18-01918-E

FOIA / PA Officer John Livornese U.S. Securities & Exchange Commission FOIA Office 100 F Street NE, Mail Stop 5100 Washington, DC 20549

RECEIVED

JAN 12 2018

Office of FOIA Services

January 12, 2018

Dear Mr. Livornese:

I request pursuant to the Freedom of Information Act (FOIA) 5 U.S.C. § 552. As Amended by Public Law No. 104-231,110 Stat. 3048, copies of the following agreement, based on the CT Order File No. 1-33093 - CF#3139.

Exhibit 10.3 to Form 10-Q filed on 08/05/2014 by Ligand Pharmaceuticals Inc.

Exhibit Title: Research And License Agreement

CIK: 886163

RoyaltyStat will pay up to \$61 for research, copies and review fees for all of the abovementioned agreements. Please forward all releasable material for copying. My daytime telephone number is 202-798-8809. Please call me or e-mail at accounts@royaltystat.com to discuss the total cost or estimated cost of this research/copies should the amount exceed the price indicated in this request.

Sincerely,

RoyaltyStat LLC 6931 Arlington Rd. # 580 Bethesda, MD 20814



UNITED STATES SECURITIES AND EXCHANGE COMMISSION

STATION PLACE 100 F STREET, NE WASHINGTON, DC 20549-2465

Office of FOIA Services

February 9, 2018

Ms. Marcia Coutinho RoyaltyStat, LLC 6931 Arlington Road, Suite 580 Bethesda, MD 20814

RE: Freedom of Information Act (FOIA), 5 U.S.C. § 552

Request No. 18-01918-E

Dear Ms. Coutinho:

This letter is in response to your request, dated and received in this office on January 12, 2018, for Exhibit 10.3 to Form 10-Q, filed on August 5, 2014, by Ligand Pharmaceuticals, Inc.

The search for responsive records has resulted in the retrieval of 38 pages of records that may be responsive to your request. They are being provided to you with this letter.

If you have any questions, please contact me at fultonc@sec.gov or (202) 551-8186. You may also contact me at foiapa@sec.gov or (202) 551-7900. You also have the right to seek assistance from Lizzette Katilius as a FOIA Public Liaison or contact the Office of Government Information Services (OGIS) for dispute resolution services. OGIS can be reached at 1-877-684-6448 or Archives.gov or via e-mail at ogis@nara.gov.

Sincerely,

Charlotte Fulton

FOIA Research Specialist

Enclosure

RESEARCH AND LICENSE AGREEMENT

Dated as of May 9, 2014

by and between

Ligand Pharmaceuticals Incorporated

and

Omthera Pharmaceuticals, Inc.

RESEARCH AND LICENSE AGREEMENT

THIS RESEARCH AND LICENSE AGREEMENT (the "Agreement") is dated as of May 9, 2014 (the "Effective Date") by and between Ligand Pharmaceuticals Incorporated, a Delaware corporation organized having its place of business at 11119 North Torrey Pines Road, Suite 200, La Jolla, CA 92037 (including its successors and permitted assigns, "Licensor"), and Omthera Pharmaceuticals, Inc., a Delaware corporation with its place of business at 707 State Road, Princeton, NJ 08540 (including its successors and permitted assigns and all of its Affiliates, "Omthera"). Omthera, on the one hand, and Licensor, on the other hand, shall each be referred to herein as a "Party" or, collectively, as the "Parties."

RECITALS:

WHEREAS, Omthera is engaged in the research, development, manufacturing and commercialization of pharmaceutical products, and Omthera is interested in developing and commercializing products containing or comprising the Compounds; and

WHEREAS, Omthera desires to license from Licensor and Licensor wishes to license to Omthera, on an exclusive basis, the right to develop and commercialize Licensor Liver Targeting Prodrug Technology prodrugs comprising the Compounds.

NOW, THEREFORE, in consideration of the foregoing and of the various promises and undertakings set forth herein, the Parties agree as follows:

ARTICLE I DEFINITIONS

Unless otherwise specifically provided herein, the following terms shall have the following meanings:

- 1.1 "Affiliate" means a Person or entity that controls, is controlled by or is under common control with a Party, but only for so long as such control exists. For the purposes of this Section 1.2, the word "control" (including, with correlative meaning, the terms "controlled by" or "under common control with") means the actual power, either directly or indirectly through one or more intermediaries, to direct the management and policies of such Person or entity, whether by the ownership of at least 50% of the voting stock of such entity, or by contract or otherwise.
- 1.2 "Agent" means any of the following natural omega-3 fatty acids: (a) EPA (i.e., icosapentaenoic acid) or an EPA ester, (b) DHA (i.e., docosahexaenoic acid) or a DHA ester, (c) a combination of EPA (or an EPA ester) with DHA (or a DHA ester) or (d) any of the individual omega-3 fatty acids or a complex mixture of the omega-3 fatty acids contained (as of the Effective Date) within EpanovaTM.
- 1.3 "Calendar Quarter" means each three month period commencing January 1, April 1, July 1 or October 1, provided however that (a) the first Calendar Quarter of the Term shall extend from the Effective Date to the end of the first full Calendar Quarter thereafter, and (b) the last Calendar Quarter of the Term shall end upon the termination or expiration of this Agreement.

- 1.4 "Calendar Year" means the period beginning on the 1st of January and ending on the 31st of December of the same year, provided however that (a) the first Calendar Year of the Term shall commence on the Effective Date and end on December 31 of the same calendar year as the Effective Date, and (b) the last Calendar Year of the Term shall commence on January 1 of the Calendar Year in which this Agreement terminates or expires and end on the date of termination or expiration of this Agreement.
- 1.5 "Combination Product" means a product containing a Licensed Product together with one or more other active ingredients, or with one or more products, devices, pieces of equipment or components.
- 1.6 "Commercialization" or "Commercialize" means any and all activities undertaken at any time for a particular Licensed Product and that relate to the manufacturing, marketing, promoting, distributing, importing or exporting for sale, offering for sale, and selling of the Licensed Product, and interacting with Regulatory Authorities regarding the foregoing.
- 1.7 "Commercially Reasonable Efforts" means, with respect to the efforts to be expended by a Party or such Party's applicable Affiliate with respect to any objective, such reasonable, diligent, and good faith efforts normally used to accomplish a similar objective under similar circumstances. Commercially Reasonable Efforts will not mean that a Party commits that it or such Party's applicable Affiliate will actually accomplish the applicable task. For clarity, references in this Agreement to Commercially Reasonable Efforts by a Party shall be deemed to include such Party's Affiliate to the extent allowable under this Agreement or as otherwise mutually agreed by the Parties.
- 1.8 "Competing Product" means any product an active pharmaceutical ingredient of which is a Compound.
- 1.9 "Compound" means an Agent's prodrug that utilizes the Licensor Liver Targeting Prodrug Technology and is discovered or Developed by or for the account of a Party pursuant to such Party's performance of its obligations under this Agreement.
- 1.10 "Compound Patent" means all Patent Rights which claim a Compound, formulations of a Compound, methods of manufacturing a Compound or its uses (but excluding the Licensor Liver Targeting Prodrug Technology and the Licensor Technology that is Controlled by Licensor or any of its Affiliates as of the Effective Date).
- 1.11 "Controlled" means, with respect to (a) Patent Rights, (b) Know-How or (c) biological, chemical or physical material, that a Party or one of its Affiliates owns or has a license or sublicense to such Patent Rights, Know-How or material (or in the case of material, has the right to physical possession of such material) and has the ability to grant a license or sublicense to, or assign its right, title and interest in and to, such Patent Rights, Know-How or material as provided for in this Agreement without violating the terms of any agreement or other arrangement with any Third Party.
- 1.12 "Development" or "Develop" means, with respect to a Licensed Product, the performance of all preclinical and clinical development (including, without limitation, toxicology, pharmacology, test method development and stability testing, process development, formulation

development, quality control development, statistical analysis), clinical trials, and manufacturing and regulatory activities that are required to obtain Regulatory Approval of such Licensed Product.

- 1.13 "EMA" means the European Medicines Agency or any successor agency.
- 1.14 "European Commission" means the authority within the European Union that has the legal authority to grant Regulatory Approvals in the European Union based on input received from the EMA or other competent Regulatory Authorities.
- 1.15 "FDA" means the United States Food and Drug Administration, or a successor federal agency thereto.
- 1.16 **"Field"** means any and all commercial pharmaceutical uses of a Compound, which shall specifically exclude any over-the-counter uses of such Compound.
- 1.17 "First Commercial Sale" means, with respect to a Licensed Product in any country, the first commercial transfer or disposition for value of such Licensed Product in such country to a Third Party by Omthera, an Affiliate of Omthera or a Sublicensee after Regulatory Approval therefor has been obtained in such country.
 - 1.18 "GAAP" means United States generally accepted accounting principles.
- 1.19 "Governmental Body" means any: (a) nation, principality, state, commonwealth, province, territory, county, municipality, district or other jurisdiction of any nature; (b) federal, state, local, municipal, foreign or other government; (c) governmental or quasi-governmental authority of any nature (including any governmental division, subdivision, department, agency, bureau, branch, office, commission, council, board, instrumentality, officer, official, representative, organization, unit, body or entity and any court or other tribunal); (d) multi-national or supranational organization or body; or (e) individual, entity, or body exercising, or entitled to exercise, any executive, legislative, judicial, administrative, regulatory, police, military or taxing authority or power of any nature.
- 1.20 "Joint Scientific Committee" means a committee, with an equal number of scientist representatives appointed by Omthera and by Licensor, respectively, to be established to collaboratively review and advise as to scientific matters encountered in connection with the Development Program. Any deadlocks in the Joint Scientific Committee that are not capable of resolution within [thirty (30)] days of escalation to the appropriate executive officers of each respective Party shall be resolved by Omthera in its sole reasonable discretion.
- 1.21 "Know-How" means any scientific or technical information, results and data of any type whatsoever, in any tangible or intangible form whatsoever, that is not in the public domain or otherwise publicly known, including, without limitation, discoveries, inventions, trade secrets, databases, practices, protocols, regulatory filings, methods, processes, techniques, software, works of authorship, plans, concepts, ideas, biological and other materials, reagents, specifications, formulations, formulae, data (including, but not limited to, pharmacological, biological, chemical, toxicological, clinical and analytical information, quality control, trial and stability data), case reports forms, data analyses, reports, studies and procedures, designs for experiments and tests and results of experimentation and testing (including results of research or development), summaries and information contained in submissions to and information from ethical committees, the FDA or other

Regulatory Authorities, and manufacturing process and development information, results and data, whether or not patentable, all to the extent not claimed or disclosed in a patent or pending patent application. The fact that an item is known to the public shall not be taken to exclude the possibility that a compilation including the item, and/or a development relating to the item, is (and remains) not known to the public. "Know-How" includes any rights including copyright, moral, trade-secret, database or design rights protecting such Know-How. "Know-How" excludes Patent Rights.

- 1.22 "Law" or "Laws" means all applicable laws, statutes, rules, regulations, ordinances and other pronouncements having the binding effect of law of any Governmental Body.
- 1.23 "Licensed Product" means any pharmaceutical product, in any dosage form, preparation, composition, formulation, presentation or package configuration that is Commercialized or undergoing research or preclinical or clinical Development that contains or comprises, in part or in whole, a Compound.
- 1.24 "Licensor Know-How" means any and all Know-How that (a) is Controlled by Licensor or any of its Affiliates as of the Effective Date or at any time thereafter during the Term and (b) relates directly and particularly to or is reasonably necessary to the practice of the Licensor Liver Targeting Prodrug Technology.
- 1.25 "Licensor Liver Targeting Prodrug Technology" means Licensor's program for the development of a liver-specific drug targeting technology for chemically modifying the molecule to render it inactive until the modification is cleaved off by a liver-specific enzyme, including all related intellectual property and other related rights of Licensor, and any and all related clinical and non-clinical data compiled by Licensor, in each case arising from the Licensor's operation of such program. For the avoidance of doubt, Licensor Liver Targeting Prodrug Technology does not include any liver-specific drug targeting technology for chemically modifying the molecule to render it inactive until the modification is cleaved off by a liver-specific enzyme, including all related intellectual property and other related rights, and any and all related clinical and non-clinical data that arise independently of Development or Commercialization and without unauthorized use of Licensor's Confidential Information.
- 1.26 "Licensor Patents" means all Patent Rights that are Controlled by Licensor or any of its Affiliates as of the Effective Date or at any time thereafter during the Term and that relate directly and particularly to and/or are reasonably necessary to the practice of the Licensor Liver Targeting Prodrug Technology. The Licensor Patents shall include, but not be limited to, all Patent Rights set forth on Schedule 1 hereto.
- 1.27 "Licensor Technology" means the Licensor Patents and the Licensor Know-How. For purposes of the license grant under Section 2.1 and related purposes, "Licensor Technology" also includes Licensor's interest in jointly owned Inventions.
- 1.28 "Major Market" means any of the [(a) United States, (b) the European Union (either in its entirety or including at least two Major Market EU Countries, as determined by Omthera in its sole discretion), or (c) Japan].
- 1.29 "Major Market EU Country" means any of [France, Germany and the United Kingdom].

- 1.30 "NDA" means a New Drug Application submitted pursuant to the requirements of the FDA, as more fully defined in 21 U.S. CFR § 314.3 et seq., a Biologics License Application submitted pursuant to the requirements of the FDA, as more fully defined in 21 U.S. CFR § 601, and any equivalent application submitted in any country, including a European Marketing Authorization Application, together, in each case, with all additions, deletions or supplements thereto.
- 1.31 "NDA Approval" means the receipt of notice from the relevant US Regulatory Authority that an NDA for a Licensed Product has met all the criteria for marketing approval.
- 1.32 "Net Sales" means the [gross amount invoiced or otherwise charged by Omthera, its Affiliates and Sublicensees] to unrelated Third Parties for a Licensed Product, less:
 - [(a) Normal and customary trade, quantity and prompt settlement discounts and credits allowed and taken;
 - (b) Discounts, refunds, rebates, chargebacks, retroactive price adjustments, and any other allowances given and taken which effectively reduce the net selling price (other than such which have already diminished the gross amount invoiced), including, without limitation, Medicaid rebates, institutional rebates or volume discounts;
 - (c) Product returns and allowances;
 - (d) Administrative fees paid to group purchasing organizations (e.g., Medicare) and government-mandated rebates;
 - (e) Shipping, handling, freight, postage, insurance and transportation charges, but all only to the extent included as a separate line item in the gross amount invoiced; provided that such deduction shall not exceed three percent (3%) of the Net Sales amount calculated after application of subsections (a) (d) and (f) of this Section; and
- (f) Any tax, tariff or duties imposed on the production, sale, delivery or use of the Licensed Product, including, without limitation, sales, use, excise or value added taxes and customs and duties, but all only to the extent included as a separate line item (e.g., "taxes") in the gross amount invoiced.]

Notwithstanding the foregoing, [amounts invoiced by Omthera and its Affiliates and Sublicensees] for sales of Licensed Products among [Omthera and its Sublicensees and their respective Affiliates] for resale shall not be included in the computation of Net Sales.

In the event that a Licensed Product is commercialized as part of a Combination Product for a single price, the Net Sales for such Licensed Product shall be calculated by [multiplying] the sales price of such Combination Product [by the fraction A/(A+B) where A is the fair market value of the Licensed Product and B is the fair market value of the other product(s) in the Combination Product]. "Fair market value" as used in the foregoing sentence shall mean the value established by mutual agreement of the Parties using standard measurement techniques for similar valuations or, in the absence of such agreement by the Parties, the value established by an independent third party selected by Licensor and reasonably acceptable to Ligand using such standard measurement techniques.

- 1.33 "Patent Right" means: (a) an issued or granted patent, including any extension, supplemental protection certificate, registration, confirmation, reissue, reexamination, extension or renewal thereof; (b) a pending patent application, including any continuation, divisional, continuation-in-part, substitute or provisional application thereof; and (c) all counterparts or foreign equivalents of any of the foregoing issued by or filed in any country or other jurisdiction.
- 1.34 **"Person"** means any natural person, corporation, firm, business trust, joint venture, association, organization, company, partnership or other business entity, or any government or agency or political subdivision thereof.
- 1.35 **"Phase I Trial"** means clinical trial in which a Licensed Product is administered to human subjects at single and/or multiple dose levels with the primary purpose of determining safety, metabolism, and pharmacokinetic and pharmacodynamic properties of the Licensed Product, and which is consistent with 21 CFR § 312.21(a).
- 1.36 "Phase II Trial" means a clinical trial of a Licensed Product in human patients conducted for purposes of preliminary determination of efficacy and/or preliminary establishment of appropriate dosage ranges for efficacy and safety in patients, as described under 21 CFR § 312.21(b) (as hereafter modified or amended) and any of its foreign equivalents.
- 1.37 "Phase III Trial" means a clinical trial of a Licensed Product in human patients, which trial is designed (a) to establish that the Licensed Product is safe and efficacious for its intended use; (b) to define warnings, precautions and adverse reactions that are associated with the Licensed Product in the dosage range to be prescribed; and (c) to be, either by itself or together with one or more other clinical trials having a comparable design and size, the final human clinical trial in support of Regulatory Approval of an NDA of the Licensed Product, and (d) consistent with 21 CFR § 312.21(c). For the purposes of the milestone payments in Section 5.1, a "Phase III Trial" shall be a clinical trial which is submitted by Omthera to the FDA as a Phase III Trial.
- 1.38 "**Proof of Concept**" means achievement of both of the following with regard to a particular Agent: (a) after oral administration in an animal model, a novel prodrug of the Agent will have improved liver targeting in comparison to the Agent (with "liver targeting" defined as liver concentration of the Agent relative to the concentration of the Agent in plasma or other tissues) and (b) such novel prodrug of the Agent will have demonstrated significant improvement in activity relative to an applicable standard (to be determined by the Joint Scientific Committee) in reducing triglyceride levels in an animal model (with the Joint Scientific Committee having determined the appropriate animal model and endpoints).
- 1.39 "Regulatory Authority" means (a) the FDA, (b) the EMA or the European Commission, or (c) any regulatory body with similar regulatory authority over pharmaceutical or biotechnology products in any other jurisdiction anywhere in the world.
- 1.40 **"Regulatory Approval"** means any and all approvals, licenses, registrations, or authorizations of the relevant Regulatory Authority, necessary for the Development, manufacture, use, storage, import, transport and Commercialization of the Licensed Product in a particular country or jurisdiction.
- 1.41 "Royalty Term" means, on a Licensed Product-by-Licensed Product and country-by-country basis, the period from the First Commercial Sale of a given Licensed Product in such

country until the latest of (a) expiry of the last-to-expire Compound Patent containing a Valid Claim to the Compound in such country; (b) expiry of the last-to-expire Licensor Patent containing a Valid Claim to the Compound in such country; or (c) the [10th] anniversary of the First Commercial Sale of such Licensed Product in such country. In a country where neither any Compound Patent containing a Valid Claim to the Compound nor any Licensor Patent containing a Valid Claim to the Compound has ever existed nor ever exists, the Royalty Term means on a product-by-product and country-by-country basis, the period from the First Commercial Sale of such product in such country until the [10th] anniversary of such First Commercial Sale of such product in such country.

- 1.42 "Sublicensee" means a Person, other than an Affiliate of Omthera, to which Omthera (or its Affiliate) has, pursuant to Section 2.2, granted sublicense rights under any of the license rights granted under Section 2.1. "Sublicense" shall be construed accordingly.
- 1.43 "Tax" or "Taxes" means any federal, state, local or foreign income, gross receipts, license, payroll, employment, excise, severance, stamp, occupation, premium, windfall profits, environmental, customs duties, capital stock, franchise, profits, withholding, social security, unemployment, disability, real property, personal property, sales, use, transfer, registration, value added, alternative or add-on minimum, estimated, or other tax of any kind whatsoever, including any interest, penalty, or addition thereto, whether disputed or not.
- 1.44 "Third Party" means any Person other than Licensor, Omthera or Affiliates of either of them, or any Sublicensees.
- 1.45 **"Third Party Action"** means any claim or action made by a Third Party against a Party that claims that a Licensed Product, or its use, Development, manufacture or sale infringes such Third Party's intellectual property rights.
- 1.46 "United States" or "US" means the United States of America and its territories and possessions.
- 1.47 "Valid Claim" means a claim of an issued and unexpired patent which has not lapsed or been revoked, abandoned or held unenforceable or invalid by a final decision of a court or governmental or supra-governmental agency of competent jurisdiction, unappealable or unappealed within the time allowed for appeal, and which has not been disclaimed, denied or admitted to be invalid or unenforceable through reissue, reexamination or disclaimer or otherwise.
- 1.48 The definition of each of the following terms is set forth in the section of the Agreement indicated below:
 - "Action" has the meaning set forth in Section 6.7(b).
 - "Claim" has the meaning set forth in Section 9.1.
 - "Confidential Information" has the meaning set forth in Section 7.1.
 - "Controlling Party" has the meaning set forth in Section 6.8(c).
 - "Covered" and "Covering" have the meaning set forth in Section 1.40.

- "Development Program" has the meaning set forth in Section 3.1.
- "Development Term" has the meaning set forth in Section 3.1.
- "Disclosing Party" has the meaning set forth in Section 7.1.
- "Indemnified Party" has the meaning set forth in Section 9.4.
- "Indemnifying Party" has the meaning set forth in Section 9.4.
- "Inventions" has the meaning set forth in Section 6.2.
- "Licensor Indemnitees" has the meaning set forth in Section 9.1.
- "Notice" has the meaning set forth in Section 7.6.
- "Omthera Indemnitees" has the meaning set forth in Section 9.2.
- "Publishing Party" has the meaning set forth in Section 7.6.
- "Receiving Party" has the meaning set forth in Section 7.1.
- "Term" has the meaning set forth in Section 10.1.

ARTICLE II LICENSES AND OTHER RIGHTS

- 2.1 **Grant of License to Omthera**. Subject to the terms and conditions of this Agreement, Licensor hereby grants to Omthera and its Affiliates an exclusive (even as to Licensor), worldwide, royalty-bearing right and license (with the right to sublicense, and to further sublicense, subject to the provisions of Section 2.2) under the Licensor Technology to research, Develop, manufacture, have manufactured, use, import and Commercialize the Licensed Products in and for the Field. Licensor and its Affiliates grant no licenses or rights to use other than as expressly set forth herein.
- discretion, to grant Sublicenses, in whole or in part, under the license granted in Section 2.1; provided, however, that the granting by Omthera of a Sublicense shall not relieve Omthera of any of its obligations hereunder; and provided, further, that Omthera's right to grant a Person a Sublicense shall be subject to Omthera including within such Sublicense express provisions binding the Sublicensee to all of the duties, obligations, restrictions and acknowledgements hereunder of Omthera (with Licensor being an express third-party beneficiary thereof), and stating that the Sublicense shall automatically terminate upon the expiration or earlier termination of this Research and License Agreement. Notwithstanding the foregoing sentence, it is not required that a Sublicense include provisions for the Sublicensee to pay Royalties or make milestone payments directly to Licensor or to provide royalty reports directly to Licensor. Omthera shall ensure that all of its Sublicensees shall comply with the terms and conditions of this Agreement (as applicable to them) and Omthera shall be and remain fully responsible for the compliance by such Sublicensees were Omthera terms and conditions of this Agreement (as applicable to them) as if such Sublicensees were Omthera

hereunder. Except for Sublicenses as expressly allowed herein, Omthera acknowledges that it has no right to, and agrees not to purport to, grant to anyone a sublicense under the Licensor Technology.

2.3 **Bankruptcy Code**. All rights and licenses granted under or pursuant to this Agreement by Licensor to Omthera are, and shall otherwise be deemed to be, for purposes of Section 365(n) of the US Bankruptcy Code, licenses of rights to "intellectual property" as defined under Section 101 of the US Bankruptcy Code. The Parties agree that Omthera, as a licensee of such rights under this Agreement, shall retain and may fully exercise all of its rights and elections under the US Bankruptcy Code.

ARTICLE III DEVELOPMENT, MANUFACTURE AND COMMERCIALIZATION

- Preclinical Development of Licensed Products by Omthera with Licensor as "General Contractor." Omthera shall, throughout the Development Term, use Commercially Reasonable Efforts to Develop one or more Licensed Products, pursuant to an Omthera preclinical development program as contemplated by this Agreement (the "Development Program"). The current working version of the Development Program is attached to this Agreement as Schedule 2. Omthera and Licensor shall use Commercially Reasonable Efforts to collaborate, through the Joint Scientific Committee, to further detail the design of the Development Program. Omthera and Licensor agree that Licensor shall, for the duration of the Development Term, serve as the "general contractor" for the Development Program with responsibility and authority to arrange, manage and oversee all material aspects of the execution of the Development Program. The "Development Term" shall begin on the Effective Date and shall end on the [second] anniversary of the Effective Date; provided, that should the Parties mutually so agree the Development Term shall be extended until the [third] anniversary of the Effective Date. For avoidance of doubt: except in case of termination of this Agreement for material breach under Section 10.2 or termination by Omthera pursuant to Section 10.4, the Development Program and the Development Term (and Omthera's obligations to Licensor in connection with the Development Program) cannot be ended before the [second] anniversary of the Effective Date. Licensor shall supply, during the Development Term, [two person-years (FTEs) per year of scientific consulting and management services of Licensor personnel] for the Development Program. In addition, during the Development Term Licensor shall use Commercially Reasonable Efforts to procure[, in Licensor's name but for Omthera's account,] all other services and all materials needed for the execution of the Development Program.
- 3.2 **Compensation**. As consideration for Licensor's Development Program work, Omthera shall:
- (a) Pay to Licensor a one-time, non-refundable project management fee of \$100,000 no later than [30] days following the Effective Date.
- (b) Pay to Licensor a one-time, non-refundable Development success fee of \$1,000,000 no later than [30] days following initial achievement of Proof of Concept.
- (c) Pay to Licensor \$[67,500] per [Calendar Quarter per FTE] to offset, on an approximated basis, the [overhead and out-of-pocket salaries and benefits] costs to Licensor of [the two FTEs]; provided, however, that such figure shall be [increased effective as of each anniversary of the Effective Date] by [multiplying it by a fraction, the numerator of which is the United States Department of Labor Bureau of Labor Statistics' All Items Consumer Price Index for All Urban

Consumers for the San Diego area ("CPI-U")] for the [6-month] period in which such [anniversary] occurs and the [denominator of which is the CPI-U] for the [6-month] period which is [one year before that]. For the [partial Calendar Quarter at the beginning] of the Development Term, Omthera shall pay [in advance] to Licensor on the Effective Date a [prorated amount].

- (d) It is understood and agreed that Omthera shall directly contract with any and all CROs for the performance of the Development Plan, except as may be otherwise mutually agreed by the Parties or as specifically set forth in the Development Plan attached hereto and amended from time to time. Without derogation of Section 3.2(c) and the first sentence of this Section 3.2(d), and further subject to reasonable documentation and Omthera's express prior authorization, Omthera shall reimburse Licensor within [thirty (30)] days of receipt of an invoice for [all out-of-pocket costs] for authorized services and materials for the execution of the Development Program.
- 3.3 **No Guaranty of Favorable Results**. Licensor does not warrant that the Development Program, Omthera's other preclinical studies and evaluation (if any) and/or Omthera's clinical studies (if any) will produce any particular results or any favorable results.
- 3.4 Omthera Responsibility and Authority for Development. Aside from the limited responsibility and authority expressly provided to Licensor for the duration of the Development Term pursuant to Section 3.1, Omthera shall have the exclusive right, and sole responsibility and decision-making authority, to research and Develop any Licensed Products in and for the Field and to conduct (either itself or through its Affiliates, agents, subcontractors and/or Sublicensees) all clinical trials and non-clinical studies Omthera believes appropriate to obtain Regulatory Approval for Licensed Products in and for the Field.
- 3.5 **Commercialization**. Omthera shall have the exclusive right, and sole responsibility and decision-making authority, to Commercialize any Licensed Products in and for the Field itself or through one or more Sublicensees or other Third Parties selected by Omthera and shall have the sole decision-making authority and responsibility in all matters relating to the Commercialization of Licensed Products.
- 3.6 **Manufacturing**. Omthera shall have the exclusive right, and sole responsibility and decision-making authority, to manufacture, at the clinical and/or commercial stage, any Licensed Product in and for the Field itself or through one or more Sublicensees selected by Omthera.
- 3.7 **Exclusivity**. Licensor and its Affiliates shall not during the Commercial Term (a) develop, manufacture, have manufactured, use, sell, offer for sale, import or export a Competing Product, (b) seek to develop, manufacture, have manufactured, use, sell, offer for sale, import or export a Competing Product, or (c) assist, in any respect, any Third Party in developing, manufacturing, having manufactured, using, selling, offering for sale, importing or exporting a Competing Product. Except as set forth in this Section 3.7, nothing in this Agreement shall be deemed to limit each Party's right to use its own technologies and assets (without use of the technologies of another Party hereto) for any purpose at any time.
- 3.8 **Reporting to Licensor**. Omthera shall, at least [once each Calendar Year], provide to Licensor an update report regarding the progress of all research and Development efforts toward Licensed Products. After the Development Term, Omthera shall, at least [once each Calendar Year], provide to Licensor an update report regarding the progress of the Development Program. Omthera

shall, at least [once each Calendar Year], provide to Licensor an update report regarding the progress of Commercialization of Licensed Products.

- 3.9 **Right to Subcontract of Omthera**. Subject to any required compliance with Section 2.2, Omthera may exercise any of the rights or obligations that Omthera may have under this Agreement (including, without limitation, any of the rights licensed in Section 2.1 hereof) by Sublicensing, but any Sublicense granted or entered into by Omthera as contemplated by this Section 3.9 or any Sublicensee's exercise or performance of all or any portion of the rights or obligations that Omthera may have under this Agreement shall not relieve Omthera from any of its obligations under this Agreement.
- 3.10 Compliance with Law. Each of the Parties undertakes and agrees that the conduct of the Development Program, the use of the Licensor Technology, and all Development, manufacture and Commercialization of a Licensed Product by it and its Affiliates and Sublicensees shall comply in all material respects with all applicable international, federal, state and local laws, rules and regulations, including, but not limited to, environmental, occupational safety/health, safety and import/export restrictions, laws, rules and regulations. For clarity, the foregoing undertaking shall only be applicable to a Party to the extent such Party (or its Affiliates or Sublicensees) engages in the conduct of the Development Program, the use of the Licensor Technology, and all Development, manufacture and Commercialization of a Licensed Product pursuant to this Agreement, except to the extent that such non-compliance by a Party outside of the scope of this Agreement would otherwise adversely affect or result in a breach of such Party's obligations or other representations or warranties hereunder.
- 3.11 **Costs and Expenses.** As between Licensor and Omthera, Omthera shall be solely responsible for all costs and expenses related to Development, manufacture and Commercialization of the Licensed Products, including without limitation costs and expenses associated with all preclinical activities and clinical trials, and all regulatory filings and proceedings relating to Licensed Products.
- 3.12 **Diligence by Omthera.** Omthera shall use Commercially Reasonable Efforts to Develop and to Commercialize at least one Licensed Product in and for the Field in the United States.
- 3.13 **Patent Marking**. Omthera agrees that with respect to each unit or package of Licensed Products sold in a given country, Omthera shall comply with the customary patent marking laws and practices of such country as to the applicable Licensor Patents.
- 3.14 **Trademarks**. As between Licensor and Omthera, Omthera shall have the sole authority to select trademarks for Licensed Products and shall own all such trademarks. Licensor does not grant Omthera the right to use any trademarks of Licensor or its Affiliates.

ARTICLE IV REGULATORY MATTERS

4.1 **Regulatory Filings.** As between Omthera and Licensor, Omthera (or its applicable Affiliate) shall own and maintain all regulatory filings made after the Effective Date for Licensed Products and all Regulatory Approvals for Licensed Products.

- 4.2 **Communications with Authorities.** Omthera (or one of its Affiliates or Sublicensees) shall be responsible for and act as the sole point of contact for communications with Regulatory Authorities in connection with the Development, Commercialization, and manufacturing of Licensed Products. At the request of Omthera, Licensor shall make available to Omthera a qualified representative who shall, together with the representatives of Omthera, participate in and contribute to meetings with the Regulatory Authorities with respect to regulatory matters relating solely to the Licensor Technology.
- 4.3 Adverse Event Reporting. Each Party agrees to comply with any and all Laws that are applicable to it as of the Effective Date and thereafter during the Term in connection with Licensed Product safety data collection and reporting (and, if applicable, recalls). Licensor shall report immediately to Omthera any serious untoward medical occurrence in a patient or subject who is administered a Licensed Product. Omthera shall provide [annually] to Licensor a listing of each serious untoward medical occurrence in a patient or subject who is administered a Licensed Product and shall, should Licensor expressly so request and Omthera approve (such approval not to be unreasonably withheld), provide Licensor with additional detail as to such ones of such occurrences as Licensor may designate.

ARTICLE V Financial Provisions

5.1 Commercial Milestone Payments. As further partial consideration for Licensor's grant of the rights and licenses to Omthera hereunder, Omthera shall pay to Licensor the following one-time, non-refundable milestone payments upon achievement of the following respective milestone events by Omthera or its Affiliate or Sublicensee with regard to the [first Licensed Product to achieve the respective milestone event]. Omthera shall promptly, but in no event later than [15] days following each achievement of a milestone event, notify Licensor in writing of the achievement of such milestone event and shall pay the relevant milestone payment within [30] days thereafter.

Milestone Event	Milestone Payment
[Enrollment of first patient in first Phase I Clinical	\$2,000,000
Trial	
Enrollment of first patient in first Phase II Clinical	\$2,000,000
Trial	
Enrollment of first patient in first Phase III Clinical	\$4,000,000
Trial	
NDA filing in the United States for a Licensed	\$7,500,000
Product	
First Commercial Sale in the United States for a	\$15,000,000
Licensed Product	
First Commercial Sale in the first Major Market	\$8,000,000
EU Country in which Regulatory Approval is	
obtained for a Licensed Product	
First Commercial Sale in Japan for a Licensed	\$5,000,000]
Product	

5.2 **Deemed Achievement of Commercial Milestones**. Upon achievement of any respective one of the [second, third, fourth or fifth] milestone events specified in Section 5.1 with regard to a particular Compound, all "prior" milestone events shall be deemed to be thereby achieved as to such Compound; and if the milestone payment for any such "prior" milestone events so deemed to be thereby achieved has not previously been paid, it shall thereupon also be paid, forthwith. For clarity, any subsequent Compound developed under this Agreement shall not trigger any milestones already paid in connection with an earlier Compound.

5.3 Royalty Payments for Licensed Products.

(a) With respect to Net Sales of Licensed Products which are Covered under a Licensor Patent: As further consideration for Licensor's grant of the rights and licenses to Omthera hereunder, Omthera shall pay to Licensor a royalty on aggregate annual worldwide Net Sales of all such Licensed Products by Omthera and its Affiliates and Sublicensees (but excluding Net Sales of a given Licensed Product after its applicable Royalty Term), at the percentage rates set forth below:

Annual Worldwide Net Sales of Such Licensed Products per Calendar Year (US Dollars)	Incremental Royalty Rate	
For Net Sales of such Licensed Products from [\$0] up to and including [\$2,000,000,000]	[5]%	
For that portion of Net Sales of such Licensed Products that is greater than [\$2,000,000,000]	[7.5]%	

By way of illustration, assume in a Calendar Year that aggregate worldwide annual Net Sales of all such Licensed Products total \$[2,950,000,000]. The total royalties due and payable by Omthera to Licensor for such Net Sales would be \$[171,250,000], calculated as follows:

[\$2,000,000,000 x 5% = \$100,000,000 \$950,000,000 x 7.5% = \$71,250,000 Total Royalty = \$171,250,000]

(b) With respect to Net Sales of Licensed Products which are not Covered under any Licensor Patent: In addition, as further consideration for Licensor's services in connection with the Development Program and/or Licensor's grant of the Licensed Know-How rights and licenses to Omthera hereunder, as may be applicable, Omthera shall pay to Licensor a royalty (or a payment in the nature of royalties) on aggregate annual worldwide Net Sales of all such Licensed Products by Omthera and its Affiliates and Sublicensees (but excluding Net Sales of a given Licensed Product after its applicable Royalty Term), at the percentage rates set forth below:

Annual Worldwide Net Sales of Such Licensed Products per Calendar Year (US Dollars)	Incremental Royalty Rate	
For Net Sales of such Licensed Products from [\$0] up to and including [\$2,000,000,000]	[3.75]%	
For that portion of Net Sales of such Licensed Products that is greater than [\$2,000,000,000]	[5.625]%	

As used in the foregoing section, "Covered" and "Covering" means, with respect to a Licensed Product, that the manufacturing, importing, using, selling, or offering for sale of such Licensed Product would, but for ownership of or a license granted under the relevant Patent Rights, infringe a Valid Claim of the relevant Patent Rights in the country in which the activity occurs.

- (c) In establishing the royalty/payment in the nature of royalties structure hereunder, the Parties recognize, and Omthera acknowledges, the substantial value of the various obligations being undertaken by Licensor under this Agreement, in addition to the grant of the license under the Licensor Patents, to enable the rapid and effective market introduction of the Licensed Products. The Parties have agreed to the payment structure set forth herein as a convenient and fair mechanism to compensate Licensor for these obligations.
- (d) For purposes of determining whether the Section 5.3(a) or Section 5.3(b) royalty/payment in the nature of royalties threshold has been attained, only Net Sales that are subject to a Section 5.3(a) payment or a Section 5.3(b) payment, respectively, shall be included in the total amount of Net Sales and any Net Sales that are not subject to such a respective payment shall be excluded. In addition, in no event shall the manufacture of a Licensed Product give rise to a royalty/payment in the nature of royalties obligation until the particular unit of Licensed Product is sold; but if Net Sales of a particular unit of Licensed Product might or might not be subject to a royalty/payment in the nature of royalties payment (e.g., manufactured in Country A where the Royalty Term has expired but sold in Country B where the Royalty Term has not expired), the sale shall be deemed to be subject to a royalty/payment in the nature of royalties payment. For clarity, Omthera's obligation to pay royalties to Licensor under Section 5.3(a) is imposed only once with respect to the same unit of Licensed Product regardless of the number of Licensor Patents pertaining thereto.
- (e) On a Licensed Product by Licensed Product and country-by-country basis, upon expiration of the Royalty Term for a Licensed Product in a country, the rights, licenses and sublicenses granted to Omthera hereunder with respect to such Licensed Product in such country shall continue in effect but become fully paid-up, royalty-free, transferable (to the extent not transferable previously), perpetual and irrevocable.
- 5.4 **Timing of Payment.** Royalties/payments in the nature of royalties payable under Section 5.3 shall be payable on actual Net Sales and shall accrue at the time provided therefor by US GAAP. Royalty/payment in the nature of royalties obligations that have accrued during a particular [Calendar Quarter] shall be paid, on a [Calendar Quarter] basis, within [45] days after the end of each [Calendar Quarter] during which the royalty/payment in the nature of royalties obligation accrued; provided that within [75] days after the conclusion of each [Calendar Year] Omthera shall provide notice to Licensor of any adjustments necessary to account for any royalties/payment in the nature of royalties which were overpaid or underpaid for such prior [Calendar Year's Calendar Quarters], and the Parties shall promptly true-up based on such adjustments. With respect to each respective royalty payment payable hereunder, Licensor shall prepare and submit to Omthera an invoice for each such payment in a form reasonably acceptable to Omthera.
- 5.5 **Royalty (Etc.) Reports and Records Retention.** Within [45] days after the end of each [Calendar Quarter] during which Licensed Products have been sold, Omthera shall deliver to Licensor, together with the applicable royalty/payment in the nature of royalties payment due, a written report, on a Licensed Product-by-Licensed Product (and specifying non-Covered status, as

applicable) and country-by-country basis, of (a) gross invoiced (or otherwise charged) amounts of sales, by Omthera and its Affiliates and Sublicensees, of Licensed Products subject to royalty payments for such [Calendar Quarter] (and, if non-Covered, subject to royalty/payment in the nature of royalties payments for such [Calendar Quarter]), (b) amounts deducted by category (following the definition of Net Sales) from such gross invoiced amounts to calculate Net Sales, (c) Net Sales subject to royalty or royalty/payment in the nature of royalties payments for such [Calendar Quarter and Calendar Year] to date and (d) the corresponding royalty or royalty/payment in the nature of royalties. Such report shall be deemed "Confidential Information" of Omthera subject to the obligations of Article VII of this Agreement. For [three] years after each sale of a Licensed Product (whether Covered or not), Omthera shall keep (and shall ensure that its Affiliates and Sublicensees shall keep) complete and accurate records of such sale in sufficient detail to confirm the accuracy of the royalty or royalty/payment in the nature of royalties calculations hereunder.

5.6 Audits.

- (a) From the First Commercial Sale until [one Calendar Year] after the conclusion of the final Royalty Term, upon the written request of Licensor, and not more than [once] in each [Calendar Year], Omthera shall permit, shall cause its Affiliates to permit, and shall use reasonable efforts to cause its Sublicensees to permit, an independent certified public accounting firm of nationally recognized standing selected by Licensor (who has not been engaged by Licensor to provide services in any other capacity at any time during the [three-year] period before such selection), and reasonably acceptable to Omthera or such Affiliate or Sublicensee, to have access to and to review, during normal business hours upon reasonable prior written notice, the applicable records of Omthera and its Affiliates or Sublicensees to verify the accuracy of the royalty and royalty/payment in the nature of royalties reports and payments under this Article V. Such review may cover: (i) the records for sales made in any [Calendar Year ending not more than three years] before the date of such request, and (ii) only those periods that have not been subject to a prior audit.
- (b) If such accounting firm concludes that additional royalties and/or royalties/payment in the nature of royalties were owed during such period, Omthera shall pay the additional royalties and/or royalties/payment in the nature of royalties within [30] days after the date such public accounting firm delivers to Omthera such accounting firm's written report. If such accounting firm concludes that an overpayment was made, such overpayment shall be fully creditable against amounts payable in subsequent payment periods or at Omthera's request, shall be reimbursed to Omthera within [30] days after the date such public accounting firm delivers such report to Omthera. If Omthera disagrees with such calculation, [Omthera may initiate a court action to seek to recover the additional payment or to increase the amount of credit or reimbursement]. [Licensor] shall pay for the cost of any audit by [Licensor], unless [Omthera has underpaid Licensor by 5% or more for a specific royalty period], in which case [Omthera] shall pay for the reasonable costs of audit.
- (c) Each Party shall treat all information that it receives under this Section 5.6 in accordance with the confidentiality provisions of Article VII of this Agreement, and shall cause its accounting firm to enter into an acceptable confidentiality agreement with the audited Party obligating such firm to retain all such financial information in confidence pursuant to such confidentiality agreement, except to the extent necessary for a Party to enforce its rights under the Agreement.

- 5.7 **Mode of Payment and Currency**. All payments to Licensor under this Agreement, whether or not in respect of Net Sales or milestone events, shall be made by deposit of US Dollars in the requisite amount to such bank account as Licensor may from time to time designate by advance written notice to Omthera. Conversion of sales or expenses recorded in local currencies to Dollars will be performed in a manner consistent with each Party's normal practices used to prepare its audited financial statements for external reporting purposes, provided that such practices use a widely accepted source of published exchange rates. Based on the resulting sales in US Dollars, the then applicable royalties/payment in the nature of royalties shall be calculated.
- 5.8 **Late Payments.** If a Party does not receive payment of any sum due to it on or before the due date therefor, simple interest shall thereafter accrue on the sum due to such Party from the due date until the date of payment at a rate equal to [the U.S. Prime Rate for the date payment was due as reported by the *Wall Street Journal*], calculated on the number of days such payments are paid after the date such payments are due. Accrual and payment of interest shall not be deemed to excuse or cure breaches of contract arising from late payment or nonpayment.
- Taxes. All amounts due hereunder exclude all applicable sales, use, and other taxes and duties, and Omthera shall be responsible for payment of all such taxes (other than taxes based on Licensor's income) and duties and any related penalties and interest, arising from the payment of amounts due under this Agreement. The Parties agree to cooperate with one another and use Commercially Reasonable Efforts to avoid or reduce tax withholding or similar obligations in respect of royalties, payments in the nature of royalties, milestone payments, and other payments made by Omthera to Licensor under this Agreement. To the extent Omthera is required to withhold taxes on any payment to Licensor, Omthera shall pay the amounts of such taxes to the proper governmental authority in a timely manner and promptly transmit to Licensor official receipts issued by the appropriate taxing authority and/or an official tax certificate, or such other evidence as Licensor may reasonably request, to establish that such taxes have been paid. Licensor shall provide Omthera any tax forms that may be reasonably necessary in order for Omthera to not withhold tax or to withhold tax at a reduced rate under an applicable bilateral income tax treaty. Licensor shall use Commercially Reasonable Efforts to provide any such tax forms to Omthera at least [45] days before the due date for any payment for which Licensor desires that Omthera apply a reduced withholding rate. Each Party shall provide the others with reasonable assistance to enable the recovery, as permitted by applicable law, of withholding taxes, value added taxes, or similar obligations resulting from payments made under this Agreement, such recovery to be for the benefit of the Party bearing such withholding tax or value added tax. [Licensor shall indemnify and hold Omthera harmless from and against any penalties, interest or other tax liability arising from any failure by Omthera (at the express request of Licensor) to withhold or by reduction (at the express request of Licensor) in its withholding].

ARTICLE VI Inventions and Patents

6.1 **Ownership.** Omthera shall own the Compounds and all intellectual property and rights pertaining thereto (but excluding the Licensor Liver Targeting Prodrug Technology and the Licensor Technology that is Controlled by Licensor or any of its Affiliates as of the Effective Date). For the avoidance of doubt, Omthera shall own all Compound Patents [regardless of inventorship (but excluding the Licensor Liver Targeting Prodrug Technology and the Licensor Technology that is Controlled by Licensor or any of its Affiliates as of the Effective Date)]. Licensor shall co-operate

with Omthera to ensure that assignments of any rights to Omthera which are required to perfect ownership of Compound Patents are carried out by Licensor and its employees or third party contractors. Omthera may choose to file such Compound Patents in a name of an Affiliate, at its sole discretion.

- 6.2 **Inventions and Know-How.** Inventorship of inventions and ownership of Know-How made by Omthera or Licensor in the course of the Development Program ("**Inventions**") shall be determined in accordance with United States laws of inventorship. Subject to Section 6.1 above:
- (a) Sole party Inventions shall be owned by such Party, subject to such rights and licenses of the other Party as may be expressly granted by this Agreement.
 - (b) Joint party Inventions shall be jointly owned by Omthera and Licensor.
- (c) To the extent any current or future-created Licensor Liver Targeting Prodrug Technology related jointly-owned Inventions are specifically and directly related to the Compounds, Licensor's interest in them is deemed to be included within the Section 2.1 license grant.
- 6.3 Inventorship Determination for Licensor Patent Rights. The Parties agree to cooperate and engage in good faith discussions regarding the inventorship of the Licensor Patent Rights appearing in Schedule 1. If the Parties do not mutually agree upon such inventorship, then the Parties agree to engage a mutually acceptable external counsel to determine the inventorship of the Licensor Patent Rights appearing in Schedule 1. Such determination shall be in accordance with United States laws of inventorship. The external counsel will be engaged at least [three] months prior to the [one-year anniversary] of the filing date of any U.S. Provisional Patent Application listed in Schedule 1. The Parties agree to be bound by the inventorship determination of the external counsel.
- 6.4 **Third Party Inventions and Know-How.** As between Licensor and Omthera, all inventions and Know-How made by a Third Party in the course of the Development Program shall be owned by [Omthera].

6.5 Patent Prosecution and Maintenance.

- (a) Licensor Patents. Licensor shall have the first right to file, prosecute and maintain Licensor Patents in Licensor's name. Licensor will, upon forming an intention to file, for any new Inventions, one or more patent applications which would become subject to the License grant in Article II, promptly inform Omthera of such intention, and [will provide Omthera with the opportunity to comment on the content of] such Licensor patent application before filing. Licensor will cooperate with Omthera to allow simultaneous filing by Omthera of Omthera owned inventions as patent applications at Omthera's request. Licensor shall keep Omthera promptly and regularly informed of the course of the filing and prosecution of Licensor Patents or related proceedings (e.g. interferences, oppositions, reexaminations, reissues, revocations or nullifications) in a timely manner, and [to take into consideration the advice and recommendations of Omthera, which may include recommending abandoning and re-filing Licensor's patent application listed in Schedule 1].
- (b) Election Not to File and Prosecute Licensor Patents. Omthera acknowledges and agrees that Licensor shall not be required to maintain Patent Rights for the Licensor Patents, or to file or prosecute Patent Rights for discoveries which might become Licensor

Patents. If Licensor elects not to file, prosecute or maintain a Licensor Patent in Licensor's name in any country, then it shall notify Omthera in writing at least [60] days before any deadline applicable to the filing, prosecution or maintenance of such Licensor Patent, as the case may be, or any other date by which an action must be taken to establish or preserve such Licensor Patent in such country. In such case, Omthera shall have the option to pursue the filing or support the continued prosecution or maintenance of such Licensor Patent in such country, at Omthera's expense.

- (c) Compound Patents. Omthera shall have the sole right to prepare, file, prosecute and maintain Compound Patents in Omthera's name (or the name of an Affiliate at Omthera's discretion). Omthera will, upon forming an intention to file, for any new Inventions, one or more patent applications which would become Compound Patents, promptly inform Licensor of such intention, and [will provide Licensor with the opportunity to comment on the content of such Omthera patent application before filing]. Licensor shall provide all support necessary including data to support such Omthera Patent Rights. Omthera shall bear the cost of prosecuting and maintaining the Omthera Patent Rights. The Parties will consult and cooperate with each other with respect to each Party's patent strategy.
- (d) Omthera shall control and fund the preparation, filing, prosecution and maintenance, enforcement and defense of Patent Rights claiming jointly-owned Inventions (with Licensor having the right to review and comment on drafts of patent submissions; and subject to Licensor rights equivalent to those expressed in Section 6.4(b), with Licensor having the rights accorded under Section 6.4(b) to Omthera.
- 6.6 Certification under Drug Price Competition and Patent Restoration Act. Each of Licensor and Omthera shall immediately give written notice to the other of any certification of which they become aware filed pursuant to 21 U.S.C. Section 355(b)(2)(A) (or any amendment or successor statute thereto) claiming that any Licensor Patents covering a Compound or a Licensed Product, or the manufacture or use of each of the foregoing, are invalid or unenforceable, or that infringement will not arise from the manufacture, use or sale in the US of a Licensed Product by a Third Party.

6.7 **Listing of Patents.**

- (a) [Omthera shall have the sole right] to determine which of the Licensor Patents, if any, shall be listed for inclusion in the Approved Drug Products with Therapeutic Equivalence Evaluations publication pursuant to 21 U.S.C. Section 355, or any successor Law in the United States, together with any comparable Laws in any other country. [Licensor will co-operate with Omthera to] list any of said Licensor Patents.
- (b) For the avoidance of doubt, [Omthera shall have the sole right] to determine which of the Compound Patents, if any, shall be listed for inclusion in the Approved Drug Products with Therapeutic Equivalence Evaluations publication pursuant to 21 U.S.C. Section 355, or any successor Law in the United States, together with any comparable Laws in any other country. [Licensor] shall cooperate with [Omthera] in connection therewith, including [meeting any submission deadlines], in each case, to the extent required or permitted by applicable Law.

6.8 **Enforcement of Patents.**

(a) **Notice.** If either Licensor or Omthera believes that a Licensor Patent is being infringed in the Field by a Third Party or if a Third Party claims that any Licensor Patent is invalid or

unenforceable, the Party possessing such knowledge or belief shall notify the other and provide it with details of such infringement or claim that are known by such Party. If Licensor believes that a Compound Patent is being infringed in the Field by a Third Party or that a Third Party claims that any Compound Patent is invalid or unenforceable, Licensor shall notify Omthera and provide Omthera with details of such infringement or claim that are known by Licensor.

- Right to Bring an Action for Licensor's Patents. If such infringement in the Field or claim is in one or more of the Major Markets in respect of Licensor Patents, [Licensor] shall have the right to attempt to resolve such infringement or claim, including by filing an infringement suit, defending against or bringing a declaratory judgment action as to such claim or taking other similar action (each, "initiation" of an "Action") and (subject to Section 6.7(e)) to compromise or settle such infringement or claim. [Omthera] may, in its sole discretion and at its expense, join in any such Action and in such case shall reasonably cooperate with [Licensor]. If [Licensor] does not intend to initiate an Action, [Licensor] shall promptly inform [Omthera]. If [Licensor] does not initiate an Action with respect to such an infringement or claim within [180] days following notice thereof, [Omthera] shall have the right to attempt to resolve such infringement or claim, including by initiating an Action, and (subject to Section 6.7(e)) to compromise or settle such infringement or claim. At [Omthera]'s request, [Licensor] shall [immediately provide Omthera] with all relevant documentation (as may be requested by [Omthera]) evidencing that [Omthera is validly empowered by the Licensor to initiate an Action]. [Licensor] shall [be under the obligation to join Omtheral in its Action if [Omthera] determines that this is necessary to demonstrate "[standing to sue]." [The Party initiating such Action] shall have the [sole and exclusive] right to select counsel for any suit initiated by it pursuant to this Section 6.7. If a Party initiates an Action but then elects not to pursue the Action, the other Party shall have the right (but not the obligation) to take over the Action, in which case the second Party shall be deemed to have been the initiating Party.
- Patents. If such infringement or claim is in one or more of the Major Markets in respect of Compound Patents or Jointly Owned Patents, [Omthera] shall have the exclusive right to attempt to resolve such infringement or claim, including by filing an infringement suit, defending against or bringing a declaratory judgment action as to such claim or taking other similar action (each, "initiation" of an "Action") and (subject to Section 6.7(e)) to compromise or settle such infringement or claim. Any suit by [Omthera] shall be either in the name of [Omthera or its Affiliate, the name of Licensor or its Affiliate, or jointly by Omthera, Licensor and their respective Affiliates, as may be required by applicable Law if the relevant court would otherwise lack jurisdiction if such Party or its Affiliate were absent from such suit]. For this purpose, [Licensor] agrees to [be joined as a party to the suit] if so required and shall [execute such legal papers and cooperate in the prosecution] of such suit as may be reasonably requested by [Omthera].
- (d) Costs of an Action. Subject to the respective indemnity obligations of the Parties set forth in Article IX and subject to Section 6.7(f), [each Party] involved in an Action under Section 6.7(b) or 6.7(c) shall pay [its own costs and expenses] incurred in connection with such Action.
- (e) **Settlement**. No Party shall settle or otherwise compromise (or resolve by consent to the entry of judgment upon) any Action by admitting that any Licensor Patent is to any extent invalid or unenforceable, or that any Licensor Know-How is not protected or has not been misappropriated, without the other Party's prior written consent[, and, in the case of Licensor,

Licensor may not settle or otherwise compromise (or resolve by consent to the entry of judgment upon) an Action in a way that adversely affects or would be reasonably expected to adversely affect any of Omthera's rights or benefits hereunder with respect to any Licensor Technology or any Licensed Product, without Omthera's prior written consent]. For the avoidance of doubt, [Licensor may not settle or otherwise compromise (or resolve by consent to the entry of judgment upon) an Action in a way that adversely affects or would be reasonably expected to adversely affect the validity of any Compound Patent].

- (f) Reasonable Assistance. Each Party (if it is not the Party enforcing or defending its Patent Rights) shall provide reasonable assistance to the other Party, including providing access to relevant documents and other evidence and making its employees and consultants available, subject to [the other Party's reimbursement of any reasonable out-of-pocket expenses incurred on an on-going basis by the non-enforcing or non-defending Party in providing such assistance].
- (g) **Distribution of Amounts Recovered.** Any amounts recovered by the Party initiating an Action pursuant to this Section 6.7, whether by settlement or judgment, shall be allocated in the following order: [(i) to reimburse the Party initiating such Action for any costs incurred; (ii) to reimburse the Party not initiating such Action for its costs incurred in such Action, if it joins (as opposed to taking over) such Action; and (iii) the remaining amount of such recovery shall be allocated to Omthera and deemed to be Net Sales for the Calendar Quarter in which the amount is actually received by Omthera and Omthera shall pay to Licensor a royalty on such remaining amount based on the royalty rates set forth in Section 5.3].

6.9 Third Party Actions Claiming Infringement.

- (a) **Notice**. If either Licensor or Omthera becomes aware of any Third Party Action, such Party shall promptly notify the other of all details regarding such claim or action that is reasonably available to such Party.
- (b) **Right to Defend.** [Omthera] shall have the right, at its sole expense, but not the obligation, to defend a Third Party Action described in Section 6.8(a) and (subject to Section 6.8(f)) to compromise or settle such Third Party Action. If [Omthera declines or fails to assert its intention to defend] such Third Party Action within [40] days of receipt/sending of notice under Section 6.8(a), then [Licensor] shall have the right, at its sole expense, to defend such Third Party Action and (subject to Section 6.8(f)) to compromise or settle such Third Party Action. The Party defending such Third Party Action shall have the sole and exclusive right to select counsel for such Third Party Action.
- (c) **Consultation.** The Party defending a Third Party Action pursuant to Section 6.8(b) shall be the "Controlling Party". The Controlling Party shall consult with the non-Controlling Party, pursuant to an appropriate joint defense or common interest agreement, on all material aspects of the defense. The non-Controlling Party shall have a reasonable opportunity for meaningful participation in decision-making and formulation of defense strategy. The Parties shall reasonably cooperate with each other in all such actions or proceedings. The non-Controlling Party will be entitled to join the Third Party Action and be represented by independent counsel of its own choice at its own expense.

- (d) Appeal. In the event that a judgment in a Third Party Action is entered against either Party and an appeal is available, the Controlling Party shall have the first right, but not the obligation, to file such appeal. In the event the Controlling Party does not desire to file such an appeal, it will promptly, in a reasonable time period (i.e., with sufficient time for the non-Controlling Party to take whatever action may be necessary) before the date on which such right to appeal will lapse or otherwise diminish, permit the non-Controlling Party to pursue such appeal [at such non-Controlling Party's own cost and expense]. If applicable Law requires the other Party's involvement in an appeal, the other Party shall be a nominal party in the appeal and shall provide reasonable cooperation to such Party [at such Party's expense].
- (e) Costs of an Action. Subject to the respective indemnity obligations of the Parties set forth in Article IX, [the Controlling Party] shall pay [all costs and expenses] associated with such Third Party Action other than [the expenses of the other Party if the other Party elects to join such Third Party Action] (as provided in the last sentence of Section 6.8(c)).
- otherwise compromise (or resolve by consent to the entry of judgment upon) any Third Party Action by admitting that any Licensor Patent is to any extent invalid or unenforceable or that any Licensed Product, or its use, Development, importation, manufacture or sale infringes such Third Party's intellectual property rights, in each case without the other Party's prior written consent[, and, in the case of Licensor, Licensor may not settle or otherwise compromise (or resolve by consent to the entry of judgment upon) a Third Party Action in a way that adversely affects or would be reasonably expected to adversely affect Omthera's rights and benefits hereunder with respect to any Licensor Technology or any Licensed Product, without Omthera's prior written consent]. For the avoidance of doubt, [Licensor may not settle or otherwise compromise (or resolve by consent to the entry of judgment upon) an Action in a way that adversely affects or would be reasonably expected to adversely affect the validity of any Compound Patent].

6.10 Other License Provisions.

- (a) All rights and licenses granted under or pursuant to this Agreement by Omthera to Licensor and its Affiliates are, and shall otherwise be deemed to be, for purposes of Section 365(n) of the US Bankruptcy Code, licenses of rights to "intellectual property" as defined under Section 101 of the US Bankruptcy Code. The Parties agree that Licensor and its Affiliates, as licensee of such rights under this Agreement, shall retain and may fully exercise all of Licensor's and its Affiliates' rights and elections under the US Bankruptcy Code.
- (b) Omthera grants no licenses or rights to use other than as expressly set forth herein.
- (c) Notwithstanding anything to the contrary in this Article VI, neither Party shall have the right to make an election under the Cooperative Research and Technology Enhancement Act of 2004, 35 U.S.C. 102C when exercising its rights under this Section without the prior written consent of the other Party. With respect to any such permitted election, the Parties shall use reasonable efforts to cooperate and coordinate their activities with respect to any submissions, filings or other activities in support thereof. The Parties acknowledge and agree that this Agreement is a "joint research agreement" as defined in the Cooperative Research and Technology Enhancement Act of 2004.

ARTICLE VII CONFIDENTIALITY

- 7.1 **Definitions.** Omther a and Licensor each recognizes that during the Term, it may be necessary for a Party (the "Disclosing Party") to provide Confidential Information (as defined herein) to another Party (the "Receiving Party") that is highly valuable, the disclosure of which would be highly prejudicial to such Party. The disclosure and use of Confidential Information shall be governed by the provisions of this Article VII. Neither Omthera nor Licensor shall use the other's Confidential Information except as expressly permitted in this Agreement. For purposes of this Agreement, "Confidential Information" means all information (including information relating to the business, operations and products of a Party or any of its Affiliates) disclosed by the Disclosing Party to the Receiving Party and which reasonably ought to have been understood to be confidential and/or non-public information at the time disclosed to the Receiving Party, or which is designated in writing by the Disclosing Party as "Confidential" (or equivalent), or which when disclosed orally to the Receiving Party is declared to be confidential by the Disclosing Party and is so confirmed in a writing delivered to the Receiving Party within [30] days after such oral disclosure, including but not limited to any technical information, Know-How, trade secrets, or inventions (whether patentable or not), that such Party discloses to another Party under this Agreement, or otherwise becomes known to another Party by virtue of or that relates to this Agreement.
- 7.2 **Obligation**. Licensor and Omthera agree that they will disclose the other Party's Confidential Information to its own (or its respective Affiliate's, or with respect to Omthera, its Sublicensees') officers, employees, consultants and agents only if and to the extent necessary to carry out their respective responsibilities under this Agreement or in accordance with the exercise of their rights under this Agreement, and such disclosure shall be limited to the maximum extent possible consistent with such responsibilities and rights. Except as set forth in the foregoing sentence, no Party shall disclose Confidential Information of the other to any Third Party without the other's prior written consent. In all events, however, any and all disclosure to a Third Party (or to any such Affiliate or Sublicensee) shall be pursuant to the terms of a non-disclosure/nonuse agreement no less restrictive than this Article VII. The Party which disclosed Confidential Information of the other to any Third Party (or to any such Affiliate or Sublicensee) shall be responsible and liable for any disclosure or use by such Third Party, Affiliate or Sublicensee (or its disclosees) which would have violated this Agreement if committed by the Party itself. No Party shall use Confidential Information of the other except as expressly allowed by and for the purposes of this Agreement. Each Party shall take such action to preserve the confidentiality of each other's Confidential Information as it would customarily take to preserve the confidentiality of its own Confidential Information (but in no event less than a reasonable standard of care). Upon expiration or termination of this Agreement, each Party, upon the other's request, shall return or destroy (at Disclosing Party's discretion) all the Confidential Information disclosed to the other Party pursuant to this Agreement, including all copies and extracts of documents, within [60] days after the request, except for one archival copy (and such electronic copies that exist as part of the Party's computer systems, network storage systems and electronic backup systems) of such materials solely to be able to monitor its obligations that survive under this Agreement.
- 7.3 **Exceptions**. The non-use and non-disclosure obligations set forth in this Article VII shall not apply to any Confidential Information, or portion thereof, that the Receiving Party can demonstrate by competent evidence:

- (a) at the time of disclosure is in the public domain;
- (b) after disclosure, becomes part of the public domain, by publication or otherwise, through no fault of the Receiving Party or its disclosees;
- (c) is made available to the Receiving Party by an independent Third Party without obligation of confidentiality; provided, however, that to the Receiving Party's knowledge, such information was not obtained by said Third Party, directly or indirectly, from the Disclosing Party hereunder; or
- (d) is independently developed by an employee of the Receiving Party not accessing or utilizing the Disclosing Party's information.

In addition, the Receiving Party may disclose information that is required to be disclosed by law, by a valid order of a court or by order or regulation of a governmental agency including but not limited to, regulations of the SEC or in the course of arbitration or litigation; provided, however, that in all cases the Receiving Party shall give the other party prompt notice of the pending disclosure and make a reasonable effort to obtain, or to assist the Disclosing Party in obtaining, a protective order or confidential-treatment order preventing or limiting (to the greatest possible extent and for the longest possible period) the disclosure and/or requiring that the Confidential Information so disclosed be used only for the purposes for which the law or regulation required, or for which the order was issued.

- 7.4 **Third Party Information**. The Parties acknowledge that the defined term "Confidential Information" shall include not only a Disclosing Party's own Confidential Information but also Confidential Information of a Third Party which is in the possession of a Disclosing Party. Omthera and Licensor agree not to disclose to the other any Confidential Information of a Third Party which is in the possession of such Party, unless the other has given an express prior written consent (which specifies the owner of such Confidential Information) to receive such particular Confidential Information.
- 7.5 **Press Releases and Disclosure.** Either Party may make press releases or public announcements regarding this Agreement or any matter covered by this Agreement, including the Development or Commercialization of Licensed Products, but such Party shall use Commercially Reasonable Efforts to provide the text of such planned disclosure to the other Party sufficiently in advance of the scheduled disclosure to afford such other Party a reasonable opportunity to review and comment upon the proposed text and the timing of such disclosure, and shall consider all reasonable comments of the other Party regarding such disclosure. (Provided, that no Party shall use the trademark or logo of the other Party, its Affiliates or their respective employee(s) in any publicity, promotion, news release or public disclosure relating to this Agreement or its subject matter, except as may be required by Law or required by the rules of an applicable US national securities exchange or except with the prior express written permission of such other Party, such permission not to be unreasonably withheld.) Notwithstanding the above, once a public disclosure has been made, either Party shall be free to disclose to third parties any information contained in said public disclosure, without further pre-review.
- 7.6 **Publication Rights**. During the Term, the following restrictions shall apply with respect to possible disclosure by either Party of the other Party's Confidential Information relating to Licensed Product in any publication or presentation. A Party (the "**Publishing Party**") shall provide

the other Party with a copy of any proposed publication or presentation at least [30] days before submission for publication by the Publishing Party or its Affiliates so as to provide such other Party with an opportunity to recommend any changes it reasonably believes are necessary to continue to maintain the Confidential Information disclosed by the other Party to the Publishing Party in accordance with the requirements of this Agreement. The incorporation of such recommended changes shall not be unreasonably refused; and if such other Party notifies ("Notice") the Publishing Party in writing, within [30] days after receipt of the copy of the proposed publication or presentation, that such publication or presentation in its reasonable judgment (a) contains an invention, solely or jointly conceived or reduced to practice by the other Party, for which the other Party reasonably desires to obtain patent protection or (b) could be expected to have a material adverse effect on the commercial value of any Confidential Information disclosed by the other Party to the Publishing Party, the Publishing Party shall prevent such publication or delay such publication for a mutually agreeable period of time. In the case of inventions, a delay shall be for a period reasonably sufficient to permit the timely preparation and filing of a patent application(s) on such invention, and in no event less than [90] days after the date of the Notice. In the case of Confidential Information, any of the non-publishing Party's Confidential Information shall be deleted as requested. [The Parties hereby agree that the need for such publication review may diminish over time and agree, at a mutually agreed upon time, and at least upon granting to AstraZeneca of a US patent to a Compound, and every six months thereafter, to discuss and agree upon whether and/or when the obligations under this Section 7.6 may be discontinued].

ARTICLE VIII REPRESENTATIONS, WARRANTIES AND COVENANTS

- 8.1 **Representations and Warranties.** (a) Omther represents and warrants to Licensor, and (b) Licensor represents and warrants to Omthera, in each case as of the Effective Date:
- (a) Such Party is a corporation duly organized and validly existing under the Laws of the jurisdiction of its incorporation;
- (b) Such Party has all right, power and authority to enter into this Agreement, and to perform its obligations under this Agreement;
- (c) Such Party has taken all action necessary to authorize the execution and delivery of this Agreement and the performance of its obligations under this Agreement;
- (d) This Agreement is a legal and valid obligation of such Party, binding upon such Party and enforceable against such Party in accordance with the terms of this Agreement, except as enforcement may be limited by applicable bankruptcy, fraudulent conveyance, insolvency, reorganization, moratorium and other laws relating to or affecting creditors' rights generally and by general equitable principles;
- (e) The execution, delivery and performance of this Agreement by such Party does not and will not conflict with, breach or create in any Third Party the right to accelerate, terminate or modify any agreement or instrument to which such Party is a party or by which such Party is bound;
- (f) All consents, approvals and authorizations from all governmental authorities or other Third Parties required to be obtained by such Party in connection with the execution and

delivery of this Agreement have been obtained; and the execution, delivery and performance of this Agreement by such Party does not and will not violate any Law of any Governmental Body having authority over such Party;

- (g) No person or entity has or will have, as a result of the execution and delivery of or as a result of the transactions contemplated by this Agreement, any right, interest or valid claim against or upon such Party for any commission, fee or other compensation as a finder or broker because of any act by such Party or its Affiliates, agents or Sublicensees; and
- (h) It has not entered into any agreement with any Third Party that is in conflict with the rights granted to any other party pursuant to this Agreement.
- 8.2 **Additional Representations and Warranties of Licensor.** Licensor represents and warrants to Omthera that:
- (a) No consent by any Third Party or Governmental Body is required with respect to the execution and delivery of this Agreement by Licensor or the consummation by Licensor of the transactions contemplated hereby;
- (b) No claims have been asserted or threatened by any Person (i) challenging the validity, effective status, or ownership of Licensor Technology, and/or (ii) to the effect that the use, reproduction, modification, manufacturing, distribution, licensing, sublicensing, sale or any other exercise of rights in any of Licensor Technology infringes or will infringe on any intellectual property right of any Person; and no such claims have been asserted or are threatened;
- (c) The Licensor Patents are subsisting and are not the subject of any litigation procedure, discovery process, interference, reissue, reexamination, opposition, appeal proceedings or any other legal dispute;
- (d) The Licensor Patents constitute all Patent Rights owned or Controlled by Licensor that relate directly and particularly to or are reasonably necessary to the research, Development, manufacture, use and Commercialization of the Licensed Products as currently envisioned:
- (e) Licensor has not subcontracted or licensed to a Third Party the right to Develop a Competing Product;
- (f) No Third Party has filed, pursued or maintained or threatened in writing to file, pursue or maintain any claim, lawsuit, charge, complaint or other action alleging that any Licensor Technology is invalid or unenforceable; and
- (g) Licensor has not previously licensed, assigned, transferred, or otherwise conveyed any right, title or interest in and to the Licensor Technology to any Third Party for the field of treatment of dyslipidemia in humans, including but not limited to any rights to any Licensor Technology or Licensed Products.
- 8.3 **Disclaimer.** Notwithstanding the representations and warranties set forth in this Article VIII, Omthera acknowledges and accepts the risks inherent in attempting to Develop and Commercialize any pharmaceutical product. There is no implied representation that the Compounds

can be successfully Developed or Commercialized. The representations and warranties set forth in this Article VIII are provided in lieu of, and EACH PARTY HEREBY DISCLAIMS, all other warranties, express and implied, relating to the subject matter of this Agreement, the Licensor Technology, the Compounds and/or the Licensed Products, including but not limited to the implied warranties of merchantability and fitness for a particular purpose, title and non-infringement of third party rights. Each Party's representations and warranties under this Agreement are solely for the benefit of the other Party and may be asserted only by the other Party and not by any Affiliate, Sublicensee or any customer of the other Party, its Affiliates or Sublicensees. Each Party, its Affiliates and Sublicensees shall be solely responsible for all representations and warranties that it, its Affiliates or Sublicensees make to any customer, Affiliates or Sublicensees.

ARTICLE IX INDEMNIFICATION; LIMITATION OF LIABILITY; INSURANCE

- 9.1 **Indemnification by Omthera.** Omthera shall indemnify, defend and hold Licensor and its Affiliates, and each of their respective employees, officers, directors and agents (the "Licensor Indemnitees") harmless from and against any and all actions, judgments, settlements, liabilities, damages, penalties, fines, losses, costs and expenses (including reasonable attorneys' fees and expenses) to the extent arising out of any Third Party claim, demand, action or other proceeding (each, a "Claim") related to (a) Omthera's performance of its obligations or exercise (by it or its Affiliates or Sublicensees) of its rights under this Agreement; or (b) breach by Omthera of its representations and warranties set forth in Article VIII; provided, however, that Omthera's obligations pursuant to this Section 9.1 shall not apply (x) to the extent such claims or suits result from the gross negligence or willful misconduct of any of the Licensor Indemnitees, or (y) with respect to claims or suits arising out of breach by Licensor of this Agreement, including without limitation of its or their representations and warranties set forth in Article VIII.
- 9.2 **Indemnification by Licensor.** Licensor shall indemnify, defend and hold Omthera and its Affiliates and each of their respective agents, employees, officers and directors (the "Omthera Indemnitees") harmless from and against any and all actions, judgments, settlements, liabilities, damages, penalties, fines, losses, costs and expenses (including reasonable attorneys' fees and expenses) to the extent arising out of any and all Claims related to (a) Licensor's performance of its obligations or exercise (by it or its Affiliates) of its or their rights under this Agreement; or (b) breach by Licensor of its representations and warranties set forth in Article VIII; provided, however, that Licensor's obligations pursuant to this Section 9.2 shall not apply (x) to the extent that such claims or suits result from the gross negligence or willful misconduct of any of the Omthera Indemnitees or (y) with respect to claims or suits arising out of a breach by Omthera of this Agreement, including without limitation its representations and warranties set forth in Article VIII.
- 9.3 No Consequential Damages. EXCEPT FOR DAMAGES FOR WHICH A PARTY IS RESPONSIBLE PURSUANT TO ITS INDEMNIFICATION OBLIGATIONS SET FORTH IN ARTICLE IX, EACH PARTY SPECIFICALLY DISCLAIMS ALL LIABILITY FOR AND SHALL IN NO EVENT BE LIABLE TO ANY OTHER PARTY OR TO ANY OTHER PARTY'S AFFILIATES FOR ANY INCIDENTAL, SPECIAL, INDIRECT OR CONSEQUENTIAL DAMAGES, EXPENSES, LOST PROFITS, LOST SAVINGS, INTERRUPTIONS OF BUSINESS OR OTHER DAMAGES OF ANY KIND OR CHARACTER WHATSOEVER ARISING OUT OF OR RELATED TO THIS AGREEMENT OR THE DEVELOPMENT PROGRAM OR THE LICENSED TECHNOLOGY OR RESULTING FROM THE MANUFACTURE, HANDLING,

MARKETING, SALE, DISTRIBUTION OR USE OF LICENSED PRODUCTS, REGARDLESS OF THE FORM OF ACTION, WHETHER IN CONTRACT, TORT, STRICT LIABILITY OR OTHERWISE, EVEN IF SUCH PARTY WAS ADVISED OF THE POSSIBILITY OF SUCH DAMAGES.

9.4 **Procedure.**

- The Party or other Person intending to claim indemnification under this Article IX (an "Indemnified Party") shall promptly notify the opposed Party (the "Indemnifying Party") of any Claim in respect of which the Indemnified Party intends to claim such indemnification (provided, that no delay or deficiency on the part of the Indemnified Party in so notifying the Indemnifying Party will relieve the Indemnifying Party of any liability or obligation under this Agreement except to the extent the Indemnifying Party has suffered actual prejudice directly caused by the delay or other deficiency), and the Indemnifying Party shall assume the defense thereof (with counsel selected by the Indemnifying Party and reasonably satisfactory to the Indemnified Party) whether or not such Claim is rightfully brought; provided, however, that an Indemnified Party shall have the right to retain its own counsel and to participate in the defense thereof, with the fees and expenses to be paid by the Indemnified Party unless the Indemnifying Party does not assume the defense or unless a representation of both the Indemnified Party and the Indemnifying Party by the same counsel would be inappropriate due to the actual or potential differing interests between them, in which case the reasonable fees and expenses of counsel retained by the Indemnified Party shall be paid by the Indemnifying Party. (Provided, that in no event shall the Indemnifying Party be required to pay for more than one separate counsel no matter the number or circumstances of all Indemnified Parties.)
- (b) If the Indemnifying Party shall fail to timely assume the defense of such Claim, the Indemnified Party shall have the right to retain or assume control of such defense and the Indemnifying Party shall pay (as incurred and on demand) the fees and expenses of counsel retained by the Indemnified Party.
- Claim settled (or resolved by consent to the entry of judgment) without the written consent of the Indemnifying Party. Also, if the Indemnifying Party shall control the defense of any such Claim, the Indemnifying Party shall have the right to settle such Claim; provided, that the Indemnifying Party shall obtain the prior written consent (which shall not be unreasonably withheld or delayed) of the Indemnified Party before entering into any settlement of (or resolving by consent to the entry of judgment upon) such Claim unless (i) there is no finding or admission of any violation of law or any violation of the rights of any person by an Indemnified Party, no requirement that the Indemnified Party admit negligence, fault or culpability, and no adverse effect on any other claims that may be made by or against the Indemnified Party and (ii) the sole relief provided is monetary damages that are paid in full by the Indemnifying Party and such settlement does not require the Indemnified Party to take (or refrain from taking) any action.
- (d) The Indemnified Party, and its employees and agents, shall cooperate fully with the Indemnifying Party and its legal representatives in the investigations of any Claim.
- (e) Regardless of who controls the defense, each Party hereto shall reasonably cooperate in the defense as may be requested.

- 9.5 **Expenses**. As the Parties intend complete indemnification, all costs and expenses of enforcing any provision of this Article IX shall also be reimbursed by the Indemnifying Party.
- 9.6 Limitation of Liability. EACH PARTY SHALL HAVE NO REMEDY, AND EACH PARTY SHALL HAVE NO LIABILITY, OTHER THAN AS EXPRESSLY SET FORTH IN THIS AGREEMENT. EXCEPT WITH RESPECT TO THE INDEMNIFICATION SPECIFICALLY PROVIDED IN ARTICLE IX OR CLAIMS FOR NON-PAYMENT, IN NO EVENT SHALL A PARTY'S TOTAL AGGREGATE LIABILITY FOR ALL CLAIMS ARISING OUT OF OR RELATED TO THIS AGREEMENT EXCEED [THE AMOUNTS ACTUALLY PAID BY OMTHERA FOR THE DEVELOPMENT PROGRAM]. NO ACTION, REGARDLESS OF FORM, ARISING OUT OF OR RELATED TO THIS AGREEMENT MAY BE BROUGHT BY EITHER PARTY MORE THAN [TWO YEARS] AFTER SUCH PARTY HAS KNOWLEDGE OF THE OCCURRENCE THAT GAVE RISE TO THE CAUSE OF ACTION OR AFTER EXPIRATION OF THE APPLICABLE STATUTORY LIMITATIONS PERIOD, WHICHEVER IS SOONER.
- 9.7 **Insurance.** During the Term and for [three years] thereafter, Omthera shall obtain and maintain, at its own cost and expense, product liability insurance (or Omthera's parent company shall obtain and maintain coverage for Omthera under its own product liability insurance policies) in amounts, that are reasonable and customary in the United States pharmaceutical and biotechnology industry for companies engaged in comparable activities. It is understood and agreed that this insurance shall not be construed to limit Omthera's liability with respect to its indemnification obligations hereunder. Omthera shall upon request provide to Licensor upon request a certificate evidencing the insurance Omthera is required to obtain and keep in force under this Section 9.7.

ARTICLE X TERM AND TERMINATION

- Date and, unless earlier terminated as provided in this Article X, shall continue in full force and effect, on a country-by-country and Licensed Product-by-Licensed Product basis until the Royalty Term in such country with respect to such Licensed Product expires, at which time this Agreement shall expire in its entirety with respect to such Licensed Product in such country. (The "Term" shall mean the period from the Effective Date until the earlier of termination of this Agreement as provided in this Article X or expiration of this Agreement upon the expiration of the last-to-expire Royalty Term.) The Parties confirm that subject to the foregoing sentence, this Agreement shall not be terminated or invalidated by any future determination that any or all of the Licensor Patents have expired or been invalidated.
- 10.2 **Termination upon Material Breach.** If a Party breaches any of its material obligations under this Agreement, the Party not in default may give to the breaching Party a written notice specifying the nature of the default, requiring it to cure such breach, and, if desired, stating its intention to terminate this Agreement if such breach is not cured within [30] days of the breaching Party's receipt of such notice. If such breach is not cured within [30] days after the receipt of such notice, the Party not in default shall (in addition to and not in lieu of all other available rights and remedies) be entitled to at its option either (a) terminate this Agreement immediately by written notice to the other Party, or (b) continue this Agreement in full force and effect and seek any legal or equitable remedies that the non-breaching Party may have. In case of a breach of an obligation to pay

money, which obligation to pay is not disputed in good faith, the cure period shall be [10] days instead of [30] days. The Parties agree that any failure by Omthera to pay when due 100% of such portion of any amount of money owing from Omthera to Licensor as is not disputed in good faith by Omthera (subject to the [10]-day cure period) shall conclusively be deemed to constitute a "material" breach.

- 10.3 **Termination for Bankruptcy.** Licensor may terminate this Agreement immediately upon written notice to Omthera in the event that Omthera has a petition in bankruptcy filed against it that is not dismissed within [60] days of such filing, files a petition in bankruptcy, or makes an assignment for the benefit of creditors. Omthera may terminate this Agreement immediately upon written notice to Licensor in the event that Licensor has a petition in bankruptcy filed against it that is not dismissed within [60] days of such filing, files a petition in bankruptcy, or makes an assignment for the benefit of creditors.
- terminate this Agreement immediately upon written notice to Licensor in the event that (a) any Research Goal (as specified in Schedule 2) is not met on schedule or is not capable of being met or (b) the Research Plan (as specified in Schedule 2) materially exceeds the applicable budget or timeline, as Omthera reasonably determines in its sole discretion. (Provided, however, that Omthera's right to terminate this Agreement under this Section 10.4 on account of any particular Research Goal not being met on schedule, any particular Research Goal not being capable of being met, the Research Plan materially exceeding the applicable budget at a particular time or the Research Plan materially exceeding the applicable timeline in a particular regard shall lapse if Omthera does not so terminate within [60] days after Licensor notifies Omthera of such particular Research Goal not being met on schedule, such particular Research Goal not being capable of being met, the Research Plan materially exceeding the applicable budget at such particular time or the Research Plan materially exceeding the applicable budget at such particular time or the Research Plan materially exceeding the applicable timeline in such particular regard). In the event of such termination, Omthera shall have no further liability or obligation to Licensor except as specifically set forth in Section 10.6.
- 10.5 **Termination Without Cause by Omthera.** From and after December 31, 2014, Omthera may terminate this Agreement for any or no reason upon written notice to Licensor specifying such termination pursuant to this Section.

10.6 Effects of Termination/Expiration.

- (a) Articles I (Definitions), VII (Confidentiality), IX (Indemnification; Limitation of Liability; Insurance) and XI (Miscellaneous Provisions) and Sections 5.5 (Royalty Reports and Records Retention), 5.6 (Audits), 5.8 (Late Payments), 5.9 (Taxes) and 10.6 (Effects of Termination/Expiration) hereof shall survive the expiration or termination of this Agreement for any reason. In addition, upon termination of this Agreement by Omthera pursuant to Sections 10.2 or 10.3, then Section 6.8 (Third Party Actions Claiming Infringement) shall survive the expiration or termination of this Agreement.
- (b) Termination or expiration of this Agreement shall not relieve the Parties of any liability that accrued hereunder before the effective date of such termination or expiration. In addition, termination or expiration of this Agreement shall not preclude either Party from pursuing all rights and remedies it may have hereunder or at Law or in equity with respect to any breach of this Agreement nor prejudice either Party's right to obtain performance of any obligation.

(c) Upon termination of this Agreement by Licensor pursuant to Sections 10.2 or 10.3 or by Omthera pursuant to Sections 10.4 or 10.5, all licenses granted to Omthera hereunder shall terminate. In the event of termination by Omthera pursuant to Section 10.2 or 10.3, the licenses granted to Omthera hereunder shall continue in effect but become fully paid-up, royalty-free, transferable (to the extent not transferable previously), perpetual and irrevocable. Notwithstanding anything to the contrary herein, in the event of termination by Omthera pursuant to Section 10.5, Omthera shall not continue to research, Develop, manufacture, have manufactured, use, import and Commercialize any Licensed Product that was made or discovered in the Development Program with Licensor Know-How that is solely owned by LIcensor.

ARTICLE XI MISCELLANEOUS PROVISIONS

11.1 **Relationship of the Parties.** Nothing in this Agreement is intended or shall be deemed to constitute a partnership, agency, joint venture or employer-employee relationship between the Parties. No Party shall have any right or authority to commit or legally bind any other Party in any way whatsoever including, without limitation, the making of any agreement, representation or warranty and each Party agrees to not purport to do so.

11.2 Assignment.

- (a) Any assignment not in accordance with this Section 11.2 shall be void.
- (b) No assignment shall relieve the assigning Party of any of its responsibilities or obligations hereunder.
- (c) Omthera may not transfer or assign its rights or licenses or delegate its obligations under this Agreement, in whole or in part, by operation of law or otherwise, to any Third Party without the prior written consent of Licensor, which consent shall not be unreasonably withheld, conditioned or delayed; provided that, notwithstanding the foregoing, Omthera may assign its rights or licenses and/or delegate its obligations under this Agreement to an Affiliate or to a successor to all or substantially all of Omthera's assets, whether by way of merger, sale of all or substantially all of its assets, sale of stock or otherwise, without Licensor's prior written consent. As a condition to any permitted assignment hereunder, the assignee must expressly assume, in a writing delivered to Licensor (and in a form reasonably acceptable to Licensor) all of Omthera's obligations under this Agreement, whether arising before, at or after the assignment.
- (d) Licensor may not transfer or assign its rights or delegate its obligations under this Agreement, in whole or in part, by operation of law or otherwise, to any Third Party without the prior written consent of Omthera, which consent shall not be unreasonably withheld, conditioned or delayed; provided that, notwithstanding the foregoing, Licensor may, without Omthera's prior written consent, assign its rights and/or delegate its obligations under this Agreement to an Affiliate, or to any person in a transaction in which Licensor also assigns all of its right, title and interest in all of its Licensor Liver Targeting Prodrug Technology assets, including without limitation, intellectual property rights, to the same party contemporaneous with the assignment of this Agreement, or to a successor, whether by way of merger, sale of all or substantially all of its assets, sale of stock or otherwise. As a condition to any permitted assignment hereunder, the assignee must expressly assume, in a writing delivered to Omthera (and in a form

reasonably acceptable to Omthera) all of Licensor's obligations under this Agreement, whether arising before, at or after the assignment.

- 11.3 **Further Actions.** Each Party agrees to execute, acknowledge and deliver such further instruments and to do all such other acts as may be necessary or appropriate in order to carry out the purposes and intent of this Agreement.
- breached or defaulted under this Agreement for failure or delay in the performance of any of its obligations under this Agreement (other than obligations for the payment of money) for the time and to the extent such failure or delay is caused by or results from acts of God, earthquake, riot, civil commotion, terrorism, war, strikes or other labor disputes, fire, flood, failure or delay of transportation, omissions or delays in acting by a governmental authority, acts of a government or an agency thereof or judicial orders or decrees or restrictions or any other like reason which is beyond the control of the respective Party. The Party affected by force majeure shall provide the other Party with full particulars thereof as soon as it becomes aware of the same (including its best estimate of the likely extent and duration of the interference with its activities), and shall use Commercially Reasonable Efforts to overcome the difficulties created thereby and to resume performance of its obligations hereunder as soon as practicable, and the time for performance shall be extended for a number of days equal to the duration of the force majeure.
- 11.5 Entire Agreement of the Parties; Amendments. This Agreement and the Schedules hereto constitute and contain the entire understanding and agreement of the Parties respecting the subject matter hereof and cancel and supersede any and all prior or contemporaneous negotiations, correspondence, understandings and agreements between the Parties, whether oral or written, regarding such subject matter (provided, that any and all previous nondisclosure/nonuse obligations are not superseded and remain in full force and effect in addition to the nondisclosure/nonuse provisions hereof). Each Party acknowledges that it has not relied, in deciding whether to enter into this Agreement on this Agreement's expressly stated terms and conditions, on any representations, warranties, agreements, commitments or promises which are not expressly set forth within this Agreement. No modification or amendment of any provision of this Agreement shall be valid or effective unless made in a writing referencing this Agreement and signed by a duly authorized officer of each Party.
- 11.6 **Governing Law.** This Agreement shall be governed by and interpreted in accordance with the laws of the State of New York, excluding application of any conflict of laws principles.
- 11.7 **Notices and Deliveries**. Any notice, request, approval or consent required or permitted to be given under this Agreement shall be in writing and shall be deemed to have been sufficiently given if and only if delivered in person, by email or by express courier service to the Party to which it is directed at its physical or email address shown below or such other physical or email address as such Party shall have last given by such written notice to the other Party.

If to Omthera, addressed to:

Omthera Pharmaceuticals, Inc. 707 State Road Princeton, NJ 08540 Attention: Chief Medical Officer Email: [mdavidson@omthera.com]

If to Licensor, addressed to:

General Counsel
Ligand Pharmaceuticals Incorporated
11119 North Torrey Pines Road, Suite 200
La Jolla, CA 92037
Email: [cberkman@ligand.com]

- 11.8 **Waiver.** No waiver of any provision of this Agreement shall be valid or effective unless made in a writing referencing this Agreement and signed by a duly authorized officer of the waiving Party. A waiver by a Party of any of the terms and conditions of this Agreement in any instance shall not be deemed or construed to be a waiver of such term or condition for the future, or of any other term or condition hereof.
- 11.9 **Rights and Remedies are Cumulative**. Except to the extent expressly set forth herein, all rights, remedies, undertakings, obligations and agreements contained in or available upon violation of this Agreement shall be cumulative and none of them shall be in limitation of any other remedy or right authorized in law or in equity, or any undertaking, obligation or agreement of the applicable Party.
- 11.10 **Severability.** This Agreement is severable. When possible, each provision of this Agreement will be interpreted in such manner as to be effective and valid under applicable Law, but if any provision of this Agreement is held to be to any extent prohibited by or invalid under applicable Law, such provision will be ineffective only to the extent of such prohibition or invalidity, without invalidating the remainder of this Agreement (or of such provision). The Parties shall make a good faith effort to replace the invalid or unenforceable provision with a valid one which in its economic effect is most consistent with the invalid or unenforceable provision.
- 11.11 **Third Party Beneficiaries**. Except for the rights of Indemnified Parties pursuant to Article IX hereof, the terms and provisions of this Agreement are intended solely for the benefit of each Party hereto and their respective successors or permitted assigns and it is not the intention of the Parties to confer third-party beneficiary rights upon any other person, including without limitation Sublicensees. The enforcement of any obligation of Licensor under this Agreement shall only be pursued by Omthera or such Indemnified Party, and not Sublicensees.
- 11.12 **No Implied License.** No right or license is granted to Omthera hereunder by implication, estoppel, or otherwise to any know-how, patent or other intellectual property right owned or controlled by Licensor or its Affiliates, except by an express license granted hereunder. No right or license is granted to Licensor hereunder by implication, estoppel, or otherwise to any know-how, patent or other intellectual property right owned or controlled by Omthera or its Affiliates, except by an express license granted hereunder.
- 11.13 **No Right of Set-Off.** Notwithstanding anything to the contrary in this Agreement, Omthera shall not have a right to set-off any royalties, milestones or other amount due to Licensor under this Agreement against any damages incurred by Omthera for a breach by Licensor of this Agreement.

- 11.14 **Equitable Relief**. Each Party recognizes that the covenants and agreements herein and their continued performance as set forth in this Agreement are necessary and critical to protect the legitimate interests of the other Party, that the other Party would not have entered into this Agreement in the absence of such covenants and agreements and the assurance of continued performance as set forth in this Agreement, and that a Party's breach or threatened breach of such covenants and agreements will cause the opposed Party irreparable harm and significant injury, the amount of which will be extremely difficult to estimate and ascertain, thus making any remedy at law or in damages inadequate. Therefore, each Party agrees that an opposed Party shall be entitled to specific performance, an order restraining any breach or threatened breach of Article VII and all other provisions of this Agreement, and any other equitable relief (including but not limited to temporary, preliminary and/or permanent injunctive relief), without the necessity of posting of any bond or security. This right shall be in addition to and not exclusive of any other remedy available to such other Party at law or in equity.
- 11.15 **Interpretation.** The language used in this Agreement is the language chosen by the Parties to express their mutual intent, and no provision of this Agreement shall be interpreted for or against a Party because that Party or its attorney drafted the provision.
- 11.16 **Construction.** The words "include," "includes" and "including" shall be deemed to be followed by the phrase "without limitation." All references herein to Articles, Sections and Schedules shall be deemed references to Articles and Sections of, and Schedules to, this Agreement unless the context shall otherwise require.
- 11.17 **Counterparts.** This Agreement may be executed in counterparts, each of which will be deemed an original, and all of which together will be deemed to be one and the same instrument. A facsimile or a portable document format (PDF) copy of this Agreement, including the signature pages, will be deemed an original.

IN WITNESS WHEREOF, the Parties have caused this Research and License Agreement to be executed and delivered by their respective duly authorized officers as of the day and year first above written.

OMTHERA PHARMACEUTICALS, INC.

By: /s/ Michael H. Davidson, MD	
Name: _Michael H. Davidson, MD	
Title:EVP & Chief Medical Officer	

LIGAND PHARMACEUTICALS INCORPORATED

By: <u>/s/ Charles Berkman</u>
Name: Charles Berkman
Title: _VP, General Counsel & Secretary_

Schedule 1

Licensor Patent Rights

Matter Code	App Serial No.	Status	Date Filed	Title
[LIGAND.224PR	61/939,615	Pending	February 13, 2014	PRODRUG COMPOUNDS AND USES FOR LIVER- TARGETING
LIGAND.228PR	61/988,118	Pending	May 2, 2014	PRODRUG COMPOUNDS AND USES THEREOF
LIGAND.224PR2	61/988,101	Pending	May 2, 2014	PRODRUG COMPOUNDS AND THEIR USES THEREOF]

Schedule 2

Development Program

[Research Goal:

Stage I: Achieve proof of concept of liver-selective delivery of a natural omega-3 fatty acid (EPA or DHA or both) via Licensor Liver Targeting Prodrug Technology prodrugs in a normal rat pharmacokinetic model and proof of concept of improved activity of Licensor Liver Targeting Prodrug Technology prodrug(s) relative to an applicable standard in a known rodent model

Stage II: Lead optimization of the Licensor Liver Targeting Prodrug Technology prodrugs to deliver a clinical candidate compound(s) (development strategy to be determined as a single omega-3 prodrug compound or a mixture containing more than one natural omega-3 fatty acid sharing a same prodrug moiety)

For the avoidance of doubt, the Development program shall not involve the use of any drug conjugated to an Agent, absent prior written approval from Omthera.

Stage I Detailed Research Plan and Budget Estimation:

- 1. Contract with WuXi AppTec in China for 8-10 chemistry FTEs on a quarterly basis with estimated budget of \$200,000 per quarter (\$80,000 a year per FTE plus special reagent cost):
- a. Prepare novel Licensor Liver Targeting Prodrug Technology prodrugs (30-50 mg each for screening in a rat pharmacokinetic model to identify orally available prodrug compounds);
- b. Scale-up of prodrugs that demonstrated oral bioavailability in the rat pk screening study for further pharmacokinetic and pharmacodynamic evaluations (200-300 mg each for rat tissue distribution study, and >1 gram quantities for efficacy study);
- c. Design and prepare additional novel Liver Targeting Prodrug Technology prodrugs based on rodent study results (repeating analog synthesis and animal testing cycle at least three times).
- 2. Evaluate oral pharmacokinetic profile of the novel prodrugs in rats at WuXi AppTec in China with estimated budget of \$300,000 per quarter:
- a. Screening rat pharmacokinetic studies (5 studies per quarter at \$20,000 per study) (standard pk study to determine oral bioavailability of prodrug/active by measuring systemic levels of the prodrug and the active free acid at two time points after single oral administration);
- b. Tissue distribution studies to characterize liver-targeting efficiency (3 studies per quarter at \$30,000 per study). The study is designed to determine hepatic uptake rate of the prodrugs by measuring and comparing portal vein and jugular vein AUCs of the prodrug and the active, and/or relative tissue distribution of the active in the liver, intestine, and other tissues of interest (see Ligand liver-targeting HCV polymerase inhibitor posters for reference).
 - 3. Establish efficacy in an animal model:
- a. Establish/transfer/validate a known rodent efficacy model in first quarter using the omega-3 acid mixture in Epanova as the standard and run one study per quarter subsequent to model validation (~\$100,000 per quarter) to evaluate the novel prodrugs against a suitable standard; the efficacy model, referenced standard, and contract research organization (CRO) will be determined by the Joint Scientific Committee.

Stage I Timeline 6-12 months with estimated budget of \$500,000 per quarter

Stage II Research Plan:

- 1. Prepare new Licensor Liver Targeting Prodrug Technology prodrugs to optimize potential human oral bioavailability of the compounds;
- 2. Profile advanced compound or mixture of compounds for liver-targeting efficiency and safety (2-3 types of prodrug compounds);

3. Development of a practical scale-up synthetic route of a candidate compound or a mixture of candidate compounds.

Collaboration management:

- 1. Omthera oversee the program and budget
- 2. Ligand oversee daily operation of the project
 - 3. Joint Scientific Committee overview progression of the program quarterly]