

EX-10.7 6 fs42021a2ex10-7_allarity.htm LICENSE AGREEMENT BETWEEN NOVARTIS
PHARMA AG AND ONCOLOGY VENTURE, APS, DATED APRIL 6, 2018

Exhibit 10.7

CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY [***], HAS BEEN OMITTED BECAUSE IT IS BOTH (i) NOT MATERIAL AND (ii) WOULD BE COMPETITIVELY HARMFUL IF PUBLICLY DISCLOSED.

Execution Version

LICENSE AGREEMENT

between

NOVARTIS PHARMA AG

and

ONCOLOGY VENTURE ApS

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Exhibit A	Convertible Promissory Note
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LICENSE AGREEMENT

This LICENSE AGREEMENT (“**License Agreement**”) is made as of the 6. day of April, 2018 (“**Effective Date**”), by and between Novartis Pharma AG, a company organized under the laws of Switzerland and located at Lichtstrasse 35, 4056 Basel, Switzerland (“**Novartis**”), and Oncology Venture ApS, a company organized under the laws of Denmark, with headquarters at Venlighedsvej 1, DK-2970 Hoersholm, Denmark (“**OV**”). Novartis and OV are each referred to individually as a “**Party**” and together as the “**Parties**.”

RECITALS

WHEREAS, Novartis and/or its Affiliates own or control the certain Intellectual Property Rights (as defined below) Covering the Compound (as defined below) and has conducted Phase II Clinical Trials and Phase III Clinical Trials of the Compound for the treatment of gastrointestinal stromal tumors (GIST), renal cell carcinoma (RCC), breast cancer, and other solid tumors.

WHEREAS, Novartis does not develop, market, sell, distribute, manufacture and/or commercialize, by itself or through Affiliates (as defined below) and/or third parties, any product having the Compound as an active ingredient in the Field (as defined below) in the Territory (as defined below);

WHEREAS, the Parties previously entered into that certain Option Agreement, dated as of July 18, 2017 (“**Option Agreement**”), under which Novartis granted OV an option to obtain an exclusive license to the Compound under the Licensed IP (as defined below) to develop, manufacture and commercialize Licensed Product (as defined below);

WHEREAS, OV has determined to exercise its option to enter into this License Agreement to further develop or have an Affiliate (“**SPV**”) develop one or more Licensed Products, up to and including completion of certain Phase II Clinical Trials described herein.

WHEREAS, to the extent the development of Licensed Product will be conducted by the SPV, OV shall assign its rights and obligations under this License Agreement to the SPV as further defined herein.

NOW, THEREFORE, in consideration of the mutual covenants and agreements herein contained, the Parties hereby agree as follows:

1. DEFINITIONS AND INTERPRETATION

1.1 Definitions. The capitalized terms used in this License Agreement shall have the meanings as defined below:

“**Accounting Standards**” means with respect to OV, IFRS (International Financial Reporting Standards) as generally and consistently applied throughout OV’s organization. OV shall promptly notify Novartis in the event that it changes the Accounting Standards pursuant to which its records are maintained, it being understood that OV may only use internationally recognized accounting principles (e.g. International Financial Reporting Standards, US GAAP, etc.).

“**Affiliate**” means, with respect to a Party, any Person that directly or indirectly controls, is controlled by, or is under common control with that Party. For the purpose of this definition, “**control**” shall mean: (a) 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; (b) fifty percent (50%) or more of the equity interest in the case of any other type of legal entity or status as a general partner in any partnership; (c) 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; (d) if a Party is exposed, or has rights, to variable returns from its involvement with an entity or Person and has the ability to affect its returns through its power over such entity or Person; or (e) 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 permitted by Law for a foreign investor may be less than fifty percent (50%), and in such case such lower percentage shall be substituted in the preceding sentence, provided that such foreign investor has the power to direct the management and policies of such entity. The Parties understand and agree that, with respect to OV, “**Affiliates**” includes Medical Prognosis Institute, ApS (“**MPI**”).

“**Auditor**” shall have the meaning set forth in Clause 8.4(b).

“**Business Day**” means a day (other than a Saturday, Sunday or a public holiday) on which the banks are open for business in Basel, Switzerland and Copenhagen, Denmark.

“**Calendar Quarter**” means the respective periods of three (3) consecutive calendar months ending on March 31, June 30, September 30 and December 31.

“**Calendar Year**” means a period of twelve (12) consecutive calendar months ending on December 31.

“**Clinical Materials**” means all forms of patient biopsy materials (including genomic data extracted from such biopsies) from prior clinical trials of Compound that are in the possession of Novartis as of the Effective Date of this Agreement. Clinical Materials to be transferred to OV are enumerated on Schedule H hereto.

“**Combination Product**” shall have the meaning set forth in Clause 7.5.

“**Commercialize**” means any and all activities directed toward marketing, promoting, detailing, distributing, importing, exporting, selling or offering to sell a Licensed Product in the Field in the Territory, including, for example, branding, pricing, distribution, market research, to sell or market the Licensed Product, preparing advertising and promotional materials, sales force training, and Manufacturing activities in support of the foregoing, and “**Commercialization**” and “**Commercializing**” shall have a corresponding meaning.

“**Commercially Reasonable Efforts**” means those diligent efforts and resources consistent with customary practices of comparable companies in the specialty pharmaceutical industry that such a company typically devotes to a product or compound owned by it or to which it has rights of the type it has hereunder, or similar market potential at a similar stage in the development or product life thereof and later Commercialization, in light of the potential profitability, price or reimbursement, the intellectual property and competitive landscape relevant to such Licensed Product, its safety and efficacy profile, the Development and Regulatory Approval risks associated with such Licensed Product, the Patent or other proprietary position of the Licensed Product (including the ability to obtain or enforce, or have obtained or enforced, such Patent or other proprietary positions), the regulatory requirements involved.

“Competition Law” means the Sherman Act, as amended, the Clayton Act, as amended, the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended, the Federal Trade Commission Act, as amended, and all other federal, state or foreign statutes, rules, regulations, orders, decrees, administrative and judicial doctrines and other Laws, including any antitrust, competition or trade regulation Laws that are designed or intended to prohibit, restrict or regulate actions having the purpose or effect of monopolization or restraint of trade or lessening competition through merger, acquisition or otherwise.

“Competitive Product” means, other than the Licensed Product, any pharmaceutical product (i) that contains the Compound as an active ingredient(s) as such approved Licensed Product; (ii) is approved for use in such country pursuant to (a) Article 10.1 of Directive 2001/83/EC of the European Parliament and Council of 6 November 2001, or any enabling legislation thereof, or any amended or successor abbreviated route of approval, or (b) any Laws or abbreviated routes of approval in any other countries worldwide that are comparable to those described above; and (iii) is sold in the same country as such Licensed Product by any Third Party that is not a sublicensee of OV or its Affiliates and did not purchase such product in a chain of distribution that included any of OV or any of its Affiliates or its sublicensees, especially in case of parallel imports. A pharmaceutical product that is AB-rated or comparably rated in any jurisdiction outside the United States to the applicable Licensed Product shall be a Competitive Product with respect to such Licensed Product in such country.

“Compound” means the compound TKI258 (a.k.a. Dovitinib), a small molecule inhibitor of multiple tyrosine kinases, as further described in **Schedule A**, and any pharmacologically and/or therapeutically active derivatives thereof, including without limitation isomers, esters, salts, hydrates, anhydrous forms and other solvates and polymorphs of such compounds.

“Control” or **“Controlled”** means, with respect to any intellectual property right, information, documents or materials of a Party, that such Party or its Affiliates, , (a) owns or has a license to such intellectual property right, information, documents or materials (other than pursuant to this License Agreement); and (b) has the ability to grant access, a license or a sublicense to such intellectual property right, information, documents or materials to the other Party as provided in this License Agreement without violating an agreement with or other rights of any Third Party.

“Convertible Promissory Note” means that certain Convertible Promissory Note for an initial principal balance equal to \$1,000,000.00, in the form attached hereto as Exhibit A, which OV shall cause its Affiliate, OV SPV2, to issue to Novartis upon the Effective Date.

“Cover”, “Covering” or **“Covered”** means, with respect to a claim of a Patent and a Licensed Product, that the manufacture, use, offer for sale, sale or importation of the Licensed Product would infringe a Valid Claim of such Patent in the country in which such activity occurred, but for the licenses granted in this License Agreement (or ownership thereof).

“Develop” or **“Development”** means drug development activities, including, without limitation, research, process development, test method development and stability testing, assay development and audit development, toxicology, formulation, pharmaceutical development, quality assurance/quality control development, statistical analysis, clinical trials, process development, packaging development, product validation activities, regulatory affairs, and the preparation, filing and prosecution of regulatory filings with regulatory authorities such as EMA and FDA.

“Development Plan” has the meaning set forth in Clause 4.1.

“Effective Date” has the meaning set forth in the preamble to the Recitals above.

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

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

“Field” shall mean any and all therapeutic and/or diagnostic uses related to cancer in humans.

“First Commercial Sale” means, with respect to the Licensed Product, the first arm’s length sale to a Third Party (other than an Affiliate or sublicensee), for use of such Licensed Product in the Field in the Territory, after such Licensed Product has been granted Regulatory Approval for distribution, marketing and sale (in each case to the extent required by applicable Laws) in the Field by the competent Regulatory Authorities in such country. For avoidance of doubt, First Commercial Sales exclude transfers or dispositions of a Licensed Product for charitable, compassionate, promotional (including samples), pre-clinical, clinical or regulatory purposes.

“Force Majeure” means any unavoidable and unforeseeable event which is beyond the reasonable control of the Party affected, including but not limited to the following events: earthquake, storm, flood, fire or other acts of nature, epidemic, war (whether or not declared), riot, public disturbance, strike or lockouts, government actions, terrorist attack or the like.

“Good Manufacturing Practice” or **“GMP”** means the current good manufacturing practices and all applicable governmental rules and regulations as applied at the site(s) of manufacture and control, as amended from time to time and in effect during the term of this License Agreement.

“Governmental Entity” means any court, agency, authority, department, legislative or regulatory body or other instrumentality of any (i) government, (ii) country, (iii) national, federal, state, provincial, regional, county, city or other political subdivision of any such government or country, (iv) supranational organization of which any such government or country is a member, or (v) quasi-governmental entity or self-regulatory organization of competent authority.

“Information” means all proprietary information and data of a financial, commercial or technical nature, including Know-How, owned or Controlled by a Party, which has been supplied or otherwise made available to the other Party or its Affiliates, under this License Agreement and whether made available orally, in writing or in electronic form, including information comprising or relating to concepts, discoveries, inventions, data, designs or formulae.

“Infringement Claim” has the meaning ascribed to such term in Clause 13.5.

“Intellectual Property Rights” means all rights in Patents, rights to inventions, copyright and related rights, rights in trade-marks, trade names and domain names, rights in designs, rights in computer software, database rights, rights in confidential information (including Know-How) and any other intellectual property rights, in each case whether registered or unregistered and including all applications (or rights to apply) for, and renewals or extensions (for their full term) of, such rights and all similar or equivalent rights or forms of protection which subsist or will subsist now or in the future in any part of the world.

“Insolvency Event” means, in relation to OV, any one of the following: (a) OV is the subject of voluntary or involuntary bankruptcy proceedings instituted on behalf of or against OV (except for involuntary bankruptcy proceedings which are dismissed within one-hundred and twenty (120) days); (b) an administrative receiver, receiver and manager, interim receiver, custodian, sequestrator or similar officer is appointed for substantially all of the assets of OV; (c) a resolution to wind up OV shall have been passed other than a resolution for the solvent reconstruction or reorganization of OV; or (d) a resolution shall have been passed by OV’s board of directors to make an application for an administration order or to appoint an administrator for substantially all of the assets of OV.

“Inventory” means the inventory of drug substance, drug product, samples of impurities, degradation products and reference compound manufactured by using the Compound as listed in **Schedule B**, in each case whether or not the shelf life has expired prior to the Effective Date.

“Know-How” means technical information, know-how and data, including inventions (whether patentable or not), discoveries, trade secrets, package specifications, chemical specifications, analytical test methods, stability data, testing data, product specifications, instructions, processes, formulation information, validation documents, materials, drawings, formulae, reports, and other technology and techniques including all biological, chemical, pharmacological, toxicological, pharmaceutical, physical and analytical, clinical safety, safety data, preclinical and clinical data.

“Law” means any statute, law, ordinance, requirement, regulatory rule, code or order of a Governmental Entity.

“Legal Proceeding” means any action, suit, litigation, arbitration, proceeding (including any civil, criminal, administrative, investigative or appellate proceeding), hearing, inquiry, audit, examination or investigation commenced, brought, conducted or heard by or before, or otherwise involving, any court or other Governmental Entity or any arbitrator or arbitration panel.

“Licensed Data” means all Know-How owned or Controlled as of the Effective Date or at any time during the Term by Novartis and/or its Affiliates that is necessary to Develop, Manufacture, or Commercialize the Compound in the Field in the Territory.

“Licensed IP” means the Licensed Patents and Licensed Data.

“Licensed Patents” means the Product-Specific Patents and the Platform Patents.

“Licensed Product(s)” means one or more pharmaceutical, therapeutic or diagnostic products containing the Compound as an active ingredient alone or in combination with other active ingredients.

“Licensed Product Activities” shall have the meaning set forth in Clause 4.

“Losses” means all claims, damages, losses, suits, proceedings, liabilities, costs (including costs of litigation and reasonable attorney’s fees), , of any kind and is not limited to matters asserted by Third Parties against a Party, but includes claims, damages, losses, suits, proceedings, liabilities, costs (including reasonable legal expenses, costs of litigation and reasonable attorney’s fees) incurred or sustained by a Party in the absence of Third Party claims; provided that no Party shall be liable to hold harmless or indemnify the indemnified Party, as applicable, for any claims, damages, losses, suits, proceedings, liabilities, costs or judgments for punitive or exemplary damages, except to the extent the Party seeking indemnification is actually liable to a Third Party for such punitive or exemplary damages in connection with a claim by such Third Party.

“Main European Countries” means Austria, Belgium, Bulgaria, Croatia, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden and the United Kingdom.

“Major Country” means the countries listed hereto on **Schedule D**.

“Manufacture” means any and all activities and operations involved in or relating to the manufacturing, quality control testing (including in-process, release and stability testing), releasing or packaging, for pre-clinical, clinical or commercial purposes of any and all Licensed Product(s), including the Compound, any component or ingredient thereof. “Manufacturing” has a corresponding meaning.

“Manufacturing Technology” means technology, Know-How and Information in each case to the extent necessary for the manufacture and/or analytical testing of the Compound in the Field, and/or other available records related to the manufacturing process and that are in existence and owned or controlled by Novartis and/or its Affiliates on the Effective Date but excluding the Licensed IP.

“Marketing Authorization Application” or **“MAA”** shall mean an application for Regulatory Approval in the European Union to market a product in any country, whether filed with the EMA under the centralized EMA filing procedure or a Regulatory Authority in any country in the European Union.

“Milestone” shall have the meaning set forth in Clause 7.2.

“NDA” means a New Drug Application (as more fully described in U.S. 21 C.F.R. Parts 314.50 et seq. or its successor regulation) and all amendments and supplements thereto, submitted to the FDA, or any equivalent filing, including an MAA, in a country or regulatory jurisdiction other than the U.S. with the applicable Regulatory Authority, or any similar application or submission for Regulatory Approval filed with a Regulatory Authority to obtain marketing approval for the Compound or any Licensed Product, in a country or in a group of countries.

“Net Sales” means the net sales on behalf of OV and any of its Affiliates or sublicensees or assignees for the Licensed Product sold to Third Parties other than sublicensees/assignees, as determined in accordance with Accounting Standards consistently applied at OV. The deductions booked by OV and its Affiliates, sublicensees and assignees to calculate the recorded net sales from gross sales include the following:

- (i) normal trade and cash discounts;
- (ii) amounts repaid or credited by reasons of defects, rejections, recalls or returns;

(iii) rebates and chargebacks to customers and Third Parties (including, without limitation, Medicare, Medicaid, Managed Healthcare and similar types of rebates), as well as related taxes;

(iv) any amounts recorded in gross revenue associated with goods provided to customers for free;

(v) amounts provided or credited to customers through coupons and other discount programs;

(vi) delayed ship order credits, discounts or payments related to the impact of price increases between purchase and shipping dates or retroactive price reductions;

(vii) fee for service payments to customers for any non-separable services (including compensation for maintaining agreed inventory levels and providing information);

(viii) freight and insurance charges for the transportation and insurance in shipping such Licensed Product, to the extent specifically included in the invoice to the Third Party; and

(ix) other reductions or specifically identifiable amounts deducted for reasons similar to these listed above in accordance with OV's Accounting Standards.

With respect to the calculation of Net Sales:

(i) Net Sales only include the value charged or invoiced on the first sale to a Third Party and sales between or among OV and its Affiliates and sublicensees/assignees shall be disregarded for purposes of calculating Net Sales;

(ii) 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 OV's Accounting Standards are met; and

(iii) distributors shall not be considered as sublicensees/assignees.

"Novartis Indemnitees" shall have the meaning set forth in Clause 12.2.

"Option Agreement" shall have the meaning set forth in the Preamble of this License Agreement.

"Patents" means (a) all issued patents and pending patent applications, including the parents thereof and issued patents maturing therefrom, in any country or supranational jurisdiction worldwide, (b) any substitutions, divisionals, continuations, continuations-in-part, reissues, renewals, registrations, confirmations, re-examinations, extensions, supplementary protection certificates and the like of any such patents or patent applications, and (c) foreign counterparts of any of the foregoing.

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

“Phase II Clinical Trial” means a human clinical trial of a product in any country that would satisfy the requirements of U.S. 21 C.F.R. Part 312.21(b) and is intended to explore a variety of doses, dose response, and duration of effect, and to generate evidence of clinical safety and effectiveness for a particular Indication or Indications in a target patient population, or a similar clinical study prescribed by the relevant Regulatory Authorities in a country other than the United States.

“Phase III Clinical Trial” means a human clinical trial of a product in any country that would satisfy the requirements of U.S. 21 C.F.R. Part 312.21(c) and is intended to (a) establish that the product is safe and efficacious for its intended use, (b) define contraindications, warnings, precautions and adverse reactions that are associated with the product in the dosage range to be prescribed, and (c) support Regulatory Approval for such product, or a similar clinical study prescribed by the relevant Regulatory Authorities in a country other than the United States.

“Platform Patents” means those Patents listed on **Schedule C** attached hereto under the heading “Platform Patents” as well as any Patent, other than the Product-Specific Patents, owned or Controlled by Novartis or its Affiliates as of the Effective Date and during the Term that: (a)(i) claims any Licensed Data, and/or (ii) is otherwise necessary to Develop, Manufacture or Commercialize the Licensed Product in the Field in the Territory, and (b) does not specifically describe or reference a Licensed Product or exploitation of a Licensed Product in the Field.

“Product-Specific Patents” means those Patents listed on **Schedule C** attached hereto under the heading “Product-Specific Patents” as well as any Patent, other than the Platform Patents, owned or Controlled by Novartis or its Affiliates as of the Effective Date and during the Term that: (a)(i) claims any Licensed Data and/or (ii) is otherwise necessary to Develop, Manufacture or Commercialize the Licensed Product in the Field in the Territory, and (b) does specifically describe or reference a Licensed Product or exploitation of a Licensed Product in the Field.

“Prosecution” or **“Prosecute”** means, with regard to a Patent, the preparation, filing, prosecution and maintenance of such Patent, as well as re-examinations, reissues, appeals, and, subject to Clause 13.2, requests for patent term adjustments and patent term extensions with respect to such Patent, together with the initiation or defense of interferences, oppositions, inter partes, re-examinations, post-grant proceedings and other similar proceedings with respect to the particular Patent, and any appeals therefrom. For clarification, “Prosecution” or “Prosecute” shall not include any other enforcement actions taken with respect to a Patent.

“Regulatory Approval” means, with respect to the Licensed Product, any approval (notwithstanding the indication), registration, license or authorization from a regulatory authority to market and sell such Licensed Product in the Field in the Territory, including (a) separate pricing or reimbursement approvals whether or not legally required in order to sell the Licensed Product in such country, and (b) the approval by the applicable Regulatory Authority of any expansion or modification of the label for the applicable indication.

“Regulatory Authority” means, with respect to any country or jurisdiction, any Governmental Entity involved in granting Regulatory Approval in that country or jurisdiction.

“Regulatory Documentation” shall mean relevant applications, registrations, licenses, authorizations, approvals and correspondence submitted to or received from Regulatory Authorities (including minutes and official contact reports relating to any communications with any Regulatory Authority) and relevant and available supporting documents in connection therewith relating to the use of the Compound by Novartis in the Field, including relevant clinical trial data as required for regulatory purposes and Licensed Data contained in any of the foregoing, including drug master files, inspection reports, related to the Compound in the Field, or as required for regulatory purposes.

“Regulatory-Based Exclusivity” means, on a Licensed Product-by-Licensed Product and country-by-country basis, that (a) OV or any of its Affiliates or Sublicensees has been granted the exclusive right by a Regulatory Authority (or is otherwise entitled to the exclusive right by operation of Law) in such country to market and sell the Licensed Product in such country, including any pediatric or orphan drug exclusivity, or (b) the data and information submitted by OV or any of its Affiliates or Sublicensees to the relevant Regulatory Authority in such country for purposes of obtaining Regulatory Approval for such Licensed Product may not be relied upon in any way by any Person other than OV, its Affiliates or Sublicensees (including by relying upon the Regulatory Authority’s previous findings regarding the safety or effectiveness of the Licensed Product) to market and sell a product for use in the same indications as such Licensed Product by a Third Party in such country.

“Regulatory Filings” means, with respect to the Licensed Product, any submission to a regulatory authority of any appropriate regulatory application.

“Royalty Term” shall have the meaning set forth in Clause 7.4(b).

“Sales & Royalty Report” shall have the meaning set forth in Clause 8.4.

“Territory” means worldwide.

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

“Upfront Payment” means the payment to be made by OV to Novartis upon the Effective Date as set forth in Clause 7.1.

“USD” or “US Dollars” means the lawful currency of the United States of America.

“Valid Claim” means, with respect to a particular country, (a) a claim of a pending Patent claiming priority from any Patent that has been pending for no more than five (5) years following the earliest priority filing date for such Patent and that has not been abandoned, finally rejected or expired without the possibility of appeal or refiling or (b) a claim of an issued and unexpired Patent that has not been held permanently revoked, held unenforceable or invalid by a decision of a court or other Governmental Authority of competent jurisdiction, which decision is unappealed or unappealable within the time allowed for appeal and has not been cancelled, withdrawn, abandoned, disclaimed or admitted to be invalid or unenforceable through reissue, re-examination, disclaimer or otherwise, in the case of (a) and (b) above, claims the composition of matter or method of use of a Licensed Product.

1.2 Interpretation. In this License Agreement unless otherwise specified:

- (a) “includes” and “including” shall mean respectively includes and including without limitation;
- (b) words denoting the singular shall include the plural and vice versa and words denoting any gender shall include all genders;
- (c) the Schedules and other attachments form part of the operative provision of this License Agreement and references to this License Agreement shall, unless the context otherwise requires, include references to the Schedules and attachments;
- (d) references to Clauses and subclauses are to Clauses and subclauses of this License Agreement unless otherwise specified;
- (e) a reference to an enactment or statutory provision is a reference to it as it may from time to time be amended, modified, consolidated, repealed or re-enacted and shall include any orders, regulations, instruments or other subordinate legislation made under the relevant statute;
- (f) the headings in this License Agreement are for information only and shall not be considered in the interpretation of this License Agreement;
- (g) any reference to “writing” or “written” includes faxes and any legible reproduction of words delivered in permanent and tangible form (but does not include email);
- (h) the words “hereof”, “herein” and “hereunder” and words of like import used in this License Agreement shall refer to this License Agreement as a whole and not to any particular provision of this License Agreement; and
- (i) the Parties agree that the terms and conditions of this License Agreement are the result of negotiations between the Parties and that this License Agreement shall not be construed in favor of or against any Party by reason of the extent to which any Party participated in its preparation.

2. LICENSE

2.1 License Grant from Novartis to OV. Subject to the terms and conditions of this License Agreement, Novartis hereby grants to OV (a) an exclusive, royalty-bearing, sublicensable (subject to Clause 2.2 below), assignable (subject to Clause 17.2 below) license under the Licensed Data and Product-Specific Patents and (b) a non-exclusive, royalty-bearing, sublicensable (subject to Clause 2.2 below), assignable (subject to Clause 17.2 below) license under the Platform Patents, in the case of (a) and (b) solely to Develop and otherwise Commercialize the Licensed Product in the Field in the Territory and to Manufacture and have Manufactured the Compound for use in a Licensed Product in the Field in the Territory as of the Effective Date.

Subject to the terms and conditions of this License Agreement, Novartis grants to OV a non-exclusive, sublicensable (subject to Clause 2.2 below), assignable (subject to Clause 17.2 below) license under the Manufacturing Technology to use the Manufacturing Technology in the Territory solely to Manufacture or have Manufactured the Compound for use in a Licensed Product for Development and/or Commercialization in the Field in the Territory.

2.2 Sublicensing.

(a) **By OV.** At any time following completion of the first Phase II Clinical Trial for the use of the Compound in the Field which satisfies the criteria set forth on Schedule E, and subject to Clause 2.2(b) below, OV may sublicense the rights granted to it under Clause 2.1 of this License Agreement without the prior written consent of Novartis.

(b) **Sublicense Requirements.** Any sublicense by OV will be subject to a written agreement that (i) requires the sublicensee to comply with all applicable obligations of this License Agreement, and (ii) is not in conflict with any term of this License Agreement. OV shall undertake to enforce the provisions of any such sublicense and shall remain responsible and jointly and severally liable with the sublicensee to Novartis for the performance of its sublicensee's obligations and for all acts or omissions of its sublicensees as if they were the acts or omissions of OV under this License Agreement.

2.3 Reservation of Rights by Novartis. Without prejudice to any other rights that Novartis may have, OV agrees that Novartis retains or shares full and unencumbered rights under the Licensed IP to exploit or have exploited the Compound in the Territory solely outside the Field. OV acknowledges and agrees that as between the Parties, Novartis and/or its Affiliates are the sole owner(s) of all right, title and interest in and to the Licensed IP, and OV has not acquired, and shall not acquire, any right, title or interest in or to the Licensed IP pursuant to this License Agreement other than the rights expressly set forth in this License Agreement.

3. TRANSFER OF INFORMATION AND DATA

3.1 Transfer of Information and Licensed Data. Novartis shall provide to OV within sixty (60) days of the Effective Date with a copy of relevant and available tangible embodiments of Licensed Data concerning the Licensed IP and Regulatory Documentation, set forth on Schedule G owned or Controlled by Novartis or its Affiliates on the Effective Date as available in Novartis global database and archives. For clarity, any additional information that is available on a country level may be transferred by Novartis or its Affiliates to the extent such transfer can be accomplished using commercially reasonable efforts and only upon OV's written request and at OV's costs. Any request for transfer of local data needs to be submitted by OV within two (2) years after the Effective Date

3.2 Assistance. For a period of six (6) months as of the Effective Date, Novartis shall use commercially reasonable efforts to provide reasonable assistance requested by OV to facilitate the transfer of technical data and processes related to the Compound to OV, and to transfer to OV the Licensed Data licensed to OV under Clause 2.1, by providing OV with reasonable access by teleconference or in-person to Novartis personnel involved in the research, Development and Manufacture of Compound; *provided* such Novartis personnel remains employed by Novartis or its Affiliates during such six (6) month period following the Effective Date. Such assistance shall not exceed seventy-five (75) man-hours in total during such six (6) month period, nor shall such period or hour commitment be extended. Novartis shall be obligated to provide such assistance solely to OV and/or its Affiliates (but not, for clarity, to any Third Party, e.g. service providers or contract manufacturers of OV). Novartis agrees not to charge OV for such assistance as described in this Clause 3.2.

3.3 Adverse Event Reporting and Safety Data Exchange. The Parties shall cooperate with regard to the reporting and handling of safety information involving or relating to the Compounds and/or the Products to the extent required by applicable Laws. Following the Effective Date, and in time to ensure that all regulatory requirements are met, and to the extent required by applicable Laws or any Regulatory Authority, the Parties will enter into a written agreement that will govern the exchange of adverse event and other safety information and the Parties', their Affiliates' and their sublicensees' respective reporting obligations relating to the Compounds and/or the Products (the "**Pharmacovigilance Agreement**"). Such Pharmacovigilance Agreement shall ensure that adverse events and other safety information is exchanged and reported to the relevant Regulatory Authorities upon terms that will permit each Party to comply with applicable Laws and requirements of Regulatory Authorities.

3.4 Transfer of Clinical Materials. Within sixty (60) days as of the Effective Date, Novartis shall provide to OV the Clinical Materials included in Schedule H. Novartis shall ship Clinical Materials, at OV's expense, to OV's U.S. headquarters: Attn: Dr. Steen Knudsen, Ph.D., Medical-Prognosis Institute, Inc. (OV), 13208 East Shea Blvd., Suite 100, Scottsdale, AZ 85259 U.S.A. OV is solely responsible for handling of the Clinical Material in strict compliance with patient informed consents relating to use of such Clinical Materials and with all applicable Laws, including data privacy laws relating to the transfer of Clinical Material and related personal information.

4. DEVELOPMENT, COMMERCIALIZATION & MANUFACTURING

4.1 Development. OV will be solely responsible for and shall, subject to the terms of this Agreement, have final decision-making authority with respect to the Development of a Licensed Product in the Field in the Territory. OV shall develop a clinical development plan for the Phase II Clinical Trial to be conducted by or on behalf of OV under this License Agreement (a "**Development Plan**") in a Major Country within ninety (90) days of the Effective Date, which Development Plan shall be in accordance with **Schedule E**. Other than in cases of an acquisition in accordance with Clause 4.3 below, OV shall bear one hundred percent (100%) of all costs and expenses associated with the Development of Products.

4.2 OV Responsibilities. OV shall use Commercially Reasonable Efforts to successfully complete a Phase II Clinical Trial for the use of the Compound in the Field. Following completion of a Phase II Clinical Trial for the Licensed Product pursuant to the Development Plan and subject to Clause 4.3, OV will use Commercially Reasonable Efforts to Develop, Manufacture and Commercialize Licensed Product(s) in the Field in all Major Countries (individually and together, the "**Licensed Product Activities**").

4.3 Third Party Acquirer. Following completion of a Phase II Clinical Trial for a Licensed Product pursuant to the Development Plan, OV may identify one or more, but not more than two (2), potential Third Party(ies) (a "**Program Acquirer**") to acquire (whether through sale, license, merger or otherwise) and, subject to Clause 17.2 and/or Clause 2.2, respectively, assume the rights and obligations to Develop, Manufacture and Commercialize the respective Licensed Product in the Field in the Territory. The Parties understand and agree that entry into any such agreement with a Program Acquirer shall be at the discretion of OV, subject to Clause 17.2 and/or 2.2, respectively. If a suitable Third Party Acquirer is not secured, OV shall use its Commercially Reasonable Efforts to, either itself or through its Affiliates, Develop and Commercialize the Licensed Product.

4.4 Reporting Obligations. OV shall provide Novartis with a written summary report on or before the first of March and on or before the first of September of each Calendar Year summarizing OV's and/or OV's Third Party collaborators' and sublicensees': (i) Licensed Product Activities for the Compound and/or the Licensed Product(s) in the Field in the Territory performed in the previous six (6) month period; and (ii) anticipated plans for the Licensed Product Activities for the Compound and/or the Licensed Product(s) in the Field in the Territory for the subsequent six (6) month period. Each such report shall contain, at a minimum, information sufficient to permit Novartis to evaluate the progress towards the respective obligations under this License Agreement, and, if so requested by Novartis, shall be followed-up or prefaced with a telephone conference between sufficiently qualified representatives of each Party at a mutually agreed time but in any event no later than thirty (30) days following Novartis' request to discuss such report in more detail. All

information and data obtained under this Clause 4.4 shall be used only for the purposes of verifying compliance with the diligence obligations under Clause 4.2 and shall be treated as OV's Confidential Information and subject to the confidentiality obligations set forth in Clause 15.

4.5 Compliance. OV agrees that in performing its obligations under this License Agreement, in particular with regard to Licensed Product(s): (a) it shall, and shall cause its Affiliates, Third Party collaborators and sublicensees to, comply with all applicable Laws, current international regulatory standards, including cGMP, cGLP, cGCP and other rules, regulations and requirements; and (b) it will not knowingly employ or use any Person that has been debarred under applicable Laws.

5. OWNERSHIP OF INTELLECTUAL PROPERTY.

5.1 OV Technology. As between the Parties, OV will be the sole owner of any Improvements to the Licensed IP and intellectual property rights therein that are discovered, generated, developed, invented or created solely by OV, its Affiliates or Third Parties acting on its or its Affiliates' behalf while conducting activities in connection with the Development, Manufacture and/or Commercialization of the Licensed Product (such Improvements and intellectual property rights, "**OV Know-How**", and any Patents that claim such OV Know-How, "**OV Patents**" and, together with the OV Know-How, the "**OV Technology**"), and will retain all of its rights, title and interest thereto.

6. REGULATORY MATTERS.

6.1 Compliance with Laws. Each Party shall comply in all material respects with all applicable Laws, including all Regulatory and data privacy laws that pertain to its activities under this License Agreement and, except as otherwise provided herein, each Party shall bear its own cost and expense of such compliance.

6.2 Transfer of Regulatory Documentation. Novartis shall transfer, within sixty (60) days after the Effective Date, to OV for its use the Regulatory Documentation for the Compound in the Territory.

7. FINANCIAL PROVISIONS

7.1 Upfront Payments. In consideration of the licenses and rights granted to OV hereunder on the Effective Date, OV shall pay to Novartis a one-time, non-refundable, non-creditable upfront payment consisting of One Million United States Dollars (\$1,000,000.00) ("**Upfront Payment**") and shall issue to Novartis the Convertible Promissory Note within ten (10) days following the Effective Date.

7.2 Milestone Payments. In further consideration for the licenses and rights granted to OV hereunder, OV shall pay to Novartis the following Milestones upon achievement of the respective Milestones events as set forth below, in each case related to the Development of the Compound in the Field in the Territory, by OV or on behalf of OV, itself or through any of its Affiliates or sublicensees, the corresponding one-time, non-refundable, non-creditable payments ("**Milestone Payments**"):

Milestone Event	Milestone Payment (US\$)
Upon enrollment of half of the patients required in the planned Phase II Clinical Trials in a Major Country according to the approved study protocol for the first Phase II Clinical Trial for a Licensed Product.	***
Upon dosing of the first patient in the first Phase III Clinical Trial for a Licensed Product.	***
Upon submission of the first NDA with the FDA for a Licensed Product in the United States.	***
Submission of an MAA to the EMA or any other Regulatory Authority for a Licensed Product in the Main European Countries	***
Upon receipt of the first authorization for a Licensed Product by the FDA in the United States to market and sell such Licensed Product (but explicitly excluding any pricing or reimbursement approvals).	***
Upon receipt of a MAA (including a respective pricing and reimbursement approval) for a Licensed Product in one or more countries belonging to the Main European Countries	***

7.3 Payment of Milestones. Each Milestone shall be deemed earned as of the first achievement of the respective Milestone event, and is payable one time only regardless of the number of Licensed Products. Subject to this Clause 7.3, from and after the date of any notice of termination by Novartis according to Clause 14.3(a) is received by OV, no further milestones with respect to the Licensed Product shall be payable by OV to Novartis, except to the extent those Milestone Payments relate to Milestones that have been achieved prior to OV's receipt of the termination notice which are unpaid.

7.4 Royalties.

(a) **Royalty Payments.** In further consideration of the license and rights granted to OV hereunder, during the Royalty Term (as defined below), OV will make royalty payments to Novartis on annual Net Sales of Licensed Product(s) in the Field in the Territory by OV and its Affiliates and sublicensees, on a Licensed Product-by-Licensed Product basis:

Annual Net Sales of a Licensed Product in the Territory in a Calendar Year during the Royalty Term (US\$)	Royalty Rate
Portion of Net Sales less than or equal to Two Hundred and Fifty Million United States Dollars (US\$ 250,000,000.00)	***
Portion of Net Sales greater than Two Hundred and Fifty Million United States Dollars (US\$ 250,000,000.00) but less than or equal to Five Hundred Million United States Dollars (US\$ 500,000,000.00)	***
Portion of Net Sales greater than Five Hundred Million United States Dollars (US\$ 500,000,000.00) but less than or equal to Seven Hundred and Fifty Million United States Dollars (US\$ 750,000,000.00)	***
Portion of Net Sales greater than Seven Hundred and Fifty Million United States Dollars (US\$ 750,000,000.00)	***

By way of example: If during the Royalty Term the annual Net Sales in the Territory for a Licensed Product in a Calendar Year is One Billion United States Dollars (US\$1,000,000,000), the royalties payable in such Calendar Year shall equal [***]. For clarity, the Net Sales are calculated based on the sum of sales in any country within the Territory where such Licensed Product is sold.

(b) **Royalty Term.** The royalties set forth in Clause 7.4(a) will be payable on a Licensed Product-by-Licensed Product and country-by-country basis from date of the First Commercial Sale of such Licensed Product in such country and shall continue to be paid in accordance with the terms of this License Agreement until the later of (a) the expiration of the last to expire Valid Claim of any Licensed Patent covering such Licensed Product in such country; or, (b) the expiration of Regulatory-Based Exclusivity for such Licensed Product in such country or (c) the ten (10) year anniversary of the date of First Commercial Sale of such Licensed Product in such country (the "**Royalty Term**").

(c) **Fully Paid-Up, Royalty Free License.** Following expiration of the Royalty Term for a Licensed Product in a given country, no further royalties will be payable in respect of sales of Product in such country and, thereafter the license granted to OV hereunder with respect to Product in such country will automatically become fully paid-up, perpetual, irrevocable and royalty-free.

(d) **Royalty Reduction.** OV's royalty obligations to Novartis under Clause 7.4(a) shall be on a country-by-country basis for the applicable Royalty Term in such country; provided that the royalty amounts payable with respect to annual Net Sales shall be reduced on a country-by-country basis, to [***] of the amounts otherwise payable pursuant to Clause 7.4(a), during any portion of the Royalty Term in which there is not at least one (1) Valid Claim of a Patent within the Licensed IP that Covers such Licensed Product in such country. Only one royalty shall be payable by OV to Novartis for each sale of a Licensed Product.

(e) **Royalty Reduction for Competitive Product Competition.** If, on a Licensed Product-by-Licensed Product, country-by-country and Calendar Quarter-by-Calendar Quarter basis,

(i) A Competitive Product(s) has a market share of greater than [***] but less than or equal to [***]; or

(ii) A Competitive Product(s) has a market share of more than [***];

then the royalties payable with respect to annual Net Sales pursuant to Clause 7.4(a) in such country during such Calendar Quarter shall be reduced by [***] if subclause (i) applies, and [***] if subclause (ii) applies, respectively, of the royalties otherwise payable pursuant to Clause 7.4(a). Market share shall be based on the aggregate market in such country of such Licensed Product and the Competitive Product(s) (based on sales of units of such Licensed Product and such Competitive Product(s) in the aggregate, as reported by IMS International, or if such data are not available, such other reliable data source as reasonably agreed by the Parties).

(f) **Royalty Reduction for Third Party Payments.** If OV reasonably determines that any Third Party intellectual property rights are necessary for the Development, Manufacture, or Commercialization of Licensed Products, then OV may negotiate and obtain a license under, or effect an acquisition for, or otherwise pay amounts with respect to any litigation regarding, such Third Party's intellectual property rights (each such Third Party license or payment referred to herein as an "**Additional Third Party License**"). Any royalty otherwise payable to Novartis under this License Agreement with respect to annual Net Sales of any Licensed Product by OV, its Affiliates or sublicensees in such country will be reduced by [***] of the amounts payable to Third Parties pursuant to any Additional Third Party Licenses, such reduction to continue (and be carried forward for use) until all such amounts have been expended.

(g) **Cumulative Effect of Royalty Reductions.** In no event shall the royalty reductions described in Clauses 7.4(d), (e) or (f) alone or together, reduce the royalties payable by OV for a given Calendar Quarter pursuant to Clause 7.4(a) to less than [***] of the amounts payable by OV for a given Calendar Quarter pursuant to Clause 7.4(a). OV may carry over and apply any such royalty reductions which are incurred or accrued in a Calendar Quarter and are not deducted in such Calendar Quarter, to any subsequent Calendar Quarter(s), and shall begin applying such reduction to such royalties as soon as practicable and continue applying such reduction on a Calendar Quarterly basis thereafter.

7.5 Royalties on Combination Products. Further, if the Licensed Product is sold or provided as part of a system, package, or combination product or service that involve one or more products or services not Covered by the Licensed Patents (each, a "**Combination Product**"), Net Sales shall be calculated by multiplying the Net Sales of such Combination Product by the fraction A/B, where "A" is the price of the Licensed Product included in such Combination Product when sold separately from any other products or services not Covered by the Licensed Patents and "B" is the price of the Combination Product. In the event that no market price is available for the Licensed Product included in such Combination Product when supplied or priced separately, Novartis and OV shall use best efforts to determine in good faith the fair market value thereof and if they cannot determine the fair market value thereof within ten (10) days of either parties request of a determination they shall select a third party mutually acceptable to make such determination.

8. REPORTS AND PAYMENT TERMS

8.1 Payment Terms.

(a) OV shall notify Novartis in writing within ten (10) days after achievement of the applicable Milestone event and Novartis shall thereafter issue to OV an invoice substantially in the form provided by Novartis in respect of the applicable Milestone payment. OV will pay such invoice to Novartis within thirty (30) days from the date of receipt of the invoice.

(b) Within forty-five (45) days after each Calendar Quarter during the term of this License Agreement following the First Commercial Sale of a Licensed Product (on a Licensed Product-by-Licensed Product basis), OV will provide to Novartis a Sales & Royalty Report. Novartis shall submit an invoice to OV substantially in the form provided by Novartis with respect to the Royalty amount shown therein. OV shall pay such Royalty amount within thirty (30) days after the date of its receipt of the invoice.

(c) All payments from OV to Novartis shall be made by wire transfer of immediately available funds in US Dollars to the credit of such bank account or accounts as may be designated by Novartis in this License Agreement or in writing to OV from time to time. Any payment which falls due on a date which is not a Business Day may be made on the next succeeding Business Day.

8.2 Currency Exchange Rate. All payments under this License Agreement shall be payable in US Dollars. The Royalty amount to be paid by OV in respect to the Net Sales of the Licensed Product in the Field in the Territory sold in a currency other than US Dollars shall be converted to the US Dollar equivalent using the buying rate for the applicable currency of the country from which the royalties are payable, certified by the United States Federal Reserve Bank of New York, as published from time to time by the United States Federal Reserve Board, on the Internet at <http://www.federalreserve.gov/releases/h10/>, or elsewhere, in respect to the last Business Day of the Quarter ending immediately prior to the date on which the applicable Royalty payment is due or the last date prior to such last Business Day for which such certified buying rate has been published by the United States Federal Reserve Board.

8.3 Taxes. OV may withhold from payment made to Novartis under this License Agreement any income tax required to be withheld by OV under the laws of the country or jurisdiction where OV has commercially sold Licensed Products. If any tax is withheld by OV, OV shall provide OV receipts or other evidence of such withholding and payment to the appropriate tax authorities on a timely basis following that tax payment. Each Party agrees to cooperate with the other Party in claiming refunds or exemptions from such deductions or withholdings under any relevant agreement or treaty which is in effect. The Parties shall discuss applicable mechanisms for minimizing such taxes to the extent possible in compliance with applicable Law. In addition, the Parties shall cooperate in accordance with applicable Law to minimize indirect taxes (such as value added tax, sales tax, consumption tax and other similar taxes) in connection with this License Agreement.

8.4 Records and Audit Rights. Within forty-five (45) days after the end of a Calendar Quarter, OV will prepare and provide Novartis a written report or reports substantially in the form set out in **Schedule F** showing each of: (a) gross sales; (b) Net Sales; (c) number of units sold; (d) all permitted reductions to or deductions from gross sales; and (e) Royalties payable for the Licensed Product in the Field in the Territory on a country-by-country basis in United States Dollars during the reporting period; and (f) date of First Commercial Sale for each Licensed Product in each country. For the avoidance of doubt such written report shall also show details on the aforementioned (a) to (c) items for: (i) OV, its Affiliates and authorized sub-licensees; (ii) last Calendar Quarter and year to date data, for example, up to the last month of the last Calendar Quarter; and (iii) for each Licensed Product ("**Sales & Royalty Report**").

(a) OV shall keep complete, true and accurate books and records in accordance with its Accounting Standards in relation to this License Agreement, including in relation to Net Sales and the Sales & Royalties Report. OV will keep such books and records for at least three (3) years following the Calendar Quarter to which they pertain.

(b) Novartis shall have the right for a period of three (3) years after receiving each Sales & Royalty Report to audit whether by itself or through its Affiliate(s) and/or to appoint an internationally-recognized independent accounting firm (whether Novartis, its Affiliate or an accounting firm, hereinafter referred to as the “**Auditor**”) to inspect the relevant records of OV and its Affiliates or its sublicensees to verify such reports, statements, records or books of accounts, as applicable. Where the Auditor is not Novartis the Auditor shall have the right to disclose to Novartis and/or other Affiliates of Novartis its conclusions regarding any payments owed under this License Agreement.

(c) OV and its Affiliates and sublicensees shall make their records available for inspection by the Auditor during regular business hours at such place or places where such records are customarily kept, upon receipt of reasonable advance notice from Novartis, its Affiliate or designated independent accounting firm, to verify the accuracy of the Sales & Royalty Reports and compliance with this License Agreement. Novartis agrees to hold in confidence all information received and all information learned in the course of any audit or inspection, except to the extent that such information is not confidential and/or it is necessary to disclose it to enforce its rights under this License Agreement or if disclosure is required by Law.

(d) Novartis shall pay for such audits, as well as its own expenses associated with enforcing its rights with respect to any payments hereunder, except that, if an underpayment of more than five percent (5%) of the total payments due hereunder for the

applicable Calendar Year is discovered, the reasonable fees and expenses charged by or incurred by the Auditor shall be paid by OV.

(e) In the event that the final result of the inspection reveals an undisputed underpayment by OV, the underpaid amount shall be settled promptly to Novartis with interest thereon at the Novartis with interest thereon at the LIBOR rate plus five percent (5%) or the highest rate permitted by law (whichever is lower), computed from the date such underpayment was due until the date that OV makes the underpayment. In the event that the final result of the inspection reveals an undisputed overpayment by OV, the underpaid amount shall be settled promptly to OV from Novartis with no interest thereon.

8.5 Reports. Following the first regulatory approval for a Licensed Product in the first country in the Territory, OV will provide Novartis with the following: (a) estimated quarterly Net Sales information within fifteen (15) days prior to the end of each Calendar Quarter; and (b) the Net Sales budget for current and following Calendar Year as soon as reasonably available. For the avoidance of doubt, the information provided by OV pursuant to this Clause 8.5 shall be deemed to be Confidential Information for purposes of this License Agreement, including, without limitation, Clause 15.

9. INVENTORY.

9.1 Inventory. Novartis will transfer the ownership to and prepare any Inventory, for pick-up by OV or a Third Party as indicated by OV within sixty (60) days of the Effective Date. For clarity, OV is responsible for obtaining all necessary import licenses and other approvals necessary to import the Inventory. Inventory will be supplied “as is” at no additional costs but with no warranties, express or implied, including any warranty that Inventory complies with applicable specification or other release requirements as defined by Novartis; Novartis shall supply to OV the certificate of analyses for such Inventory (if available). For clarity, in case OV has not picked-up the Inventory in writing within sixty (60) days after the Effective Date, Novartis shall be entitled to destroy or dispose of the Inventory at OV’s cost and expense.

9.2 Requalification. OV is aware and acknowledges that certain quantities forming part of the Inventory are expired and can only be used upon successful requalification. OV is responsible for the retesting of the Inventory prior to use and assumes the full responsibility for the use of the Inventory.

10. FURTHER OBLIGATIONS

10.1 Actions. Neither Party shall do or omit to do anything that would substantially diminish or impair the rights of Novartis or OV in the Licensed IP, provided however, that the foregoing shall not restrict OV's discretion as to the Development and Commercialization of the Licensed Product(s) so long as OV complies with its obligation to use Commercially Reasonable Efforts in accordance with Clause 4. If any Party becomes aware of any claim or challenge to, the validity of the Licensed IP, it shall promptly inform the other Party.

10.2 Further Assurances. The Parties shall, and shall cause their Affiliates to, promptly cooperate with each other and their Affiliates and provide such information and assistance as may be reasonably requested by the other in connection with any filings or other actions contemplated by any Competition Law. In connection with and without limiting the foregoing, the Parties shall and shall cause their respective Affiliates to, subject to applicable Law and except as prohibited by any applicable Governmental Entity:

(i) promptly notify the other Party of any written communication to that Party or its Affiliates from any Governmental Entity concerning this License Agreement or the transactions contemplated hereby, and permit the other Party to review in advance (and to consider any comments made by the other Party in relation to) any proposed written communication to any of the foregoing;

(ii) not agree to participate or participate in any substantive meeting with any Governmental Entity in respect of any filings, investigation or inquiry concerning this License Agreement or the transactions contemplated hereby unless it consults with the other Parties in advance and, to the extent permitted by such Governmental Entity, gives the other Parties the opportunity to attend and participate; and

(iii) furnish the other Party (through outside counsel) with copies of all correspondence, filings and written communications (and memoranda setting forth the substance thereof) between it and its Affiliates and their respective representations on the one hand, and any Governmental Entity, or members of their respective staffs on the other hand, with respect to this License Agreement and the transactions contemplated hereby.

11. REPRESENTATIONS AND WARRANTIES

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

(a) it is a company 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 License Agreement, and has taken all corporate action required by Law and its organizational documents to authorize the execution and delivery of this License Agreement and the consummation of the transactions contemplated by this License Agreement;

(c) this License Agreement has been duly executed and delivered by it and constitutes its legal, valid and binding obligation, enforceable against it in accordance with its terms; and

(d) the execution, delivery and performance by it of this License Agreement, and the consummation by it of the transactions contemplated hereby, have been duly authorized and approved by all necessary corporate or equivalent action on its part.

11.2 Intellectual Property Matters. Novartis hereby represents and warrants to OV that:

(a) **Ownership.** Novartis has sole and exclusive ownership of Licensed IP. Novartis has not granted to any Person other than OV a license, covenant not to sue or similar right with respect to any component of the Licensed IP in the Field in the Territory. The Licensed IP in the Field in the Territory is free of any lien, covenant, easement, lien, lease, sublease, option, encumbrance, security interest, mortgage, pledge or claim of any nature, including limitations on transfer or any subordination arrangement in favor of a Third Party.

(b) **Patents.** **Schedule C** sets forth a complete and correct list of all Licensed Patents owned or otherwise Controlled by Novartis and its Affiliates, and, except as set forth on **Schedule C**, Novartis, together with its

Affiliates, is the sole and exclusive owner of, and has the sole right, title and interest in and to, the Licensed Patents listed on **Schedule C** (as updated from time to time) and the related Know-How.

(c) **No Additional IP.** To Novartis's actual knowledge, there is no intellectual property right, in particular no Licensed Patents, owned by or licensed to Novartis or its Affiliates other than the Licensed IP, that are necessary for OV or its Affiliates and sublicensees to Develop and Commercialize the Licensed Product as set forth herein.

(d) **Third Party Obligations.** Novartis and its Affiliate are not subject to any payment obligations to Third Parties as a result of the execution or performance of this License Agreement.

(e) **Licensed Data and Information.** Novartis has furnished or made available to OV the material information that is in Novartis's or its Affiliates' possession concerning the Licensed IP and the Compound relevant to the safety, efficacy, or CMC data thereof, and to Novartis's knowledge on the Effective Date of the Option Agreement, such information is accurate in all material respects.

(f) **IP Claims.** As of the Effective Date of the Option Agreement, Novartis has not received, nor to the knowledge of Novartis has any Person threatened, any written or oral, claim of ownership, inventorship or Patent infringement, or any other claim of intellectual property misappropriation or violation, from any Third Party (including by current or former officers, directors, employees, consultants, or personnel of Novartis or any predecessor) with respect to the Licensed IP, or initiated a lawsuit against Novartis, in any case (i) challenging the ownership, validity or enforceability of any of the Licensed IP in the Field in the Territory, (ii) alleging that the license, use or practice of them infringes, violates or misappropriates: (A) the intellectual property rights of any Person; or (B) the rights of any Third Party, or (iii) seeking to enjoin or restrain such use or practice.

(g) **Claims.** There are no claims, litigations, suits, actions, disputes, arbitrations, or legal, administrative or other proceedings or governmental investigations pending or, to Novartis' knowledge, threatened against Novartis, nor is Novartis a party to any judgment or settlement, which would be reasonably expected to adversely affect or restrict the ability of Novartis to consummate the transactions contemplated under this License Agreement and to perform its obligations under this License Agreement, or which would affect the Licensed IP, or Novartis' Control thereof, or the Licensed Product.

11.3 Novartis Covenants.

(a) Novartis will not, and will cause its Affiliates not to (i) license, sell, assign or otherwise transfer to any Person any Licensed IP (or agree to do any of the foregoing) or (ii) incur or permit to exist, with respect to any Licensed IP, any lien, encumbrance, charge, security interest, mortgage, liability, grant of license to Third Parties or other restriction (including in connection with any indebtedness).

(b) Neither Novartis nor any of its Affiliates will enter into any new agreement, transfer ownership of the Licensed IP, or obligate itself to any Third Party, or amend an existing agreement with a Third Party, in each case, in a manner that restricts, limits, or encumbers the rights granted to OV under this License Agreement.

11.4 Novartis Representation and Warranty. Except as provided for in Clause 11, NOVARTIS TO THE EXTENT PERMITTED BY LAW MAKES NO REPRESENTATIONS, EXTENDS NO WARRANTIES OF ANY KIND, EITHER EXPRESS OR IMPLIED AND ASSUMES NO RESPONSIBILITY OR LIABILITY AFTER THE EFFECTIVE DATE IN RESPECT OF THE COMPOUND, LICENSED DATA, INVENTORY AND/OR THE INTELLECTUAL PRPOERTY RIGHTS, INCLUDING THE LICENSED IP OR THE APPLICATION, OPERATION, OWNERSHIP, NON-INFRINGEMENT OR USE THEREOF, WHICH OV TAKES "AS-IS" AND WITH ALL FAULTS.

11.5 OV Representation and Warranty. OV represents and warrants to Novartis that as at the Effective Date:

(a) OV, nor, to the actual knowledge, following reasonable inquiry, of OV, any employee, agent or subcontractor of OV, involved or to be involved in the Development and/or Commercialization of the Compound or the

Licensed Product has been debarred under Subsection (a) or (b) of Section 306 of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 335a); (ii) no Person who is known by OV to have been debarred under Subsection (a) or (b) of Section 306 of said Act will be employed by OV in the performance of any activities hereunder; and (iii) to the actual knowledge, following reasonable inquiry, of OV, no Person on any of the FDA clinical investigator enforcement lists (including, but not limited to, the (1) Disqualified/Totally Restricted List, (2) Restricted List and (3) Adequate Assurances List will participate in the performance of any activities hereunder.

(b) OV is a licensed pharmaceutical company which, together with its Affiliates and distributors, has the necessary resources and expertise (or the resources to acquire the expertise) to carry out its obligations hereunder.

(c) OV is not and has not been (and has no Affiliates that are or have been) subject to any litigation by customers or investigation by local and/or regulatory authorities which would materially negatively impact OV's obligations hereunder.

There is no suit, action, investigation or proceeding pending or threatened against OV that challenges or seeks to prevent or enjoin the transactions contemplated by this License Agreement.

11.6 Disclaimer. Except as otherwise expressly set forth in this License Agreement, NEITHER PARTY MAKES ANY REPRESENTATION OR EXTENDS ANY WARRANTY OF ANY KIND, EITHER EXPRESS OR IMPLIED, INCLUDING ANY WARRANTY THAT ANY PATENTS ARE VALID OR ENFORCEABLE, AND EXPRESSLY DISCLAIMS ALL IMPLIED WARRANTIES, INCLUDING IMPLIED WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE AND NONINFRINGEMENT. Without limiting the generality of the foregoing, each Party disclaims any warranties with regards to: (a) the success of any Development activities related to the Compound or the Licensed Products; (b) the safety or usefulness for any purpose of the technology or materials, including the Compound or Licensed Product, it provides or discovers under this License Agreement; or (c) the validity, enforceability, or non-infringement of any intellectual property rights or technology it provides or licenses to the other Party under this License Agreement.

11.7 Special, Indirect and Other Losses. Except for (claims arising out of a Party's willful misconduct, or a Party's breach of Clause 15 or any other confidentiality obligations under this License Agreement, TO THE MAXIMUM EXTENT PERMITTED BY LAW NO PARTY NOR ANY OF ITS 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, DIMINUTION IN VALUE OR FOR ANY CONSEQUENTIAL OR INDIRECT LOSS WHATSOEVER, INCLUDING BUT NOT LIMITED TO LOSS OF PRODUCTION, LOSS OF USE, LOSS OF CONTRACTS AND LOSS OF PROFITS SUFFERED BY ANY OTHER PARTY. NO REPRESENTATIONS OR WARRANTIES ARE MADE, INCLUDING AS TO FITNESS FOR PURPOSE, MERCHANTABILITY AND/OR NON-INFRINGEMENT, EXCEPT AS EXPRESSLY STATED HEREIN.

For the avoidance of doubt, nothing in this Clause 11.6 is intended to affect the Option Fee, the Upfront Payment, the Milestone and Royalty Payments due and payable by OV to Novartis pursuant to Clause 7, including Novartis' right to bring a claim, to recover such Option Fee, the Upfront Payment, the Milestone and Royalty Payments in the event that they are not paid in accordance with the terms of this License Agreement. No Party excludes any liability for death or personal injury caused by its negligence or that of its employees, agents or subcontractors.

11.8 Survival. The representations and warranties made by the Parties and contained in this License Agreement shall survive the Effective Date for, and all claims for indemnification in connection therewith shall be asserted not later than twelve (12) months following the Effective Date. Notwithstanding the foregoing, if, prior to the close of business on the last day a claim for indemnification may be asserted hereunder, an indemnifying party shall have been properly notified of a claim for indemnity hereunder and such claim shall not have been finally resolved or disposed of at such date, such claim shall continue to survive and shall remain a basis for indemnity hereunder until such claim is finally resolved or disposed of in accordance with the terms hereof.

12. INDEMNIFICATION.

12.1 Indemnification Obligations of Novartis. Novartis shall indemnify and hold OV, its Affiliates and its respective officers, directors, agents and employees ("OV Indemnitees") harmless from and against any and all Losses

arising out of or resulting from any claim, demand, action, suit or proceeding (“**Claim**”) against or incurred by the OV Indemnitees to the extent arising or resulting from:

(a) any material breach of any representation or warranty of Novartis set forth in this License Agreement;

(b) any material breach of any covenant, agreement or undertaking made by Novartis in this License Agreement; or

(c) any gross negligent or willful act or omission of Novartis or its Affiliates or any of their respective employees relating to the activities in connection with this License Agreement;

provided however that, such indemnity shall not apply to the extent OV has an indemnification obligation pursuant to Clause 12.2 for such damages or claims.

12.2 Indemnification Obligations of OV. OV shall indemnify and hold Novartis, its Affiliates and their respective officers, directors, agents and employees (“**Novartis Indemnitees**”) harmless from and against any and all Losses arising out of or resulting from any Claim to the extent arising or resulting from:

(a) any material breach of any representation or warranty of OV set forth in this License Agreement;

(b) any breach of any covenant, agreement or undertaking made by OV in this License Agreement;

(c) any violation by OV or its Affiliates of applicable Laws or any Development, Manufacturing or Commercialization of the Compound or Licensed IP after the Effective Date, including without limitation any claims or Losses arising from any use of Inventory by OV; or

(d) any gross negligent or willful act or omission of OV or its Affiliates or any of their respective employees or agents relating to the activities in connection with this License Agreement;

provided however that, such indemnity shall not apply to the extent Novartis has an indemnification obligation pursuant to Clause 12.1 for such damages or claims.

12.3 Insurance. As of the Effective Date, each Party shall maintain insurance with creditworthy insurance companies or self insure in accordance with applicable Laws against such risks and in such amounts as are usually maintained or insured against by such Party.

12.4 Indemnification Procedure.

(a) For the avoidance of doubt, all Claims in respect of a Novartis Indemnatee or OV Indemnatee shall be made solely by Novartis or OV, respectively.

(b) A Party seeking indemnification hereunder (“**Indemnified Party**”) shall notify the other Party (“**Indemnifying Party**”) in writing promptly after the assertion against the Indemnified Party of any Claim or fact in respect of which 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 shall 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 shall 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 shall 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 paragraph (f) below, the Indemnified Party shall not make any admission of liability, conclude any agreement in relation to such liability or make any compromise with any Person, body or authority in relation to such liability without the prior written consent of the Indemnifying Party.

(d) Subject to the provisions of paragraphs (e) and (f) below, the Indemnifying Party shall have the right, upon written notice given to the Indemnified Party within thirty (30) days after receipt of the Indemnification Claim Notice to assume the defence and handling of such Claim, at the Indemnifying Party’s sole expense, in which case

the provisions of paragraph (e) below shall govern. The assumption of the defence of a Claim by the Indemnifying Party shall not be construed as acknowledgement that the Indemnifying Party is liable to indemnify any indemnitee in respect of the Claim, nor shall it constitute a waiver by the Indemnifying Party of any defences it may assert against any Indemnified Party's claim for indemnification. In the event that 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 shall reimburse the Indemnifying Party for any and all reasonable and justifiable costs and expenses (including attorneys' fees and costs of suit) incurred by the Indemnifying Party in its defence of the Claim. If the Indemnifying Party does not give written notice to the Indemnified Party, within thirty (30) days after receipt of the Indemnification Claim Notice, of the Indemnifying Party's election to assume the defence and handling of such Claim, the provisions of paragraph (f) below shall govern.

(e) Upon assumption of the defence of a Claim by the Indemnifying Party: (i) the Indemnifying Party shall have the right to and shall 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 defence and handling of such Claim any law firm or counsel reasonably selected by the Indemnifying Party; (iii) the Indemnifying Party shall keep the Indemnified Party informed of the status of such Claim; and (iv) the Indemnifying Party shall have the right to settle the Claim on any terms the Indemnifying Party chooses; provided, however, that it shall 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 shall cooperate with the Indemnifying Party and shall be entitled to participate in, but not control, the defence of such Claim with its own counsel and at its own expense. In particular, the Indemnified Party shall, at the Indemnifying Party's expense furnish such records, information and testimony, provide witnesses and attend such conferences, discovery proceedings, hearings, trials and appeals as may be reasonably requested in connection therewith. Such cooperation shall 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.

(f) If the Indemnifying Party does not give written notice to the Indemnified Party as set forth in paragraph (d) or fails to conduct the defence 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 defence 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 shall keep the Indemnifying Party timely apprised of the status of such Claim and shall not settle such Claim without the prior written consent of the Indemnifying Party, which consent shall not be unreasonably withheld. If the Indemnified Party defends or handles such Claim, the Indemnifying Party shall cooperate with the Indemnified Party, at the Indemnified Party's request but at no expense to the Indemnified Party, and shall be entitled to participate in the defence and handling of such Claim with its own counsel and at its own expense.

12.5 Mitigation of Loss. Each Indemnified Party will take and will ensure 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 13. Nothing in this Agreement shall or shall be deemed to relieve any Party of any common law or other duty to mitigate any losses incurred by it.

13. PROSECUTION, ENFORCEMENT AND DEFENSE OF PATENTS.

13.1 Patent Filings, Prosecution and Maintenance of Licensed IP.

(a) The Parties agree to cooperate in the Prosecution of all Patents and Patent applications under this Clause 13, including obtaining and executing necessary powers of attorney and assignments by the named inventors, providing relevant technical reports to the filing Party concerning the invention disclosed in such Patents and Patent applications, obtaining execution of such other documents which are needed in the Prosecution of such Patents and Patent applications, and shall cooperate with the other Party so far as reasonably necessary with respect to furnishing all information and data in its possession reasonably necessary to obtain or Prosecute such Patents and Patent applications.

(b) OV shall have the first right and option (but not the obligation) to Prosecute any Patents and Patent applications for Product-Specific Patents, in OV's name and at its sole expense, and to control any interferences, oppositions, reissue proceedings, reexaminations, post-grant proceedings and any other similar proceeding relating thereto, in the Territory.

(c) Novartis shall have the sole right and option (but not the obligation) to Prosecute any Patents and Patent applications for Platform Patents, in Novartis's name and at its sole expense, and to control any interferences, oppositions, reissue proceedings, reexaminations, post-grant proceedings and any other similar proceeding relating thereto, in the Territory.

13.2 Extensions of Patent Term for Products. OV shall have the sole right, but not the obligation, under Product-Specific Patents to seek, in Novartis's name if so required, patent term extensions, adjustments, restorations, or supplementary protection certificates under Applicable Law for the Licensed Product in the Territory. OV, its agents and attorneys will give due consideration to all suggestions and comments of Novartis regarding any such activities, including the choice of which Product-Specific Patent to apply term extensions to, but in the event of a disagreement between the Parties, OV shall have the final decision making authority.

13.3 Enforcement of Licensed IP.

(a) If either Party learns of any infringement or violation by a Third Party of any Licensed IP in the Territory, whether or not within the Field, it shall notify the other Party as soon as practicable. Thereafter, (i) OV shall have the sole right (but not the obligation) to take the appropriate steps to enforce or defend all Product-Specific Patents against Third Parties and (ii) Novartis shall have the sole right (but not the obligation) to take the appropriate steps to enforce or defend all Platform Patents against Third Parties. Any settlements, damages or other monetary awards relating to such infringement or violation by a Third Party of any Product-Specific Patents (a **"Recovery"**) recovered by either Party pursuant to a suit, action or proceeding brought pursuant to this Clause 13.3(a) will be allocated first to the costs and expenses of OV, and second, all remaining Recoveries shall be deemed Net Sales.

(b) If OV brings any suit, action or proceeding under this Clause 13.3, Novartis agrees to be joined as party plaintiff if necessary to prosecute the suit, action or proceeding and to give OV reasonable authority to file and prosecute the suit, action or proceeding; provided, however, that OV will not be required to transfer any right, title or interest in or to any property to Novartis to confer standing on Novartis hereunder. Novartis will provide reasonable assistance to OV, including by providing access to relevant documents and other evidence and making its employees available, subject to OV's reimbursement of any reasonable out-of-pocket Costs incurred by Novartis in providing such assistance.

13.4 Enforcement of OV Technology. If either Party learns of any infringement or violation by a Third Party of any OV Technology in the Territory, it shall notify the other Party as soon as practicable. Thereafter, OV shall have the sole right to (a) enforce all OV Technology against Third Parties and (b) any settlements, damages or other monetary awards recovered pursuant to a suit, action or proceeding brought pursuant to this Clause 13.4.

13.5 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. If the Parties cannot settle such Infringement Claim with the Third Party within thirty (30) days after receipt of the notice pursuant to the notice pursuant to this Clause 13.5, then subject to indemnification requirements of Clause 12, the following shall apply:

(a) In the case of any such Infringement Claim against either Party individually or against both Novartis and OV, in each case, with respect to the Licensed Product in the Field in the Territory, then (i) with respect to any Product-Specific Patents, OV shall assume control of the defense of such Infringement Claim and (ii) with respect to any Platform Patents, Novartis shall assume control of the defense of such Infringement Claim. The non-controlling Party, upon request of the controlling Party and if required by Applicable Law, agrees to join in any such litigation at the controlling Party's expense, and in any event to reasonably cooperate with the controlling Party at the controlling Party's expense. The non-controlling Party will have the right to consult with the controlling Party concerning such Infringement Claim and to participate in and be represented by independent counsel in any litigation in which non-controlling Party is a party, at its own expense. The controlling Party shall have the exclusive right to settle any Infringement Claim against the controlling Party alone or both Parties without the consent of the other Party, unless such settlement shall have a

material adverse impact on the non-controlling Party or requires any payment by or imposes any restrictions on the non-controlling party (in which case the consent of non-controlling Party shall be required).

(b) If either Party individually shall control the defense of any such Infringement Claim described in this Clause 13.5 the other Party shall cooperate, and shall cause its and its Affiliates' employees to cooperate, with the controlling Party in all reasonable respects in connection therewith, including giving testimony and producing documents lawfully requested, and using its reasonable efforts to make available to the controlling Party, at the controlling Party's cost, such employees who may be helpful with respect to such suit, investigation, claim or other proceeding.

14. TERM AND TERMINATION

14.1 Term. This License Agreement shall become effective on the Effective Date and, unless earlier terminated pursuant to this Clause 14 shall remain in full force and effect as follows (the “**Term**”):

(a) on a Licensed Product-by-Licensed Product and country-by-country basis, this License Agreement shall expire on the date of the expiration of all applicable Royalty Terms with respect to such Licensed Product in such country; and

(b) in its entirety upon the expiration of all applicable Royalty Terms under this License Agreement with respect to all Licensed Products in all countries in the Territory.

14.2 Effect of Expiration. After the expiration of the Term pursuant to Clause 14.1 above, the following terms shall apply:

(a) **Licenses after Term Expiration in a Country.** After expiration of all applicable Royalty Terms (but not after early termination) with respect to a Licensed Product in the Territory pursuant to Clause 14.1(a), OV shall have an exclusive, fully-paid, royalty-free, irrevocable, non-terminable, worldwide right and license, with the right to grant sublicenses, under the Licensed IP to Develop, Manufacture, have Manufactured, use, offer for sale, sell, import and otherwise Commercialize such Licensed Product in the Field in such country in the Territory, for so long as it continues to do so.

(b) **Licenses after Expiration of Term in the Territory.** After expiration of all applicable Royalty Terms (but not after early termination) with respect to this License Agreement in its entirety pursuant to Clause 14.1(b), OV shall have an exclusive, fully-paid, royalty-free, irrevocable, non-terminable, worldwide right and license, with the right to grant sublicenses, under the Licensed IP to Develop, Manufacture, have Manufactured, use, offer for sale, sell, import and otherwise Commercialize Licensed Products in the Field in the Territory, for so long as it continues to do so.

14.3 Rights of Termination.

(a) **Termination for Material Breach.** In the event that a Party commits a material breach of this License Agreement that is not cured within thirty (30) days, after such Party receives written notice from the non-breaching Party, which notice shall specify the nature of the breach.

(b) **Termination for Convenience.** Prior to its expiration, OV may terminate this License Agreement in its entirety, in its sole discretion, at any time upon at least one hundred and twenty (120) days prior written notice to Novartis for any reason.

(c) **Bankruptcy.** This License Agreement may be terminated by written notice by Novartis in case an Insolvency Event occurs.

14.4 Surviving Rights and Obligations. Any provisions required for the interpretation or enforcement of this License Agreement shall survive the expiration or termination of this License Agreement. Expiration or termination of this License Agreement shall not relieve any Party of any obligations that are expressly indicated to survive expiration or termination or that accrued prior to the expiration or termination. Except as otherwise expressly provided, expiration or termination of this License Agreement for any reason shall be without prejudice to any rights that shall have accrued to the benefit of any Party prior to such expiration or termination.

14.5 Effect of Termination.

(a) **Termination by OV Pursuant to Clauses 14.3(b) or (c), or by Novartis Pursuant to Clauses 14.3(a) or (c).** In the event this License Agreement is terminated by OV pursuant to Clauses 14.3(b) or (c), or by Novartis pursuant to Clauses 14.3(a) or (c), then notwithstanding anything contained in this License Agreement to the contrary, upon the effective date of such termination, all rights and licenses granted to OV under this License Agreement shall terminate, OV shall cease any and all Development and Commercialization activities with respect to all Licensed Products, and all rights and licenses granted by Novartis to OV shall revert to Novartis. For clarity, any payment obligations that result in payments owed prior to the effective date of the termination shall become due and payable on the effective date of the termination.

(b) **Termination by OV Pursuant to Clauses 14.3(a).** In the event this License Agreement is terminated by OV pursuant to Clauses 14.3(a), then all rights and obligations of the Parties under and this License Agreement shall terminate, except (i) the licenses granted in Clause 2, (ii) OV's payment obligations (accrued as of the effective date of such termination).

14.6 Survival. The termination of this License Agreement shall not relieve the Parties of any obligation accruing prior to such expiration or termination. Without limiting the foregoing the provisions of Clauses 1, 5, 10, 11, 12, 14, 15, 16 shall survive the termination of this License Agreement.

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

15. CONFIDENTIALITY

15.1 Duty of Confidence. Subject to the other provisions of this Clause 15, all Information will be maintained by the Parties in confidence and otherwise safeguarded by the Parties. Each Party may only use the Information strictly for the purposes of this License Agreement and pursuant to the rights and obligations of such Party under this License Agreement. Subject to the other provisions of this Clause 15, each Party shall hold as confidential such Information of the other Party or such Party's Affiliates (in the case of Novartis, where Affiliates of Novartis disclose Information) 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 Clause 15, a Party may only disclose Information to employees, agents, contractors, consultants and advisers of such Party and its Affiliates, and in the case of OV, OV may also disclose to its sublicensees to the extent reasonably necessary for the purposes of, and for those matters undertaken pursuant to, this License Agreement; provided that such Persons are bound to maintain the confidentiality of the Information in a manner consistent with the confidentiality provisions of this License Agreement.

15.2 Exceptions. The obligations under this Clause 15 shall 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 License Agreement by the recipient Party or, including in the case of Novartis, its Affiliates or in the case of OV, through its Affiliates and/or their sublicensees;

(b) with respect to OV, was known to, or was otherwise in the possession of, OV or its Affiliates, prior to the time of disclosure by Novartis 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 Information disclosed by the disclosing Party (or its Affiliates) under this License Agreement.

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

15.3 Authorized Disclosures.

(a) In addition to disclosures allowed under Clause 15.2, OV may disclose Information belonging to Novartis or its Affiliates to the extent such disclosure is necessary in connection with the Regulatory Filings or Patent filings for a Licensed Product.

(b) In addition to disclosures allowed under Clause 15.2, either Party may disclose Information belonging to the other Party (and/or its Affiliates) to the extent such disclosure is necessary to: (i) prosecute or defend litigation as permitted by this License Agreement; and/or (ii) comply with applicable court orders or governmental regulations.

(c) In the event the recipient Party is required to disclose Information of the disclosing Party by Law or in connection with bona fide legal process, such disclosure shall not be a breach of this License 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.

15.4 Ongoing Obligation for Confidentiality. Upon early termination of this License Agreement for any reason, each Party and its Affiliates shall immediately (i) return to the other Party or destroy any Information supplied or disclosed by the other Party together with all hard copies thereof, except for (A) such copies as must be retained pursuant to applicable Law, and (B) one copy which may be retained in its confidential files for archive purposes, (ii) destroy all notes and all summaries or extracts in any medium prepared by or on behalf of recipient derived from this Information, and (iii) use all reasonable efforts to procure that all third parties, to which this Information was disclosed, destroy or erase any Information contained in any materials and documentation recorded in any memory device.

16. PRESS RELEASE. 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 License Agreement without the other Parties' prior written consent, which shall not be unreasonably withheld. Where consent is forthcoming, the Parties agree to consult with each other regarding the content of any such press release or other announcement. The aforementioned restriction shall not apply to announcements required by any Regulatory Authority or Governmental Entity under applicable Law or stock exchange rule provided that in such event the Parties shall coordinate the wording and OV shall take into consideration any requests of Novartis. Each Party hereto acknowledges that OV and Novartis shall have the right to disclose a brief summary of the transaction, including the amounts payable by OV under this License Agreement, in its official financial reports.

17. MISCELLANEOUS

17.1 Governing Law; Venue. This License Agreement (and any Legal Dispute) shall be governed by and is construed under the Laws of New York, USA, without giving effect to the conflicts of Laws provision thereof, and with the exclusion of the International Sale of Goods Vienna Convention on the International Sale of Goods. Any Legal Proceeding relating to this License Agreement or the enforcement of any provision of this License Agreement shall be brought or otherwise commenced in, and each Party expressly and irrevocably consents and submits to the jurisdiction of the courts of Federal District Courts of New York, USA.

17.2 Assignment.

(a) Within sixty (60) days after the Effective Date, OV will inform Novartis in writing if the Development of Licensed Product will be conducted by the SPV and, if so, simultaneously assign all of its rights and obligations under this License Agreement to the SPV in accordance with Clause 17.2(c).

(b) Other as set forth above, no Party may assign its rights and obligations under this License Agreement without the other Party's prior written consent, except that (i) Novartis may assign its rights and obligations under this License Agreement or any part hereof to one or more of its Affiliates without the consent of OV and/or to a successor entity or acquirer of the business to which the Licensed Agreement relates and/or in the event of a change of control; and (ii) upon completion of the first Phase II Clinical Trial for use of the Compound in the Field in accordance with Clause 2.2(a), OV may, assign this License Agreement in its entirety to an Affiliate or a successor to all or substantially all of its business or assets to which this License Agreement relates; provided in all cases, that any permitted assignee shall assume all obligations of its assignor under this License Agreement (or related to the assigned portion in case of a partial assignment), and no permitted assignment shall relieve the assignor of liability hereunder. Any attempted assignment in contravention of the foregoing shall be void and not binding to the other Party. Subject to the terms of this License Agreement, this License Agreement will be binding upon and inure to the benefit of the Parties and their respective successors and permitted assigns.

(c) Any assignment by either Party will be subject to a written agreement that (i) requires the assignee to comply with all applicable obligations of this License Agreement, and (ii) is not in conflict with any term of this License Agreement. OV shall undertake to enforce the provisions of any such assignment and shall remain responsible and jointly and severally liable with the assignee to Novartis hereunder for the performance of assignee's obligations and for all acts or omissions of its assignees as if they were the acts or omissions of OV under this License Agreement.

17.3 Injunctive Relief. The Parties understand and agree that monetary damages may not be a sufficient remedy for breach of this License Agreement and that each Party will be entitled to seek equitable relief, including injunction and specific performance for any such breach. Nothing contained in this License Agreement shall be construed as limiting a Party's right to any other remedies it may have under this License Agreement or in Law, including, without limitation, the recovery of damages for breach of this License Agreement.

17.4 Force Majeure. If and to the extent that any Party is prevented or delayed by Force Majeure from performing any of its obligations under this License Agreement and promptly so notifies in writing the other Party, specifying the matters constituting Force Majeure together with such evidence in verification thereof as it can reasonably give and specifying the period for which it is estimated that the prevention or delay will continue, then the Party so affected shall be relieved of liability to the other for failure to perform or for delay in performing such obligations (as the case may be), but shall nevertheless use its Commercially Reasonable Efforts to resume full performance thereof.

17.5 Notices. All notices, consents, waivers, and other communications under this License Agreement must be in writing and will be deemed to have been duly given when: (a) delivered by hand (with written confirmation of receipt); (b) sent by fax (with written confirmation of receipt), provided that a copy is immediately sent by an internationally recognized overnight delivery service (receipt requested); or (c) when received by the addressee, if sent by an internationally recognized overnight delivery service (receipt requested), in each case to the appropriate addresses and fax numbers set forth below (or to such other addresses and fax numbers as a Party may designate by written notice):

If to OV:

Oncology Venture ApS
Venlighedsvej 1
DK-2970 Hoersholm, Denmark
Attention: Chief Executive Officer
Email: pbj@oncologyventure.com

With a copy to:

Dechert LLP
1900 K St., N.W.
Washington, D.C. 20006
Attention: David E. Schulman
Telephone: (202) 261-3440
Fax: (202) 261-3334

If to Novartis:

Novartis Pharma AG
Lichtstrasse 35
4056 Basel, Switzerland
Attn: Head of BD&L
Fax: +41 61 324 2100

With a copy to:

Novartis Pharma AG
Lichtstrasse 35
CH-4056 Basel, Switzerland
Attn: General Counsel
Fax: +41 61 324 7399

Each Party may change its address for purposes of this License Agreement by written notice to the other Party.

17.6 Waiver and Amendments. The failure of any Party to assert a right hereunder or to insist upon compliance with any term or condition of this License Agreement shall not constitute a waiver of that right or excuse a similar subsequent failure to perform any such term or condition by the other Party. No waiver shall be effective unless it has been given in writing and signed by the Party giving such waiver. No provision of this License Agreement may be amended or modified other than by a written document signed by authorized representatives of each Party.

17.7 Severability. Without prejudice to any other rights that the Party may have pursuant to this License Agreement, every provision of this License Agreement is intended to be severable. If any provision of this License Agreement shall be invalid or unenforceable, such invalidity or unenforceability shall not affect the other provisions of this License Agreement, which shall remain in full force and effect. The Parties hereto agree to consult each other and to agree upon a new stipulation which is permissible under the Law and which comes as close as possible to the original purpose and intent of the invalid, void or unenforceable provision.

17.8 Entire Agreement. This License Agreement constitutes the entire agreement and supersedes all prior agreements and understandings, both written and oral, between the Parties with respect to the subject matter hereof.

17.9 Relationship of the Parties. Nothing contained in this License Agreement shall be deemed to constitute a partnership, joint venture, or legal entity of any type between Novartis and OV, or to constitute one as the agent of the other. Moreover, each Party agrees not to construe this License Agreement, or any of the transactions contemplated hereby, as a partnership for any tax purposes. Each Party shall act solely as an independent contractor, and nothing in this License Agreement shall be construed to give any Party the power or authority to act for, bind, or commit the other.

17.10 Expenses. Except as otherwise expressly provided in this License Agreement, each Party shall 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 License Agreement.

17.11 Further Assurances. Novartis and OV hereby covenant and agree without the necessity of any further consideration, to 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 License Agreement.

17.12 Compliance with Law. Each Party shall perform its obligations under this License Agreement in accordance with all applicable Laws, including data privacy laws. No Party shall, or shall be required to, undertake any activity under or in connection with this License Agreement which violates, or which it believes, in good faith, may violate, any applicable Law.

17.13 Headings. Titles or captions of clauses contained in this License Agreement are inserted only as a matter of convenience and for reference, and in no way define, limit, extend, or describe the scope of this License Agreement or the intent of any provision hereof.

17.14 English Language. This License Agreement is written and executed in the English language. Any translation into any other language shall not be an official version of this License Agreement and in the event of any

conflict in interpretation between the English version and such translation, the English version shall prevail.

17.15 Counterparts. This License Agreement may be executed in two or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.

[Remainder of Page Intentionally Left Blank; Signature Page Follows]

The parties to this License Agreement have caused this License Agreement to be executed and delivered as of the date first written above.

ONCOLOGY VENTURE APS

By: _____
Name: _____
Title: _____

[Signature Page to License Agreement]

The parties to this License Agreement have caused this License Agreement to be executed and delivered as of the date first written above.

NOVARTIS PHARMA AG

By: _____
Name: _____
Title: _____

NOVARTIS PHARMA AG

By: _____
Name: _____
Title: _____

[Signature Page to License Agreement]

SCHEDULE A

COMPOUND

TKI258 lactate salt (TKI258 or TKI258LC) is designated chemically as (4 Amino 5 fluoro 3

[6 (4 methyl 1 piperaziny) 1H benzimidazol 2 yl] 2(1H) quinolinone mono DL lactate) and its structural formula is:

TKI258 is a yellow to orange and/or brownish tinged, nonhygroscopic solid that dissociates into TKI258 free base and lactic acid between 125 to 250oC. Its molecular formula is $C_{21}H_{21}FN_6O \cdot C_3H_6O_3$ (molecular weight 482.5). TKI258 is freely soluble in water, DMSO, 1 methy 2 pyrrolidone, and acetic acid. In buffered aqueous solutions, depending on the prevailing pH, TKI258 reverts back to the appropriate ionized species or free base. Since the degree of ionization is pH dependent, the solubility of TKI258 varies with pH (e.g., 6 µg/mL at pH 7 and 13.6 mg/mL at pH 2).

SCHEDULE B

INVENTORY

SCHEDULE C
LICENSED PATENTS

Platform Patents

PCT/US2003/010463

Product-Specific Patents

PCT/US2001/042131

PCT/EP2011/055906

PCT/EP2011/060949

PCT/US2013/023781

PCT/US2003/010463

PCT/US2012/029205

SCHEDULE D

MAJOR COUNTRIES

United States, Canada, Main European Countries, China, Japan, Russia, Brazil, and Australia.

SCHEDULE E
DEVELOPMENT PLAN

[***]



SCHEDULE F
SALES & ROYALTY REPORTING FORM

[***]

SCHEDULE G
LICENSED DATA

[***]

SCHEDULE H
CLINICAL MATERIALS

[***]

EXHIBIT A

CONVERTIBLE PROMISSORY NOTE
