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“PRV Notice” has the meaning set forth in Section 5.10(a).

“PRV Proceeds” means the net proceeds received by Novartis or its Affiliate from a PRV Sale (taking into account all costs and expenses incurred by Novartis or its Affiliate in connection with such sale, transfer or other disposition of the Priority Review Voucher, including legal, consulting, advisory and financial advisory fees, but not including consideration paid to Pharming under this Agreement).

“PRV Purchase” has the meaning set forth in Section 5.10(a).

“PRV Sale” means the sale, transfer or other disposition by Novartis or its Affiliate to a Third Party of a Priority Review Voucher that was previously transferred to Novartis or its designee under this Agreement.

“Publications” has the meaning set forth in Section 10.4.

“Quality Assurance Agreement” means, collectively, one or more quality assurance agreements entered into by the Parties or their Affiliates that address the quality related obligations of the Parties with respect to the Licensed Compound and Licensed Products supplied under or pursuant to this Agreement.

“Regulatory Approval” means, with respect to a Licensed Product in any country or jurisdiction, any approval, registration, license or authorization from a Regulatory Authority in a country or other jurisdiction that is reasonably necessary to market and sell a Licensed Product in such country or jurisdiction.

“Regulatory Authority” means any governmental authority or agency responsible for authorizing or approving the marketing or sale of products in a country or jurisdiction (e.g., the FDA, EMA, Japanese Ministry of Health, Labour and Welfare, Chinese FDA, and corresponding national or regional regulatory agencies or organizations in other countries or jurisdictions).

“Regulatory Documentation” means all material written correspondence, reports and other filings submitted to or received from Regulatory Authorities relating to the Development, manufacture or Commercialization of CDZ173 or the Lead Product.

“Regulatory Exclusivity” means, with respect to a Licensed Product in a country, the period of time during which:

- (a) a Party or its Affiliate or Sublicensee has been granted the exclusive legal right by a Regulatory Authority (or is otherwise entitled to the exclusive legal right by operation of Applicable Law) in such country to market and sell the Licensed Product; or
- (b) the data and information submitted by a Party or its Affiliate, licensee or Sublicensee to the relevant Regulatory Authority in such country for purposes of obtaining Regulatory Approval and Pricing and Reimbursement Approval may not be disclosed, referenced, or relied upon in any way by a Third Party or such Regulatory Authority (including by relying upon the Regulatory Authority’s previous findings regarding the safety or effectiveness of the Licensed Product) to support the Regulatory Approval and Pricing and Reimbursement Approval or marketing of any product by a Third Party in such country.

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“Regulatory Filing Transfer” has the meaning set forth in Section 5.6(c).

“Regulatory Filings” means, with respect to the Licensed Compound or a Licensed Product, any submission to a Regulatory Authority of any appropriate regulatory application, and includes any submission to a regulatory advisory board, marketing authorization application, and any supplement or amendment thereto. For the avoidance of doubt, Regulatory Filings will include any IND, NDA, MAA or the corresponding application in any other country or group of countries.

“Royalty Term” means, on a country-by-country and Licensed Product-by-Licensed Product basis, the period commencing on the First Commercial Sale of a Licensed Product in a specified country and continuing until the *latest to occur of*:

- (a) the expiration of the last to expire Valid Claim of the Licensed Patents that Covers such Licensed Product in such country;
- (b) the expiration of any Regulatory Exclusivity for such Licensed Product in such country; or
- (c) the ten (10) year anniversary of the First Commercial Sale of the Licensed Product in such country

“Safety Database Transfer” has the meaning set forth in Section 5.5(e).

“Sales & Royalty Report” means a written report or reports showing each of:

- (a) the Net Sales of each Licensed Product, on a country-by-country basis, during the reporting period by Pharming, its Affiliates and Sublicensees (in all cases itemizing the various deductions taken from gross to compute Net Sales as set forth in the definition of Net Sales, above); and
- (b) the royalties payable, in USD, which will have accrued hereunder with respect to such Net Sales.

“Sales Milestones” has the meaning set forth in Section 8.3(a).

“Sales Milestone Payments” has the meaning set forth in Section 8.3(a).

“Senior Officers” means, for Novartis, the Global Head, Business Development & Licensing of Novartis Institutes for BioMedical Research, Inc. (an Affiliate of Novartis) or his or her designee, and for Pharming, its Vice President, Global Business Development, or his or her designee.

“Site Agreement” means a clinical trial agreements between Novartis or its Affiliate and a clinical trial site for the Ongoing Trial and/or Extension Study.

“Specifications” means the specifications applicable to the manufacture, packaging, labelling or storage of the CDZ173 Material, as current at any given time.

“Subcommittee” has the meaning set forth in Section 3.1(e).

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“Sublicense” means a Person, other than an Affiliate of Pharming, that is granted a sublicense under the Licensed IP by Pharming or its Affiliate(s).

“STT” has the meaning set forth in Section 3.3(a).

“Technology Transfer Plan” has the meaning set forth in Section 3.3(c).

“Territory” means worldwide.

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

“Third Party Infringement” has the meaning set forth in Section 9.4(a).

“Third Party License” has the meaning set forth in Section 8.4(d).

“Transferred Regulatory Filings” has the meaning set forth in Section 5.6(a).

“Transition Committee” has the meaning set forth in Section 3.1(a).

“Transition Plan” has the meaning set forth in Section 5.7(a).

“Trial Budget” means the Initial Trial Budget as updated by Novartis in accordance with this Agreement.

“Trial Data” means all data (together with all clinical trial reports and the results of analyses thereof) derived or generated in the Ongoing Trial or the Extension Study by or on behalf of Novartis or its Affiliate, to the extent transferable to Pharming under this Agreement in accordance with Applicable Law.

“United States” or “US” means the United States of America, its territories and possessions.

“USD” or “\$” means US Dollars.

“Valid Claim” means:

- (a) a claim of an issued and unexpired patent included within the Licensed Patents that:
  - (i) covers the manufacture, use, offer for sale, sale or import of the relevant Licensed Compound or Licensed Product in the relevant jurisdiction;
  - (ii) has not been irrevocably or unappealably disclaimed or abandoned, or been held unenforceable, unpatentable or invalid by a decision of a court or other governmental agency of competent jurisdiction; and
  - (iii) has not been admitted to be invalid or unenforceable through reissue, disclaimer, or otherwise; or
- (b) a claim included in a pending patent application within the Licensed Patents that:

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- (i) would cover the manufacture, use, offer for sale, sale or import of the relevant Licensed Compound or Licensed Product in the relevant jurisdiction if such claim was to issue; and
  - (ii) has not been cancelled, withdrawn or abandoned, nor been pending for more than [\*\*\*] years from the earliest priority date to which such patent application or claim is entitled.

1.2 **Interpretation.** In this agreement unless otherwise specified:

- (a) “includes” and “including” mean, respectively, includes without limitation and including without limitation;
- (b) a Party includes its permitted assignees and the respective successors in title to substantially the whole of its undertaking;
- (c) a statute or statutory instrument or any of their provisions is to be construed as a reference to that statute or statutory instrument or such provision as the same may have been or may from time to time hereafter be amended or re-enacted;
- (d) words denoting the singular will include the plural and vice versa and words denoting any gender will include all genders;
- (e) the word “or” is used in the inclusive sense (and/or);
- (f) the Exhibits and other attachments form part of the operative provision of this Agreement and references to this Agreement shall, unless the context otherwise requires, include references to the Exhibits and attachments;
- (g) the headings in this Agreement are for information only and will not be considered in the interpretation of this Agreement;
- (h) general words will not be given a restrictive interpretation by reason of their being preceded or followed by words indicating a particular class of acts, matters or things;
- (i) references to days means calendar days unless otherwise indicated; and
- (j) the terms of this Agreement are the result of negotiations between the Parties, and this Agreement will not be construed in favor of or against any Party by reason of the extent to which any Party participated in the preparation of this Agreement.

**2. INTELLECTUAL PROPERTY LICENSE**

- 2.1 **License Grant.** Subject to the terms of this Agreement, Novartis and its Affiliates hereby grant to Pharming a license (with the right to sublicense in accordance with Section 2.2) in, to and under the Licensed IP, to research, Develop, make and have made, use and Commercialize Licensed Compound and Licensed Product in the Field and in the Territory. Subject to the retained rights set forth in Section 2.3, the license set forth in this Section 2.1 shall be exclusive (even as to Novartis and its Affiliates) to Pharming.

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- 2.2 **Sublicense Rights.** Pharming may sublicense (through multiple tiers) the license set forth in Section 2.1 to any Affiliates or Third Party at any time at its sole discretion, but subject to the applicable terms of this Agreement. Pharming shall provide Novartis with a copy of any such sublicense agreement within [\*\*\*] days after the execution thereof, *provided*, that such copy may be subject to redaction as required thereunder or as Pharming reasonably believes necessary to protect sensitive financial provisions not required for Novartis to confirm compliance with the terms and conditions of this Agreement. Each sublicense of the Licensed IP shall be consistent with the terms of this Agreement (including with respect to Section 12.2(c)), and Pharming will remain liable for the acts and omissions of its Sublicensees and Affiliates as if such Sublicensees and Affiliates were Pharming hereunder.
- 2.3 **Retained Rights; No Implied Licenses.** Except for the licenses expressly granted to Pharming pursuant to this Agreement, Novartis grants no other rights or licenses, including any other rights or licenses under the Licensed Patents and the Licensed Know-How, or under any other Patent Rights, Know-How or other intellectual property rights of Novartis, whether by implication, estoppel or otherwise. Without limiting the generality of the foregoing, except for the tangible materials referenced on Exhibit D or as agreed in the Transition Plan or the Technology Transfer Plan, and the Manufacturing Technology, neither Novartis nor its Affiliates has any obligation to transfer any tangible materials to Pharming. Novartis, its Affiliates and its and their agents will retain the right to practice the Licensed IP (i) to perform its obligations, exercise its rights and comply with Applicable Law under this Agreement, and (ii) for its internal research purposes and subject to Novartis' obligations under Section 10.
- 2.4 **Know-How Relating to Other Compounds.** Pharming acknowledges that some of the documentation within the Licensed Know-How that is transferred to Pharming pursuant to this Agreement may include information or data that is not Licensed Know-How or which relates to a program or compound other than the Licensed Compound or otherwise outside the scope of the license granted under Section 2.1, and Novartis will use Commercially Reasonable Efforts to redact or delete such information and data prior to the transfer of the Licensed Know-How to Pharming under this Agreement. However, to the extent that information or data relating to a program or compound other than the Licensed Compound or Licensed Product or otherwise outside the scope of the license granted under Section 2.1 is transferred to Pharming or its Affiliate or their representative or designee, no license is granted to Pharming or any such Person to use such information or data for any purpose or to disclose such information to any Third Party, and such information and data shall be deemed to be Novartis' Confidential Information and not subject to disclosure pursuant to Section 10.3(b) or otherwise.

### 3. GOVERNANCE; INFORMATION UPDATES

#### 3.1 Transition Committee.

- (a) Promptly, but no later than [\*\*\*] days after the Effective Date, the Parties will establish a joint transition committee (the "Transition Committee"), composed of an equal number of representatives of each Party as mutually agreed (one (1) of whom will be each Party's Alliance Manager) and which representatives for each Party, collectively, shall have a general understanding of clinical drug development and manufacturing. Each Party may replace its representatives on



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the Transition Committee on written notice to the other Party. The Transition Committee will have the responsibilities set forth herein and will, unless otherwise mutually agreed, dissolve [\*\*\*] days following the Final Transfer Date.

- (b) The Transition Committee will (i) review, discuss and oversee clinical development and other activities conducted under this Agreement, (ii) review, discuss and approve the Transition Plan, (iii) review and discuss interactions and communications with Third Parties and Regulatory Authorities in connection with such activities, (iv) oversee general transition matters, and (v) consider and discuss such other matters as specified in this Agreement or otherwise in connection with the Parties' activities hereunder. For the avoidance of doubt, the Transition Committee and its Subcommittees will have no responsibility for or authority over Development activities outside the scope of this Agreement, including activities of Pharming with respect to the Licensed Compound or Licensed Products to be conducted following the transition contemplated by this Agreement, or Pharming's planning, strategy, or analysis therefor.
- (c) Pharming will designate one of its members as the chairperson of the Transition Committee. The chairperson or his or her designee, in collaboration with Pharming's Alliance Manager, will be responsible for calling meetings, preparing and circulating an agenda in advance of each meeting, and preparing and issuing minutes of each meeting within [\*\*\*] days thereafter. Such minutes will be deemed finalized unless any Transition Committee member objects to the accuracy of such minutes within [\*\*\*] days of receipt of such minutes.
- (d) The Transition Committee shall meet (i) [\*\*\*] during the period beginning on the Effective Date and ending on the last day of the [\*\*\*] full calendar month immediately following the Effective Date (the "Initial Transition Period") unless otherwise agreed by the Parties, and (ii) after the Initial Transition Period, at such times as the Parties may agree, but not less than quarterly. The first meeting of the Transition Committee shall be held as soon as reasonably practicable, but in no event later than [\*\*\*] days following the Effective Date. At the first meeting of the Transition Committee, the members shall reasonably and in good faith determine how it will function with respect to timelines and other administrative matters not otherwise specified in this Agreement. Meetings shall be held at such place or places or by teleconference or videoconference as mutually agreed.
- (e) The Transition Committee also may, at any time it deems necessary or appropriate, establish additional joint subcommittees or project teams (each, a "Subcommittee") and delegate such of its responsibilities as it determines appropriate to such Subcommittee. Each Subcommittee will report to, and its activities will be subject to the oversight of, the Transition Committee. No Subcommittee's authority may exceed that of the Transition Committee. Any disagreement between the representatives of the Parties on any Subcommittee will be referred to the Transition Committee for resolution in accordance with Section 3.4.
- (f) Each Party may from time to time invite a reasonable number of non-member participants, in addition to its representatives, to attend Transition Committee meetings with the consent of the other Party (which consent shall not be unreasonably withheld, conditioned or delayed).

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- (g) For the avoidance of doubt, neither the Transition Committee nor any Subcommittee shall have any responsibility or authority with respect to any strategic matters relating to Pharming's research, Development, manufacturing or Commercialization of the Licensed Compound or Licensed Products (including any planning or analysis therefor or the execution thereof), and Novartis and its Affiliates shall have no responsibility or liability with respect to such matters (including with respect to any views or opinions on such matters that may be expressed by representatives of Novartis on the Transition Committee or any Subcommittee).

### 3.2 **Joint Clinical Team.**

- (a) Promptly, but not more than [\*\*\*] days after the Effective Date, the Parties and the Transition Committee will establish a joint clinical team ("JCT"), which JCT will be a Subcommittee of the Transition Committee and will have the responsibilities provided for herein. Unless otherwise mutually agreed, the JCT will dissolve [\*\*\*] days following the Final Trial Transfer Date.
- (b) The JCT shall meet (i) at least [\*\*\*] during the Initial Transition Period, and (ii) after the Initial Transition Period, at such times as the Parties may agree, but not less than quarterly.
- (c) The JCT will (i) review and discuss the Joint Trial Plan (and updates thereto), the Trial Budget, the Development Plan and Development Reports, (ii) facilitate the flow of information between the Parties with respect to clinical development of the Lead Product under this Agreement, (iii) coordinate and oversee the completion of the Ongoing Trial and the conduct and transfer of the Extension Study, in each case, in accordance with this Agreement, (iv) review and discuss interactions and communications with Regulatory Authorities in connection with such activities, and (v) perform such other functions as appropriate to further the purposes of this Agreement as determined by the Parties or the Transition Committee.
- (d) Without limiting the foregoing, the JCT shall consider any proposal from Pharming for Development activities to be undertaken by Pharming or its Affiliates for or in connection with the Ongoing Trial or the Extension Study prior to the Final Transfer Date ("Pharming Activities"). As soon as reasonably practicable after the Effective Date, the JCT shall discuss and agree a plan in reasonable detail, setting out the activities to be performed including the Pharming Activities (and the timelines associated therewith) with respect to the Ongoing Trial and the Extension Study, and the transfer of the Extension Study pursuant to Section 5.7(b) ("Joint Trial Plan"), such that the JCT can present the first version of the Joint Trial Plan to the Transition Committee on or before [\*\*\*] days after the Effective Date. Either Party may propose updates to the Joint Trial Plan to the JCT. Pharming may not conduct or cause to be conducted any Pharming Activities without the prior approval of the JCT or the Transition Committee. Any such Pharming Activities will be conducted at Pharming's sole cost and expense, and subject to the oversight of the JCT.

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Novartis and its Affiliates will have no liability with respect to any Pharming Activities, and will not be responsible for any adverse effect Pharming Activities may have on the Ongoing Trial, the Extension Study, the Licensed Compound or Licensed Product, or the activities of Novartis under this Agreement.

### 3.3 **Supply Transition Team.**

- (a) Promptly, but not more than [\*\*\*] days after the Effective Date, the Parties and the Transition Committee will establish a supply transition team (“**STT**”), which STT will be a Subcommittee of the Transition Committee and will have the responsibilities provided for herein. Unless otherwise mutually agreed, the STT will dissolve [\*\*\*] days following the Completion of Technology Transfer.
- (b) Prior to its dissolution, the STT shall meet (i) at least [\*\*\*] during the Initial Transition Period, and (ii) if applicable, after the Initial Transition Period, at such times as the Parties may agree, but not less than quarterly.
- (c) As soon as reasonably practicable after the Effective Date, the STT shall discuss and agree a plan in reasonable detail, setting out the activities and timelines with respect to the matters described in Section 6.7 (the “Technology Transfer Plan”), such that the STT can present the Technology Transfer Plan to the Transition Committee on or before [\*\*\*] days after the Effective Date. Either Party may propose updates to the Technology Transfer Plan to the STT.
- (d) The STT will (i) review and discuss the Technology Transfer Plan (and updates thereto), (ii) facilitate the flow of information between the Parties with respect to CMC, manufacturing, supply and quality matters related to CDZ173 and the Lead Product, (iii) coordinate and oversee manufacturing aspects of the technology transfer contemplated by Article 4 and Article 5, in each case, in accordance with this Agreement, (iv) review, discuss and coordinate matters related to the technology transfer of Manufacturing Technology to a Third Party contractor of Pharming as contemplated by Section 6.7, (v) review and discuss interactions and communications with Regulatory Authorities in connection with such activities, (vi) review, discuss and coordinate matters related to the clinical supply of Licensed Products including to enable the activities of the Parties under this Agreement, and (vii) perform such other functions as appropriate to further the purposes of this Agreement as determined by the Parties or the Transition Committee.

### 3.4 **Decision-Making.**

- (a) Each Party’s representatives on the Transition Committee and each Subcommittee will, collectively, have one (1) vote on all matters brought before such committee for a decision. The Transition Committee and each Subcommittee will make decisions as to matters within its ambit by unanimous vote, which vote may be reflected either in the minutes of the committee meeting or by an action by written consent signed by at least one (1) representative appointed by each

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Party or their designee(s). Decisions of the Transition Committee and each Subcommittee shall be made at a meeting, and no vote will be binding on either Party unless each Party has at least one (1) representative in attendance at the relevant meeting.

- (b) If the representatives of the Parties on any Subcommittee are unable to agree on or resolve any matter before such Subcommittee after the use of good faith efforts, either Party or its representatives on such Subcommittee may refer such matter to the Transition Committee for resolution.
- (c) If the representatives of the Parties on the Transition Committee are unable to agree on or resolve any matter before the Transition Committee after the use of good faith efforts (including any matter referred to the Transition Committee under Section 3.4(b)) within [\*\*\*] days after the matter is referred to the Transition Committee (or such longer period as the Parties or the Transition Committee may mutually agree), then either Party may, by providing written notice to the other Party, refer such matter for resolution in accordance with the dispute resolution procedures contained in Section 15.5.
- (d) Notwithstanding the foregoing, in the case of any matter before the Transition Committee regarding, or that otherwise would or would reasonably be expected to impact, Novartis' obligations under Applicable Law, any health or safety matter, the Trial Budget, or any ethical requirement concerning the treatment of study subjects in connection with (i) the Ongoing Trial prior to the Final Transfer Date, or (ii) the Extension Study prior to the applicable Extension Study Transition Date on a trial site-by-trial site basis (including any proposed amendment to the Ongoing Trial Protocol or the Extension Study Protocol prior to such date), which cannot be resolved within [\*\*\*] days after the matter is referred to the Transition Committee (or such longer period as the Parties or the Transition Committee may mutually agree), then the resolution and course of conduct shall be determined by Novartis, subject to Section 3.5. For the avoidance of doubt, matters subject to Novartis final decision-making authority under this Section 3.4(d) are not subject to the dispute resolution procedures contained in Section 15.5.
- (e) Notwithstanding anything in this Agreement to the contrary, if Pharming or its representatives on the Transition Committee or any Subcommittee request any change to the Transition Plan or Joint Trial Plan, or an amendment to the Ongoing Trial Protocol or the Extension Study Protocol, Novartis shall not (and shall procure that its representatives on the Transition Committee or any Subcommittee shall not) unreasonably withhold consent for such request; *provided*, that if such requested change would or would reasonably be expected to increase any anticipated Development Costs compared to the Development Costs to be incurred under the Initial Trial Budget or Trial Budget, as applicable, for any Calendar Quarter, then the Budget Cap shall be increased by an amount equal to such increase to the anticipated Development Costs. Novartis shall update the Trial Budget to reflect the reasonably anticipated increases in such Development Costs, and shall use Commercially Reasonable Efforts to avoid or limit such increases. For the avoidance of doubt, Novartis and its representatives on the Transition Committee or any Subcommittee shall have no obligation to accept or otherwise

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consent to any proposed change to the Transition Plan or Joint Trial Plan, any amendment to the Ongoing Trial Protocol or the Extension Study Protocol, or any other activity under this Agreement, that would either (i) impose on Novartis or its Affiliates any additional material obligations, including financial obligations or any obligation to hire, retain, or maintain any specific employee, consultant, agent or service provider or any class or category thereof, or (ii) require activities that Novartis or its Affiliates are unable or unwilling to conduct (whether due to constraints on internal Novartis resources, internal Novartis policies, or otherwise); *provided, that at Pharming's request, the Parties shall discuss and consider in good faith the possibility of Pharming or its designee taking on the activities contemplated by such change or amendment as Pharming Activities hereunder.*

- 3.5 **General Authority.** Notwithstanding anything to the contrary contained in this Agreement, neither (i) the Transition Committee or any Subcommittee nor (ii) Novartis in exercising its final decision-making authority under Section 3.4(d), will have the right to make any decisions:
- (a) that amend or modify, or waive compliance with, this Agreement or any agreement entered into between the Parties or their Affiliates pursuant to this Agreement;
  - (b) in a manner that negates any consent right or other right specifically allocated to a Party under this Agreement;
  - (c) to resolve any dispute involving the breach or alleged breach of this Agreement;
  - (d) in a manner that would require either Party to perform any act that would cause such Party to violate any Applicable Law or the requirements of any Regulatory Authority, or otherwise breach any of its obligations hereunder;
  - (e) impose any obligation on either Party that would be in violation of such Party's written standard operating procedures, written business policies, or written compliance policies or procedures; or
  - (f) otherwise expand or reduce the rights or the obligations of either Party under this Agreement.
- 3.6 **Alliance Managers.** Within [\*\*\*] days after the Effective Date, each Party will appoint (and notify the other Party of the identity of) a senior representative having a general understanding of pharmaceutical development and commercialization issues to act as its alliance manager under this Agreement ("Alliance Manager"). The Alliance Managers will (a) serve as the contact point between the Parties for the purpose of providing Novartis with information on the progress of Pharming's Development and Commercialization of Licensed Products; (b) be primarily responsible for facilitating the flow of information and otherwise promoting communication, coordination, and collaboration between the Parties; (c) provide a single point of communication for seeking consensus both internally within the respective Party's organization; and (d) raise crossParty or cross-functional disputes in a timely manner. Each Party may replace its Alliance Manager on written notice to the other Party.

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3.7 **Development Plans; Development Reports.**

- (a) Within [\*\*\*] days after the Effective Date, Pharming, through the JCT (and after discussion by JCT members) will provide the Transition Committee with a high-level development plan setting forth the anticipated Development activities to be conducted by or on behalf of Pharming, its Affiliates and Sublicensees related to the Licensed Compound and Licensed Products (for clarity, not including the Ongoing Trial, the Extension Study, or activities to be conducted by Novartis or its Affiliates under this Agreement) during the following eighteen (18) month period (a "Development Plan"). For clarity, Pharming Activities are anticipated to be included in the Joint Trial Plan and not the Development Plan. Together with each Development Report delivered by Pharming pursuant to Section 3.7(b), until the First Commercial Sale of a Licensed Product, Pharming will update the Development Plan and describe, in reasonable detail, the anticipated Development activities to be conducted by or on behalf of Pharming, its Affiliates and Sublicensees during the following eighteen (18) month period, provided that, prior to the Final Transfer Date, such update to the Development Plan shall be delivered through the JCT (and after discussion by JCT members) to the Transition Committee .
- (b) On every [\*\*\*] month anniversary of the Effective Date during the Agreement Term until the First Commercial Sale of a Licensed Product, Pharming will provide to Novartis a high-level written summary report describing all Development activities related to the Licensed Compound and Licensed Products that Pharming and its Affiliates or their respective agents, licensees or Sublicensees have conducted in the prior [\*\*\*] month period (each, a "Development Report"). The Development Reports will include sufficient information to reasonably demonstrate that Pharming is meeting its diligence obligations under Section 5.3(c) and Section 7.2 of this Agreement.

3.8 **Clinical Trial Budget.** Within [\*\*\*] days after the Effective Date, Novartis will provide Pharming with a high-level budget setting forth on a quarterly basis Novartis' good faith estimate of its expected Development Costs in performing the Ongoing Trial and the Extension Study in accordance with the then existing Ongoing Trial Protocol and Extension Study Protocol until the Final Trial Transfer Date (the "Initial Trial Budget"). To the extent necessary, Novartis shall update the Initial Trial Budget (or Trial Budget, as applicable) on a Calendar Quarter basis and provide such updates to Pharming through the JCT. The JCT shall review and discuss the Trial Budget and any amendments thereto. For clarity (and without limiting the foregoing), Novartis shall be permitted to amend the Trial Budget from time to time as necessary to reflect Novartis' good faith estimate of the Development Costs without the approval of Pharming, the JCT or the Transition Committee, but Pharming's obligation to reimburse Novartis for Development Costs shall remain subject to the Budget Cap and Section 8.5.

3.9 **Alliance Manager Meetings.** During the period commencing on the Effective Date until [\*\*\*] days following the Final Transfer Date, the Alliance Managers will meet (either in person or by teleconference) at least once each month (or as otherwise agreed by the Parties or the Transition Committee), to review the Development Plan, the Development Reports and to discuss the Parties' Development activities with respect to the Licensed Compound and Licensed Products.

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#### 4. DISCLOSURE OF LICENSED KNOW-HOW & COOPERATION

- 4.1 **Transfer of Licensed Know-How.** Subject to the timing and obligations of the Parties with respect to the transfer of documents and information contemplated by Article 5 (including with respect to the CSR, the Safety Database Transfer, the Clinical Database, the Existing INDs, the transfer of Third Party agreements, and as provided in the Transition Plan, the Pharmacovigilance Agreement or the Quality Assurance Agreement), Novartis shall transfer to Pharming or its designee, on the timetable set forth on Exhibit B-1, a copy (in electronic format if available in electronic format, or hard copy if not available in electronic format) of the documentation and other Know-How listed on Exhibit B-2 (the “Manufacturing Technology”) and Exhibit B-3, in each case, to the extent such documentation or other Know-How is in the possession and Control of Novartis or its Affiliates as of the Effective Date after the use of Commercially Reasonable Efforts to investigate the records of Novartis and its Affiliates (it being understood that Novartis will have the right to exclude or redact any information relating to compounds or programs that are not within the scope of the license granted under Section 2.1). To the extent reasonably requested by Pharming and mutually agreed by the Transition Committee, Novartis will provide to Pharming, at Pharming’s cost, copies (in electronic format if available in electronic format, or hard copy if not available in electronic format) of such other documents embodying Licensed Know-How in the possession and Control of Novartis or its Affiliates that are reasonably necessary for the Development or Commercialization of the Licensed Compound or Licensed Product; *provided*, that any request for the transfer of local or country-level data must be submitted not later than three (3) months after the Effective Date. The Parties acknowledge that the transfer by Novartis of such Licensed Know-How will consist of the transfer of data residing in Novartis’ databases, and will not include the transfer of any database architecture. All documentation within the Licensed Know-How will be provided in the language such documentation was generated and will not be translated. Notwithstanding anything else in this Agreement to the contrary, the Parties acknowledge that Novartis shall have no obligation to transfer clinical samples or take any action inconsistent with or that would require any amendment or modification to a Site Agreement or a clinical study subject’s informed consent; *provided*, that the Parties will cooperate and endeavor in good faith to ensure that all Licensed Know-How (including clinical data) necessary for the Development, manufacture or Commercialization of the Licensed Compound and Licensed Products can be lawfully transferred to Pharming or its designee.
- 4.2 **Licensed Know-How Transfer Assistance.**
- (a) For up to [\*\*\*] days following the Effective Date (or such time period mutually agreed by the Transition Committee), Novartis shall use Commercially Reasonable Efforts to (i) promptly answer questions and, upon Pharming’s reasonable request, provide clarifications, in each case, related to the Manufacturing Technology transferred to Pharming or its designated contractor pursuant to Section 4.1 and Section 6.7, and (ii) provide such support to Pharming as is reasonably necessary for the transfer of Manufacturing

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Technology contemplated by Section 6.7 as set forth in the Technology Transfer Plan or the Transition Plan or otherwise mutually agreed by the STT or the Transition Committee, in each case, at no additional cost to Pharming, not to exceed a total of [\*\*\*] hours.

- (b) For up to [\*\*\*] days following the Completion of the Ongoing Trial and the Final Transfer Date of the Extension Study (or such time period mutually agreed by the Transition Committee), Novartis shall use Commercially Reasonable Efforts to (i) promptly answer questions and, upon Pharming's reasonable request, provide clarifications, in each case, related to the Licensed Know-How other than Manufacturing Technology transferred to Pharming or its designated contractor pursuant to Section 4.1 and Article 5, and (ii) reasonably support and cooperate with Pharming on its Regulatory Filings under this Agreement, in each case, at no additional cost to Pharming. Such support and cooperation may involve attending a meeting with Regulatory Authorities as set forth in the Transition Plan or otherwise mutually agreed by the Transition Committee, but Pharming shall be responsible for the preparation and strategy for all such meetings with Regulatory Authorities, including the preparation of all Regulatory Filings and meeting materials.
- (c) For the avoidance of doubt, the support and assistance contemplated by this Section 4.2 shall be limited to assisting Pharming in interpreting the Licensed Know-How provided to Pharming pursuant to Section 4.1 and Article 5, and in no event will Novartis provide strategic guidance, analysis or other consulting services relating to Pharming's research, Development, manufacturing or Commercialization activities with respect to the Licensed Compound or Licensed Products. Such support and assistance with respect to regulatory matters will be limited to the extent such support and assistance is necessary in order to consummate the transactions expressly contemplated by this Agreement, and Novartis and its Affiliates will have no obligation to support or assist Pharming or its Affiliates in their Development activities outside the scope of this Agreement.
- (d) The Transition Committee and the Parties' Alliance Managers will agree on the format, timing, and scope of the relevant Licensed Know-How transfer assistance; *provided*, that except as expressly set forth in Sections 5.1 or 5.2 or as mutually agreed in the Transition Plan, in no event will Novartis or its Affiliates be required to conduct any additional experiments or research for the purpose of or in connection with the transfer of Licensed Know-How pursuant to this Agreement.
- (e) With respect to any additional assistance reasonably requested by Pharming (*i.e.*, outside the time periods contemplated by Section 4.2(a) or Section 4.2(b), or with respect to the Manufacturing Technology in excess of the [\*\*\*] hours set forth in Section 4.2(a)) and mutually agreed by the Transition Committee, (i) the relevant activities shall be agreed upon by the Parties in a written task order describing the scope of the agreed upon activities; and (ii) Pharming will reimburse Novartis at the FTE Rate for such services. For clarity, amounts reimbursed under this Section 4.2 shall not be included in the Trial Budget or subject to or counted against the Budget Cap.



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(f) To the extent that the assistance described in this Section 4.2 or otherwise agreed by the Transition Committee requires Novartis to engage a Third Party service provider to perform services, the costs of such activities will be paid exclusively by Pharming.

- 4.3 **Disclaimer of Warranties.** Except as otherwise provided in, and without prejudice to Novartis' obligations under, this Agreement: (a) Pharming acknowledges that all of the Licensed Know-How transferred to Pharming pursuant to Section 4.1 and Article 5 and any assistance provided to Pharming pursuant to this Agreement is provided "as is" and without representation or warranty of any kind, except as expressly provided in Article 13; (b) Novartis hereby expressly disclaims any implied warranties of merchantability or fitness for a particular purpose with respect to such Licensed Know-How and assistance; (c) Novartis will have no obligation to update, revise, amend, or modify any of the Licensed Know-How or assistance provided to Pharming pursuant to this Article 4 or otherwise pursuant to this Agreement; and (d) the use of such Licensed Know-How and assistance in the research, Development, manufacture and Commercialization of the Licensed Compound and Licensed Products will be at Pharming's sole risk.
- 4.4 **Third Party Agreements.** The Parties acknowledge that except as expressly set forth in Section 5.9(a) or as otherwise contemplated by Section 5.9(b), Novartis and its Affiliates will not transfer or assign any agreements that it or they may have with vendors or service providers or any other Third Party in connection with the transfer of Licensed Know-How or licenses set forth in this Agreement. However, to the extent Pharming intends to engage one or more of such vendors or service providers in connection with the Development, manufacture, or Commercialization of the Licensed Compound or Licensed Products, at Pharming's written request (to the extent such request is delivered within [\*\*\*] months following the Effective Date), Novartis will issue a letter of authorization permitting Pharming to request access to or copies of any Licensed Know-How held by such vendors or service providers, at Pharming's sole cost and expense and pursuant to separate written agreement(s) to be negotiated and entered into by and between Pharming and such Third Party vendors or service providers.

## 5. REGULATORY; DEVELOPMENT

### 5.1 Novartis' Obligations Regarding Ongoing Trial.

- (a) Subject to the terms and conditions of this Agreement, including Section 6.2 and Section 8.5, Novartis shall be responsible for the performance of, and shall continue to perform, the Ongoing Trial in accordance with the Ongoing Trial Protocol until Completion of the Ongoing Trial.
- (b) Prior to Completion of the Ongoing Trial, Novartis shall be permitted to amend the Ongoing Trial Protocol: (i) to the extent required by Applicable Law or any relevant Regulatory Authority; (ii) to the extent required under the terms of an applicable Site Agreement; (iii) if Novartis determines in good faith that any such amendment is necessary or appropriate for health or safety reasons; or (iv) with the prior written consent of Pharming (such consent not to be unreasonably withheld, conditioned, or delayed). Pharming may propose amendments to the Ongoing Trial Protocol through the JCT, which shall consider any such proposed amendment in good faith.

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- (c) At least once every month following the Effective Date until Completion of the Ongoing Trial (at regularly scheduled monthly JCT meetings or as reasonably requested by Pharming), Novartis will provide a clinical update regarding the Ongoing Trial to Pharming through the JCT which shall indicate the number of enrolled subjects per trial site and such other information as agreed by the JCT.

**5.2 Novartis' Obligations Regarding Extension Study.**

- (a) Subject to the terms and conditions of this Agreement, including Section 6.2 and Section 8.5, Novartis shall be responsible for the performance of, and shall continue to perform, the Extension Study in accordance with the Extension Study Protocol until, on a country-by-country or trial site-by-trial site basis, as mutually agreed by the Parties, the applicable Extension Study Transition Date.
- (b) Prior to the Extension Study Transition Date with respect to all trial sites (the "Final Trial Transfer Date"), Novartis shall be permitted to amend the Extension Study Protocol, and following the Final Trial Transfer Date, Pharming shall be permitted to amend the Extension Study Protocol, in each case: (i) to the extent required by Applicable Law or any relevant Regulatory Authority; (ii) to the extent required under the terms of an applicable Site Agreement; (iii) if such Party determines in good faith that any such amendment is necessary or appropriate for health or safety reasons; or (iv) with the prior written consent of the other Party (such consent not to be unreasonably withheld, conditioned, or delayed). Without limiting the foregoing, either Party may propose amendments to the Extension Study Protocol through the JCT, which shall consider any such proposed amendment in good faith. Notwithstanding the foregoing, following the First Commercial Sale of Licensed Product on a country-by-country basis, this Section 5.2(b) will no longer apply to Pharming with respect to the Extension Study Protocol as it relates to Extension Study subjects in such country.
- (c) At least once every Calendar Quarter following the Effective Date until the Final Trial Transfer Date, Novartis will provide a clinical update regarding the Extension Study to Pharming through the JCT which shall indicate the number of enrolled subjects per trial site and such other information as agreed by the JCT until the Site Agreement for such site has been transferred to Pharming or its designee.

**5.3 Pharming's Obligations.**

- (a) Except for obligations of Novartis with respect to the Ongoing Trial and the Extension Study expressly set forth in Sections 5.1 and 5.2 or as otherwise expressly stated in this Article 5, from and after the Effective Date, Pharming will be solely responsible for all Development of the Licensed Compound and Licensed Products at its sole cost and expense, including by making payments required under Section 8.5. For the avoidance of doubt, following the Effective Date Pharming will be solely responsible for all Development of the Licensed Compound and Licensed Products for any pediatric Indication at its sole cost and expense.

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- (b) Except for obligations of Novartis under Applicable Law prior to the transfer of the Existing INDs contemplated by Section 5.6 or as otherwise expressly stated in the Pharmacovigilance Agreement, from and after the Effective Date, Pharming will be solely responsible for all regulatory matters arising in connection with the Development of the Licensed Compound and Licensed Products at its sole cost and expense.
  - (c) Pharming will itself, or through its Affiliates or Sublicensees, use Commercially Reasonable Efforts to Develop and seek Regulatory Approval (and, if applicable, Pricing and Reimbursement Approval) for at least one Licensed Product in (i) [\*\*\*], (ii) [\*\*\*], and (iii) [\*\*\*].

5.4 **Adverse Event Reporting and Safety Data Exchange.** Novartis and Pharming shall cooperate with regard to the reporting and handling of safety information involving or relating to the Licensed Compound and the Licensed Products at least to the extent required by Applicable Laws. As soon as practicable but not more than [\*\*\*] days following the Effective Date, and in time to ensure that all regulatory requirements are met, the Parties (directly or through their Affiliates) will enter into written agreements in form and substance reasonably requested by Novartis containing customary terms that will govern the exchange of adverse event and other safety information reporting obligations relating to the Licensed Compound and the Licensed Products (collectively, "Pharmacovigilance Agreement") to ensure that adverse events and other safety information is exchanged and reported to the relevant Regulatory Authorities in compliance with the Applicable Laws and requirements of Regulatory Authorities.

5.5 **Global Safety Database; Clinical Database.**

- (a) Within [\*\*\*] days after the later of (i) the execution of the Pharmacovigilance Agreement and (ii) the Completion of the Ongoing Trial, Novartis shall transfer to Pharming data for the Licensed Compound and Licensed Products in Novartis' global safety database in accordance with the Transition Plan, understanding that certain information will be redacted or retained by Novartis in accordance applicable data privacy laws.
- (b) To the extent not previously transferred to Pharming or its designee, Novartis shall transfer to Pharming data from Novartis' clinical database for the Licensed Compound and Licensed Products ("Clinical Database") in accordance with the Transition Plan, understanding that certain information will be redacted or retained by Novartis in accordance applicable data privacy laws.
- (c) The Parties acknowledge that the transfer by Novartis of data from its relevant databases will include data residing in such databases, but not any database architecture. Pharming shall be solely responsible for establishing appropriate database structures for receipt of the relevant data, which it shall complete not later than [\*\*\*] days after execution of the Pharmacovigilance Agreement or such other date as may be mutually agreed by the JCT or Transition Committee.

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- (d) The Transition Committee and the Parties' Alliance Managers will agree on (i) the format, timing, and process for the transfer of data contemplated by this Section 5.5, and (ii) any access to information in Novartis' databases reasonably requested by Pharming prior to the completion of such data transfers. For clarity, the Parties may agree to transfer data contained in the Clinical Database, in whole or in part, on a schedule agreed by the JCT or Transition Committee, including on a country-by-country or trial site-by-trial site basis.
  - (e) Following the completion of the transfer of data from Novartis' global safety database contemplated by this Section 5.5 (the "Safety Database Transfer"), Pharming shall establish, hold and maintain the global safety database(s) for the Licensed Compound and each Licensed Product (the "Global Safety Database") into which it shall enter information on all adverse events concerning the Licensed Compound and each Licensed Product occurring anywhere in the world in accordance with the Pharmacovigilance Agreement and Applicable Law.

#### 5.6 **Transfer of Sponsorship of Existing INDs.**

- (a) Within [\*\*\*] days after the later of (i) the execution of the Pharmacovigilance Agreement, (ii) the Completion of the Ongoing Trial, and (iii) completion of the Safety Database Transfer, Novartis and its Affiliates shall assign and transfer to Pharming the sponsorship of the Existing INDs and the other Regulatory Filings identified on Exhibit E (the "Transferred Regulatory Filings") and any other Regulatory Documentation (if applicable), in each case, in accordance with the Transition Plan. If Novartis is restricted under Applicable Law from transferring ownership of any Transferred Regulatory Filing or Regulatory Documentation, Novartis will grant, and hereby does grant, to Pharming (or its designee) a right of reference to use to such Transferred Regulatory Filing or Regulatory Documentation in accordance with Applicable Law. Novartis will use Commercially Reasonable Efforts to take such actions as are reasonably necessary to effect such transfer or grant of right of reference or use to Pharming or its designee;
- (b) To effect the transfer described in Section 5.6(a), Novartis will file with relevant Regulatory Authorities a notification that the sponsorship of the Transferred Regulatory Filings is being transferred from Novartis to Pharming, and Pharming will submit to the relevant Regulatory Authorities a notification that it is assuming the sponsorship of the Transferred Regulatory Filings. These notifications shall be filed simultaneously by the Parties unless otherwise required by Applicable Law. Thereafter, Pharming shall have sole responsibility to maintain the Existing INDs and any other IND related to the Licensed Compound or Licensed Products, and shall be responsible for all future communications with the relevant Regulatory Authorities regarding the Transferred Regulatory Filings and any and all subsequent Regulatory Filings relating to the Licensed Compound or Licensed Products under the Transferred Regulatory Filings or otherwise. If, at any time after the Transferred Regulatory Filings are transferred to Pharming, a Regulatory Authority requests information, data, or documentation Controlled by Novartis or its Affiliates, Novartis will provide such information, data, or documentation, to

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the extent that such information, data and documentation is accessible by Novartis using Commercially Reasonable Efforts, and shall reasonably cooperate with Pharming with respect to responding to requests from Regulatory Authorities.

- (c) Without limiting the foregoing, the Transition Committee and the Parties' Alliance Managers will coordinate the transfer of the Transferred Regulatory Filings and Regulatory Documentation contemplated by this Section 5.6 in accordance with the Transition Plan, which may be sequenced on a country-by-country basis (with respect to each applicable country, the "Regulatory Filing Transfer").

**5.7 Transition Plan; Transition of Extension Study.**

- (a) Within [\*\*\*] days following the Effective Date, the Transition Committee shall discuss and agree an initial transition plan describing in reasonable detail the activities to be carried out by each Party, in order to facilitate, the prompt and orderly transfer to Pharming or its designee the Licensed Know-How and all Development, regulatory and manufacturing activities undertaken by or on behalf of Novartis or its Affiliates as of the Effective Date with respect to CDZ173 and the Lead Product (other than the Ongoing Trial) and allow Pharming to assume responsibility for such activities. Without limiting the foregoing, such transition plan shall set out in reasonable detail a process for (i) the transition of the Extension Study from Novartis to Pharming, (ii) the delivery to Pharming or its designee of any Licensed Know-How not previously delivered, and (iii) the technology transfer contemplated by Section 6.7, in each case ((i) through (iii)), in accordance with the terms of this Agreement and Applicable Laws, including the timing and sequence for the transition of the Extension Study on a country-by-country or trial site-by-trial site basis, the Third Party agreements to be transferred to Pharming or its designee pursuant to the Ancillary Agreement in connection with the transition of the Extension Study, and the other transition activities to be undertaken by the Parties and the timing therefor. In agreeing on the Transition Plan, the Transition Committee shall incorporate the Joint Trial Plan and the Technology Transfer Plan as discussed and agreed by the applicable Subcommittee. Such plan, as approved by the Transition Committee, in whole or in part, is referred to herein as the "Transition Plan." The Transition Committee may review and approve any portion or component of such plan independently, and once approved by the Transition Committee, each such portion or component shall be regarded as part of the "Transition Plan" hereunder. Once approved, the Transition Plan may only be amended by mutual agreement of the Parties through the Transition Committee (or, with respect to the Joint Trial Plan and Technology Transfer Plan, the applicable Subcommittee). Each Party shall use Commercially Reasonable Efforts to perform their respective activities under the Transition Plan in accordance with the schedules and timetables thereunder. No breach or alleged breach by a Party of its obligations under the Transition Plan shall excuse the performance by the other Party of its obligations under the Transition Plan to the extent such obligations may be performed in accordance with the material terms and conditions of this Agreement and Applicable Law.

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- (b) Within [\*\*\*] days following the applicable Regulatory Filing Transfer, the Parties shall transition the Extension Study from Novartis to Pharming, including with respect to the applicable Site Agreement and by transferring sponsorship and operational control with respect to the relevant trial site, on a country-by-country or trial site-by-trial site basis as of the applicable Extension Study Transition Date in accordance with the Transition Plan, standard industry practice and Applicable Law. Such transition shall be mutually agreed by and subject to the oversight and input of the Alliance Managers and the JCT. From and after the Extension Study Transition Date on a country-by-country or trial site-by-trial site basis, Pharming (i) shall be the sponsor of the Extension Study, and (ii) shall, at its own cost and expense, manage, conduct, and perform the Extension Study in a good scientific manner and in compliance with Applicable Law until at least the date of the First Commercial Sale of Licensed Product in the relevant country and the completion of the Extension Study as defined in the Extension Study Protocol.
- (c) Within [\*\*\*] days following the Extension Study Transition Date on a country-by-country or trial site-by-trial site basis, as mutually agreed by the JCT, Novartis shall provide or cause to be provided to Pharming subject to Section 4.1 a copy (in electronic format if available in electronic format, or hard copy if not available in electronic format) of any Trial Data not previously provided to Pharming.

5.8 **Named Patient and Compassionate Use.** Not later than the Completion of Technology Transfer and the transfer of the applicable IND(s) to Pharming, Pharming will assume responsibility, at its sole cost and expense, for the supply of Licensed Products for any post-trial access, compassionate use, named patient, or similar programs involving Licensed Product existing as of the Effective Date or arising in connection with the Ongoing Trial or Extension Study; *provided*, that Pharming shall be responsible, at its sole cost and expense, for the supply of Licensed Products for any such programs initiated following the Effective Date at Pharming's request. Prior to the Final Transfer Date, Pharming may not initiate any such program without the prior written consent of Novartis, not to be unreasonably withheld. To the extent reasonably requested by Novartis and set forth in the Transition Plan, or otherwise mutually agreed by the Parties, any agreements between Novartis or its Affiliate and one or more Third Parties relating to such managed access programs ("MAP Agreements") shall be assigned or transferred to Pharming or its designee pursuant to the Ancillary Agreement.

5.9 **Assignment of Third Party Agreements.**

- (a) In connection with the rights and licenses granted hereunder, the Parties shall execute and deliver as of the Effective Date an Assignment and Assumption Agreement in the form of Exhibit F pursuant to which Novartis shall assign to Pharming and Pharming shall assume all of Novartis' rights and obligations under the [\*\*\*]. From and after the Effective Date, Pharming shall be responsible at its sole cost and expense for the performance of Novartis' obligations under the [\*\*\*].
- (b) Within [\*\*\*] days after the Parties first mutually agree on a Transition Plan (or such other date mutually agreed by the Transition Committee), the Parties will execute or cause to be executed an ancillary agreement between the Parties or their

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Affiliates (the “Ancillary Agreement”) regarding the assignment or transfer to Pharming or its designee, to the extent transferable, or other disposition of the Site Agreements, the MAP Agreements, and any other Third Party agreements relating to the Licensed Compound or Licensed Products mutually agreed by the Parties in the Transition Plan or otherwise in writing to be assigned or transferred to Pharming or its designee. The timing of and any conditions precedent for the assignment or transfer of such agreements shall be set forth in the Ancillary Agreement. If, after the effective date of the Ancillary Agreement, the Parties, through their Alliance Managers and the JCT, mutually agree that additional related agreements should be assigned or transferred to Pharming or its designee, the Parties shall amend the Ancillary Agreement to include such additional agreements.

**5.10 Priority Review Voucher.**

- (a) If following the Effective Date Pharming or its Affiliate or Sublicensee receives a Priority Review Voucher in connection with its or their Development of the Licensed Compound or a Licensed Product, Pharming shall promptly notify Novartis in writing (a “PRV Notice”). Within [\*\*\*] days of Novartis’ receipt of the PRV Notice, Novartis may elect by written notice to Pharming to purchase the Priority Review Voucher (a “PRV Purchase”). The consideration to be paid by Novartis to Pharming or its designee in connection with a PRV Purchase (“PRV Consideration”) shall equal: [\*\*\*]. The PRV Consideration shall be paid to Pharming or its designee promptly following its determination in accordance with the terms of the PRV Documents.
- (b) The sale and transfer of a Priority Review Voucher to Novartis or its designee pursuant to Section 5.10(a) shall be consummated pursuant to documents and instruments mutually agreed between Novartis and Pharming which shall be consistent with terms and conditions customary in the industry for the purchase and sale of Priority Review Vouchers save for the PRV Consideration and provisions related thereto (the “PRV Documents”). If Novartis exercises its option to purchase a Priority Review Voucher under Section 5.10(a), Novartis and Pharming shall negotiate in good faith and seek to agree on the form and substance of PRV Documents consistent with the terms of this Agreement within [\*\*\*] days of Novartis’ election. In the event the Parties do not execute and deliver PRV Documents within such [\*\*\*] day period, either Party may refer such matter for resolution in accordance with the dispute resolution procedures contained in Section 15.5.

**6. MATERIAL TRANSFER; MANUFACTURING**

- 6.1 **Initial Transfer of CDZ173 Material.** Subject to Section 6.4, promptly following the Effective Date and on the timetable set forth on Exhibit D-1, Novartis will make available for pick-up [\*\*\*] the CDZ173 Materials specifically identified on Exhibit D-1, in the form and quantities set forth on Exhibit D-1 and as such CDZ173 Material then exists, from Novartis’ facilities where such CDZ173 Material is currently stored as identified on Exhibit D-1. The pickup of the CDZ173 Material must be completed within [\*\*\*] days after the date that Novartis notifies Pharming that such CDZ173 Material is available for pick up (or within [\*\*\*] days if Novartis delivers such notice within [\*\*\*] days after the Effective Date).

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6.2 **Clinical Supply of CDZ173 Material.**

- (a) Following the Effective Date, Novartis shall be entitled to retain and maintain (in its own possession and Control or in the possession of an Affiliate or Third Party including clinical trial sites) the CDZ173 Material set forth on **Exhibit D2** (the “Existing Clinical Supply”) for use in the Ongoing Trial and the Extension Study. For clarity, Novartis and its Affiliates shall have no obligation under this Agreement to manufacture or have manufactured any Licensed Compound or Licensed Products following the Effective Date. If prior to the Completion of Technology Transfer, Pharming requires assistance in connection with the manufacture of CDZ173 or the Lead Product Novartis shall consider such request in good faith.
- (b) Pursuant to its obligations under Section 5.1(a) and Section 5.2(a), Novartis will supply or cause to be supplied Licensed Products (i) for the Ongoing Trial until the Completion of the Ongoing Trial, and (ii) for the Extension Study until the Extension Study Transition Date on a country-by-country or trial site-by-trial site basis, in each case ((i) and (ii)), from the Existing Clinical Supply. Without limiting any obligations of Novartis under this Agreement with respect to the transfer of Manufacturing Technology contemplated by Section 6.7, the Parties acknowledge and agree that Novartis’ obligations under this Agreement with respect to the supply of Licensed Product, including for the Ongoing Trial and Extension Study, will be satisfied by the Existing Clinical Supply.
- (c) Novartis warrants, represents and undertakes that: (i) all CDZ173 Material delivered to Pharming or its designee will on delivery to Pharming or such designee conform to Applicable Law, the terms of any applicable Quality Assurance Agreement, and the Specifications, and shall be accompanied with the related certificate of analysis and certificate of compliance; and (ii) without limiting the foregoing, it shall, and shall procure that its Affiliates and their respective subcontractors shall, comply and have complied with all Applicable Law (including GMP) in manufacturing, handling and storing the CDZ173 Materials (the “Product Warranty”).

6.3 **Transfer of Remaining Clinical Supply of CDZ173 Material.**

- (a) Following the Completion of the Ongoing Trial and the Extension Study Transition Date on a country-by-country or trial site-by-trial site basis, Novartis shall transfer or cause to be transferred to Pharming or its designee, to the extent Pharming requests such transfer, any then-remaining unused portion of the CDZ173 Material set forth on **Exhibit D-2** that is not necessary or useful for Novartis in the performance of its obligations under this Agreement. The timing, documentation and process for the transfer of such CDZ173 Material shall be mutually agreed in the Transition Plan and shall comply with all Applicable Laws. Novartis may destroy any such CDZ173 Material not requested by Pharming at its own discretion.



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- (b) Without limiting the foregoing, the Transition Committee and the Parties' Alliance Managers will oversee and coordinate the transfer of such CDZ173 Material as contemplated by this Section 6.3 in accordance with the Transition Plan and in a manner that permits Novartis to comply with its Development and transfer obligations under this Agreement on a prompt and orderly basis in accordance with all Applicable Laws.
- (c) Prior to the delivery of CDZ173 Material to Pharming or its designee or its destruction in accordance with this Article 6, the Specifications for such CDZ173 Material shall be determined by Novartis in accordance with Applicable Law.
- 6.4 **Quality Assurance Agreements.** Upon the reasonable request of either Party and prior to the supply or delivery of any CDZ173 Material to Pharming or its designee, the Parties or their Affiliates shall enter into one or more Quality Assurance Agreements containing customary terms with respect to the CDZ173 Material or any other Licensed Compound or Licensed Product supplied by or on behalf of Novartis under this Agreement.
- 6.5 *EXCEPT WITH RESPECT TO THE PRODUCT WARRANTY AND THE WARRANTIES SET OUT IN ARTICLE 13, NOVARTIS AND ITS AFFILIATES HEREBY EXPRESSLY DISCLAIM ANY AND ALL WARRANTIES WITH RESPECT TO THE CDZ173 MATERIAL, INCLUDING ANY IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.*
- 6.6 **\*\*\*] Manufacturing and Supply.** From and after the Effective Date and except as expressly provided in this Article 6 or the Transition Plan, **\*\*\*]** will be solely responsible for and shall, subject to the terms of this Agreement, have final decisionmaking authority with respect to **\*\*\*]**.
- 6.7 **Technology Transfer.** To the extent not previously provided or made available to Pharming, the Technology Transfer Plan shall provide for (a) a technology transfer of the Manufacturing Technology from or on behalf of Novartis to Pharming or its designee intended to enable Pharming to have manufactured drug substance for the Lead Product through a Third Party contract manufacturer selected by Pharming and reasonably acceptable to Novartis who shall be engaged by Pharming or its Affiliate in accordance with Applicable Law and (b) the collaborative activities of the Parties necessary to effect such transfer. The Technology Transfer Plan shall provide for the initiation of such technology transfer no later than **\*\*\*]** days following the Effective Date (unless otherwise mutually agreed by the Parties or the STT) and describe in reasonable detail the activities and the associated timelines to be undertaken by the Parties and their Affiliates in furtherance of such technology transfer through such time as Pharming has manufactured **\*\*\*]** in accordance with Applicable Law. Pharming will and will cause its contract manufacturer to use Commercially Reasonable Efforts to complete such technology transfer as soon as reasonably practicable, but not later than **\*\*\*]** months following the Effective Date, or otherwise in accordance with timelines mutually agreed in the Technology Transfer Plan. Novartis will provide reasonable assistance and support for such technology transfer in good faith, and each Party will use Commercially Reasonable Efforts to perform its activities under the Technology Transfer Plan in accordance with the schedules and timetables thereunder as provided in Section 5.7, in each case, until the Completion of Technology

Transfer, but, for clarity, Novartis and its Affiliates will have no liability for any delay or failure to consummate such technology transfer resulting from acts or omissions of Pharming, its Affiliates, their Sublicensees, or any Third Party. The STT and the Parties' Alliance Managers will oversee and coordinate the transfer of such Manufacturing Technology as contemplated by this Section 6.7 in accordance with the Technology Transfer Plan.

## 7. COMMERCIALIZATION

- 7.1 **Commercialization.** [\*\*\*] will be solely responsible for [\*\*\*].
- 7.2 **Efforts.** [\*\*\*] will itself, or through its Affiliates or Sublicensees, use Commercially Reasonable Efforts to Commercialize at least one Licensed Product in (i) [\*\*\*], (ii) [\*\*\*], and (iii) [\*\*\*].

## 8. FINANCIAL PROVISIONS

- 8.1 **Upfront Payment by Pharming.** Pharming will make a one-time, nonrefundable payment to Novartis in the amount of Twenty Million and 00/100 U.S. Dollars (USD \$20,000,000.00) via wire transfer within fifteen (15) days after the Effective Date.
- 8.2 **Development and Regulatory Milestone Payments.**
- (a) In further consideration of the rights and licenses granted to Pharming hereunder, upon achievement of each of the Development and regulatory Milestones set forth below by or on behalf of Pharming, its Affiliates or Sublicensees, the corresponding Milestone Payments will be payable to Novartis in USD:

<u>Milestone</u>	<u>Milestone Payment (USD)</u>
[***]	[***]
[***]	[***]
[***]	[***]

- (b) Each Milestone Payment in the table above will be paid only once and will be deemed earned as of the first achievement of the corresponding Milestone by the

first Licensed Product. Pharming will provide Novartis with written notice of the achievement of each Milestone within [\*\*\*] days after such Milestone is achieved by or on behalf of Pharming, its Affiliates or their respective Sublicensee(s), and the relevant Milestone Payment will be paid by Pharming within [\*\*\*] days after the relevant Milestone is achieved.

8.3 **Sales Milestone Payments.**

- (a) Pharming will make each of the following one time Milestone Payments for sales (the “Sales Milestone Payments”) when worldwide, aggregate Net Sales of Licensed Products by or on behalf of Pharming, its Affiliates or Sublicensees in a given Calendar Year first meets the corresponding Net Sales thresholds set forth in the chart below (such thresholds, the “Sales Milestones”):

<u>Calendar Year Net Sales Milestones (in USD)</u>	<u>Sales Milestone Payment (in USD)</u>
<u>First time annual Net Sales of Licensed Products exceed [***]</u>	[***]
<u>First time annual Net Sales of Licensed Products exceed [***]</u>	[***]
<u>First time annual Net Sales of Licensed Products exceed [***]</u>	[***]
<u>First time annual Net Sales of Licensed Products exceed [***]</u>	[***]
<u>First time annual Net Sales of Licensed Products exceed [***]</u>	[***]
<u>First time annual Net Sales of Licensed Products exceed [***]</u>	[***]

- (b) Each Sales Milestone Payment in the table above will be paid only once, and will be deemed irrevocably earned as of the first achievement of the corresponding Sales Milestone. If more than one unmet Sales Milestone is achieved in a given Calendar Year, a Sales Milestone Payment will be made with respect to the highest unmet Sales Milestone achieved in such Calendar Year in accordance with the following sentence, and a Sales Milestone Payment will be made with respect to each lesser included Sales Milestone within [\*\*\*] days after the anniversary of such payment, one Sales Milestone Payment per Calendar Year, until all earned Sales Milestone Payments have been made. Pharming will provide Novartis with written notice of the achievement of each Sales Milestone within [\*\*\*] days after such Sales Milestone is achieved by or on behalf of Pharming, its Affiliates or their respective Sublicensee(s), and the corresponding Sales Milestone Payment will be paid by Pharming within [\*\*\*] days after the Calendar Year in which the relevant Sales Milestone is achieved.

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8.4 **Royalty Payments.**

- (a) **Royalty Rates.** During the applicable Royalty Term, Pharming will make royalty payments to Novartis based on Calendar Year Net Sales of Licensed Products in the Territory by Pharming, its Affiliates and Sublicensees at the applicable rates set forth below.

<u>Calendar Year Net Sales of Licensed Products in the Territory</u>	<u>Royalty Rate</u>
Portion of Net Sales less than or equal to [***]	[***]
Portion of Net Sales greater than [***] and less than or equal to [***]	[***]
Portion of Net Sales greater than [***]	[***]

- (b) Royalties will be payable on a Licensed Product-by-Licensed Product and country-by-country basis during the Royalty Term for each such Licensed Product in such country. After the expiration of the applicable Royalty Term for a Licensed Product in a country, the licenses granted to Pharming pursuant to this Agreement with respect to such Licensed Product in such country will continue in effect, but will become fully paid-up, royalty-free, transferable, perpetual and irrevocable, and the Net Sales for such Licensed Product in such country will be excluded from Section 8.4(a).
- (c) If, during the Royalty Term, on a country-by-country basis, the relevant Licensed Product is (i) not Covered by a Valid Claim in the applicable country, or (ii) there is a Loss of Market Exclusivity in such country, then for so long as there is (1) no such Valid Claim in such country during the Royalty Term, or (2) there is a Loss of Market Exclusivity in such country during the Royalty Term, then the royalty rates in such country for such Licensed Product will be reduced to [\*\*\*] of the rates set forth in the table above. If this clause (c) applies, Net Sales for the affected Licensed Product(s) shall continue to be aggregated with other Net Sales in the Territory for assessing the annual Net Sales thresholds for each royalty tier; *provided*, that for purposes of determining the royalty rate applicable to Net Sales of the affected Licensed Product(s) and calculating the royalties payable hereunder, the Net Sales for such affected Licensed Product(s) shall be deemed to have been distributed among each applicable royalty tier in the same proportion as the Net Sales of nonaffected Licensed Product(s) are distributed among each applicable royalty tier in such Calendar Year.
- (d) In the event Pharming, its Affiliate or Sublicensee make a good faith determination that Third Party Patent Rights are required to practice the Licensed IP or to

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Develop, manufacture, or Commercialize CDZ173 or [\*\*\*] under this Agreement, Pharming shall promptly notify Novartis in writing. The Parties shall thereafter discuss the facts and circumstances related to such Third Party Patent Rights in good faith, and Pharming shall provide to Novartis copies of such documents and information related to such Third Party Patent Rights or the activities of Pharming, its Affiliates or Sublicensees as Novartis may reasonably request. If Novartis agrees that both (A) such Third Party Patent Rights are necessary to Develop, manufacture, or Commercialize CDZ173 or the Lead Product under this Agreement, and (B) the royalty reduction contemplated by this Section 8.4(d) should apply, then:

- (i) Novartis shall promptly notify Pharming in writing of such determination;
- (ii) Pharming, its Affiliate or Sublicensee may enter into an in-license or otherwise acquire from a Third Party such Patent Rights that Cover CDZ173 or a Lead Product in any country (a "Third Party License") (provided that Novartis shall be afforded a reasonable period of time to review and comment on the proposed form of any such Third Party License and Novartis shall have approved in writing the final form and substance of such Third Party License prior to its execution and delivery by Pharming, its Affiliate or Sublicensee); and
- (iii) in any Calendar Quarter during which royalties are payable to Novartis under Section 8.4(a) Pharming shall be entitled to offset, against such royalties payable to Novartis, [\*\*\*] (or such other percentage as the Parties may agree in writing) of the amounts payable by Pharming, such Affiliate or Sublicensee (as applicable) under such Third Party License on account of the sale of such Licensed Product in such country in such Calendar Quarter to the extent such payments relate to the practice of the Licensed IP, in each case, subject to Section 8.4(e); *provided*, that any such amount not offset against royalties payable to Novartis under this Agreement on account of Section 8.4(e) shall be carried forward to the next Calendar Quarter(s) until such amounts have been fully offset.

In the event of any Dispute between the Parties regarding the extent to which payments under a Third Party License relate to the practice of Licensed IP, in lieu of resolving such Dispute pursuant to Section 15.5, [\*\*\*] shall be entitled to revoke its consent to such Third Party License and the application of the royalty reduction in this Section 8.4(d). For the avoidance of doubt, (1) no reduction to royalties payable to Novartis may be made under this Section 8.4(d) without the prior written consent of Novartis (including with respect to the final form and substance of any proposed Third Party License), (2) Novartis shall have no obligation under this Agreement or otherwise to consent to the entry into any Third Party License or a reduction of royalties under this Section 8.4(d), and (3) nothing in this Section 8.4(d) shall prevent Pharming, its Affiliate or Sublicensee from entering into any Third Party License without the prior written consent of Novartis.

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- (e) Notwithstanding anything else contained herein to the contrary, in no event will any royalty payment due to Novartis from Pharming during any Calendar Quarter be reduced by [\*\*\*] of the royalty rates set forth in the table in Section 8.4(a) through the operation of Section 8.4(c), Section 8.4(d), or any other reduction hereunder.
  - (f) Within [\*\*\*] days after each Calendar Quarter during the Agreement Term after the First Commercial Sale of a Licensed Product, Pharming will provide a Sales & Royalty Report to Novartis. Novartis will submit an Invoice to Pharming with respect to the royalty amount shown therein. Pharming will pay such royalty amount within [\*\*\*] days after receipt of the Invoice.

8.5 **Development Cost Reimbursement to Novartis.** Within [\*\*\*] days after each Calendar Quarter during which Novartis or its Affiliates incurred Development Costs, Novartis shall provide Pharming with a report setting forth the amount of Development Costs incurred by or on behalf of Novartis or its Affiliates in such Calendar Quarter. Pharming shall be obligated to reimburse Novartis for such Development Costs by payment of such amount to Novartis within [\*\*\*] days after receipt of such report, provided that the aggregate amount of Development Costs to be reimbursed by Pharming under this Agreement shall not exceed the Budget Cap.

8.6 **Payments.**

- (a) All payments from Pharming to Novartis will be made by wire transfer in USD to the credit of such bank account as may be designated by Novartis in this Agreement or in writing to Pharming. Any payment which falls due on a date which is not a business day in the location from which the payment may be made shall occur on the next succeeding business day in such location. Unless otherwise provided in this Agreement, all payment terms will be net [\*\*\*] days. For the avoidance of doubt, Novartis may deliver an invoice for a Milestone Payment payable under this Agreement prior to its receipt of a corresponding Milestone notice, and the failure of Pharming to deliver a Milestone notice in accordance with this Agreement will have no effect on Pharming's obligation to pay the corresponding Milestone Payment.
- (b) All payments under this Agreement will be payable in USD. When conversion of payments from any foreign currency is required to be undertaken by Pharming, the US Dollar equivalent will be calculated using Pharming's then current standard exchange rate methodology as applied in its external reporting. If there is no standard exchange rate methodology applied by Pharming in its external reporting in accordance with Pharming's Accounting Standards, then any amount in a currency other than USD shall be converted to US Dollars using the exchange rate most recently quoted in the *Wall Street Journal* in New York as of the last business day of the applicable Calendar Quarter.
- (c) Novartis will pay any and all taxes levied on account of any payments made to it under this Agreement. If any taxes are required to be withheld by Pharming, Pharming will: (i) deduct such taxes from the payment made to Novartis; (ii) timely pay the taxes to the proper taxing authority; (iii) send proof of payment to

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Novartis; and (iv) reasonably assist Novartis in its efforts to obtain a credit for such tax payment. Each Party will reasonably assist the other Party in lawfully claiming exemptions from or minimizing such deductions or withholdings under double taxation laws or similar circumstances.

- (d) Without limiting any other rights or remedies available to Novartis hereunder, if Pharming does not pay any amount due on or before the due date, any such payment shall bear interest at a rate of [\*\*\*] on the date the payment was due or [\*\*\*], computed from the date such payment was due until the date Pharming makes the payment.

**8.7 Records and Audit Rights.**

- (a) Pharming will keep, and will cause its Affiliates and Sublicensees to keep, complete, true and accurate books and records in accordance with its Accounting Standards in relation to Milestones, Net Sales and royalties payable to Novartis hereunder with respect to the Licensed Compound and Licensed Products. Pharming will keep, and will cause its Affiliates, licensees and Sublicensees to keep, such books and records for at least [\*\*\*] years after the Calendar Quarter to which they pertain.
- (b) Novartis may, upon written notice to Pharming, appoint an internationally recognized independent accounting firm (which is reasonably acceptable to Pharming) (the “Auditor”) to inspect the relevant reports, statements, records or books of accounts (as applicable) of Pharming or its Affiliates, licensees or Sublicensees to verify the accuracy of any Sales & Royalty Report. Before beginning its audit, the Auditor will execute an undertaking reasonably acceptable to Pharming by which the Auditor will keep confidential all Confidential Information reviewed during such audit. The Auditor will only have the right to disclose to Novartis its conclusions regarding any payment owed under this Agreement.
- (c) Pharming will, and will cause its Affiliates and Sublicensees to, make their records available for inspection by such Auditor during regular business hours at such place or places where such records are customarily kept, upon receipt of reasonable advance notice from Novartis. The records will be reviewed solely to verify the accuracy of the Sales & Royalty Reports. Such inspection right will not be exercised more than [\*\*\*] in any Calendar Year and not more frequently than once with respect to records covering any specific period of time. In addition, Novartis will only be entitled to audit the relevant books and records of Pharming relating to a Sales & Royalty Report for a period of [\*\*\*] Calendar Years after receipt of the applicable Sales & Royalty Report. Novartis will hold in confidence all Confidential Information received and all Confidential Information learned in the course of any audit or inspection, except to the extent necessary to enforce its rights under this Agreement or if disclosure is required by Applicable Law.
- (d) The Auditor will provide its audit report and basis for any determination to Pharming at the time such report is provided to Novartis, before it is considered

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final. Pharming will have the right to request a further determination by such Auditor as to matters which Pharming disputes within [\*\*\*] days after receipt of such report. Pharming will provide Novartis and the Auditor with a reasonably detailed statement of the grounds upon which it disputes any findings in the audit report and the Auditor will undertake to complete such further determination within [\*\*\*] days after the dispute notice is provided, which determination will be limited to the disputed matters. Any matter that remains unresolved will be resolved in accordance with the dispute resolution procedures contained in Section 15.5.

- (e) If the final result of the inspection reveals an undisputed underpayment or overpayment by Pharming, the underpaid or overpaid amount will be settled promptly.
- (f) Novartis will pay for any such audits, as well as its own expenses associated with enforcing its rights with respect to any payments hereunder, except that if there is an upward adjustment in aggregate amounts payable for any Calendar Quarter shown by such audit of more than [\*\*\*] of the amount paid, Pharming will pay for such audit.

8.8 **No Projections.** Novartis and Pharming acknowledge that nothing in this Agreement will be construed as representing an estimate or projection of anticipated sales of any Licensed Product, and that the Milestones and Net Sales levels set forth above or elsewhere in this Agreement or that have otherwise been discussed by the Parties are merely intended to define the Milestone Payments and royalty obligations to Novartis if the applicable Milestones or Net Sales levels are achieved. *PHARMING MAKES NO REPRESENTATION OR WARRANTY, EITHER EXPRESS OR IMPLIED, THAT IT WILL BE ABLE TO SUCCESSFULLY COMMERCIALIZE ANY LICENSED PRODUCT OR, IF COMMERCIALIZED, THAT ANY PARTICULAR NET SALES LEVEL OF SUCH LICENSED PRODUCT WILL BE ACHIEVED.*

## 9. Intellectual Property.

- 9.1 **Inventions and Know-How.** All inventions, whether or not reduced to practice, KnowHow and other forms of intellectual property rights arising from a Party's activities under this Agreement, including activities conducted by or on behalf of such Party, its Affiliates or sublicensees, and any Patent Rights claiming such inventions that arise from such activities after the Effective Date, will be owned by such Party; *provided*, that in the case of any such inventions, Know-How and other forms of intellectual property rights generated by or on behalf of the Parties jointly (including by their respective Affiliates or sublicensees on their behalf) (such inventions, Know-How, and other forms of intellectual property rights, the "Joint Arising IP"), will be owned by the Parties jointly, in each case, subject to the rights and licenses granted hereunder (as applicable). The inventorship or creation of any such Patent Rights, Know-How, or other forms of intellectual property rights arising from a Party's activities under this Agreement will be determined under and in accordance with the Applicable Laws of the United States governing the inventorship or creation of Patent Rights.
- 9.2 **Ownership of Results and Data.** All data and results arising from a Party's activities under this Agreement, including activities conducted by or on behalf of such Party, its Affiliates or



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sublicensees, including Development, clinical and regulatory data and information generated for regulatory purposes relating to Licensed Compound or Licensed Product will be owned by such Party, subject to the rights and licenses granted hereunder (as applicable).

**9.3 Patent Prosecution and Maintenance After the Effective Date.**

- (a) Pharming will control the filing, prosecution and maintenance of the Licensed Patents at Pharming's sole cost and expense, using counsel reasonably acceptable to Novartis. Novartis will, and will cause its Affiliates, to reasonably cooperate with Pharming with respect to all matters regarding the filing, prosecution, and maintenance of the Licensed Patents anywhere throughout the world, including without limitation, communicate to Pharming any facts known to Novartis or its Affiliates respecting the invention, to have executed all lawful documents and provide oaths and declarations relating to the invention, including those which are reasonable or necessary to establish patentability, have executed and delivered any and all papers that may be necessary or desirable to perfect the title to the invention, and have employees testify in any judicial or administrative proceeding, in each case, as reasonably requested so to do by Pharming.
- (b) Pharming will keep Novartis informed of matters relating to the filing, prosecution and maintenance of the Licensed Patents, and will provide Novartis with copies of documents relevant to such prosecution and maintenance in sufficient time for Novartis to review and comment thereon in accordance with this Section 9.3. With respect to communications issued by patent offices concerning the Licensed Patents, Pharming will notify Novartis of said communications no later than [\*\*\*] days after their issuance. With respect to documents to be filed at patent offices concerning Licensed Patents, Pharming will notify Novartis no later than [\*\*\*] days prior to the filing of such documents to allow for review and comment by Novartis. To allow the Parties sufficient time to confer and prepare filings, Novartis shall provide to Pharming such review and comment, and any information or documentation relating to Section 9.3(a) above, no later than [\*\*\*] days prior to Pharming's intended filing date. Pharming will reasonably consider all of Novartis' comments in good faith. Pharming will notify Novartis of any decision not to continue to pay the expenses of prosecution and maintenance of any Licensed Patent, which notice must be delivered at least [\*\*\*] days prior to any payment due date or the relevant action's due date. If Pharming determines not to continue to pay the expenses of prosecution and maintenance of any Licensed Patent, then Novartis, at its sole discretion, shall have the right to continue the prosecution and maintenance of such Licensed Patent in such country. If Novartis undertakes such prosecution and maintenance, (a) Pharming will provide Novartis with all reasonable assistance and cooperation in relation thereto, including providing any necessary powers of attorney and any other required documents or instruments to effect such transfer, (b) Novartis will be solely responsible for the expenses of such prosecution and maintenance, and (c) the licenses granted to Pharming to such Licensed Patent in such country shall thereupon terminate.

**9.4 Third Party Infringement.**

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- (a) Each Party will promptly notify the other of any infringement by a Third Party of any of the Licensed Patents or misappropriation of any Licensed Know-How of which it becomes aware, including any filing of an Abbreviated New Drug Application (“ANDA”) in the United States or such similar filing under Applicable Law in jurisdictions other than the United States. Each Party shall provide the other Party with all available evidence supporting such infringement, suspected infringement, unauthorized use or misappropriation or suspected unauthorized use or misappropriation (collectively, “Third Party Infringement”).
  - (b) Pharming will have the first right to bring and control any legal action in connection with the Third Party Infringement relating to any Licensed Patent at its own expense as it reasonably determines appropriate, and Novartis will have the right, at its own expense, to be represented in any such action by counsel of its own choice. If Pharming fails to bring an action or proceeding with respect to such Third Party Infringement of any Licensed Patent (i) within [\*\*\*] days after the notice of alleged infringement (or [\*\*\*] days after Pharming receives the relevant ANDA notification), or (ii) prior to [\*\*\*] days before the time limit, if any, set forth in the Applicable Laws for the filing of such actions, whichever occurs first, Novartis will have the right to bring and control any such action at its own expense and by counsel of its own choice, and Pharming will have the right, at its own expense, to be represented in any such action by counsel of its own choice.
  - (c) At the request of the Party controlling the Third Party Infringement claim, the other Party will provide assistance in connection therewith, and will cause its Affiliate, as applicable, to provide such assistance, including by executing reasonably appropriate documents, access to such Party’s or its Affiliates’ employees, cooperating reasonably in discovery and joining as a party to the action if required, testifying in any proceeding, in each case, as reasonably requested so to do by such Party.
  - (d) In connection with any such proceeding, neither Party will enter into any settlement admitting the invalidity of, or otherwise impairing such Party’s rights in, the Licensed IP without the prior written consent of the other Party, which will not be unreasonably withheld or delayed.
  - (e) Any recoveries resulting from such an action relating to a Third Party Infringement will be first applied against payment of each Party’s costs and expenses in connection therewith. If Pharming brought such action, the remainder of such recoveries will be [\*\*\*]; *provided*, that any such amount will be considered Net Sales hereunder and will be subject to the payment of royalties and Sales Milestone Payments (as applicable) to Novartis under this Agreement. If Novartis brought such action, the remainder of such recoveries will be [\*\*\*].

9.5 **Third Party Patent Invalidation Claim.** If a Third Party at any time asserts a claim that any Licensed Patent is invalid or otherwise unenforceable (an “Invalidity Claim”), whether as a defense in an infringement action brought by a Party pursuant to Section 9.4, in a declaratory judgment action or any patent office proceeding anywhere in the world (*e.g.*, inter-partes review or European opposition), Pharming shall have the first right, but not the obligation,

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to defend such Invalidity Claim and Novartis shall cooperate with Pharming in preparing and formulating a response to such Invalidity Claim and provide the assistance set forth in Section 9.4(c). If Pharming does not defend an Invalidity Claim brought against a Licensed Patent, Novartis may defend such Invalidity Claim and the coordination provisions of Section 9.4(c) will apply to such Invalidity Claim, *mutatis mutandis* as they apply to Third Party Infringement suits. No Party may, without the consent of the other Party, settle or compromise any Invalidity Claim in any manner which would (a) [\*\*\*] or (b) [\*\*\*] (*provided, however,* that the Party asserting or defending such suit may settle such suit without such consent if [\*\*\*]). To the extent an Invalidity Claim is raised as a defense in an infringement action brought by a Party pursuant to Section 9.4, the expense provisions of Section 9.4 will apply and counsel to the Party controlling the infringement action shall act as the ministerial liaison with the court.

- 9.6 **Pharming Patent Invalidity Claim.** The Parties have determined the value of the Licensed IP based on their understanding of the validity and enforceability of the relevant Licensed Patents and Licensed Know-How. If Pharming at any time asserts an Invalidity Claim in a declaratory judgment action or any patent office proceeding anywhere in the world against a Licensed Patent (excluding any such Invalidity Claim to the extent resulting from a requirement by legal process for Pharming to be joined as a party in such proceedings first initiated by a Third Party, or any proceedings first initiated by Novartis or its Affiliates against Pharming, its Affiliates or Sublicensees, in connection with Pharming's, its Affiliates' or Sublicensees' activities) and such challenge does not result in a material diminution of the scope of the relevant Licensed Patent, i.e., to exclude CDZ173 from its scope, then the terms of this Agreement shall continue in full force and effect, but all payment amounts set forth in Section 8.2, Section 8.3, Section 8.4 and Section 8.5 shall be [\*\*\*].
- 9.7 **Defense of Infringement Claims of Licensed IP.** If any Third Party asserts a claim, demand, action, suit or proceeding against a Party (or any of its Affiliates), alleging that any Licensed Product or the use or practice of the Licensed IP infringes, misappropriates or violates the intellectual property rights of any Person (any such claim, demand, action, suit or proceeding being referred to as an "**Infringement Claim**"), the Party first having notice of the Infringement Claim shall promptly notify the other Party thereof in writing specifying the facts, to the extent known, in reasonable detail and the following shall apply:
- (a) In the case of any such Infringement Claim against either Party individually or against both Novartis and Pharming, in each case, with respect to the Licensed Product, [\*\*\*] shall assume control of the defense of such Infringement Claim. Novartis, upon request of Pharming and if required by Applicable Law, will join in any such litigation at Pharming's expense, and in any event will reasonably cooperate with Pharming at Pharming's expense. Novartis will have the right to consult with Pharming concerning such Infringement Claim and to participate in and be represented by independent counsel in any litigation in which Pharming is a party, at its own expense. Pharming shall not have the right to settle any Infringement Claim without the written consent of Novartis.
  - (b) During the period in which such Infringement Claim is pending and following the resolution thereof, [\*\*\*] shall bear all costs incurred in connection therewith (including litigation costs, attorneys' fees, costs of settlement) including damage awards, and any other payment resulting therefrom.

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9.8 **Trademarks.** Pharming will have the right to brand the Licensed Products using Pharming related trademarks and any other trademarks and trade names it Controls and determines appropriate for Licensed Products, which may vary by country or within a country (“**Product Marks**”). Pharming will own all rights in the Product Marks and register and maintain the Product Marks in the countries and regions it determines reasonably necessary.

9.9 **Patent Extensions.**

- (a) If requested by Pharming and at Pharming’s cost, Novartis will cooperate in obtaining patent term restoration (including under the Drug Price Competition and Patent Term Restoration Act), supplemental protection certificates or their equivalents, and patent term extensions with respect to Licensed Patents in any country or region where applicable. At Pharming’s cost, Novartis will provide all reasonable assistance requested by Pharming, including permitting Pharming to proceed with applications for such in the name of Novartis, if deemed appropriate by Pharming, and executing documents and providing any relevant information to Pharming.
- (b) As between the Parties, Pharming shall have the first right to determine whether or not to seek a patent term restoration, supplemental protection certificates or their equivalents, and patent term extensions with respect to Licensed Patents in any country or region where applicable. If Pharming decides not to apply for such extension with respect to a Licensed Patent, Pharming will provide Novartis with at least [\*\*\*] days’ notice prior to the relevant application deadline, and Novartis will have the right to apply to extend the term of such Licensed Patent at its cost; *provided, however*, that Novartis will give Pharming prior written notice before doing so, with sufficient time for Pharming to provide its input which shall be considered in good faith by Novartis with respect to the extension of any Licensed Patents.

**10. CONFIDENTIALITY**

10.1 **Duty of Confidence.**

- (a) Subject to the other provisions of this Article 10, all Confidential Information disclosed by a Party or its Affiliates under this Agreement will be maintained in confidence and otherwise safeguarded by the recipient Party. The recipient Party may only use the Confidential Information for the purposes of this Agreement and pursuant to the rights granted to the recipient Party under this Agreement. Subject to the other provisions of this Article 10, each Party will hold as confidential such Confidential Information of the other Party or its Affiliates in the same manner and with the same protection as such recipient Party maintains its own confidential information. Subject to the other provisions of this Article 10, a recipient Party may only disclose Confidential Information of the other Party to employees, agents, contractors, consultants and advisers of the Party and its Affiliates and Sublicensees and to Third Parties to the extent reasonably necessary for the purposes of, and for those matters undertaken pursuant to, this Agreement; *provided*, that such Persons are bound to maintain the confidentiality of the

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Confidential Information in a manner consistent with the confidentiality provisions of this Agreement.

- (b) With respect to Novartis' obligations under this Article 10, the Licensed KnowHow, including the Manufacturing Technology, and the Trial Data will be considered Confidential Information of Pharming during the Agreement Term, and, subject to Section 10.4, Novartis will maintain in confidence and otherwise safeguard such Licensed Know-How, including the Manufacturing Technology, and Trial Data as such in accordance with this Article 10 (it being understood that the exception in Section 10.2(b) will not apply to Novartis with respect to Licensed Know-How, including the Manufacturing Technology, and Trial Data).

10.2 **Exceptions.** The obligations under this Article 10 will not apply to any information to the extent the recipient Party can demonstrate by competent evidence that such information:

- (a) is (at the time of disclosure) or becomes (after the time of disclosure) known to the public or part of the public domain through no breach of this Agreement by the recipient Party or its Affiliates;
- (b) was known to, or was otherwise in the possession of, the recipient Party or its Affiliates prior to the time of disclosure by the disclosing Party or any of its Affiliates;
- (c) is disclosed to the recipient Party or an Affiliate on a non-confidential basis by a Third Party who is entitled to disclose it without breaching any confidentiality obligation to the disclosing Party or any of its Affiliates; or
- (d) is independently developed by or on behalf of the recipient Party or its Affiliates, as evidenced by its written records, without reference to the Confidential Information disclosed by the disclosing Party or its Affiliates under this Agreement.

Specific aspects or details of Confidential Information will not be deemed to be within the public domain or in the possession of the recipient Party merely because the Confidential Information is embraced by more general information in the public domain or in the possession of the recipient Party. Further, any combination of Confidential Information will not be considered in the public domain or in the possession of the recipient Party merely because individual elements of such Confidential Information are in the public domain or in the possession of the recipient Party unless the combination and its principles are in the public domain or in the possession of the recipient Party.

10.3 **Authorized Disclosures.**

- (a) Neither Party shall issue any press release, trade announcement or make any other public announcement or statement with regard to the transactions contemplated by this Agreement without the other Parties' prior written consent.
- (b) In addition to disclosures permitted pursuant to Sections 10.1 and 10.2, either Party may disclose Confidential Information belonging to the other Party or its Affiliates to the extent such disclosure is necessary in the following instances: (i) filing or

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prosecuting Licensed Patents as permitted by this Agreement; (ii) in connection with Regulatory Filings for Licensed Products; (iii) prosecuting or defending litigation as permitted by this Agreement; (iv) complying with applicable court orders, governmental regulations, or the inquiries of Regulatory Authorities; (v) in connection with an offering of securities or securities law or listing organization disclosure requirements if counsel determines that such disclosure is required; or (vi) to the extent otherwise necessary or appropriate in connection with exercising its rights and licenses or performing its obligations under this Agreement. In addition to the foregoing, Pharming acknowledges that Novartis has previously provided Licensed Compound, Licensed Product, or Licensed Know-How to one or more academic institutions (the “Novartis Collaborators”) pursuant to material transfer or clinical trial agreements, and such academic institutions may have the right to publish information relating to the Licensed Compound, Licensed Products, or Licensed Know-How. Any such disclosure in accordance with Section 10.4 will not be deemed to be a breach of Novartis’ obligations of confidentiality hereunder.

- (c) If the recipient Party is required to disclose Confidential Information of the disclosing Party by law or in connection with a *bona fide* legal process, such disclosure will not be a breach of this Agreement; *provided*, that the recipient Party (i) informs the disclosing Party as soon as reasonably practicable of the required disclosure; (ii) limits the disclosure to the required purpose; and (iii) at the disclosing Party’s request and expense, assists in an attempt to object to or limit the required disclosure or to otherwise receive “confidential” or “trade secret” treatment with respect to relevant portions of such disclosure.

10.4 **Scientific Publications.** Pharming recognizes that the publication of papers regarding the Licensed Compound or Licensed Products or Licensed Know-How generated by or on behalf of Novartis, its Affiliates or Novartis Collaborators, including oral presentations and abstracts, may be beneficial to Novartis, Pharming, the Novartis Collaborators or to the scientific community; *provided*, that such publications are subject to reasonable controls to protect the Licensed IP. If Novartis intends to, or has been informed by any Novartis Collaborator of its intention to, make oral or written publications or other disclosures regarding the Licensed Compound or Licensed Products or Licensed Know-How containing information generated by or on behalf of Novartis or its Affiliates (or such Novartis Collaborator, as applicable) (“Publications”), Novartis will provide Pharming with a copy of the proposed manuscript or article or a summary of any other Publication (in the case of Novartis Collaborators, to the extent it has access to such Publication) at least [\*\*\*] days prior to the date of the planned publication, oral presentation or other disclosure. Pharming will have the right to provide comments and suggestions for modifications with respect to any Publication to protect its Confidential Information, and Novartis shall consider and discuss such comments and suggestions with Pharming in good faith. If requested by Pharming: (a) with respect to Publications by Novartis, Novartis agrees to withhold publication or disclosure (including oral presentation) for up to [\*\*\*] days to allow the Parties to seek patent protection in accordance with this Agreement, it being understood that Novartis may continue with and allow such Publication after the expiration of such [\*\*\*] day period; and (b) with respect to Publications by any Novartis Collaborator, Novartis shall exercise any of its rights under the applicable agreement with such Novartis Collaborator, in

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order to implement any request by Pharming to delay the Publication in question to the fullest extent possible. Disclosures made in accordance with this Section 10.4 will not be deemed to be a breach of Novartis' obligations of confidentiality under this Agreement.

- 10.5 **Clinical Trial Register.** Notwithstanding anything to the contrary contained herein, Novartis and its Affiliates, as required by Applicable Laws, shall have the right to publish the results or summaries of results of clinical trials (including meta-analysis or observational studies) conducted by or on behalf of Novartis or its Affiliates with respect to the Licensed Compound or Licensed Products in any clinical trial register maintained by Novartis or its Affiliates and the protocols of clinical trials relating to the Licensed Compound or Licensed Products on [www.clinicaltrials.gov](http://www.clinicaltrials.gov) (and/or in each case publish the results, summaries and/or protocols of clinical trials on such other websites and/or repositories as required by Applicable Laws or policies of Novartis or its Affiliates). Each such publication made in accordance with this Section 10.5 shall not be a breach of Novartis' obligations of confidentiality under this Agreement.
- 10.6 **Existing CDA.** This Agreement supersedes the Existing CDA; *provided, however*, that this shall not limit any remedies available to either Party with respect to any breach of the Existing CDA that occurred prior to the Effective Date. All Confidential Information (as defined in the Existing CDA) exchanged between the Parties under the Existing CDA shall be deemed to be Confidential Information under this Agreement and from and after the Effective Date shall be subject to the terms of this Article 10.
- 10.7 **Ongoing Obligation of Confidentiality.** Upon early termination of this Agreement for any reason, each Party and its Affiliates will immediately return to the other Party or destroy any Confidential Information disclosed by the other Party, except for one copy which may be retained in its confidential files for archive purposes.

## 11. TERM AND TERMINATION

### 11.1 Agreement Term.

- (a) The term of this Agreement will commence on the Effective Date and unless earlier terminated pursuant to this Article 11, shall expire as follows: (a) on a Licensed Product-by-Licensed Product and country-by-country basis, upon expiration of the Royalty Term for such Licensed Product in such country; and (b) in its entirety upon the expiration of the Royalty Term with respect to the last Licensed Product then being Developed, manufactured or Commercialized in all countries of the Territory. The period commencing on the Effective Date and ending on the termination or expiration date of this Agreement in its entirety shall be referred to herein as the "Agreement Term."
- (b) Notwithstanding anything herein to the contrary, if this Agreement is terminated by either Party for any reason or no reason, and a clinical trial of a Licensed Compound or Licensed Product is ongoing as of the effective date of termination, the Parties shall discuss in good faith the appropriate steps to take regarding the closure or handover of such clinical trial, and in no event will the Party sponsoring

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the clinical trial be required to breach any Applicable Law or ethical requirement concerning treatment of study subjects.

**11.2 Termination for Cause.**

- (a) If either Novartis or Pharming is in material breach of this Agreement, the nonbreaching Party may give written notice to the breaching Party specifying the claimed particulars of such breach, and if such material breach is not cured or the breaching Party has not taken steps as would be considered reasonable to effectively cure such breach within [\*\*\*] days after such notice (or, within [\*\*\*] days after such notice in the case of a payment breach), the non-breaching Party will have the right (but not the obligation) thereafter to terminate this Agreement immediately by giving written notice to the breaching Party to such effect.
- (b) Any termination under this Section 11.2 shall be stayed and the cure period tolled in the event that, during the [\*\*\*] period, as applicable, described in Section 11.2(a), the non-terminating Party shall have initiated dispute resolution in accordance with Section 15.5 with respect to the alleged breach, which stay and tolling shall continue until such dispute has been resolved in accordance with Section 15.5. If the arbitrators determine that the terminating Party's allegation of material breach by the other Party was unfounded, then the notice delivered by the terminating Party to the other Party specifying the claimed particulars of such alleged material breach under Section 11.2(a) shall be of no effect.
- (c) Any termination by either Party under this Section 11.2 and the effects of such termination provided herein will be without prejudice to any damages or other legal or equitable remedies to which it may be entitled.

**11.3 Insolvency.** If an Insolvency Event occurs, (a) the Party subject to the Insolvency Event will give immediate (not longer than [\*\*\*] days') notice to the other Party of such occurrence, and (b) the other Party will have the right to immediately terminate this Agreement by written notice to the Party that is subject to the Insolvency Event.

**11.4 Termination by Pharming Without Cause.** Pharming may terminate this Agreement without cause at any time after the Effective Date on [\*\*\*] days' prior written notice to Novartis.

**12. EFFECT OF TERMINATION**

**12.1 Termination by Pharming for Cause.** Upon termination of this Agreement by Pharming pursuant to Section 11.2 or 11.3:

- (a) the licenses and other rights granted by Novartis to Pharming under the Licensed IP will terminate and Pharming shall not have any rights to use or exercise any rights under the Licensed IP, and the sole right to prosecute and maintain all Licensed Patents shall be transferred to Novartis;
- (b) within [\*\*\*] days' after the effective date of termination (or such later date as Novartis may request) Pharming shall return to Novartis or its designee all



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quantities of CDZ173 Material then in its possession or control, at Novartis' sole cost and expense and at book value (as determined by Pharming's Accounting Standards consistently applied and in accordance with Novartis' reasonable shipping and delivery instructions and assign the [\*\*\*] to Novartis or its designee;

- (c) Novartis shall provide such assistance as reasonably requested by Pharming, and the Parties shall cooperate in good faith, to ensure that Pharming's involvement in and responsibilities for any ongoing clinical trials with respect to any Licensed Product shall be discontinued and ceased in a prompt and orderly manner in accordance with Applicable Law (including GCP) and ethical standards; and
- (d) except as set forth in this Section 12.1 and in Section 12.3, the rights and obligations of the Parties hereunder will terminate effective as of the date of such termination;
- (e) Alternative to Termination: If Pharming is entitled to terminate this Agreement under Section 11.2(a), in lieu of termination Pharming may notify Novartis of its election to continue with this Agreement on its terms; *provided*, that with respect to any amounts that become payable to Novartis after the date of such notice, each amount of Milestone Payment set out in the table in Section 8.2 and the table in Section 8.3, each royalty rate set out in the table in Section 8.4(a) and the amounts payable under Section 8.5, shall be [\*\*\*] of such amount or rate (as applicable), and this Agreement shall be deemed to be amended to reflect such reduced Milestone Payments, royalty rates and amounts effective from the date of such notification to Novartis. Any such election by Pharming shall be without prejudice to Pharming's right to terminate this Agreement at a later date pursuant to Section 11.2(a); *provided, further*, and without limiting Section 11.2(b), Pharming's ability to exercise its rights under this Section 12.1(e), or if previously exercised the application of this Section 12.1(e), shall each be stayed, and all relevant cure or notice periods tolled, during the pendency of any dispute resolution process under Section 15.5 relating to any alleged breach of this Agreement, Pharming's right to terminate this Agreement, or Pharming's exercise of rights under this Section 12.1(e), which stay and tolling shall continue until such dispute has been resolved in accordance with Section 15.5. If the arbitrators determine that Pharming does not or did not have the right to terminate the Agreement or exercise rights under this Section 12.1(e), then any notice delivered by Pharming to Novartis in respect of this Section 12.1(e) shall be of no effect.

**12.2 Termination by Novartis for Cause or by Pharming Without Cause.** Upon termination of this Agreement by Novartis pursuant to Section 11.2 or 11.3 or by Pharming pursuant to Section 11.4:

- (a) all licenses and other rights granted by Novartis to Pharming under the Licensed IP will terminate and Pharming shall not have any rights to use or exercise any rights under the Licensed IP, and the sole right to prosecute and maintain all Licensed Patents shall be transferred to Novartis, and all sublicenses under the Licensed IP granted directly or indirectly by Pharming or its Affiliates shall automatically terminate;

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- (b) within [\*\*\*] days' after the effective date of termination (or such later date as Novartis may request) Pharming shall return to Novartis or its designee all quantities of CDZ173 Material then in its possession or control, if any, at Pharming's sole cost and expense and in accordance with Novartis' shipping and delivery instructions and, at Novartis' written request, assign the [\*\*\*] to Novartis or its designee;
- (c) at Novartis' written request, which must be delivered to Pharming not later than [\*\*\*] days after receipt of Pharming's or Novartis' (as applicable) notice of termination, the following provisions shall apply:
- (i) within [\*\*\*] days' after receipt of Novartis' written request, Pharming will provide to Novartis a fair and accurate summary report of the status of the Development, manufacture and Commercialization of the Licensed Compound and Licensed Products in each country through the effective date of termination;
  - (ii) Pharming will grant, and hereby does grant (effective on Novartis' delivery of the notice pursuant to Section 12.2(c)), and will cause its Affiliates to grant, to Novartis and its Affiliates, solely for the research, Development, manufacture and Commercialization of Licensed Products, a perpetual, irrevocable, exclusive (to the extent Pharming has exclusive rights), worldwide, fully paid-up license (subject to the remainder of this Section 12.2(c)), with the right to grant sublicenses, under Patent Rights and Know-How Controlled by Pharming and its Affiliates as of the effective date of termination (in whole or in part, as elected by Novartis), that are related to, and actually used and applied prior to or as of the date of such termination for the research, Development, manufacture or Commercialization of Licensed Products, to research, Develop, manufacture and Commercialize Licensed Products; *provided*, that with respect to any Patent Rights and Know-How that is Controlled by Pharming or its Affiliates pursuant to an agreement with a Third Party, to the extent Novartis elects to obtain a license or sublicense under such Third Party agreement, Novartis will pay all amounts due under any such Third Party agreement as a result of Novartis' exercise of the rights granted thereunder;
  - (iii) to the extent permitted by Applicable Law, Pharming will, and will cause its Affiliates to, promptly transfer to Novartis or its designee, solely for the Development, manufacture and Commercialization of Licensed Products, the entire right, title, and interest in and to all Know-How, including preclinical and clinical data, and all other supporting data, including pharmacology, toxicology, chemistry and biology data, and documented technical and other information or materials Controlled by Pharming and its Affiliates to the extent exclusively related to the Development, manufacture and Commercialization of Licensed Products; *provided*, that Pharming may retain a single copy of such items for its records as required by Applicable Law;

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- (iv) to the extent permitted by Applicable Law, Pharming will, and will cause its Affiliates, promptly transfer to Novartis or its designee all Regulatory Filings, Regulatory Approvals and Pricing and Reimbursement Approvals, the contents of Global Safety Database, records of all interactions with Regulatory Authorities, in each case to the extent related to Licensed Products, that Pharming and its Affiliates Control as of the effective date of such termination; *provided, however*, that if Pharming is restricted under Applicable Law from transferring ownership of any of the foregoing items to Novartis or its designee, Pharming will grant, and hereby does grant, to Novartis (or its designee) a right of reference or use to such item. Pharming will use Commercially Reasonable Efforts to take such actions as are reasonably necessary to effect such transfer or grant of right of reference or use to Novartis or its designee;
- (v) to the extent reasonably requested by Novartis, Pharming will use Commercially Reasonable Efforts to transfer to Novartis any license agreements or other contracts between Pharming or any of its Affiliates and any Third Party that are related to Licensed Compound or Licensed Product (including, as applicable, clinical trial and manufacturing agreements), to the extent such agreements are in effect as of the effective date of termination and such assignment or transfer is permitted at no cost or expense to Pharming, and to facilitate introductions of Novartis to the applicable subcontractors, licensors, manufacturing vendors, clinical trial sites, clinical trial investigators and the like;
- (vi) Novartis will have the right to purchase from Pharming (in whole or in part) all of the inventory of Licensed Compound and Licensed Product held by or on behalf of Pharming or its Affiliates as of the effective date of termination other than CDZ173 Material at a price to be determined by the Parties in good faith and in no event [\*\*\*], determined in accordance with Pharming's Accounting Standards; *provided*, that Pharming will provide Novartis with assistance in confirming that such Licensed Compound or Licensed Product inventory meets the applicable release specifications and were maintained under GMP conditions and remain GMP compliant as applicable, including, if requested by Novartis enabling Novartis to conduct an audit of Pharming's or its Affiliate's Third Party holder or supplier of Licensed Compound or Licensed Product;
- (vii) for a period of [\*\*\*] months after the delivery of such notice, Pharming will provide such assistance as may be reasonably necessary to transfer manufacturing documents and materials that are Controlled by Pharming and its Affiliates (or their subcontractor(s)) and actually used and applied as of the date of such termination in the manufacture of Licensed Products, and cooperate with Novartis in reasonable respects to transfer to Novartis, or Novartis' designated contract manufacturer, the manufacturing technologies (including all relevant Know-How) related to the Licensed Products that are used in the manufacture of the Licensed Products, and Novartis shall reimburse Pharming for such assistance at Pharming's standard rates;

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- (viii) Novartis will thereafter indemnify, defend and hold Pharming and the Pharming Indemnitees harmless in the manner forth in Section 14.2(a) as if Novartis were Pharming and the Pharming Indemnitees were the Novartis Indemnitees, *mutatis mutandis* for all claims arising after the effective date of such termination, and Pharming's indemnification obligations under Section 14.2(a) shall thereupon cease for claims arising after the effective date of such termination;
  - (ix) to the extent that any personal data, including the Global Safety Database, is to be transferred pursuant to this Section 12.2(c), the Parties shall amend this Agreement or enter into a new agreement regarding data protection prior to such transfer;  
*provided*, that if with respect to a Licensed Product and a country, the license to such Licensed Product for such country has become fully paid up pursuant to Section 8.4(b), then the provisions of (a) to (ix) shall not apply with respect to such Licensed Product in such country; and
  - (d) except as set forth in this Section 12.2 and in Section 12.3, the rights and obligations of the Parties hereunder will terminate as of the date of such termination.
- 12.3 **Survival.** Expiration or termination of this Agreement will not relieve the Parties of any obligation accruing prior to such expiration or termination. Without limiting the foregoing, [\*\*\*], will survive the expiration or termination of this Agreement for any reason. [\*\*\*] will survive the termination or expiration of this Agreement for a period of [\*\*\*] after the effective date of termination or expiration (as the case may be).
- 12.4 **Termination Not Sole Remedy.** Termination is not the sole remedy under this Agreement and, whether or not termination is effected and notwithstanding anything contained in this Agreement to the contrary, all other remedies will remain available except as agreed to otherwise herein. For the avoidance of doubt, nothing in this Agreement shall obligate a Party to terminate this Agreement if the other Party breaches any obligation of this Agreement, and failure to terminate this Agreement shall not prohibit or modify the recovery of damages available to it pursuant to Section 15.5 or at law.

### 13. REPRESENTATIONS, WARRANTIES AND COVENANTS

- 13.1 **Representations and Warranties by Each Party.** Each Party represents and warrants to the other as of the Effective Date that:
- (a) it is a corporation duly organized, validly existing, and in good standing under the laws of its jurisdiction of formation;
  - (b) it has full corporate power and authority to execute, deliver, and perform this Agreement, and has taken all corporate action required by law and its organizational documents to authorize the execution and delivery of this Agreement and the consummation of the transactions contemplated by this Agreement;

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- (c) this Agreement constitutes a valid and binding agreement enforceable against it in accordance with its terms, except as enforceability may be limited by bankruptcy, fraudulent conveyance, insolvency, reorganization, moratorium and other laws relating to or affecting creditors' rights generally and by general equitable principles and public policy constraints (including those pertaining to limitations or exclusions of liability, competition laws, penalties and jurisdictional issues including conflicts of laws);
  - (d) all consents, approvals and authorizations from all governmental authorities or other Third Parties required to be obtained by such Party in connection with this Agreement have been obtained;
  - (e) the execution and delivery of this Agreement and all other instruments and documents required to be executed pursuant to this Agreement, and the consummation of the transactions contemplated hereby do not and will not (i) conflict with or result in a breach of any provision of its organizational documents; (ii) result in a breach of any agreement to which it is a party; or (iii) violate any law; and
  - (f) neither such Party nor, to the actual knowledge of such Party, any employee, agent or subcontractor of such Party involved or to be involved in the Development or manufacture of any Licensed Compound or Licensed Product has been debarred under Subsection (a) or (b) of Section 306 of the FD&C Act (21 USC §§ 335a) or has been convicted of any crime or engaged in any conduct that would reasonably be expected to result in exclusion under 42 U.S.C. Section 1320a-7 or any similar Applicable Law.

13.2 **Covenants by Pharming.** Pharming covenants that:

- (a) No Person who is known by Pharming (i) to have been debarred under Subsection (a) or (b) of Section 306 of the FD&C Act (21 USC §§ 335a), or (ii) to be on any of the FDA clinical investigator enforcement lists will be employed by or on behalf of Pharming or its Affiliates or their respective licensees or Sublicensees, or otherwise participate in the performance of any activities hereunder.
- (b) During the Agreement Term and for a period of [\*\*\*] thereafter, Pharming shall maintain, at its cost, a program of insurance against liability and other risks associated with its activities and obligations under this Agreement (including with respect to its clinical trials and the Commercialization of Licensed Products), and its indemnification obligations hereunder, in such amounts, subject to such deductibles and on such terms as are customary and reasonable for the activities to be conducted by it under this Agreement (and in any event with combined limits of not less than [\*\*\*] per claim and annually in the aggregate). Such insurance shall not be construed to create a limit on either Party's liability with respect to its indemnification obligations under Article 14, or otherwise. At Novartis' written request, Pharming will provide Novartis with evidence of Pharming's insurance.

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Pharming will name Novartis as an additional insured party under such insurance policy, and will provide to Novartis at least [\*\*\*] days prior written notice of any change or cancellation to Pharming's insurance program; and

- (c) Pharming will conduct its Development, manufacturing, and Commercialization activities relating to the Licensed Compound and Licensed Products in accordance with all Applicable Laws (including data privacy laws, current international regulatory standards, including, as applicable, GMP, GLP, GCP, and other rules, regulations and requirements), and will cause any Affiliates, licensees, collaborators and Sublicensees to comply with such Applicable Laws.

13.3 **Representations and Warranties by Novartis.** Novartis represents and warrants to Pharming as of the Effective Date that:

- (a) to the knowledge of the Novartis associates responsible for such matters, (1) Exhibit C sets forth a true, complete and correct list of the Patent Rights owned by Novartis or its Affiliates as of the Effective Date that Cover the composition or method of use of CDZ173 (unless such Patent Rights are identified to be licensed to Novartis or its Affiliates in Exhibit C); and (2) no Patent Rights are Controlled by Novartis or its Affiliates as of the Effective Date that Cover the formulation or Manufacturing Technology of CDZ173;
- (b) Novartis and its Affiliates are the sole and exclusive owners of the entire right, title and interest in, to and under or have exclusive rights to the Licensed IP, free and clear of all Encumbrances that would interfere with Pharming's rights, except as provided in Schedule 13.3, and Novartis and its Affiliates have the right to grant the licenses to Pharming under this Agreement;
- (c) to the knowledge of the Novartis associates responsible for such matters, each of the Licensed Patents properly identifies each and every inventor of the claims thereof as determined in accordance with the Applicable Laws of the jurisdiction in which such Licensed Patent is issued or patent application is pending;
- (d) each Person who has or has had any rights in or to any Licensed IP owned by Novartis or its Affiliate has assigned by virtue of employment or written assignment its entire right, title and interest in and to such Licensed IP to Novartis or its Affiliate;
- (e) to the knowledge of the Novartis associates responsible for such matters, Novartis has filed and prosecuted patent applications within the Licensed Patents owned by Novartis or its Affiliate in good faith and complied with all duties of disclosure with respect thereto;
- (f) except as set forth on Schedule 13.3, Novartis and its Affiliates have not granted to any Third Party, including any academic organization or agency, any license, option or other rights to research, Develop, manufacture, use or Commercialize the Licensed Compound or Licensed Products;
- (g) Novartis has not received in writing, and neither Novartis nor its associates responsible for such matters is aware, of any claims or allegations (including

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threatened interference actions or oppositions) alleging that the (1) research, Development, registration, manufacture, use or Commercialization of the Licensed Compound or Licensed Products infringes the Patent Rights or misappropriates the Know-How, or other intellectual property rights, of any Third Party, (2) that a Third Party has any right or interest in or to the Licensed IP owned by Novartis or its Affiliate, or (3) that any of the Licensed Patents are invalid or unenforceable, and to the knowledge of the Novartis associates responsible for such matters, there are no facts that could form the basis of any of (1) to (3);

- (h) to the knowledge of the Novartis associates responsible for such matters, there are no facts that could form the basis for the invalidation or unenforceability of the Licensed Patents or Licensed Know-How;
- (i) Novartis and its Affiliates have not initiated or been involved in any proceedings or Claims in which it alleges that any Third Party is or was infringing or misappropriating any Licensed IP relating to the Licensed Compound or Licensed Products;
- (j) to the knowledge of the Novartis associates responsible for such matters, there are no activities by Third Parties that would constitute infringement or misappropriation of the Licensed IP (in the case of pending claims, evaluating them as if issued);
- (k) Novartis and its Affiliates have not entered into any agreement with any Third Party that is in conflict with the rights granted to Pharming under this Agreement, and has not taken any action that would prevent it from granting the rights granted to Pharming under this Agreement, or that would otherwise materially conflict with or adversely affect the rights granted to Pharming under this Agreement;
- (l) Novartis and its Affiliates have conducted all Development and manufacturing activities relating to the Licensed Compound and Licensed Products in accordance with all Applicable Laws (including data privacy laws and, as applicable, GMP, GLP, GCP) in all material respects;
- (m) as of the Effective Date, neither Novartis nor any Affiliate has received any written notifications from any Regulatory Authority raising any material issues in any jurisdiction requiring the termination or suspension of any clinical trials related to the Licensed Products conducted by or on behalf of Novartis or its Affiliates; and
- (n) (1) the agreement appended to **Exhibit G** is a true and accurate copy of the [\*\*\*] as of the Effective Date; (2) the [\*\*\*] is in full force and effect, and there is no breach of the [\*\*\*] by Novartis or its Affiliates or, to the knowledge of the Novartis associates responsible for such matters, any other party thereto; and (3) all Milestone Payments (save for the Milestone Payment for the Milestone for “EU Regulatory Approval or US Regulatory Approval of a Product”) (each as such terms are used in the [\*\*\*]) have been fully paid by Novartis.

13.4 **Covenants of Novartis.** Novartis covenants that:

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- (a) it will not grant any Encumbrance or other interest in the Licensed IP that is inconsistent with the terms of this Agreement;
  - (b) it will conduct its obligations hereunder with respect to the Ongoing Trial and the Extension Study following the Effective Date in accordance with all Applicable Laws (including data privacy laws, current international regulatory standards, including, as applicable, GMP, GLP, GCP, and other rules, regulations and requirements), and will cause any Affiliates, licensees, collaborators and sublicensees to comply with such Applicable Laws; and
  - (c) if, at any time after execution of this Agreement, it becomes aware that it or any employee, agent or subcontractor of Novartis or its Affiliates who participated in the Development or manufacture of Licensed Compound or Licensed Product is on, or is being added to the FDA Debarment List or to any of the FDA clinical investigator enforcement lists, it will provide written notice of this to Pharming within [\*\*\*] business days after becoming aware of this fact.

13.5 **No Other Warranties.** Except as expressly provided in this Article 13, nothing in this Agreement shall be construed as a representation made or warranty given by Novartis that it has been or will be successful in prosecuting any Licensed Patents, that any patents will issue based on pending applications or that any such pending applications or patents issued thereon will be valid. *EXCEPT AS EXPRESSLY STATED IN THIS ARTICLE 13 OR ELSEWHERE IN THIS AGREEMENT, (A) NO REPRESENTATION, CONDITION OR WARRANTY WHATSOEVER IS MADE OR GIVEN BY OR ON BEHALF OF NOVARTIS OR ITS AFFILIATES; AND (B) ALL OTHER CONDITIONS AND WARRANTIES WHETHER ARISING BY OPERATION OF LAW OR OTHERWISE ARE HEREBY EXPRESSLY EXCLUDED, INCLUDING ANY CONDITIONS AND WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE OR NONINFRINGEMENT.*

#### 14. INDEMNIFICATION; LIABILITY

14.1 **Indemnification by Novartis.** Novartis will indemnify and hold Pharming, its Affiliates, and their respective officers, directors and employees (“Pharming Indemnitees”) harmless from and against any Claims against them to the extent arising or resulting from:

- (a) any activities conducted by Novartis, its Affiliates, licensees and sublicensees, and their respective employees, agents and subcontractors, in connection with the Development, manufacture and Commercialization of the Licensed Compound or any Licensed Products, on or prior to the Effective Date or after termination of this Agreement;
- (b) the breach of any of the obligations, covenants, warranties or representations: (a) made by Novartis to Pharming under this Agreement; (b) made by Novartis or made by its Affiliates (if any such obligations, covenants, warranties or representations exist) under the [\*\*\*] on or prior to the Effective Date; or (c) made by Novartis or its Affiliates under any Third Party agreement transferred to Pharming or its designee under the Ancillary Agreement on or prior to the effective date of such transfer, subject to any applicable terms of the Ancillary Agreement;



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- (c) the gross negligence, intentional misconduct, or violation of Applicable Law by any Novartis Indemnitee; or
  - (d) subject to and except as provided in Sections 4.3, 6.5 and 13.5, any activities conducted by Novartis or its Affiliates and their respective employees, agents and subcontractors, in connection with the Ongoing Trial or Extension Study following the Effective Date;

*provided, however,* that Novartis will not be obliged to so indemnify, defend and hold harmless the Pharming Indemnitees for any Claims to the extent Pharming has an obligation to indemnify Novartis Indemnitees pursuant to Section 14.2 or to the extent that such Claims arise from the breach, negligence or willful misconduct of Pharming or the Pharming Indemnitees.

14.2 **Indemnification by Pharming.** Pharming will indemnify and hold Novartis, its Affiliates, and their respective officers, directors and employees (“Novartis Indemnitees”) harmless from and against any Claims against them to the extent arising or resulting from:

- (a) any activities conducted by Pharming, its Affiliates, licensees and Sublicensees, and their respective employees, agents and subcontractors in connection with the Development, manufacture or Commercialization of the Licensed Compound or any Licensed Products, including, for the avoidance of doubt, (i) any Pharming Activities conducted hereunder, (ii) the gross negligence, intentional misconduct, or violation of Applicable Law by any Pharming Indemnitee, and (iii) all product liability claims (whether arising during Development, manufacture or Commercialization) relating to the Licensed Compound or any Licensed Product (whether pursuant to design defect, manufacturing defect, failure to notify, or otherwise) after the Effective Date; or
- (b) the breach of any of the obligations, covenants, warranties, or representations made by: (i) Pharming to Novartis under this Agreement, (ii) Pharming under the [\*\*\*] following effective assignment of such agreement to Pharming, or (iii) Pharming or its designee under any Third Party agreement transferred to Pharming or its designee pursuant to the Ancillary Agreement following the effective date of such transfer, subject to any applicable terms of the Ancillary Agreement;

*provided, however,* that Pharming will not be obliged to so indemnify, defend and hold harmless the Novartis Indemnitees for any Claims to the extent Novartis has an obligation to indemnify Pharming Indemnitees pursuant to Section 14.1 or to the extent that such Claims arise from the breach, negligence or willful misconduct of Novartis or the Novartis Indemnitees.

14.3 **Indemnification Procedure.**

- (a) For the avoidance of doubt, all indemnification claims in respect of a Pharming Indemnitee or Novartis Indemnitee will be made solely by Pharming or Novartis, respectively.
- (b) A Party seeking indemnification hereunder (“Indemnified Party”) will notify the other Party (“Indemnifying Party”) in writing reasonably promptly after the assertion against the Indemnified Party of any Claim or fact in respect of which

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the Indemnified Party intends to base a claim for indemnification hereunder (“Indemnification Claim Notice”), but the failure or delay to so notify the Indemnifying Party will not relieve the Indemnifying Party of any obligation or liability that it may have to the Indemnified Party, except to the extent that the Indemnifying Party demonstrates that its ability to defend or resolve such Claim is adversely affected thereby. The Indemnification Claim Notice will contain a description of the claim and the nature and amount of the Claim (to the extent that the nature and amount of such Claim is known at such time). Upon the request of the Indemnifying Party, the Indemnified Party will furnish promptly to the Indemnifying Party copies of all correspondence, communications and official documents (including court documents) received or sent in respect of such Claim.

- (c) Subject to the provisions of Sections 14.3(d) and 14.3(e), the Indemnifying Party will have the right, upon written notice given to the Indemnified Party within [\*\*\*] days after receipt of the Indemnification Claim Notice, to assume the defense and handling of such Claim, at the Indemnifying Party’s sole expense, in which case the provisions of Section 14.3(d) will govern. The assumption of the defense of a Claim by the Indemnifying Party will not be construed as acknowledgement that the Indemnifying Party is liable to indemnify any indemnitee in respect of the Claim, nor will it constitute a waiver by the Indemnifying Party of any defenses it may assert against any Indemnified Party’s claim for indemnification. If it is ultimately decided that the Indemnifying Party is not obligated to indemnify or hold an indemnitee harmless from and against the Claim, the Indemnified Party will reimburse the Indemnifying Party for any and all costs and expenses (including attorneys’ fees and costs of suit) and any losses incurred by the Indemnifying Party in its defense of the Claim. If the Indemnifying Party does not give written notice to the Indemnified Party, within [\*\*\*] days after receipt of the Indemnification Claim Notice, of the Indemnifying Party’s election to assume the defense and handling of such Claim, the provisions of Section 14.3(e) will govern.
- (d) Upon assumption of the defense of a Claim by the Indemnifying Party: (i) the Indemnifying Party will have the right to and will assume sole control and responsibility for dealing with the Claim; (ii) the Indemnifying Party may, at its own cost, appoint as counsel in connection with conducting the defense and handling of such Claim any law firm or counsel reasonably selected by the Indemnifying Party; (iii) the Indemnifying Party will keep the Indemnified Party informed of the status of such Claim; and (iv) the Indemnifying Party will have the right to settle the Claim on any terms the Indemnifying Party chooses; *provided, however*, that it will not, without the prior written consent of the Indemnified Party, agree to a settlement of any Claim which could lead to liability or create any financial or other obligation on the part of the Indemnified Party for which the Indemnified Party is not entitled to indemnification hereunder or which admits any wrongdoing or responsibility for the claim on behalf of the Indemnified Party. The Indemnified Party will cooperate with the Indemnifying Party and will be entitled to participate in, but not control, the defense of such Claim with its own counsel and at its own expense. In particular, the Indemnified Party will furnish such records, information and testimony, provide witnesses and attend such

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conferences, discovery proceedings, hearings, trials and appeals as may be reasonably requested in connection therewith. Such cooperation will include access during normal business hours by the Indemnifying Party to, and reasonable retention by the Indemnified Party of, records and information that are reasonably relevant to such Claim, and making the Indemnified Party, the indemnitees and its and their employees and agents available on a mutually convenient basis to provide additional information and explanation of any records or information provided.

- (e) If the Indemnifying Party does not give written notice to the Indemnified Party as set forth in Section 14.3(c) or fails to conduct the defense and handling of any Claim in good faith after having assumed such, the Indemnified Party may, at the Indemnifying Party's expense, select counsel reasonably acceptable to the Indemnifying Party in connection with conducting the defense and handling of such Claim and defend or handle such Claim in such manner as it may deem appropriate. In such event, the Indemnified Party will keep the Indemnifying Party timely apprised of the status of such Claim and will not settle such Claim without the prior written consent of the Indemnifying Party, which consent will not be unreasonably withheld. If the Indemnified Party defends or handles such Claim, the Indemnifying Party will cooperate with the Indemnified Party, at the Indemnified Party's request but at no expense to the Indemnified Party, and will be entitled to participate in the defense and handling of such Claim with its own counsel and at its own expense.

14.4 **Mitigation of Loss.** Each Indemnified Party will take and will procure that its Affiliates take all such reasonable steps and action as are necessary or as the Indemnifying Party may reasonably require in order to mitigate any Claims (or potential losses or damages) under this Article 14. Nothing in this Agreement will or will be deemed to relieve any Party of any common law or other duty to mitigate any losses incurred by it.

14.5 **Special, Indirect and Other Losses.** NO PARTY NOR ANY OF SUCH PARTY'S AFFILIATES SHALL BE LIABLE IN CONTRACT, TORT, NEGLIGENCE BREACH OF STATUTORY DUTY OR OTHERWISE FOR ANY SPECIAL, INDIRECT, INCIDENTAL, PUNITIVE OR CONSEQUENTIAL DAMAGES OR FOR ANY ECONOMIC LOSS OR LOSS OF PROFITS SUFFERED BY THE OTHER PARTY, EXCEPT TO THE EXTENT ANY SUCH DAMAGES ARE REQUIRED TO BE PAID TO A THIRD PARTY AS PART OF A CLAIM FOR WHICH A PARTY PROVIDES INDEMNIFICATION UNDER THIS ARTICLE 14 OR FOR A BREACH OF ARTICLE 9 OR ARTICLE 10.

## 15. GENERAL PROVISIONS

15.1 **Assignment.** No Party may assign its rights and obligations under this Agreement without the other Party's prior written consent, except that either Party may (i) assign its rights and obligations under this Agreement or any part hereof to one or more of its Affiliates; or (ii) assign this Agreement in its entirety to a successor to all or substantially all of its business or assets to which this Agreement relates. Any permitted assignee will assume all obligations of its assignor under this Agreement. Any attempted assignment in contravention of the foregoing will be void. Subject to the terms of this Agreement, this Agreement will be binding upon and inure to the benefit of the Parties and their respective successors and

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permitted assigns. Novartis shall not (and shall procure that its Affiliates shall not) assign or otherwise transfer any or all of the Licensed IP to a Third Party unless Novartis (or its Affiliate) has shown such Third Party a copy of this Agreement and has obtained a written agreement that such Third Party will take the Licensed IP subject to any of Pharming's continuing rights and Novartis's continuing obligations under this Agreement.

- 15.2 **Extension to Affiliates.** Pharming will have the right to extend the rights, immunities and obligations granted in this Agreement to one or more of its Affiliates. All applicable terms of this Agreement will apply to any such Affiliate to which this Agreement has been extended to the same extent as such terms apply to Pharming. Pharming will remain primarily liable for any acts or omissions of its Affiliates.
- 15.3 **Severability.** Should one or more provisions of this Agreement become void or unenforceable as a matter of law, then this Agreement will be construed as if such provision were not contained herein and the remainder of this Agreement will be in full force and effect, and the Parties will use their commercially reasonable efforts to substitute for the invalid or unenforceable provision a valid and enforceable provision which conforms as nearly as possible with the original intent of the Parties.
- 15.4 **Governing Law and Jurisdiction.** This Agreement will be governed by and construed under the laws of [\*\*\*], without giving effect to the conflicts of laws provision thereof. The United Nations Convention on Contracts for the International Sale of Goods (1980) will not apply to the interpretation of this Agreement.
- 15.5 **Dispute Resolution.**
- (a) In the event of a dispute relating to, arising under or out of, or in any way connected with this Agreement or any term hereof, or the performance by either Party of its obligations hereunder, except for any matter subject to resolution under Section 3.4(d) or as provided in Section 8.4(d) (a "Dispute"), the Parties will refer the Dispute to the Alliance Managers for discussion and resolution. If the Alliance Managers are unable to resolve the Dispute within [\*\*\*] days after the Dispute is referred to them, either Party may require that the Parties forward the matter to the Senior Officers (or designees with similar authority to resolve such dispute), who will attempt in good faith to resolve the Dispute. If the Senior Officers cannot resolve the Dispute within [\*\*\*] days after the matter is referred to them, either Party will be free to initiate the arbitration proceeding set forth in Section 15.5(b) to resolve the matter.
- (b) Any unresolved Disputes between the Parties, whether arising before or after termination of this Agreement, will be resolved by final and binding arbitration. Whenever a Party decides to institute arbitration proceedings, it will give written notice to that effect to the other Party. Arbitration will be held in [\*\*\*], in accordance with the commercial arbitration rules of the [\*\*\*]. The arbitration will be conducted by a panel of three (3) arbitrators appointed in accordance with [\*\*\*] rules; *provided*, that each Party will, within [\*\*\*] days after the institution of the arbitration proceedings, appoint an arbitrator, and such arbitrators will together, within [\*\*\*] days, select a third arbitrator as the chair of the arbitration panel, and each arbitrator will have significant experience in the biopharmaceutical industry.

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If the two (2) initial arbitrators are unable to select a third arbitrator within such thirty (30) day period, the third arbitrator will be appointed in accordance with [\*\*\*] rules. The arbitrators will render their opinion within [\*\*\*] days after the final arbitration hearing. No arbitrator (nor the panel of arbitrators) will have the power to award punitive damages or to award costs and expenses of the proceeding or reasonable attorneys' fees to either Party under this Agreement and such award is expressly prohibited. Decisions of the panel of arbitrators will be final and binding on the Parties. Judgment on the award so rendered may be entered in any court of competent jurisdiction.

- (c) Notwithstanding Section 15.4 and Section 15.5(b), any dispute, controversy or claim relating to the scope, validity, enforceability or infringement of any Patent Right Covering the manufacture, use, importation, offer for sale or sale of any Licensed Compound or Licensed Product or of any trademark rights relating to any Licensed Product shall be submitted to a court of competent jurisdiction in the country in which such Patent Right or trademark rights were granted or arose.
- 15.6 **Force Majeure.** If either Party is prevented from performing its obligations under this Agreement as a result of any contingency beyond its reasonable control ("Force Majeure"), including any actions of governmental authorities or agencies, war, hostilities between nations, civil commotions, riots, national industry strikes, lockouts, sabotage, shortages in supplies, energy shortages, fire, floods and acts of nature such as typhoons, hurricanes, earthquakes, or tsunamis, the Party so affected will not be responsible to the other Party for any delay or failure of performance of its obligations hereunder, for so long as Force Majeure prevents such performance. In the event of Force Majeure, the Party immediately affected thereby will give prompt written notice to the other Party specifying the Force Majeure event complained of, and will use diligent efforts to cure such failure or omission as soon as is practicable after the occurrence of the Force Majeure event. Notwithstanding the foregoing, if such Force Majeure induced delay or failure of performance continues for more than [\*\*\*] days, either Party may terminate this Agreement upon written notice to the other Party.
- 15.7 **Waivers and Amendments.** The failure of any Party to assert a right hereunder or to insist upon compliance with any particular term of this Agreement will not constitute a waiver of that right or excuse a similar subsequent failure to perform any such term by the other Party. No waiver will be effective unless it has been given in writing and signed by the Party giving such waiver. No provision of this Agreement may be amended or modified other than by a written document signed by authorized representatives of each Party.
- 15.8 **Relationship of the Parties.** Nothing contained in this Agreement will be deemed to constitute a partnership, joint venture, or legal entity of any type between Novartis and Pharming or their Affiliates, or to constitute one as the agent of the other. Moreover, each Party will not construe this Agreement, or any of the transactions contemplated hereby, as a partnership for any tax purposes. Each Party will act solely as an independent contractor, and nothing in this Agreement will be construed to give any Party the power or authority to act for, bind, or commit the other.
- 15.9 **Notices.** All notices, consents, waivers, and other communications under this Agreement must be in writing and will be deemed to have been duly given when: (a) delivered by hand

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(with written confirmation of receipt); or (b) when received by the addressee, if sent by an internationally recognized overnight delivery service (receipt requested), in each case to the appropriate addresses set forth below (or to such other addresses as a Party may designate by notice):

If to Pharming:

Pharming Group N.V.  
Darwinweg 24,  
Leiden 2333 CR,  
The Netherlands  
Attn: Legal Department,

with a required copy to: Pharming  
Healthcare, Inc.  
685 Route 202/206, Bridgewater,  
New Jersey 08807  
Attn: Legal Department

If to Novartis:

Novartis International Pharmaceutical AG  
Lichtstrasse 35  
CH-4056 Basel  
Switzerland  
Attn: General Counsel

with a required copy to:

Novartis Institutes for BioMedical Research, Inc.  
250 Massachusetts Avenue  
Cambridge, MA 02139 USA  
Attn: General Counsel

- 15.10 **Further Assurances.** Pharming and Novartis will execute, acknowledge and deliver any and all such other documents and take any such other action as may be reasonably necessary to carry out the intent and purposes of this Agreement.
- 15.11 **Compliance with Law.** Each Party will perform its obligations under this Agreement in accordance with all Applicable Laws. No Party will, or will be required to, undertake any activity under or in connection with this Agreement which violates, or which it believes, in good faith, may violate, any Applicable Law.
- 15.12 **No Third Party Beneficiary Rights.** The provisions of this Agreement are for the sole benefit of the Parties and their successors and permitted assigns, and they will not be construed as conferring any rights to any Third Party (including any Third Party beneficiary rights).
- 15.13 **Cumulative Remedies.** No remedy referred to in this Agreement is intended to be exclusive, but each will be cumulative and in addition to any other remedy referred to in this Agreement or otherwise available under law.

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- 15.14 **Expenses.** Except as otherwise expressly provided in this Agreement, each Party will pay the fees and expenses of its respective lawyers and other experts and all other expenses and costs incurred by such Party incidental to the negotiation, preparation, execution and delivery of this Agreement.
- 15.15 **Entire Agreement.** This Agreement, together with its Exhibits and schedules, sets forth the entire agreement and understanding of the Parties as to the subject matter hereof and supersedes all proposals, oral or written, and all other prior communications between the Parties with respect to such subject matter, including the Existing CDA. In the event of any conflict between a substantive provision of this Agreement and any Exhibit or schedule hereto, the substantive provisions of this Agreement will prevail.
- 15.16 **Counterparts.** This Agreement may be executed in two or more counterparts, each of which will be deemed an original, but all of which together will constitute one and the same instrument. Signatures provided by facsimile transmission or in Adobe Portable Document Format (.pdf) sent by electronic mail shall be deemed to be original signatures.

*[signature page follows]*

In witness thereof, the Parties, intending to be legally bound, have caused this License Agreement to be executed by their duly authorized representatives of the Company as of the Effective Date

**Novartis International Pharmaceutical AG**

By: /s/Charlotte Retzler

Name: Charlotte Retzler

Title: Authorized Signatory

By: /s/ Riccarda Racine

Name: Riccarda Racine

Title: Authorized Signatory

**Pharming Group N.V.**

By: /s/ Sijmen De Vries

Name: Sijmen De Vries

Title: Chief Executive Officer

By: /s/ Robin Wright

Name: Robin Wright

Title: Chief Financial Officer