18-02591-8

Debra Smetana ktMINE 940 West Adams Suite 100 Chicago, IL 60607

2/20/2018

U.S. Securities & Exchange Commission
Office of FOIA and Privacy Act Operations
100 F Street, NE
Mail Stop 2465
Washington, DC 20549-5100

RECEIVED

FEB 20 2018

Office of EOIA Service

Dear Sir or Madam:

Under the Freedom of Information Act (FOIA), please send the confidential portions (i.e. unredacted documents) corresponding to the expiration of the Confidential Treatment Order submitted under Rule 24b-2 of the following company

Exhibit 10.44 to the 12/31/06 10-K, filed by Oscient Pharmaceuticals Corp. on 3/15/2007

We authorize \$0 for search and review fees, as these documents have been previously requested. Please contact me if search will require additional fees beyond the above mentioned. My daytime phone number is (312) 667-0267

Sincerely,

Debra Smetana



UNITED STATES SECURITIES AND EXCHANGE COMMISSION

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

Office of FOIA Services

March 20, 2018

Ms. Debra Smetana ktMine 940 West Adams, Suite 100 Chicago, IL 60607

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

Request No. 18-02591-E

Dear Ms. Smetana:

This letter is in response to your request, dated and received in this Office on February 20, 2018, for Exhibit 10.44 to the Form 10-K, filed by Oscient Pharmaceuticals Corp. on March 15, 2007.

The search for responsive records has resulted in the retrieval of 65 pages of records that may be responsive to your request. They are being provided to you with this letter.

No fees have been assessed for the processing of this request. If you have any questions, please contact me at andersonc@sec.gov or (202) 551-8315. You may also contact me at foiapa@sec.gov or (202) 551-7900. You also have the right to seek assistance from Ray J. McInerney 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,

Clarissa Anderson FOIA Research Specialist

Parissa Anderson

Enclosure

LICENSE, SUPPLY AND MARI

THIS LICENSE, SUPPLY AND MARKETING AGREEMENT (this "Agreement") is made effective as of December 28th, 2006 (the "Effective Date") by and between Oscient Pharmaceuticals Corporation, a Massachusetts corporation with a principal place of business at 1000 Winter Street, Suite 2200, Waltham, Massachusetts ("Oscient"), Menarini International Operation Luxembourg SA, a Luxembourgian company with a place of business at 1, Avenue de La Gare, L-1611 Luxembourg GD ("MIOL") Oscient and MIOL are each hereafter referred to individually as a "Party" and together as the "Parties".

WHEREAS, Oscient is the owner or licensee of certain patent rights, know-how, trademark rights and other intellectual property rights relating to the Compound in MAR 1 6 2007 Territory (each as defined below); and

OFFICE OF THE SECRETARY

WHEREAS, Oscient wishes to grant MIOL rights under such intellectual property rights and appoint MIOL as its exclusive distributor of the Finished Product (as defined below) in the Territory and MIOL wishes to obtain such a license on the terms and subject to the conditions set forth below; and

WHEREAS, the Active Pharmaceutical Ingredient (as defined below) for the Finished Product is manufactured by L.G. Life Sciences Ltd and supplied to Oscient to fulfill Oscient and its sublicensees' requirements for Active Pharmaceutical Ingredient; and

WHEREAS, the Parties desire that Oscient supply MIOL with such Active Pharmaceutical Ingredient under this Agreement on the terms and subject to the conditions set forth below.

NOW THEREFORE, in consideration of the mutual covenants contained herein, and for other good and valuable consideration, the receipt and adequacy of which are hereby acknowledged, the Parties hereby agree as follows:

1. DEFINITIONS AND INTERPRETATION

- 1.1 <u>Definitions</u>. Whenever used in the Agreement with an initial capital letter, the terms defined in this Section 1.1 shall have the meanings specified.
 - (a) "ABS" shall mean acute bacterial sinusitis.
 - (b) "Active Pharmaceutical Ingredient" shall mean the Compound in active bulk form meeting the Specifications.
 - (c) "Actual Weighted Average Price Per Tablet" shall mean, subject to Section 9.2(d)(iii), the product of (i) the quotient equal to (A) the sum of the Gross Sales in Euros for each country in the Territory for the applicable Quarter, divided by (B) the total number of Tablets sold by MIOL and its Affiliates and Sub-Distributors in the Territory in the applicable Quarter (as determined using verifiable, written data from MIOL), multiplied by (ii) 29%, multiplied by (iii) the Calculated Exchange Rate; provided that, Gross Sales and the total number of Tablets sold by MIOL and its Affiliates and Sub-Distributors in the Territory for the first whole Quarter after the First Commercial Sale shall

include Gross Sales and Tablets sold by MIOL and its Affiliates and Sub-Distributor in the prior partial Quarter, if any.

- (d) "Additional Products" shall mean any pharmaceutical product that (i) is not the Finished Product, and (ii) is a formulation of a product containing the Compound as an active ingredient except any single enantiomer-based product containing gemifloxacin as an active ingredient.
- (e) "<u>Adverse Event</u>" shall have the meaning as set forth in the Pharmacovigilance Joint Operating Policy to be agreed between the Parties pursuant to Section 8.3.
- (f) "AECB" shall mean acute bacterial exacerbations of chronic bronchitis.
- (g) "Affiliate" shall mean in respect of any Party any corporation, firm, limited liability company, partnership or other entity which controls or is controlled by or is under common control with such Party. For the purpose of this definition only, "control" means direct or indirect beneficial ownership of fifty percent (50%) or more of the shares of stock entitled to vote for the election of directors, in the case of a corporation, or fifty percent (50%) or more of the equity interests in the case of any other type of legal entity, status as a general partner in any partnership, or any other arrangement whereby a party controls or has the right to control the Board of Directors or equivalent governing body of a corporation or other entity.
- (h) "Annual Exchange Rate" shall mean the quotient determined by dividing (i) the sum of the conversion rate for Euros to U.S. Dollars existing in the United States (as reported in *The Wall Street Journal*) on each Business Day in the twelve-month period preceding the date upon which the Annual Exchange Rate is to be calculated, by (ii) the number of Business Days in such twelve-month period. If *The Wall Street Journal* ceases to be published, then the rate of exchange to be used shall be that reported in such other business publication of national circulation in the United States as the Parties reasonably agree.
- (i) "Annual Calculated Exchange Rate" shall be equal to (i) if the Annual Exchange Rate is greater than 95% of the Base-Exchange Rate and less than 105% of the Base-Exchange Rate, the Annual Exchange Rate, or (ii) if the Annual Exchange Rate is less than 95% of the Base-Exchange Rate or greater 105% of the Base-Exchange Rate, the number equal to:

<u>Base-Exchange Rate – Annual Exchange Rate</u> + Annual Exchange Rate

(j) "Applicable Law" shall mean all applicable laws, rules and regulations, including any rules, regulations, guidelines or other requirements of any Regulatory Authority and industry guidelines or codes of conduct, that may be in effect from time to time, including relevant provisions of Directive 2001/83/EC, Regulation (EC) 726/2004, relevant national, International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use ("ICH"), European Commission and

Committee for Medicinal Products for Human Use ("CHMP") guidance and, in particular, those guidelines published by the European Commission in the Rules Governing Medicinal Products in the European Union, as updated and amended from time to time and, in each case where relevant, the national implementations of these rules.

- (i) the weighted Average Price Per Tablet" shall mean the product of (i) the weighted average reimbursed ex-factory per tablet price in Euros (as determined or accepted by the applicable Regulatory Authority (as set forth in Section 9.5(b) herein) at the time of calculation) for branded moxifloxacin in each Major Country in the Territory where moxifloxacin has been granted a marketing authorization and reimbursed for at least four Quarters, as determined within thirty (30) days of the date of the first calculation of the Transfer Price, multiplied by (ii) 29%, multiplied by (iii) the Calculated Exchange Rate; provided that, (A) on and after the second anniversary of the First Commercial Sale, the Assumed Weighted Average Price Per Tablet shall be equal to the last Actual Weighted Average Price Per Tablet calculated pursuant to Section 9.2(c) below, and (B) in no event shall the Assumed Weighted Average Price Per Tablet.
- (1) "Base-Exchange Rate" shall be the currency factor for conversion of Euros to Dollars equal to 1.27.
- (m) "Business Day" shall mean any day other than a Saturday or Sunday on which banking institutions in both Massachusetts, United States of America and Grand Duchy of Luxemburg are open for business.
- (n) "Calculated Exchange Rate" shall be equal to (i) if the Quarterly Exchange Rate is greater than 95% of the Base-Exchange Rate and less than 105% of the Base-Exchange Rate, the Quarterly Exchange Rate, or (ii) if the Quarterly Exchange Rate is less than 95% of the Base-Exchange Rate or greater 105% of the Base-Exchange Rate, the number equal to:

Base-Exchange Rate — Quarterly Exchange Rate + Quarterly Exchange Rate 2

- (o) "<u>Call</u>" shall mean a personal visit by a Sales Representative to a member of the Target Audience in the Territory.
- (p) "CAP" shall mean community-acquired pneumonia of mild-to-moderate severity.
- (q) "<u>Centralized Procedure</u>" shall mean the centralized procedure for obtaining a Marketing Authorization in the European Union as set forth in Regulation (EC) 726/2004.
- (r) "Commercialize" and "Commercialization" shall mean (i) all activities relating to the marketing, promotion, handling, distribution, storage, sale, shipping, offer for sale and importation for sale of the Finished Product in the Territory and (ii) all activities relating to the handling, storage, shipping and importation of the Active Pharmaceutical Ingredient for the Finished Product.

- (s) "Compound" shall mean the form of gemifloxacin mesylate having the molecular formula (R,S)-7-[(4Z)-3-(aminomethyl)-4-(methoxyimino)-1-pyrrolidinyl]-1-cyclopropyl-6-fluoro-1,4-dihydro-4-oxo-1,8-naphthyridine-3-carboxylic acid methanesulfonate sesquihydrate.
- (t) "Confidential Information" shall mean with respect to a Party (the "Receiving Party"), all information and materials (including compositions of matter, assays and biological materials (if any)) which are disclosed by another Party (the "Disclosing Party") to the Receiving Party hereunder or to any of its employees, consultants, Affiliates, licensees or, in the case of MIOL, Third-Party Manufacturers or Sub-Distributors, except to the extent that the Receiving Party can demonstrate by written record or other suitable physical evidence that such information, (i) as of the date of disclosure is demonstrably known to the Receiving Party or its Affiliates other than by virtue of a prior confidential disclosure to the Receiving Party or its Affiliates by the Disclosing Party; (ii) as of the date of disclosure is in, or subsequently enters, the public domain, through no fault or omission of the Receiving Party; (iii) is obtained from a Third Party having a lawful right to make such disclosure free from any obligation of confidentiality to the Disclosing Party; or (iv) is independently developed by or for the Receiving Party without reference to or reliance upon any Confidential Information of the Disclosing Party.
- (u) "Controlled" shall mean, with respect to any Patent Rights, know how, Regulatory Documentation, Trademarks, the MIOL Information, the Oscient Information or other intellectual property right, possession of the right, whether directly or indirectly, and whether by ownership, license or otherwise (other than pursuant to this Agreement), to grant access to such information or Regulatory Documentation or to assign, or grant a license, sublicense or other right to or under, such Patent Rights, information, Regulatory Documentation, Trademarks or other intellectual property right as provided for herein, without violating the terms of any agreement, or other arrangement, with any Third Party.
- (v) "Copyrights" shall mean all copyright works including literary and artistic works
- (w) "Detail" or "Detailing" shall mean the communication by a Sales Representative during a Call (i) involving face-to-face contact; (ii) describing in a fair and balanced manner the approved indicated uses and other relevant characteristics of the Finished Product; (iii) using marketing, promotional and educational materials in an effort to increase the Target Audience prescribing and/or hospital ordering preferences of the Finished Product for its approved indicated uses; and (iv) made at the Target Audience member's office, in a hospital, at marketing meetings sponsored by MIOL or a Sub-Distributor for the Finished Product or other appropriate venues conducive to pharmaceutical product informational communication where the principal objective is to place an emphasis, either primary, secondary or tertiary, on the Finished Product and not simply to discuss the Finished Product with a member of the Target Audience.

- (x) "Develop" and "Development" shall mean all activities relating to obtaining advice on, seeking, obtaining and/or maintaining Regulatory Approvals and public and private formulary listings, including clinical studies and trials (subject to Section 6.3 herein), regulatory affairs, statistical analysis and report writing and the preparation, submission, review and development of data related thereto and all other pre-approval activities, but excluding (i) activities relating to synthesis, manufacture or otherwise making or having made any Active Pharmaceutical Ingredient, or any component or formulation thereof; or (ii) non-clinical research and drug development activities of the Finished Product.
- (y) "<u>Development Plan</u>" shall mean the plan for the Development of the Finished Product in the Territory developed and agreed to by the Steering Committee on an annual basis.
- (z) "Diligent Efforts" shall mean using commercially reasonable efforts and resources, consistent with prudent business judgment, including the carrying out of obligations or tasks consistent with the standard of practice in the research-based pharmaceutical industry for the commercialization of a pharmaceutical product having similar market potential, profit potential or strategic value as the Finished Product, based on conditions then prevailing, including the maturity of the Finished Product and the intellectual property protection surrounding the Finished Product. Diligent Efforts requires that MIOL, at a minimum, provided that such actions are commercially reasonable: (i) determine the general industry practices with respect to the applicable activities; (ii) reasonably promptly assign responsibility for such obligations to specific employee(s) who are held accountable for progress, and monitor such progress on an on-going basis; (iii) set and consistently seek to achieve specific and meaningful objectives for carrying out such obligations; and (iv) make and implement decisions and allocate resources designed to advance progress with respect to such objectives; provided that, MIOL will not be found not to have met its Diligent Effort obligations hereunder to the extent such failure has been caused by Oscient's failure to perform its obligations under this Agreement.
- (aa) "EMEA" shall mean the European Medicines Agency and any successor agency thereto.
- (bb) "Exploit" shall mean to Develop, Manufacture or Commercialize and "Exploitation" means the act of Exploiting.
- (cc) "Finished Product" shall mean the pharmaceutical product containing the Compound in finished tablet form labeled and packaged in accordance with Applicable Law in the Territory, including the package inserts and other components reasonably necessary for its sale or distribution in the Territory, and ready for sale to the market or distribution as professional samples in the Territory, but specifically excluding any single enantiomer-based product or non-oral formulations.
- (dd) "First Commercial Sale" shall mean the date of the first arm's length sale of Finished Product in a country in the Territory after Regulatory Approval for

- the Finished Product has been obtained in such country by or on behalf of MIOL, other than sales by MIOL to Sub-Distributor.
- (ee) "Gross Sales" shall mean gross invoiced sales of the Finished Product sold by MIOL, its Affiliates or a Sub-Distributor to Third Parties throughout the Territory minus any Government Payments (calculated on a Per Tablet basis) for the applicable period.
- (ff) "Government Payment" shall mean any mandatory rebate imposed by, or any sum to be paid to, any national, supra-national, regional, state or local regulatory agency, department, bureau, commission, council or other governmental entity with respect to, in whole or in part, the Finished Product to the extent identified on the relevant invoice or through other written, verifiable evidence.
- (gg) "Good Manufacturing Practices" or "GMP" shall mean the then current standards for good manufacturing practices in the Territory as promulgated under Applicable Law, including Directive 2001/83/EC, Directive 2003/94/EC and any applicable guidance on good manufacturing practices adopted pursuant to Section 47 of Directive 2001/83/EC, in particular relevant guidance on good manufacturing practices contained in Volume 4 of the Rules Governing Medicinal Products in the European Union and the national implementations of these rules.
- (hh) "ICH Q7A" shall mean the good manufacturing practice guidance for active pharmaceutical ingredients developed under the auspices of the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use.
- (ii) "LG" shall mean L.G. Life Sciences Ltd or its successors or assigns.
- (jj) "LG License" shall mean the License and Option Agreement between Oscient (formerly Genesoft Pharmaceuticals, Inc.) and LG dated October 22, 2002, as amended from time to time.
- (kk) "<u>Licensed Patent Rights</u>" shall mean the Patent Rights set forth in <u>Schedule</u> 1.1(kk) attached hereto.
- (ll) "Major Countries" shall mean each of France, Germany, Italy, Spain and the United Kingdom.
- (mm) "Mandatory Supply Term" shall mean the period commencing on the First Commercial Sale and continuing, until the later of (i) the expiration of the last to expire of the Patent Rights granted in the Territory set forth in Schedule 1.1(mm), or (ii) the expiration of the period of data and market exclusivity for the Finished Product in the Territory provided for by Directive 2001/83/EC.
- (nn) "Manufacture" shall mean the activities related to the fill-finish manufacturing of Finished Product in accordance with the written specifications delivered to MIOL by Oscient, including the conversion of Active Pharmaceutical Ingredient into Finished Product, manufacturing of

supplies of Finished Product for commercial sale, packaging, labeling, inprocess and finished product testing, release of product or any component or ingredient thereof, quality assurance activities related to manufacturing and release of product, ongoing stability tests and regulatory activities related to any of the foregoing; but excluding activities relating to synthesis, manufacture or otherwise making or having made any Active Pharmaceutical Ingredient, or any component or formulation thereof.

- (00) "Marketing Authorization" shall mean an authorization issued by the relevant Regulatory Authority to market Finished Product in the Territory or in a country in the Territory as the case may be.
- (pp) "MIOL Information" shall mean all information, know-how, materials, data, documents and plans relating to the Active Pharmaceutical Ingredient and/or Finished Product, excluding Oscient Information, but including Regulatory Documentation and data resulting from clinical trials, Controlled by MIOL and/or its Third-Party Manufacturer and/or Sub-Distributors from time to time during the Term.
- (qq) "Minimum Labeling Requirements" shall mean the approved label for Finished Product in a particular country in the Territory which contains (i) Regulatory Approval for CAP and either ABS or AECB; and (ii) is otherwise substantially consistent with the minimum criteria set forth on Schedule 1.1(qq).
- (rr) "Net Sales" shall mean the gross invoiced sales price for all Finished Products sold by MIOL, its Affiliates or a Sub-Distributor to Third Parties throughout the Territory during each Quarter, less the following amounts incurred or paid by MIOL or Sub-Distributor during such Quarter with respect to sales of Finished Products regardless of the Quarter in which such sales were made:
 - (i) trade, cash and quantity discounts or rebates actually allowed or taken, where permitted by law;
 - (ii) credits or allowances actually given or made for rejection of, and for uncollectible amounts on, or return of previously sold Finished Products;
 - (iii) reasonable transportation and insurance charges directly related to the sale of the Finished Products to a Third Party in the Territory, each to the extent separately invoiced and paid by MIOL; and
 - (iv) any tax, tariff, duty, Government Payment and governmental charge levied on the sales, transfer, transportation or delivery of the Finished Products to a Third Party, other than franchise or income tax of any kind whatsoever.

Provided that, any amount deducted from gross invoiced sales in item "(iv)" above which is later paid back to MIOL shall be deemed to be Net Sales upon receipt by MIOL.

Deductions due to (i), (ii) and (iii) above shall not exceed a total of one and one-half percent (1.5%) of the gross invoiced sales. "Net Sales" shall not include sales or transfers of Finished Products between MIOL and its Affiliates or Sub-Distributors, unless the Finished Product is consumed by such Affiliate or Sub-Distributor. For the purpose of this definition and the definition of Gross Sales, Finished Product shall be deemed to have been sold by MIOL or a Sub-Distributor at the earliest of (A) such Finished Product being shipped to the Third Party purchaser by MIOL or a Sub-Distributor as the case may be, (B) such Third Party being invoiced by MIOL or a Sub-Distributor, or (C) such Finished Product being paid for, by or on behalf of MIOL's or Sub-Distributor's customer.

- (ss) "Oscient Information" shall mean all information and know-how relating to the Oscient Product Controlled by Oscient that is necessary or reasonably required by MIOL to enable MIOL to obtain advice on, apply for or maintain Regulatory Approvals in accordance with this Agreement, including information relating to toxicology, pharmacology, pharmacokinetics, metabolism, general chemistry and pharmacy of the Oscient Product and any information provided to MIOL pursuant to Section 6.3(a); provided that Oscient Information shall not include any information relating to the bulk chemical manufacture or the formulation of the Compound or Active Pharmaceutical Ingredient, other than information that is included in the Applicant's Part of the Active Substance Master File submitted to EMEA or any other relevant Regulatory Authority.
- (tt) "Oscient Intellectual Property" shall mean the Licensed Patent Rights, Trademarks and any Copyrights or other intellectual property rights in the Oscient Information.
- (uu) "Oscient Product" shall mean gemifloxacin mesylate 320 mg tablets for oral administration sold in the United States of America under the trade name Factive ® Tablets.
- (vv) "Patent Rights" shall mean any and all (i) patents, (ii) pending patent applications, including all provisional applications, continuations, continuations-in-part, divisions, reissues, renewals, and all patents granted on such pending patent applications, (iii) all patents-of-addition, reissue patents, re-examinations and extensions or restorations by existing or future extension or restoration mechanisms, supplementary protection certificates or the equivalent thereof, and (iv) any equivalent of any of the foregoing in any jurisdiction.
- (ww) "Person" shall mean any individual, firm, corporation, partnership, limited liability company, trust, joint venture, governmental entity, or other entity or organization.
- (xx) "Printed Materials" shall mean product labels, printed packaging materials or packaging inserts relating to the Finished Product.

- (yy) "Quarter" shall mean each successive period of three (3) months commencing January 1, April 1, June 1 or September 1 and "Quarterly" shall have a corresponding meaning.
- (zz) "Quarterly Exchange Rate" shall mean the quotient determined by dividing (i) the sum of the conversion rate for Euros to U.S. Dollars existing in the United States (as reported in *The Wall Street Journal*) on the first Business Day and the last Business Day of the applicable Quarter immediately preceding the date upon which the Assumed Weighted Average Price Per Tablet or Actual Weighted Average Price Per Tablet, as the case may be, is to be calculated, by (ii) two. If *The Wall Street Journal* ceases to be published, then the rate of exchange to be used shall be that reported in such other business publication of national circulation in the United States as the Parties reasonably agree.
- (aaa) "Regulatory Approval" shall mean any and all approvals (including any applicable supplements, amendments, variations, pre- and post-approvals, governmental price and reimbursement approvals and approvals of applications for regulatory exclusivity), product and establishment licenses, registrations or authorizations of any kind of any Regulatory Authority necessary for the Exploitation of the Finished Product in the Territory, including, for the avoidance of doubt, all registrations, licenses and authorizations required to permit the Active Pharmaceutical Ingredient of the Finished Product to be imported into the Territory.
- (bbb) "<u>Regulatory Authority</u>" shall mean the EMEA or any other national, supranational, regional, state or local regulatory agency, department, bureau, commission, council or other governmental entity with authority with respect to the Development, Manufacture or Commercialization of the Finished Product in the Territory.
- (ccc) "Regulatory Documentation" shall mean all applications, registrations, governmental licenses, authorizations and approvals (including all Regulatory Approvals), all correspondence submitted to or received from Regulatory Authorities and all supporting documents and all results of pre-clinical and clinical studies and tests, relating to the Finished Product, and all data contained in any of the foregoing.
- (ddd) "Reimbursement Price" shall mean, for each country within the Territory, the price per Tablet, expressed in Euros, at which the Finished Product is or will be reimbursed, in whole or in part, by the national health system or any broadly equivalent scheme in that country at the time of calculation.
- (eee) "Sales Representative" shall mean a professional pharmaceutical sales representative engaged or employed by MIOL or any of its Affiliates or Sub-Distributors to conduct, among other sales responsibilities, Detailing and other promotional efforts with respect to the Finished Product.
- (fff) "Serious Adverse Event" shall have the meaning as set forth in the Pharmacovigilance Joint Operating Policy to be agreed between the Parties pursuant to Section 8.3.

- (ggg) "Specifications" shall mean, for the Active Pharmaceutical Ingredient for the Finished Product, such specifications as set forth in Schedule 1.1(ggg), as such specifications may be supplemented or modified from time to time hereafter in accordance with the provisions of this Agreement or as provided by Regulatory Authorities.
- (hhh) "<u>Sub-Distributor</u>" shall mean any Affiliate or Third Party (as hereinafter defined) to whom MIOL has granted the right to promote and distribute the Finished Product in the Territory (or part of it) in accordance with the terms of this Agreement.
- (iii) "Tablet" shall mean one 320mg tablet of Finished Product.
- (jjj) "Target Audience" shall mean, for the Finished Product, general practitioners and specialists involved in the treatment of upper and lower respiratory infections who prescribe pharmaceutical products or issue hospital orders for pharmaceutical products in the Territory as identified in the applicable Marketing Plan, as may be amended from time to time by the Steering Committee.
- (kkk) "Territory" shall mean France, Germany, the United Kingdom, Luxembourg, Ireland, Italy, Spain, Portugal, Belgium, the Netherlands, Austria, Greece, Sweden, Denmark, Finland, Norway, Iceland, Switzerland, Andorra, Monaco, San Marino, Vatican City, Cyprus, Czech Republic, Estonia, Hungary, Latvia, Lithuania, Malta, Poland, Slovakia, Slovenia, Bulgaria, Romania, Croatia, Macedonia and Liechtenstein.
- (lll) "Third Party" shall mean any Person other than Oscient or MIOL or their respective Affiliates.
- (mmm)"<u>Transfer Price Per Kilo</u>" shall mean the product of: (i) the Assumed Weighted Average Price Per Tablet, *multiplied by* (ii) 2,230.
- (nnn) "<u>Trademarks</u>" shall mean the trademarks described in <u>Schedule 1.1(nnn</u>) attached hereto as may be amended from time to time in accordance with this Agreement.

1.2 Interpretation.

In this Agreement a reference to:

- (i) a particular Article, Section, Schedule or Exhibit shall be a reference to that article, section, schedule or exhibit in or to this Agreement;
- (ii) the singular shall include the plural and vice versa and a reference to any gender shall include all genders;
- (iii) a statutory provision includes a reference to the statutory provision as modified or re-enacted or both from time to time before or after the date of this Agreement and any subordinate legislation made under the statutory provision (as so modified or re-enacted) before or after the date of this Agreement;

- (iv) a document (or section thereof) is a reference to that document as modified, amended, restated or replaced from time to time;
- (v) a "month" is a reference to a calendar month;
- (vi) "herein", "hereof", "hereunder", "hereafter", and words of similar import refer to this Agreement as a whole and not to any particular Article or Section hereof;
- (vii) money herein or "\$" are references to United States Dollars unless otherwise specifically noted; and
- (viii) "include", "includes", "including" and "in particular" are to be construed as if they were immediately followed by the words "without limitation".
- 1.3 If any payment is required to be made or other action required to be taken pursuant to this Agreement, except for any action required to be taken pursuant to Section 8.3, on a day which is not a Business Day, then such payment or action shall be made or taken on the next Business Day.
- 1.4 In calculating interest payable under this Agreement for any period of time, the first day of such period shall be included and the last day of such period shall be excluded.
- 1.5 The table of contents hereto and the headings of any Article, Section or part thereof are inserted for purposes of convenience only and do not form part of this Agreement.

2. LICENSE RIGHTS

- 2.1 <u>Appointment and License</u>. Subject to the terms and conditions of this Agreement, Oscient hereby appoints MIOL as its exclusive distributor of the Finished Product in the Territory and in connection with such appointment hereby grants to MIOL subject to Section 2.2:
- (a) the exclusive sublicense and right under the Licensed Patent Rights to import into the Territory Active Pharmaceutical Ingredient supplied by Oscient in accordance with Articles 3 and 4 ("Oscient API");
- (b) the exclusive, subject as set out below, sublicense and right under the Licensed Patent Rights to Exploit Finished Product, in which the only Active Pharmaceutical Ingredient is Oscient API, under the Trademark throughout the Territory;
- (c) subject to Section 6.3, the exclusive right to use the Oscient Information to Exploit the Finished Product, in which the only Active Pharmaceutical Ingredient is Oscient API, under the Trademark throughout the Territory; and
- (d) the exclusive right to use the Trademarks solely in connection with the Exploitation of Finished Product in which the only Active Pharmaceutical Ingredient is Oscient API in the Territory.
- 2.2 <u>Right to Appoint Third-Party Manufacturer/Sub-Distributor</u>. MIOL may appoint (A) Sub-Distributors and/or (B) Third Parties to Manufacture Finished Product pursuant to Section 3.4 herein (each a "Third-Party Manufacturer"); <u>provided</u>, <u>however</u>, that (i) Oscient shall be notified of and shall have consented to such appointment, such consent

not to be unreasonably withheld; provided however, that, Oscient confirms its consent to the appointment of any Affiliates of MIOL as a Sub-Distributor or Third-Party Manufacturer; (ii) the terms of the agreement with any Sub-Distributor or Third-Party Manufacturer shall be consistent with the terms and conditions of this Agreement; (iii) a Sub-Distributor shall have no right to Develop or Manufacture or further appoint a sub-distributor, nor to assign or delegate all or any part of its rights; (iv) a Third-Party Manufacturer shall have no right to Develop or further sub-contract its obligations to Manufacture and shall sell all Finished Products manufactured by it to MIOL or MIOL's Affiliates; (v) such appointment shall not relieve MIOL of any of its obligations under this Agreement and in particular MIOL shall remain obligated for the payment to Oscient of all of its payment obligations hereunder, including the payment of any fees described in Article 9 hereof; (vi) to the maximum extent permitted by Applicable Law, each Sub-Distributor shall be required to purchase all its requirements of Finished Product from MIOL; and (vii) except as Oscient may in its discretion agree in writing, any agreement with any Sub-Distributor or Third-Party Manufacturer shall terminate upon termination of this Agreement.

- **Retained Rights**. Subject to the other terms of this Agreement, Oscient retains the right (a) to use and exploit the Trademarks and the Oscient Information for (i) uses in the Territory relating to governmental obligations or requirements and investor promotions (i.e., Oscient exhibit booths or magazine publications discussing Oscient's business); and (ii) any and all uses outside of the Territory and (b) to conduct clinical trials for Oscient Product in the Territory and fill-finish Oscient Product in the Territory for sale outside the Territory. All rights not expressly granted under this Agreement to MIOL are reserved to Oscient. For the avoidance of doubt, MIOL is not granted any rights to use Oscient Information to seek any approval from EMEA or any other regulatory authority to market or otherwise exploit any product other than Finished Product in which the only Active Pharmaceutical Ingredient is Oscient API.
- Modification of Product. Oscient reserves the right to modify, change, develop or improve the Active Pharmaceutical Ingredient, including changes in the manufacturing process or the site at which such manufacture is to occur, (an "Alteration") during the Term and shall give prior notice to MIOL of any Alteration which could give rise to notification requirements to Regulatory Authorities or the need for any Regulatory Approval under Applicable Law; provided that any material change to the Specifications shall require MIOL's consent, not to be unreasonably withheld. Any reasonable and verifiable costs associated with any such Alteration shall be borne by Oscient. It is however understood that if an Alteration requires a Regulatory Approval no Active Pharmaceutical Ingredient manufactured after implementation of such Alteration shall be supplied pursuant to this Agreement before the Regulatory Approval is granted. The Parties agree to pursue diligently any such Regulatory Approvals following notice of any proposed Alteration from Oscient. Oscient agrees that it shall not cause an Alteration to be made after MIOL submits an application for Marketing Authorization and prior to receipt of such Market Authorization.
- 2.5 Grant of Rights to Oscient. MIOL shall, and shall procure that each Third-Party Manufacturer and Sub-Distributor shall, during the Term, promptly make available to Oscient all MIOL Information and MIOL hereby grants to Oscient a non-exclusive, perpetual, fully paid-up, irrevocable, worldwide (not including the Territory during the Term) license to use the MIOL Information with the right to grant sublicenses. In connection with such use, Oscient may disclose MIOL Information to any Regulatory Authority or equivalent regulatory authority outside the Territory.

3. SUPPLY OF PRODUCT

Supply Terms. Until expiration of the Mandatory Supply Term, Oscient shall supply to MIOL, and MIOL will exclusively purchase from Oscient, all of MIOL's requirements for Active Pharmaceutical Ingredient for use in Manufacturing Finished Product in the Territory pursuant to purchase orders delivered from time to time by MIOL to Oscient in accordance with Section 4.2. During the Mandatory Supply Term, neither Oscient nor any of its Affiliates shall have the right to manufacture or supply any Active Pharmaceutical Ingredient for or to any Third Party in the Territory (except to a Third Party appointed to manufacture Oscient Product for sale outside the Territory as permitted by Section 2.2). Notwithstanding any other provision of this Agreement to the contrary, Oscient will not be liable to MIOL with regard to Finished Product or Active Pharmaceutical Ingredient sold into the Territory by, or otherwise originating from, customers of Oscient located outside of the Territory, nor will such sales constitute a breach by Oscient of this Agreement. Unless otherwise specified herein or expressly consented to in writing by MIOL and Oscient, MIOL shall have no direct relationship with LG regarding all activities necessary to supply MIOL with Active Pharmaceutical Ingredient manufactured by or on behalf of LG as contemplated hereunder. The relationship with LG shall be maintained by Oscient acting according to reasonable standard industry practice. All manufacturers of Active Pharmaceutical Ingredient supplied to MIOL pursuant to this Agreement shall manufacture Active Pharmaceutical Ingredient for supply pursuant to this Agreement in compliance with GMP. Unless provided otherwise and only as and if permitted herein, a Party's sublicensing, subcontracting or delegating activities to be performed under this Agreement to an Affiliate or Third Party shall not release such Party from the performance of any of its responsibilities hereunder.

After the expiry of the Mandatory Supply Term, MIOL shall have the right to source Active Pharmaceutical Ingredient, the Compound and the Finished Product from any Third Party and to continue using the Trademarks and the Regulatory Approvals subject to the payment obligations set forth in Section 9.4.

- 3.2 <u>Initial Supply of Finished Product</u>. Oscient agrees to discuss with MIOL its ability to supply MIOL with Finished Product instead of Active Pharmaceutical Ingredient until the transfer of technology pursuant to Section 3.4 is completed. Any such supply shall be on the terms of a supply agreement to be agreed to by the Parties.
- 3.3 <u>Miscellaneous Supply of API by Oscient in the Territory</u>. Notwithstanding anything to the contrary contained herein, Menarini agrees to allow Oscient to supply certain amounts of Active Pharmaceutical Ingredient to Third Parties in the Territory solely for academic, non-commercial purposes.
- 3.4 MIOL Manufacturing and Packaging. MIOL shall Manufacture (or have Manufactured on its behalf (subject to Section 2.2 above)) Finished Product for distribution in the Territory in accordance with Applicable Law and the specifications provided by Oscient. If requested by Oscient, MIOL shall provide Oscient with all artwork, copy or other material developed or produced by MIOL or any Sub-Distributor for such Printed Materials. All use of Trademarks shall be in accordance with Sections 7.6 and 11.8 and unless otherwise specified by Oscient, the Finished Product shall indicate that the Trademark is a registered trademark, if applicable. Pursuant to the provisions of Article 6 below, MIOL shall submit for approval proposed labeling (including package inserts and primary packages) for Finished Product to the Regulatory Authority, to the extent approval by the Regulatory Authority is

required, at MIOL's sole cost and expense. Notwithstanding anything to the contrary herein, MIOL is responsible for ensuring all Printed Materials comply with Applicable Law.

- 3.5 Technology Transfer and Support Activities. To the extent not previously disclosed, Oscient shall, without additional compensation, disclose and make available to MIOL the Oscient Information promptly after the Effective Date and thereafter shall reasonably promptly disclose any additional Oscient Information. Reasonably in advance before Menarini starts to Manufacture the Finished Product, Oscient shall provide to MIOL (or its Third Party Manufacturer) for a period not exceeding nine (9) months such assistance as MIOL may reasonably request in connection with the technology transfer of the Oscient Information. Such supporting activities shall include the assistance to MIOL's technical staff both at Oscient and at the MIOL's production site, transfer of relevant chemical and microbiological analyses and technical documentation including all available stability data forming part of the Oscient Information provided that if MIOL requests Oscient's representatives to visit any MIOL facility, Oscient shall only be required to make up to two (2) appropriate representatives available for up to ten (10) days each and MIOL shall reimburse Oscient for its reasonable and verifiable expenses of travel and accommodations for such representatives.
- 3.6 Quality Agreement. Oscient and MIOL shall negotiate and agree to, within ninety (90) days following the Effective Date, a quality agreement with respect to Oscient's supply of Active Pharmaceutical Ingredient (the "Quality Agreement"), which shall (a) be on terms consistent with those standard in the industry for transactions similar to this Agreement and (b) become effective as of the Effective Date. Each Party agrees to comply with the Quality Agreement. To the extent there are any inconsistencies or conflicts between this Agreement and the Quality Agreement, the terms and conditions of this Agreement shall control unless otherwise agreed to in writing by Oscient and MIOL in the form of an amendment to this Agreement. In the event that the Quality Agreement contains material provisions that differ from Applicable Law, Applicable Law shall control.
- 3.7 <u>Documentation, Monitoring and Recordkeeping.</u> Oscient (or its Third Party licensors), MIOL and all Sub-Distributors and Third-Party Manufacturers shall maintain complete and accurate documentation of all validation data, stability testing data, batch records, quality control and laboratory testing, as applicable, and any other data required under Applicable Law and other requirements of any relevant Regulatory Authority generated in connection with the performance of any manufacturing hereunder. Throughout the Term, and for so long thereafter as is required by Applicable Law, each Party shall monitor and maintain reasonable records respecting its compliance with GMP for Finished Product (in the case of MIOL) and ICH Q7A (in the case of Oscient), including through the establishment and implementation of such operating procedures as are reasonably necessary to assure such compliance.

4. FORECASTING, ORDERING AND SHIPPING

4.1 Rolling Forecasts. Throughout the Term, MIOL shall provide Oscient, by the 15th day of every month of each calendar year, with a rolling forecast ("Forecast") prepared in good faith by MIOL projecting MIOL's requirements of Active Pharmaceutical Ingredient for the twenty-four (24) month period commencing on the first day of the next calendar month (i.e. 1 March, 1 June, 1 September or 1 December, as the case may be), specifically indicating such projected requirements for each month during such twenty-four (24) month

period and forecasted monthly prescription volumes of Tablets for each country in the Territory.

- 4.2 <u>Submission of Purchase Orders</u>. MIOL shall issue a purchase order, in substantially the format attached hereto as Exhibit A, for the Active Pharmaceutical Ingredient to be manufactured and shipped to it on a date (the "Required Delivery Date") not less than one hundred twenty (120) days from the date of such purchase order. The quantities of Active Pharmaceutical Ingredient ordered in each such purchase order shall be firm and binding on MIOL and shall not be subject to reduction by MIOL. All purchase orders shall be sent by MIOL to the attention of the employee of Oscient as may from time to time be designated by Oscient. To the extent the terms of any purchase order or acknowledgment thereof are inconsistent with, or additional to, the terms of this Agreement, such terms are of no force and effect.
- 4.3 Terms of Delivery. Oscient shall execute all accepted purchase orders consistent with this Agreement and use commercially reasonable efforts to deliver Active Pharmaceutical Ingredient to MIOL's designated carrier at Oscient's designated facility (determined in Oscient's reasonable discretion, currently in South Korea), within +/- seven (7) days of the delivery date specified in MIOL's purchase orders in accordance with Section 4.2. MIOL shall be responsible for arranging, at its expense, all shipping, freight and insurance, customs clearance and payment of any customs duties and import fees for its orders of Active Pharmaceutical Ingredient. Title and risk of loss will pass to MIOL when each order of Active Pharmaceutical Ingredient is delivered to MIOL's designated carrier at Oscient's designated facility. If MIOL does not timely indicate in writing its selection of a carrier to Oscient, Oscient shall be entitled to select an appropriate carrier. Oscient shall package each order of Active Pharmaceutical Ingredient for shipment in accordance with customary industry practices therefor, unless otherwise reasonably specified in writing by MIOL.
- 4.4 <u>Accompanying Documentation</u>. With each shipment of Active Pharmaceutical Ingredient, Oscient shall provide MIOL with (i) all appropriate documentation directly related to the Active Pharmaceutical Ingredient necessary to allow MIOL to export the Active Pharmaceutical Ingredient and (ii) with a certificate of analysis and certificate of conformity pursuant to the terms of the Quality Agreement.
- 4.5 <u>Retention of Samples</u> Oscient or its Third Party manufacturer shall properly store and retain appropriate samples of the Active Pharmaceutical Ingredient that it supplies to MIOL in conditions and for times consistent with Applicable Law and to permit appropriate or required internal and regulatory checks and references.

5. INSPECTION AND DEFECTIVE PRODUCTS

5.1 Receipt of Active Pharmaceutical Ingredient by MIOL. MIOL shall be entitled to reject any portion or all of any shipment of Active Pharmaceutical Ingredient that does not conform to the certificate of analysis and certificate of conformity or otherwise fails to comply with the warranties set forth in Section 12.1(e) of this Agreement (unless such nonconformity was attributable to an act or omission of MIOL, Third-Party Manufacturer, Sub-Distributor or the common carrier once the Active Pharmaceutical Ingredient was delivered by Oscient to such common carrier); provided, that MIOL shall notify Oscient within twenty five (25) days after receipt of such shipment if it is rejecting a shipment pursuant to this Section 5.1. If no notice is provided by MIOL within the relevant time

periods, then MIOL shall be deemed to have accepted the shipment. Any notice of rejection by MIOL shall be accompanied by a reasonably detailed statement of its reasons for rejection and a report of any pertinent analysis performed by MIOL on the allegedly nonconforming product, together with the methods and procedures used. Oscient shall notify MIOL as promptly as reasonably possible, but in any event within thirty five (35) days after receipt of such notice of rejection, whether it accepts MIOL's assertions of nonconformity.

- 5.2 Replacement Active Pharmaceutical Ingredient. Whether or not Oscient accepts MIOL's assertion of nonconformity, promptly upon receipt of a notice of rejection, unless otherwise specified by MIOL, Oscient shall use its commercially reasonable efforts to provide replacement Active Pharmaceutical Ingredient for that rejected by MIOL in the original shipment. If the Active Pharmaceutical Ingredient rejected by MIOL from such original shipment ultimately is found to be nonconforming (whether pursuant to Section 5.3 or if Oscient so acknowledges in writing), Oscient shall bear all expenses for such replacement Active Pharmaceutical Ingredient (including all transportation and/or disposal charges and cost of manufacture for such nonconforming Active Pharmaceutical Ingredient) to the extent MIOL previously paid for any corresponding nonconforming Active Pharmaceutical Ingredient. If it is determined subsequently that such Active Pharmaceutical Ingredient was in fact conforming (whether pursuant to Section 5.3 or if MIOL so acknowledges in writing), then MIOL shall be responsible not only for the purchase price of the allegedly nonconforming Active Pharmaceutical Ingredient (including all transportation charges), but also, upon receipt and acceptance by MIOL in accordance with the procedures (and at the same price charged in the original shipment) set forth above, the replacement Active Pharmaceutical Ingredient. Replacement shipments shall also be subject to the procedures contained in Article 4.
- Independent Laboratory Analysis. If Oscient disagrees with any alleged nonconformity timely notified to Oscient under Section 5.1, then an independent laboratory (or other expert) of recognized repute reasonably acceptable to Oscient and MIOL (the "Independent Laboratory") shall analyze (i) a sample from the relevant shipment provided by MIOL and (ii) a Shipment Sample as retained by Oscient in accordance with Section 4.5, as may be necessary to substantiate whether the shipment rejected by MIOL conformed in all material respects to the certificate of analysis and the pertinent Specifications or otherwise failed to comply with the warranties set forth in Section 12.1(e) of this Agreement at the time of delivery to the common carrier. At the same time each of Oscient and MIOL furnishes to the Independent Laboratory its sample, such Party shall also furnish to the other Party a split sample of such sample. In conducting its analysis hereunder, the Independent Laboratory shall use the same analytical methodology used by Oscient. Oscient shall provide a reasonably detailed description of such analytical methodology to the Independent Laboratory. Both Oscient and MIOL agree to cooperate with the Independent Laboratory's reasonable requests for assistance in connection with its analysis hereunder. The Independent Laboratory's results of analysis, absent manifest error, shall be deemed final as to any dispute over compliance of the Active Pharmaceutical Ingredient in all material respects with the certificate of analysis and/or the pertinent Specifications and/or the warranties set forth in Section 12.1(e) of this Agreement. If the analysis of the Independent Laboratory shows that the Active Pharmaceutical Ingredient did not at the material time(s) conform in all material respects to the certificate of analysis or the pertinent Specifications or the warranties set forth in Section 12.1(e) of this Agreement at the time of delivery to the common carrier, the costs of such analysis shall be paid by Oscient. If the analysis of the Independent Laboratory shows that the Active Pharmaceutical Ingredient did at the material time(s) conform in all

material respects to the certificate of analysis and the pertinent Specifications and the warranties set forth in Section 12.1(e) of this Agreement at the time of delivery to the common carrier, the costs of such analysis shall be paid by MIOL.

Disposition of Non-Conforming Active Pharmaceutical Ingredient. If Oscient acknowledges an alleged nonconformity (or if the Independent Laboratory concludes that the Active Pharmaceutical Ingredient was nonconforming in accordance with Section 5.3), Oscient promptly (and in any case within thirty (30) days thereafter) shall make arrangements for the return, reworking or disposal, at Oscient's option, of the nonconforming Active Pharmaceutical Ingredient. If Oscient requests that MIOL dispose of such nonconforming Active Pharmaceutical Ingredient, Oscient shall give MIOL written instructions as to how MIOL or its agent shall, at Oscient's expense, lawfully dispose of any nonconforming Active Pharmaceutical Ingredient, and MIOL shall provide Oscient with written certification of such destruction. Oscient shall pay, or reimburse MIOL, for any reasonable return shipping charges or out-of-pocket costs incurred by MIOL for such return shipment or lawful disposal of such nonconforming Active Pharmaceutical Ingredient in accordance with Oscient's instructions.

6. DEVELOPMENT OF PRODUCTS

6.1 Regulatory Approval.

- Subject to Steering Committee review as set forth below, MIOL shall use Diligent Efforts in, and be responsible for, all activities relating to obtaining and/or maintaining all Regulatory Approvals from Regulatory Authorities in the Territory for the Commercialization and Manufacture of the Finished Product in the Territory, including using Diligent Efforts (A) to obtain Marketing Authorizations for ABS, CAP and AECB indications for the Finished Product consistent with the Minimum Labeling Requirements according to the Development Plan, (B) to request a scientific advice meeting with the EMEA on eligibility of the Finished Product for the Centralized Procedure, proposed risk management plan, scientific data supporting the Marketing Authorization application; in case of non-eligibility possibility to request further advice from other national Regulatory Authorities, (C) to submit the letter of intent to submit a Marketing Authorization application to the EMEA, (D) to prepare the Common Technical Document for submission to the EMEA or other relevant Regulatory Authorities, (E) to submit the application for a Marketing Authorization to the EMEA or other relevant Regulatory Authorities, and (F) to follow up on all the regulatory applications. MIOL agrees: (i) to keep Oscient informed as to the status of its draft regulatory applications and to permit Oscient to review, in advance, any filing, correspondence, communication or other documentation to be filed with Regulatory Authorities during their preparation, (ii) to confer with Oscient regarding the preparation of such filings and communications and the registration process, (iii) to provide Oscient, upon request, with copies of all written communications with Regulatory Authorities with respect thereto, and (iv) where practical, to give reasonable prior notice to Oscient in order to allow Oscient to attend all material meetings with Regulatory Authorities. MIOL shall conduct all such regulatory activities in accordance with Applicable Law. Subject to Section 9.7 below, costs of Development and related Regulatory Approvals shall be borne by MIOL. Immediately upon obtaining any Regulatory Approval, MIOL shall provide true copies of the same to Oscient.
- (b) Subject to Section 6.1(a), MIOL shall be responsible for communications with the Regulatory Authorities with respect to the Regulatory Documentation. Oscient shall

provide reasonable assistance to MIOL in preparing documentation to support pre- and postauthorization meetings and in responding to any queries from a Regulatory Authority. Oscient will be responsible for the transfer of all the relevant information on the Active Pharmaceutical Ingredient and the Finished Product to allow MIOL to prepare the necessary documentation for Regulatory Applications (both pre- and post-authorization) including electronic version of the preclinical and clinical documentation to be included in the Regulatory Documentation. Notwithstanding anything to the contrary herein, Oscient shall not be required to deliver any information or data not already in its Control or to perform any development activities; in particular Oscient shall be under no obligation to provide to MIOL any information relating to the bulk chemical manufacture or the formulation of the Compound or Active Pharmaceutical Ingredient, other than information that is included in the Applicant's Part of the Active Substance Master File submitted to EMEA or any other relevant Regulatory Authority. Oscient shall or shall procure that LG shall be responsible for supplying Active Pharmaceutical Ingredient manufacturing process information direct to the EMEA or any other relevant Regulatory Authorities and will respond to relevant queries from Regulatory Authorities regarding the same. MIOL shall advise Oscient of material developments and events relating to regulatory issues in writing within three (3) Business Days after notice of such material developments and events. MIOL shall take the steps necessary to ensure that all information submitted to Regulatory Authorities is kept confidential.

- (c) For the avoidance of doubt, during the Development and subject to the Steering Committee review and approval pursuant to Sections 6.2 and 6.3 herein, MIOL shall have the right, but not the obligation, to perform clinical trials necessary to obtain the Regulatory Approval(s), at MIOL's sole discretion.
- (d) As soon as reasonably possible, Oscient agrees to withdraw the regulatory application previously submitted to MHRA by Oscient.

6.2 Joint Steering Committee.

- (a) Within ninety (90) days of the date of this Agreement, a joint steering committee, comprised of equal representation by both Parties (up to a maximum of three (3) representatives per Party (the "Steering Committee")), shall be established by both Parties. Except as otherwise provided in this Agreement, the Steering Committee shall have authority to make all necessary strategic decisions relating to the Development of Finished Product and the implementation of any Development Plan. The Steering Committee shall also review and approve any amendments to the Development Plans and shall review the MIOL Information and all filings made with any Regulatory Authority as well as to perform such other functions as appropriate to further the purposes of this Agreement as determined by the Parties. In addition, MIOL shall keep Oscient informed of the following matters through the Steering Committee:
 - (i) Plans and updates relating to the Commercialization of the Finished Product, including updates on achievement of objectives set forth in the applicable Marketing Plan (as defined in Section 7.2 below), progress towards sales goals, and related sales and marketing activities;
 - (ii) Prices, discounts, rebates and similar policies for the Finished Product in each country in the Territory;

- (iii) Reporting and pricing information to government authorities in accordance with Applicable Law;
- (iv) Manufacturing issues; and
- (v) Summary and analysis of any Adverse Event information or other medical inquires specified in Section 8.3 herein.
- (b) A Party may change or replace its representatives on the Steering Committee as it deems appropriate, by notice to the other Party provided that all such representatives shall be individuals of suitable authority and seniority with significant experience or expertise in pharmaceutical drug development, commercialization or marketing. Any member of the Steering Committee may designate a substitute of equal experience and seniority to attend and perform the functions of that member at any meeting of the Steering Committee. Each Party may invite (at its discretion and with the consent of the other Party) additional employees, or consultants to attend Steering Committee meetings. The Steering Committee shall hold meetings at such times and places as shall be determined by the co-chairpersons. The meetings shall be held no less frequently than (i) once every three (3) months prior to the grant of a Marketing Authorization obtained through the Centralized Procedure or, if Marketing Authorizations are sought on a country by country basis (rather than via the Centralized Procedure), the grant of a Marketing Authorization in each of the Major Countries and (ii) once every six (6) months thereafter. Steering Committee meetings may be held in person or by telephone or video conference.
- (c) In the event of a dispute within the Steering Committee such that no decision can be made with respect to a particular issue, the matter may be referred by either Party to Oscient's chief executive officer and MIOL's Managing Director for attempted resolution by good faith negotiation. If such individuals are unable to resolve the dispute within thirty (30) days after referral, subject to Section 6.3 below, then MIOL shall make the final determination to the extent not inconsistent with the terms and conditions of this Agreement, provided that any such determination shall be commercially reasonable and consistent with Applicable Law and MIOL shall not be entitled to make a unilateral determination: (i) if the proposed Development activities would be inconsistent with the U.S. label for the Oscient Product or might reasonably be expected to have an adverse effect on the development, manufacture or commercialization of Oscient Product or any other product containing the Compound outside the Territory, or (ii) to apply for Marketing Authorizations on a country by country basis (rather than via the Centralized Procedure); and any such determination shall require Oscient's prior written consent. Prior to resolving any such dispute unilaterally, MIOL shall consider in good faith Oscient's position in reaching any such decision and shall act in good faith and in the best interests of the Development and Commercialization of the Finished Product.
- (d) The Steering Committee shall only have such powers as are expressly delegated to it in this Agreement. The Steering Committee is not a substitute for the rights or obligations of the Parties and shall not have the authority to amend this Agreement.
- (e) Each Party will designate one of its members of the Steering Committee to act as a co-chairperson to facilitate the performance of its rights and satisfaction of its obligations hereunder.

6.3 Clinical Development.

- (a) Subject to Oscient's review and agreement, the Parties agree that MIOL may, but is not obligated to, pursue in the Territory Regulatory Approval for additional indications beyond the currently approved U.S. indications for the Oscient Product, CAP and AECB; provided that, the Parties agree that MIOL will seek to obtain Marketing Authorizations for each of ABS and CAP based on a 5-day duration of therapy. Any activities relating to additional indications shall form part of the Development Plan and shall be subject to review and approval by the Steering Committee. Oscient shall provide to MIOL data from new clinical studies for the Oscient Product conducted or completed by Oscient or its Affiliates or its licensee after the Effective Date if and to the extent Controlled by Oscient, to support MIOL if MIOL pursues such additional indications. Oscient shall promptly provide to MIOL data from post-marketing clinical trials concerning the Oscient Product before and after the Effective Date if and to the extent Controlled by Oscient in order to include them in the Regulatory Documentation.
- (b) Upon reasonable notice, Oscient shall have the right to (a) review any raw data generated in any clinical trial conducted by or on behalf of MIOL or its Affiliates with respect to the Finished Product, (b) visit clinical investigators and centers involved in the performance of such clinical trials, and (c) discuss any such clinical trial and its results in detail with such clinical investigators. MIOL shall provide Oscient with the data resulting from all clinical trials conducted by MIOL in accordance with Section 6.3(a). Oscient shall be free to use the results of any or all such clinical trials in connection with the marketing, promotion, packaging, handling, distribution, use, storage, sale and offer for sale and product licensing of Oscient Product outside the Territory. Except as required by Applicable Law, the results of any clinical studies shall not be publicized or published in any way without the prior written consent of Oscient. All patentable inventions conceived, discovered, developed or otherwise made by or on behalf of MIOL or its Affiliates which are Developed hereunder shall be jointly owned in accordance with Section 11.1.

6.4 <u>Inspections, Inquiries and Complaints</u>.

- (a) MIOL shall advise Oscient of any visit to, or written or oral inquiry about, any facilities or procedures relating to the Manufacture and/or Commercialization of the Finished Product by or from any Regulatory Authority, promptly (but in no event later than one (1) Business Day) after notice of such visit or inquiry is received by MIOL or its Affiliates or Third-Party Manufacturer or Sub-Distributors. MIOL shall, within three (3) Business Days of receipt or submission, furnish to Oscient any report or correspondence issued by or provided to the Regulatory Authority in connection with such visit or inquiry.
- (b) Oscient shall advise MIOL of any visit to, or written or oral inquiry about, any facilities or procedures relating to the manufacture of the Active Pharmaceutical Ingredient by or from any Regulatory Authority, or comparable regulatory authority outside the Territory, promptly (but in no event later than one (1) Business Day) after notice of such visit or inquiry is received by Oscient.
- (c) MIOL shall advise Oscient within twenty four (24) hours of any investigation, complaint, claim or potential claim, whether from a Regulatory Authority or not, about the Finished Product relating to a safety issue, and shall also advise Oscient within two (2) Business Days of any issue that may give rise to a potential recall.

7. COMMERCIALIZATION OF PRODUCT

- Responsibility and Efforts. From and after the Effective Date, MIOL shall have full 7.1 control and authority over the Commercialization of Finished Products in the Territory, and shall exercise Diligent Efforts in Commercializing Finished Products in the Territory. MIOL shall (i) diligently seek formulary listings and Reimbursement Prices in each country in the Territory, in order to maximize the commercial potential for the Finished Product in the Territory, and (ii) Commercialize the Finished Product in each country in the Territory in which MIOL receives a Reimbursement Price of at least \$3.16 (after applying the Annual Calculated Exchange Rate in effect at such time) (the "Acceptable Country"); provided that, if the Actual Weighted Average Price Per Tablet at the time of receipt of a Reimbursement Price is less than \$1.08, then, MIOL shall not be obligated to Commercialize the Finished Product in such Acceptable Country. All activities relating to Commercialization under this Agreement shall be undertaken at MIOL's sole cost and expense. MIOL and Oscient shall discuss and agree in good faith, at least three months before the launch in each of the Major Countries that have received Marketing Authorization approval, on the minimum number of Calls to be made by MIOL in each of the Major Countries using as a reference the projections used to develop the target promotional plan set forth in Schedule 7.1.
- Annual Marketing Plan. Within sixty (60) days of the First Commercial Sale and 7.2 thereafter not later than each anniversary date of the First Commercial Sale, MIOL shall submit to Oscient a business and marketing plan for the following year for each country in the Territory (each a "Marketing Plan"). The Marketing Plan shall be in a form reasonably required by Oscient, and shall include: (i) a description of the market and marketing, promotional and customer service programs anticipated for the following year and budgets for each on a country by country basis; (ii) an outline of training and regulatory activities expected for the following year, (iii) the number and type of Details to be performed; (iv) the aggregate amount of Commercializing expenses to be incurred; (v) a three-year forecast of purchases of Active Pharmaceutical Ingredient from Oscient and sales of the Finished Product to customers; (vi) an inventory status report; and (vii) such other information concerning the market, the status of customers and competitors, the business of MIOL or such other matters related to the Finished Product as Oscient may reasonably request. MIOL shall consider in good faith any comments made by Oscient in connection with any Marketing Plan and in particular any concerns that Oscient may have that execution of any Marketing Plan in accordance with its terms would not constitute Diligent Efforts in Commercializing Finished Products in the relevant country.
- 7.3 <u>Standards and Sales Activities</u>. MIOL shall, at its sole expense, Commercialize the Finished Product in accordance with good commercial practice with respect to regulated pharmaceutical products, including Applicable Law. MIOL shall avoid using any practice that would prejudice Oscient's name, the Trademarks, or the quality of the Finished Product. MIOL shall market the Finished Product in a manner that maximizes the goodwill and the value over the long term of the Finished Product.
- 7.4 <u>Training</u>. MIOL shall ensure that each of its and its Sub-Distributors' sales force and employees are fully trained with respect to the Finished Product and reporting of Adverse Event information in accordance with Applicable Law.
- 7.5 <u>Sales Outside the Territory</u>. MIOL and its Sub-Distributors shall not: (i) establish any branch, sales offices, warehouse or other facilities outside of the Territory with respect to the Finished Product, (ii) adopt a policy of selling the Finished Product outside the Territory

nor undertake the sale or promotion of sales of the Finished Product outside the Territory, (iii) seek customers or solicit orders from any prospective customer whose principal address or place of business is located outside the Territory, (iv) provide any price quotations for the Finished Product to any prospective customer whose principal address or place of business is located outside the Territory, and/or (v) directly or indirectly sell to any person (including a pharmacy or wholesaler) that MIOL knows or has reason to believe, directly or indirectly sells to any person outside of the Territory. If MIOL or Sub-Distributor receives an order from a prospective customer located outside the Territory, MIOL and Sub-Distributor shall immediately refer that order to Oscient. Without Oscient's prior consent, MIOL, or Sub-Distributor may not deliver or tender, or cause to be delivered or tendered, the Finished Product (or any sample of the Product) outside the Territory. Neither MIOL, nor Sub-Distributor shall sell any Finished Product to any purchaser if (A) it knows, or has reason to believe, that such purchaser intends to remove the Finished Product from the Territory, either directly or indirectly, or if (B) such purchaser is known to remove pharmaceuticals from the Territory, either directly or indirectly or indirectly.

7.6 Marketing, Promotional and Educational Materials. Unless otherwise agreed by Oscient, the Finished Product shall be sold under the trade name Factive ®; provided, however, that MIOL may propose alternative trade names for specific countries, and upon Oscient's prior written consent, not to be unreasonably withheld, and subject to any necessary Regulatory Approvals, the Finished Product shall be marketed under such trade name (the "New Trademark"). The New Trademark shall be the property of Oscient or its designee and shall be registered by Oscient or its designee. If the New Trademark is initially registered by MIOL, MIOL shall promptly on request assign all its rights and interest in any such New Trademark to Oscient or as Oscient may direct. The definition of "Trademark" hereunder shall include any such New Trademark registered in Oscient's name. All marketing, promotional and educational materials related to the Finished Product and prepared for use in the Territory by MIOL or a Sub-Distributor (the "Promotional Materials") shall be prepared in a manner consistent with Applicable Law and relevant self-regulatory codes of conduct and guidelines. Oscient shall be presented at least thirty (30) days in advance of use with samples or proofs of all such Promotional Materials for review and comments. Notwithstanding this, MIOL shall remain at all times responsible for ensuring that all Promotional Materials and their use are in compliance with Applicable Law. All Promotional Materials shall display the Trademarks in a manner that promotes the Finished Product and each of the Parties in a manner consistent with good commercial practice in dealing with regulated pharmaceutical products and shall unless otherwise agreed by Oscient indicate that any Trademark is a registered trademark, if applicable. Oscient shall have the right to reproduce, distribute and otherwise use outside the Territory all Promotional Materials. MIOL shall provide and distribute to customers and prospective customers marketing, promotional and educational materials reasonably necessary to promote the Finished Product in the Territory. MIOL shall be responsible for all expenses relating to the advertising, promotion or sales of the Finished Product. Oscient shall provide MIOL with samples of Product-related marketing and promotional materials prepared by Oscient, including related logos and graphics, for use by MIOL in connection with the development of Promotional Materials.

8. RECORDS AND REPORTS

8.1 <u>Records</u>. MIOL shall maintain complete and accurate records of all inventories, Finished Product in storage, movements, shipments, sales and potential problems involving

the Finished Product by unit, by batch number and by customer so that all such matters can be traced quickly and effectively. Upon request, MIOL shall provide copies of such records to Oscient, and shall provide Oscient, or its representatives, with access to the place where the Finished Product is Manufactured, stored and/or shipped and other facilities used by MIOL in carrying out this Agreement, during normal business hours and upon reasonable notice, for the purpose of inspecting such facilities for compliance with the terms of this Agreement. MIOL shall maintain all such records for at least five (5) years or such longer period as may be required by Applicable Law.

- 8.2 Reports. MIOL shall provide Oscient with written reports regarding the Development and Commercialization of the Finished Product. MIOL shall provide such written reports no less frequently than annually during the Term. In addition, MIOL shall provide Oscient with prompt written notice of the occurrence of the First Commercial Sale of the Finished Product in each country in the Territory. All reports, updates, Adverse Event information and other information provided by one Party to another Party under this Agreement shall be considered Confidential Information of the Disclosing Party, subject to the terms of Article 10 hereof.
- The Parties shall comply with the Pharmacovigilance Joint 8.3 Adverse Events. Operating Policy, which shall be negotiated and agreed to within ninety (90) days from the Effective Date, with respect to the investigation and reporting of Adverse Events and shall regularly review and update the Pharmacovigilance Joint Operating Policy as may be required to enable both Parties to comply with Applicable Law relating to pharmacovigilance. The Parties shall provide each other on a regular basis and in accordance with the Pharmacovigilance Joint Operating Policy with any information which has become available to them and which is relevant to the safe use of the Finished Product or the Oscient Product or which is required by Applicable Law in all countries where the Finished Product or the Oscient Product is marketed or is in a clinical study. MIOL, at its sole expense, shall be responsible for conducting any post-marketing surveillance of the Finished Products sold by MIOL pursuant to this Agreement and for reporting Serious Adverse Events and Non-Serious Adverse Events arising in connection with any Finished Product to the appropriate Regulatory Authorities in the Territory in accordance with Applicable Law. Oscient, or its Third Party sublicensor and sublicensees shall be responsible for making all Adverse Event reports outside the Territory. The Parties shall transmit to each other a copy of any report relating to a Serious Adverse Event for a Finished Product or an Oscient Product made to any Regulatory Authority, comparable regulatory authority outside the Territory or ethics committee within two (2) calendar days following submission to the relevant regulatory authority or ethics committee made by MIOL, its Affiliates or its Sub-Distributors (or within two (2) calendar days following notice of submission to the relevant regulatory authority made by a Third Party (other than a Sub-Distributor)) by transmitting it in accordance with such procedures as the Parties may agree in writing from time to time.
- **8.4** MIOL Information. During the Term MIOL shall promptly provide to Oscient copies of any and all MIOL Information.

9. PAYMENTS AND FEES

9.1 <u>License Fee.</u> In consideration of the license described in Article 2 hereof, MIOL agrees to pay to Oscient a non-refundable license fee of \$1,000,000 within ten (10) Business Days from the Effective Date

9.2 Transfer Price.

- (a) Oscient shall supply free of any charge up to one (1) kilogram of Active Pharmaceutical Ingredient ordered by MIOL for the purposes of obtaining necessary Regulatory Approvals to Commercialize the Finished Product in the Territory; provided that, any such Active Pharmaceutical Ingredient may not be used to Manufacture Finished Product to be Commercialized in the Territory.
- (b) For each kilogram of Active Pharmaceutical Ingredient delivered by Oscient to MIOL during the Term, MIOL shall pay to Oscient an amount per kilogram of Active Pharmaceutical Ingredient equal to the Transfer Price Per Kilo. Each invoice for Active Pharmaceutical Ingredient shall specify the purchase order number to which it corresponds. All amounts due to Oscient pursuant to Sections 9.2(a) and 9.2(d) shall be paid by MIOL within fifty (50) days following the date of invoice and otherwise in accordance with this Article 9.
- (c) Within twenty (20) days following the end of every Quarter after the First Commercial Sale, MIOL shall provide to Oscient a report detailing (i) the Gross Sales (including specifics related to applicable Government Payments) and Net Sales (including an accounting of deductions taken in the calculation of Net Sales) for each country in the Territory for the applicable Quarter, (ii) the total number of Tablets sold by MIOL or its Affiliates or Sub-Distributors in each such country in that Quarter, and (iii) the reconciliation of the Assumed Weighted Average Price Per Tablet and the Actual Weighted Average Price Per Tablet (calculated for the applicable Quarter) pursuant to Section 9.2(d) below (the "Quarterly Report"). MIOL shall cause its or the applicable Affiliate's Managing Director to certify that the information contained in each Quarterly Report is complete and accurate.
- (d)(i) If in any Quarter the Actual Weighted Average Price Per Tablet is greater than the Assumed Weighted Average Price Per Tablet for the same Quarter, then MIOL shall owe and pay to Oscient an amount equal to (A) the difference between the Actual Weighted Average Price Per Tablet and the Assumed Weighted Average Price Per Tablet, multiplied by (B) the number of Tablets sold (including the number of professional samples of Tablets given to medical professionals without cost) by MIOL and its Affiliates and Sub-Distributors (as determined using verifiable, written data from MIOL) in the applicable Quarter, to be paid to Oscient pursuant to the provisions of Section 9.8 below).
- (ii) If in any Quarter the Assumed Weighted Average Price Per Tablet is greater than the Actual Weighted Average Price Per Tablet for the same Quarter, then Oscient shall owe to MIOL an amount equal to (A) the difference between the Assumed Weighted Average Price Per Tablet and the Actual Weighted Average Price Per Tablet, multiplied by (B) the number of Tablets sold (including the number of professional samples of Tablets given to medical professionals without cost) by MIOL and its Affiliates and Sub-Distributors (as determined using verifiable, written data from MIOL) in the applicable Quarter, such sum to be paid to MIOL pursuant to the provisions of Section 9.8 below.
- (iii) Notwithstanding anything hereunder to the contrary, when calculating the Actual Weighted Average Price Per Tablet for any applicable Quarter for purposes of the reconciliation set forth in this Section 9.2(d), in no event shall the Actual Weighted Average Price Per Tablet be less than \$.97 per Tablet. In the event the Actual Weighted Average Price Per Tablet calculated for two (2) consecutive Quarters would, but for this Section 9.2(d)(iii), be less than \$.97 per Tablet, MIOL may notify Oscient in writing that it wishes to

negotiate in good faith a new minimum per Tablet price which is mutually acceptable to both Parties.

- (e) During the Mandatory Supply Term, MIOL shall provide to Oscient, on the 75th day after the end of each Quarter, IMS audit data detailing Gross Sales, the total number of Tablets sold by MIOL and its Affiliates and Sub-Distributors and the total number packs of Finished Product sold to pharmacies (pharmacy sell-in) (including corresponding Tablets per package in each case in the Quarter, in the Territory. At the end of every Sales Year (as defined below), the Parties shall reconcile such IMS data received by Oscient against the Quarterly information presented by MIOL and shall make appropriate payments to each other if use of the IMS data would have resulted in a change of such payments made pursuant to this Section 9.2 in such Sales Year of greater than two percent (2%) of the actual payments made pursuant to this Section 9.2 during such Sales Year.
- (f) For purposes of clarification, <u>Schedule 9.2</u> is attached hereto to provide hypothetical forecasted examples of the calculation of the Actual Weighted Average Price Per Tablet.
- 9.3 Additional Payments. In further consideration of the grant of the license and rights by Oscient pursuant to Article 2, and subject to the other terms of this Agreement (including the remainder of this Section 9.3), commencing on the date of the First Commercial Sale and continuing for the duration of the Mandatory Supply Term, if Annual Net Sales in any Sales Year are in excess of \$200 million, MIOL shall make a non-refundable payment to Oscient in an amount equal to one and one-half percent (1.5%) of such Annual Net Sales which are in excess of \$200 million in that Sales Year multiplied by the Annual Calculated Exchange Rate (as calculated on the last day of the applicable Sales Year) ("Additional Payment"). Unless otherwise expressly provided, MIOL shall make any Additional Payment owed to Oscient hereunder in arrears, within twenty (20) days from the end of each Sales Year in which such Additional Payment accrues. MIOL shall provide to Oscient, by no later than twenty (20) days after each Sales Year, a report detailing sales of Finished Products in the preceding Sales Year in the Territory and specifying: for each month in the relevant Sales Year, on a country by country basis, the Gross Sales (including specifics related to applicable Government Payments) and Net Sales in the Territory and aggregate gross sales and Net Sales; the amounts payable, including an accounting of deductions taken in the calculation of Net Sales; and the applicable Annual Calculated Exchange Rate to convert from Euros into United States Dollars under this Section 9.3
- 9.4 Royalties After Mandatory Supply Term. During the Term, following expiration of the Mandatory Supply Term, MIOL shall make Quarterly royalty payments to Oscient on Net Sales in each country in the Territory equal to two and one half percent (2.5%) of Net Sales in the relevant Quarter multiplied by the Annual Calculated Exchange Rate (as calculated on the last day of the applicable Quarter) (the "Quarterly Royalty") for so long as MIOL or any Affiliate or Sub-Distributor continues to use the Trademarks, the Regulatory Approvals or otherwise Commercializes the Finished Product in such country. Unless otherwise expressly provided, MIOL shall make any Quarterly Royalty owed to Oscient hereunder in arrears, within twenty (20) days from the end of the Quarter in which such Quarterly Royalty accrues. Each Quarterly Royalty made pursuant to this Section 9.4 shall be accompanied by a report detailing for each month in the relevant Quarter on a country by country basis sales of Finished Products covered by such statement and specifying: the gross sales and Net Sales, the amounts payable, including an accounting of deductions taken in the

calculation of Net Sales, and the applicable Annual Calculated Exchange Rate to convert from Euros into United States Dollars. MIOL shall cause its or the applicable Affiliate's Managing Director to certify that the information contained in each such report is complete and accurate.

9.5 Milestone Payments.

(a) Approval Milestones Payment. In further consideration of the rights granted hereunder and subject to the other terms and conditions of this Agreement, MIOL shall: (i) if a Marketing Authorization for the Finished Product is granted via the Centralized Procedure and MIOL has not elected to terminate the Agreement pursuant to Section 15.4below, make a non-refundable, non-creditable payment of \$4 million within thirty (30) days of the grant by the European Commission of such Marketing Authorization for the Finished Product or (ii) if MIOL has applied for any Marketing Authorization by a procedure other than the Centralized Procedure, (A) make a non-refundable, non-creditable payment of \$1 million to Oscient within thirty (30) days of receipt of Marketing Authorization in at least three (3) the Major Countries, and (B) make the following non-refundable, non-creditable payments to Oscient within (30) days of the first occurrence of each of the following events:

Milestone	Payment
Upon grant of the first Marketing Authorization in the United Kingdom.	\$600,000
Upon grant of the first Marketing Authorization in France.	\$600,000
Upon grant of the first Marketing Authorization in Germany.	\$600,000
Upon grant of the first Marketing Authorization in Italy	\$600,000
Upon grant of the first Marketing Authorization in Spain	\$600,000

(b) Reimbursement Milestones Payment. In further consideration of the rights granted hereunder and subject to the other terms and conditions of this Agreement, MIOL shall make the following nonrefundable, non-creditable payments to Oscient within thirty (30) days of the occurrence of each of the following events or circumstances ("Reimbursement Milestones"):

Milestone	Payment
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Upon inclusion of the Finished Product in Part VIII \$600,000 of the National Health Service Drug Tariff for England and Wales.

Upon publication in the Journal Officiel of the price for such Finished Product agreed with or set by the Comité Économique des Produits de Santé in France.	\$600,000
If, 60 days after the first Marketing Authorization has been granted in Germany, the Gemeinsamer Bundesausschuss has not published a determination that the Finished Product may not be reimbursed.	\$600,000
Upon publication in the Italian Official Gazette of a Decision of the Agenzia Italiana del Farmaco to reimburse the Finished Product in Italy.	\$600,000
Upon resolution of the Ministerio de Sanidad y Consumo to reimburse the Finished Product in Spain.	\$600,000

In the event that the specific Reimbursement Milestone described above for a Major Country has not occurred, but the Finished Product is nevertheless marketed in that Major Country and is in fact reimbursed, in whole or in part, by the national health system or any broadly equivalent scheme in that Major Country, the Reimbursement Milestone for that Major Country shall be deemed to have occurred and MIOL shall pay the relevant Reimbursement Milestone payment within thirty (30) days of the first such reimbursement.

(c) <u>Sales Milestone Payment</u>. In further consideration of the rights granted hereunder and subject to the other terms and conditions of this Agreement, MIOL shall make the following nonrefundable, non-creditable payments to Oscient within thirty (30) days of the first occurrence of each of the following milestones ("Sales Milestones"):

Milestone	Payment
Annual Net Sales exceed \$50 million dollars	\$3,000,000
Annual Net Sales exceed \$100 million dollars	\$5,000,000
Annual Net Sales exceed \$150 million dollars	\$4,000,000
Annual Net Sales exceed \$200 million dollars	\$4,000,000

For the avoidance of doubt, each of the Sales Milestones detailed in this Section 9.5(c) are payable only once but may fall due for payment in the same Sales Year. For example, if Annual Net Sales are \$105 million in a Sales Year and no payment has previously been made by MIOL on Annual Net Sales exceeding \$50 million, MIOL shall pay Oscient a non-refundable, non-creditable sum of \$8,000,000.

(d) <u>Determination that Payments are Due.</u> MIOL shall promptly (and in any event within ten (10) Business Days) provide Oscient with written notice upon its or its Affiliates'

or Sub-Distributors' achievement of each of the milestones set forth in Sections 9.5(a), (b) and (c). In the event that Oscient believes any milestone payment is due pursuant to Sections 9.5(a), (b) and (c) in spite of not having received notice from MIOL, it shall so notify MIOL and shall provide to MIOL the data and information supporting its belief that the conditions for payment have been achieved. If MIOL does not provide adequate evidence that such milestone has not been achieved within thirty (30) days of receipt of the data and information from Oscient, the conditions for payment shall be deemed to have been achieved.

- (e) <u>Milestone Payments Terms</u>. Unless otherwise expressly provided, MIOL shall make any milestone payment owed to Oscient pursuant to this Section 9.5 in arrears, within thirty (30) days from the achievement of such milestone.
- 9.6 <u>Calculation of Annual Net Sales</u>. For purposes of Section 9.3 and Section 9.5, "Annual Net Sales" shall be calculated (i) based on the twelve (12) month period commencing on the first day of the first full Quarter following the First Commercial Sale of the Finished Product (the "First Sales Year") and each successive twelve (12) month period thereafter (each a "Sales Year"); provided that, Annual Net Sales in the First Sales Year shall also include any Net Sales completed in the Quarter in which the First Commercial Sale occurred; and (ii) using the Annual Calculated Exchange Rate as calculated at the end of each Quarter.
- Development Expenses. Within thirty (30) day of the end of each Quarter following 9.7 the Effective Date, MIOL shall provide Oscient with a statement setting forth the costs and expenses incurred by MIOL (together with the relevant invoices and such supporting documentation as Oscient may reasonably require), and Oscient shall reimburse MIOL within thirty (30) days of receipt of such statement all reasonable and verifiable expenses incurred by MIOL in such Quarter in undertaking Development of the Finished Product in accordance with this Agreement (the "MIOL Development Expenses"); provided that, (i) Oscient shall not be obligated to pay more than two Hundred Thousand Dollars (\$200,000) in any applicable Quarter and (ii) the aggregate amount to be paid by Oscient for such expenses shall not exceed One Million Dollars (\$1,000,000). MIOL shall keep complete and accurate books and financial records pertaining to its costs and expenses of Developing the Finished Product, which books and financial records shall be retained by MIOL until two (2) years after the end of the Quarter to which they pertain. Oscient shall have the right to inspect and audit, during normal business hours and upon reasonable prior written notice, the books and financial records of MIOL relating to its costs and expenses of Developing the Finished Product during any Quarter; provided that Oscient shall not have the right to inspect or audit any Quarter more than once and will not go back over records more than two (2) years old unless a discrepancy is found.
- **9.8** Payment Terms. All sums payable by MIOL pursuant to this Agreement shall be paid in United States dollars by bank wire transfer in immediately available funds to the following account unless MIOL is otherwise notified in writing by Oscient:

Bank Account: Citizens Bank

28 State Street Boston, MA 02109

USA

1-877-471-1961

Account Number:

Bank ABA Number: 011500120

- 9.9 Overdue Payments. Subject to the other terms of this Agreement, any payments not paid within the time period set forth in this Article 9 shall bear interest at a rate of LIBOR plus two percent (2%) for the applicable month from the due date until paid in full, provided that in no event shall said annual rate exceed the maximum interest rate permitted by law in regard to such payments. Such payment when made shall be accompanied by all interest so accrued. Said interest and the payment and acceptance thereof shall not negate or waive the right of Oscient to any other remedy, legal or equitable, to which it may be entitled because of the delinquency of the payment.
- Tax Withholding; Restrictions on Payment. It is the Parties' understanding that no withholding or deduction should be required to be made from any payment made to Oscient pursuant to this Article 9. Any payments payable by either Oscient or MIOL (the "Withholding Party") to the other under this Agreement may be reduced by the amount required to be withheld or deducted from such payment pursuant to any applicable law ("Withholding Taxes"); provided however, that Withholding Party shall withhold taxes at the lowest tax rate allowed in the applicable tax treaties. The Withholding Party shall submit to the other Party a copy of an original receipt received by the Withholding Party showing payment thereof to the relevant governmental authority, or if such receipt is not available, other reasonable proof of such payment of any Withholding Taxes withheld or deducted, together with an accounting of the calculations of such taxes, as promptly as practicable but in no case later than thirty (30) days after such Withholding Taxes are remitted to the proper governmental authority. All taxes ("Other Taxes") other than Withholding Taxes shall be borne by the Party upon which such Other Tax is imposed. Oscient and MIOL will cooperate reasonably in completing and filing documents required under the provisions of any applicable Luxembourg tax law or under any other applicable Luxembourg law in connection with the making of any required withholding or deduction, or in connection with the payment of any such withholding or deduction to the proper governmental authority or in connection with any claim to a refund of or credit for any such payment.

9.11 Records Retention; Review.

- (a) Records. Commencing as of the date of First Commercial Sale of the Finished Product hereunder, MIOL and Sub-Distributors shall keep for at least five (5) years from the end of the calendar year to which they pertain complete and accurate records of sales by MIOL or Sub-Distributor, as the case may be, of the Finished Product and the reimbursement price from time to time in each country in the Territory and total units of Finished Products dispensed in each country by month, in sufficient detail to allow the accuracy of the payments hereunder to be confirmed.
- (b) Review. Subject to the other terms of this Section 9.11, at the request of Oscient, which shall not be made more frequently than once per calendar year during the Term, upon at least thirty (30) days' prior written notice from Oscient, and at the expense of Oscient (except as otherwise provided herein), MIOL shall permit independent accountants (who may be certified public accountants or chartered accountants) reasonably selected by Oscient to inspect (during regular business hours) the relevant records required to be maintained by MIOL under this Section 9.11. Results of any such review shall be binding on the Parties absent manifest error. Each Party agrees to treat the results of any such accountant's review of the Party's records under this Section 9.11 as Confidential Information of such other Party subject to the terms of Article 10. If any review reveals a

deficiency in the calculation and/or payment of royalties by MIOL, then (i) MIOL shall promptly pay Oscient the amount remaining to be paid, and (ii) if such underpayment is by ten percent (10%) or more, MIOL shall pay the reasonable out-of-pocket costs and expenses incurred by Oscient in connection with the review.

(c) <u>Sub-Distributors</u>. MIOL shall include in any agreement with the Sub-Distributor terms requiring such party to retain records as required in this Section 9.11 and to permit Oscient to inspect such records as required by this Section 9.11.

10. TREATMENT OF CONFIDENTIAL INFORMATION

- 10.1 Confidential Obligations. Oscient and MIOL each recognize that the other Party's Confidential Information constitutes highly valuable and proprietary confidential information. Oscient and MIOL each agree that during the Term and for five (5) years thereafter, it will keep confidential, and will cause its employees, consultants, Affiliates and, in the case of MIOL, Third-Party Manufacturer, Sub-Distributors and, in the case of Oscient, LG to keep confidential, all Confidential Information of the Disclosing Party; provided that, MIOL agrees to keep, and will cause its employees, consultants, Affiliates and Third-Party Manufacturer and Sub-Distributors to keep, Confidential Information regarding the manufacturing process for Active Pharmaceutical Ingredient confidential for a further period of ten (10) years after expiration or termination of this Agreement. Neither Oscient nor MIOL nor any Third-Party Manufacturer nor Sub-Distributor, nor any of their respective employees, consultants or Affiliates shall use the Disclosing Party's Confidential Information for any purpose whatsoever other than exercising any rights granted to it or reserved by it hereunder. Without limiting the foregoing, the Receiving Party may disclose information to the extent such disclosure is reasonably necessary to (a) file and prosecute patent applications and/or maintain patents which are filed or prosecuted in accordance with the provisions of this Agreement, or (b) file, prosecute or defend litigation in accordance with the provisions of this Agreement or (c) comply with Applicable Law, court orders or the rules of any nationally recognized securities exchange, quotation system or over-the-counter market on which the Receiving Party or its Affiliates or, in the case of MIOL, the relevant Third-Party Manufacturer or Sub-Distributor is listed or traded; provided, however, that if the Receiving Party is required to make any such disclosure of the Disclosing Party's Confidential Information in connection with any of the foregoing, it will give reasonable advance notice to the Disclosing Party of such disclosure requirement and, except to the extent inappropriate in the case of patent applications, will use reasonable efforts to assist the Disclosing Party in efforts to secure confidential treatment of such information required to be disclosed.
- 10.2 Limited Disclosure and Use. Oscient and MIOL each agree that any disclosure of the Disclosing Party's Confidential Information to any officer, employee, consultant or agent of the Receiving Party or any of its Affiliates, or in the case of Menarini, any Third-Party Manufacturer or Sub-Distributor, shall be made only if and to the extent necessary to carry out its rights and responsibilities under this Agreement, shall be limited to the maximum extent possible consistent with such rights and responsibilities and shall only be made to the extent any such persons are bound by written confidentiality obligations to maintain the confidentiality thereof and not to use such Confidential Information except as expressly permitted by this Agreement. Oscient and MIOL each further agree not to disclose or transfer the Disclosing Party's Confidential Information to any Third Parties under any circumstance without the prior written approval from the Disclosing Party (such approval not to be unreasonably withheld), except as otherwise required by Applicable Law, and except as otherwise expressly permitted by this Agreement. Oscient shall be permitted to disclose

Confidential Information to LG to the extent required pursuant to the LG License. The Receiving Party shall take such action, and shall cause its Affiliates to take such action, to preserve the confidentiality of the Disclosing Party's Confidential Information as it would customarily take to preserve the confidentiality of its own Confidential Information, using, in all such circumstances, not less than reasonable care. The Receiving Party, upon the request of the Disclosing Party, will return all the Confidential Information disclosed or transferred to it by the Disclosing Party pursuant to this Agreement, including all copies and extracts of documents and all manifestations in whatever form, within sixty (60) days of such request or, if earlier, the termination or expiration of this Agreement; provided however, that the Receiving Party may retain (a) any Confidential Information of the Disclosing Party which is the subject of a continuing license to the Receiving Party at the time of such request or termination or expiry of this Agreement as the case may be and (b) one (1) copy of all other Confidential Information in inactive archives solely for the purpose of establishing the contents thereof.

- 10.3 Publicity. Neither Oscient nor MIOL may publicly disclose the existence or terms or any other matter of fact regarding this Agreement without the prior written consent of the other Party, which consent shall not be unreasonably withheld or delayed; provided, however, that any Party may make such a disclosure (a) to the extent required by Applicable Law or by the requirements of any nationally recognized securities exchange, quotation system or overthe-counter market on which such Party has its securities listed or traded, (b) to any investors, prospective investors, lenders and other potential financing sources who are obligated to keep such information confidential, or (c) in the case of Oscient, as required under the LG License. In the event that such disclosure is required as aforesaid, the Party required to make such disclosure shall make reasonable efforts to provide the other Party with notice beforehand and to coordinate with the other Party with respect to the wording and timing of any such disclosure. The Parties, upon the execution of this Agreement, will mutually agree to a press release with respect to this transaction for publication. Once such press release or any other written statement is approved for disclosure by the Parties, either Party may make subsequent public disclosure of the contents of such statement without the further approval of the other Party.
- 10.4 <u>Use of Name</u>. No Party shall employ or use the name of another Party in any promotional materials or advertising relating to this Agreement without the prior express written permission of the other Party or as specifically set out in this Agreement.
- 10.5 Access to Information. If MIOL, Third-Party Manufacturer or Sub-Distributor receives an access to information or freedom of information request relating to Finished Product, it shall notify Oscient within two days of such request, and provide a copy of its proposed response to such request to Oscient at least five days before the deadline for responding. If Oscient suggests that the proposed response should be amended to keep additional information confidential, MIOL, Third-Party Manufacturer or Sub-Distributor, as applicable, shall amend the proposed response accordingly.

11. INTELLECTUAL PROPERTY RIGHTS

11.1 Ownership of Intellectual Property.

(a) Oscient Intellectual Property. Subject to the license granted by Oscient to MIOL under this Agreement, as between the Parties, Oscient shall own and retain all right, title and interest in and to the Oscient Intellectual Property.

- Joint Intellectual Property. As between the Parties, each Party shall own an (b) undivided one-half interest in and to any patentable invention conceived, discovered developed or otherwise made, by or on behalf of MIOL, its Affiliates or its Third-Party Manufacturer or Sub-Distributors pursuant to this Agreement (a "Joint Invention") regardless of inventorship, provided that Oscient may designate LG or any Affiliate of LG (a "Designee") as the joint owner of any Joint Invention in its place, with full ownership rights in and to any field and each Party and any Designee shall have the right, subject to the rights and licenses granted under, and the other provisions of, this Agreement, to freely exploit, transfer, license or encumber its rights in any Joint Invention (together with all Patent Rights in that subject matter (the "Joint Patent Rights")) without the consent of, or payment or accounting to, the other Party, and each Party waives any right it may have under any Applicable Law to require such payment, accounting or consent. This Section 11.1 shall survive termination of this Agreement howsoever caused. During the Term, MIOL shall and shall procure that each Third-Party Manufacturer and Sub-Distributor shall, promptly disclose to Oscient in writing, the characterization, conception, development or making of any Joint Invention and notwithstanding any other provision of this Agreement, Oscient shall be free to disclose details of such Joint Invention to LG or any Designee. MIOL shall, and does hereby, assign, and shall cause its Affiliates, Third-Party Manufacturers and Sub-Distributors to so assign, to Oscient, or as Oscient may direct, without additional compensation, such right, title and interest in and to any Joint Inventions as well as any Patent Rights therein, as is necessary to fully effect the joint ownership provided for in this Section.
- 11.2 Patent Filing, Prosecution and Maintenance. As between the Parties, Oscient shall be responsible for preparing, filing, prosecuting, obtaining and maintaining, at its sole cost, expense and discretion (but acting reasonably), all Licensed Patent Rights and Joint Patent Rights in the Territory; provided however, MIOL shall reimburse Oscient one-half of the costs and expenses relating to the Joint Patent Rights in the Territory. Oscient will keep MIOL reasonably informed of the status of such filing, prosecution, obtaining and maintenance and MIOL, at its cost, shall provide such assistance as Oscient may reasonably require in connection with such filing, prosecution, obtaining and maintenance.
- 11.3 <u>Trademarks Filing, Prosecution and Maintenance</u>. Oscient may seek and maintain such registrations as it deems advisable in respect of the Trademarks in the Territory, and will keep MIOL reasonably informed of the status of such registrations and applications therefore. Oscient may from time to time add to, modify or delete any Trademarks.
- 11.4 <u>Infringement</u>. If, during the Term, any Party learns of any actual, alleged or threatened infringement by a Third Party of any of the Oscient Intellectual Property or the Joint Patent Rights, such Party shall promptly notify the other Party and shall provide the other Party with available evidence of such infringement and the Parties shall consult in good faith to determine the appropriate action to be taken in relation to such infringement.
- 11.5 <u>Violation of Intellectual Property by Third Party(ies)</u>. MIOL shall have the first right (but not the obligation), at its own expense and with legal counsel of its own choice, to bring suit (or take other appropriate legal action) against any actual, alleged or threatened infringement or other violation of the Oscient Intellectual Property or the Joint Patent Rights in the Territory. Oscient and LG shall have the right, at their own expense, to be independently represented in any such action by MIOL by counsel of Oscient's own choice; provided, however, that under no circumstances shall the foregoing affect the right of MIOL to control the suit as described in the first sentence of this Section 11.5. If MIOL does not

notify Oscient of its decision as to whether it intends to file an action or proceeding against a material infringement or other violation (the "Notice") within thirty (30) days after the later of (i) MIOL's notice to Oscient under Section 11.4 above, or (ii) a written request from Oscient to take action with respect to such infringement (the "Notice Date") or, having given notice of its intention to file an action or proceeding, MIOL fails to initiate such action or proceeding or having done so fails to diligently prosecute such action or proceeding then Oscient (or LG) shall have the right (but not the obligation), at its own expense, to bring suit (or take other appropriate legal action) against such actual, alleged or threatened infringement, with legal counsel of its own choice. MIOL acknowledges that LG, as the person licensing certain of the Oscient Intellectual Property to Oscient, is entitled to be represented in suits or actions involving the Oscient Intellectual Property in the Territory, and to have its costs and expenses incurred in respect of such litigation reimbursed, pro rata with Oscient, from any damages, monetary awards, costs or other amounts recovered through such suits or actions, or settlement thereof; subject to any deductions required to be made in order to reimburse LG as aforesaid. Any damages, monetary awards, costs or other amounts recovered, whether by judgment or settlement, pursuant to any suit, proceeding or other legal action taken under this Section 11.5, shall applied as follows:

- (a) First, to reimburse Oscient, LG and MIOL for their respective costs and expenses (including reasonable legal fees, expert fees and other disbursements) incurred in prosecuting such enforcement action;
- (b) Second, to reimburse MIOL for MIOL's profits on lost sales associated with Finished Products and to reimburse Oscient for Oscient's profits on lost sales of Active Pharmaceutical Ingredient to MIOL and Additional Payments, Quarterly Royalties and milestone payments owing hereunder based on such lost sales;
- (c) Third, any amounts remaining shall be allocated as follows: (A) if Oscient is the Party bringing such suit or proceeding or taking such other legal action, one hundred percent (100%) to Oscient, (B) if MIOL is the Party bringing such suit or proceeding or taking such other legal action, one hundred percent (100%) to MIOL, and (C) if the suit is brought jointly, fifty percent (50%) to each of Oscient and MIOL.

If either of Oscient or MIOL brings any such action or proceeding hereunder, the other agrees to be joined as party plaintiff if necessary to prosecute such action or proceeding, and to give the Party bringing such action or proceeding reasonable assistance and authority to file and prosecute the suit; provided, however, that neither Oscient nor MIOL shall be required to transfer any right, title or interest in or to any property to the other, to any Sub-Distributor or any Third Party to confer standing on a Party hereunder.

The Party that controls the prosecution of any such action or proceeding shall also have the right to control settlement of such action; provided, however, that no settlement shall be entered into without the written consent of the other Party if such settlement would materially adversely affect the interests of such other Party.

11.6 Infringement of Third Party Patents.

If MIOL receives notice from a Third Party claiming that the importation of Active Pharmaceutical Ingredient into the Territory or the Exploitation of the Finished Product in the Territory by MIOL or its Affiliates or Sub-Distributors infringes or misappropriates any Patent Rights of such Third Party in any country in the Territory, MIOL shall promptly notify

Oscient and the Parties shall consult in good faith to determine the appropriate action to be taken in relation to such alleged infringement or misappropriation. MIOL shall have the first right, but not the obligation, through counsel of its choosing, to negotiate and obtain a license from such Third Party as necessary for MIOL and its Affiliates to import Active Pharmaceutical Ingredient into the relevant country and/or MIOL and its Affiliates, Sub-Distributors and Third-Party Manufacturers to Exploit the Finished Products in the Territory or the relevant country (a "Third Party License"). Oscient shall have the right, but not obligation, at its own expense, to participate in any such negotiations and to be independently represented by counsel of Oscient's own choice. MIOL shall conduct any negotiations with such Third Party in co-operation with Oscient, and shall not conclude any Third Party License without the prior written consent of Oscient, such consent not to be unreasonably withheld or delayed.

In the event that MIOL is required to pay a royalty based on Net Sales of the Finished Product pursuant to a Third Party License (a "Third Party Royalty"), Oscient shall during the Mandatory Supply Term, reimburse MIOL (or, if the Parties agree, pay to the Third Party directly), Quarterly in arrears an amount equal to fifty percent (50%) of the Third Party Royalty payable by MIOL with respect to the preceding Quarter; provided that the amount to be paid by Oscient with respect to any Quarter shall not exceed the lower of:

- (i) two and a half percent (2.5%) of Net Sales in that Quarter; and
- (ii) an amount equal to the product of (A) the Actual Weighted Average Price Per Tablet in that Quarter *minus* \$0.97, multiplied by (B) the number of Tablets sold by MIOL or its Affiliates or Sub-Distributors in that Quarter (as determined in accordance with Section 9.2).

If, with respect to one or more countries in the Territory, MIOL reasonably determines that it requires, but is unable to obtain a Third Party License on commercially reasonable terms, MIOL shall have the right to cease Commercialization in such country upon not less than ninety (90) days written notice to Oscient; provided that prior to serving any such notice, MIOL shall promptly notify Oscient in writing of such determination together will all relevant information with respect to such determination and the Parties shall consult in good faith to determine the appropriate action to be taken.

- 11.7 Right to Use Intellectual Property. MIOL acknowledges that it has no interest in, and agrees that it will not at any time assert or claim any interest in, nor register or attempt to register any form of intellectual property which would infringe or otherwise violate any of the Oscient Intellectual Property, and will cooperate with Oscient to secure Oscient's rights under the Oscient Intellectual Property in the Territory. All benefit and goodwill arising from MIOL's or Sub-Distributor's use of the Trademarks shall, as among the Parties, inure to the benefit of Oscient.
- 11.8 <u>Trademarks</u>. No right, title or interest of any kind in or to the Trademarks is transferred by this Agreement to MIOL, except the rights granted pursuant to Section 2.1. MIOL agrees that it will not, in the Territory, use, except in accordance with the terms hereof, or attempt to register, the Trademarks, or any marks similar thereto, in any language or adopt any trademark that is confusingly similar to or a colorable imitation of the Trademarks.

- 11.9 Patent Term Extensions. Oscient shall make all determinations as to whether to seek patent term extensions, including supplementary protection certificates and any other extensions that are now or become available in the future regarding the Licensed Patent Rights with respect to the Finished Product and MIOL shall not seek any such extensions or any extension of any other Patent Rights with respect to the Finished Product without Oscient's prior written consent. MIOL shall provide Oscient with a copy of any and all Marketing Authorizations within four (4) weeks of obtaining such Marketing Authorization(s), shall timely and in writing provide any other data reasonably required by Oscient to complete any applications for such patent term extensions and agrees to provide such assistance as Oscient may reasonably require in connection with such extensions.
- 11.10 <u>Further Assurance</u>. Each Party undertakes that all employees, consultants and agents shall be engaged on terms, recorded in writing, that provide that all discoveries and inventions conceived or reduced to practice by that individual as a result of or in connection with such engagement shall be promptly reported, fully disclosed, and assigned to the engaging Party. In the event that a patent application is filed directed to the subject matter of any such discovery or invention, any such assignment shall be promptly recorded in the appropriate patent office(s).

12. WARRANTIES

12.1 Oscient Warranties. Oscient warrants to MIOL that:

- (a) the execution and delivery of this Agreement and the performance of the transactions contemplated hereby have been duly authorized by all appropriate Oscient corporate action;
- (b) this Agreement is a legal and valid obligation binding upon Oscient and enforceable in accordance with its terms, and the execution, delivery and performance of this Agreement by the Parties does not conflict with any agreement, instrument or understanding to which Oscient is a party or by which it is bound;
- (c) Oscient has the full right and legal capacity to grant the rights granted to MIOL hereunder in the Territory without violating the rights of any Third Party;
- (d) Oscient is not aware of any Third Party patent, patent application or other intellectual property rights in the Territory that would be infringed (i) by using the Trademarks, or (ii) by making, using, distributing, offering for sale or selling the Finished Product; and
- (e) Oscient warrants exclusively to MIOL to manufacture the Active Pharmaceutical Ingredient in accordance with Applicable Law. Oscient warrants exclusively to MIOL that all Active Pharmaceutical Ingredient shipped in accordance with this Agreement: (i) shall meet Oscient's specifications for the shelf life of such Product when stored and handled in accordance with Oscient's labeled conditions, (ii) shall be manufactured in accordance with ICH Q7A and Applicable Law in effect at the time of manufacture, and (iii) shall conform with Oscient's specifications for the Finished Product. Subject to Section 14.1 (b), Oscient's sole obligation and MIOL's sole remedy under this warranty is replacement of any Active Pharmaceutical Ingredient or a refund of the purchase price that Oscient reasonably determines to be covered by this warranty.

12.2 MIOL Warranties. MIOL warrants to Oscient that:

- (a) the execution and delivery of this Agreement and the performance of the transactions contemplated hereby have been duly authorized by all appropriate MIOL corporate action;
- (b) this Agreement is a legal and valid obligation binding upon MIOL and enforceable in accordance with its terms, and the execution, delivery and performance of this Agreement by the Parties does not conflict with any agreement, instrument or understanding to which MIOL is a party of or by which it is bound.
 - (c) MIOL has the capacity to fulfill all its obligations under this Agreement.
- (d) MIOL warrants that it shall Manufacture, Commercialize and Develop the Finished Product in accordance with Applicable Law.

12.3 No Warranties.

- (a) Nothing in this Agreement is or shall be construed as:
- a warranty or representation by any Party as to the validity or scope of any patent application or patent licensed hereunder; or
- (ii) a warranty or representation that anything made, used, sold or otherwise disposed of under any license granted pursuant to this Agreement is or will be free from infringement of patents, copyrights, and other rights of Third Parties.
- (b) Except as expressly set forth in this Agreement, NO PARTY MAKES ANY REPRESENTATION OR EXTENDS ANY WARRANTIES OR CONDITIONS OF ANY KIND, EITHER EXPRESS OR IMPLIED. ALL OTHER WARRANTIES, CONDITIONS AND TERMS, EXPRESS OR IMPLIED BY OPERATION OF LAW, BY STATUTE OR OTHERWISE, WHETHER OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, OR OF NON-INFRINGEMENT OF ANY PATENT, COPYRIGHT, TRADEMARK, OR OTHER RIGHTS OF THIRD PARTIES, OR ANY OTHER EXPRESS OR IMPLIED WARRANTIES ARE HEREBY EXPRESSLY EXCLUDED TO THE MAXIMUM EXTENT PERMITTED BY APPLICABLE LAW.

13. PRODUCT RECALL

In the event that: (i) a Regulatory Authority or any other governmental agency or authority issues a request or orders that the Finished Product be recalled; (ii) a court of competent jurisdiction in the Territory orders that the Finished Product be recalled; or (iii) Oscient reasonably determines, after consultation with MIOL, that the Finished Product should be recalled or a notice is required relating to restrictions on use of the Finished Product, MIOL and Sub-Distributor shall attend to the same, as determined by the mutual agreement of Oscient and MIOL, and the Parties shall co-operate in a manner which is appropriate and take all appropriate corrective action. In the event such action results from: (a) Oscient's negligence or willful misconduct, Oscient shall be responsible for the expenses thereof or, if applicable, a proportionate share of such recall costs according to the extent to which Oscient is responsible, (b) MIOL's, its Affiliate's and/or Third-Party Manufacturer's and/or Sub-Distributor's negligence or willful misconduct, MIOL shall be responsible for the expenses

thereof or, if applicable, a proportionate share of such recall costs according to the extent to which they are responsible; and (c) otherwise, Oscient and MIOL shall share equally the expenses of the action. For purposes of this Agreement, the expenses of the action shall be the expenses of notification and return or destruction (if authorized by Oscient) of the Finished Product, the cost of replacement of the Finished Product, and any costs directly associated with the distribution of replacement Finished Product. Oscient, MIOL, Third-Party Manufacturer and Sub-Distributor shall cooperate fully with one another in carrying out such action.

14. INDEMNIFICATION

14.1 Indemnification.

- (a) MIOL Indemnity. MIOL shall indemnify, defend and hold harmless Oscient, its Affiliates and their respective directors, officers, employees, stockholders and agents and their respective successors, heirs and assigns (the "Oscient Indemnitees") from and against any liability, damage, loss or expense (including reasonable legal fees and expenses of litigation) incurred by or imposed upon such Oscient Indemnitees, or any of them, in connection with any Third Party claims, suits, actions, demands or judgments, including personal injury and product liability matters, to the extent arising out of (i) handling of the Active Pharmaceutical Product, or the Manufacture, Development or Commercialization of the Finished Product, by MIOL, its Affiliates, Third-Party Manufacturers or Sub-Distributors, or (ii) any material breach of this Agreement by MIOL, all except to the extent of Oscient's responsibility therefor under Section (b) below.
- (b) Oscient Indemnity. Subject to Section 14.1(a) above, Oscient shall indemnify, defend and hold harmless MIOL, its Affiliates and their respective directors, officers, employees, and agents, and their respective successors, heirs and assigns (the "MIOL Indemnitees"), from and against any liability, damage, loss or expense (including reasonable legal fees and expenses of litigation) incurred by or imposed upon such MIOL Indemnitees, or any of them, in connection with any Third Party claims, suits, actions, demands or judgments, including personal injury and product liability matters, to the extent arising out of (i) any material breach of this Agreement by Oscient, or (ii) any supply of Active Pharmaceutical Ingredient in violation of warranties set forth in Section 12.1(e).
- In the event that any Indemnitee is seeking Indemnification Procedures. indemnification under Section 14.1 above from a Party (the "Indemnifying Party"), the other Party shall notify the Indemnifying Party of such claim with respect to such Indemnitee as soon as reasonably practicable after the Indemnitee receives notice of the claim, and the Party (on behalf of itself and such Indemnitee) shall permit the Indemnifying Party (or if the Indemnifying Party is Oscient, LG) to assume direction and control of the defense of the claim (including the right to settle the claim solely for monetary consideration) and shall cooperate as requested (at the expense of the Indemnifying Party) in the defense of the claim. The indemnification obligations under Section 14.1 shall not apply to any harm suffered as a direct result of any delay in notice to the Indemnifying Party hereunder or to amounts paid in settlement of any claim, demand, action or other proceeding if such settlement is effected without the consent of the Indemnifying Party, which consent shall not be withheld or delayed unreasonably. The Indemnitee, its employees and agents, shall reasonably cooperate with the Indemnifying Party and its legal representatives in the investigation of any claim, demand, action or other proceeding covered by Section 14.1.

Insurance Covenant. From the Effective Date and for a period of five years after the termination of this Agreement, each Party shall obtain, and thereafter maintain, at its sole cost and expense, product liability insurance in amounts which are reasonable and customary in the U.S. pharmaceutical industry (with respect to Oscient) and the Territory (with respect to Menarini) for companies of comparable size and activities. Such product liability insurance shall insure against all liability arising as a result of administration of Finished Product to humans (including liability for personal injury, physical injury, and property damage). The Parties expressly agree that, for the period commencing as of the Effective Date and ending as of the fifth anniversary of the Effective Date, the reasonable and customary amount of product liability insurance shall be construed to be as follows: Primary coverage in the amount of at least ten million dollars (\$10,000,000) per occurrence and ten million dollars (\$10,000,000) in the annual aggregate. Each Party shall provide written proof of the existence of such insurance to the other Party promptly upon request. MIOL may self insure any or a portion of the above required insurance if (i) such self-insurance is effected through a captive insurance company duly authorized by an appropriate authority in a favorably recognized domicile; or (ii) MIOL can demonstrate to have proceeded with adequate accruals in its balance sheet destined only for product liability self-insurance.

15. TERM AND TERMINATION

- 15.1 <u>Termination Rights for Breach</u>. Subject to the other terms of this Agreement, this Agreement and the rights and options granted herein may be terminated (i) by Oscient upon any material breach by MIOL, or (ii) by MIOL upon any material breach by Oscient, of any material obligation or condition, effective thirty (30) days after giving written notice to the breaching Party of such termination, which notice shall describe such breach in reasonable detail. The foregoing notwithstanding, if such default or breach is cured or remedied or shown to be non-existent within the aforesaid thirty (30) day period, the notice shall be automatically withdrawn and of no effect.
- 15.2 <u>Termination for Bankruptcy</u>. In the event that either Oscient or MIOL files for protection under bankruptcy laws, makes an assignment for the benefit of creditors, appoints or suffers appointment of a receiver or trustee over its property, files a petition under any bankruptcy or insolvency act or has any such petition filed against it which is not discharged within sixty (60) days of the filing thereof, or any other analogous event occurs in any jurisdiction, then the other may terminate this Agreement effective immediately upon written notice to such Party.
- 15.3 Oscient Right to Terminate. Upon thirty (30) days' written notice to MIOL, Oscient shall have the right to terminate this Agreement if: (i) MIOL challenges the validity of any of the Oscient Intellectual Property, (ii) in the event that aggregate Net Sales in the Sales Year commencing on or after the third anniversary of the date of First Commercial Sale are less than \$50 million (calculated pursuant to Section 9.6); provided that MIOL has prior to the end of that Sales Year launched the Finished Product in at least three (3) Major Countries, (iii) if MIOL has applied for a Marketing Authorization by a Centralized Procedure, MIOL has not received Marketing Authorization on or before the third anniversary of the Effective Date, (iv) if MIOL has applied for any Marketing Authorization by a procedure other than the Centralized Procedure, MIOL has not received Marketing Authorization in at least two (2) of the Major Countries on or before the third anniversary of the Effective Date, (v) MIOL manufactures or has manufactured Active Pharmaceutical Ingredient, or purchases Active Pharmaceutical Ingredient from any Third Party, for Exploitation in the Territory, or (vi)

MIOL has not secured a Reimbursement Price of at least \$2.98 (after applying the Annual Calculated Exchange Rate in effect at such time) in at least one (1) of the Major Countries on or before the third anniversary of the Effective Date.

- MIOL Right to Terminate. Upon thirty (30) days' written notice to Oscient, MIOL 15.4 shall have the right to terminate this Agreement: (i) if, prior to MIOL submitting an application for a Marketing Authorization via the Centralized Procedure, the EMEA confirms to MIOL in writing before or after the scientific advice Procedure that (A) the Finished Product is not eligible for approval via the Centralized Procedure and/or (B) that the riskbenefit ratio for more than one of the proposed indications is not favorable, subject to the Minimum Labeling Requirements; (ii) in the event that MIOL has submitted an application for a Marketing Authorization via the Centralized Procedure, if (a) at any time following MIOL's response to the list of questions from the EMEA's Committee for Medicinal Products for Human Use ("CHMP"), customarily provided on day 120 of the Centralized Procedure, the CHMP or the CHMP's Rapporteurs for the Marketing Authorization application inform MIOL that the CHMP will adopt a negative opinion, recommending that the Commission do not grant a Marketing Authorization in accordance with the Minimum Labeling Requirements, or (b) if the CHMP in fact adopts any such negative opinion; or (c) the Commission has granted a Marketing Authorization not in compliance with the Minimum Labeling Requirements; (iii) in the event that MIOL has applied for any Marketing Authorization by a procedure other than the Centralized Procedure, if the Regulatory Authorities in at least three (3) Major Countries have refused to grant a Marketing Authorization in accordance with the Minimum Labeling Requirements; or (iv) if, within three (3) months of the date on which MIOL serves notice on Oscient pursuant to Section 9.2(d)(iii) above, the Parties are unable to establish a new minimum per Tablet price for the Actual Weighted Average Price Per Tablet; provided that in each case notice of such termination shall be served within thirty (30) days of the occurrence of the relevant trigger event and shall include reasonably satisfactory evidence of such event.
- 15.5 <u>Term</u>. The term of the agreement shall commence on the Effective Date and continue, until the fifth (5th) anniversary after the expiry of the Mandatory Supply Term (the "Initial Term"); provided that, MIOL may, prior to the expiry of the Initial Term, extend the term for an additional ten (10) years following the Initial Term upon not less than six (6) month written notice to Oscient (the "Extended Term" and together with the Initial Term, the "Term"); provided however, that, Oscient shall have no obligations under this Agreement during the Extended Term other than the granting of the Trademark and the Oscient Information license set forth in Sections 2.1(c). and 2.1(d).
- 15.6 <u>Termination of LG License</u>. This Agreement shall automatically terminate on the termination of the LG License. Provided that MIOL is not in breach of this Agreement on such termination or has committed willful misconduct with respect to this Agreement, Oscient hereby has furnished MIOL with a letter dated the date hereof from LG (the LG Warranty Letter") under which, if requested by MIOL in writing within thirty (30) days of such termination, LG shall have a direct relationship with MIOL concerning the subject matter of this Agreement at terms and conditions set forth in such LG Warranty Letter.

15.7 Effects of Termination.

(a) Upon termination of this Agreement for any reason, as of the effective date of such termination, all relevant licenses and sublicenses granted by Oscient to MIOL hereunder shall terminate automatically and MIOL shall and shall procure that and any Third-Party

Manufacturer and Sub-Distributor shall cease Manufacturing, Commercializing or Developing the Finished Product or using the Oscient Intellectual Property.

- (b) Upon termination of this Agreement for any reason (other than where LG and MIOL enter into the LG/MIOL Agreement pursuant to Section 15.6 herein), MIOL shall transfer, assign and fully release to Oscient, or its designee, at Oscient's expense, any and all Regulatory Approvals obtained by MIOL pursuant to this Agreement. For purposes of the foregoing, MIOL shall, on or before the expiry of ten (10) Business Days after such expiration or termination, transfer the Regulatory Documentation to Oscient and take all measures and execute such documents as Oscient considers necessary or reasonably useful to perfect the transfer of all Regulatory Approvals to Oscient or its designee. For the avoidance of doubt, no compensation shall be payable to MIOL for such transfer of Regulatory Approvals.
- (c) Upon termination of this Agreement, MIOL shall co-operate with Oscient in the cancellation of all or any licenses registered pursuant to this Agreement and shall execute such documents and do all acts and things as may be necessary to effect such cancellation.
- (d) Upon termination of this Agreement, MIOL shall immediately deliver to Oscient, or such other person as it may designate, all promotional material, including catalogues, Finished Product price lists, and any other documents or material (including any material delivered in electronic form and Confidential Information) provided by Oscient to MIOL or prepared or developed by MIOL with respect to the Finished Product or its Commercialization in the Territory.
- (e) For a period of one (1) year from termination of this Agreement, MIOL shall cooperate with Oscient, its representatives and agents, including any new distributor designated by Oscient in place of MIOL, in taking over the importing into the Territory of the Active Pharmaceutical Ingredient and the Commercialization of the Finished Product in place of MIOL.
- (f) From and after the termination of this Agreement, MIOL shall have a period of four (4) months to sell its remaining inventory of the Finished Product (with royalties and other fees to be paid to Oscient on all Net Sales of such Finished Products as provided for in Sections 9.3, 9.4 and 9.5, if applicable), provided it shall do so at a price not less than its market price in effect immediately prior to the termination.
- (g) From and after the termination of this Agreement, the Oscient license of MIOL Information set forth in Section 2.4 shall be expanded to allow Oscient to use and sublicense such information and data in the Territory.
- (h) MIOL agrees, upon Oscient request, to provide services for the continued Development of the Finished Product in the Territory in consideration for reasonable industry standard fees related to such regulatory Development services for a maximum period of two (2) years from termination of this Agreement,
- (i) If MIOL terminates the Agreement pursuant to Sections 15.4(i), or 15.4(ii), or 15.4(iii) herein, Oscient shall pay to MIOL all MIOL Development Expenses incurred by MIOL through such date of termination; provided that, the aggregate amount to be paid by Oscient for such MIOL Development Expenses at such date of termination shall not exceed

One Million Dollars (\$1,000,000) minus all amounts previously paid by Oscient pursuant to Section 9.7 above.

- 15.8 <u>Remedies</u>. Except as otherwise expressly set forth in this Agreement, the termination provisions of this Article 15 are in addition to any other relief and remedies available to the Parties at law.
- 15.9 <u>Surviving Provisions</u>. Notwithstanding any provision herein to the contrary, the rights and obligations of the Parties set forth in Sections 1.1 (to the extent applicable to other surviving provisions), 1.2, 2.5 (only for purposes of the perpetual license granted therein), 4.5, 8.1, 9.11, 10, 11.1, 11.7, 11.8, 14, 15.7, 15.8, 15.9, 16 and 18 (other than 18.21) as well as any rights or obligations otherwise accrued hereunder (including any accrued payment obligations), shall survive the expiration or termination of the Term. Without limiting the generality of the foregoing, MIOL shall have no obligation to make any milestone or royalty payment to Oscient that has not accrued prior to the effective date of any termination of this Agreement, but shall remain liable for all such payment obligations accruing prior to the effective date of such termination.

16. DISPUTES

16.1 <u>Negotiation</u>. The Parties recognize that a bona fide dispute as to certain matters may from time to time arise during the Term which relates to any Party's rights and/or obligations hereunder. In the event of the occurrence of such a dispute, any Party may, by written notice to the other Party, have such dispute referred to their respective senior officials designated below or their successors or designees, for attempted resolution by good faith negotiations within thirty (30) days after such notice is received. Said designated senior officials are as follows:

For MIOL: Managing Director

For Oscient: Chief Executive Officer

In the event the designated senior officials are not able to resolve such dispute within the thirty (30) day period, any Party may invoke the provisions of Section 16.2.

Arbitration. Subject to Section 16.1, any dispute, controversy or claim initiated by any Party arising out of, or in connection with this Agreement, or the performance by another Party of its obligations under this Agreement (other than bona fide third party actions or proceedings filed or instituted in an action or proceeding by a Third Party against a Party), whether before or after termination of this Agreement, including any question regarding its existence, validity or termination, shall be finally settled under the Rules of Arbitration of the International Chamber of Commerce of Paris by a panel of three arbitrators appointed in accordance with such Rules. Any such arbitration shall be held in London (UK) and the language of the arbitration shall be English. The arbitrators shall have the power to grant injunctions and/or specific performance and to allocate amongst the Parties the costs of arbitration in such equitable manner as they determine. Judgment upon any award rendered by the arbitration panel may be entered in any court having jurisdiction or application may be made to such court for judicial acceptance of any award and for an order of enforcement, as the case may be. In no event shall a demand for arbitration be made after the date when institution of a legal or equitable proceeding based upon such claim, dispute or other matter in question would be barred by the applicable statute of limitations. Notwithstanding the

foregoing, any Party shall have the right, without waiving any right or remedy available to such Party under this Agreement or otherwise, to seek and obtain from any court of competent jurisdiction any interim or provisional relief that is necessary or desirable to protect the rights or property of such Party, pending the selection of the arbitrators hereunder or pending the arbitrators' determination of any dispute, controversy or claim hereunder.

17. NON-COMPETITION

17.1 MIOL shall not and shall procure that its Affiliates and Sub-Distributors shall not directly or indirectly for a period of five (5) years from the date of the first Marketing Authorization, develop, import, market, promote, distribute, sell, offer for sale or otherwise exploit in such country of the Territory any (i) oral based anti-bacterial product falling in ATC class J01MA (which, for purposes of clarification, includes products which are members of the quinolone therapeutic class), or (ii) product that contains the Compound, except in each case Finished Product containing Active Pharmaceutical Ingredient supplied by Oscient pursuant to this Agreement ("Competitive Products"). The Parties hereby agree that the foregoing provisions of this Article 17 shall not apply to the products listed in Schedule 17.1 that are sold and/or marketed by MIOL or any MIOL's Affiliates in the Territory on the Effective Date.

In addition, MIOL shall not and shall procure that its Affiliates and their respective directors, officers and employees shall not directly or indirectly during the Term and for one (1) year thereafter, solicit any of Oscient's employees or take any action to cause or that might reasonably be expected to cause Oscient to lose any of its employees, agents, distributors, customers, customer contacts or other elements of its goodwill.

17.2 During the period beginning on the fifth anniversary of the date of the first Marketing Authorization, until the expiry of the Mandatory Supply Term, MIOL shall and shall procure that its Affiliates shall purchase from Oscient at least eighty 80% of the Active Pharmaceutical Ingredient required by MIOL in connection with the supply of the Finished Product or Competitive Products in the Territory.

18. MISCELLANEOUS

18.1 <u>Notification</u>. All notices, requests and other communications hereunder shall be in writing, shall be addressed to the receiving Party's address set forth below or to such other address as a Party may designate by notice hereunder, and shall be either (i) delivered by hand, (ii) made by facsimile transmission (to be followed with written fax confirmation), (iii) sent by international courier service providing evidence of receipt, or (iv) sent by airmail. The addresses and other contact information for the Parties are as follows:

If to Oscient:

Oscient Pharmaceutical Corporation

1000 Winter Street, Suite 2200

Waltham, MA 02451

Attention: Chief Executive Officer

With a copy to:

Oscient Pharmaceutical Corporation

1000 Winter Street, Suite 2200

Waltham, MA 02451

Attention: Legal

If to MIOL:

Menarini International Operations Luxembourg SA

1, Avenue de la Gare, L-1611 Luxembourg

Attention: Menaring Director

With a copy to:

A. Menarini Industrie Farmaceutiche Riunite Srl

3, Via Sette Santi

50131 Florence – Italy

Attention: Legal Affairs

All notices, requests and other communications hereunder shall be deemed to have been given either (i) if by hand, at the time of the delivery thereof to the receiving Party at the address of such Party set forth above, (ii) if made by telecopy or facsimile transmission, at the time that receipt thereof has been acknowledged by the recipient, (iii) if sent by international courier, on the day such notice is delivered to the recipient, or (iv) if sent by airmail, on the fifth (5th) Business Day following the day such mailing is made.

- 18.2 <u>Language</u>. This Agreement has been prepared in the English language and the English language shall control its interpretation.
- 18.3 Governing Law. This Agreement will be construed, interpreted and applied in accordance with the laws of England (excluding its body of law controlling conflicts of law).
- 18.4 Entire Agreement. This is the entire Agreement between the Parties with respect to the subject matter hereof and supersedes all prior representations, understandings and agreements whether written or oral between the Parties with respect to the subject matter hereof. Each Party confirms that, in agreeing to enter into this Agreement, it has not relied on

any representation, warranty, collateral contract or other assurance except those set out in this Agreement (and in respect of which the only remedy shall be for breach of contract) and to the extent any other representation, warranty, collateral contract or assurance was made to a Party, such Party waives all rights and remedies with respect thereto. Nothing in this Agreement will operate or limit to exclude a Party's liability for fraud. No modification of this Agreement shall be effective unless in writing with specific reference to this Agreement and signed by the Parties.

- 18.5 <u>Waiver</u>. The terms or conditions of this Agreement may be waived only by a written instrument executed by the Party waiving compliance. The failure of any Party at any time or times to require performance of any provision hereof shall in no manner affect its rights at a later time to enforce the same. No waiver by any Party of any condition or term shall be deemed as a continuing waiver of such condition or term or of another condition or term.
- 18.6 <u>Headings</u>. Article, Section and subsection headings are inserted for convenience of reference only and do not form part of this Agreement.
- 18.7 Assignment. Neither this Agreement nor any right or obligation hereunder may be assigned, delegated or otherwise transferred, in whole or part, by any Party without the prior express written consent of the others; provided, however, that Oscient may without the written consent of MIOL, assign this Agreement and its rights and delegate its obligations hereunder to its Affiliates, or in connection with the transfer or sale of all or substantially all of its assets or business, or in the event of its merger, consolidation, change in control or similar transaction. Any permitted assignee shall assume all obligations of its assignor under this Agreement. Any purported assignment in violation of this Section 18.7 shall be void. The terms and conditions of this Agreement shall be binding upon and inure to the benefit of the permitted successors and assigns of the Parties.
- 18.8 Force Majeure. No Party shall be liable for failure of or delay in performing obligations set forth in this Agreement (excluding any payment obligation under this Agreement), and no Party shall be deemed in breach of its obligations, if such failure or delay is due to natural disasters, labor strikes or any other form of industrial action, trade embargo, fire explosion, flood, act of God, civil disturbance, terrorism, pandemic, epidemic or any other cause beyond the reasonable control of such Party. In event of such force majeure, the Party affected thereby shall given prompt notice to the other Parties and use reasonable efforts to cure or overcome the same and resume performance of its obligations hereunder.
- 18.9 <u>Construction</u>. The Parties hereto acknowledge and agree that: (i) each Party and its counsel reviewed and negotiated the terms and provisions of this Agreement and have contributed to its revision; (ii) the rule of construction to the effect that any ambiguities are resolved against the drafting Party shall not be employed in the interpretation of this Agreement; and (iii) the terms and provisions of this Agreement shall be construed fairly as to all Parties hereto and not in favor of or against any Party, regardless of which Party was generally responsible for the preparation of this Agreement.
- 18.10 <u>Severability</u>. If any provision(s) of this Agreement are or become invalid, are ruled illegal by any court of competent jurisdiction or are deemed unenforceable under then current applicable law from time to time in effect during the Term hereof, it is the intention of the Parties that the remainder of this Agreement shall not be affected thereby. The Parties hereto covenant and agree to renegotiate any such term, covenant or application thereof in good faith in order to provide a reasonably acceptable alternative to the term, covenant or condition

of this Agreement or the application thereof that is invalid, illegal or unenforceable, it being the intent of the Parties that the basic purposes of this Agreement are to be effectuated.

- 18.11 Status. Nothing in this Agreement is intended or shall be deemed to create a relationship of co-venturers, partners, associates, principal and agent, master and servant, employer and employee, or any similar relationship between the Parties. MIOL shall perform its duties under the terms of this Agreement as an independent contractor acting as a principal for its own account. MIOL is not the representative of Oscient for any purpose and shall not have the power or authority as agent or in any other capacity to represent, act for, bind, or otherwise create or assume any obligation on behalf of Oscient for any purpose whatsoever. Neither MIOL nor Oscient has or shall represent or hold itself out to a Third Party as having power or authority to bind the other in any way.
- 18.12 Limitation of Liability. EXCEPT FOR ANY BREACH OF ANY CONFIDENTIALITY OBLIGATIONS OR THE PROVISIONS OF SECTION 7.5 HEREUNDER OR TO THE EXTENT CAUSED BY RECKLESSNESS OR WILFUL MISCONDUCT BY A PARTY, IN NO EVENT SHALL ANY PARTY BE LIABLE TO THE OTHER OR ANY OF THEIR AFFILIATES FOR LOSS OF REVENUE, LOSS OF ACTUAL OR ANTICIPATED PROFITS, LOSS OF BUSINESS OR LOSS OF GOOD WILL (WHETHER SUCH LOSSES WERE DIRECT OR INDIRECT OR FORESEEN OR FORESEEABLE) NOR FOR ANY CONSEQUENTIAL, INCIDENTAL, INDIRECT, SPECIAL, PUNITIVE OR EXEMPLARY DAMAGES SUFFERED OR INCURRED BY SUCH OTHER PARTY OR ITS AFFILIATES IN CONNECTION WITH A BREACH OR ALLEGED BREACH OF THIS AGREEMENT, WHETHER IN CONTRACT, WARRANTY, TORT, STRICT LIABILITY OR OTHERWISE.

18.13 Export Compliance.

- (a) MIOL shall be responsible for the importation of the Active Pharmaceutical Ingredient for the Finished Product into the Territory, in its name as importer of record, and shall obtain at its expense, all permits and authorizations, and shall comply with all customs laws, regulations and official standards applicable to such importation into the Territory and shall pay any customs duties and import fees associated therewith.
- (b) MIOL shall comply with all European and United States laws and regulations controlling the export of certain commodities and technical data, including all Export Administration Regulations of the United States Department of Commerce (collectively, "Export Control Laws"). Among other things, these Export Control Laws prohibit or require a license for the export of certain types of commodities and technical data to specified countries. MIOL hereby gives written assurance that it will comply with, and will cause its Affiliates, Third-Party Manufacturers and Sub-Distributors to comply with, all Export Control Laws, that it bears sole responsibility for any violation thereof by itself or its Affiliates Third-Party Manufacturers or Sub-Distributors, and that it will indemnify, defend, and hold Oscient harmless (in accordance with Article 14) for the consequences of any such violation.
- 18.14 Anti-Corruption. MIOL shall not and shall procure that none of its Affiliates, Third-Party Manufacturers or Sub-Distributors, or any of their respective employees, consultants or representatives make any payment, contribution or gift (including any payoff, bribe, rebate or kickback) to any official or employee of any government, Regulatory Authority or other agency or instrumentality of any government, or to any prescriber or potential prescriber of

the Finished Products for the purpose of obtaining Regulatory Approvals, medical reimbursement coverage, favorable treatment in securing or maintaining business, influencing prescribing decisions or influencing in any other way any act or decision of such person.

- 18.15 Further Assurances. Each Party agrees to execute, acknowledge and deliver such further instructions, 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. In particular, by way of security, MIOL shall on the date of notice of termination of the Agreement pursuant to Section 15 herein execute, or have executed by any Affiliate, a perpetual irrevocable power of attorney in favor of Oscient in the form set out in Exhibit B (the "Power of Attorney") to enable Oscient to effect the transfer, assignment and release of any and all Regulatory Approvals on termination of this Agreement for any reason. If requested by Oscient upon termination, MIOL shall, and shall procure that any Affiliate at that time holding a Marketing Authorization shall, execute such further documents as Oscient considers necessary or reasonably useful to enable Oscient or its designee, as the case may be, to effect the transfer, assignment and release of any and all Regulatory Approvals on termination of this Agreement for any reason.
- 18.16 <u>Counterparts</u>. This Agreement may be executed simultaneously in one or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.
- 18.17 Third Party Beneficiaries. None of the provisions of this Agreement shall be for the benefit of or enforceable by any Third Party, including any creditor of any Party whether pursuant to The Contracts (Rights of Third Parties) Act 1999 or otherwise. No such Third Party shall obtain any right under any provision of this Agreement or shall by reasons of any such provision make any claim in respect of any debt, liability or obligation (or otherwise) against any Party.
- 18.18 <u>LG</u>. MIOL acknowledges that certain rights granted pursuant to this Agreement are designed to enable Oscient to comply with its obligations to LG under the LG License. Without creating any direct relationship between MIOL and LG, MIOL shall permit Oscient to exercise its rights under this Agreement for the benefit of LG; provided that, OSCIENT represents and warrants that any Confidential Information of MIOL shall be treated by LG as per the terms of this Agreement.
- 18.19 Non-Solicitation. Until the one (1) year anniversary of the termination or expiration of this Agreement, no Party nor its respective Affiliates shall, and shall cause each of its Affiliates not to, directly or indirectly, without the other Parties' prior written consent, solicit the employment of any employee (or former employee bound by a non-competition obligation know to that Party) of the other Parties or their respective Affiliates with whom it has come in contact in conducting activities under this Agreement; provided, however, that the foregoing provisions shall not apply to a general advertisement or solicitation program that is not specifically targeted at such persons.
- 18.20 <u>United Nations Convention on Sale of Goods</u>. The United Nations Convention on Sale of Goods is hereby expressly excluded from application to this Agreement.
- 18.21 Additional Product Option.

- (a) Oscient hereby grants MIOL for the Mandatory Supply Term an exclusive option (the "Option") to acquire an exclusive sublicense for the Territory under the Licensed Patents Rights (and any other relevant patents to which Oscient has Control), to develop and commercialize Additional Products. Oscient shall notify MIOL in the event that it is planning to commercialize an Additional Product in the Territory (the "Notice"), and the Notice shall contain all relevant information available in connection therewith (provided that, any such information shall be deemed to be Confidential Information of Oscient for the purposes of Section 10.1 herein). MIOL will have thirty (30) days from the date of receipt of such Notice from Oscient to give written notice to Oscient of MIOL's election to exercise the Option, failing which the Option shall expire and be of no further force or effect. In the event that MIOL elects to exercise the Option, the Parties shall enter into good faith negotiations regarding the terms and conditions of such sublicense and further agree to negotiate economic terms that are fair and reasonable to both Parties.
- (b) In the event that the Parties fail to reach an agreement regarding the economic terms of such sublicense within ninety (90) days after MIOL's exercise of the Option (the "Negotiation Period"), then Oscient may offer any and all rights to such Additional Products to one or more Third Parties; provided, however, that, prior to consummating a transaction with a Third Party, Oscient shall offer to MIOL a right to acquire the sublicense on the same economic terms and conditions as agreed upon with the Third Party, if the economic terms for rights to the Additional Product are, in the aggregate, more favorable to such Third Party than the terms and pricing last offered to MIOL by Oscient. MIOL shall thereupon have thirty (30) days to accept such terms and conditions in which case, Oscient shall grant such sublicense to Menarini on such terms and conditions.

IN WITNESS WHEREOF, the Parties have caused this Agreement to be executed by their duly authorized representative in two (2) originals.

Luxembourg SA	CORPORATION
Ву:	By:
Title:	Title:

Licensed Patent Rights

TITLE	COUNTRY	APP. NO./ APP. DATE	PATENT/PUB. NO. GRANT/PUB. DATE	STATUS
Salt of	EUROPEAN (EP)	98908300.1	EP 0981527	Granted
Naphythyridine	EOROI EAIV(EI)	20MR1998	07MY2003	Granted
Carboxylic Acid	AUSTRIA (AT)	ZOIVIICI	ATE239724	Granted
Derivative Acid	AUSTRIA (AT)		07MY2003	Granied
Delivative	DELCHIM (DE)			Constal
	BELGIUM (BE)		EP 0981527	Granted
	DENMARK (DV)		07MY2003	Countril
	DENMARK (DK)		EP 0981527	Granted
	EDIL AND CEN		07MY2003 EP 0981527	Control
	FINLAND (FI)			Granted
	ED ANGE (ED)		07MY2003	0 1
	FRANCE (FR)		EP 0981527	Granted
	APPLICATION OF THE PROPERTY OF		07MY2003	-
	GERMANY (DE)		69814378	Granted
			07MY2003	
	GREECE (GR)		20030402691	Granted
			07MY2003	
	IRELAND (IE)		EP 0981527	Granted
			07MY2003	
	ITALY (IT)		EP 0981527	Granted
			07MY2003	
	LUXEMBOURG (LU)		EP 0981527	Granted
			07MY2003	
	THE NETHERLANDS		EP 0981527	Granted
	(NL)		07MY2003	
	PORTUGAL (PT)		EP 0981527	Granted
			07MY2003	
	SPAIN (ES)		EP 0981527	Granted
			07MY2003	
	SWEDEN (SE)		EP 0981527	Granted
			07MY2003	
	UNITED KINGDOM (GB)		EP 0981527	Granted
			07MY2003	
	MONACO (MC)		EP 0981527	Granted
			07MY2003	
	SWITZERLAND (CH)		EP 0981527	Granted
			07MY2003	
	ICELAND (IS)		IS 5181A	Granted
			07MY2003	
	NORWAY (NO)		NO 312515B	Granted
			07MY2003	

TITLE	COUNTRY	APP. NO./ APP. DATE	PATENT/PUB. NO. GRANT/PUB. DATE	STATUS
349003	ALBANIA		EP 0981527 07MY2003	Granted
	BULGARIA (BG)		BG 63972 B 07MY2003	Granted
	LATIVA (LV)		EP 0981527 07MY2003	Granted
	LIECHTENSTEIN (LI)		EP 0981527 07MY2003	Granted
	LITHUANIA (LT)		EP 0981527 07MY2003	Granted
	POLAND (PL)		P 335812 A 07MY2003	Granted
	SLOVENIA (SI)		SI0981527 07MY2003	Granted
	ROMANIA (RO)		EP 0981527 07MY2003	Granted
	MACEDONI, Former Yugoslav Republic (MK)		EP 0981527 07MY2003	Granted
	CZECH REPUBLIC (CZ)		CZ 288673B 07MY2003	Granted
	SLOVAKIA (SK)		SK 284107 B 08SE2004	Granted
	HUNGARY (HU)		HU200000728 28SE2000	Granted
Salt of Naphythyridine	EUROPEAN (EP)	01203507.7 20MR1998	EP 1179533 14JA2004	Granted
Carboxylic Acid Derivative	AUSTRIA (AT)		ATE257836 14JA2004	Granted
	BELGIUM (BE)		EP 1179533 14JA2004	Granted
	DENMARK (DK)		EP 1179533 14JA2004	Granted
	FINLAND (FI)		EP 1179533 14JA2004	Granted
	FRANCE (FR)		EP 1179533 14JA2004	Granted
	GERMANY (DE)		69821147 14JA2004	Granted
	GREECE (GR)		20040400648 14JA2004	Granted
	IRELAND (IE)		EP 1179533 14JA2004	Granted
	ITALY (IT)		EP 1179533 14JA2004	Granted
	LUXEMBOURG (LU)		EP 1179533 14JA2004	Granted

TITLE	COUNTRY	APP. NO./ APP. DATE	PATENT/PUB. NO. GRANT/PUB. DATE	STATUS
	THE NETHERLANDS (NL)		EP 1179533 14JA2004	Granted
	PORTUGAL (PT)		EP 1179533 14JA2004	Granted
	SPAIN (ES)		EP 1179533 14JA2004	Granted
	SWEDEN (SE)		EP 1179533 14JA2004	Granted
	UNITED KINGDOM (GB)		EP 1179533 14JA2004	Granted
	ICELAND (IS)	7952 14AU1999	IS 7952B 14JA2004	Granted
	MONACO (MC)		EP 1179533 14JA2004	Granted
	SWITZERLAND (CH)		EP 1179533 14JA2004	Granted
	ALBANIA		EP 1179533 14JA2004	Granted
	CZECH REPUBLIC (CZ)		CZ 288715B 14JA2004	Granted
	HUNGARY (HU)		HU 225412B1 28NO2006	Pending
	LATIVA (LV)		EP 1179533 14JA2004	Granted
	LITHUANIA (LT)		EP 1179533 14JA2004	Granted
	LIECHTENSTEIN (LI)		EP 1179533 14JA2004	Granted
	SLOVENIA (SI)		SI1179533 14JA2004	Granted
	ROMANIA (RO)		EP 1179533 14JA2004	Granted
	MACEDONI, Former Yugoslav Republic (MK)		P/EP-20040016 14JA2004	Granted
Quinoline Carboxylic Acid Derivatives Having 7-(4- amino-methyl-3- oxime)	EUROPEAN (EP)	95250143.5 14JE1995	EP 688772 06MY1999	Granted
	DENMARK (DK)	11021773	EP 688772 06MY1999	Granted
	FRANCE (FR)		EP 688772 06MY1999	Granted
Pyrrolidine Substituents &	GERMANY (DE)		69509442 06MY1999	Granted
Process for Their Preparation	ITALY (IT)		EP 688772 06MY1999	Granted
	NETHERLANDS (NL)		EP 688772 06MY1999	Granted

TITLE	COUNTRY	APP. NO./ APP. DATE	PATENT/PUB. NO. GRANT/PUB. DATE	STATUS
	SWEDEN (SE)		EP 688772 06MY1999	Granted
	UNITED KINGDOM (GB)		EP 688772 06MY1999	Granted
	SWITZERLAND (CH)		EP 688772 06MY1999	Granted
	LIECHTENSTEIN (LI)		EP 688772 06MY1999	Granted
Process for Preparing a	EUROPEAN (EP)	99906566.7 04MR1999	EP 1068182 08JE2005	Granted
Protected 4- Aminomethyl-	AUSTRIA (AT)	04WIK1999	AT297379T T 15JE2005	Granted
Pyrrolidin-3-one	BELGIUM (BE)		EP 1068182 08JE2005	Granted
	DENMARK (DK)		DK1068182T T3 04JL2005	Granted
	FINLAND (FI)		EP 1068182 08JE2005	Granted
	FRANCE (FR)		EP 1068182 08JE2005	Granted
	GERMANY (DE)		DE69925721T T2 23MR2006	Granted
	GREECE (GR)		EP 1068182 08JE2005	Granted
	IRELAND (IE)		EP 1068182 08JE2005	Granted
	ITALY (IT)		EP 1068182 08JE2005	Granted
	LUXEMBOURG (LU)		EP 1068182 08JE2005	Granted
	THE NETHERLANDS (NL)		EP 1068182 08JE2005	Granted
	PORTUGAL (PT)		EP 1068182 08JE2005	Granted
	SPAIN (ES)		ES2242382T T3 01NO2005	Granted
	SWEDEN (SE)		EP 1068182 08JE2005	Granted
	UNITED KINGDOM (GB)		EP 1068182 08JE2005	Granted
	ICELAND (IS)	5600 04MR1999	IS5600 22AU2000	Granted
	NORWAY (NO)	200004288 04MR1999	NO 317258B 27SE2004	Granted
	MONACO (MC)		EP 1068182 08JE2005	Granted

TITLE	COUNTRY	APP. NO./ APP. DATE	PATENT/PUB. NO. GRANT/PUB. DATE	STATUS
	SWITZERLAND (CH)		EP 1068182 08JE2005	Granted
	BULGARIA (BG)		BG 64674B 30NO2005	Granted
	SLOVENIA (SI)		EP 1068182 08JE2005	Granted
	ROMANIA (RO)		EP 1068182 08JE2005	Granted
	HUNGARY (HU)		HU200101094 A2 28AU2001	Granted
	POLAND (PL)		PL 343416 A 13AU2001	Granted
	LIECHTENSTEIN (LI)		EP 1068182 08JE2005	Granted
Process of Production of a	EUROPEAN (EP)	99950532.4 15SE1999	EP 1114050 30AU2006	Granted
Naphythyridine Carboxylic Acid	AUSTRIA (AT)		AT337315T T 15SE2006	Granted
Derivative (Methanesulfonate	BELGIUM (BE)		EP 1114050 23AU2006	Granted
Sesquihydrate)	DENMARK (DK)		DK1114050T T3 09OC2006	Granted
	FINLAND (FI)		EP 1114050 23AU2006	Granted
	FRANCE (FR)		EP 1114050 23AU2006	Granted
	GERMANY (DE)		DE69932938D D1 05OC2006	Granted
	GREECE (GR)		EP 1114050 23AU2006	Granted
	IRELAND (IE)		EP 1114050 23AU2006	Granted
	ITALY (IT)		EP 1114050 23AU2006	Granted
	LUXEMBOURG (LU)		EP 1114050 23AU2006	Granted
	THE NETHERLANDS (NL)		EP 1114050 23AU2006	Granted
	PORTUGAL (PT)		EP 1114050 23AU2006	Granted
	SPAIN (ES)		EP 1114050 23AU2006	Granted
	SWEDEN (SE)		EP 1114050 23AU2006	Granted
	UNITED KINGDOM (GB)		GB9820405D D0 11NO1998	Granted

TITLE	COUNTRY	APP. NO./ APP. DATE	PATENT/PUB. NO. GRANT/PUB. DATE	STATUS
	NORWAY (NO)		NO317997B B1	Granted
			17JA2005	
	MONACO (MC)		EP 1114050	Granted
			23AU2006	
	SWITZERLAND (CH)		EP 1114050 23AU2006	Granted
	LIECHTENSTEIN (LI)		EP 1114050 23AU2006	Granted
	POLAND (PL)		P3 46656 A1 25FE2002	Granted
	CZECH REP. (CZ)		PV2001-978 A3 16JA2002	Granted
	HUNGARY (HU)		P0103914 A2 28MR2002	Granted
Methods of use of	EUROPEAN (EP)	00948537.6	EP 1223935	Pending
Fluoroquinolone	ALICEPIA	29JE2000	24JL2002	
Compounds	AUSTRIA (AT)			
Against Bacteria	BELGIUM (BE)			
	DENMARK (DK)			
	FINLAND (FI)			
	FRANCE (FR)			
	GERMANY (DE)			
	GREECE (GR) IRELAND (IE)			
	ITALY (IT)			
	LUXEMBOURG (LU)			
	THE NETHERLANDS (NL)			
	PORTUGAL (PT)			
	SPAIN (ES)			
	SWEDEN (SE)			
	UNITED KINGDOM (GB)			
	MONACO (MC)			
	SWITZERLAND (CH)			
	CYPRUS (CY)			
	LIECHTENSTEIN (LI)			
Methods of Fluoroquinolone	EUROPEAN (EP)	00993844.0 31AU2000	EP 1401140 31MR2004	Pending
Compounds	AUSTRIA (AT)	211102000		
Against Bacteria	BELGIUM (BE)			
	DENMARK (DK)			
	FINLAND (FI)			
	FRANCE (FR)			
	GERMANY (DE)			
	GREECE (GR)			

TITLE	COUNTRY	APP. NO./ APP. DATE	PATENT/PUB. NO. GRANT/PUB. DATE	STATUS
	IRELAND (IE)			
	ITALY (IT)			
	LUXEMBOURG (LU)			
	THE NETHERLANDS			
	(NL)			
	PORTUGAL (PT)			
	SPAIN (ES)			
	SWEDEN (SE)			
	UNITED KINGDOM (GB)			
	MONACO (MC)			
	SWITZERLAND (CH)			
	ALBANIA (AL)			
	CYPRUS (CY)			
	LIECHTENSTEIN (LI)			
	LATIVA (LV)			
	LITHUANIA (LT)			
	SLOVENIA (SI)			
	ROMANIA (RO)			
	MACEDONI, Former			
	Yugoslav Republic (MK)			
Methods of use of Fluoroquinolone	EUROPEAN (EP)	05075938.0 22SE2000	EP 1561465 10AU2005	Pending
Compounds	AUSTRIA (AT)			4
Against Bacteria	BELGIUM (BE)			
	DENMARK (DK)			
	FINLAND (FI)			
	FRANCE (FR)			
	GERMANY (DE)			
	GREECE (GR)			
	IRELAND (IE)			
	ITALY (IT)			
	LUXEMBOURG (LU)			
	THE NETHERLANDS (NL)			
	PORTUGAL (PT)			
	SPAIN (ES)			
			-	
	SWEDEN (SE)			
	SWEDEN (SE) UNITED KINGDOM (GB)			
	UNITED KINGDOM (GB)			

TITLE	COUNTRY	APP. NO./ APP. DATE	PATENT/PUB. NO. GRANT/PUB. DATE	STATUS
Process for	EUROPEAN (EP)	00956706.6	EP 1212321	Granted
Production of	EUROPEAN (EP)	01SE2000	07JL2004	Gramed
Naphthyridine 3-	AUSTRIA (AT)	01022000	AT270671T T	Granted
Carboxylic Acid	1100111111(111)		15JL2004	O Lanve
Derivatives	BELGIUM (BE)		EP 1212321	Granted
	BBB of the (BB)		07JL2004	Cidino
	DENMARK (DK)		DK1212321T T3	Granted
			25OC2004	
	FINLAND (FI)		EP 1212321	Granted
			07JL2004	
	FRANCE (FR)		EP 1212321	Granted
			07JL2004	
	GERMANY (DE)		DE60012028T T2	Granted
			18AU2005	
	GREECE (GR)		EP 1212321	Granted
			07JL2004	
	IRELAND (IE)		EP 1212321	Granted
			07JL2004	
	ITALY (IT)		EP 1212321	Granted
			07JL2004	
	LUXEMBOURG (LU)		EP 1212321	Granted
			07JL2004	
	THE NETHERLANDS		EP 1212321	Granted
	(NL)		07JL2004	
	PORTUGAL (PT)		EP 1212321	Granted
			07JL2004	
	SPAIN (ES)		ES2223570T T3	Granted
			01MR2005	
	SWEDEN (SE)		EP 1212321	Granted
			07JL2004	,,,,,
	UNITED KINGDOM (GB)		GB9920919D D0	Granted
			10NO1999	
	NORWAY (NO)		NO20021043D D0	Granted
			01MR2002	
	MONACO (MC)		EP 1212321	Granted
			07JL2004	
	SWITZERLAND (CH)		EP 1212321	Granted
			07JL2004	
	CYPRUS (CY)		EP 1212321	Granted
			07JL2004	
	LIECHTENSTEIN (LI)		EP 1212321	Granted
	ar or my war are		07JL2004	
	SLOVENIA (SI)		EP 1212321	Granted
	DOLLAND (DT.)		07JL2004	
	POLAND (PL)		P354725A	Granted
	CAECH DED (CA)		09FE2004	C
	CZECH REP (CZ)		PV20020759 A3	Granted
	Committee of the second		12JE2002	

TITLE	COUNTRY	APP. NO./ APP. DATE	PATENT/PUB. NO. GRANT/PUB. DATE	STATUS
	HUNGARY (HU)	- IIII	P0202733 A2	Granted
(1)	and the second s		28JA2003	
Intermediates for	EUROPEAN (EP)	00958776.7	EP 1214321	Granted
the production of	Bottor E. II. (EL)	01SE2000	14JL2004	Grantea
Naphthyridine-3-	AUSTRIA (AT)		AT271050TT	Granted
Carboxylic Acid	rios riai (ili)		15JL2004	Oranica
Derivatives	BELGIUM (BE)		EP 1214321	Granted
			14JL2004	
	DENMARK (DK)		DK1214321T T3	Granted
			25OC2004	
	FINLAND (FI)		EP 1214321	Granted
			14JL2004	
	FRANCE (FR)		EP 1214321	Granted
	,		14JL2004	
	GERMANY (DE)		DE60012196T T2	Granted
			18AU2005	
	GREECE (GR)		EP 1214321	Granted
			14JL2004	-
	IRELAND (IE)		EP 1214321	Granted
			14JL2004	3000
	ITALY (IT)		EP 1214321	Granted
			14JL2004	
	LUXEMBOURG (LU)		EP 1214321	Granted
			14JL2004	
	THE NETHERLANDS		EP 1214321	Granted
	(NL)		14JL2004	
	PORTUGAL (PT)		PT1214321T T	Granted
			29OC2004	
	SPAIN (ES)		ES2223574T T3	Granted
			01MR2005	
	SWEDEN (SE)		EP 1214321	Granted
			14JL2004	
	UNITED KINGDOM (GB)		GB9920917D D0	Granted
			10NO1999	
	MONACO (MC)		EP 1214321	Granted
			14JL2004	
	SWITZERLAND (CH)		EP 1214321	Granted
			14JL2004	
	CYPRUS (CY)		EP 1214321	Granted
			14JL2004	
	LIECHTENSTEIN (LI)		EP 1214321	Granted
			14JL2004	
	SLOVENIA (SI)		EP 1214321	Granted
			14JL2004	
		0400.5	75 (44.00)	
Methods of use of	EUROPEAN (EP)	01985001.5	EP 1337252	Pending
Fluoroquinolone		08NO2001	16MY2002	

TITLE	COUNTRY	APP. NO./ APP. DATE	PATENT/PUB. NO. GRANT/PUB. DATE	STATUS
Compounds	AUSTRIA (AT)			
Against	BELGIUM (BE)			
Helicobacter	DENMARK (DK)			
Pathogenic	FINLAND (FI)			
Bacteria	FRANCE (FR)			
	GERMANY (DE)			
	GREECE (GR)			
	IRELAND (IE)			
	ITALY (IT)			
	LUXEMBOURG (LU)			
	THE NETHERLANDS			
	(NL)			
	PORTUGAL (PT)			
	SPAIN (ES)			
	SWEDEN (SE)			1
	UNITED KINGDOM (GB)			
	MONACO (MC)			
	SWITZERLAND (CH)			
	ALBANIA (AL)			
	CYPRUS (CY)			
	LATVIA (LV)			
	LIECHTENSTEIN (LI)			f-1
	LITHUANIA (LT)			
	MACEDONI, Former			
	Yugoslav Republic (MK)			
	ROMANIA (RO)			
	SLOVENIA (SI)			

TITLE	COUNTRY	APP. NO./ APP. DATE	PATENT/PUB. NO. GRANT/PUB. DATE	STATUS
Process for the	EUROPEAN (EP)	02755123.3		Pending
production of		04FE2004		
Amino Protected	AUSTRIA (AT)			
Derivatives of 4-	BELGIUM (BE)			
Aminomethylene-	DENMARK (DK)			
Pyrrolidin-3-One	FINLAND (FI)			
and/or 4- Aminomethylene-	FRANCE (FR)			
Pyrrolidin-	GERMANY (DE)			
3Alkoxyimino	GREECE (GR)			
Derivatives	IRELAND (IE)			
and/or	ITALY (IT)			
Gemifloxacin or a	LUXEMBOURG (LU)			
Salt Thereof	THE NETHERLANDS			
	(NL)			
	PORTUGAL (PT)			
	SPAIN (ES)			
	SWEDEN (SE)			
	UNITED KINGDOM (GB)	,		
	MONACO (MC)			
	SWITZERLAND (CH)			
	ALBANIA (AL)			-
	BULGARIA (BG)			***
	CYPRUS (CY)			
	CZECH REPUBLIC (CZ)			
	ESTONIA (EE)			
	LATVIA (LV)			-
	LIECHTENSTEIN (LI)			No. (Date No.
	LITHUANIA (LT)			
	MACEDONI, Former			
	Yugoslav Republic (MK)			
	ROMANIA (RO)			
	SLOVAKIA (SK)	1		
	SLOVENIA (SI)			

Out Fr

Composition of Matter Patent

EUROPEAN (EP) Patent: EP 688772

Title: Quinoline Canboxylic Acid Derivates Having 7-(4-Amino-Methyl-3-Oxime) Pyrolidine Substitutes & Process for their preparation

Filed: 14 June 1995

Expires: 14 June 2015

Minimum Label Requirements

1. Dosing:

once a day

5-day treatment of AECB and ABS, as the case may be
 maximum of 7-day treatment of CAP

2. Safety:

•no additional warnings, precautions, drug-to-drug interactions or adverse event information than currently listed on product label for FACTIVE for sale in the United States if such additional warnings, precautions, drug-to-drug interactions or adverse event information would reasonably be expected to have a significant impact on Menarini's ability to commercialize Factive in the EU

Specifications

ENI	SPC-	087-02	
Superse	des:	Page No.: I of I	
	OCT 1 3 2005		
Title: Gemil			
is:	Vendor Part Number:		
	70011392		
Inc.	Vendor Specification No.	umber:	
ture	36 Months		
	Recontrol Period: 24 Months		
Consideration		Method	
		Visual Examination	
		Nujol Mull or includes	
		mesylate counter-ion	
		00107	
		C8167	
On an anhydro	ous and solvent free basis		
Maria and			
		C8166	
NMT 1.5% PA	R		
		C8171	
NMT 0.1% w/s	W	CONT	
	*		
NMT 20 ppm		USP <231> method II	
NMT 0.1% w/s	w	USP <281> (1g of sample)	
4.0% -7.0% w	/w	USP <921> method la	
	ompared to the reference	TLC Test (result taken from	
	Title: Gemili Specification Gemifloxacin Might brown soil IR Spectrum c Retention time 98.0 – 102.0% On an anhydro NMT 0.1% PA NMT 0.1% PA NMT 0.1% PA NMT 0.5% wh NMT 0.5% wh NMT 0.5% wh NMT 0.5% wh	Supersedes: OCT 1 3 2005 Title: Gemifloxacin Mesylate —Petheon Se: Vendor Part Number: 70011392 Inc. Vendor Specification Note of the period: 36 Months Recontrol Period: 24 Months Specification Gemifloxacin Mesylate occurs as a white to light brown solid. IR Spectrum conforms to standard Retention time conforms to standard Retention time conforms to standard 98.0 – 102.0% of w/w On an anhydrous and solvent free basis NMT 0.2% PAR NMT 0.1% PAR NMT 1.5% PAR NMT 0.1% W/w NMT 0.5% w/w	

Confidential

Trademarks

Name	Country	Class	Application No.	Application Date	Registration No.	Registration Date	Status
FACTIVE	European Union (EU)	5	000950352	08OC1998	000950352	31JA2000	Registered
	Andorra (AD)	5	12191	19NO1998	11723	19NO1998	Registered
	Austria (AT)	5	AM2218/96	12AP1996	166024	30AU1996	Registered
	Benelux (includes Belgium, the Netherlands & Luxembourg)	5	861618	18DE1995	582148	18DE1995	Registered
	Denmark (DK)	5	VA199600283	16JA1996	VR199600791	02FE1996	Registered
	Finland (FI)	5	T199802485	21JL1998	214152	14MY1999	Registered
	France (FR)	5	95600030	07DE1995	95600030	07DE1995	Registered
	Greece (GR)	5	128137	31JA1996	128137	17MR1998	Registered
	Iceland (IS)	5	351-1996	12MA1996	1216/1996	25NO1996	Registered
	Ireland (IE)	5	95/8291	05DE1995	171292	05DE1995	Registered
Itali Mo (Mo Net Ant Noi (NO	Italy (IT)	5	MI95C012228	06DE1995	00733838	14NO1997	Registered
	Monaco (MC)	5	020534	17FE1999	99.20373	17FE1999	Registered
	Netherlands Antilles	5	D-900	24DE1998	21301	09FE1999	Registered
	Norway (NO)	5	200112664	25OC2001	215319	08AU2002	Registered
	Portugal (PT)	5	314842	15JA1996	314842	14OC1996	Registered
	Spain (ES)	5	2184599	18SE1998	2184599	05OC1999	Registered
	Sweden (SE)	5	95-14489	13DE1995	315811	09AU1996	Registered
	Switzerland (CH)	5	00225/1996	16JA1996	433454	30DE1996	Registered
	United Kingdom (GB)	5	2041126	13OC1995	2041126	13OC1995	Registered
	Bosnia & Herzegovina (BA)	5	BAZ983258A	24NO1998	BAZ983258	08DE2003	Registered
FACTIVE	Bulgaria (BG)	5	91821	29NO2006			Pending
	Croatia (HR)	5	Z960414A	12AP1996	Z960414	21JA1998	Registered
	Cyprus (CY)	5	44991	16AP1996	44991	16AP1996	Registered

Name	Country	Class	Application No.	Application Date	Registration No.	Registration Date	Status
FACTIVE	European Union (EU)	5	001721273	23JE2000	001721273	29MY2001	Registered
Device	Andorra (AD)	5		14JL2000	14905	14JL2000	Registered
	Austria (AT)	5	AM4560/2000	21JE2000	195230	04AP2001	Registered
	Iceland (IS)	5	2304/2000	29JE2000	1149/2000	01SE2000	Registered
	Monaco (MC)	5	022925	06JL2001	01.22636	06JL2001	Registered
	Netherlands Antilles	5	D-395	10JL2000	22486	01NO2000	Registered
	Norway (NO)	5	200007413	27JE2000	205945	07DE2000	Registered
	Switzerland (CH)	5	07922/2000	03JL2000	480382	18JA2001	Registered
	United Kingdom (GB)	5	2236543	20JE2000	2236543	20JE2000	Registered
	Bosnia &Herzegovina (BA)	5	BAZ004330A	23JE2000	BAZ004330	16SE2005	Registered
	Bulgaria (BG)	5	50649	29JE2000	40449	20SE2001	Registered
	Croatia (HR)	5	Z20001047A	21JL2000	Z20001047	21JL2000	Registered
	Cyprus (CY)	5	56960	03JL2000			Pending
	Czech Republic (CZ)	5	O-156893- 2000	27JE2000	233848	23MY2001	Registered
	Estonia (EE)	5	M200000991	07JL2000	34540	24AU2001	Registered
	Hungary (HU)	5	M0003577	05JL2000	168794	07FE2002	Registered
	Latvia (LV)	5	M-00-876	30JE2000	M47939	20JE2001	Registered
	Liechtenstein (LI)	5	11745	04OC2000	11745	04OC2000	Registered
	Lithuania (LT)	5	20001336	18JL2000	42208	14MR2001	Registered
	The former Yugoslav Republic of Macedonia (MK)	5	Z-20000901	19JL2000	9935	23FE2004	Registered
	Malta (MT)	5	31915	24JE2000	31915	06JL2000	Registered
	Poland (PL)	5	Z-220757	04JL2000	152927	04JL2000	Registered
	Romania (RO)	5	M200002847	27JE2000	42959	27JE2000	Registered
	Slovakia (SK)	5	1957-2000	04JL2000	197373	12NO2001	Registered
	Slovenia (SI)	5	Z-200071081	30JE2000	200071081	22FE2001	Registered
	Serbia and Montenegro (CS)	5	Z-645/2000	12JL2000	45897	18JE2003	Registered

Forecasted Marketing Plan

The following table summarizes the targeted number of calls forecasted as of the Effective Date by MIOL's or its Affiliates' sales force during the first three years following First Commercial Sale; provided that, approved label includes CAP, ABS and AECB with reference to MDRSP for each of the Major Countries.

Country	Relevant Competitor*	Registered number of calls (12 months ending June 05)	Target Calls - Launch Year	Target Calls – Year 2	Target Calls – Year 3
Germany	Bayer Avalox (moxifloxacin)	225.000	290,000	290.000	290.000
Italy**	GSK Levoxacin (levofloxacin)	360.000	940.000	825.000	800.000
Spain	Bayer Actira (moxifloxacin)	251.000	239.000	239.000	239,000
France	Bayer Izilox (moxifloxacin)	245.000	218.000	218.000	166.000
United Kingdom	Sanofi-Aventis (Tavanic (levofloxacin)	8.000	1.000	1.000	1.000

^{*}Total calls completed in the 12 month by the most relevant competitor in each country.

^{**2} Menarini companies

performed or claimed to be performed under it) is governed by and shall be construed in accordance with Luxembourg law and the Courts of Luxembourg shall have exclusive jurisdiction to hear and decide any suit, action or proceedings and/or settle any disputes which may arise in connection with this power of attorney or its formation or any act performed or claimed to be performed under it.

IN WITNESS whereof this power of atto-	
Executed as a deed by	*
Menarini International Operations tembourg S.A.	Ś
acting by	
Director	