18-02720-E

February 23, 2018

Dear SEC FOIA Office:

I am requesting a copy of
Exhibit 4A filed by Akzo Nobel NV Form 20-F on 04/29/2004.
I am willing to pay up to $61.00.

Thank you,

Diane Martin

AUS Consultants Inc.
155 Gaither Dr, Suite A
Mt. Laurel
NJ 08054
856.234.9200

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
STATION PLACE
100 F STREET, NE
WASHINGTON, DC 20549-2465

Office of FOIA Services

March 23, 2018

Ms. Diane Martin
AUS Consultants, Inc.
155 Gaither Dr., Suite A
Mt. Laurel, NJ 08054

RE: Freedom of Information Act (FOIA), 5 U.S.C. § 552
Request No. 18-02720-E

Dear Ms. Martin:

This letter is in response to your request, dated and received in this Office on February 23, 2018, for Exhibit 4(A) filed to the Form 20-F by Akzo Nobel N.V. on April 29, 2004.

The search for responsive records has resulted in the retrieval of 129 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 directly 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

Clarissa Anderson
FOIA Research Specialist

Enclosure

4(A)

CONFIDENTIAL TREATMENT REQUESTED BY AKZO NOBEL N.V.

CLEAN COPY

LICENSE AND COLLABORATION AGREEMENT

dated October 20, 2003

by and between

ORGANON (IRELAND) LTD.

and

PFIZER INC.

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LICENSE AND COLLABORATION AGREEMENT

This **License and Collaboration Agreement** (hereinafter the "Agreement"), is made this 20th day of October, 2003, by and between:

Organon (Ireland) Ltd., an Irish company, having an address at Churerstrasse 160b, Pfaffikon 8808, Switzerland (hereinafter "Organon"),

and

Pfizer Inc., a corporation organized under the laws of the State of Delaware, having an address at 235 East 42nd Street, New York, New York 10017-5755 (hereinafter "Pfizer").

WHEREAS, Organon is the owner of confidential data and know-how in relation to a pharmaceutical compound known as asenapine with the potential application, if successfully developed, approved by Regulatory Authorities (as defined below) and commercialized in product form, in the treatment of schizophrenia and bipolar disorders;

WHEREAS, Organon has identified the need for additional technical, commercial and financial resources which are not available within its own organization in order to carry out and complete the successful development, obtain Regulatory Approval and commercialize the Product (as defined below) and thus requires the collaboration of a party with appropriate expertise, resources and reputation in the central nervous system ("CNS") field;

WHEREAS, Pfizer has considerable experience in the research, development and commercialization of pharmaceutical products, particularly in the CNS field, and has the technical, commercial and financial resources to collaborate with Organon on the development of the Product, to obtain Regulatory Approval for and Launch (as defined below) the Product in accordance with the terms of this Agreement; and

WHEREAS, Organon and Pfizer have agreed to collaborate on the development and commercialization of the Product, all as more particularly described in, and subject to the terms and conditions of this Agreement.

NOW THEREFORE, the Parties mutually agree as follows:

ARTICLE 1

DEFINITIONS

Whenever used in this Agreement, unless otherwise clearly required by the context, the following terms will have the following meanings and will include both the singular and the plural.

1.1 **"Act"** means both the United States Food, Drug and Cosmetic Act, as amended from time to time, and the regulations promulgated under the foregoing.

1.2 **"ADME Study"** means the clinical study described in Schedule 1.2 to this Agreement.

1.3 **"Affiliate"** of a Party means any entity which, through ownership of a majority of shares or otherwise, either directly or indirectly, is in control of, controlled by or under common control with such Party, and for so long as such control shall continue. For the avoidance of doubt, neither of the Parties to this Agreement shall be deemed to be an "Affiliate" of the other solely as a result of their entering into this Agreement.

1.4 **"Agreement"** means this document, including the Schedules hereto, each of which is incorporated by reference herein.

1.5 **"Alliance Agreements"** means this Agreement, the Xanax Agreement, the Intermediate Supply Agreement, the Primary Packaged Product Supply Agreement, the Finished Product Supply Agreement and the Guaranty.

1.6 **"Application for Regulatory Approval"** means the foreign equivalent to an NDA in Countries of the Territory other than the United States.

1.7 **"Bankruptcy Code"** means 11 U.S.C §§ 101-1330, as amended.

1.8 **"beneficial ownership"** (and other correlative terms) by a Person means, with respect to any security: (i) such Person or any of such Person's subsidiaries directly or indirectly owns such security; (ii) such Person or any of such Person's subsidiaries has the right to acquire such security (whether such right is exercisable immediately or only after the passage of time) pursuant to any agreement, arrangement or understanding (whether or not in writing) or upon the exercise of conversion rights, exchange rights, rights, warrants or options, or otherwise; or (iii) ownership, direct or indirect, by any other Person with which such Person or any of such Person's subsidiaries has any agreement, arrangement or understanding for the purpose of acquiring, holding, voting or disposing of such security; provided, however, that a Person shall not be deemed to have beneficial ownership of any security by virtue of an agreement, arrangement or understanding to vote such security that arises solely from a revocable proxy or consent given to such Person in response to a public proxy or consent solicitation made pursuant to, and in accordance with, the applicable rules and regulations of the Securities Exchange Act of 1934, as amended.

1.9 **"Business Day"** means a day that is not a Saturday, Sunday or a day on which banking institutions in New York, New York or Geneva, Switzerland, are authorized by Law to remain closed.

1.10 **"Calendar Quarter"** means each of the periods ending on March 31, June 30, September 30 and December 31.

1.11 **"CCC"** means the Country Commercialization Committees described in Article 10.6.

1.12 **"CDRC"** means the Clinical Development/Regulatory Committee described in Article 10.3.

1.13 **"cGMP"** means the then-current Good Manufacturing Practices (i) in the Country where such manufacture occurs and (ii) in all of the Countries in which a Party is Developing,

Co-Promoting and/or otherwise marketing and selling the Product, as promulgated by the FDA and/or other Regulatory Authorities.

1.14 "Change in Control" means, with respect to a Party, an event described in (i), (ii), (iii) or (iv) where:

(i) Creation of New Control Person:

(a) solely with respect to Pfizer, any Person or group of Persons acquires beneficial ownership of Voting Stock of Pfizer entitling the holder(s) thereof to at least 40% of the voting power of the then outstanding Voting Stock of Pfizer; and

(b) solely with respect to Organon, any Person or group of Persons (other than Organon Parent and its subsidiaries) acquires or possesses beneficial ownership of Voting Stock of Organon or of any Organon Group Parent entitling the holder(s) thereof to at least 40% of the voting power of the then outstanding Voting Stock of Organon or such Organon Group Parent other than pursuant to a Permitted Transaction.

(ii) Loss of Existing Control: solely with respect to Organon:

(a) Organon Parent ceases to beneficially own Voting Stock of Organon or of any Organon Group Parent which has a majority of the voting power of the outstanding Voting Stock of Organon or such Organon Group Parent, other than pursuant to a Permitted Transaction or Qualified Split Off Transaction, and Organon or such Organon Group Parent, as applicable, is not Listed; or

(b) If Organon or any Organon Group Parent is Listed (in either case a "Listed Organon Entity") and such Listed Organon Entity enters into a merger, consolidation, reorganization or similar transaction (including a series of related transactions) with another Person as a result of which, immediately following such transaction (or series of transactions), less than a majority of the voting power of the then outstanding Voting Stock of the surviving entity of such transaction is beneficially owned by Persons who beneficially owned Voting Stock of such Listed Organon Entity immediately prior to such transaction or series of related transactions; provided, that (x) a Permitted Transaction shall not be deemed a "Change in Control" under this Article 1.14(ii) and (y) for purposes of this Article 1.14(ii) if any specific shares of Voting Stock which are beneficially owned by Organon Parent are also beneficially owned by any entity which is not a subsidiary of Organon Parent, then Organon Parent shall not be deemed to beneficially own such shares of Voting Stock.

(iii) Asset Sale: the Party sells to any Third Party in one or more related transactions properties or assets representing all or substantially all of the properties and assets of such Party or all or substantially all of its properties and assets relating to the business to which this Agreement pertains; it being understood and agreed that, if within any two-year period, the Organon Group was involved in any asset sale, share sale, merger or other transfer whereby at least 50% of the Organon Group (as measured from the beginning to the end of such two-year period based upon assets, net sales and/or net income under GAAP) was sold or otherwise transferred to any Third Party, then

Organon shall be deemed to have undergone a "Change in Control" under this Article 1.14(iii); or

(iv) Organon Parent Change of Control: solely with respect to Organon

(a) (1) any Person or group of Persons acquires or possesses beneficial ownership of Voting Stock of Organon Parent entitling the holder(s) thereof to at least 40% of the voting power of the then outstanding Voting Stock of Organon Parent or otherwise obtains (whether pursuant to any shareholder agreement, articles or other applicable constitutional documents or otherwise) the power to elect a majority of the board of directors (or other comparable body) of Organon Parent or obtains the right or power to nominate or elect directors (or other comparable persons) having, in the aggregate, a majority of the voting power of all directors (or comparable persons) on the board of directors (or other comparable body), of Organon Parent; or

(2) Organon Parent enters into a merger, consolidation, reorganization or similar transaction (including a series of related transactions) with another Person as a result of which, immediately following such transaction, less than a majority of the number of shares or the voting power of the then outstanding Voting Stock of the surviving entity of such transaction is beneficially owned by Persons who were shareholders of Organon Parent immediately prior to such transaction or series of related transactions; and

(b) (1) within 18 calendar months after such event such Person or group of Persons is or becomes a Competitor or becomes an Affiliate of a Competitor, or

(2) within 18 calendar months after such event any of the following occur, or Organon Parent or the acquiring or surviving entity, as applicable, publicly announces that any of the following is expected to occur:

(X) the resignation or removal of any two of the following individuals: President, Organon International, President, Organon USA Inc., Executive Vice President, Global Manufacturing and Quality Affairs or Senior Vice President, Global Research, as such positions are operationally defined from time to time within the Organon Group;

(Y) the divestiture of any material part of the Organon Group other than pursuant to a Permitted Transaction or a Qualified Split Off Transaction; or

(Z) actual pharmaceutical-specific research and development spending by the Organon Group, as a percentage of sales of the Organon Group, for the twelve month period following such event is less than such spending for the twelve month period immediately preceding such event by more than 15%.

1.15 **"Clinical QTc Study"** means the Product Study described on Schedule 1.15.

1.16 "Clinical Supplies" means Product for purposes of the Development of the Product, including placebo.

1.17 "Code" or **"Codes"** means the Code on Interactions with Healthcare Professionals promulgated by the Pharmaceutical Research and Manufacturers of America (PhRMA), the American Medical Association Guidelines on Gifts to Physicians, and the Department of Health and Human Services Office of Inspector General Compliance Program Guidance for Pharmaceutical Manufacturers, released April, 2003, as any of the foregoing may be amended, from time to time, and any comparable codes or guidelines in effect in each Country in the Territory.

1.18 "Co-Market" or "Co-Marketing" means, with respect to the Product, the separate marketing and sale in a Co-Marketing Country of the Product by Organon and Pfizer under separate and distinct trademarks.

1.19 "Co-Marketing Country" means each Country other than a Pfizer Exclusive Country or an Organon Exclusive Country in which Co-Promotion is not permitted under local Law, but in which Co-Marketing is permitted under local Law.

1.20 "Collaboration Intellectual Property" means all Technical Information and all confidential business and commercial information and trade secrets, in each case developed or acquired by either Party, or jointly by the Parties, or by their respective Affiliates, in the course of the Parties' and their respective Affiliates' activities pursuant to this Agreement.

1.21 "Collaboration Inventions" means any and all patentable inventions and discoveries, conceived and reduced to practice during the Term and arising out of the activities of the Parties or their respective Affiliates pursuant to this Agreement.

1.22 "Combination Product" means any Product which contains, in addition to the Compound, one or more other therapeutically active ingredients.

1.23 "Commercially Reasonable Efforts" means, those efforts and resources that Organon or Pfizer, respectively, would use were it developing, manufacturing, promoting and detailing its own pharmaceutical products which are of similar market potential as the Product, taking into account product labelling, market potential, past performance, economic return, the regulatory environment and competitive market conditions in the therapeutic area, all as measured by the facts and circumstances at the time such efforts are due. For the avoidance of doubt, in evaluating economic return, Pfizer shall not consider the Initial Fee, Event Milestone Payments and Performance Milestone Payments payable to Organon under this Agreement.

1.24 "Competing Product" means any prescription antipsychotic that is approved by FDA or EMEA for the treatment of schizophrenia or bipolar disorder other than (i) the Product, (ii) Geodon, and (iii) on a Country-by-Country basis prior to the initial Launch of the Product in a Country, and provided that Organon is then-detailing Risperdal in such Country, Risperdal.

1.25 "Competitor" means (a) a company having an interest in the pharmaceutical business that sells a Competing Product with aggregate annual sales, as reported by IMS or such other reliable third party data provider, of more than $300,000,000 in the last full calendar year prior to any event described in Article 1.14(iv)(b) or that has a Competing Product with that sales potential in Phase III development, or (b) any pharmaceutical company that, together with

its affiliates, has in excess of $3 billion of net sales, calculated on a worldwide basis, in the last full calendar year prior to any event described in Article 1.14(iv)(b).

1.26 "Compound" means the active pharmaceutical ingredient called asenapine as described in Schedule 1.26 in any chemical form, including without limitation, salts, solvates, metabolites, prodrugs, polymorphs and enantiomers.

1.27 "Confidential Information" means all trade secrets or other proprietary information, including without limitation any proprietary data and materials (whether or not patentable or protectable as a trade secret), regarding a Party's technology, products, business or objectives or regarding the Product, or Xanax or any improvements or changes to either product, that is disclosed by a Party to the other Party pursuant to the Alliance Agreements. Notwithstanding the foregoing, there shall be excluded from the foregoing definition of Confidential Information any of the foregoing that:

(i) was known by the receiving Party prior to its date of disclosure to the receiving Party as shown by the receiving Party's written records; or

(ii) either before or after the date of the disclosure to the receiving Party is lawfully disclosed to the receiving Party by a Third Party not in violation of any obligation to the disclosing Party; or

(iii) either before or after the date of the disclosure to the receiving Party becomes published or generally known to the public through no fault or omission on the part of the receiving Party or its Affiliates; or

(iv) is independently developed by or for the receiving Party without reference to or reliance upon the Confidential Information as demonstrated by contemporaneous written records of the receiving Party; or

(v) is required to be disclosed by the receiving Party to comply with applicable Laws, to defend or prosecute litigation or to comply with governmental regulations or the regulations or requirements of any internationally-recognized stock exchange or NASDAQ, provided that the receiving Party provides prior notice of such disclosure to the other Party (and takes reasonable and lawful actions to avoid and/or minimize the degree of such disclosure).

For the purpose of this Article 1.27 "Party" shall include Affiliates of such Party.

1.28 "Consensus Matter" means a matter that requires a decision by mutual agreement of the Parties pursuant to this Agreement.

1.29 "Control" or "Controlled" means, with respect to any intellectual property right, the possession (whether by ownership or license) by a Party (or by any Affiliate of a Party) of the ability to grant to the other Party a license under such right without violating the terms of any agreement with any Third Party.

1.30 "Conversion Date" shall have the meaning set forth in Article 6.8(ii)(a).

1.31 "Conversion Date Statement" shall have the meaning set forth in Article 6.8(iii).

1.32 "Co-Promotion" or **"Co-Promote"** means the joint marketing and promotion, including without limitation Detailing, of the Product under a single Trademark (where one Party is making sales) in the Co-Promotion Countries undertaken by a Party pursuant to the then-current Global Marketing Plan.

1.33 "Co-Promotion Criteria" means that, in any Country, a Party:

(i) has Sales Representatives able to provide no less than 30% of the agreed-upon Details for such Country as specified in the relevant Country Marketing Plan; and

(ii) has a local Affiliate with the ability to provide sales, marketing, medical, and other pharmaceutical product support services as is usual and customary in the pharmaceutical industry for such Country.

1.34 "Co-Promotion Country" or "Co-Promotion Countries" means those Countries listed on Schedule 1.33 as may be amended from time to time by the Parties in accordance with this Agreement; provided, however, that if either Party is prohibited by Law from doing business in any Country listed on Schedule 1.33, then, for so long as such prohibition remains in place, the other Party (provided that the other Party is not so prohibited) shall have the exclusive right to commercialize the Product in such Country.

1.35 "Cost of Goods" means (i) Manufacturing Costs, plus or minus, as applicable, (ii) Manufacturing Cost variances between the standard cost components of Manufacturing Costs and the actual costs incurred that such standard cost component(s) are intended to cover, (iii) Out-of-Pocket Costs directly related to shipping of finished Product to the final warehouse prior to sale of such Product to an unaffiliated Third Party in a Co-Promotion Country; and (iv) non-standard other cost of sales items such as process improvements (other than process development for the initial manufacturing process for the Product described in Schedule 9.8), obsolete inventory, inventory revaluation, and expense portion of capital projects, provided that such costs described in this subparagraph (iv) are agreed upon by the MSC.

1.36 "Country" or "Countries" means all of the countries in the Territory whether a Co-Promotion Country, Co-Marketing Country, Organon Exclusive Country, or Pfizer Exclusive Country; it being understood and agreed, in the event that any such Country is subdivided or otherwise partitioned, the definition of "Country" will include each such subdivided and/or partitioned geographical area and, for purposes of this Agreement, Details, Net Sales, and other obligations will be appropriately adjusted.

1.37 "Country Marketing Plan" means the marketing plan prepared by the CCC for the applicable Co-Promotion Country or group of Co-Promotion Countries.

1.38 "Current Product" means the Product in the current formulation which Product is currently being used by Organon in clinical trials and is being developed for the Initial Indications, all as of the Effective Date.

1.39 "Detail" means a face-to-face contact of either an Organon Sales Representative or a Pfizer Sales Representative, as the case may be, with a medical professional with prescribing authority during which scientific and/or medical information about the Product is discussed. A Detail does not include a reminder or sample drop. Details shall be

measured by each Party's internal recording of such activity; provided that, such measurement shall be on the same basis as the recording Party's measurement for its sales representatives detailing of such recording Party's other products, consistently applied throughout the Term. When used as a verb, the term "Detailing" means to engage in the activity of a Detail.

1.40 "Detail Requirement" means the number of Details that each Party's Sales Representatives are required to perform in each Co-Promotion Country in each Year of the Term pursuant to the Global Marketing Plan or Country Marketing Plan then in effect, subject to Schedule 1.40.

1.41 "Development" means, with respect to the Product, the performance of all pre-clinical, clinical and regulatory activities required to obtain Regulatory Approval of the Product in the Territory, all in accordance with the Development Plan. When used as a verb **"Develop"** means to engage in any such activities.

1.42 "Development Costs" means all Out-of-Pocket Costs incurred by a Party in connection with Product Studies pursuant to the Development Plan, including, without limitation, the following:

(i) the cost of materials used in the development of the Product (including clinical supplies, chemicals, animals and lab supplies);

(ii) .the costs for outside professional services, including, but not limited to, toxicology studies or clinical studies performed by Third Parties;

(iii) costs incurred in connection with regulatory submissions; and

(iv) costs for process development of the manufacturing process for the Product described in Schedule 9.8.

1.43 "Development Plan" means the written annual development plan which currently has as one of its goals the development of the Product with attributes as described in the Product Profile, including preclinical and clinical study plans and a corresponding budget for each such study, which plan may be amended from time to time in accordance with Article 10.3.

1.44 "Distribution Costs" means the direct, Out-of-Pocket Costs accrued or paid by Organon in connection with the shipment by Organon or its Affiliate of finished packaged Product to unaffiliated Third Parties in the Co-Promotion Countries.

1.45 "DOJ" means the United States Department of Justice.

1.46 "Effective Date" means the HSR Clearance Date.

1.47 "EMEA" means the European Agency for Evaluation of Medicinal Products, or any successor agency thereto.

1.48 "Estimated Development Costs" shall have the meaning set forth in Article 4.4.

1.49 "FDA" means the United States Food and Drug Administration, or any successor agency thereto.

1.50 **"Finished Product Supply Agreement"** means the agreement between Pfizer Export Company and Organon executed simultaneously with this Agreement by which Organon shall sell finished, packaged Product to Pfizer Export Company for sale by Pfizer Export Company or its Affiliate in the Pfizer Exclusive Countries and Co-Marketing Countries.

1.51 **"FTC"** means the United States Federal Trade Commission.

1.52 **"GAAP"** means, with respect to Pfizer, US generally accepted accounting principles, consistently applied, and with respect to Organon, International Financial Reporting Standards, consistently applied. All financial determinations made under this Agreement shall be made in accordance with GAAP.

1.53 **"GCC"** means the Global Commercial Committee described in Article 10.4.

1.54 **"Generic Competition"** shall exist during a given Pfizer Quarter or Calendar Quarter with respect to the Product in any Pfizer Exclusive Country, or Organon Exclusive Country in the Territory if, during such Pfizer Quarter or Calendar Quarter, one or more Generic Products shall be commercially available in such Country and shall have, in the aggregate in such Country, a [twenty] percent (20%) or more share of total sales of the aggregate of the Product and Generic Products based on data provided by IMS International, or if such data is not available, such other reliable data source as reasonably determined by Pfizer (or, in the Organon Exclusive Countries, reasonably determined by Organon) and agreed by Organon (or, in the Organon Exclusive Countries, agreed by Pfizer) (such agreement not to be unreasonably withheld) as measured by unit sales.

1.55 **"Generic Products"** means any pharmaceutical products (other than the Product commercialized by Organon and Pfizer pursuant to this Agreement) that contain the Compound and can reasonably be or are reasonably used for the same indication or indications as the Product.

1.56 **"Geodon"** means any human pharmaceutical product containing as an active ingredient the compound generically known as ziprasidone including, without limitation, the product presently promoted or sold under either the Geodon® or Zeldox® trademark.

1.57 **"Global Marketing Costs"** means Marketing Costs that are not incurred pursuant to a Country Marketing Plan and relate to cross-border activities including, but not limited to, cross-border advertising, Phase IIIb/Phase IV Product Studies (excluding Local Phase IIIb/ IV Product Studies) and are incurred by, the Parties centrally.

1.58 **"Global Marketing Plan"** means the proposed plan for commercialization of the Product in the Co-Promotion Countries, including, without limitation: (a) general strategies for the Detailing and marketing of the Product and allocation of responsibilities for marketing activities between the Parties; (b) each Party's Detail Requirement (subject to Schedule 1.40) and sampling activities, if any; (c) market and sales forecasts; (d) pricing and discounting analysis; (e) advertising, public relations and other promotional programs, including professional symposia and speaker and activity programs to be used in the Co-Promotion of the Product; (f) Phase IIIb/IV Product Studies; and (g) an annual budget for the activities described in the Global Marketing Plan.

1.59 **"Governmental Authority"** means any court, agency, department or other instrumentality of any foreign, federal, state, county, city or other political subdivision.

1.60 "group" will have the meaning as the term "group" is interpreted pursuant to Rule 13d-5 under the Securities Exchange Act of 1934, as amended.

1.61 "Guaranty" means the guaranty agreement dated the date hereof between Pfizer and Akzo Nobel N.V.

1.62 "HSR Act" means the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended (15 U.S.C. Sec. 18a), and the rules and regulations promulgated thereunder.

1.63 "HSR Clearance" means either (a) early termination of the applicable waiting period under the HSR Act with respect to the HSR Filings; or (b) expiration of the applicable waiting period under the HSR Act with respect to the HSR Filings.

1.64 "HSR Clearance Date" means, with respect to the HSR Filings, the earlier of (a) the date on which the FTC or DOJ shall notify Organon and Pfizer of early termination of the applicable waiting period under the HSR Act; or (b) the day after the date on which the applicable waiting period under the HSR Act expires.

1.65 "HSR Filings" means the filings by Pfizer and Organon with the FTC and the Antitrust Division of the DOJ of a Notification and Report Form for Certain Mergers and Acquisitions (as that term is defined in the HSR Act) with respect to the matters set forth in this Agreement, together with all required documentary attachments thereto.

1.66 "Improved Product" means any and all new developments or versions to the Current Product, that are made by or on behalf of either Party, including, but not limited to, Combination Products, New Indications, new formulations, new dosage forms, or new regimens and developments intended to enhance the safety and/or efficacy of the Product.

1.67 "Initial Indications" means the treatment of schizophrenia and bipolar disorders (including, without limitation, acute manic episodes associated with bipolar disorder) in humans.

1.68 "Interim Statement" shall have the meaning set forth in Article 6.8(iii).

1.69 "Intermediate" means the chemical substance designated as compound [5] on Schedule 9.8; provided, however that if the Parties agree that the chemical substance designated as compound [7] on such schedule is sufficiently stable to be shipped to Pfizer (or its Affiliate), then the Parties will discuss whether the Intermediate should be compound [7] rather than compound [5].

1.70 "Intermediate Supply Agreement" means the agreement between Pfizer Ireland Pharmaceuticals and Organon executed simultaneously with this Agreement by which Organon shall sell Intermediate to Pfizer Ireland Pharmaceuticals.

1.71 "JOC" means the Joint Operating Committee described in Article 10.7.

1.72 "Key EU Country" means any of the United Kingdom, France, Germany, Spain or Italy.

1.73 "Law" or **"Laws"** means all laws, statutes, rules, Codes, regulations, orders, decrees, judgments and/or ordinances of any Governmental Authority.

1.74 "Launch" means, on a Country by Country basis, the first shipment after the first Regulatory Approval and Price Approval of a Product in commercial quantities for commercial sale by a Party to an unaffiliated Third Party.

1.75 "Listed" means, with respect to any entity, shares of common equity of such entity are listed for trading on any internationally-recognized stock exchange or authorized for trading on NASDAQ ; provided that the market value of shares of such common equity held by Persons that are not Affiliates of such entity is at least $40,000,000.

1.76 "Local Phase IIIb/IV Product Studies" mean those Phase IIIb/IV Product Studies conducted solely in a Country and intended to be primarily used to support local marketing.

1.77 "Managed Care and Institutional Customers" means systems that integrate the financing and delivery of health care services to covered members including but not limited to: PBMs, HMOs, PPOs, Independent Physicians Associations (IPAs), Integrated Health Delivery System (IHDS), VA, DoD, GPOs.

1.78 "Major Market Countries" means the United States, France, Germany, Italy, United Kingdom, Spain, Japan and Canada.

1.79 "Major Market Country Forecast" means the forecast of Net Sales in each Major Market Country for each Year as initially determined by the Parties within 180-days after the Effective Date.

1.80 "Manufacturing Costs" means costs that relate to (i) Product supplied by an unaffiliated Third Party; or (ii) Product manufactured directly by a Party or an Affiliate of a Party. In the case of (i), Manufacturing Costs shall be a "standard cost" per unit, (calculated for each Year of the Term) which standard cost shall include (a) the amount paid to such Third Party, plus (b) the manufacturing Party's (i.e., the Party responsible for overseeing the manufacturing of the Third Party) direct and identifiable Internal Costs and Out-of Pocket Costs, which amounts shall be subject to the other Party's reasonable approval, incurred by the manufacturing Party in connection with quality assurance, supply chain management and similar activities comprising the manufacturing Party's oversight of the manufacturing process of the Third Party. In the case of (ii), Manufacturing Costs shall be a "standard cost" per unit, (calculated Yearly and at a time to align with the Parties internal budget processes) which standard cost shall include the cost of raw materials, labor, and other direct and identifiable variable costs and appropriate costs for equipment pools, plant operations and plant support services. The costs for plant operations and support services would include utilities, maintenance, engineering, safety, human resources, finance, plant management and other similar activities. The plant operations and support services costs would be allocated on a mutually agreed basis consistent with GAAP. Costs which cannot be identified to a specific activity supporting Product manufacturing, such as charges for corporate overhead which are not controllable by the manufacturing plant, shall not be included in standard cost. "Internal Costs" in Manufacturing Costs means a Party's and/or its Affiliate's costs and expenses related solely to direct and identifiable personnel compensation and benefits.

1.81 "Marketing Costs" means all Out-of-Pocket Costs paid or accrued by a Party pursuant to the Global Marketing Plan or a Country Marketing Plan and directly related to the

Co-Promotion of the Products in the Co-Promotion Countries, including those in connection with:

(i) Phase III(b)/IV Product Studies;

(ii) materials and programs used for ongoing training of Sales Representatives and of sales trainers;

(iii) advertising for the Products (including agency fees);

(iv) materials used in promoting the Products (including detail aids, leave-behinds and all other similar materials);

(v) patient samples and starter kits; and

(vi) marketing the products through any means (including, but not limited to, consumer directed advertising, journals, newspaper, radio, internet or place-based advertisements, promotional literature, market research, patient education, field and headquarters' grants, exhibits, direct mail, advisory boards, symposia, congress activities and dinner programs).

All other Out-of-Pocket Costs incurred in the Co-Promotion of the Products in the Co-Promotion Countries, but not specifically identified above, but which have been approved by the GCC or provided for in the Global Marketing Plan or a Country Marketing Plan, shall be accounted for and deemed Marketing Costs for all purposes of this Agreement

1.82 "Material Default" means:

(i) any default by any Party hereto of its representations or warranties or covenants, agreements or other performance obligations under this Agreement (other than a payment obligation) that, when aggregated with any other such uncured defaults by such Party, is (a) material to this Agreement taken as a whole, and (b) shall have continued for 60 days after written notice thereof was provided to the alleged defaulting Party by the non-defaulting Party (or, if such default cannot be cured within such 60 day period, if the alleged defaulting Party does not promptly commence and diligently continue all reasonable actions to cure such defaults during such 60 day period or does not cure in full such default within 90 days after written notice thereof was provided to the alleged defaulting Party); or

(ii) any default by any Party hereto of its payment obligations hereunder that shall have continued for 15 days after written notice thereof was provided to the alleged defaulting Party by the non-defaulting Party; provided that, in the event of a good faith payment dispute, such 15 day cure period shall be extended through the fifteenth day following the date on which such dispute is resolved if the alleged defaulting Party paid all undisputed amounts when due and provided the non-defaulting Party with a reasonably detailed written explanation of the alleged defaulting Party's basis for disputing the payment obligation within the 15 day period following the written notice of the default by the non-defaulting Party.

Notwithstanding anything to the contrary contained herein, for purposes of determining the existence of any "Material Default," no Party shall be deemed to be in material breach or material default if its actions or omissions resulted from (x) compliance with any decision of a committee or subcommittee under this Agreement that is mutually agreed to by the Parties, or (y) compliance with any Law or the express terms of this Agreement, or (z) any such Party's use of Commercially Reasonable Efforts.

1.83 "MSC" means the Manufacturing and Supply Committee described in Article 10.5.

1.84 "NDA" means a New Drug Application filed with the FDA with respect to the Product.

1.85 "Net Sales" means the gross sales of the Product that is due, or otherwise received by, a Party, or its Affiliates from unaffiliated Third Parties for such Product, less:

(i) credited allowances actually granted to such Third Party customers for spoiled, damaged, rejected, recalled, outdated and returned Product and for reasonable retroactive price reductions;

(ii) the amounts of trade and cash discounts actually allowed, to the extent such trade and cash discounts are specifically allowed on account of the purchase of the Product;

(iii) sales taxes, value added taxes, excise taxes, use taxes and import/export duties actually due or incurred in connection with the sales of the Product to any Third Party, and freight and insurance (to the extent that the Party bears the cost of freight and insurance for the Product); and

(iv) actual bad debts relating to the Product; adjustments, reimbursements, administration fees, discounts, chargebacks and rebates, in each case actually granted to Third Parties, including, but not limited to, rebates actually given to health care organizations or other Third Parties, and any bona fide payment made in respect of any sales of Product to any governmental or quasi-governmental body or agency, accruing on sales that took place during the Term.

Net Sales shall be determined from books and records maintained in accordance with GAAP, and shall not arise from sales of Product among either Party or their Affiliates or between its Affiliates and subcontractors.

1.86 "New Indication" means any indication for the Product other than the Initial Indications.

1.87 "New Indication Development Costs" means all Out-of-Pocket Costs incurred by Organon in connection with New Indication Development Studies

1.88 "New Indication Development Studies" means pre-clinical and clinical studies, including formulation studies, that are designed to support approval for marketing of a New Indication in the US Territory and/or any other Major Market Country.

1.89 "Noncompete Term" shall have the meaning set forth in Article 6.10.

1.90 "Organon Exclusive Countries" means all Countries in the Territory in which Organon has the exclusive right to make, use, sell, offer for sale, Detail and promote the Product.

1.91 "Organon Group" means the group of Affiliates of Akzo Nobel N.V. which are engaged in the ethical pharmaceutical business activities (known as the Organon business

unit), but explicitly excluding those businesses primarily devoted to vaccines (known as Nobilon), animal health (known as Intervet) and active pharmaceutical ingredients and biotech (known as Diosynth). As of the date hereof, the Organon Group consists of Organon USA Inc., Organon International Inc., N.V. Organon, Organon Nederland B.V., Organon Europe B.V., Horus B.V. and Organon Holding B.V and each of their respective direct and indirect subsidiaries.

1.92 "Organon Group Parent" means any of the following: Organon International Inc., Organon Espanola S.A., Organon Italia S.p.A., Organon USA Inc., N.V. Organon, Organon S.A., Organon GmbH and Organon Laboratories Ltd., and any successors to and assigns of all or substantially all of the business or assets of any such entity.

1.93 "Organon Parent" means Akzo Nobel N.V. and its successors; provided that, following a Qualified Split Off Transaction, Organon Parent shall mean the Split Off Parent.

1.94 "Organon Patent Rights" means all Patent Rights, now or hereafter during the Term, Controlled by Organon or its Affiliates, including without limitation Organon's interest in any Collaboration Inventions, relating to, or useful in connection with, the manufacture, use or sale of the Compound or the Product, including without limitation, the patents and patent applications set forth on Schedule 1.94.

1.95 "Organon Technical Information" means all scientific or technical information and related know-how and trade secrets now or hereafter during the Term Controlled by Organon or its Affiliates relating to the Compound or the Product or any developments or changes thereof (such as New Indications) or otherwise developed or acquired by Organon or its Affiliates in the course of the activities of Organon or its Affiliates under this Agreement, including but not limited to: (i) medical, clinical, toxicological, pharmacological, or other scientific data, and (ii) processes and analytical methodology used in the development, testing, analysis, manufacture or packaging of the Compound or the Product or any developments or changes thereto.

1.96 "Out-of-Pocket Costs" means costs and expenses paid or accrued to Third Parties, other than Affiliates or employees, by either Party after the Effective Date.

1.97 "Parent" means any corporation or other Person which, directly or indirectly, beneficially owns (i) at least 50% of the voting power of all outstanding capital stock or other ownership interests of any Organon Group entity or (ii) the right to receive at least 50% of the net assets of any Organon Group entity available for distribution to the holders of capital stock or other ownership interests upon a liquidation or dissolution of any Organon Group entity.

1.98 "Party" or "Parties" means Organon and Pfizer.

1.99 "Patent Rights" means the rights and interest in and to all issued patents and pending patent applications in any Country, including, without limitation, all divisionals, continuations, renewals, continuations-in-part, patents of addition, supplementary protection certificates, extensions, registration or confirmation patents and reissues thereof.

1.100 "Permitted Transaction" means a transaction as a result of which a Person or group of Persons (other than Organon Parent and its subsidiaries) acquires 40% or more of the voting power of the outstanding Voting Stock of Organon or any Organon Group Parent, but such Person or group of Persons (x) does not acquire or at any time possess beneficial

ownership of Voting Stock of Organon or of such Organon Group Parent having more voting power than the Voting Stock of Organon or such Organon Group Parent than that beneficially owned by Organon Parent, and (y) does not otherwise obtain or at any time possess (whether pursuant to any shareholder agreement, articles or other applicable constitutional documents or otherwise) the power to elect a greater number of directors (or other comparable persons) than that possessed by Organon Parent and/or any subsidiaries of Organon Parent or the right or power to nominate or elect directors (or other comparable persons) having, in the aggregate, any greater voting rights than the aggregate voting rights of the directors that Organon Parent and/or subsidiaries of Organon Parent have the right or power to elect or nominate.

1.101 "Person" means any natural person or any corporation, company, partnership, joint venture, firm or other entity, including without limitation a Party.

1.102 "Pfizer Exclusive Countries" means all Countries in the Territory that, as of the Effective Date, are neither Co-Promotion Countries nor Co-Marketing Countries, until such time, if at all, that such Countries become Organon Exclusive Countries.

1.103 "Pfizer Patent Rights" means all Patent Rights, if any, hereafter during the Term, Controlled by Pfizer or its Affiliates, including without limitation Pfizer's interest in any Collaboration Inventions, in each case relating to the Product, the Compound or the manufacturing thereof, that contain claims that would be infringed by the manufacture, use, sale, offer for sale, or importation of the Compound, Product, or any component thereof.

1.104 "Pfizer Technical Information" means all scientific or technical information and related know-how and trade secrets hereafter during the Term Controlled by Pfizer or its Affiliates relating to the Compound or the Product or any developments or changes thereof (such as New Indications) or otherwise developed or acquired by Pfizer or its Affiliates in the course of the activities of Pfizer or its Affiliates under this Agreement, including but not limited to: (i) medical, clinical, toxicological, pharmacological, or other scientific data and (ii) processes and analytical methodology used in the development, testing, analysis, manufacture or packaging of the Compound or the Product or any developments or changes thereto.

1.105 "Pfizer Quarter" means, in the US Territory, each of the four (4) thirteen (13) week periods as used by Pfizer in its audited financial reports, the first commencing on January 1 of any Year, and (b) outside the US Territory, each of the four (4) thirteen (13) week periods as used by Pfizer in its audited financial reports, the first commencing on December 1 of any Year.

1.106 "Pharmaceutical Company" means, with respect to any time at which the "Change in Control" is assessed, any of the leading 100 pharmaceutical companies as measured by trailing twelve (12) month sales of prescription pharmaceutical products and reported by IMS in the most recent global review of the pharmaceutical market.

1.107 "Phase III Clinical Study" means a Product Study with study design and statistical power intended to meet the requirement for Regulatory Approval.

1.108 "Phase IIIb/IV Product Study" means a clinical study designed to support the Product but not intended to be included as the basis of any regulatory filing for Regulatory Approval for marketing of the Product, or conducted as a condition of the Regulatory Approval from any Regulatory Authority for marketing of the Product.

1.109 "Price Approval" means, in Countries where governmental or regulatory authorities authorize for reimbursement, or approve or determine pricing for pharmaceutical products for reimbursement or otherwise, such authorization, approval or determination.

1.110 "Primary Packaged Product Supply Agreement" means the agreement between Pfizer Ireland Pharmaceuticals and Organon executed simultaneously with this Agreement, by which Pfizer Ireland Pharmaceuticals shall sell finished Product in primary packaging to Organon.

1.111 "Proceeding" means any suit, action or proceeding relating to this Agreement.

1.112 "Product" means, subject to Article 4.9, all human pharmaceutical formulations and dosage forms which contain the Compound either alone or in combination with other therapeutically active ingredients.

1.113 "Production Agreements" means the Intermediate Supply Agreement, the Primary Packaged Product Supply Agreement, and the Finished Product Supply Agreement, each of which is being entered into for the purpose of effectuating the worldwide collaboration between Pfizer and Organon as described in this Agreement.

1.114 "Product Profile" means the Product profile described in Schedule 1.114 hereto.

1.115 "Product Specifications" means the specifications for the manufacture and packaging of the Product consistent with the NDA and other Regulatory Approvals.

1.116 "Product Studies" means clinical, preclinical, safety, and other studies that are designed to support FDA or other Regulatory Authority approval for marketing of the Product. For the avoidance of doubt, Product Studies shall not include Phase IIIb/IV Product Studies.

1.117 "Qualified Split Off Transaction" means any transaction or series of related transactions in which the Organon Group is separated, in whole or in part, from Akzo Nobel N.V. (either as a stand-alone business unit or as part of or together with other business units of Akzo Nobel N.V. being so separated in such transaction or series of transactions) and, immediately after giving effect thereto,

(i) no Person or group of Persons other than Akzo Nobel N.V. and its subsidiaries beneficially owns Voting Stock of the Split Off Parent entitling the holder(s) thereof to at least 40% of the voting power of the then outstanding Voting Stock of the Split Off Parent except as contemplated by the definition of Permitted Transaction; and

(ii) Akzo Nobel N.V. does not beneficially own less than a majority of the voting power of the outstanding Voting Stock of the Split Off Parent except as contemplated by the definition of Permitted Transaction, unless the Split Off Parent is Listed.

1.118 "Rat and Mouse Carcinogenicity Studies" mean the rat and mouse carcinogenicity studies presently being performed by Organon.

1.119 "Regulatory Approval" means authorization granted by a Regulatory Authority to market and sell the Product in a Country in the Territory that is required before the Product may be commercially marketed and sold in such Country.

1.120 "Regulatory Authority" means any Governmental Authority with responsibility for granting any licenses or approvals necessary for the marketing and sale of pharmaceutical products including, without limitation, the FDA and any drug regulatory authority of countries of the European Union, and Japan, and where applicable any ethics committee or any equivalent review board.

1.121 "Scherer" means Cardinal Health Company 409 formely R.P. Scherer Corporation.

1.122 "Scherer Agreement" mean the License and Development Agreement between R.P. Scherer Corporation and Organon dated March 27, 1997.

1.123 "Scherer Patent Rights" means those Patent Rights owned or licensed by Scherer and are the subject of the license under the Scherer Agreement.

1.124 "Sales Representative" means an individual employee of a Party who engages in Detailing and other promotional efforts in the field with respect to the Product and who has been trained by either Party.

1.125 "Split Off Parent" means the ultimate Parent of any entities formerly within the Organon Group following a Qualified Split Off Transaction.

1.126 "Standstill Period" shall mean the period commencing on the Effective Date of this Agreement and terminating on the third (3rd) anniversary of such date.

1.127 "Steering Committee" means the Steering Committee described in Article 10.8.

1.128 "Supporting Information" means, with respect to each New Indication, the following:

(i) the NDA or other Application for Regulatory Approval, as applicable, including draft or final labelling, as the case may be, for such New Indication; and

(ii) all other material information regarding the toxicology, CMC data, safety and efficacy of such New Indication; status of discussions with FDA or any Governmental Authorities directly relating thereto; and any relevant patent information, all as of the date of the applicable Opt-In-Notice provided by Organon to Pfizer under Article 4.7; and

(iii) all Third Party Licenses relating to such New Indication.

1.129 "Technical Information" means Organon Technical Information or Pfizer Technical Information.

1.130 "Territory" means all territories and Countries of the world.

1.131 "Third Party" means any entity or person other than Pfizer or Organon or any of their respective Affiliates.

1.132 "Third Party License" means any agreement with a Third Party necessary to obtain a license or right to any intellectual property right owned or controlled by a Third Party in order to make, have made, use, sell, offer to sell, or import, the Product or, as applicable under Article 4.5, an Improved Product.

1.133 "Third Party License Fees" means any fees, royalties and/or other amounts paid to any Third Party under a Third Party License. For the avoidance of doubt, all consideration paid or due to Scherer and specified in Schedule 1.133 shall be deemed to be Third Party License Fees.

1.134 "Trademark" or "Trademarks" means, the trademark or trademarks selected by the JOC for use on the Product and/or accompanying logos, trade dress and/or indicia of origin, in each case as selected by the JOC.

1.135 "US Territory" means the United States, its territories, possessions and Puerto Rico.

1.136 "Valid Claim" means any claim from an issued and unexpired patent included within the Organon Patent Rights which has not been revoked or held unenforceable or invalid by a decision of a court or other Governmental Authority of competent jurisdiction, and which has not been disclaimed, denied or admitted to be invalid or unenforceable through reissue or disclaimer or otherwise.

1.137 "Voting Stock" means, with respect to any Person, any capital stock or other ownership interest in such Person which entitles the holder thereof to vote for the election of directors (or other comparable persons) of such Person.

1.138 "Year" means, with respect to the first Year, the period beginning on the Effective Date and ending on December 31 of such calendar year (the "First Year"), and (b) with respect to each subsequent Year the twelve (12) month period beginning on the day following the end of the First Year and each succeeding twelve (12) month period thereafter.

1.139 "Xanax" means the human pharmaceutical product containing as the sole active ingredient the compound generically known as alprazolam (in an extended-release formulation) presently promoted and sold in the United States under the XANAX XR® trademark.

1.140 "Xanax Agreement" means the agreement between Pfizer Inc. and Organon USA Inc., executed simultaneously with this Agreement and providing for the detailing of Xanax by Organon Pharmaceuticals USA Inc. pursuant to the terms of such agreement.

ARTICLE 2

SCOPE OF THE COLLABORATION

2.1 Organon Grants. Subject to the terms of this Agreement, Organon hereby grants to Pfizer, and Pfizer hereby accepts:

(i) an exclusive license under the Organon Patent Rights and Organon Technical Information, and under Organon's rights in Collaboration Intellectual Property, solely to develop, use, sell, offer for sale, import, and have imported Products in the Co-Promotion Countries and the Pfizer Exclusive Countries;

(ii) a co-exclusive (with Organon) license under the Organon Patent Rights and Organon Technical Information, and under Organon's rights in Collaboration Intellectual Property, to make or have made Products in the Territory, provided, however, that Pfizer's right to make or have made the Product in the Organon Exclusive Countries shall be limited to Product made in such Organon Exclusive Country for sale outside of the Organon Exclusive Countries; and

(iii) a co-exclusive license (with Organon) under the Organon Patent Rights and Organon Technical Information, and under Organon's rights in Collaboration Intellectual Property, to develop, use, sell, offer for sale, import, and have imported Products in the Co-Marketing Countries.

2.2 Pfizer Grants. Subject to the terms of this Agreement, Pfizer hereby grants to Organon, and Organon hereby accepts:

(i) the exclusive right to Develop and Co-Promote (including the right to sell) the Product together with Pfizer in the Co-Promotion Countries in addition to any rights under the Organon Patent Rights, Organon Technical Information and Organon's rights in Collaboration Intellectual Property as may be necessary for Organon to perform its obligations under and enjoy the benefits of this Agreement;

(ii) a co-exclusive right (with Pfizer) and license under the Pfizer Patent Rights and Pfizer Technical Information, and under Pfizer's rights in Collaboration Intellectual Property, solely to exercise Organon's rights and perform Organon's obligations under this Agreement with respect to the Product in the Co-Promotion Countries and Co-Marketing Countries; and

(iii) an exclusive license under the Pfizer Patent Rights and Pfizer Technical Information, and under Pfizer's rights in Collaboration Intellectual Property, solely to develop, use, sell, offer for sale, import, and have imported Products in the Organon Exclusive Countries.

2.3 Sublicenses. Either Party may sublicense any of its rights or obligations under this Agreement, directly or indirectly, in whole or in part to any of its Affiliates as it deems appropriate; provided that any such sublicensee must agree to be bound by the provisions of this Agreement. Notwithstanding the foregoing, the sublicensing Party shall remain fully responsible for all its obligations hereunder.

2.4 Distribution and Booking of Sales. Organon shall have title to all inventory of Product in the Co-Promotion Countries and be responsible for packaging such Product in final packaging, and distribution, invoicing, credit and collection for the Product in the Co-Promotion Countries. Organon will have the right to book all sales of Products in the Co-Promotion Countries.

2.5 Contract Sales Forces. Without the consent of the other Party, neither Pfizer nor Organon may use any contract sales force to Co-Promote (including to Detail) the Product in the Co-Promotion Countries.

2.6 Compliance With Law and Codes. Both Pfizer and Organon will market, promote and Detail the Products in accordance with applicable Law, the terms of this Agreement and, with the then-current Global Marketing Plan. Neither Party shall be required to undertake any action or inaction (including without limitation any Product Launch), or to incur expenditures in connection with any such action or inaction under this Agreement that it believes, in good faith, may violate any Law.

2.7 Training.

(i) Pfizer and Organon shall, each at its own expense, comply with any reasonable training plan contained in any Global Marketing Plan or Country Marketing Plan.

(ii) No later than eighteen (18) months before the first anticipated Product Launch in a Major Market Country which permits Co-Promotion, Pfizer and Organon will jointly develop sales training materials. Pfizer and Organon will thereafter cause their training personnel to train such persons with such training materials and Promotional Materials (as defined in Article 2.9 below). The Parties shall each receive reasonable quantities of training materials for marketing, Detailing and promoting the Product consistent with their Detail Requirements.

2.8 Product-Related Meetings. If a Party organizes Product-related meetings of its employees (such as launch meetings or periodic briefings of its Sales Representatives), it will make reasonable efforts to keep the Product-related portions of such meetings independent from other matters and to give the other Party advance notice of such meetings. If requested by the other Party, the Party organizing such meeting will permit representatives of the other Party to attend and participate in such meetings or such portions thereof which relate to the promotion of the Product, in either case at the other Party's sole cost and expense.

2.9 Promotional Materials. The Party's respective Sales Representatives will only utilize promotional, advertising, communication and educational materials (including all written, graphic, electronic, audio and video pieces and including journal advertisements, direct mail, direct to consumer advertising, internet postings, broadcast advertisements and sales aids (pens, cups, note pads and the like)) relating to the Product (collectively "Promotional Materials") and only conduct promotional activities for the Product which, in each case, have been approved in the Global Marketing Plan, a Country Marketing Plan, or otherwise by the GCC. All Promotional Materials must be consistent with the Global Marketing Plan and approved by the applicable CCC. In addition, promptly after the Effective Date, for the US Territory, and, as mutually agreed upon by the Parties, for other Co-Promotion Countries, the Parties will mutually agree upon procedures whereby designated representatives of each Party representing the marketing, legal, medical and regulatory functions, will meet, whether in

person, by telephone, or by videoconference, in order to conduct a review of all promotional activities (other than Detailing) and Promotional Materials prior to final approval thereof. Promotional Materials shall be allotted to each Party according to that Party's Detail Requirement for the applicable Year. All promotional activities conducted by the Parties' Sales Representatives shall be consistent with the Promotional Materials so approved and the then-current Global Marketing Plan.

2.10 Samples. Following Launch of the Product, Organon shall provide Pfizer with Product samples as required in the applicable Global Marketing Plan or Country Marketing Plan. Samples will be allocated fairly between the Organon sales force and Pfizer sales force in accordance with the number of Details the respective field forces are required to undertake as set forth in the Global Marketing Plan or Country Marketing Plan. Organon shall ship such samples to a central location designated by Pfizer. Organon and Pfizer shall use samples strictly in accordance with the then-current Global Marketing Plan or Country Marketing Plan and shall store and distribute all samples in full compliance, and otherwise fully comply, with all applicable Laws, including, in the US Territory, the requirements of the Prescription Drug Marketing Act of 1987, as amended (the "PDMA"). Pfizer and Organon each will maintain those records required by the PDMA and all other Laws with respect to the samples allocated to each of them. Organon and Pfizer shall be responsible for the filing of any necessary reports to FDA or other Regulatory Authorities in connection with the PDMA and other applicable Laws with respect to the samples allocated to each of them. Each Party will destroy any samples not distributed by its Sales Representatives at its sole expense.

2.11 Medical Inquiries. The GCC and CDRC will provide the Parties with information and materials relevant or appropriate to allow the Parties' medical and sales professionals, as appropriate, to respond to those medical questions or inquiries from the medical and paramedical professions and consumers relating to any FDA (or other Regulatory Authority) approved use of the Product. Each of the Parties will only use these materials, which shall be consistent with the relevant approved Product labeling, when answering such questions and inquiries so as to ensure that medical and sales professionals from both Parties are responding to such questions or inquiries in the same manner. The GCC and CDRC will provide the Parties with information, materials and instructions to allow medical professionals from both Parties to respond to medical questions or inquiries concerning matters not consistent with FDA (or other Regulatory Authority) approved Product labelling in accordance with the procedures for responding to unsolicited medical inquiry requests on off-label use, which procedures shall be agreed upon by the Parties.

2.12 Collaboration Principles. It is the intention of the Parties, as expressed in this Agreement and the Production Agreements, that, other than with respect to certain Development Costs as set forth in Article 4.4, each Party shall be responsible for fifty percent (50%) of the Marketing Costs, Distribution Costs, Development Costs and Cost of Goods in the Co-Promotion Countries, and will each be entitled to receive fifty percent (50%) of the Net Sales of the Product in the Co-Promotion Countries.

2.13 Commercially Reasonable Efforts. The Parties covenant and agree to use Commercially Reasonable Efforts with respect to carrying out each of their respective obligations under this Agreement.

ARTICLE 3

REPRESENTATIONS AND WARRANTIES

3.1 Representations and Warranties of Organon. Organon hereby represents, warrants as of the date hereof to Pfizer that:

(i) Organon (a) is a company validly existing and in good standing under the Laws of the Republic of Ireland, (b) is duly qualified and in good standing under the Laws of each jurisdiction where its ownership or lease of property or the conduct of its business requires such qualification, except where the failure to be so qualified would not have a material adverse effect on its financial condition or its ability to perform its obligations hereunder including any adverse effect on the Organon Patent Rights, Organon Technical Information, the Compound or the Current Product (an "MAE"), (c) has the requisite power and authority and the legal right to conduct its business as now conducted and hereafter contemplated to be conducted, (d) has or will obtain all necessary licenses, permits, consents and approvals from or by, and has made or will make all necessary filings with, all Governmental Authorities having jurisdiction over Organon, to the extent required for the ownership and operation of its business, except where the failure to obtain such licenses, permits, consents or approvals, or to make such notices, would not have an MAE, and (e) is and its Affiliates are in compliance with its applicable charter documents, with the power and authority to enter into each Alliance Agreement to which it is a party and to perform its obligations under such agreements;

(ii) The execution, delivery and performance of the Alliance Agreements to which it is a party by Organon and each of its Affiliates and all instruments and documents to be delivered by Organon hereunder and the consummation of the transactions contemplated hereby and thereby (a) are within the corporate power of Organon or the applicable Affiliate, (b) have been duly authorized by all necessary or proper action, (c) do not conflict with any provision of Organon's or the applicable Affiliate's charter documents, (d) will not violate any Law or regulation or any order or decree of any court or Governmental Authority, (e) except for filings pursuant to HSR Act, will not require any filing, permit, authorization, consent or other approval from any Governmental Authority or from any other person, firm or corporation, and (f) will not violate or conflict with any terms of any indenture, mortgage, deed of trust, lease, agreement, or other instrument (A) to which Organon or its applicable Affiliate is a party, or by which Organon or its applicable Affiliate or any of its or its applicable Affiliate's property is bound (including the Organon Patent Rights, Organon Technical Information, the Compound or the Current Product, but excluding the Scherer Patent Rights), or (B) to the actual knowledge of Organon and its Affiliates ("Organon's knowledge"), to which Scherer is a party which relates to Organon Patent Rights, Organon Technical Information, the Compound or the Current Product, which violation would have an MAE;

(iii) This Agreement has been duly executed and delivered by Organon and constitutes the valid, binding and enforceable obligation of Organon;

(iv) (a) The Organon Patent Rights, as set forth on Schedule 1.94, and Organon Technical Information licensed hereunder constitute all of the intellectual property and know-how under its and its Affiliates' control with respect to the manufacture, use, sale, offer to sell or import of the Compound and the Current Product;

(b) Organon is the legal and beneficial owner of all Organon Patent Rights (other than the Scherer Patent Rights) and all Organon Technical Information, and no other person, firm, corporation or other entity has any right, interest or claim in or to, and Organon has not entered any agreement (other than the Scherer Agreement) granting any right, interest or claim in or to, the Organon Patent Rights or Organon Technical Information; and (c) none of the Organon Patent Rights (other than the Scherer Patent Rights) (and to Organon's knowledge, none of the Scherer Patent Rights) are currently involved in any interference, reissue, reexamination, or opposition proceeding, and neither Organon nor any of its Affiliates has received any written notice from any Third Party of any actual or threatened claim or assertion to the contrary;

(v) To Organon's knowledge: (a) no Third Party is infringing any claims of any issued patents encompassed within the Organon Patent Rights with respect to the Product; and (b) the manufacture, use sale, offer to sell or import by Pfizer or Organon of the Compound or the Current Product does not and will not infringe the intellectual property rights of any Third Party. Neither Organon nor any of its Affiliates has received a notice, claim or assertion from any Third Party to the effect thereof, or that challenges or questions the right of Organon or its Affiliates to use any of the Organon Patent Rights or Organon Technical Information to manufacture, use, sell, offer to sell or import the Compound or the Current Product. Organon has furnished to Pfizer all material information in its possession requested by Pfizer as to the foregoing statements. The Organon Patent Rights include claims that by their terms would be infringed by making, having made, using, selling and having sold the Current Product in the Countries covered by the Organon Patent Rights. To Organon's knowledge, the issued or granted claims in the Organon Patent Rights and the Scherer Patent Rights are valid and enforceable.

(vi) None of the rights granted (or intended to be granted) to Pfizer by Organon hereunder, including without limitation the Organon Patent Rights (other than the Scherer Patent Rights) and the Organon Technical Information, are subject to any lien, charge, claim, pledge, security interest, charge, conditional sale agreement or other title retention agreement, lease, mortgage, security agreement, option or other encumbrance (including without limitation the filing of, or agreement to give, any financing statement under the Uniform Commercial Code of any jurisdiction in the US Territory or other comparable filing in any other Country in the Territory);

(vii) Schedule 1.94 sets forth a true and complete list of all Organon Patent Rights (other than the Scherer Patent Rights), and to the Organon's knowledge, a true and complete list of the Scherer Patent Rights;

(viii) Schedule 3.1(viii) contains a complete list of all material agreements with Third Parties relating to the development and manufacture of the Product. Organon has previously disclosed and provided complete copies to Pfizer of all such agreements, none of which have been modified, supplemented or amended;

(ix) There is no Proceeding pending with respect to the Organon Patent Rights (other than the Scherer Patent Rights), Organon Technical Information, the Compound or the Current Product, including without limitation to the conduct of any clinical trials, manufacturing activities or other activities relating to the transactions contemplated by the Alliance Agreements, or to Organon's knowledge, pending with respect to the Scherer Patent Rights. To Organon's knowledge, there is no Proceeding

threatened against Organon or Scherer or either of their Affiliates, with respect to the Organon Patent Rights, Organon Technical Information, the Compound or the Current Product, including without limitation to the conduct of any clinical trials, manufacturing activities or other activities relating to the transactions contemplated by the Alliance Agreements;

(x) The Scherer Agreement heretofore delivered by Organon to Pfizer together with all Development Programmes to the Scherer Agreement (which have not been amended in any respect) represents the complete agreement between and among Scherer and Organon and its Affiliates relating to the Compound and the Product including, without limitation, the manufacturing thereof. The Scherer Agreement is in full force and effect, all payments to date required to be made thereunder by Organon and its Affiliates, as applicable, have been made, and no default exists under the Scherer Agreement;

(xi) Organon has disclosed to Pfizer all material information known to Organon or its Affiliates relating to (i) the safety and efficacy of the Product and the Compound, (ii) the drug quality, including stability, variability, impurities and delivery performance in each case relating to the Compound, and (iii) the status of discussions with FDA or any Governmental Authorities directly relating to the Product and the Compound;

(xii) All manufacturing operations conducted by Organon and its Affiliates (or by Third Parties on their behalf) relating to the manufacturing of the clinical supplies of the Current Product are being conducted in material compliance with cGMP and other applicable requirements and standards of any Governmental Authority in which such manufacturing is being conducted; and

(xiii) Organon represents and warrants that Organon together with the entities listed in the definition of "Organon Group Parent" represent the companies through which Organon conducts its most significant marketing and research activities, and in the aggregate, comprise at least sixty five (65%) of the Organon Group (as measured from the beginning to the end of the most recently completed fiscal year based upon assets, net sales and/or net income under GAAP).

3.2 Representations and Warranties of Pfizer. Pfizer hereby represents, warrants as of the date hereof to Organon that:

(i) Pfizer (a) is a company validly existing and in good standing under the Laws of the State of Delaware, (b) is duly qualified and in good standing under the Laws of each jurisdiction where its ownership or lease of property or the conduct of its business requires such qualification, except where the failure to be so qualified would not have a material adverse effect on its financial condition or its ability to perform its obligations hereunder, (c) has the requisite power and authority and the legal right to conduct its business as now conducted and hereafter contemplated to be conducted, (d) has or will obtain all necessary licenses, permits, consents, or approvals from or by, and has made or will make all necessary notices to, all Governmental Authorities having jurisdiction over Pfizer, to the extent required for the ownership and operation of its business, except where the failure to obtain such licenses, permits, consents or approvals, or to make such notices, would not have a material adverse effect on its financial condition or its ability to perform its obligations hereunder, and (e) is in

compliance with its charter documents, with the power and authority to enter into the Alliance Agreements and to perform its obligations under such agreements;

(ii) The execution, delivery and performance of the Alliance Agreements by Pfizer and all instruments and documents to be delivered by Pfizer hereunder and the consummation of the transactions contemplated hereby and thereby (a) are within the corporate power of Pfizer, (b) have been duly authorized by all necessary or proper action, (c) do not conflict with any provision of Pfizer's charter documents, (d) will not violate any Law or regulation or any order or decree of any court or Governmental Authority, (e) except for filings pursuant to the HSR Act, will not require any filing, permit, authorization, consent or other approval from any Governmental Authority or from any other person, firm or corporation, and (f) will not violate or conflict with any terms of any indenture, mortgage, deed of trust, lease, agreement, or other instrument to which Pfizer is a party, or by which Pfizer or any of its property is bound, which violation would have a material adverse effect on its financial condition or on its ability to perform its obligations hereunder; and

(iii) This Agreement has been duly executed and delivered by Pfizer and constitutes the valid, binding and enforceable obligation of Pfizer.

3.3 Additional Covenants. Organon covenants and agrees with Pfizer that Organon shall maintain the Scherer Agreement in good standing and shall not take any actions (or omit or fail to take any actions) which would result in a material breach of the Scherer Agreement. Organon agrees that (i) it shall not amend, modify or supplement the Scherer Agreement, or (ii) agree to or consent to any amendment, modification or supplement to the Scherer Agreement in either case without the consent of Pfizer, which consent will not be unreasonably withheld. In addition, Organon shall not sell, assign, convey, pledge, hypothecate or otherwise transfer the Scherer Agreement or Organon's rights or obligations thereunder, or otherwise make any commitments in a manner that conflicts with Pfizer's rights hereunder without the consent of Pfizer, which consent will not be unreasonably withheld. Organon shall immediately notify Pfizer upon receipt by Organon or its Affiliates of any notice from Scherer of Scherer's intent to terminate the Scherer Agreement, exercise its respective rights or remedies thereunder, or otherwise take any action which may affect Pfizer's rights under this Agreement. Organon shall cause each of its Affiliates to comply with this Agreement and meet the obligations that such Affiliates may have to Pfizer.

3.4 Disclaimer of Warranties. NEITHER PARTY MAKES ANY REPRESENTATION OR WARRANTY OTHER THAN THOSE EXPRESSLY PROVIDED HEREUNDER AND EACH PARTY HEREBY DISCLAIMS ALL SUCH OTHER WARRANTIES, EXPRESS OR IMPLIED, INCLUDING WITHOUT LIMITATION ANY WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE OF THE PRODUCT. THE PARTIES UNDERSTAND AND AGREE THAT, NOTWITHSTANDING ANY OF THE REPRESENTATIONS AND WARRANTIES CONTAINED HEREIN, THERE ARE INHERENT RISKS ATTENDANT TO PHARMACEUTICAL PRODUCT DEVELOPMENT AND THEREFORE THERE CAN BE NO ASSURANCES THAT THE PRODUCT WILL RECEIVE REGULATORY APPROVAL IN ANY COUNTRY IN THE TERRITORY; IT BEING UNDERSTOOD AND AGREED, HOWEVER, THAT THIS SENTENCE SHALL NOT BE DEEMED TO ALTER OR OTHERWISE MODIFY ANY OF THE REPRESENTATIONS AND WARRANTIES CONTAINED HEREIN IN ANY WAY.

ARTICLE 4

PRODUCT DEVELOPMENT

4.1 Development Plan and Budgets. The Parties will jointly pursue the Development of the Product to attain the attributes as described in the Product Profile in accordance with the Development Plan, as such Product Profile may be revised by mutual agreement of the Parties pursuant to Article 10. The draft of the initial Development Plan is attached to this Agreement as Schedule 4.1. Such plan will be reviewed and modified as deemed appropriate by the CDRC commencing promptly after the Effective Date. Thereafter, the Development Plan will be reviewed by the CDRC at least every six (6) months and updated on at least an annual basis (or more frequently as may be determined by the CDRC). The Parties agree that beginning on the Effective Date, they will discuss those activities that are reasonably necessary for the Development of the Product, with Pfizer taking the lead and having the right to (a) propose the development strategy for the Product, (b) develop or modify, as applicable, all protocols for all Product Studies and, in coordination with the GCC, Phase IIIb IV Product Studies, (c) conduct and monitor, or engage a Third Party to conduct and monitor, all preclinical and clinical studies included in the Development Plan.

4.2 Completed and Ongoing Studies. Promptly after the Effective Date, Organon shall provide to Pfizer a list of the Product Studies that have been completed to date on the Product, as well as a list of those Product Studies that are in the process of being conducted.

4.3 Budget Planning. The Parties will on or before October 31 of each Year (commencing with the Second Year) determine the budget to be included in the Development Plan for the subsequent Year, and agree on a non-binding forecast for the subsequent Year.

4.4 Development Costs.

(i) Subject to this Article 4.4, all Development Costs incurred by the Parties in the Development of the Product, including Development Costs incurred by Organon prior to the Effective Date, will be shared fifty percent (50%) by Pfizer and fifty percent (50%) by Organon, provided, however, that Pfizer's share of Development Costs incurred by Organon prior to the Effective Date (the "Prior Development Costs") shall not exceed $10,000,000 USD in total. Promptly after execution of this Agreement, Organon shall provide Pfizer with supporting information setting forth, in detail, the then-current Prior Development Costs incurred by Organon and a forecast of additional Prior Development Costs that Organon expects to incur prior to the Effective Date. Within five (5) Business Days after the Effective Date, Organon shall provide Pfizer with a final accounting of the Prior Development Costs, and Pfizer shall have fifteen (15) Business Days to review such accounting. Within twenty (20) Business Days of receipt of such accounting, Pfizer shall pay, in accordance with Article 9.5, its fifty percent (50%) share of all such Prior Development Costs that are not in good faith disputed by Pfizer.

(ii) If Pfizer declines to exercise its rights to terminate this Agreement either under (x) Article 13.5(i)(c) based on the results of the Clinical QTc Study or (y) Article 13.5(ii)(a) based on the results of the ADME Study then, commencing with the date on which all of Pfizer's termination rights under those Articles have expired (the "Adjustment Date"), Development Costs for the Current Product for the Initial Indications will be shared sixty-five percent (65%) by Pfizer and thirty-five percent (35%) by Organon, and

such adjustment will also apply retroactively, subject to the limitation described in Article 4.4(i), for all Development Costs for the Current Product for the Initial Indications incurred by the Parties prior to the Adjustment Date.

(iii) If Pfizer has declined to exercise its right to terminate this Agreement under (x) Article 13.5(i)(c); and (y) Article13.5(ii)(a), then, within ten (10) Business Days of the Adjustment Date, Pfizer will send a written notice to that effect to Organon which notice shall identify any amounts due as a result of the retroactive application of the adjustment to the Parties' sharing of Development Costs set forth in subparagraph (ii) above (the "Adjustment Amount"). Within ten (10) Business Days of the date of such notice, Pfizer will pay Organon the Adjustment Amount in accordance with the provisions of Article 9.5.

(iv) The Parties have determined that the total Development Costs required to obtain a Regulatory Approval for a Product meeting the Product Profile in the Major Market Countries is three hundred and twenty million (US$320,000,000) (the "Estimated Development Costs"). The Parties agree that either Party may exceed the Estimated Development Costs by up to ten percent (10%) if such excess expenditure is necessary to comply with such Party's obligations under the then-current Development Plan, provided, however, that unless mutually agreed-upon by the Parties, neither Party shall be required to reimburse the other for any Development Costs incurred by the other Party in excess of one hundred and ten percent (110%) of such Party's share of the Estimated Development Costs.

4.5 Development of Improved Products. At the request of either Party, the Parties shall in good faith meet and discuss jointly developing Improved Products where preclinical and/or clinical results provide a reasonable basis for pursuing such additional development or the pursuit of such additional development is otherwise potentially commercially attractive. If the Parties agree to pursue such additional development, the Parties shall amend the Development Plan accordingly. If the Parties do not agree to pursue such additional development, then, neither Party shall have the right to pursue such development other than Organon's right to pursue development of a New Indication in accordance with Articles 4.6, 4.7 and 4.8.

4.6 New Indications. With respect to development of any New Indication that the Parties do not agree to develop jointly pursuant to Article 4.5, Organon shall have the right to pursue the development of such New Indication at its sole expense; provided, however, that (i) Organon's development of any such New Indication would not, based on the best available scientific evidence, be reasonably likely to have a materially adverse effect on the Product then being Co-Promoted by the Parties; and (ii) the Product for any such New Indications is sold under a trademark or trademarks other than the Trademark(s) (unless prohibited by the FDA or other Regulatory Authority, in which case the Trademark(s) may be used) and is developed and sold in a formulation and dosage strength that does not create a reasonable potential that the Product for such New Indication could be substituted by prescribers, dispensers and/or Third Party payers for any Product being Co-Promoted by the Parties (the "Substitution Product"). For the avoidance of doubt, it is understood that "reasonable potential" may include situations where the Substitution Product is marketed, promoted, distributed or sold for use other than for use in the Initial Indications (or any other indication then being Co-Promoted by the Parties), utilizing a different trademark from the Trademark(s), and where the Substitution Product is labeled for use in indications that are solely outside the field of psychiatric disorders. In furtherance of, but without otherwise limiting Organon's obligations pursuant to this Article 4.6,

Organon covenants and agrees that during the Term in each Country in the Territory, Organon shall not, and shall ensure that its Affiliates and licensees shall not, market, promote, distribute or sell any Product for a New Indication in a sublingual or buccal formulation with a 2.5 mg, 5 mg, 7.5 mg, 10 mg, 15 mg or 20 mg dosage strength.

4.7 Pfizer Opt-In Right. Subject to Article 4.8, if Organon or any of its Affiliates intends to directly or indirectly, market, sell, detail, promote or distribute the Product for a New Indication in any Country in the Territory at any time during the applicable Term, then, Organon shall provide Pfizer with notice to that effect (the "Opt-In Notice") within: (x) sixty (60) days after filing by Organon or any of its Affiliates of the first NDA or other Application for Regulatory Approval for such New Indication with FDA or other Regulatory Authority, as applicable; or (y) sixty (60) days after the acquisition by Organon or any of its Affiliates, whether by merger, acquisition, license, or other similar transaction, of the rights to the Product for a New Indication for which an NDA or other Application for Regulatory Approval, as applicable, has already been filed with or approved by the FDA or other Regulatory Authority. Such Opt-In Notice shall include the Supporting Information with respect to the New Indication as well as a detailed statement of the New Indication Development Costs. Pfizer shall have the option, exercisable at its sole discretion, but in no event later than ninety (90) days after Pfizer's receipt of the Opt-In Notice to notify Organon whether Pfizer elects to Co-Promote such New Indication with Organon in the Co-Promotion Countries (the "Election Notice"). If Pfizer elects to Co-Promote such New Indication with Organon in the Co-Promotion Countries:

(i) then Pfizer shall pay Organon one hundred twenty-five percent (125%) of the New Indication Development Costs for such New Indication as of the date of the Opt-In Notice in two (2) equal installments, the first within thirty (30) days of Organon's receipt of the Election Notice, and the second within 12-months after payment of the first installment; and

(ii) such New Indication shall be deemed a Product for all purposes under this Agreement and Co-Promoted under the same terms and conditions as the Current Product.

4.8 Sales for New Indications. If Pfizer does not elect to Co-Promote the Product for a particular New Indication with Organon pursuant to Article 4.5 or Article 4.7, and Organon Launches the Product for such New Indication in a Country in the Territory, Organon acknowledges that Launch of the Product for such New Indication may require that the Parties distinguish sales of the Product for such New Indication from sales of the Product for the Initial Indications (or any other indication for which the Parties are then Co-Promoting the Product). In order to allow for such distinction where necessary, after the Effective Date but prior to the Launch in the Territory of the first New Indication, the Parties will mutually agree upon a Third Party vendor (e.g., IMS, Verispan, etc.) which Third Party vendor shall periodically, but no less often than calendar monthly, measure, as accurately as is reasonably possible, in accordance with Schedule 4.8, sales of the Product in the Territory for New Indications. The agreement as to such Third Party shall not be unreasonably withheld or delayed by either Party and the Third Party named in Schedule 4.8 is hereby deemed approved by both Parties. For purposes of calculating Organon's payments to Pfizer pursuant to Article 9.1, Net Sales of the Product will be reduced by the percentage of Product sales reported for the applicable accounting period by such Third Party vendor as representing sales for New Indications not being Co-Promoted by the Parties. The determination of the Third Party as to the sales for any such New Indication shall be final and binding on the Parties, absent manifest error, and shall not be subject to audit under this Agreement. If due to changes made by Third Party vendors, available information, or

other unforeseen circumstances, the methodology set forth on Schedule 4.8 cannot be employed by the Parties, then the Parties shall mutually agree upon the use of an alternative vendor or methodology, as applicable, in order to accomplish the purpose described in this Article, and neither Party will unreasonably withhold or delay its agreement to any such alternative.

4.9 If the Parties do not agree to jointly develop the Product for a specific New Indication pursuant to Article 4.5 and Pfizer does not thereafter elect to Co-Promote the Product with Organon for such New Indication pursuant to Article 4.7, then, effective as of such time as Pfizer elects not to Co-Promote the Product for the specific New Indication in accordance with Article 4.7 (the "Organon-Only Product"), such Organon-Only Product will be excluded from the definition of "Product" hereunder (other than with respect to the calculation of payments owed to Pfizer pursuant to Article 9.1 as described above in Article 4.8 and other than with respect to the applicable provisions necessary for purposes of such calculation including, without limitation, Article 8A).

ARTICLE 5

MANUFACTURING AND SUPPLY

5.1 Production Agreements. The Parties acknowledge that on the date hereof each of them or their respective Affiliates are entering into the Production Agreements for, among other things, the manufacture of Products in accordance with the respective terms of the Production Agreements.

5.2 Supply Allocation. At any time following Launch in more than one Country, in the event that (a) the GCC and MSC agree that the availability of the Product shall be insufficient whether due to a shortage of Intermediate, or the Compound or otherwise, to meet the forecasted need for Product for the following Calendar Quarter as determined by the CCCs and aggregated by the GCC, or (b) availability of Product is in fact insufficient to fill orders on an ongoing basis, then the GCC and MSC shall confer to resolve such insufficiency. In the event the GCC and MSC cannot resolve such insufficiency, then (i) there shall be no further Launches of Product in any Country until the insufficiency is eliminated, (ii) to the extent the insufficiency continues, then all safety stock and sampling in any Country where the Product is sold will be utilized in sales in such Country, and (iii) to the extent the insufficiency still continues, then unless otherwise agreed, the available Product shall be allocated to the Countries where the Product is sold in proportion with the then-current forecasted sales for the Product in each such Country.

5.3 Manufacturing Process Plans. The Parties shall work together to monitor future requirements and the production capabilities of Organon and Pfizer to ensure the timely and adequate production of the Intermediate and the Product. In order to help ensure adequate supply of the Intermediate and the Product, the Parties shall, within ninety (90) days of the Effective Date, agree upon the existing development plan for the processes for manufacturing the Compound and the Product for the initial Launch of the Product (such processes, the "First Generation Process", and such plan, the "First Generation Process Plan"). The First Generation Process Plan will include, without limitation, all information required to support submission of the First Generation Process to the FDA and other Regulatory Authorities in accordance with the timeline agreed upon by the Parties. In addition, the Parties shall, within one hundred and eighty (180) days of the Effective Date, explore options for a commercially viable and technically feasible alternative process and then agree upon a corresponding

development plan for establishing an improved, or "second generation," process for manufacturing the Compound (such process, the "Second Generation Process", and such plan, the "Second Generation Process Plan"). The Second Generation Process Plan will have, as one of its objectives, the completion of work by the Parties, as such work is allocated in the Second Generation Process Plan, on the Second Generation Process, no later than the first date of an action by FDA or another Regulatory Authority which action could result in a Regulatory Approval for the Product. Each of the First Generation Process Plan and the Second Generation Process Plan shall allocate responsibilities for accomplishing the tasks set forth in such plan between Pfizer and Organon, and the Parties shall use all reasonable and diligent efforts to cooperate with each other, including, without limitation, sharing any of its Technical Information with the other Party, in order to successfully execute the applicable plan. Without limiting the foregoing, either Party may, at its own expense, undertake additional work on the manufacturing process for the Compound or the Product. If the Parties successfully develop a Second Generation Process that is acceptable to each Party, then the Parties will discuss sourcing strategies for implementing the Second Generation Process with the goals of (i) maintaining consistency with the principles set forth in the Production Agreements; and (ii) arriving at the most cost-effective manufacturing process reasonable achievable under the circumstances.

5.4 Capacity Plans. Promptly after the Effective Date, the MSC will (i) develop a standard for measuring Intermediate and Compound capacity at the Parties' (or their Affiliates' or subcontractors') manufacturing facilities, and (ii) develop a plan (the "Capacity Plan") designed to ensure that the capacity of the manufacturing facilities at which Organon or Pfizer or their respective Affiliates intends to manufacture or have manufactured the Intermediate and the Compound have optimum capacity to meet the forecasts set by the GCC and safety stocks agreed by the MSC. Unless otherwise established by the MSC, the following safety stocks will be kept: (a) six (6) months of Intermediate; (b) nine (9) months of Compound; and (c) two (2) months of Primary Packaged Product. Pfizer or its Affiliate will own title to and will keep the safety stocks of Intermediate, Compound and Primary Packaged Product. Pfizer will have the right to keep the safety stocks of Primary Packaged Product at a warehouse facility owned or leased by Organon or its Affiliates. The Capacity Plan will include timelines and milestone dates by which the Parties must establish that the Intermediate, Compound and Primary Packaged Product can be manufactured at the forecasted scale. Each Party shall be responsible for having the agreed-upon capacity installed at those manufacturing locations owned by such Party, its Affiliate or subcontractor, provided, however, that the Parties shall mutually agree upon investments in capacity at Scherer. In addition, each Party or its Affiliate will be responsible for securing commercial and/or quality agreements, as applicable, for raw materials or services, as necessary under the circumstances, in order for such Party or its Affiliate to carry out its obligations under the Production Agreements.

5.5 Release Testing. Each Party will be responsible for release testing and the release of the Product (or component thereof), for that portion of the supply chain for which such Party is responsible.

ARTICLE 6

COMMERCIALIZATION

6.1 Co-Promotion. Upon obtaining Regulatory Approval and Price Approval in a Co-Promotion Country, the Parties shall use Commercially Reasonable Efforts to Launch and

Co-Promote the Product in such Co-Promotion Country in accordance with the Global Marketing Plan and the applicable Country Marketing Plan.

6.2 Detail Requirements. Subject to Schedule 1.40 to this Agreement, the Global Marketing Plan, and the applicable Country Marketing Plan, the Parties will develop, review and mutually agree upon appropriate Detailing efforts regarding targets, call frequency, and other sales force deployment issues in order to achieve sales objectives consistent with the forecasts developed by the GCC with input from the CCCs. Such efforts are to be reviewed and updated by the Parties at least on an annual basis. Commencing with the first Launch of the Product in the US Territory until the second anniversary of such Launch, Pfizer Sales Representatives in the US Territory will be instructed to Detail the Product in the first or second position to all prescribers who are in the top twenty percent (20%) of prescribers of antipsychotic drugs as determined by Pfizer, through the use of reputable third party data, consistent with the manner in which Pfizer makes such determinations for its own similar products (the "High Prescribers"). However, during the initial six (6) months after first Launch of the Product in the US Territory, such Pfizer Sales Representatives may be instructed to Detail the Product to such High Prescribers in the third position provided that such instructions are based on Pfizer's reasonable judgment that Detailing the Product in the third position would give such Detail the greatest emphasis during the particular call.

6.3 Marketing Costs. In each Co-Promotion Country during each Year of the Term, Pfizer will be responsible for fifty percent (50%) of the Marketing Costs, and Organon will be responsible for fifty percent (50%) of the Marketing Costs. Such Marketing Costs shall be reflected in the Parties' Quarterly Marketing Cost Reports pursuant to Article 8A.1. Pfizer shall be solely responsible for all Out-of-Pocket Costs and other costs solely related to the marketing and promotion of Product in any Pfizer Exclusive Country, and Organon shall be solely responsible for all Out-of-Pocket Costs and other costs solely related to the marketing and promotion of Product in any Organon Exclusive Country. In each Co-Marketing Country, each Party shall be responsible for one hundred percent (100%) of its respective Marketing Costs. Parties are only responsible for payments related to those Marketing Costs defined in the Global Marketing Plan or a Country Marketing Plan, or otherwise approved by the GCC or CCC. Unless otherwise agreed as a Consensus Matter, each Party agrees that the Global Marketing Plan and Country Marketing Plans shall require each Party to spend up to its share of the minimum Marketing Costs (by Country or region, as applicable) as reflected on Schedule 6.3 plus the Excess Marketing Expenditure described in the next sentence. Absent mutual agreement of the Parties, however, neither Party shall be responsible for (and shall not be reimbursed by the other Party for) any cost or expense that exceeds the annual budgeted Marketing Costs for the applicable Country by more than five (5%) percent of such budgeted amounts (the "Excess Marketing Expenditure").

6.4 Reduction of Detailing Requirements and Marketing Costs in the Major Market Countries.

(i) Each of Pfizer and Organon shall have the right, upon one hundred (180) days prior notice to the other Party given prior to the end of the second consecutive Year described below, to reduce its Detailing Requirements in the Major Market Countries and its Marketing Cost obligations if in any two consecutive Years after (a) the second Year after the Launch of the Product in such Major Market Country, if such Launch occurs on or before June 30 of the calendar year, or (b) the third Year after such Launch, if the Launch occurs after June 30 of the calendar year, Net Sales in any such Major Market Country are less than seventy percent (70%) of the applicable Major Market Country

Forecast for such Major Market Country; provided that such notifying Party is not then (i) in Material Default of its obligations under this Agreement, (ii) is not a Shortfall Party in such Major Market Country, (iii) is not a Detail Breaching Party in such Major Market Country, and (iv) there is no Force Majeure in such Major Market Country that is continuing at such time and provided further that such notice shall only be effective if such percentage is not actually achieved by the end of the second consecutive Year. The notice provided to the other Party shall specify the amount in percentage terms by which it intends to so reduce its obligations. In the event such notice provided above is given, the other Party shall be permitted to give notice, no later than sixty (60) days prior to the end of such Year, of its intention to reduce its Detailing and Marketing Cost obligations, which notice shall also describe in percentage terms the amount by which it intends to reduce its Detailing and Marketing Cost obligations. If the Net Sales in a Major Market Country are less than said seventy percent (70%) in such second consecutive Year, each Party's Detailing and Marketing Cost obligations in each subsequent Year in such Major Market Country shall be reduced by the amount corresponding to the percentage specified in such Party's notice, but in no event shall either Party's respective Detailing and Marketing Cost obligations be reduced below the product of (a) such Party's Detailing Requirement and Marketing Cost obligations applicable under this Agreement for the then current Year, without giving effect to this Article 6.4(i), and (b) a fraction, the numerator of which is the mean average Net Sales for such Country during the two consecutive Years referred to in the first sentence, and the denominator of which is the mean average Major Market Country forecast for such Country during such Years, as illustrated on Schedule 6.4.

(ii) Other Readjustments in the Major Market Countries. In the event Net Sales in any Major Market Country shall be between 70% and 100% of the Major Market Country Forecast for such Major Market Country, either Party shall have the right to initiate discussions as to the appropriate readjustment in the terms of such Party's participation in commercialization in such Major Market Country; provided, however (a) mutual agreement of the Parties will be required to make any amendments or adjustments to the terms of this Agreement; and (b) no Party shall have any obligation of any kind to make any such amendments or adjustments or in connection with failing to make any such amendments or adjustments.

(iii) Adjustments for Detailing Requirements and Marketing Costs in Other Co-Promote Countries. Each of Pfizer and Organon shall have the right, provided such Party is not then in Material Default of its obligations under this Agreement and is not a Shortfall Party or a Detail Breaching Party, and there is no Force Majeure which is continuing at such time, upon ninety (90) days prior notice to the other Party given prior to the end of such Year described below, on a Country-by-Country basis with respect to all Co-Promotion Countries, other than Major Market Countries ("Other Countries"), to reduce its Detailing Requirements and the amount of Marketing Costs as provided in this Article 6.4. In each Other Country, the adjustment will only become effective after the end of the third full Year after Launch, and the procedure set forth herein shall be applied for each subsequent Year (starting with the Fifth Year) until expiration of the Term for each such Other Country:

(a) For the first eight months during each Year (January 1 through August 31) the Net Product Sales during such eight month period ("8 Month Sales") will be determined and compared to the Net Sales forecast for such period ("8 Month Forecast") as set forth in the applicable Country Marketing Plan. If the

8 Month Sales are less than seventy percent (70%) of the 8 Month Forecast, then the ratio ("Ratio") shall be determined by dividing the 8 Month Sales by the 8 Month Forecast, and the resulting Ratio shall be used (as specified in subsection (b) below) to determine the Detailing Requirements and the amount of Marketing Costs for the following Year.

(b) To determine the Detailing Requirements and the amount of Marketing Costs, the then applicable Detailing Requirement and Marketing Cost number would be multiplied by the Ratio, and the result would be the Detailing Requirement and Marketing Cost obligations for the following Year.

6.5 Co-Promotion Resources. It is the intention of Organon and Pfizer that, during the Term in each Co-Promotion Country, each of Organon and Pfizer will devote adequate resources to the Co-Promotion of the Product in the Co-Promotion Countries and to otherwise discharge its obligations under this Agreement. If Organon and Pfizer agree that one Party should provide more than fifty percent (50%) of the Details in a Co-Promotion Country, whether because additional Detailing is necessary beyond that contemplated in this Agreement or otherwise, or one Party is requested to devote other resources in excess of its appropriate share, the Parties shall first determine fair compensation to such Party for its additional efforts. Without limiting the foregoing, other than as set forth in Article 6.5A below with respect to each of the United Kingdom, Spain, Germany, France and Canada, each Party must be willing, in the applicable Country Marketing Plan, to undertake to perform at least thirty percent (30%) of the total Product Details in each Co-Promotion Country in each Year of the applicable Term (the "Minimum Detail Percentage"). Subject to Article 2.5, Organon may engage a contract sales force in Japan in order to satisfy the Minimum Detail Percentage, and Pfizer's consent to such engagement shall not be unreasonably withheld. If either Party (the "Nonperforming Party") is not willing to undertake to perform the Minimum Detail Percentage in a Co-Promotion Country in any Year, then (i) if Pfizer is the Nonperforming Party, Organon shall have the right to terminate this Agreement pursuant to Article 13.3 solely with respect to such Co-Promotion Country; and (ii) if Organon is the Nonperforming Party, Pfizer shall have the right to convert such Co-Promotion Country from a Co-Promotion Country to a Pfizer Exclusive Country.

6.5A Co-Promotion in Canada and Certain Key EU Countries.

(i) Notwithstanding the provisions of Article 6.5 above, the Parties agree that, the Minimum Detail Percentage shall not apply in each of the United Kingdom, Spain, Germany, France and Canada (the "Big 5 Countries"). In each of the Big 5 Countries, the applicable CCC shall determine each Party's Detail Requirement for each Year of the Term, and each Party shall have the right to perform fifty percent (50%) of the Details in each such Country in each Year. If either Party (the "Low Detailing Party") elects to perform fewer than fifty percent (50%) of the total Details determined by the CCC to be warranted in one or more of the Big 5 Countries in any Year, then (a) the other Party may, in its sole discretion, elect to perform the Details that the Low Detailing Party was not able to perform; and (b) the Low Detailing Party's share of the Net Sales of the Product in such Country for such Year shall be reduced by applying the following formula:

N = P - (50% - R)

N = The Low Detailing Party's new Net Sales share under this Agreement

P = The Low Detailing Party's original Net Sales share under this Agreement (i.e., for Organon, P=80% and for Pfizer, P=20%)

R = the fraction (expressed as a percentage) the numerator of which is number of Details that the Low Detailing Party has agreed to perform in such Country in the applicable Year and the denominator of which is the total Details agreed to be performed by the Parties in such Country in the applicable Year.

6.6 Co-Marketing.

(i) In the event the Parties are legally unable to Co-Promote the Product in a particular Co-Promotion Country in which they are both in agreement that the Product should be commercialized, the Parties will endeavor to decide whether such Country will be a Pfizer Exclusive Country or an Organon Exclusive Country. In the absence of such agreement, the Parties will be entitled to Co-Market the Product independently in the Country. For the Co-Marketing Countries, Pfizer and Organon shall each have access to all Promotional Materials developed jointly by the Parties. If a single Trademark is used for the Product in the Co-Promotion Countries, Organon shall have the right to use such Trademark in the Co-Marketing Countries. Each Party shall market the Product in a manner substantially consistent with the general strategies expressed in the Global Marketing Plan, but shall otherwise be free to market the Product in such Co-Marketing Country as it deems appropriate in its sole discretion. Organon and Pfizer shall each bear all of its own costs and expenses in advertising and promoting the Product in the Co-Marketing Countries. Each Party shall retain all revenues accrued by such Party (or its relevant local Affiliate) on its sales of any Product in each Co-Marketing Country. Within sixty (60) days following the end of each Calendar Quarter following Product Launch in any Co-Marketing Country, each Party shall provide the JOC with a detailed report of Net Sales made by the Party or its local Affiliate in Co-Marketing Countries. The format of such reports shall be mutually agreed-upon by the JOC.

(ii) In the event that the Parties mutually agree to convert a Co-Marketing Country to a Pfizer Exclusive Country, Pfizer shall pay Organon a royalty of twenty percent (20%) of Net Sales in such Country, in lieu of the fifteen percent (15%) royalty set forth in Article 9.2. Such twenty percent (20%) royalty shall be subject to adjustment pursuant to Articles 9.2(i) and 9.2(ii).

6.7 Exclusive Countries. Pfizer and Organon shall each have access to all Promotional Materials developed jointly by the Parties for the Co-Promotion Countries and shall bear all of its own costs and expenses in advertising and promoting the Product in the Pfizer Exclusive Countries and the Organon Exclusive Countries, respectively. In the Pfizer Exclusive Countries and the Organon Exclusive Countries, each of Pfizer and Organon, as applicable, shall conduct its business consistent with the Global Marketing Plan and the Development Plan.

6.8 Conversion of Countries

(i) Initial Conversion from Co-Promotion Country to Pfizer Exclusive Country. As soon as is practicable following the Effective Date but in no event later than November 15, 2004, Organon shall provide Pfizer with a list of each Co-Promotion Country in which Organon does not intend to Co-Promote the Product with Pfizer. Upon Pfizer's receipt of such notice, the Co-Promotion Country or Co-Promotion Countries identified in such notice shall be designated a Pfizer Exclusive Country.

(ii) Conversion from a Pfizer Exclusive Country to a Co-Promotion Country or Co-Marketing Country.

(a) Notwithstanding anything to the contrary contained in this Agreement, if Organon can demonstrate to Pfizer the Co-Promotion Criteria for a Pfizer Exclusive Country, then at any time from the Effective Date through and including the period ending three (3) years from the date of Product Launch in such Pfizer Exclusive Country, Organon may elect, upon not less than one hundred eighty (180) days written notice to Pfizer, to convert any Pfizer Exclusive Country to a Co-Promotion Country or, if the applicable Law in such Country does not permit the conversion into a Co-Promotion Country, to a Co-Marketing Country. During the one hundred eighty (180) days following the receipt of Organon's notice of election, the Parties shall undertake the development of a joint marketing plan for such Country. Any such conversion shall be effective as of the close of business on the date which is one hundred eighty (180) days from the date of such notice (the "Conversion Date").

(b) In the event that Organon is unable to demonstrate its ability to conduct a Co-Promotion in any Co-Promotion Country, that Country shall continue to be designated as a Pfizer Exclusive Country.

(c) The Parties agree to amend Schedule 1.33 to reflect the updated list of Co-Promotion Countries, respectively.

(iii) If a Pfizer Exclusive Country is converted into a Co-Promotion Country within three (3) years of Product Launch in such Country, then no later than two (2) months prior to the Conversion Date, Pfizer shall deliver to Organon a statement (the "Interim Statement") setting forth, in reasonable detail (a) itemized Development Costs and Marketing Costs attributable to such Country ("Exclusive Country Costs") for the Product for all periods ending three (3) months prior to the Conversion Date, and (b) Pfizer's Net Sales of the Product in the Country for the nine (9) month period ending on the date that is three (3) months prior to the Conversion Date. Organon shall pay to Pfizer, within thirty (30) days following receipt of the Interim Statement, an amount equal to fifty-five percent (55%) of the Exclusive Country Costs, and one hundred twenty-five percent (125%) of the foregoing Net Sales (if applicable), all as shown on the Interim Statement. No later than thirty (30) days following the Conversion Date, Pfizer shall deliver to Organon a statement (the "Conversion Date Statement") setting forth, in reasonable detail, Exclusive Country Costs for the Product during the three (3) month period ending on and including the Conversion Date and Pfizer's Net Sales of the Product in the Country (if any) for the three (3) month period ending on the Conversion Date. Organon shall pay to Pfizer, within thirty (30) days following receipt of the Conversion Date Statement, an amount equal to fifty-five percent (55%) of the Exclusive Country Costs and one hundred twenty-five percent (125%) of the Net Sales (if applicable), all as shown on the Conversion Date Statement.

(iv) Beginning on the Conversion Date, Products in the applicable Country shall be treated as a Product in a Co-Promotion Country; provided, however, that for a reasonable transition period of up to one hundred and eighty (180) days, Pfizer shall be entitled to continue to purchase Product and book sales thereof but shall then pay Organon thirty-five percent (35%) of such Net Sales as a Co-Promotion fee during such

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P = The Low Detailing Party's original Net Sales share under this Agreement (i.e., for Organon, P=80% and for Pfizer, P=20%)

R = the fraction (expressed as a percentage) the numerator of which is number of Details that the Low Detailing Party has agreed to perform in such Country in the applicable Year and the denominator of which is the total Details agreed to be performed by the Parties in such Country in the applicable Year.

6.6 Co-Marketing.

(i) In the event the Parties are legally unable to Co-Promote the Product in a particular Co-Promotion Country in which they are both in agreement that the Product should be commercialized, the Parties will endeavor to decide whether such Country will be a Pfizer Exclusive Country or an Organon Exclusive Country. In the absence of such agreement, the Parties will be entitled to Co-Market the Product independently in the Country. For the Co-Marketing Countries, Pfizer and Organon shall each have access to all Promotional Materials developed jointly by the Parties. If a single Trademark is used for the Product in the Co-Promotion Countries, Organon shall have the right to use such Trademark in the Co-Marketing Countries. Each Party shall market the Product in a manner substantially consistent with the general strategies expressed in the Global Marketing Plan, but shall otherwise be free to market the Product in such Co-Marketing Country as it deems appropriate in its sole discretion. Organon and Pfizer shall each bear all of its own costs and expenses in advertising and promoting the Product in the Co-Marketing Countries. Each Party shall retain all revenues accrued by such Party (or its relevant local Affiliate) on its sales of any Product in each Co-Marketing Country. Within sixty (60) days following the end of each Calendar Quarter following Product Launch in any Co-Marketing Country, each Party shall provide the JOC with a detailed report of Net Sales made by the Party or its local Affiliate in Co-Marketing Countries. The format of such reports shall be mutually agreed-upon by the JOC.

(ii) In the event that the Parties mutually agree to convert a Co-Marketing Country to a Pfizer Exclusive Country, Pfizer shall pay Organon a royalty of twenty percent (20%) of Net Sales in such Country, in lieu of the fifteen percent (15%) royalty set forth in Article 9.2. Such twenty percent (20%) royalty shall be subject to adjustment pursuant to Articles 9.2(i) and 9.2(ii).

6.7 Exclusive Countries. Pfizer and Organon shall each have access to all Promotional Materials developed jointly by the Parties for the Co-Promotion Countries and shall bear all of its own costs and expenses in advertising and promoting the Product in the Pfizer Exclusive Countries and the Organon Exclusive Countries, respectively. In the Pfizer Exclusive Countries and the Organon Exclusive Countries, each of Pfizer and Organon, as applicable, shall conduct its business consistent with the Global Marketing Plan and the Development Plan.

6.8 Conversion of Countries

(i) Initial Conversion from Co-Promotion Country to Pfizer Exclusive Country. As soon as is practicable following the Effective Date but in no event later than November 15, 2004, Organon shall provide Pfizer with a list of each Co-Promotion Country in which Organon does not intend to Co-Promote the Product with Pfizer. Upon Pfizer's receipt of such notice, the Co-Promotion Country or Co-Promotion Countries identified in such notice shall be designated a Pfizer Exclusive Country.

(ii) Conversion from a Pfizer Exclusive Country to a Co-Promotion Country or Co-Marketing Country.

(a) Notwithstanding anything to the contrary contained in this Agreement, if Organon can demonstrate to Pfizer the Co-Promotion Criteria for a Pfizer Exclusive Country, then at any time from the Effective Date through and including the period ending three (3) years from the date of Product Launch in such Pfizer Exclusive Country, Organon may elect, upon not less than one hundred eighty (180) days written notice to Pfizer, to convert any Pfizer Exclusive Country to a Co-Promotion Country or, if the applicable Law in such Country does not permit the conversion into a Co-Promotion Country, to a Co-Marketing Country. During the one hundred eighty (180) days following the receipt of Organon's notice of election, the Parties shall undertake the development of a joint marketing plan for such Country. Any such conversion shall be effective as of the close of business on the date which is one hundred eighty (180) days from the date of such notice (the "Conversion Date").

(b) In the event that Organon is unable to demonstrate its ability to conduct a Co-Promotion in any Co-Promotion Country, that Country shall continue to be designated as a Pfizer Exclusive Country.

(c) The Parties agree to amend Schedule 1.33 to reflect the updated list of Co-Promotion Countries, respectively.

(iii) If a Pfizer Exclusive Country is converted into a Co-Promotion Country within three (3) years of Product Launch in such Country, then no later than two (2) months prior to the Conversion Date, Pfizer shall deliver to Organon a statement (the "Interim Statement") setting forth, in reasonable detail (a) itemized Development Costs and Marketing Costs attributable to such Country ("Exclusive Country Costs") for the Product for all periods ending three (3) months prior to the Conversion Date, and (b) Pfizer's Net Sales of the Product in the Country for the nine (9) month period ending on the date that is three (3) months prior to the Conversion Date. Organon shall pay to Pfizer, within thirty (30) days following receipt of the Interim Statement, an amount equal to fifty-five percent (55%) of the Exclusive Country Costs, and one hundred twenty-five percent (125%) of the foregoing Net Sales (if applicable), all as shown on the Interim Statement. No later than thirty (30) days following the Conversion Date, Pfizer shall deliver to Organon a statement (the "Conversion Date Statement") setting forth, in reasonable detail, Exclusive Country Costs for the Product during the three (3) month period ending on and including the Conversion Date and Pfizer's Net Sales of the Product in the Country (if any) for the three (3) month period ending on the Conversion Date. Organon shall pay to Pfizer, within thirty (30) days following receipt of the Conversion Date Statement, an amount equal to fifty-five percent (55%) of the Exclusive Country Costs and one hundred twenty-five percent (125%) of the Net Sales (if applicable), all as shown on the Conversion Date Statement.

(iv) Beginning on the Conversion Date, Products in the applicable Country shall be treated as a Product in a Co-Promotion Country; provided, however, that for a reasonable transition period of up to one hundred and eighty (180) days, Pfizer shall be entitled to continue to purchase Product and book sales thereof but shall then pay Organon thirty-five percent (35%) of such Net Sales as a Co-Promotion fee during such

transition period, in lieu of any royalty payments due under Article 9.2. In the event that Organon's local Affiliate is not capable of booking sales of the Product in a particular Co-Promotion Country by the end of such transition period, then the local Pfizer Affiliate shall be entitled to continue book such sales.

(v) If a Pfizer Exclusive Country is converted into a Co-Marketing Country, then, no later than two (2) months prior to the Conversion Date, Pfizer shall deliver to Organon an Interim Statement setting forth, in reasonable detail, Exclusive Country Costs for the Product for all periods ending three (3) months prior to the Conversion Date, all Internal Costs incurred by Pfizer in relation to the Country in question directly related to complying with the registration requirements of the Country for the Product for all periods ending three (3) months prior to the Conversion Date ("Internal Registration Costs"), and Pfizer's Net Sales of the Product in the Country for the nine (9) month period ending on the date that is three (3) months prior to the Conversion Date. Organon shall pay to Pfizer, within thirty (30) days following the receipt of the Interim Statement an amount equal to fifty percent (50%) of such Internal Registration Costs, fifty percent (50%) of such Exclusive Country Costs and fifty percent (50%) of Net Sales, all as shown on the Interim Statement. No later than thirty (30) days following the Conversion Date, Pfizer shall deliver to Organon a Conversion Date Statement setting forth, in detail, Exclusive Country Costs for the Product and all Internal Registration Costs incurred by Pfizer in relation to the Country in question during the three (3) month period ending on and including the Conversion Date and Pfizer's Net Sales of the Product in the Country for the three (3) month period ending on the Conversion Date. Organon shall pay to Pfizer, within thirty (30) days following the receipt of the Conversion Date Statement, an amount equal to fifty percent (50%) of such Internal Registration Costs, fifty percent (50%) of such Exclusive Country Costs and fifty percent (50%) of Net Sales, all as shown on the Conversion Date Statement. The license granted by Organon to Pfizer pursuant to Article 2.1 will remain applicable with respect to such Country, any and all ongoing Development Costs shall be shared by the Parties in accordance with Article 4.4, and Marketing Costs shall be borne independently by the Parties.

(vi) In the event that each Party is required by Law to operate through a local distributor in a Co-Promotion Country then such Country shall remain a Co-Promotion Country; provided, however, that the distributor for the Product in such Country shall be selected (x) by the Party that maintains management services in such Country through its own employees, or (y) if both Parties maintain management services in such Country then as mutually agreed to by the Parties.

(vii) Conversion to Organon Exclusive Country. If Pfizer (a) does not file for Regulatory Approval in a Pfizer Exclusive Country within twelve (12) months after Launch of the Product in the US Territory (or, if Regulatory Approval in such Pfizer Exclusive Country requires that the Product receive Regulatory Approval in a particular Country other than the US Territory, such as the Country of manufacture of the Product or a Key EU Country, then within twelve (12) months after Launch in such Country), or (b) fails to Launch the Product in such Pfizer Exclusive Country within twelve (12) months of receipt of both Regulatory Approval and Price Approval in such Country, then Organon may request, and Pfizer shall agree, to convert such Country into an Organon Exclusive Country. To the extent that Pfizer has taken steps in such Country to obtain Regulatory Approval, Pfizer shall in such event, at Organon's sole expense, provide transitional assistance to Organon as may be reasonably necessary with the Regulatory

Authorities in the relevant Country to facilitate Organon to obtain Regulatory Approvals in such Country.

6.9 Detail Shortfalls

(i) In the event that either Party fails to perform (such Party, a "Shortfall Party") at least ninety percent (90%) of its Detail Requirement in any Year as reported pursuant to Article 8A.6 or verified pursuant to Article 8A.7 in any of the Major Market Countries, the Shortfall Party shall pay to the other Party as liquidated damages an amount equal to the Detail Cost, multiplied by the applicable factor set forth below (the "Shortfall Factor") multiplied by the total number of Details in the shortfall (the Detail Cost, multiplied by the number of Details in the shortfall, multiplied by the Shortfall Factor, the "Detail Shortfall Payment Amount"), on an incremental basis as set forth below:

	Detail Shortfall Level	Shortfall Factor
For such portion of shortfall which is:	≥80% but <100% of Detail Requirement	1.5
For such portion of shortfall which is:	≥65% but <80% of Detail Requirement	2
For such portion of shortfall which is:	≥50% but <65% of Detail Requirement	2.5
For such portion of shortfall which is:	<50% of Detail Requirement	3

For purposes of this Article 6.9, "Detail Cost" for the U.S. means $100, and Detail Cost for the other Major Market Countries means $70. If a Party wishes to verify the Details performed by the other Party in any Year, such Party shall give notice to the other Party that the notifying Party wishes to verify Details pursuant to Article 8A.7 within forty-five (45) days after receipt of the other Party's last Detailing Report set forth in Article 8A.6 for such Year.

(ii) With respect to any Year in which only one of the Parties was a Shortfall Party, the Shortfall Party shall, within sixty (60) days after the end of such Year (or within thirty (30) days after completion of any verification(s) of Details pursuant to Article 8A.7 conducted pursuant to Article 6.9(i) for such Year, if such verification(s) have not been completed within thirty (30) days after the end of such Year), pay the Detail Shortfall Payment Amount to the other Party.

(iii) With respect to any Year in which both Parties are Shortfall Parties, the Party having performed the highest percentage of its Detail Requirement in such Year (the "Highest Performing Party") shall be deemed not to be a Shortfall Party and the percentage of such Party's Detail Requirement performed by such Party shall be deemed to equal one hundred percent (100%) of that Party's Detail Requirement in such Year. The other Party shall continue to be required to pay a Detail Shortfall Payment Amount in accordance with Article 6.9(ii); provided, however, such Detail Shortfall Payment Amount to be paid by such other Party shall be reduced by (a) multiplying such other Party's Detail Requirement for such Year by the percentage of the Highest Performing Party's Detail Requirement actually performed by the Highest Performing Party during such Year, and (b) recalculating such other Party's Detail Shortfall Payment

Amount using the reduced Detail Requirement for such other Party calculated in accordance with the immediately preceding clause (a).

(iv) In the event that either Party fails to perform at least fifty percent (50%) of its aggregate Detail Requirement (such Party, the "Detail Breaching Party") in any Co-Promotion Country for any two (2) consecutive Years during the Term in such Country (a "Detail Shortfall Period"), then:

(a) If Pfizer is the Detail Breaching Party, Organon shall have the right, in addition to the remedies provided for in Article 6.9(ii) and 6.9(iii) above, exercisable upon notice to Pfizer given within sixty (60) days after the end of such Detail Shortfall Period (or within thirty (30) days after completion of any verification of Pfizer's Details pursuant to Article 8A.7 conducted at Organon's request pursuant to Article 6.9(i) for such Detail Shortfall Period, if such verification has not been completed within thirty (30) days after the end of such Detail Shortfall Period), such notice to be effective sixty (60) days after the date of such notice to Pfizer (or thirty (30) days after completion of any verification of Pfizer's Details for such Detail Shortfall Period requested by Organon, if later), to terminate Pfizer's rights under this Agreement with respect to the Co-Promotion Countries in which such Detail Shortfall has occurred. For purposes of this Agreement, such termination shall be treated as a termination pursuant to Article 13.3; and

(b) If Organon is the Detail Breaching Party, Pfizer shall have the right, in addition to the remedies provided for in Article 6.9(ii) and 6.9(iii) above, exercisable upon notice to Organon given within sixty (60) days after the end of such Detail Shortfall Period (or within thirty (30) days after completion of any verification of Organon's Details pursuant to Article 8A.7 conducted at Pfizer's request pursuant to Article 6.9(i) for such Detail Shortfall Period, if such verification has not been completed within thirty (30) days after the end of such Detail Shortfall Period), such notice to be effective sixty (60) days after the date of such notice to Organon (or thirty (30) days after completion of any verification of Organon's Details for such Detail Shortfall Period requested by Pfizer, if later), to convert the Co-Promotion Country(ies) in which such Detail Shortfall has occurred from a Co-Promotion Country to a Pfizer Exclusive Country.

(v) The Parties understand and agree that the Detail Shortfall Payment Amount shall be paid as liquidated damages and not as a penalty and that such sum represents a pre-estimate of the loss the Parties believe would be suffered as a result of Detail shortfalls. In the event of any Detail shortfall under Article 6.9, the remedies and compensation as provided herein shall govern, and neither Party shall have any further claim for breach of this Agreement on account of such Detail shortfall.

6.10 Non-Compete

(i) Neither Party (nor their respective Affiliates) shall, from the Effective Date, on a Country-by-Country basis, until the earlier of (a) the second anniversary of the first receipt of a Regulatory Approval for the Product in each Country in the Territory, and (b) the third anniversary of the first receipt of a Regulatory Approval for the Product in the US Territory, (the "Noncompete Term"), market or sell any Competing Product in such Country without the prior written consent of the other Party.

(ii) Notwithstanding the foregoing, it is understood and agreed that the non-compete restriction set forth in Article 6.10(i) does not prohibit either Party or their Affiliates from marketing or selling a Competing Product (a "De minimis Product") where such Party has (a) acquired a business from a Third Party as part of a larger transaction where the business has a Competing Product, or (b) entered into a merger or other business combination with a Third Party, where the Third Party has a Competing Product, in each of (a) and (b) above, only if the sales of the Competing Product represent less than 20% of the aggregate sales revenue of the entire business that is the subject of such larger transaction or of the Third Party (based on the most recently-available twelve (12) months of sales of such Third Party as of the date of the announcement of such transaction), and provided further that sales in such twelve (12) month period of the Competing Product, as the sales of such Competing Product are reported by IMS, do not exceed USD $300,000,000.

(iii) Without limiting the provisions of Article 6.10(i) above, if during the Noncompete Term in any Country, Pfizer or Organon or any of their respective Affiliates acquires or agrees to acquire a Competing Product in such Country through acquisition of or merger or other business combination with a company or entity, Pfizer or Organon, as applicable, shall, provided that such Competing Product is not a De minimis Product, have thirty (30) days from the date of public announcement of the closing date of the acquisition, merger or other business combination to notify the other Party as to whether Pfizer or Organon, as applicable, intends to divest its interest in such Competing Product. In the event that Pfizer or Organon, as applicable, elects to divest its interest in such Competing Product, such Party shall use reasonable efforts to identify a Third Party purchaser to whom such Party will divest its interest in such Competing Product and to enter into a definitive agreement with such Third Party for such divestiture as soon as reasonably practicable under the circumstances. If Pfizer or Organon, as applicable, elects not to divest its interest in such Competing Product or fails to divest its interest in such Competing Product within twelve (12) months after the closing of the transaction for which Pfizer or Organon, as applicable, has provided the other Party with notice, then the other Party shall have the option, upon written notice to Pfizer or Organon, as applicable, given no later than ninety (90) days after the earlier of: (i) Pfizer's or Organon's written notice, as applicable, of its election not to divest such Competing Product; and (ii) the end of such twelve (12) month period described above, to terminate this Agreement for the Country or Countries in which Pfizer or Organon, as applicable, has failed to divest the Competing Product pursuant to Article 13.3, treating such election not to divest or failure to divest such Competing Product as a breach of Article 6.10(i).

ARTICLE 7

REGULATORY MATTERS

7.1. Regulatory Matters in Co-Marketing Countries. The Parties shall cause the development of the Product in the Co-Marketing Countries to be conducted in a manner allowing Pfizer and Organon to each secure Regulatory Approvals for the Product issued contemporaneously and under the same terms and conditions, including without limitation maintaining bio-equivalence of the Parties' respective Products.

7.2. Regulatory Matters in the Co-Promotion Countries. This Article 7.2 shall apply to regulatory matters relating to the Product in the Co-Promotion Countries.

(i) All NDAs and other Applications for Regulatory Approvals within the Co-Promotion Countries relating to the Product shall be the property of Organon and held in the name of Organon or its designated Affiliates. Organon's designated representative shall serve as the designated regulatory official for Product in the Co-Promotion Countries for purposes of receiving communications from Regulatory Authorities. Notwithstanding the foregoing, each Party will have the exclusive right to and will be responsible for interacting with Regulatory Authorities on matters concerning each Party's manufacturing site(s) that are involved in the manufacture of the Intermediate, Compound or the Product pursuant to the Alliance Agreements. In the event that applicable Law requires that Organon respond to a Regulatory Authority in the Territory on behalf of Pfizer, then Organon may do so provided, however, that Pfizer and Organon mutually agree on Organon's response to such Regulatory Authority.

(ii) Organon will provide Pfizer with copies, which copies may be in draft form, of all substantive submissions (subject to the last sentence of this Article 7.2(ii)) to Regulatory Authorities through the CDRC. Organon will provide Pfizer with such copies at least twenty (20) Business Days prior to planned submission to the FDA or other Regulatory Authority by Organon, whereupon Pfizer shall provide comments to Organon regarding such submission at least ten (10) days prior to such planned submission, and, subject to the determination of the CDRC, Organon shall incorporate the comments given by Pfizer prior to making such submission. With respect to any NDA, supplemental NDA, or other Application for Regulatory Approval, the CDRC (and, with respect to the Chemistry, Manufacturing and Controls ("CMC") section of the NDA, and comparable sections in other Applications for Regulatory Approval in the Co-Promotion Countries, the MSC) will agree upon a separate review schedule in order to take into account the volume and scope of such submissions.

(iii) Organon shall provide notice to Pfizer within two (2) Business Days of: (a) discovery by Organon of any event that triggers an FDA (or other Regulatory Authority) filing requirement promptly after the discovery of such an event; and (b) any FDA requirements which FDA may impose with respect to the Regulatory Approval, (including without limitation, additional clinical studies) and of all FDA (or other Regulatory Authority) inquiries requiring a response. Organon shall promptly provide copies of any correspondence, and copies of all FDA (or other Regulatory Authority) contact reports produced by Organon, or other submission relating to this Article 7.2(iii) to the Parties' representatives on the regulatory working group of the CDRC, and such representatives shall discuss in good faith, and on a timely basis determine, the most effective and expeditious means of responding to such FDA (or other Regulatory Authority) filing requirement.

(iv) In connection with Articles 7.2(i), (ii) and (iii) above, Organon shall provide Pfizer with notice of all meetings, conferences, and discussions (including without limitation, advisory committee meetings and any other meeting of experts convened by FDA or other Regulatory Authorities concerning any topic relevant to the Product) scheduled with FDA or such other Regulatory Authority concerning any pending NDA, Application for Regulatory Approval, or other regulatory matters relating to the Product within two (2) Business Days after Organon receives notice of the scheduling of such meeting, conference, or discussion. Pfizer shall be entitled to have appropriate

representation present at all such meetings as determined by the CDRC. Organon and Pfizer, through the CDRC, shall agree in advance on the scheduling of such meetings and on the objectives to be accomplished at such meetings, conferences, and discussions and the agenda and strategy for the meetings, conferences, and discussions with FDA or other Regulatory Authority.

7.3. Regulatory Matters in the Pfizer Exclusive Countries. This Article 7.3 shall apply to clinical and regulatory matters relating to Product in the Pfizer Exclusive Countries.

(i) After the Effective Date, Pfizer will assume sole ownership, control of and responsibility for all regulatory filings in the Pfizer Exclusive Countries, and Organon shall cooperate with Pfizer in connection with such filings as reasonably requested by Pfizer and at Pfizer's sole cost and expense. Organon shall be responsible for providing Pfizer with Product samples for use in connection with regulatory filings relating to Product in the Pfizer Exclusive Countries at Pfizer's sole cost and expense.

(ii) All Regulatory Approvals in the Pfizer Exclusive Countries relating to the Product shall be deemed the property of Pfizer and held in Pfizer's or its Affiliate's name. Upon termination of Pfizer's rights in any Pfizer Exclusive Country prior to the end of the applicable Term, Pfizer will promptly transfer to Organon or its designee, all Regulatory Approvals, Price Approvals and other approvals relating to the Product in the applicable Country as may be required by Organon or such party to market the Product in such Country. The transfer fees and any fees assessed by any Governmental Authorities for such transfer will be borne by Organon.

(iii) Pfizer will provide Organon with (a) notice of any revocations of Product Regulatory Approvals and any Product recalls in the Pfizer Exclusive Countries; and (b) responses to reasonable inquiries by Organon regarding the regulatory approval and commercialization processes for the Product in the Pfizer Exclusive Countries.

7.4. Inquiries, Adverse Events, etc.

(i) Organon and Pfizer shall be responsible for the surveillance, receipt, evaluation, and reporting of Product complaints and reports of adverse drug experiences, for the Product in, as to Organon, the Co-Promotion Countries and Organon Exclusive Countries, and, as to Pfizer, in the Pfizer Exclusive Countries, in accordance with Article 7.5 below. In addition, each of Organon and Pfizer will be responsible for such matters with respect to any Regulatory Approvals that they own in any Co-Marketing Countries.

(ii) Organon shall be responsible for promptly investigating Product complaints and reports of adverse drug experiences and other required safety information (e.g., PSURs and annual safety reports) associated with the use of any Product in the Co-Promotion Countries and Organon Exclusive Countries. As to each Product, Organon shall submit reports of all adverse drug experiences associated with the use of the Product and other required safety information to the FDA or other Regulatory Authority and, where appropriate, clinical investigators, in accordance with applicable Law. Organon shall submit a copy of each such report to Pfizer contemporaneously with its submission of the report to FDA or the applicable Regulatory Authority, or in advance of such submission if, and as, reasonably necessary to permit Pfizer to comply with any Law applicable to it, if practicable.

(iii) Pfizer shall promptly investigate Product complaints and reports of adverse drug experiences and other required safety information (e.g., PSURs and annual safety reports) associated with the use of any Product in the Pfizer Exclusive Countries. As to the Product, Pfizer shall submit reports of all adverse drug experiences associated with the use of the Product and other required safety information to the applicable Governmental Authorities and, where appropriate, clinical investigators in the Pfizer Exclusive Countries in accordance with applicable Law. Pfizer shall submit a copy of each such report to Organon for inclusion in the global database contemporaneously with its submission of the report to the applicable Regulatory Authority in the Pfizer Exclusive Countries, or in advance of such submission if, and as, reasonably necessary to permit Organon to comply with any Law applicable to it, if practicable.

(iv) Organon shall have the sole responsibility for implementing decisions of the CDRC and revising the Product labeling for the Co-Promotion Countries, the Organon Exclusive Countries, and for Regulatory Approvals owned by Organon in Co-Promotion Countries accordingly, and Pfizer shall have sole responsibility for revising the Product labeling for the Pfizer Exclusive Countries and for Regulatory Approvals owned by Pfizer in Co-Marketing Countries, subject to review by the CDRC, as needed, to adequately warn of the potential risks identified by reports of adverse drug experiences associated with the use of the Product and from Product complaints.

(v) Each Party shall notify the other Party within two (2) Business Days after it receives information about the initiation of any investigation, review or inquiry by FDA or other Governmental Authority concerning the distribution, promotion or sale of the Product, not otherwise described above.

7.5. Product Surveillance. The Parties will cooperate in the collection, review, assessment, tracking and filing of information related to adverse events associated with the Product in accordance with 21 CFR 312.32, 314.80, or comparable Laws in other Countries. As soon as reasonably practicable after the Effective Date, and subject to the oversight of the CDRC, the pharmacovigilance departments of both Parties shall meet and determine the approach to be taken for the collection, review, assessment, tracking and filing of information related to adverse events associated with the Product, which shall be documented in a separate drug safety exchange agreement between the Parties. In the event of any conflict between the terms of Articles 7.4 and 7.5 of this Agreement and the terms of such separate drug safety agreement as those terms relate to adverse events relating to the Product, the terms of such separate drug safety agreement shall control. Until such time as the Parties have agreed upon such adverse event exchange procedures, without limiting the terms of Article 7.4 above, each Party will notify the other Party of fatal/life-threatening serious clinical trial adverse event involving the Product within 96 hours following receipt by the Party. All other serious clinical trial adverse event reports involving the Product will be exchanged within fifteen (15) calendar days of receipt by the Party. Organon shall be responsible for maintaining a global safety database for the Product consistent with pharmaceutical industry practice and all applicable Laws.

7.6. Data Sharing. Each Party shall provide to the other Party, on a timely basis copies of all pre-clinical and clinical data and all regulatory filings, applications and registrations in the Territory concerning the Product. Such data, filings and other information received from a Party shall be treated by the other Party as Confidential Information of the disclosing Party. Each Party agrees to identify non-material, routine, regulatory filings which such Party will not have to provide, pursuant to this Article 7.6.

7.7. Product Recalls. Any decision to initiate a recall or withdrawal of Product in the Co-Promotion Countries shall be made by the Steering Committee. Before the Steering Committee initiates a recall or withdrawal, and upon the request for a recall or withdrawal by either Party, the Parties shall promptly and in good faith discuss the reasons therefor. Under no circumstances shall either Party unreasonably object to a recall or withdrawal requested by the other Party, and neither Party shall have any right to object to a recall or withdrawal requested by the other Party for failure of a Product to meet the Specifications, for material safety concerns or for noncompliance with the Act, and such recall shall be initiated by the Party that requested the recall (the "Requesting Party"). In the event of any recall or withdrawal, the Requesting Party shall implement any necessary action, with assistance from the other Party as reasonably requested. In addition, and except as set forth in Article 12, the Parties shall bear equally all costs and expenses of any such recall or withdrawal, including, without limitation, documented and direct Out-of-Pocket Costs incurred in relation thereto, expenses and other costs or obligations to Third Parties, the cost and expense of notifying customers and the costs and expenses associated with shipment of the recalled Product and the cost and expense of destroying the Product removed from the market, if necessary.

ARTICLE 8A

REPORTS

8A.1 Marketing Cost Reports. Within 30-days after the end of each Calendar Quarter or Pfizer Quarter as applicable, each Party shall provide the other Party and the GCC with a detailed, activity-based statement of Marketing Costs on a Country-by-Country basis, if any, incurred by such Party during such Calendar Quarter or Pfizer Quarter, as applicable, for each Co-Promotion Country, as well as the details of any adjustments to be made to the amounts submitted for the previous Calendar Quarter or Pfizer Quarter, as applicable (such report the "Quarterly Marketing Cost Report" which shall be in a format to be agreed-upon by the GCC promptly after the Effective Date).

8A.2 Development Cost Reports. Within 30-days after the end of each Calendar Quarter or Pfizer Quarter, as applicable, during the Term, each Party shall provide the other Party and the CDRC with a detailed, activity-based statement of Development Costs on a Country-by-Country basis, if any, incurred during such Calendar Quarter or Pfizer Quarter, as applicable, for each Co-Promotion Country, as well as the details of any adjustments to be made to the amounts submitted for the previous Calendar Quarter or Pfizer Quarter, as applicable (such report the "Quarterly Development Cost Report" which shall be in a format to be agreed-upon by the CDRC promptly after the Effective Date).

8A.3 Distribution Cost Reports. Within 30-days after the end of each Calendar Quarter during the Term, Organon shall provide Pfizer with a detailed statement of Distribution Costs on a Country-by-Country basis, if any, incurred during such Calendar Quarter for each Co-Promotion Country (such report the "Quarterly Distribution Cost Report" which shall be in a format to be agreed-upon by the MSC promptly after the Effective Date).

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8A.4 Net Sales Reports. Each Party shall itself report (or shall cause its Affiliates to report on its behalf) to the other Party or its Affiliates on a Country-by-Country basis with respect to each Co-Promotion Country and Organon Exclusive Country (in the case of Organon) or each Pfizer Exclusive Country (in the case of Pfizer) in the applicable local currency within thirty (30) days following the end of each Calendar Quarter or Pfizer Quarter, as applicable, the Net Sales for each calendar month of such Calendar Quarter or Pfizer Quarter, as applicable, together with information in sufficient detail (including itemization of the gross sales and any deductions thereto that each Party is entitled to take pursuant to Article 1.85) in order to allow the other Party to calculate Net Sales.

8A.5 Reconciliation. Within 45-days after the end of each Calendar Quarter, Organon shall submit to Pfizer a written report (the "Reconciliation Report") setting forth in a format to be agreed-upon by the Parties promptly after the Effective Date, the calculations of any amounts owed by Organon to Pfizer or by Pfizer to Organon, as the case may be, in order to ensure the appropriate sharing of Marketing Costs, and Development Costs, in accordance with this Agreement.

8A.6 Detail Reports. Each of Organon and Pfizer shall maintain an adequate internal system (and necessary records) for the reporting of Details by its Sales Representatives. Each Party shall provide to the appropriate CCC in each Co-Promotion Country a report within forty-five (45) days following the end of each month setting forth the number of Details (provided that neither Party shall be required to identify any of its other pharmaceutical products in such report) made by such Party's Sales Representatives. Each Party's report of Details shall also include a calculation of such Party's Details for such Year ended for the purposes of reporting compliance with Article 6.9.

8A.7 Detail Verification. As soon as is practical after the Effective Date, Pfizer and Organon shall meet to discuss their respective current methods of accounting for Details, in order to establish (in a manner mutually agreeable to each Party) a mutually beneficial, objective and efficient method of recording, maintaining and verifying the number of Details reported by each Party. Both Parties shall keep accurate and complete records of each Detail carried out by its Sales Representatives under this Agreement consistent with the procedures described in the relevant Country Marketing Plan and mutually agreed to by the Parties. If within one-hundred and twenty (120) days of receipt of the Detail report set forth in Article 8A.6 delivered following the end of each respective Year, a Party wishes to verify whether the number of Details of the Party providing such report (the "Detail Reporting Party") are consistent with the requirements of this Agreement, the Detail Reporting Party shall make its records available for inspection and review by an independent accountant that is recognized as having expertise in the pharmaceutical industry, selected by the Party wishing to verify the other Party's number of Details (as to which firm the other Party has no reasonable objection) for the purpose of so verifying the number of Details performed by such Party. All costs and expenses incurred in connection with any such verification shall be paid by the Party requesting such verification, provided, that the Detail Reporting Party shall pay such costs and expenses if the number of Details determined by the independent accountant is at least ten percent (10%) lower than the number of Details reported by the Detail Reporting Party under Article 8A.6 for such Year. Such independent accountant shall not reveal to the Party seeking verification the details of its review,

except for such information as is required to be disclosed under this Agreement or to determine compliance with this Agreement. Such independent accountant must agree to be subject to confidentiality obligations consistent with the provisions of Article 14. The independent accountant shall deliver its report to each Party within thirty (30) days of receipt of all relevant materials from the Detail Reporting Party. The report of the independent accountant shall be final and binding. If upon verification by the independent accountant, it is determined at the end of the applicable Year that the Detail Reporting Party is a Shortfall Party then within thirty (30) days of receipt of such audit report, the Shortfall Party shall make payment to the other Party of all amounts due under Article 6.9.

ARTICLE 8

MILESTONES

8.1 Initial Fee. Pfizer shall pay to Organon an initial fee of one hundred million US Dollars (USD $100,000,000) ("Initial Fee"), payable within ten (10) days after the Effective Date. Also within ten (10) days after the Effective Date, Pfizer will pay to Organon interest on the Initial Fee from the date that is five (5) Business Days after signing of this Agreement to the date of payment, at the ninety (90) day U.S. dollar LIBOR rate as published in *The Financial Times* effective for the date that is five (5) Business Days after signing of this Agreement, and computed on an actual/360 day basis.

8.2 Event Milestone Payments. Subject to the terms and conditions of this Agreement, Pfizer shall pay Organon a milestone payment (each, an "Event Milestone Payment") in respect of each of the following events (each, an "Event Milestone") in the particular amounts specified below no later than thirty (30) days after the occurrence of the corresponding Event Milestone:

(i) twenty-five million US Dollars (USD 25,000,000) upon acceptance of filing of an NDA with the FDA for the Product for schizophrenia;

(ii) ten million US Dollars (USD 10,000,000) upon acceptance of filing of an NDA with the FDA for the Product for bipolar disorder;

(iii) seventy-five million US Dollars (USD 75,000,000) upon receipt of Regulatory Approval from the FDA for the Product for schizophrenia;

(iv) forty-five million US Dollars (USD 45,000,000) upon receipt of Regulatory Approval from the FDA for the Product for bipolar disorder;

(v) ten million US Dollars (USD 10,000,000) upon acceptance of filing of an Application for Regulatory Approval in the first Key EU Country or application validation of an Application for Regulatory Approval filed centrally with EMEA, in either case for the Product for schizophrenia;

(vi) five million US Dollars (USD 5,000,000) upon acceptance of filing of an Application for Regulatory Approval in the first Key EU Country or application validation of an Application for Regulatory Approval filed centrally with EMEA, in either case for the Product for bipolar disorder;

(vii) twenty-five million US Dollar (USD 25,000,000) upon the Launch of the Product for schizophrenia in the first Key EU Country;

(viii) ten million US Dollars (USD 10,000,000) upon the Launch of the Product for bipolar disorder in the first Key EU Country; and

(ix) fifteen million US Dollars (USD 15,000,000) upon Launch of the Product for schizophrenia in Japan.

8.3 Performance Milestones.

(i) Subject to the terms and conditions of this Agreement, Pfizer shall pay to Organon the following payments (each, a "Performance Milestone Payment") in respect of each of the following milestone events (each, a "Performance Milestone"):

	Milestone Event	Payment Amount
(a)	In the event Net Sales in the Territory equal or exceed $1.5 Billion in any Year.	$25 million
(b)	In the event Net Sales in the Territory equal or exceed $3 Billion in any Year.	$25 million

The Parties understand and agree that each of the Event Milestone Payments referenced under Article 8.2, and each of the Performance Milestone Payments referenced in this Article 8.3(i) shall be payable only once, upon the first occurrence of the applicable Event Milestone or Performance Milestone, and are subject to the terms and conditions set forth in Article 8.2 and Article 8.3(ii), as applicable.

(ii) Performance Milestone Payments shall be due and owing, on or before the date sixty (60) days after the end of the applicable Year.

8.4 Fee Conditions. Each and every payment made under this Article 8 shall be independent, cumulative, non-refundable, and shall not be considered an advance or credit on any royalties or other obligation received or owed. In addition, except as provided under this Agreement, neither Party shall be entitled to reimbursement of any of its Development Costs or Marketing Costs.

8.5 Notice of Termination.

(i) In the event that a Party has given the other Party notice of termination of this Agreement in its entirety, no further Event Milestone Payments or Performance Milestone Payments shall become due during such notice period, and Net Sales of the Product during such notice period shall not be counted in determining whether a Performance Milestone has been attained.

(ii) In the event that a Party has given the other Party notice of termination of this Agreement with respect to a Country or Countries, no further Event Milestone Payments pertaining to such Country or Countries shall become due, and Net Sales of the Product in such Country or Countries during such notice period shall not be counted in determining whether a Performance Milestone has been attained.

ARTICLE 9

REVENUE SHARING AND ROYALTIES

9.1 Organon Co-Promotion Payments to Pfizer. During the Term and subject to the terms and conditions hereof, Organon shall pay to Pfizer for each Co-Promotion Country, twenty percent (20%) of Net Sales of the Product in such Co-Promotion Country (the "Co-Promotion Payment"). Payments by Organon to Pfizer of such amounts shall be made in accordance with the procedures set forth below in this Article 9.

9.2 Pfizer Royalties to Organon. Subject to Articles 9.2(i) and (ii) below, and provided that Organon is not in Material Default of its obligations under this Agreement, Pfizer shall pay to Organon a royalty of fifteen percent (15%) of such Net Sales in each Pfizer Exclusive Country.

(i) Royalty Adjustments for Generic Products. If, during a given Pfizer Quarter, there is Generic Competition in any Pfizer Exclusive Country in the Territory, then, for each such Country in which there is Generic Competition, the royalties payable to Organon for the Net Sales of the Product in such Country during such Pfizer Quarter will be reduced by one percent for each percentage of market share (as measured by unit sales) of Generic Products for such Pfizer Quarter, in such Country, subject to a maximum royalty reduction of fifty percent (50%).

(ii) Revenue Share Term. Royalty payments under Article 9.2 shall continue on a Country-by-Country basis for the applicable Term; provided that during portions of any Term in which no Valid Claim exists with respect to a Product in a Pfizer Exclusive Country, the royalty set forth in Article 9.2 (as it may be reduced pursuant to subsection (i) above) shall be reduced by thirty-three percent (33%).

(iii) Limitation on Royalty Adjustment. Notwithstanding subsections (i) and (ii) above, in no event shall the royalty payable pursuant to this Article 9.2 be less than five percent (5%).

9.2A Organon Royalties to Pfizer. Subject to Articles 9.2A(i) and (ii) below, and provided that Pfizer is not in Material Default of its obligations under this Agreement, Organon shall pay to Pfizer a royalty of fifteen percent (15%) of such Net Sales in each Organon Exclusive Country.

(i) Royalty Adjustments for Generic Products. If, during a given Calendar Quarter, there is Generic Competition in any Organon Exclusive Country in the Territory, then, for each such Country in which there is Generic Competition, the royalties payable to Pfizer for the Net Sales of the Product in such Country during such Calendar Quarter will be reduced by one percent for each percentage of market share

(as measured by unit sales) of Generic Products for such Calendar Quarter, in such Country, subject to a maximum royalty reduction of fifty percent (50%).

(ii) Revenue Share Term. Royalty payments under Article 9.2A shall continue on a Country-by-Country basis for the applicable Term, subject to subsection (iii) below; provided that during portions of any Term in which no Valid Claim exists with respect to a Product in an Organon Exclusive Country, the royalty set forth in Article 9.2A (as it may be reduced pursuant to subsection (i) above) shall be reduced by thirty-three percent (33%).

(iii) Limitation on Royalty Adjustment. Notwithstanding subsections (i) and (ii) above, in no event shall the royalty payable pursuant to this Article 9.2A be less than five percent (5%).

(iv) Limitation on Royalties in Organon Exclusive Countries. Pfizer's right to receive royalty payments under Article 9.2A in a particular Country above shall terminate when the aggregate of all royalty payments made by Organon to Pfizer pursuant to this Article 9.2A equals the Exclusive Country Costs accrued or paid by Pfizer for such Country together with interest which shall accrue thereon at the rate of ten percent (10%) per annum, compounded quarterly, from the date such costs were incurred until the effective date of the conversion of such Country to an Organon Exclusive Country.

9.3 Payments.

(i) Organon shall make payments arising under Article 9.1 to Pfizer in the currency or currencies as the Parties mutually agree (and, if the Parties are unable to agree, in the applicable local currency) for each Co-Promotion Country for each Calendar Quarter, within sixty (60) days following the end of the applicable Calendar Quarter, in accordance with the terms of Article 9.5.

(ii) Pfizer shall make payments to Organon arising under Article 9.2 for each Pfizer Quarter for each Pfizer Exclusive Country in Euros sixty (60) days following the end of the applicable Pfizer Quarter, and Organon shall make payments to Pfizer arising under Article 9.2A for each Calendar Quarter for each Organon Exclusive Country in US dollars sixty (60) days following the end of the applicable Calendar Quarter.

(iii) Any Development Costs payment due from one Party to the other Party pursuant to the Reconciliation Report shall be paid in U.S dollars within sixty (60) days following the end of the applicable Calendar Quarter.

(iv) Any Distribution Cost payment due from Pfizer to Organon pursuant to the Quarterly Distribution Cost Report shall be paid in U.S dollars within sixty (60) days following the end of the applicable Calendar Quarter.

(v) Subject to the last sentence of this Article 9.3(v) Marketing Costs due from one Party (or its local Affiliate) to the other Party (or its local Affiliate) pursuant to the Reconciliation Report shall be paid at a local level in the Country in which the Marketing Costs were incurred, in the applicable functional currency of the local Affiliate of the Party required to make such payment, within sixty (60) days following the end of the applicable Calendar Quarter. Global Marketing Costs due from one Party to the

other Party shall be paid from one Party to the other Party in U.S. dollars within sixty (60) days following the end of the applicable Calendar Quarter.

9.4 Currency Conversion.

(i) Royalties. For the purposes of determining the amount of royalties due to Organon or to Pfizer pursuant to Article 9.3(ii) for the relevant Pfizer Quarter or Calendar Quarter, as applicable, the amount of Net Sales in any foreign currency shall be computed by (a) converting such amount for the relevant Pfizer Quarter or Calendar Quarter, as applicable, into Euros or US Dollars, as applicable, at the spot rate of exchange for purchasing Euros or US Dollars, with such currency as published in the Financial Times five (5) Business Days before the date payment is made.

(ii) Performance Milestones. For the purposes of determining whether the applicable Performance Milestones have been met, the amount of Net Sales in any foreign currency will be computed by converting such amount for the relevant Year into U.S. dollars at the Average Exchange Rate for the Year. The "Average Exchange Rate for the Year" means, for each Country in each Year, the weighted average calculated by dividing (a) the sum of the amounts calculated for each month of that Year as the product of 1) the average of the spot U.S. dollar exchange rates for such Country's local currency in effect each day of such calendar month as published by the Board of Governors of the Federal Reserve System in Statistical Release G.5 (http://www.federalreserve.gov/releases/g5/) and 2) Net Sales of the Product in local currency in such month by (b) Net Sales of the Product in local currency in such Year.

(iii) Co-Promotion Payments. For the purpose of determining the amount of any Co-Promotion payment due from Organon to Pfizer that is to be paid, by mutual agreement of the Parties, in some currency other than the local currency of the applicable Co-Promotion Country, the amount of the Co-Promotion Payment due shall first be computed in the relevant local currency and shall then be converted into the currency of payment at the spot rate of exchange for purchasing such payment currency with such local currency as published in the Financial Times five (5) Business Days before the date payment is made.

(iv) Development Costs. For the purpose of determining the amount of Development Costs to be shared by the Parties, Development Costs incurred in any currency other than U.S. dollars shall be converted into U.S. dollars at the spot rate of exchange for purchasing U.S. dollars with such currency as published in the Financial Times two (2) Business Days before the applicable Reconciliation Report is issued

9.5 Method of Payments. All payments under this Agreement shall be made on or before the due date by electronic transfer in immediately available funds to the respective account designated in writing by each Party at least two (2) Business Days before the payment is due. Pfizer shall notify Organon's Treasurer, or such other Organon representative as Organon's Treasurer shall designate in writing, by facsimile transmission as to the date and amount of any payment that Pfizer shall make at least two (2) Business Days prior to such transfer. Organon shall notify Pfizer's Treasurer, or such other Pfizer representative as Pfizer's Treasurer shall designate in writing, by facsimile transmission as to the date and amount of any payment that Organon shall make at least two (2) Business Days prior to such transfer. All payments under this Agreement shall bear interest from the date due until paid at a rate equal to

the prime rate of the Bank of America as announced on the date such payment was due plus three percent (3%). In addition, the Party liable for late payment shall reimburse the other Party for all reasonable costs and expenses, including without limitation reasonable attorneys' fees and legal expenses, incurred in the collection of late payments.

9.6 Records. Each of Pfizer and Organon (the "Payor") shall, and shall cause its Affiliates and sublicensees to, keep full and accurate books and records setting forth Development Costs, Cost of Goods, Marketing Costs, gross sales, Net Sales, and any amounts payable to the other Party (the "Payee"). The Payor shall permit the Payee, at the Payee's sole expense, by an internationally recognized independent accountant selected by the Payee (as to which the Payor has no reasonable objection), to examine such books and records upon at least thirty (30) days' advance written notice during normal business hours and in a manner that does not materially interfere with the Payor's business, but not later than three (3) years following the rendering of any such reports, accountings and payments. The foregoing right of review may be exercised only once with respect to each such periodic report and payment. Such independent accountant may be required by the Payor to enter into a reasonably acceptable confidentiality agreement, and in no event shall such independent accountant reveal to the Payee the details of its review except insofar as is necessary to verify the accuracy of reports and payments made or due hereunder. The results of any such audit shall be delivered in writing to each Party. Any underpayment determined by such audit shall promptly be paid or refunded by the Payor. If the Payor has underpaid amounts due under this Agreement by more than five percent (5%) over any reporting period, the Payor shall also reimburse the Payee for the cost of such audit (with the cost of the audit to be paid by the Payee in all other cases), plus interest at the interest rate set forth in Article 9.5, from the date of any such underpayment.

9.7 Withholding Tax.

(i) Any taxes required to be paid or withheld by either Party or its Affiliates for the account of the other Party on amounts payable under this Agreement shall be deducted from the amounts payable at the rates specified by applicable Law. In addition, the paying Party shall provide promptly to the other Party receipts from the government or taxing authority-evidencing payment of such taxes.

(ii) Each Party shall be indemnified against and held harmless by the other Party (or its assignee) from any incremental tax liability (including but not limited to VAT or withholding taxes) imposed on such Party as the result of an assignment by the other Party of its rights or obligations under this Agreement pursuant to Article 16.5. In the event of any such assignment, (a) the assignee shall gross up any payments it makes to the extent necessary so that the net payment received by the non-assigning Party after any such incremental tax liability equals the amount the non-assigning Party would have received if no assignments had made by the other Party or its Affiliates under this Agreement; and (b) for the avoidance of doubt, the non-assigning Party shall not be required to pay any gross up or other amounts to the assigning Party on account of any taxes (including but not limited to VAT or withholding taxes) that would not have been imposed but for such assignment. The Parties further agree that if the non-assigning Party uses a tax credit to reduce its taxes within five (5) years and as a result of any incremental tax liability related to such assignment and paid by the assigning party pursuant to the preceding sentence, the non-assigning Party shall reimburse the assigning Party the amount of such realized tax credit.

(iii) For the avoidance of doubt, the Initial Fee, Event Milestone Payments and Performance Milestones Payments made by Pfizer to Organon under this Agreement shall be exclusive of VAT. The Parties agree that at the date of this Agreement all payments due hereunder are outside the scope of VAT. Organon agrees to inform Pfizer if Organon concludes that there is a change in VAT law or practice that requires it to account for VAT on any payments due pursuant to this Agreement at any time after the execution date. In the event of any such change in VAT law or practice, Organon shall pay VAT on behalf of Pfizer and Pfizer shall prior thereto assign to Organon Pfizer's refund claim in respect thereof, and Pfizer shall co-operate with Organon in securing a refund to Organon of the full amount of such VAT payment.

9.8 Third Party License Fees. Organon shall be responsible for all Third Party License Fees relating to (i) the Current Product and (ii) the manufacturing process identified in Schedule 9.8, provided however that Third Party License Fees payable to Scherer as set forth on Schedule 1.133 hereto shall be shared fifty percent (50%) by Pfizer and fifty percent (50%) by Organon. Unless otherwise agreed, the Parties shall share fifty percent (50%) by Pfizer and fifty percent (50%) by Organon all other Third Party License Fees relating to (x) all Products other than the Current Product, and (y) the Current Product as a result of a change to the manufacturing process identified in Schedule 9.8. With respect to Pfizer's responsibility for fifty percent (50%) of the royalties payable by Organon to Scherer, Organon shall send Pfizer a Calendar Quarterly invoice that shall be based on Organon's Calendar Quarterly report of Net Sales pursuant to Article 8A.4 and shall reflect the amounts due from Pfizer under this Article 9.8. Pfizer shall, within fifteen (15) days after its receipt of such invoice, make payment under such invoice by electronic transfer in immediately available funds to the account designated in writing by Organon, which designation shall take place at least two (2) Business Days before the payment is due.

9.9 Adjustment of Commercial Terms. It is agreed by the Parties that the Parties' Co-Promotion of a Combination Product may require a change to the applicable financial terms of this Agreement with respect to the sharing of Net Sales of such Combination Product Accordingly, upon the request of either Party, the Parties shall undertake good faith negotiations to reasonably adjust the same in accordance with the principles set forth in this Agreement.

ARTICLE 10

DECISION MAKING

10.1 Committees/subcommittees. In order to fulfill the objectives of this Agreement, the Parties agree to establish a Steering Committee, Joint Operating Committee ("JOC"), a Clinical Development/Regulatory Committee ("CDRC"), a Global Commercialization Committee ("GCC"), a Manufacturing and Supply Committee ("MSC"), Country Commercialization Committees, and such other committees and subcommittees as may be established by mutual consent of Organon and Pfizer. Each committee and subcommittee shall have two co-chairpersons, one designated by each of Organon and Pfizer. All decisions of the committees and subcommittees shall be by a vote of the chairpersons, each co-chairperson having one vote, and unless otherwise stated herein, all decisions shall be by unanimous consent of the co-chairpersons.

10.2 Meetings. The chairperson(s) of the Steering Committee, JOC, CDRC, GCC, MSC, or any other committee or subcommittee established pursuant to Article 10, shall call meetings when deemed by the co-chairpersons to be appropriate, but not less often than Calendar Quarterly (except that the Steering Committee shall meet not less often than semi-annually). The meetings may be held in person, by telephone, or by video conference call. Each Party shall use all reasonable efforts to cause their members on each committee and subcommittee to attend any meeting called by the chairpersons of that committee or subcommittee. Subject to the foregoing, a quorum will consist of at least two (2) members appointed by each Party. The location of the meetings of each committee or subcommittee shall alternate between sites selected by each co-chairperson. The hosting Party of committee or subcommittee meetings shall keep accurate minutes of its meetings, including all actions recommended or taken. The Parties shall bear their respective expenses in attending committee or subcommittee meetings. In addition to formal committee or subcommittee meetings, the members of each committee or subcommittee shall communicate on an as needed basis, as they may determine including telephone conference calls. Additional participants may be invited by any representative to attend meetings where appropriate (*e.g.*, personnel from regulatory affairs or outside consultants). Such additional participants shall not be deemed to have, or have any rights or responsibilities of, a member of such committee or subcommittee. The Parties shall cause their respective representatives on the committees to use diligent efforts, acting in good faith, to resolve all matters presented to them as expeditiously as possible.

10.3 Clinical Development/Regulatory Committee. The CDRC shall consist of research and development, commercial, regulatory and marketing/medical managers (as needed) from each of Organon and Pfizer, each of which will confirm to the other its designees.

(i) The CDRC will be responsible for, among other activities relating to the Development of the Product, the following, which activities shall, in the first instance, before reference to the entire CDRC, be performed by a clinical development working group:

(a) Creating the Development Plan and sending the Development Plan to the JOC for review;

(b) Implementing the Development Plan including allocation of responsibilities between the Parties;

(c) Proposing clinical trials (including, in coordination with the GCC, Phase IIIb/Phase IV Product Studies to be conducted for the Initial Indications and any New Indications);

(d) Overseeing and monitoring the progress of, the clinical issues relating to Product Studies and Phase IIIb/IV Product Studies, including specifying timelines and priorities and which Party, or whether a Third Party, is to be responsible for such activity, and, with respect to Product Studies, reviewing costs and activities against the Development Plan; provided, however, that as between the Parties, only Pfizer is expected to engage in or contract for such activities absent subsequent agreement of the Parties to the contrary;

(e) Assessing the therapeutic relevance of clinical trials;

(f) Providing updates on its activities to the JOC;

(g) Recommending, in conjunction with the GCC, New Indications and new formulations or dosage forms for the Product; and

(h) Such other matters as the Parties may assign to the clinical development working group of the CDRC from time to time.

(ii) The CDRC will also be responsible for, among other activities relating to regulatory activities concerning the Product, the following, which activities shall, in the first instance, before reference to the entire CDRC, be performed by a regulatory working group:

(a) Conducting the necessary activities to obtain and maintain Regulatory Approvals in the Co-Promotion Countries at the earliest practicable date;

(b) Overseeing, monitoring and coordinating all regulatory issues with the relevant Regulatory Authorities, including, but not limited to, communications, filings, submissions, labeling (including development of such label), and other regulatory actions;

(c) Facilitating the exchange and use of relevant data to prepare and file applications for Regulatory Approvals;

(d) Providing recommendations for the filing of any NDA or other Application for Regulatory Approval for the Product;

(e) Coordinating preparation for and attendance at Regulatory Authority meetings;

(f) Coordinating responses to Regulatory Authority requirements and inquiries;

(g) Recommending a regulatory strategy and plan for obtaining Regulatory Approvals for the Products in the Territory;

(h) Facilitating the exchange of information in conjunction with Articles 7.4 and 7.5 of this Agreement in order to ensure that significant issues concerning adverse event information and safety issues are addressed consistently among Regulatory Authorities in the Territory;

(i) Providing updates on its activities to the JOC; and

(j) Such other matters as the Parties may assign to the regulatory working group of the CDRC from time to time.

(iii) Neither Party shall make any change to any annual Development Plan without the prior approval of the CDRC, and all Development Plans and Development Costs provided therein shall be consistent with the terms of this Agreement.

(iv) If the CDRC is unable to reach a decision on any issue within ten (10) Business Days after presentation, Pfizer shall have the final decision-making authority if such issue relates to the clinical and preclinical development of the Product. With

respect to any other issues for which the CDRC is unable to reach a decision on any issue within ten (10) Business Days after presentation, either Party may refer such issue to the JOC for resolution.

10.4 Global Commercialization Committee.

(i) The GCC shall consist of members from each of Organon and Pfizer, each of which shall confirm to the other its designees. The GCC will be responsible for the following:

(a) Preparing and implementing annually the Global Marketing Plan for the Co-Promotion Countries, including reviewing and making recommendations for the Parties' sales, promotional and marketing activities in the Co-Promotion Countries. To the extent feasible, the GCC shall allocate responsibilities equally between Pfizer and Organon. The Parties shall prepare the initial Global Marketing Plan within 180-days of the Effective Date;

(b) Developing positioning and marketing strategies for the Product in the Co-Promotion Countries consistent with the Global Marketing Plan subject to local requirements, including making recommendations to develop New Indications;

(c) Establishing long and short term forecasts for worldwide Product sales and coordinating such forecasts with the MSC in order to facilitate the operations of the Parties and their Affiliates under the Production Agreements;

(d) Developing global promotional and advertising materials for use in marketing the Product in the Co-Promotion Countries, designing packaging and overseeing educational and professional symposia and speaker and activity programs for the Product in the Co-Promotion Countries;

(e) Providing technical and medical support for the sales and marketing of the Product in the Co-Promotion Countries;

(f) Discussing the prices at which the Product will be sold to unaffiliated Third Parties throughout the Co-Promotion Countries and developing core materials and tools to enable each CCC to develop strategies and documentation to gain reimbursement and product access and listing in the Co-Promotion Countries;

(g) Coordinating with the CDRC with respect to regulatory issues and the development of New Indications to be undertaken pursuant to a Development Plan and proposing Phase IIIb/IV Product Studies;

(h) Obtaining clearance of publications relating to the Product;

(i) Developing strategies for obtaining listing on managed care formularies in the Co-Promotion Countries;

(j) Facilitating, to the extent legally permissible, the exchange of information with respect to the sales and marketing of Product in the Pfizer

Exclusive Countries, Organon Exclusive Countries and Co-Marketing Countries; and

(k) such other matters as the Parties may mutually assign the GCC from time to time.

(ii) All Global Marketing Plans shall be consistent with the terms of this Agreement.

(iii) If the GCC is unable to reach a decision on any issue within ten (10) Business Days after presentation, either Party may refer such issue to the JOC for resolution.

10.5 Manufacturing and Supply Committee.

(i) The MSC shall consist of members from each of Organon and Pfizer, each of which shall confirm to the other its designees. Consistent with the Production Agreements, the MSC shall be responsible for:

(a) Overseeing manufacturing activities underway as of the Effective Date, including stability studies and management of clinical supplies of the Product;

(b) Establish the adequacy of, and periodically (no less than once per Calendar Quarter) review and monitor, all development plans relating to manufacture of the Intermediate and the Compound; establish the adequacy of, and periodically (no less than once per Calendar Quarter) review and monitor, all development plans relating to manufacture of the Intermediate and the Compound, including the First Generation Process Plan and Second Generation Process Plan; Overseeing the manufacturing of registration batches of Product; reviewing the CMC section of the NDA for the Product; reviewing and approving Specifications for purposes of the NDA and other Applications for Regulatory Approval and for Launch; overseeing the preparation for and execution of any pre-approval inspections of the Product manufacturing sites; and monitoring the manufacture of validation lots;

(c) Monitoring worldwide quality assurance efforts and ensuring that the Intermediate, the Compound, and all Products are manufactured in accordance with the Parties' quality standards; and overseeing any routine or non-routine inspections by FDA and other Regulatory Authorities and ensuring adherence to compliance standards following Product approval;

(d) Monitoring the manufacture of the Intermediate, the Compound and the Product;

(e) Determining methods of obtaining cost efficiency, including by developing more efficient manufacturing processes, and reviewing sourcing alternatives of Product components;

(f) Coordinating with the GCC and CDRC as appropriate;

(g) Evaluating the forecasts provided in each Global Marketing Plan as well as inventory levels for the Intermediate, the Compound and the Product;

(h) Establish a method for measuring the Parties' respective manufacturing capacity for the Intermediate, the Compound and the Product, and periodically review and monitor all capacity expansion plans; overseeing the Capacity Plan; and

(i) Providing updates on the MSC's activities and achievements to the JOC.

(ii) The MSC shall establish, at a minimum, the following subcommittees: (a) Supply Chain Subcommittee, (b) Quality Subcommittee, (c) Technical Subcommittee, and (d) Finance Subcommittee. Each subcommittee will report its decisions to the MSC, which shall have jurisdiction over all matters handled initially at the subcommittee level. In addition to the functions described below, the subcommittees will lead the functions outlined in this Article 10.5 and other matters as agreed by the MSC.

(a) The Supply Chain Subcommittee will be responsible for preparation of Product forecasts, the determination of orders for Product and Intermediate, and the logistics of Product supply.

(b) The Quality Subcommittee will be responsible for preparation of quality agreements between the Parties, overseeing the execution of such quality agreements, and managing matters relating to Product quality such as change control, Product complaint investigations and Product recalls.

(c) The Development Subcommittee will be responsible for development of manufacturing processes for the active pharmaceutical product and finished Product for Launch and for continued improvement to those processes.

(d) The Finance Subcommittee will be responsible for establishing and managing processes between the manufacturing finance groups of Pfizer and Organon, including, without limitation, matters relating to payments and reconciliations under the Production Agreements.

(iii) If the MSC is unable to reach a decision on any issue within ten (10) Business Days after presentation, either Party may refer the issue to the JOC for resolution.

10.6 Country Commercialization Committee. The Parties agree to establish a CCC in each Co-Promotion Country or group of Co-Promotion Countries as appropriate and agreed upon by the Parties. The general manager/country manager, or a senior-level member of the general manager's/country manager's leadership team, in each applicable Co-Promotion Country will be included in the relevant CCC. The general managers/country managers will include other representatives from each Party, as needed.

(i) CCC Commercialization Responsibilities. Subject to the provisions of this Agreement and the Global Marketing Plan, each CCC will oversee the Co-Promotion in the relevant Co-Promotion Country or groups of Co-Promotion Countries, as the case may be. In addition, each CCC will be responsible for the following:

(a) Designate the individuals responsible for preparing the Country Marketing Plan for the relevant Co-Promotion Country or group of Co-Promotion Countries each consistent with the Global Marketing Plan;

(b) Develop forecasts, on a at least an annual basis, for the Product in the relevant Co-Promotion Country or group of Co-Promotion Countries

(c) Prepare and submit the Country Marketing Plan for the relevant Country or group of Co-Promotion Countries and submit any deviation in the budget from the Global Marketing Plan, and/or any material change in the Country Marketing Plan to the GCC for approval;

(d) Monitor compliance with the relevant Country Marketing Plan and approve any immaterial change in the relevant Country Marketing Plan;

(e) Review and approve expenses for inclusion as Marketing Costs;

(f) Adapting GCC-approved advertising materials and strategies and promotional materials for the relevant Co-Promotion Country or group of Co-Promotion Countries, and otherwise developing local Promotional Materials consistent with the Global Marketing Plan;

(g) Adapting GCC-approved packaging for the relevant Co-Promotion Country or group of Co-Promotion Countries;

(h) Develop and discuss strategies for the Detailing and marketing of the Product in the relevant Co-Promotion Country or group of Co-Promotion Countries including allocation of responsibility for marketing activities;

(i) Plan and conduct educational and professional symposia in the relevant Co-Promotion Country or group of Co-Promotion Countries;

(j) Suggest to the GCC appropriate marketing-oriented clinical trials and monitor implementation in the relevant Co-Promotion Country or group of Co-Promotion Countries;

(k) Monitor advertising placement and market responses in the relevant Co-Promotion Country or group of Co-Promotional Countries;

(l) Define and establish a set of procedures to forecast and order Product (including samples) in the relevant Co-Promotion Country or group of Co-Promotion Countries, with responsibility for recommendation of production and supply activities;

(m) Initiate and monitor market research in the relevant Co-Promotion Country or group of Co-Promotion Countries;

(n) Develop local pricing and reimbursement strategies and strategies related to obtaining listing on managed care formularies for the relevant Co-Promotion Country, which strategies must be consistent with the Global Marketing Plan; and

(o) Establish the number of Details to be made by each Party's Sales Representatives in the relevant Co-Promotion Country or group of Co-Promotion Countries for each Calendar Quarter, which shall be similar to the number of Details provided in the pharmaceutical industry in such Co-Promotion Country or group of Co-Promotion Countries for products with similar potential and magnitude in light of prevailing market conditions and the competitive landscape.

(ii) CCC Product Development Responsibilities Subject to the provisions of this Agreement and the Development Plan, each CCC shall implement the relevant Development Plan insofar as it relates to the relevant Co-Promotion Country or group of Co-Promotion Countries. In particular, each CCC shall:

(a) Facilitate the exchange of all development information and data;

(b) Submit recommendations for the Development Plan to the CDRC;

(c) Review local activities against the Development Plan;

(d) Recommend allocation of development activities to the CDRC; and

(e) Monitor, directly or indirectly, all local regulatory activities.

(iii) If the CCC is unable to reach a decision on any issue within ten (10) Business Days after presentation, such issues shall be referred to the CDRC or GCC, as applicable.

10.7 Joint Operating Committee. The JOC shall consist of the chairpersons of the CDRC, GCC, and MSC, and, as the co-chairpersons of the JOC, each Party will designate a senior-level executive with responsibility for the applicable therapeutic area in such Party's organization. The JOC will be responsible for the following:

(i) Establishing the strategic objectives and general directions for the Co-Promotion and Detailing of the Product in the Co-Promotion Countries

(ii) Review and approval of the Global Marketing Plan and review of the Development Plan;

(iii) Making go/no go decisions with respect to filing NDA's, other Applications for Regulatory Approvals, and other significant regulatory filings;

(iv) Resolution of disputes which cannot be resolved at the subcommittees;

(v) To raise disputes which cannot be resolved by the JOC to the Steering Committee; and

(vi) Such other matters as the Parties may mutually assign the JOC from time to time.

If the JOC is unable to resolve any issue within ten (10) Business Days after presentation, either Party's co-chairperson on the JOC may refer the issue to the Steering Committee for resolution.

10.8 Steering Committee. The Steering Committee shall consist of four (4) executives, two (2) from each of Organon and Pfizer, each of which shall confirm to the other its designees. In addition, the co-chairpersons of the JOC shall attend meetings of the Steering Committee in order to participate in Steering Committee discussions, but shall not have the right to vote. The Steering Committee shall have general oversight and review of the activities of the JOC and shall be responsible for resolving any issues referred by the JOC.

(i) In the event of a tied vote of the Steering Committee, the chairperson designated by Pfizer shall have the final decisionmaking authority with respect to the following subject matters:

(a) issues related to pricing and reimbursement strategy and strategies for obtaining Pricing Approval in the Co-Promotion Countries, as well as the price at which the Product is sold to unaffiliated Third Parties in the Co-Promotion Countries, including any discounts, rebates, chargebacks or other matters impacting the price effectively paid by any such Third Parties;

(b) contracting with Managed Care and Institutional Customers and any issues in respect of such organizations in the Co-Promotion Countries; and

(c) manufacturing matters pertaining exclusively to (x) the manufacture of the Compound from the Intermediate, or the manufacture of the Product in primary packaging; and (y) the manufacturing facilities of Pfizer and its Affiliates; provided, however, that if any of the matters described in (x) or (y) above could reasonably be expected to have an effect on the manufacturing activities of Organon or its Affiliates under the Production Agreements, or any Regulatory Approval owned by Organon or its Affiliates, then such matter shall remain a Consensus Matter.

(ii) In the event of a tied vote of the Steering Committee, the chairperson designated by Organon shall have the final decisionmaking authority with respect to manufacturing matters pertaining exclusively to (x) the manufacture of the Intermediate and the packaging of the Finished Product; and (y) the manufacturing facilities of Organon and its Affiliates; provided, however, that if any of the matters described in (x) or (y) above could reasonably be expected to have an effect on the manufacturing activities of Pfizer or its Affiliates under the Production Agreements or any Regulatory Approval owned by Pfizer or its Affiliate, then such matter shall remain a Consensus Matter.

(iii) Except as otherwise provided in this Agreement, all other matters within the purview of the Committees or subcommittees shall be Consensus Matters.

10.9 Alliance Managers. In addition to the committees and subcommittees, the Parties will each appoint a senior representative with a general understanding of the clinical, regulatory, manufacturing and commercial issues relating to the Product to act as an alliance manager ("Alliance Manager"). It is envisioned that the Alliance Managers will serve as a single focal point for all information in order to maintain a complete overview of the alliance and to serve as the main contact within each Party with responsibility for facilitating communication and collaboration between the Parties. The Alliance Managers shall attend committee and subcommittee meetings. The Alliance Managers will work together to resolve such issues or potential disputes, and to enable the committees to reach decisions with the intent of averting the escalation of such issues or potential disputes.

ARTICLE 11

INTELLECTUAL PROPERTY

11.1 Ownership of Collaboration Inventions. As between Organon and Pfizer, (i) Organon shall solely own all Collaboration Inventions invented solely by Organon's employees and agents, (ii) Pfizer shall solely own all Collaboration Inventions invented solely by Pfizer's employees and agents, and (iii) the Parties shall jointly own all Collaboration Inventions invented by employees and agents of both Parties. The Parties agree that inventorship shall be determined in accordance with United States patent law, provided, however, that, without limiting the foregoing, in preparing patent applications for Collaboration Inventions, each Party shall follow the Laws of the Country in which such application is being filed. Each Party shall have the first right to prosecute and maintain Patent Rights included in the Collaboration Inventions solely owned by such Party. Neither Party shall abandon any Patent Rights included in the Collaboration Inventions that such Party has the first right to prosecute and maintain without at least 90 days' prior written notice of such abandonment to the other Party. If a Party decides to abandon any such Patent Rights, the other Party shall have the option to continue the prosecution and maintenance of such Patent Rights in the name(s) of the Party or Parties owning such Patent Rights and at such other Party's expense. The costs of prosecuting and maintaining Patent Rights included in the Collaboration Inventions shall be shared equally by the Parties in each Co-Promotion Country and Co-Marketing Country, Pfizer will bear all such costs in the Pfizer Exclusive Countries, Organon will bear all such costs in the Organon Exclusive Countries, and provided that either Party may elect not to pay such costs with respect to any given Patent Rights included in the Collaboration Inventions being prosecuted and/or maintained by the other Party incurred from and after such time as such Party notifies the other Party of such election, and thereafter any licenses granted in this Agreement by the other Party to the Party making such election shall exclude such Patent Rights. Such costs of prosecuting and maintaining Patent Rights included in the Collaboration Inventions in the Co-Promotion Countries shall be shared equally by the Parties and included in the Parties' Quarterly Marketing Cost Reports pursuant to Article 8A.1 of this Agreement. Pfizer shall reimburse Organon for all such costs of prosecuting and maintaining Patent Rights included in the Collaboration Inventions in the Pfizer Exclusive Countries incurred by Organon within thirty (30) days after receiving any invoice from Organon for such costs.

11.2 Jointly Owned Collaboration Inventions. With respect to any Collaboration Inventions that are jointly owned by the Parties, the Parties shall consult with each other regarding the filing, prosecution and maintenance of any such Patent Rights, and responsibility for such activities shall belong to Organon. Organon shall undertake such filings, prosecutions and maintenance in the names of both Parties as co-owners. Organon shall have the following obligations with respect to the filing, prosecution and maintenance of Patent Rights in jointly owned Collaboration Inventions: (i) Organon shall permit Pfizer to review and comment at least two (2) weeks prior to the filing of any priority patent application by Organon; (ii) Organon shall notify Pfizer within thirty (30) days after the filing of a patent application by Organon; (iii) Organon shall notify Pfizer within six (6) months from the filing of the priority patent application whether and in which Countries it intends to file convention patent applications; (iv) Organon shall provide Pfizer promptly with copies of all communications received from or filed in patent offices with respect to such filings; and (v) Organon shall provide Pfizer, a reasonable time prior to taking or failing to take action that would affect the scope or validity of rights under any patent

applications or Patents (including but not limited to substantially narrowing or canceling any claim without reserving the right to file a continuing or divisional patent application, abandoning any Patent or not filing or perfecting the filing of any patent application in any country), with notice of such proposed action or inaction so that Pfizer has a reasonable opportunity to review and make comments, and take such actions as may be appropriate in the circumstances. In the event that Organon materially breaches the foregoing obligations and such breach is not cured within thirty (30) days of a written notice from Pfizer to Organon describing such breach, or in the event that Organon fails to undertake the filing of a patent application within ninety (90) days of a written request by Pfizer to do so, Pfizer may assume Organon's responsibility for filing, prosecution and maintenance of any such jointly owned Patent Right in the manner described in Article 11.6.

11.3 Collaboration Intellectual Property. All Collaboration Intellectual Property shall be jointly owned by the Parties, and each Party shall have the right freely to use all Collaboration Intellectual Property for all purposes and uses.

11.4 Cooperation. Each Party agrees to cooperate with the other with respect to the preparation, filing, prosecution and maintenance of patents and patent applications pursuant to this Article 11 including, without limitation, the execution of all such documents and instruments and the performance of such acts (and causing its relevant employees to execute such documents and instruments and to perform such acts) as may be reasonably necessary in order to permit the other Party to continue any preparation, filing, prosecution or maintenance of any Patent Rights that such Party has elected not to pursue as provided for in Article 11.2. Organon shall recommend to the JOC which of the Organon Patent Rights for which to seek an extension of term in Co-Promotion Countries in which any such extension is available. Upon confirmation of the recommendation of Organon with respect to patent term extension by the JOC, Organon will file for said patent term extension, and the Parties shall bear equally the costs thereof.

11.5 Notification. If either Party during the Term makes a Collaboration Invention, such Party promptly shall make or cause disclosure to the other of such Collaboration Invention.

11.6 Maintenance of Patent Rights other than Jointly Owned Patent Rights.

(i) Organon will maintain in full force and effect all Organon Patent Rights. Organon shall cooperate with Pfizer in the continued prosecution and maintenance by Organon or the licensor or sublicensor, as applicable, of the Organon Patent Rights. After the Effective Date, Organon shall not, without Pfizer's consent, enter into any Third Party license agreement relating to Patent Rights that Organon proposes to license from a Third Party and that Organon reasonably foresees would, upon the execution of such Third Party license agreement, result in the creation of any Pfizer obligation pursuant to this Agreement to share in or pay any portion of the royalties or other amounts payable under such Third Party license agreement.

(ii) Organon shall not abandon any Organon Patent Rights with respect to which Organon or any of its Affiliates controls prosecution and maintenance activities, either directly or through step-in rights granted to Organon in any Third Party license agreement, without at least 90 days' prior notice of such abandonment to Pfizer. If Organon decides to abandon any such Patent Rights, Pfizer shall have the option to continue the prosecution and maintenance of such Patent Rights in Organon's name at Pfizer's expense, subject to any limitations set forth in Organon's agreements with Organon's licensors and sublicensors. If Pfizer desires that Organon file any application

for a patent in a specific Country or Countries, or file any patent applications on improvements and variations upon inventions disclosed in the Organon Patent Rights set forth on Schedule 1.94 or otherwise relating to the Compound or the Product, Pfizer shall advise Organon of such Country or Countries or improvements, variations or inventions, as the case may be. Organon shall consider Pfizer's request in good faith and shall not unreasonably decline to file the requested patent application and, if Organon files the patent applications as requested, Pfizer shall pay fifty percent (50%) of all reasonable expenses, including reasonable fees for patent counsel, for filing and for prosecuting such requested patent applications. If Organon declines to file the patent applications as requested, Pfizer may, at its sole expense, file and prosecute such applications. Pfizer shall have reasonable access to all documentation, filings and communications to or from the respective patent offices and shall be kept advised as to the status of all pending applications to the extent pertaining to the Compound or the Product. Unless otherwise explicitly set forth above in this Article 11.6, the Parties shall each be responsible for 50% of the Parties' patent prosecution and maintenance costs relating to the Organon Patent Rights. Organon shall include all such costs in Organon's Quarterly Marketing Cost Reports pursuant to Article 8A.1 of this Agreement.

11.7 Trademarks and Corporate Logos.

(i) Subject to the provisions of this Article 11.7, each Party shall retain all right, title and interest in and to its respective corporate name and logo.

(ii) In the Co-Promotion Countries, the Product shall be promoted and sold solely under the Trademark(s) and shall use a trade dress mutually agreed by the Parties that includes Pfizer's and Organon's logos. In the Co-Promotion Countries, subject to the requirements of Law, Organon and Pfizer shall be identified and given equal exposure and prominence on all Product package inserts, trade packages, packaging, samples, and Promotional Materials; provided, however, that if Organon or Pfizer cannot be given equal exposure and prominence on all Product package inserts, trade packages, packaging, samples, and promotional materials in one or more Co-Promotion Countries as a result of the requirements of applicable Law, then Organon or Pfizer, as the case may be, shall be given as close to equal exposure and prominence as possible, consistent with applicable Law. In the Pfizer Exclusive Countries, Pfizer will promote and sell the Product under a Trademark, but shall have the sole right and obligation to determine the trade dress and packaging for the Product, provided that it makes such determinations in a manner consistent with the Global Marketing Plan. In the Organon Exclusive Countries, Organon will promote and sell the Product under a Trademark, but shall have the sole right and obligation to determine the trade dress and packaging for the Product, provided that it makes such determinations in a manner consistent with the Global Marketing Plan.

(iii) It is the Parties' intention to utilize a single trademark for the Product throughout the Territory other than in the Co-Marketing Countries where the Product must be marketed and sold by the Parties under different Trademarks by operation of local Law; provided, however, if any Governmental Authority in the Territory fails to approve the Trademark as an acceptable trademark for the Product, or if either Party reasonably determines that use of the Trademark in a particular Country may violate the rights of any Third Party in such Country, then the Parties shall select an alternative Trademark for the Product in such Country or Countries. In either event, Organon shall be solely responsible for registering and maintaining such alternative Trademark in the

Pfizer Exclusive Countries and shall be the owner thereof. Pfizer shall not register or seek to register the Trademark or any alternative Trademark selected by the Parties in any Country of the Territory.

(iv) During the Term, Pfizer grants to Organon the non-exclusive right, free of charge, to use the Pfizer name and logo in the Co-Promotion Countries solely for the purpose of Co-Promoting of the Products in accordance with the terms of this Agreement, and Organon grants to Pfizer the non-exclusive right, free of charge, to use the Organon name and logo in the Co-Promotion Countries solely for the purpose of Co-Promotion of the Products in accordance with the terms of this Agreement; provided that such rights shall be exercised, and all Products bearing such names and/or logos shall be manufactured, in accordance with the quality standards established by the GCC.

(v) During the Term, and thereafter as provided in Article 13.8, Organon grants to Pfizer the non-exclusive right to use the Trademarks in connection with the marketing, promotion and sale of the Product in (a) the Pfizer Exclusive Countries and, (b) other than the Trademark being used by Organon in each such Co-Marketing Country, the Co-Marketing Countries.

(vi) Organon shall remain the owner of the Organon name and logo and the Trademark(s) and the goodwill pertaining thereto. Organon shall be solely responsible for registering and maintaining the Trademark(s) in the Territory and shall remain the owner thereof. Except as contemplated herein, Organon shall have no rights in or to the Pfizer name or logo or the goodwill pertaining thereto. Except as contemplated herein, Pfizer shall have no rights in the Trademark(s) in the Territory or to the Organon name or logo, or the goodwill pertaining thereto.

(vii) Organon and Pfizer shall each be responsible for fifty percent (50%) of the cost of registering and maintaining the Trademark(s) in the Territory. Organon shall include all such Territory costs in Organon's Quarterly Marketing Cost Reports pursuant to Article 8A.1.

(viii) Copyrights and Proprietary Programs. The Parties shall jointly own all copyrights relating to Promotional Materials developed for use in the Co-Promotion Territory for the Product. Pfizer and Organon shall each retain all rights including, without limitation, copyrights and trademarks, to all of their respective existing programs and materials in all formats (print, video, audio, digital, computer, etc.) regarding sales training, patient education and disease management programs owned by each of them as of the Effective Date, as well as any modifications each may develop in the future which are not specific to the Product. Organon and Pfizer shall, from time to time, endeavor to each notify the other as to the identity of such existing programs and materials. In addition, all new programs regarding sales training, patient education and disease management jointly developed by Organon and Pfizer for the Products pursuant to this Agreement shall be jointly owned by Organon and Pfizer, and each Party shall have the right to use and exploit such developed programs freely without any need to obtain the consent of the other Party and without any duty to account to the other Party for such use or exploitation. Each Party hereby assigns to the other Party all rights, title and interests, including all intellectual property rights, in and to such Promotional Materials and programs as necessary to give effect to the provisions of this Article 11.7.

(ix) Domain Names. Organon shall be solely responsible for registering and maintaining domain names comprising the Trademark(s) in the Territory and shall be the owner thereof. Organon and Pfizer shall each be responsible for fifty percent (50%) of the costs for registering and maintaining the domain names comprising the Trademark(s). Organon shall include all such costs in Organon's Quarterly Marketing Cost Reports pursuant to Article 8A.1.

(x) Copyrights and Internet Sites. The Parties shall jointly own all copyrights relating to internet sites jointly developed by Organon and Pfizer for use in the Territory pursuant to this Agreement. Organon and Pfizer shall each be responsible for fifty percent (50%) of the costs of registering and maintaining such copyrights and internet sites.

11.8 Disclosure. Organon shall disclose to Pfizer the complete texts of all patent applications within the Organon Patent Rights filed by Organon, or by Organon's licensors to the extent Organon is permitted to provide such texts to Pfizer under the terms of Organon's agreements with such licensors, as well as information received concerning the institution or possible institution of any interference, opposition, re-examination, reissue, revocation or any official proceeding involving patents and patent applications within the Organon Patent Rights prosecuted and/or maintained by Organon, or by Organon's licensors to the extent Organon receives such information, anywhere in the Territory. Pfizer shall have the right to review all such pending applications and other proceedings and make recommendations to Organon, and to Organon's licensors if permitted under the terms of Organon's agreements with such licensors, concerning such applications and proceedings and their conduct. Organon agrees, subject to any limitations set forth in Organon's agreements with Organon's licensors, to keep Pfizer promptly and fully informed of the course of such patent prosecution and other proceedings including, without limitation, by providing Pfizer with copies of all substantive communications submitted to or received from patent offices throughout the Territory. The provisions of this Article 11.8 also shall be deemed to apply in all respects to Pfizer as it relates to Pfizer Patent Rights in Collaboration Inventions.

11.9 Patent Term Extensions. The Parties shall cooperate, if necessary and appropriate, with each other in gaining patent term extensions wherever applicable to Organon Patent Rights. The Parties shall, if necessary and appropriate, use reasonable efforts to agree upon a joint strategy relating to patent term extensions, but, in the absence of mutual agreement with respect to any extension such, and subject to Law, a patent shall be extended if either Party elects to extend such patent. The Parties shall each be responsible for fifty percent (50%) of the costs of seeking and/or obtaining patent term extensions relating to the Organon Patent Rights in the Territory. Organon shall include all such costs in Organon's Marketing Cost Reports pursuant to Article 8A.1 of this Agreement.

11.10 Infringement, Unauthorized Use and Challenge. If either Party becomes aware that a Third Party is or may be infringing or otherwise making unauthorized use of, or challenge to, any Organon Patent Rights, Patent Rights in jointly owned Collaboration Inventions, Trademarks or Organon Technical Information, the Party learning of such infringement or unauthorized use or challenge shall promptly notify the other Party and provide it with any available evidence of such possible infringement or unauthorized use or challenge. In the Pfizer Exclusive Countries, Pfizer shall have the first right to bring suit and to take action against such infringer or unauthorized user or challenger in its own name, or in the name of Organon where necessary, in which case Pfizer shall control the prosecution of any such suit or claim, including without limitation the choice of counsel, and shall have the exclusive right to settle or dispose of

any such suit or claim. In the Organon Exclusive Countries and the Co-Marketing Countries, Organon shall have the first right to bring suit and to take action against such infringer or unauthorized user or challenger in its own name, in which case Organon shall control the prosecution of any such suit or claim, including without limitation the choice of counsel, and shall have the exclusive right to settle or dispose of any such suit or claim. In the Co-Promotion Countries, as between Pfizer and Organon, and subject to any rights retained by Organon's licensors, Organon shall have the first right to bring suit and to take action against such infringer or unauthorized user or challenger in its own name, in which case Organon shall control the prosecution of any such suit or claim, including without limitation the choice of counsel, and shall have the exclusive right to settle or dispose of any such suit or claim. Notwithstanding anything to the contrary in this Article 11.10, if a Party fails to initiate a suit or take other appropriate action that it has the initial right to initiate or take pursuant to this Article 11.10 or the Parties fail to agree on the initiation or taking thereof within ninety (90) days after becoming aware of the basis for such suit or action, then the other Party shall have the right, in its discretion, to initiate a suit or take other appropriate action that it believes is reasonably required to protect the intellectual property rights at issue. Notwithstanding the foregoing provisions of this Article 11.10, in the case of an infringement action pursuant to Section 505(b) of the Act, subject to any legal obligations of Organon to its licensors with respect to Organon Patent Rights, if the Party that has the initial right to initiate such action fails to notify the other Party, at least fifteen (15) days prior to such Party's deadline under the Act for bringing such action, that such Party will bring such action, then the other Party may, in its discretion, initiate such action after giving written notice of such election to the Party with the initial right to initiate such action. The proceeds of any recovery, court award or settlement of such action shall, after any required payments to Organon's licensors, first be applied to reimburse the Parties for the costs and expenses of such prosecution and the balance shall be paid 50% to Pfizer and 50% to Organon. The Parties shall cooperate and take action to assist the other as is reasonably necessary in relation to all suits or claims brought under this Article 11.10.

11.11 Scherer Agreement. Organon covenants and agrees with Pfizer that Organon: (a) shall not execute any amendment, modification or waiver of the license(s) contained in the Scherer Agreement without the prior written consent of Pfizer, (b) shall not make any election or exercise any right or option (or omit to take any action) that would terminate or relinquish in whole or in part the Scherer Agreement, (c) shall comply with all of its obligations under the Scherer Agreement in all material respects, (d) shall take such reasonable actions as shall be necessary to keep in full force and effect the Scherer Agreement, and (e) shall give prompt notice to Pfizer, together with a summary of outstanding issues if Pfizer so requests and of any actual or alleged defaults, breaches, violations, proposed amendments or proposed modifications of, or any proposed waivers under, the Scherer Agreement by any party to the Scherer Agreement.

ARTICLE 12

CLAIMS

12.1 Notice from the Parties. Each Party shall promptly notify the other Party in writing of any potential or actual litigation or governmental activity in the Territory relating to the Intermediate, the Compound or the Product.

12.2 Indemnification by Organon. Organon shall indemnify and hold harmless Pfizer and its Affiliates and their respective directors, officers and employees (the "Pfizer Parties") from

and against any and all Losses (as defined below) arising from or relating to any claim, demand, lawsuit, action or proceeding (a "Claim") arising from or relating to:

(i) any violation of Law Organon or its Affiliates;

(ii) the storage, promotion, sale or distribution or use of the Product based on the gross negligence or intentionally wrongful conduct of Organon or its Affiliates;

(iii) any actual or alleged infringement, misappropriation or other violation of a Third Party's intellectual property rights arising out of or related to the Organon Patent Rights, the Organon Technical Information and/or the manufacture (by the process described on Schedule 9.8), use, sale, offer for sale, or importation of the Current Product or any Organon-Only Product;

(iv) Organon's or any of its Affiliates' failure to manufacture and package in accordance with the Production Agreements, or to cause Third Parties to manufacture, the Product in accordance with (A) the then-existing Product Specifications as determined in accordance with the terms of this Agreement, or (B) cGMP;

(v) Organon's use, sale, offer for sale, or importation of any Organon-Only Product; or

(vi) any breach by Organon or any of its Affiliates of any representation, warranty or covenant given in any of the Alliance Agreements.

Notwithstanding anything to the contrary contained herein, none of the indemnities in this Article 12.2 shall apply to the extent that any Loss is the result of any breach of this Agreement by Pfizer or of any willful misconduct of Pfizer Parties.

12.3 Indemnification by Pfizer. Pfizer shall indemnify and hold harmless Organon and its Affiliates and their respective directors, officers and employees (the "Organon Parties") from and against any and all Losses arising from or relating to any Claim arising from or relating to:

(i) any violation of Law by Pfizer or its Affiliates; or

(ii) the storage, promotion, sale or use of the Product based on the gross negligence or intentionally wrongful conduct of Pfizer or its Affiliates;

(iii) any breach by Pfizer or any of its Affiliates of any representation or warranty given in any of the Alliance Agreements; or

(iv) Pfizer's or any of its Affiliates' failure to manufacture in accordance with the Production Agreements, or to cause Third Parties to manufacture, Products in accordance with (A) the then-existing Product Specifications as determined in accordance with the terms of this Agreement, or (B) cGMP (other than, in all cases, any failures which are the subect of Article 12.2(iv)).

Notwithstanding anything to the contrary contained herein, none of the indemnities in this Article 12.3 shall apply to the extent that any Loss is the result of any breach of this Agreement by Organon or of any willful misconduct of Organon Parties or is the subject of the indemnity contained in Article 12.2 (including without limitation Article 12.2(v)).

12.4 Co-Indemnification.

(i) Product Liability. Organon shall indemnify, defend and hold the Pfizer Parties harmless from and against one hundred percent (100%) of the amount of any and all Losses arising out of or resulting from any Third Party Claim involving death, bodily injury or property damage actually or allegedly arising out of or resulting from the manufacture, packaging, distribution, marketing, use and/or sale of the Product (other than with respect to the matters for which one Party is obligated to indemnify the other Party pursuant to Article 12.2 or 12.3 above) (any and all such Losses, "Product Liability") up to, in the aggregate, the Threshold Amount with respect to all Product Liability Occurences in the Territory after the date hereof and prior to the initial Launch of the Product on a Country-by-Country basis. Organon shall indemnify, defend and hold the Pfizer Parties harmless from and against fifty percent (50%) of the amount of any and all Product Liability (a) prior to the initial Launch of the Product in each Country, in excess of the Threshold Amount or (b) with respect to any Product Liability Occurrences after the initial Launch of the Product in a Country, and Pfizer shall indemnify, defend and hold Organon Parties harmless from and against fifty percent (50%) of the amount of any and all of such Product Liability (a) prior to the initial Launch of the Product in each Country, in excess of the Threshold Amount or (b) with respect to any Product Liability Occurrences after the initial Launch of the Product in a Country. For purposes of this Article 12: (A) "Threshold Amount" shall mean the aggregate sum of Seventy-Five Million U.S. Dollars ($75,000,000) of Product Liability determined on a first-to-be incurred or discovered basis (whichever is earlier), and (B) "Product Liability Occurences" means, with respect to all Product Liability, the initial time of sale or other provision to the plaintiff of the relevant Product for which any Product Liability relates based upon available records or other reliable means.

(ii) Organon shall indemnify, defend and hold the Pfizer Parties harmless from and against fifty percent (50%) of the amount of any and all Losses arising out of or resulting from any Third Party Claim involving any actual or alleged infringement, misappropriation or other violation of a Third Party's intellectual property rights arising out of or related to the Organon Patent Rights, the Organon Technical Information and/or use, promotion, manufacture, commercialization, distribution, offering for sale, sale or importation of the Product (but in all cases excluding Losses for which one Party is obligated to indemnify the other Party pursuant to this Article 12, including without limitation, Article 12.2(iii) above) (any and all such Losses, the "IP Liability"), and Pfizer shall indemnify, defend and hold Organon Parties harmless from and against fifty percent (50%) of the amount of any and all of such IP Liability; it being understood and agreed that the purpose of the provisions of this sentence is that Pfizer and Organon shall pay for and otherwise share the cost of the IP Liability equally.

(iii) For the avoidance of doubt, the reference to "Product" in this Article 12.4 excludes Organon-Only Product.

12.5 Procedures for Third Party Claims.

(i) In the event that any Third Party asserts a Claim with respect to any matter for which a Party (the "Indemnified Party") is entitled to indemnification hereunder (a "Third Party Claim"), then the Indemnified Party shall promptly notify the Party

obligated to indemnify the Indemnified Party (the "Indemnifying Party") thereof in writing; provided, however, that no delay on the part of the Indemnified Party in notifying the Indemnifying Party shall relieve the Indemnifying Party from any obligation hereunder unless (and then only to the extent that) the Indemnifying Party is prejudiced thereby.

(ii) The Indemnifying Party shall have the right, exercisable by written notice to the Indemnified Party within ten (10) days of receipt of notice from the Indemnified Party of the commencement of or assertion of any Third Party Claim, to assume the defense of such Third Party Claim; provided, however, that (A) the Third Party Claim seeks (and continues to seek) solely monetary damages and the Indemnifying Party expressly agrees in such notice that, as between the Indemnifying Party and the Indemnified Party, the Indemnifying Party shall be solely obligated to satisfy and discharge the Third Party Claim (or, in the case of matters which are the subject of Article 12.4, such amounts as required in accordance with Article 12.4), (B) the defense of such Third Party Claim by the counsel representing the Indemnifying Party does not, in the reasonable judgment of the Indemnified Party, constitute a conflict of interest under the applicable cannons or rules of legal professional ethics, (C) in such case as Pfizer or another of the Pfizer Parties is the Indemnified Party, such Third Party Claim does not relate, directly or indirectly, to Geodon, Xanax, or any other product under development by Pfizer, its Affiliates or licensees, and (D) the Indemnifying Party makes reasonably adequate provision to ensure the Indemnified Party of the ability of the Indemnifying Party to satisfy the full amount of any adverse monetary judgment that would reasonably be expected to result therefrom (the conditions set forth in clauses (A), (B), (C) and (D) are collectively referred to as the "Litigation Conditions"). In no event shall Organon have the right to control any Third Party Claim to the extent such Third Party Claim relates, directly or indirectly, to Geodon, Xanax, or any other product (other than the Product) being developed or commercialized by Pfizer, its Affiliates or licensees. If both Parties are Indemnifying Parties pursuant to co-indemnification obligations under Article 12.4 with respect to the same Third Party Claim, the Parties shall determine by mutual agreement, within twenty (20) days following their receipt of notice of commencement or assertion of such Third Party Claim (or such lesser period of time as may be required to properly respond to such claim), which Party shall assume the lead role in the defense thereof. Should the Parties be unable to mutually agree on which Party shall assume the lead role in the defense of such Third Party Claim, both Parties shall be entitled to participate in such defense through counsel of their respective choosing; provided that in the case of any Third Party Claim with respect to which (i) both Parties are Indemnifying Parties pursuant to co-indemnification obligations under Article 12.4 and (ii) the Parties are unable to agree upon which Party shall assume the lead role in the defense of such claim, then the Parties agree to discuss strategies for defending such claim and will, to the extent reasonably practicable, coordinate such defense through their respective counsel.

(iii) Within ten (10) days after the Indemnifying Party has given notice to the Indemnified Party of its intended exercise of its right to defend a Third Party Claim, the Indemnified Party shall give notice to the Indemnifying Party of any objection thereto based upon the Litigation Conditions. If the Indemnified Party reasonably so objects, the Indemnified Party shall continue to defend the Third Party Claim, at the expense of the Indemnifying Party, until such time as such objection is withdrawn. If no such notice is given, or if any such objection is withdrawn, the Indemnifying Party shall be entitled, at its sole cost and expense, to assume and conduct such defense, with counsel selected by the Indemnifying Party and reasonably acceptable to the Indemnified Party, until such

time as the Indemnified Party shall give notice that any of the Litigation Conditions, in its reasonable judgment, are no longer satisfied.

(iv) During such time as the Indemnifying Party is controlling the defense of such Third Party Claim, the Indemnified Party shall cooperate, and cause its Affiliates and agents to cooperate, to the extent commercially reasonable, upon request of the Indemnifying Party in the defense or prosecution of the Third Party Claim, including by furnishing such records, information and testimony and attending such conferences, discovery proceedings, hearings, trials or appeals as may reasonably be requested by the Indemnifying Party.

(v) In the event that the Indemnifying Party fails to satisfy the Litigation Conditions or does not notify the Indemnified Party in writing of the Indemnifying Party's intent to defend any Third Party Claim within ten (10) days after notice thereof, the Indemnified Party may (without further notice to the Indemnifying Party) undertake the defense thereof with counsel of its choice and at the Indemnifying Party's expense (including attorneys' fees and costs and expenses of enforcement or defense).

(vi) The Indemnifying Party or the Indemnified Party, as the case may be, shall have the right to join in (including the right to conduct discovery, interview and examine witnesses and participate in all settlement conferences), but not control, at its own expense, the defense of any Third Party Claim which the other Party is defending as provided in this Agreement.

(vii) The Indemnifying Party, if it shall have assumed the defense of any Third Party Claim as provided in this Agreement, shall not consent to a settlement of, or the entry of any judgment arising from, any such Third Party Claim without the prior written consent of the Indemnified Party (which consent shall not be unreasonably withheld or delayed). The Indemnifying Party shall not, without the prior written consent of the Indemnified Party, enter into any compromise or settlement which commits the Indemnified Party to take, or to forbear to take, any action. The Indemnified Party shall have the sole and exclusive right to settle any Third Party Claim, on such terms and conditions as it deems reasonably appropriate, to the extent such Third Party Claim involves equitable or other non-monetary relief, and shall not have the right to settle such Third Party Claim to the extent such Third Party Claim involves monetary damages without the prior written consent of the Indemnifying Party.

(viii) The Indemnified Party shall be entitled to reimbursement for all costs and expenses, including attorneys' fees and costs and expenses of enforcement or defense, on an "as incurred" basis. The Indemnifying Party will reimburse the Indemnified Party for such amounts within fifteen (15) days after receiving an invoice from the Indemnified Party therefor.

12.6 Losses. For purposes of Articles 11 and 12, "Losses" shall mean any and all (a) claims, losses, liabilities, damages, fines, royalties, governmental penalties or punitive damages, deficiencies, interest, awards, and judgments, and (b) with respect to Third Parties, settlement amounts and all of the items referred to in clause (a) above which, in accordance with Article 12.7, include special, indirect, incidental and consequential damages (including without limitation lost profits), and (c) in connection with all of the items referred in clauses (a) and (b) above, any and all costs and expenses (including reasonable attorneys' fees and all other expenses reasonably incurred in investigating, preparing or defending any litigation or

proceeding, commenced or threatened). Notwithstanding anything to the contrary, the Parties understand and agree that no Losses for which one Party has agreed to indemnify any of the the other Party under this Agreement shall be included in Development Costs, Cost of Goods or Marketing Costs or shall be applied as a reduction in the calculation of Net Sales.

12.7 Limitation on Damages. IN NO EVENT SHALL PFIZER OR ORGANON BE LIABLE FOR SPECIAL, INDIRECT, INCIDENTAL OR CONSEQUENTIAL DAMAGES (INCLUDING, WITHOUT LIMITATION, LOSS OF PROFITS) SUFFERED BY ANY ORGANON PARTIES OR ANY PFIZER PARTIES, RESPECTIVELY UNDER THE ALLIANCE AGREEMENTS, EXCEPT (A) TO THE EXTENT OF ANY SUCH DAMAGES PAID TO A THIRD PARTY AS PART OF A THIRD PARTY CLAIM, AND (B) FOR PURPOSES OF INDEMNIFICATION PURSUANT TO ARTICLE 12, IN THE EVENT OF AN INTENTIONAL AND WILLFUL BREACH IN BAD FAITH OF ANY REPRESENTATION, WARRANTY, COVENANT OR AGREEMENT BY ORGANON OR PFIZER (AS THE CASE MAY BE) OF THIS AGREEMENT, AND (C) AS PROVIDED IN ARTICLE 12.8 BELOW. EXCEPT AS EXPRESSLY PROVIDED IN THIS AGREEMENT, INDEMNIFICATION PURSUANT TO THIS ARTICLE 12 SHALL BE THE SOLE AND EXCLUSIVE REMEDY (WHETHER BASED ON CONTRACT, TORT OR ANY OTHER LEGAL THEORY) AVAILABLE TO ORGANON OR PFIZER FOR ANY MISREPRESENTATION UNDER OR BREACH OF THIS AGREEMENT.

12.8 Available Damages. Notwithstanding anything to the contrary contained in this Agreement, in the case of any claim by Pfizer alleging any breach of this Agreement by Organon, the following in each case will not be considered as constituting special, incidental, indirect or consequential damages under this Agreement: (x) payments due to Pfizer pursuant to Article 6 or Article 9 of this Agreement, and (y) Losses as and to the extent such Losses aggregate up to the sum of all amounts previously paid to Organon by Pfizer under any of the Alliance Agreements.

ARTICLE 13

TERM AND TERMINATION

13.1 Term. Unless terminated sooner pursuant to this Article 13 hereof and except as otherwise provided herein, this Agreement shall become effective as of the Effective Date and shall continue in full force and effect, on a Country-by-Country basis in each Country of the Territory for a period equal to the longer of (A) fifteen (15) years following Launch of the Product in such Country, and (B) such date the Product is no longer embraced within any Valid Claim under Organon Patent Rights in such Country (the "Term").

13.2 Bilateral Termination. This Agreement may be terminated at any time by written consent of each of the Parties. Such termination will be effective thirty (30) days following such written consent.

13.3 Material Default. Organon shall have the rights set forth below in this Article 13.3 by notice to Pfizer, and Pfizer shall have the rights set forth below in this Article 13.3 by notice to Organon:

(i) Upon Organon's notice to Pfizer that a Material Default by Pfizer has occurred, the Parties will meet to discuss in good faith whether a plan to remedy the Material Default can be mutually agreed. If the Parties fail to so agree within thirty (30) days after the date of such notice, Article 13.3(ii) below shall apply. Notwithstanding the

foregoing provisions of this Article 13.3(i), in the case of a payment default, the provisions of Article 13.3(ii) below shall apply without any obligation to meet to discuss remedies pursuant to this Article 13.3(i).

(ii) Subject to the terms hereof, upon the occurrence of any Material Default by Pfizer, Organon may, upon ninety (90) days prior written notice, terminate this Agreement, provided, however, that in case of a default of a payment obligation such notice will lapse without effect if Pfizer cures such default within thirty (30) days after receipt of such notice. Organon may give the notice specified in this Article 13.3(ii) concurrently with the notice specified in Article 13.3(i) and shall not give the notice specified in this Article 13.3(ii) later than sixty (60) days after the date of the notice specified in Article 13.3(i).

(iii) Upon Pfizer's notice to Organon that a Material Default by Organon has occurred, the Parties will meet to discuss in good faith whether a plan to remedy the Material Default can be mutually agreed. If the Parties fail to so agree within thirty (30) days after the date of such notice, Article 13.3(iv) below will apply. Notwithstanding the foregoing provisions of this Article 13.3(iii), in the case of a payment default, the provisions of Article 13.3(iv) below shall apply without any obligation to meet to discuss remedies pursuant to this Article 13.3(iii).

(iv) Subject to the terms hereof, upon the occurrence of any Material Default by Organon, Pfizer may, upon ninety (90) days prior notice, terminate this Agreement, provided, however, that in case of a default of a payment obligation such notice will lapse without effect if Organon cures such default within thirty (30) days after receipt of such notice. Pfizer may give the notice specified in this Article 13.3(iv) concurrently with the notice specified in Article 13.3(iii) and shall not give the notice specified in this Article 13.3(iv) later than sixty (60) days after the date of the notice specified in Article 13.3(iii).

(v) Notwithstanding Organon's right of termination described in this Article 13.3, Organon acknowledges that it shall have no claim whatsoever against Pfizer under this Agreement, and no right to terminate this Agreement, for any breach or alleged breach by Pfizer of the Alliance Agreements other than this Agreement, and that, under those circumstances, this Agreement shall remain in full force and effect according to its terms.

13.4 Change in Control. Organon may terminate this Agreement by written notice to Pfizer in the event of a Change in Control of Pfizer, or in the event that Pfizer assigns this Agreement to a Third Party in violation of Article 16.5 below. Pfizer may terminate this Agreement by written notice to Organon in the event of a Change in Control of Organon, or in the event that Organon assigns this Agreement to a Third Party in violation of Article 16.5 below.

13.5 Pfizer Termination Rights.

(i) Net Sales, Product Profile and Clinical QTc Study Termination. Pfizer may terminate this Agreement in its entirety as follows:

(a) Low Net Sales. If during the three (3) year period commencing with the second anniversary of the Launch of the Product in the US Territory, the Net Sales in the US Territory for any two (2) of the years during such three (3)

year period (with each such year referenced in this Article 13.5(i)(a) commencing on the second, third and fourth anniversary of such Launch) are less than $650 million, $800 million and $1.0 billion, respectively, for the first, second and third years in such three (3) year period, then Pfizer may elect, at any time within 120 days following determination of Net Sales for each of the fourth and fifth years, to terminate this Agreement in its entirety upon one hundred and eighty (180) days notice to Organon; or

(b) Product Profile. Pfizer may terminate this Agreement in its entirety by giving Organon one hundred and eighty (180) days prior written notice at any time, but in no event later than twenty (20) days after the earlier of receipt of (x) an approvable letter in respect of the Product from the FDA, and (y) Regulatory Approval of the Product in the US Territory, in the event that Pfizer, in the exercise of its reasonable judgment based on the data and results from the Product Studies under the Development Plan, concludes in good faith that the Product Profile will not be, or has not been, as applicable, achieved at the time of such approvable letter or Regulatory Approval (and in connection with any such termination pursuant to this Article 13.5(i)(b), Pfizer agrees to contemporaneously provide Organon with a written summary of the reasons for its conclusion); or

(c) Clinical QTc Study. Pfizer may terminate this Agreement in its entirety by giving Organon one hundred and eighty (180) days prior written notice in the event that within thirty (30) days following Pfizer's receipt of the final study report for the Clinical QTc Study, the results of the Clinical QTc Study do not satisfy the endpoints for such study as such endpoints are described in Schedule 1.15.

(ii) Termination for ADME Study and Rat and Mouse Carcinogenicity Studies; at Will. Pfizer may terminate this Agreement as follows:

(a) ADME Study and Rat and Mouse Carcinogenicity Studies. Pfizer may terminate this Agreement in its entirety by giving Organon ninety (90) days prior written notice in the event that, within thirty (30) days following (x) Pfizer's receipt of the final study reports of the ADME Study or (y) Pfizer's meeting with the Third Party peer reviewer engaged by Organon in connection with each of the Rat and Mouse Carcinogenicity Studies, as applicable, the results of any of the foregoing studies fail to satisfy the endpoints described in Schedule 1.2, with respect to the ADME Study or the endpoints described in Schedule 13.5(ii)(a), with respect to the Rat and Mouse Carcinogenicity Studies; or

(b) At Will. Pfizer may terminate this Agreement in its entirety upon (x) twelve (12) months prior written notice to Organon from Pfizer of termination of this Agreement pursuant to this Article 13.5(ii)(b) if such notice is given prior to the first Launch of a Product in the US Territory, (y) nine (9) months prior written notice to Organon from Pfizer of termination of this Agreement pursuant to this Article 13.5(ii)(b) if such notice is given prior to the third anniversary of the first Launch of a Product in the US Territory or (z) six (6) months prior written notice to Organon from Pfizer of termination of this Agreement pursuant to this Article 13.5(ii)(b) if such notice is given after the third anniversary of the first Launch of a Product in the US Territory. Pfizer shall be entitled to submit the above notice

from time to time in its absolute and sole discretion. Without limiting the foregoing:

(1) if the effective date of termination pursuant to this Article 13.5(ii)(b) is expected to fall after the first Launch of the Product in the US Territory but prior to the first anniversary of such Launch, then Organon may, at its option, on written notice to Pfizer given no more than thirty (30) days after the date of Pfizer's notice of termination, (A) shorten the applicable notice period so that this Agreement terminates one (1) month prior to such Launch; or (B) extend the notice period so that this Agreement terminates on the first anniversary of such Launch; and

(2) if the effective date of termination pursuant to this Article 13.5(ii)(b) is expected to fall prior to the first Launch of the Product in the US Territory, then Organon may, at its option, on written notice to Pfizer given no more than thirty (30) days after the date of Pfizer's notice of termination, extend the effective date of such termination by an additional one hundred and eighty (180) days (the "Additional Notice Period"), during which time Pfizer will continue its role in connection with the clinical development of the Product in the same manner as it was conducting such clinical development activities prior to giving such notice of termination, and will continue to be responsible for its share of any Development Costs incurred or accrued during the Additional Notice Period related to such clinical development activities applicable pursuant to Article 4.4 and with such cost sharing percentage in effect at the time of Pfizer's notice of termination (the "Additional Development Costs"), but Pfizer will be relieved of all of its other obligations (including payment obligations) under this Agreement. Pfizer will provide Organon with a report setting forth such Additional Development Costs within sixty (60) days after the end of the Additional Notice Period.

13.6 Bankruptcy. Each Party may, in addition to any other remedies available to it by law or in equity, exercise the rights set forth below by written notice to the other Party, which in the case of Organon, shall refer to the Organon Group (the "Insolvent Party"), in the event the Insolvent Party shall have become insolvent or bankrupt, or shall have made a general assignment for the benefit of its creditors, or there shall have been appointed a trustee or receiver of the Insolvent Party or for all or a substantial part of its property, or any case or proceeding shall have been commenced or other action taken by or against the Insolvent Party in bankruptcy or seeking reorganization, liquidation, dissolution, winding-up arrangement, composition or readjustment of its debts or any other relief under any bankruptcy, insolvency, reorganization or other similar act or law of any jurisdiction now or hereafter in effect, and any such event shall have continued for sixty (60) days undismissed, unbonded and undischarged. All rights and licenses granted under or pursuant to this Agreement by Organon and Pfizer are, and shall otherwise be deemed to be, for purposes of Article 365(n) of the U.S. Bankruptcy Code, licenses of rights to "intellectual property" as defined under Article 101 of the U.S. Bankruptcy Code. The Parties agree that the Parties as licensees of such rights under this Agreement shall retain and may fully exercise all of their rights and elections under the U.S. Bankruptcy Code. The Parties further agree that, in the event of the commencement of a bankruptcy proceeding by or against either Party under the U.S. Bankruptcy Code, the other Party shall be entitled to a complete duplicate of (or complete access to, as appropriate) any such intellectual property and all embodiments of such intellectual property, and same, if not

already in their possession, shall be promptly delivered to it (i) upon any such commencement of a bankruptcy proceeding upon its written request therefore, unless the Party subject to such proceeding elects to continue to perform all of its obligations under this Agreement or (ii) if not delivered under (i) above, upon the rejection of this Agreement by or on behalf of the Party subject to such proceeding upon written request therefore by the other Party.

13.7 Termination Upon HSR Denial or Failure to Satisfy Conditions. This Agreement may be terminated by either Party, effective upon notice to the other Party, if the HSR Clearance Date shall not have occurred on or prior to the date 180 days after the Parties make their respective HSR Filings pursuant to the terms and conditions of this Agreement.

13.8 Rights of Pfizer and Organon Upon Expiration. Subject to the other terms and conditions herein,

(i) Upon the expiration of all of Pfizer's payment obligations to Organon under Article 9.2 of this Agreement in a particular Pfizer Exclusive Country, or upon the expiration of the Term in a Co-Marketing Country, Pfizer shall have a fully paid-up non-exclusive license under the Organon Patent Rights, Organon Technical Information and the Trademarks, and under Organon's rights in Collaboration Intellectual Property solely to make, have made, sell, offer for sale, use and import the Product in each such Pfizer Exclusive Country or Co-Marketing Country; and

(ii) Upon the expiration of all of Organon's payment obligations to Pfizer under Article 9.1 of this Agreement in a particular Co-Promotion Country, Organon shall have a fully paid-up non-exclusive license under the Pfizer Patent Rights and Pfizer Technical Information, and under Pfizer's rights in Collaboration Intellectual Property solely to make, have made, sell, offer for sale, use and import the Product in each such Co-Promotion Country.

(iii) Upon the expiration of all of Organon's payment obligations to Pfizer under Article 9.1 of this Agreement in a particular Co-Promotion Country, Pfizer shall have a fully paid-up non-exclusive license under the Organon Patent Rights and Organon Technical Information, and under Organon's rights in Collaboration Intellectual Property, solely to make, have made, sell, offer for sale, use and import the Product in each such Co-Promotion Country.

13.9 Residual Royalty. Subject to the other terms and conditions herein, upon termination of this Agreement:

(i) by Organon pursuant to Article 13.3(ii) (Material Default) or by Pfizer pursuant to Article 13.5(ii)(a) (Termination for ADME Study and Rat and Mouse Carcinogenicity Studies), Pfizer shall not be entitled to receive any royalty regarding Net Sales of the Product in any Country during the Post-Termination Period described below;

(ii) by Pfizer pursuant to Article 13.5(ii)(b) (At Will), Pfizer shall not be entitled to receive any royalty regarding Net Sales of the Product during the Post-Termination Period described below, provided, however, that, within sixty (60) days of the first Launch of the Product in a Major Market Country, Organon shall reimburse Pfizer for any Additional Development Costs incurred by Pfizer pursuant to Article 13.5(ii)(b)(2);

(iii) by Pfizer pursuant to Article 13.3(iv) (Material Default), Organon shall pay Pfizer a royalty equal to ten (10%) percent of Net Sales of the Product in each Country in the Territory as provided herein during the Post-Termination Period described below;

(iv) by Pfizer pursuant to Article 13.5(i)(a) (Low Net Sales), Organon shall pay Pfizer a royalty with respect to Net Sales of the Product in each Country in the Territory as provided herein during the Post-Termination Period described below as follows: (A) five (5%) percent of the aggregate of the Net Sales in all Countries up to five hundred million dollars ($500,000,000) for the initial 12-month period commencing on the effective date of termination pursuant to Article 13.5(i)(a) and for each 12-month period thereafter, and (B) ten (10%) percent of the aggregate of Net Sales in all Countries in excess of five hundred million dollars ($500,000,000) for the initial 12-month period commencing on the effective date of termination pursuant to Article 13.5(i)(a) and for each 12-month period thereafter; and

(v) by Pfizer pursuant to Article 13.5(i)(b) (Product Profile) or pursuant to Article 13.5(i)(c) (the Clinical QTc Study), Organon shall pay Pfizer a royalty equal to five (5%) percent of Net Sales of the Product in each Country in the Territory as provided herein during the Post-Termination Period described below, provided, however, that, such royalty shall terminate when the aggregate of all royalty payments made by Organon to Pfizer pursuant to this Article 13.9(iv) equals the sum of all Development Costs and Marketing Costs paid or accrued by Pfizer pursuant to this Agreement, and all amounts paid or accrued by Pfizer under Production Agreements (other than amounts paid or accrued in connection with improvements or expansions in manufacturing facilities owned by Pfizer or its Affiliates), in all cases together with interest which shall accrue thereon at the rate of ten percent (10%) per annum, compounded quarterly, from the date such payments were made or costs were incurred until the effective date of termination.

The Parties understand and agree that all payments by Organon to Pfizer of the royalties required under this Article 13: (x) shall be calculated and made in accordance with the procedures set forth in this Article 13 and Article 9 as if this Agreement had not otherwise terminated, and (y) shall be calculated and apply, on a Country-by-Country basis, in each Country of the Territory for the period ("Post-Termination Period"), subject to the limitation set forth in Article 13.9(iv), commencing on the effective date of termination and ending on the later of (A) fifteen (15) years following Launch of the Product in such Country, and (B) such date the Product is no longer embraced within any Valid Claim under Organon Patent Rights in such Country (assuming all of the defined terms and related provisions used in this clause (y) survived termination of this Agreement); and (z) shall remain due and owing without regard to the expiration of the Post-Termination Period referred to in clause (y) of this sentence.

13.10 Survival of Rights and Obligations upon Termination or Expiration. Upon expiration or termination of this Agreement, the rights and obligations of the Parties hereunder shall cease, except as follows:

(i) The obligations set forth in Article 14 (Confidentiality) shall survive for the period provided therein;

(ii) The obligations set forth in Article 11 (Intellectual Property), Article 12 (Claims), Article 13 (Term and Termination) and Article 15 (Dispute Resolution) shall survive without limitation.

(iii) The Parties shall not be relieved of any obligations accruing prior to such applicable expiration or termination under this Agreement (including without limitation all payment obligations which relate to all periods on or prior to such expiration or termination), other than as set forth in Article 8; and

(iv) The terminated Party under this Article 13 shall be obligated to pay any amounts otherwise reimbursable or due to the other Party under this Agreement in accordance with the terms hereof, including, without limitation, pursuant to the then most current, as applicable Development Plan or Global Marketing Plan, but only to the extent such amounts were actually incurred or accrued by either Party under any Third Party contract arising in accordance with the terms of such Third Party contract prior to the date of the notice of termination. The terminated Party under this Article 13 shall, at the other Party's expense, use its reasonable efforts to assist in the transition of any activities or obligations which were being performed by such Party to the other Party or its designee.

(v) Upon termination of this Agreement by Pfizer pursuant to Article 13.3, 13.4 or 13.5, the license and the other rights granted to it under this Agreement shall terminate and it shall have no further right to develop, use, sell, offer for sale, import and have imported Products in the Territory. In such case, where applicable the Regulatory Filings and/or Regulatory Approvals shall be assigned and transferred promptly by Pfizer to Organon or any other party designated by Organon. This transfer upon termination shall be arranged promptly, but in any event within one hundred and eighty (180) days after termination.

(vi) Upon termination of this Agreement, Pfizer shall assign, and Organon shall accept assignment of, all of Pfizer's rights and obligations under any tolling or similar agreement between Pfizer or its Affiliate and Scherer or its Affiliate, regarding the manufacture of the Product, and Organon shall purchase from Pfizer, at Pfizer's book value, any equipment or other similar items purchased by Pfizer directly in connection with Pfizer's or its Affiliate's obligations under the Production Agreements installed and primarily used in the manufacture of the Compound and/or Product.

13.11 Consequences of a Change in Control.

(i) (a) If at any time during any Term of this Agreement, there shall occur a Change in Control with respect to Organon, then, within forty-five (45) days after the closing or other effective date of such event Pfizer may by written notice delivered to Organon elect to cause a valuation of the entire interests, rights and obligations of Pfizer under this Agreement but excluding in all cases the Excepted Rights (the "Pfizer Interest") and the entire interests, rights and obligations of Organon under this Agreement but excluding in all cases the Excepted Rights (the "Organon Interest") under the provisions of this Article 13.11. Within 15 days following such valuation, Pfizer shall make the further election to do any of the following: (1) sell to Organon the Pfizer Interest in accordance with Article 13.11(ii), or (2) purchase the Organon Interest in accordance with Article 13.11(ii), or (3) elect not to terminate this Agreement (in which case, from and after the closing or other effective date of the Change in Control, Pfizer shall have final decision-making authority for all Consensus Matters with respect to

manufacturing, Product positioning and, prior to first filing an application for Regulatory Approval in a Major Market Country, regulatory matters) or (4) terminate this Agreement in accordance with Article 13.4.

(b) If at any time during the Term of this Agreement, there shall occur a Change in Control with respect to Pfizer, then within forty-five (45) days after the closing or other effective date of such event Organon may by written notice delivered to Pfizer elect to cause a valuation of the entire interests, rights and obligations of the "Organon Interest" and the Pfizer Interest under the provisions of Article 13.11(ii). Within 15 days following such valuation, Organon shall make the further election to do any of the following: (1) sell to Pfizer the Organon Interest in accordance with Article 13.11(ii) or (2) purchase the Pfizer Interest in accordance with Article 13.11(ii) or (3) elect not to terminate this Agreement (in which case, from and after the closing or other effective date of the Change in Control, Organon shall have final decision-making authority for all Consensus Matters with respect to manufacturing, Product positioning and, prior to first filing an application for Regulatory Approval in a Major Market Country, regulatory matters) or (4) terminate this Agreement in accordance with Article 13.4.

(ii) (a) The price (the "Organon Price" and the "Pfizer Price", respectively) to be paid to purchase the Organon Interest or the Pfizer Interest, as the case may be, under this Agreement, shall be conclusively determined by two internationally recognized investment banking firms, one of which shall be retained and paid by Organon and one of which shall be retained and paid by Pfizer; provided that, if either Party fails to deliver notice to the other Party of its selection of an investment banking firm within twenty (20) days after notice by the other Party that it has selected an investment banking firm (which notice shall identify such firm), the determination shall be rendered by the single investment banking firm so selected (whose fees, in such case, shall be borne equally by the Parties). Organon and Pfizer shall promptly notify each other of its respective selection. The investment banking firms selected in accordance with the foregoing procedure shall each independently determine the fair market value of the Organon Interest and the Pfizer Interest as contained in written reports prepared in accordance with Article 13.11 and shall submit their determinations of such value to Organon and Pfizer within thirty (30) days after their selection, which value shall be an amount that, on the basis of market and other conditions prevailing at such time, could reasonably be expected to be paid therefor by a Third Party in an arm's-length transaction, assuming that the buyer and seller are under no compulsion to buy or sell; it being further understood and agreed that the Organon Price and the Pfizer Price shall be the same except for differences resulting from the ability of Pfizer to commercialize the Product in Pfizer Exclusive Countries and resulting from the ability of Organon to commercialize the Product in the Organon Exclusive Countries .

(b) The Organon Price or the Pfizer Price, as the case may be, shall be the amount equal to the sum of such fair market values for the Organon Interest or the Pfizer Interest, respectively, determined by each investment banking firm divided by two (2) or if only one investment banking firm is involved as contemplated above, such individual fair market values, except that if there is more than a ten percent (10%) difference between such values for either the Organon Interest or the Pfizer Interest, as applicable, a third investment banking firm (which is independent of both Organon and Pfizer and has not been retained by either Pfizer or Organon or any of their respective Affiliates as a financial advisor within the two (2) prior years) selected by the first two investment banking firms shall determine such fair market value by selecting one (but

only one (1)) of the two (2) pairs of values previously determined by the first two investment banking firms pursuant to this Article 13.11(ii). The cost of such third investment banking firm shall be borne one-half by Organon and one-half by Pfizer.

(iii) Any purchase and sale of an Organon Interest or Pfizer Interest pursuant to this Article 13.11 shall be transferred free and clear of all liens and other encumbrances and shall be consummated at closing at the principal offices of Pfizer, in the case of an event under Article 13.11(i)(a), or Organon, in the case of an event under Article 13.11(i)(b), on a business day within forty-five (45) days following the last determination of the Organon Price and the Pfizer Price, as the case may be, and upon at least 5 business days' prior notice by Pfizer or Organon, as the case may be, to the other Party; provided that such period shall be extended for ninety (90) additional days, or such shorter period of time, as shall be necessary in order to obtain requisite governmental or regulatory approvals with respect to such transaction. At such closing, the buying Party shall pay the selling Party the Organon Price or the Pfizer Price, as the case may be, by wire transfer of immediately available funds.

(iv) Upon the closing of the transactions contemplated by this Article 13.11, the Parties shall use their respective commercially reasonable efforts to perform such matters and to execute such other documents as are necessary to transfer all of the Organon Interest or Pfizer Interest, as the case may be, to (x) the buying Party in order to ensure that the buying Party or its designee shall be able to enjoy the benefits contemplated by this Agreement, and (y) the selling Party in order to release the selling Party from all obligations under the Agreement effective as of the time of such sale (other than with respect to any obligations under this Agreement then due and owing and other than with respect to all obligations, whether or not due and owing, pursuant to Article 12, all of which shall remain obligations of the selling Party). Pfizer agrees that, if it is the buyer of the Organon Interest, Pfizer shall not for a period of eighteen months following any such purchase terminate any of the manufacturing activities for which Organon has contracted Diosynth to perform in accordance with the terms of the Alliance Agreements. As used herein, "Excepted Rights" means any rights of any of the Parties to receive payments under this Agreement immediately prior to the date of any closing contemplated by this Article 13.11 and shall, in all events, exclude all intellectual property and other rights which relate to Geodon and any changes to or improvements thereon.

13.12 Standstill. Pfizer hereby agrees that, during the Standstill Period, unless the restrictions set forth in this Article 13.12 have been specifically waived in writing by Organon, Pfizer shall not (and shall cause its direct and indirect subsidiaries not to):

(i) acquire or agree or make any public announcement to acquire, directly or indirectly, by purchase or otherwise, ownership (including beneficial ownership) of (a) more than five (5%) percent of the outstanding voting securities, or direct or indirect rights or options to acquire more than five (5%) percent of the outstanding voting securities, of Organon or any successor, or (b) more than five (5%) percent of the outstanding voting securities, or direct or indirect rights or options to acquire more than five (5%) percent of the outstanding voting securities, of Akzo Nobel N.V. for so long as Akzo Nobel N.V. is a Parent of Organon, or (c) all or substantially all of the assets of Organon or any successor (other than with respect to the matters contemplated by this Agreement); or

(ii) engage in any "solicitation" (as soliciting party) of "proxies" (as such terms are used in the proxy rules of the Securities and Exchange Commission) or consent to vote any voting securities of Akzo Nobel N.V. or, commencing at such time as Akzo Nobel N.V. is no longer the Parent of Organon, Organon or any successor; or

(iii) submit a proposal for, or offer of (with or without conditions), any extraordinary transaction involving all or substantially all of the assets of Organon or Akzo Nobel N.V., other than pursuant to a confidential communication to management or the Board of Management of Akzo Nobel N.V.; or

(iv) make a public announcement with respect to any of the foregoing; or

(v) form, join or in any way participate in a "group" (as defined under the 1934 Act) with respect to any acquisition by any such person of securities of Organon or enter into any discussions or arrangements with any Third Party with respect to any of the foregoing prohibited matters.

(vi) Notwithstanding the foregoing provisions of this Article 13.12, neither Pfizer nor any of its Affiliates will be subject to any of the restrictions set forth above in this Article 13.12: (a) if Organon or Akzo Nobel N.V. announces publicly that it is seeking any purchaser for a controlling interest in its business or enters into negotiations for the sale of such controlling interest which negotiations are publicly announced, or (b) if it is publicly announced that (1) another person or group has offered or proposed to acquire, directly or indirectly, by purchase, tender offer, merger, consolidation or otherwise, a controlling interest in Organon or Akzo Nobel N.V. or, alternatively, assets representing at least thirty (30%) percent of the market capitalization of Akzo Nobel N.V. or Organon, or (2) that Akzo Nobel or Organon has entered into an agreement in principle or definitive agreement providing for a transaction described in the immediately preceding clause (1), or (c) if a party unaffiliated with Akzo Nobel N.V. shall have publicly announced an intention to seek a change of control of the governing board of Akzo Nobel N.V through the solicitation of proxies or otherwise, or (d) with respect to the matters described in the last sentence of this Article 13.12, or (e) with respect to any acquisition of any assets or securities of Organon or any Parent, as debtor, in a transaction subject to the approval of the United States Bankruptcy Court pursuant to proceedings under the United States Bankruptcy Code, or (f) with respect to matters required or permitted by this Agreement. For the purposes of this Article the term "controlling interest" shall mean the possession, through ownership of voting securities or otherwise, of the ability to direct the management and affairs of Akzo Nobel N.V. or Organon, and, without limitation, shall be conclusively presumed to be present in the case of the direct or indirect ownership of a majority of the voting securities and/or equity interests of Akzo Nobel N.V. or Organon, as applicable, without precluding the existence of control in the case of the ownership of a lesser amount of such securities.

(vii) Notwithstanding anything to the contrary contained herein, the prohibitions set forth in this Article 13.12 shall not apply to (a) any investment in any securities of Organon or Akzo Nobel N.V. by or on behalf of any pension or employee benefit plan or trust, including without limitation (1) any direct or indirect interests in portfolio securities held by an investment company registered under the Investment Company Act of 1940, as amended, or (2) interests in securities comprising part of a mutual fund or broad based, publicly traded market basket or index of stocks approved for such a plan or trust in which such plan or trust invests; or (b) securities of Organon or

Akzo Nobel N.V. held by a Person acquired by Pfizer on the date such Person first entered into an agreement to be acquired by Pfizer or acquired after such Person was acquired by Pfizer pursuant to an agreement requiring (but only to the extent requiring) such Person to acquire such securities, which agreement was in effect on the date such Person first entered into an agreement to be acquired by Pfizer, or (c) any sale by Pfizer of securities in a tender or exchange offer initiated by a Person other than Pfizer and/or any vote securities owned by it in favor of or against any such sale.

ARTICLE 14

CONFIDENTIALITY

14.1 Treatment of Confidential Information. Subject to the provisions of Article 11, and further subject to the terms of this Article 14, during the Term and for a period of five (5) years thereafter, each of the Parties shall maintain Confidential Information of the other Party in confidence, and shall not disclose, divulge or otherwise communicate such Confidential Information to others (except for agents and advisors under obligations of confidentiality) or use it for any purpose other than in connection with the development, manufacture, marketing, promotion, distribution or sale of the Product or Xanax and any improvements or changes thereto, or as otherwise permitted in this Agreement and the other Alliance Agreements, and each Party agrees to exercise reasonable efforts to prevent and restrain the unauthorized disclosure of such Confidential Information by any of its directors, officers, employees, consultants, subcontractors, licensees or agents, which reasonable efforts shall be at least as diligent as those generally used by such Party in protecting its own confidential and proprietary information.

14.2 Right to Disclose. To the extent it is reasonably necessary or appropriate to fulfill its obligations or exercise its rights under this Agreement or any rights which survive termination or expiration hereof, each of the Parties may consistent with its obligations under the Alliance Agreements disclose Confidential Information to its Affiliates, consultants, outside contractors, clinical investigators or other Third Parties on a need to know basis and on the condition that such entities or persons agree in writing:

(i) to keep the Confidential Information confidential for the same time periods and to a comparable extent as the disclosing Party is required to keep the Confidential Information confidential; and

(ii) to use the Confidential Information only for such purposes as the disclosing Party is entitled to use the Confidential Information.

14.3 Required Disclosures.

(i) To the extent, if any, that a Party concludes in good faith that it is required to file or register this Agreement (or any other Alliance Agreement) or a notification thereof with any Governmental Authority, including without limitation the US Securities and Exchange Commission, or the US Federal Trade Commission, in accordance with applicable Laws, such Party may do so. The other Party shall cooperate in such filing or

notification and shall execute all documents reasonably required in connection therewith. In such situation, the Parties will request and will use their reasonable efforts to obtain confidential treatment of all proprietary and other commercially-sensitive provisions of the Agreement (or other Alliance Agreement, as applicable), all to the extent permitted by Law. The Parties shall promptly inform each other as to the activities or inquiries of any such Governmental Authority relating to the Alliance Agreements, and shall cooperate to respond to any request for further information therefrom.

(ii) Each Party or its Affiliates may disclose such Confidential Information to Governmental Authorities to the extent that such disclosure (a) is reasonably necessary to obtain Regulatory Approvals; or (b) is otherwise legally required. Without limiting the generality of the foregoing and notwithstanding anything in this Agreement or in any other agreement to the contrary, each Party (and each employee, representative, or other agent of each Party) may (but is not required to) disclose to any and all persons, without limitation of any kind, the tax treatment and tax structure of the transaction contemplated by this Agreement and the other agreements and instruments to be executed in connection herewith, as of the earlier of (x) the date of public announcement of discussions relating to the transactions contemplated by this Agreement, (y) the date of public announcement of such transactions, or (z) the date of the execution of the agreement to enter into such transactions; provided, however, that such disclosure shall be prohibited to the extent required to comply with any applicable federal or state securities laws; and provided further that the confidentiality provisions of this agreement and the other agreements and instruments relating to the transactions between the Parties shall continue to apply to information that is irrelevant to understanding the tax treatment or tax structure of the transactions contemplated hereby and thereby (including, without limitation, the names and other identifying details of any Party to this Agreement). The preceding sentences are intended to cause the transaction contemplated herein to be treated as not having been offered under conditions of confidentiality for purposes of Article 1.6011-4(b)(3) (or any successor provision) of the Internal Revenue Code ("Code") and shall be construed in a manner consistent with such purpose. Each Party recognizes that the privilege each has with respect to the confidentiality of the transaction contemplated by this Agreement or the confidentiality of a communication relating to such transaction, including a confidential communication with its attorney or with a federally authorized tax practitioner under Article 7252 of the Code, is not intended to be waived by the foregoing.

14.4 Return of Confidential Information. Upon any termination of this Agreement and the other Alliance Agreements, each Party shall promptly return to the other Party all written Confidential Information, and all copies thereof, of such other Party, except that each Party may retain one copy of such Confidential Information solely to discern its continuing obligations under this Article 14.

ARTICLE 15

DISPUTE RESOLUTION

15.1 Governing Law. The validity, construction and performance of this Agreement will be governed by and construed in accordance with the substantive laws of the State of New York with regard to principles of conflict of laws.

15.2 Negotiation. The Parties will attempt in good faith to resolve promptly any dispute arising out of or relating to this Agreement by negotiation. If the matter can not be resolved in the normal course of business any interested Party may give the other Party written notice of any such dispute not resolved, after which the dispute will be referred to more senior executives of both Parties, who will likewise attempt to resolve the dispute. If the dispute has not been resolved by negotiation within thirty (30) days of the disputing Party's written notice, or if the Parties fail to meet within twenty (20) days as from the date of such notice, either Party may commence a mediation pursuant to Article 15.3 below.

15.3 Mediation. If the dispute has not been resolved by negotiation within thirty (30) days of the disputing Party's written notice, or if the Parties fail to meet within twenty (20) days as from such notice, the Parties will attempt to settle the dispute by non-binding mediation under the supervision of and in accordance with the CPR Model Mediation Procedures. Unless otherwise agreed to by the Parties, the CPR will appoint an independent mediator. The language of mediation will be English and the mediation will take place in New York, New York. If within thirty (30) days of the commencement of mediation in accordance with the above procedures, the Parties have not resolved their dispute, then either Party may commence a Proceeding pursuant to Article 15.4 below.

15.4 Jurisdiction. With respect to any Proceeding, each Party hereto irrevocably (i) subject to the final sentence of this Article 15.4, agrees and consents to be subject to the exclusive jurisdiction of the United States District Court for the Southern District of New York or any New York state court sitting in New York, New York, United States of America (any such court, the "New York Court") and (ii) waives any objection which it may have at any time to the laying of venue of any Proceeding brought in any such New York Court and waives any claim that such Proceeding has been brought in an inconvenient forum and further waives the right to object, with respect to such Proceeding, that such Court does not have any jurisdiction over such Party. Notwithstanding the foregoing: (i) each Party shall be entitled to seek injunctive relief and specific performance (including but not limited to any relief or recovery under any Alliance Agreement) in any court in the world, and (ii) if the Court adjudicating such Proceeding refuses for any reason to exercise jurisdiction over the dispute, either Party shall be free to bring such Proceeding in any other Court in New York State as provided above and, in the event such other Court(s) refuse for any reason to exercise jurisdiction over the dispute, either Party shall be free to bring such Proceeding in any other court. Organon shall at all times maintain an agent for service of process and any other documents in proceedings in New York, New York, and hereby designates CT Corporation System, with offices located at 111 Eighth Avenue, 13th Floor, New York, New York 10011, as its agent. Organon shall promptly provide Pfizer with written notice of any change in the identity of such agent. Any pleading, judgment or other notice of legal process shall be sufficiently served on Organon if delivered to its agent at its then-current address.

ARTICLE 16

MISCELLANEOUS

16.1 Force Majeure. Neither Party shall be held liable or responsible to the other Party nor be deemed to have defaulted under or breached this Agreement for failure or delay in fulfilling or performing any Term, other than an obligation to make payments hereunder, when such failure or delay is caused by or results from fire, floods, embargoes, government regulations, prohibitions or interventions, war, acts of war (whether war be declared or not), insurrections, riots, civil commotions, acts of God or any other cause beyond the reasonable

control of the affected Party to anticipate, prevent, avoid or mitigate (a "Force Majeure Event"); provided, however, that any failure or delay in fulfilling a term shall not be considered a result of a Force Majeure Event if it arises from a failure of Pfizer or Organon to comply with applicable laws and regulations.

16.2 Further Assurances. Each Party hereto agrees to perform such acts, execute such further instruments, documents or certificates, and provide such cooperation in proceedings and actions as may be reasonably requested by the other Party in order to carry out the intent and purpose of this Agreement, including without limitation the registration or recordation of the rights granted hereunder.

16.3 Notices. Any notice required or permitted to be given hereunder shall be in writing and shall be deemed to have been properly given if delivered in person, or if mailed by registered or certified mail (return receipt requested) postage prepaid, or by a nationally recognized overnight courier, or by facsimile (and promptly confirmed by registered, certified mail or overnight courier), to the addresses given below or such other addresses as may be designated in writing by the Parties from time to time during the Term. Any notice sent by registered, certified mail or overnight courier as aforesaid shall be deemed to have been given when mailed.

In the case of Organon:

Organon (Ireland) Ltd.
Churerstrasse 160b
Pfaffikon 8808
Switzerland
Attention: Director

Facsimile: 41 55 415 1974

With a required copy to:

Akzo Nobel Legal Affairs - Pharma
P.O. Box 20
5340 BH Oss
The Netherlands
Facsimile: 41 2 666 373

In the case of Pfizer:

Pfizer Inc.
235 East 42nd Street
New York, New York 10017
Attention: President, Pfizer Global Pharmaceuticals

Facsimile No.: 212-808-8652

With a required copy to:

Pfizer Inc.
235 East 42nd Street
New York, New York 10017
Attention: Senior Vice President and General Counsel

Facsimile No.: 212-808-8924

16.5 Assignment. This Agreement may not be assigned or otherwise transferred by either Party without the written consent of the other Party, provided, however, that either Party may, without such consent, assign this Agreement, in whole or in part:

(i) if such Party or its Affiliates is required to, or reasonably believes that it will be required to, divest either the Product or a competing product in order to comply with the Law or the order of any Governmental Authority as a result of a merger or acquisition, provided, however, that, if permitted by the applicable Governmental Authority, the other Party shall be invited to submit a bid for the rights to be assigned;

(ii) to any of its Affiliates (provided the assigning Party continues at all times to remain liable for all obligations of such Party under this Agreement without regard to such assignment);

(iii) in connection with the transfer or sale of all or substantially all of its business related to this Agreement; or

(iv) in accordance with Article 13.11.

Any purported assignment in violation of this Article 16.5 shall be void. Any permitted assignee shall assume all obligations of its assignor under this Agreement.

16.6 Non-Solicitation. During the Term, neither Party shall, directly or indirectly, recruit or solicit any employee of the other Party (including employee's of Affiliates) with whom such Party has come into contact or interacted for the purposes of performing this Agreement, without the prior consent of the other Party, except pursuant to general solicitation not targeted at such employees.

16.7 Amendment. The Parties hereto may amend, modify or alter any of the provisions of this Agreement, but only by a written instrument duly executed by both Parties hereto.

16.8 Entire Agreement. This Agreement, along with the other Alliance Agreements, contains the entire understanding of the Parties with respect to the subject matter hereof.

16.9 Waiver. The failure of a Party to enforce at any time for any period any of the provisions hereof shall not be construed as a waiver of such provisions or of the rights of such Party thereafter to enforce each such provisions.

16.10 No Implied Licenses. Except as expressly and specifically provided under this Agreement, the Parties agree that neither Party is granted any implied rights to or under any of the other Party's current or future patents, trade secrets, copyrights, moral rights, trade or service marks, trade dress, or any other intellectual property rights.

16.11 Independent Contractors. The Parties agree that their relationship established by this Agreement is that of independent contractors. Furthermore, the Parties agree that this Agreement does not, is not intended to, and shall not be construed to, establish a partnership or joint venture, and nor shall this Agreement create or establish an employment, agency or any other relationship. Except as may be specifically provided herein, neither Party shall have any right, power or authority, nor shall they represent themselves as having any authority to assume, create or incur any expense, liability or obligation, express or implied, on behalf of the other Party, or otherwise act as an agent for the other Party for any purpose.

16.12 Compliance with Law and Severability. It is the intention of the Parties in establishing their collaboration pursuant to this Agreement to comply with all applicable laws and regulations, including all competition laws. If during the Term there are any changes in factual circumstances of market conditions affecting the legality of this Agreement or to any applicable law or regulation (including the expiry or withdrawal of any exemption or approval) then on written notice from one Party to the other the Parties shall review their collaboration pursuant to this Agreement. Such review shall consider such changes as may be required to

the structure or operation of the collaboration, including the terms of this Agreement, which shall then be negotiated in good faith with the objective of preserving, so far as legally permissible, the terms set out herein and, in relation to any changes, of ensuring that the commercial benefits and detriments arising from the required changes are shared equally between the Parties. Neither Party shall seek to exploit the requirement to make any such changes to its own commercial advantage. In addition, if any provision of this Agreement is held unenforceable by a court or tribunal of competent jurisdiction in a final unappealable order because it is invalid or conflicts with any Law of any relevant jurisdiction, then such provision shall be inoperative in such jurisdiction and the remainder of this Agreement shall remain binding upon the Parties hereto.

16.13 Registration and Filing of the Agreement. To the extent, if any, that a Party concludes in good faith that it is required under applicable Laws to file or register this Agreement or a notification thereof with any Governmental Authority, including without limitation the US Securities and Exchange Commission, or the US Federal Trade Commission, in accordance with applicable Laws, such Party may do so and shall provide the other Party to this Agreement with a written copy of all proposed filings or registrations to allow for a reasonably sufficient time for review and comment by the other Party. The other Party shall cooperate in such filing or notification and shall execute all documents reasonably required in connection therewith. In such situation, the Parties will request confidential treatment of sensitive provisions of the Agreement, to the extent permitted by Law. The Parties shall promptly inform each other as to the activities or inquiries of any such Governmental Authority relating to this Agreement, and shall cooperate to respond to any request for further information therefrom.

16.14 Announcements.

(i) Coordination. The Parties agree on the importance of coordinating their public announcements respecting the Alliance Agreements and the subject matter of such agreements. Organon and Pfizer will, from time to time, and at the request of the other Party discuss and agree on the general information content relating to this Agreement and the License Agreement which may be publicly disclosed.

(ii) Announcements. The joint press release announcing the signing of the transactions contemplated by this Agreement and the Alliance Agreements is attached hereto as Schedule 16.14 and will be promptly disseminated following signing.

(iii) The above-referenced releases may be Organon releases or joint Organon/Pfizer releases at Pfizer's option, and the Parties agree to jointly draft and agree on the content of such disclosure. Except as otherwise provided in this Article 16.14, neither Party will make any public announcement regarding the fact of execution of this Agreement by the Parties hereof, the terms of or events related this Agreement, and/or the collaboration without the prior consent of the other. Notwithstanding the foregoing, a Party may make any disclosure where in a Party's reasonable legal opinion it is required by applicable Law or applicable stock exchange regulation or order or other ruling of a competent court, provided that prior to such disclosure, the disclosing Party shall use reasonable efforts to notify the other Party prior to making such disclosure, and will provide the other Party with an opportunity to review and comment prior to release, provided the disclosing Party shall not be required to delay such disclosures by more than forty-eight (48) hours to receive and discuss such comments, so long as the disclosing Party has provided to the other Party as much advance notice as is reasonably practicable under the circumstances. Each Party agrees that it shall

reasonably cooperate with the other with respect to all disclosures regarding this Agreement to the Securities Exchange Commission and any other governmental or regulatory agencies, including requests for confidential treatment of proprietary information of either Party included in any such disclosure.

16.15 HSR Filings. Each of Organon and Pfizer shall as promptly as possible file with the FTC and the Antitrust Division of the DOJ, any HSR Filing required of it under the HSR Act with respect to the transactions contemplated by this Agreement, and shall each use commercially reasonable efforts to make such filing within four (4) weeks of the date of execution of this Agreement. The Parties shall cooperate with one another to the extent necessary in the preparation of any HSR Filing required to be filed under the HSR Act. Each Party shall be responsible for its own costs, expenses, and filing fees associated with any HSR Filing.

16.16 HSR Cooperation; Further Assurances. Organon and Pfizer agree, and shall cause each of their respective Affiliates, to cooperate and to use their respective commercially reasonable efforts to obtain any HSR Clearance required for the consummation of the transactions contemplated under this Agreement and to respond to any government requests for information under the HSR Act. The Parties will consult and cooperate with one another, and consider in good faith the views of one another, in connection with any analyses, appearances, presentations, memoranda, briefs, arguments, opinions and proposals made or submitted by or on behalf of either Party in connection with proceedings under or relating to the HSR Act. For the avoidance of doubt, it is agreed that neither Party shall be obligated in any way to (i) sell, transfer or otherwise dispose of (including without limitation by way on any "hold separate" or similar arrangement) any asset or product or business, (ii) terminate any contractual relationship, or (iii) amend, terminate or otherwise modify any licenses or other intellectual property agreements, in order to obtain HSR Clearance with respect to the transactions contemplated by this Agreement.

16.17 Activities Prior to the Effective Date. The Parties shall not engage in any of the activities contemplated by this Agreement, other than seeking to obtain HSR Clearance, prior to the Effective Date.

16.18 Headings. The Article and Article headings contained in this Agreement are for reference purposes only and shall not affect in any way the meaning or interpretation of this Agreement.

16.19 Counterparts. This Agreement may be executed in any number of counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same document.

IN WITNESS WHEREOF, the Parties have executed this Agreement as of the date hereof.

ORGANON (IRELAND) LTD.

By : _____
Name : _____
Title : _____

By : _____
Name : _____
Title : _____

PFIZER INC.

By : _____
Name : _____
Title : _____

By : _____
Name : _____
Title : _____

SCHEDULE 1.2

ADME STUDY

Summary	
Protocol Number	TBD
Title	Metabolism and Excretion of [^{14}C]Asenapine in Humans
Objectives	To determine pathways of metabolism, and extent and routes of excretion of total drug-related material
Statistical Power	Calculations of mean +/- SD values
Registration Status	Essential Phase 1 Study
Methods	
Major Inclusion Criteria	Healthy Human Subjects (including smokers and non-smokers)
Major Exclusion Criteria	Obesity, Concomitant Medications
Design	Open label
Duration of Treatment	Single Dose
Dosing regimen	Sublingual Dose of 10 mgA asenapine containing 100 uCi [^{14}C]asenapine
Main Assessments	Mass Balance in Excreta
Reference Therapy	None
Main Outcome Variables	Mass Balance, Quantitative metabolite profiles of parent drug and metabolites in urine and fecal homogenates, Pharmacokinetics of parent drug and total radioactivity in plasma, quantitative profile of metabolites in plasma
Main Safety Variables	AE's, vital signs, ECG. Laboratory, physical exam
Endpoints	Mass Balance in Excreta
Planning	
Number of Subjects	6
Study Duration	Subjects are kept under study until two consecutive days in which less than 1% of dose is measured in excreta
Expected Start Preparatory Work	October 2003 (preparation of radiolabelled dose)
Expected Initiation	January 2004
Expected Completion	Clinical: January 2004; Sample Analysis: April 2004
Country	TBD
Number of Centers	1
Subjects per Center	6
Interim Analysis Required	Continuous measurement of excreted radioactivity is necessary to determine when study subjects can leave the clinical site
Special Remarks	In-Patient

Satisfaction of Endpoints for the ADME Study means:

1. Mean mass balance of greater than 80%.

2. Extraction recovery of radioactivity from plasma samples greater than 85%.

3. Demonstration of no metabolite unique to human circulation, vs animal species used in preclinical safety assessments (i.e. rat, dog, mouse). The term unique metabolite is defined as a metabolite accounting for 5% or more of the total circulating radioactivity in human and less than 1% of the total circulating radioactivity in rat, dog, and mouse. This definition does not include metabolites arising by glucuronidation or sulfation reactions.

SCHEDULE 1.15
CLINICAL QTC STUDY

Summary	
Protocol Number	TBD
Title	A Study to Evaluate the Effects of Asenapine on the QT/QTc Interval
Objectives	Primary: Within the therapeutic dose range of asenapine (5-15 mg BID), • to evaluate the effects of asenapine at steady state concentrations on the QT/QTc interval, with and without metabolic inhibitor • to compare the effects of asenapine at steady state concentrations on the QT/QTc interval to those of quetiapine at steady state concentrations, with and without metabolic inhibitor Secondary: • To evaluate the relationship between concentrations of asenapine and its effects on QT/QTc, with and without metabolic inhibitor
Sample size	Approximately 30 subjects per treatment group
Registration Status	Essential Phase 1 Study
Methods	Triplicate ECGs at multiple timepoints on several days (before dosing, after first dose, and at steady state with and without the metabolic inhibitor) QTcF will be the primary correction. Results will also be reported using Bazett's correction. In the event that neither correction fits the data well, a baseline correction may also be applied and will be fully justified. The QT and RR intervals will also be analyzed to assess potential pre- and post-dose changes in heart rate and effects on the QT/RR relationship.
Major Inclusion Criteria	Stable patient with schizophrenia (including smokers and non-smokers)
Major Exclusion Criteria	Concomitant Medications
Design	Double-Blind, Parallel Group (potentially placebo-controlled)

Duration of Treatment	17 days (including dose titration for 8 days, steady state dosing for 4 days and co-administration with metabolic inhibitor for 5 days)
Dosing regimen	Asenapine 5 mg S/L BID (+Fluvoxamine 50 → 100 mg Qd) Asenapine 15 mg S/L BID (+Placebo*)
Main Assessments	To determine if asenapine alone produces a statistically significant effect on the QT/QTc interval; to determine if asenapine is non-inferior to quetiapine with respect to effects on the QT/QTc interval
Reference Therapy	Quetiapine 375 mg BID (+Ketoconazole 200 mg BID) (Placebo is being considered)
Main Outcome Variables	See Endpoints below
Main Safety Variables	AE's, vital signs, ECG. Laboratory, physical exam
Endpoints	Primary Endpoint: The largest mean change from baseline in QTc at any nominal time point at steady state concentrations Secondary Endpoints: Maximum post-dose QT/QTc intervals; maximum post-dose increases in QTc; Mean change from baseline at therapeutic concentrations, predicted by PK/PD modeling.
Planning	
Number of Subjects	~ 30 subjects per group
Study Duration	12 months
Expected Start Preparatory Work	October 2003
Expected Initiation	January 2004
Expected Completion	November 2004
Country	USA
Number of Centers	5-10
Subjects per Center	10-24
Interim Analysis Required	Not required
Special Remarks	In-Patient

* For safety reasons, the Asenapine 15 mg BID group will receive placebo instead of the metabolic inhibitor Fluvoxamine.

For purposes of Article 13.5(i)(c), all 5 endpoints below must be satisfied:

1. Comparison to baseline (within treatment) for asenapine, with or without inhibitor: the upper limit of the 90% confidence interval for the largest time-matched mean change from baseline by nominal time post dose at steady state concentrations is < 10 msec.

2. Comparison of asenapine (with or without inhibitor) to quetiapine (with or without inhibitor): either (a) the 95% confidence interval for the difference between treatments (asenapine minus quetiapine) in the largest time-matched mean change from baseline by nominal time post dose at steady state concentrations contains zero, or (b) the upper bound for the 95% confidence interval for the difference is less than or equal to zero.

3. Pharmacokinetic interactions for asenapine, with or without inhibitor: the upper limit of the 90% confidence interval for the mean change from baseline at steady state concentrations with metabolic inhibitor for asenapine 15 mg BID as predicted by PK/PD modeling is less than 10 msec.

4. No subject on asenapine has a maximum post-dose increase in QTc of >= 60 msec and no subject has a maximum post-dose QTc or QT >= 500 msec (these two assessments are for asenapine alone, with or without inhibitor), and the number of subjects in the 30 - < 60 msec category on asenapine minus the number of subjects in the 30 - < 60 category on quetiapine is less than or equal to 3 subjects (this comparison is for asenapine with or without inhibitor compared to quetiapine with or without inhibitor.)

5. Adverse events (asenapine alone, with or without inhibitor): there is no occurrence of Torsades de Pointes, and there are no clinically significant adverse events attributed to delayed repolarization.

SCHEDULE 1.26

DESCRIPTION OF COMPOUND

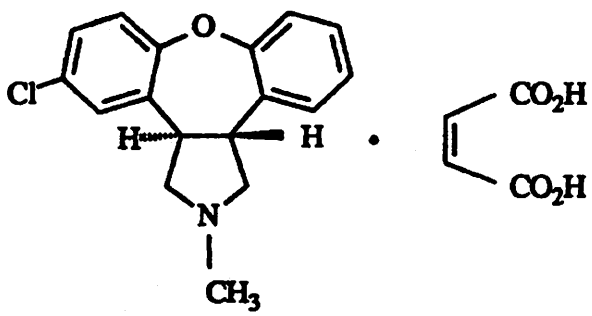
Laboratory code:
Org 5222

Chemical name:
trans-5-chloro-2,3,3a,12b-tetrahydro-2-methyl-1H-dibenz[2,3:6,7]oxepino [4,5-c] pyrrole (Z)-2-butenedioate (1:1)

Physical form:
Odorless, white crystalline powder

Optical isomerism:
racemic mixture

Structural formula:



Molecular formula:
$C_{17}H_{18}ClNO.C_4H_4O_4$

Relative molecular mass:
401.85 (free base: 285.78)

SCHEDULE 1.33

CO-PROMOTION COUNTRIES

North America
United States of America
Canada

Latin America
Argentina
Brazil
Chile
Columbia
Ecuador
Mexico
Venezuela
Peru
Dominican Republic
Costa Rica
Guatemala
Honduras
Nicaragua
Panama
El Salvador

Europe
Belgium
Luxembourg
Germany
Netherlands
United Kingdom
Ireland
Austria
Denmark
Finland
Norway
Sweden
Switzerland
France
Italy (co-marketing)
Spain
Turkey
Greece
Portugal
Russia
Czech Republic
Slovak Republic
Hungary
Poland
Romania

Ukraine
Bulgaria
Croatia
Estonia
Latvia
Lithuania
Macedonia
Slovenia
Serbia-Montenegro
Armenia
Belarus
Georgia
Moldavia
Kazakhstan
Kyrgystan
Tajikistan
Turkmenistan
Uzbekistan
Albania

Middle East/Africa
Morocco
Tunisia
Algeria
Egypt
South Africa
Israel
Ivory Coast
Cameroon
Gabon
Congo
Senegal
Bahrain
Iran
Iraq
Jordan
Kuwait
Lebanon
Libya
Oman
Qatar
Saudi Arabia
Sudan
Syria
United Arab Emirates
Yemen
Palestine

Asia
Japan
Australia
China
India
Indonesia
Bangladesh
Hong Kong
South Korea
Malaysia
Singapore
Pakistan
Philippines
Taiwan
Thailand
New Zealand
Vietnam
North Korea

SCHEDULE 1.40

MINIMUM DETAIL REQUIREMENTS

- In each Year of the Term in the US Territory, the Parties will perform, in the aggregate, a minimum of 1.75 million Details in the US Territory.

- With respect to each of the other Major Market Countries, the applicable CCC will, at a date that is at least six (6) months prior to the anticipated Launch of the Product in such Major Market Country, determine a minimum Detail Requirement for the Term in such Major Market Country.

- The minimum Detail Requirement for any Year that is not a full calendar year shall be prorated by multiplying the figure set forth above by a fraction, the numerator of which is the number of days between the date of Launch and December 31, and the denominator of which is 365.

Each Party shall be responsible for 50% of the total Details in the US Territory during each Year of the Term.

SCHEDULE 1.94

ORGANON PATENT RIGHTS

Patent Series ref. 1994.070
Convention priority of EPO application no. 94200521 filed 2 March 1994

Country	Application Number	Patent Number
Australia	19478/95	692530
Austria	95912188.0	E 167057
Belgium	95912188.0	0746317
Brazil	PI 1100625.0	PI1100625.0
Canada	2182981	
China	95191906.7	ZL95191906.7
Czech Republic	PV2541/96	284633
Denmark	95912188.0	0746317
European Patent Convention (EP)	95912188.0	0746317
Finland	963398	
France	95912188.0	0746317
Germany	95912188.0	69502939.8
Greece	980401974	3027796
Hong Kong	98109126.1	HK1008417
Hungary	P9602383	
Ireland	95912188.0	0746317
Italy	69698/BE/98	0746317
Japan	522703/95	
Korea, Republic of	96/704774	0330942
Luxembourg	95912188.0	0746317
Mexico	9603713	197583
Monaco	95912188.0	0746317
The Netherlands	95912188.0	0746317
New Zealand	282394	282394
Norway	963639	308772
Poland	P316080	180465
Portugal	95912188.0	0746317
Russian Federation	1996/120090	2139051
Spain	95912188.0	2118584

Sweden	95912188.0	0746317
Switzerland	95912188.0	0746317
United Kingdom	95912188.0	0746317
United States of America	08/693064	5763476

Patent Series ref. 2003.789
Convention priority of (1) EPO application no. 03076062.3 filed 11 April 2003 and (2) EPO application no. 03102677.6 filed August 29, 2003

Country	Application Number	Patent Number
European Patent Office	03076062.3	
European Patent Office	03102677.6	

Patent Series ref. 2003.793
Convention priority of EPO application no. 03101721.3 filed 12 June 2003

Country	Application Number	Patent Number
European Patent Office	03101721.3	

Patent Series ref. 2003.798
Convention priority of EPO application no. 03102124.9 filed 11 July 2003

Country	Application Number	Patent Number
European Patent Office	03102124.9	

Scherer Organon contract reference 9
Convention priority US 92 985040 filed 1 Dec 1992

Country	Application Number	Patent Number*
Australia	94 56545	677030B2
Brazil	9305805A	
Canada	93 2129254AA	
China	93 121709	1066937B
European Patent Convention (EP)	EP94203739 EP94902027	0646367B1 0710101B1
Finland	943537	105149B1

France	EP94203739 EP94902027	0646367B1 0710101B1
Germany	EP94203739 EP94902027	69311109C0 69318429T2
Greece	EP94203739	3023853T3
Hong Kong	98 106782 98 114532	1007489A1 1013245A1
Hungary	9402091	216509B
Ireland	EP94902027	EP 0646367B1
Italy	EP94902027 EP94203739	EP 0646367B1 EP 0710101B1
Japan	WO/GB9302459 95 85912	2568479B2 2796578B2
Korea, Republic of	9472574	227315B
Netherlands	EP94203739	EP 0710101B1
New Zealand	93 258600	258600A
Norway	942805	303161B1
Spain	EP94203739 EP94902027	2102143T3 2118368T3
Switzerland	EP94902027 EP94203739	EP 0710101B1 EP 0646367B1
United Kingdom	EP94902027 EP94203739	EP 0646367B1 EP 0710101B1
United States of America	92 985040 95 448469	5343672A 5729958A

Scherer/Organon contract reference 11

Convention priority US 93 104486 filed 1 Oct 1993, except for last mentioned US patent.

Country	**Application Number**	**Patent Number***
Australia	94 78014A1	
Austria	EP 94928661	197542E
Canada	2149659AA	
European Patent Convention (EP)	EP 94928661	721325B1
Switzerland	EP 94928661	721325B1
Ireland	EP 94928661	721325B1
Germany	EP 94928661	69426305T2
Italy	EP 94928661	721325B1

Spain	EP 94928661	2152991T3
Denmark	EP 94928661	721325T3
France	EP 94928661	721325B1
Portugal	EP 94928661	721325T
United Kingdom	EP 94928661	721325B1
Greece	EP 94928661	3035407T3
Japan	510851	3155554B2
United States of America	93 104486	5457895A
United States of America	2000 541156	6212791BA

Scherer/Organon contract reference 10
Convention priority US 92 954888 filed 30 Sept 1992

Country	**Application Number**	**Patent Number***
Japan	WO/GB 9302034	3030422B2
United States of America	94 198644	5358118A

Scherer/Organon contract reference 7
Convention priority US 90 615489 filed 19 Nov 1990

Country	**Application Number**	**Patent Number***
United States of America	90 615489	5046618A

SCHEDULE 1.114

PRODUCT PROFILE

Asenapine Product Profile

Schizophrenia	*Data or Results to be Demonstrated in at least Two Phase 3 Clinical Studies for Asenapine*	*Data or Results to be Demonstrated in at least One Phase 3 Clinical Study for Asenapine*
Efficacy	• In patients meeting DSM-IV criteria for schizophrenia, 6 week treatment with asenapine produced a reduction in total Positive and Negative Syndrome Scale (PANSS) score that was statistically superior to placebo ($p<0.05$) ➢ Reduction in the PANSS positive subscale was statistically significantly superior to placebo ($p<0.05$) Reduction in the PANSS negative subscale was statistically significantly superior ($p<0.05$) to placeboOnset of action (mean reduction in PANSS total score statistically significantly superior to placebo) was by wk 1 and maintained for the duration of treatment • Improvement in some measures of cognitive performance, as measured by a cognitive battery of tests or the PANSS cognitive factor, was statistically significantly superior to placebo ($p<0.05$)	• In patients meeting DSM-IV criteria for schizophrenia, 6 week treatment with asenapine produced a reduction in total PANSS score that was numerically better than with risperidone and numerically equal to olanzapine ➢ Reduction in the PANSS positive subscale was numerically equal to risperidone and olanzapineReduction in the PANSS negative subscale was statistically significantly superior ($p<0.05$) to olanzapine ➢ Improvement in some measures of cognitive performance, as measured by a cognitive battery of tests or the PANSS cognitive factor [PANSS Items: N5, P2, G5, G10, G11 (Lindemayer, et al 1994)] was numerically superior to risperidone and olanzapine ➢ Reduction in depression symptom as measured by the Calgary Depressions Scale for Schizophrenia (CDSS) was statistically superior to placebo ($p<0.05$) and numerically equal to or better than olanzapine based on meta analysis. • In a placebo-controlled trial involving the follow-up for up to 52 weeks of stable schizophrenic patients, asenapine was shown to delay the time to and rate of relapse compared to placebo ($p<0.05$) • Increase in social and interpersonal functioning (as measured by interpersonal relations, and social role subscales of the QLS) was statistically superior to placebo ($p<0.05$) and numerically superior to olanzapine

		• Patient satisfaction with treatment as rated on an appropriate patient satisfaction scale selected by Pfizer was statistically superior to placebo ($p<0.05$) and numerically superior to olanzapine

Bipolar Mania	*Data or Results to be Demonstrated in at least Two Phase 3 Clinical Studies for Asenapine*	*Data or Results to be Demonstrated in at least One Phase 3 Clinical Study for Asenapine*
Efficacy	• In patients meeting DSM IV criteria for Bipolar I Disorder with manic or mixed episodes, with or without psychotic features, 3- to 4- week treatment with asenapine produced a reduction in the 11-item Young Mania Rating Scale (Y-MRS) that was statistically superior to placebo ($p<0.05$) • Reduction in the PANSS positive subscale was statistically significantly superior to placebo ($p<0.05$) • Reduction in the PANSS agitation subscale was statistically significantly superior to placebo ($p<0.05$)	• In patients meeting DSM IV criteria for Bipolar I Disorder with manic or mixed episodes, 3- to 4- week treatment with asenapine produced a reduction in the Young Mania Rating Scale (Y-MRS) numerically equal to olanzapine • Reduction in the PANSS positive subscale was numerically equal to olanzapine • Reduction in the PANSS agitation subscale was numerically equal to olanzapine • Improvement in health status as measured by the SF-36 was statistically superior to placebo ($p<0.05$) and numerically equal to olanzapine • Patient satisfaction with medication as rated on an appropriate patient satisfaction scale selected by Pfizer was statistically superior to placebo ($p<0.05$) and numerically superior to olanzapine

Special Populations	• No dose adjustment was required in patients with Renal Impairment • No clinically significant hepatic toxicity observed that will limit use of asenapine in patients • No differences in efficacy and adverse events observed in patient subpopulation of different Race and Gender • No difference in efficacy observed between smoking and non-smoking patients

Safety and Tolerability	• Data from Phase 3 studies indicate that usage in patients with Schizophrenia or Bipolar I Disorder (other than Special Populations above) will not be limited due to adverse events. The incidence of discontinuation due to adverse events after six weeks of treatment is similar to placebo and not worse than both olanzapine and risperidone. • The incidence of total adverse events after 6 weeks of treatment is equal to or lower than with both olanzapine and risperidone. • The severity of adverse events observed after 6 weeks of treatment is equal to or lower than with both olanzapine and risperidone. • The incidence of neuroleptic malignant syndrome, tardive dyskinesia, orthostatic hypotension, seizures, hyperprolactinemia, increased risk for diabetes, transaminase elevations, cognitive and motor impairment, body temperature dysregulation, dysphagia, suicide and skin rash is equal or lower than with both olanzapine and risperidone. • No clinically significant drug-drug interactions, including interactions with drugs that prolong QT • The incidence of anticholinergic side effects was lower than with both risperidone and olanzapine, not clinically different from placebo • The incidence of extrapyramidal side effects was lower than with both risperidone and olanzapine, not clinically different from placebo, and not greater than 6% • The incidence of spontaneously reported sexual dysfunction was not greater than 1% • The incidence of weight gain (>/=7% of body weight) was lower than with both risperidone and olanzapine, and not greater than 8% in short term (4 to 6 weeks) treatment, and not greater than 10% in long term (52 weeks) treatment • The incidence of elevated blood glucose levels or diabetic ketoacidosis was no higher than with both risperidone and olanzapine, and not clinically significantly different from placebo • No drug related clinically significant QTc prolongation detected in the Phase 3 studies, such as: ➢ any incidence of Torsades de Pointes; or ➢ any incidence of QTc >= 500 msec, or ➢ higher than placebo incidence of delta QTc >= 60 msec; or ➢ > 5% mean QTc prolongation from baseline in the recommended dose range (whether or not in the presence of a metabolic inhibitor or other drugs that decrease clearance) • The incidence of LFT elevations or other laboratory abnormalities was no higher than with both risperidone and olanzapine, and not clinically different from placebo. The incidence of LFT elevations of >/=3 times the upper limit of normal not greater than 2% • No clinically significant ocular changes (for example: color, Snellen, peripheral vision) observed in Phase 3 studies • The pharmacokinetic profile of asenapine when water is ingested immediately after tablet dissolution was equivalent to asenapine when taken without water

	• The safety profile of asenapine was not significantly different when taken with or without food

	• The safety profile of asenapine was not significantly different when taken with or without food

SCHEDULE 3.1(VIII)

THIRD PARTY DEVELOPMENT AND MANUFACTURE AGREEMENTS

- License and Development Agreement between R.P. Scherer Corporation and N.V. Organon dated March 27, 1997.

- **SCHEDULE 4.1**

DEVELOPMENT PLAN

(See Attached)

SCHEDULE 4.8

METHODOLOGY FOR TRACKING SALES IN NEW INDICATIONS

1. In order to allocate Product sales across sales in the indications being Co-Promoted by the Parties and sales for New Indications, the Parties will make use of an external physician audit, Verispan's Physician Drug and Diagnosis Audit (the "Audit"). This office-based physician audit will enable the Parties to determine the extent to which physicians recommend the use of the Product in conjunction with patient visits for specifically coded and identified medical conditions (ICD-9 codes).

2. At the time of Regulatory Approval for each New Indication, the GCC will determine what ICD-9 codes should be associated with the New Indication (the "New Indication Codes"). Using Example 1 below for illustration, in the data for Paxil® shown, 6.2% of sales are associated with Panic Disorder, 1.8% are associated with Panic Attack, etc.

3. The Net Sales of the Product for all indications as reported by Organon for the relevant period ("Total Net Sales") will be multiplied by the sum of the percentage shares for all New Indication Codes during such period ("New Indication Percentage"). This amount will then be subtracted from the Total Net Sales for such period, with the remainder reflecting the sales of Product to be used by Organon in its calculation of Net Sales for such period pursuant to this Agreement ("Sharable Sales"). The formula is shown here:

   Sharable Sales = Total Net Sales – (Total Net Sales X New Indication Percentage)

See Example 1 below for further clarification.

4. Subject to paragraph 6 of this exhibit, this calculation shall be performed after the end of each of the first three (3) Calendar Quarters in each Year during the Term commencing with the first Regulatory Approval of the Product for the first New Indication in connection with Organon's preparation of its Calendar Quarterly Net Sales report described in Article 8A.4 of this Agreement. For each such Calendar Quarterly calculation, the prior six (6) months of Audit data will be used to determine the Sharable Sales.

5. Subject to paragraph 6 below, the Sharable Sales for the last Calendar Quarter in any Year during the Term shall represent a Year-end reconciliation, and be equal to the following amount less the cumulative Sharable Sales with respect to the first three (3) Calendar Quarters of such Year: the Total Net Sales for such Year ("Annual Net Sales") minus the product of the Annual Net Sales and the New Indication Percentage for such Year (the "Annual New Indication Percentage"). The formula is shown here:

Fourth Calendar Quarter Sharable Sales = (Annual Net Sales – (Annual Net Sales X Annual New Indication Percentage)) - Cumulative Sharable Sales for first Three (3) Calendar Quarters of such Year

6. The first Calendar Quarterly calculation described in paragraph 3 above will not take place until at least 6 months of Audit data is available for each New Indication. In addition, the first Year-end reconciliation described in paragraph 5 above will not take place until at least six

(6) months of Audit data is available for such New Indication. Thus, in the event that a New Indication for the Product is approved after July 1 of a Year, the first Year-end reconciliation for such New Indication will not take place until the end of the following Year. See Examples 2 and 3 below.

Example 1

Consider the following Audit data for Paxil®

	MAT/APR/02 Uses (000)	Share %
Paxil	11114	100
311020 DEPRESSION NOS	3727	33.5
300000 ANXIETY STATE NOS	1200	10.8
300010 PANIC DISORDER	686	6.2
300410 ANXIETY DEPRESSION	393	3.5
300020 GENERALIZED ANXIETY DIS	316	2.8
300230 SOCIAL PHOBIA	284	2.6
300011 PANIC ATTACK	204	1.8
300210 AGORAPHOBIA WITH PANIC	119	1.1
All Others	4185	37.7

If a collaboration agreement required the exclusion from total Paxil® sales of sales associated with Panic Disorder, the calculation of the sharable sales between the collaborators would be:

Sharable sales = Total Net sales – (Total Net sales X 6.2%)

However, if the collaboration agreement required the exclusion both of sales for Panic Disorder and sales for Panic Attack, the calculation of sharable sales would be:

Sharable sales = Total Net sales - (Total Net sales X 8.0%)

EXAMPLE 2

A New Indication is approved on April 8, 2005. Calendar Quarterly calculations will not be done for the Calendar Quarters ending June 30, 2005 or September 30, 2005 because 6 months of Audit data reflecting such New Indication would not yet be available.

A year-end reconciliation will take place, however, after December 31, 2005, taking into account Audit data of such New Indication for the months of April through December, 2005.

The first Calendar Quarterly calculation will take place for the Calendar Quarter ending March 31, 2006, using data from the prior 6-month period, namely October 1, 2005 - March 31, 2006.

Calendar Quarterly calculations and Year-end reconciliation will proceed thereafter as discussed above.

EXAMPLE 3

A New Indication is approved on July 28, 2005. A Calendar Quarterly calculation will not be done for the Calendar Quarter ending September 30, 2005, and a Year-end reconciliation will not be done after December 31, 2005, because 6 months of Audit data reflecting such New Indication would not yet be available.

The first Calendar Quarterly calculation will take place for the Calendar Quarter ending March 31, 2006, using data from the prior 6-month period, namely October 1, 2005 - March 31, 2006.

Calendar Quarterly calculations will proceed thereafter as discussed above.

After December 31, 2006, a Year-end reconciliation will take place for the period commencing July 28, 2005 through December 31, 2006.

Year-end reconciliations will proceed thereafter as discussed.

	[illegible]	First Year	Second Year	Third Year	Fourth Year & Fifth Year	Subsequent Years
Minimum	$15	40	40	40	Prior Year Minimum + CPI	Fifth Year Minimum
Maximum	$30	80	80	80	Prior Year Maximum + CPI	Fifth Year Maximum

In the event that the Parties are unable to agree upon budgeted Marketing Costs in the Global Marketing Plan or Country Marketing Plan for a particular Year, then the applicable Minimum Marketing Costs for such Year shall apply.

For the US Territory, "+CPI" means that the minimum and maximum Marketing Costs are adjusted annually, with the first such adjustment taking place for Year 4, according to changes in the Consumer Price Index for All Urban Consumers (CPI-U): U.S. city average, for the preceding Year.

For the Key EU Countries, "+CPI" means the United Kingdom "Retail Price Index"

Calendar Quarterly calculations and Year-end reconciliation will proceed thereafter as discussed above.

EXAMPLE 3

A New Indication is approved on July 28, 2005. A Calendar Quarterly calculation will not be done for the Calendar Quarter ending September 30, 2005, and a Year-end reconciliation will not be done after December 31, 2005, because 6 months of Audit data reflecting such New Indication would not yet be available.

The first Calendar Quarterly calculation will take place for the Calendar Quarter ending March 31, 2006, using data from the prior 6-month period, namely October 1, 2005 - March 31, 2006.

Calendar Quarterly calculations will proceed thereafter as discussed above.

After December 31, 2006, a Year-end reconciliation will take place for the period commencing July 28, 2005 through December 31, 2006.

Year-end reconciliations will proceed thereafter as discussed.

SCHEDULE 6.3
MARKETING COSTS

All amounts are expressed in Millions of US dollars.

US Territory

	Pre-Launch*	First Year	Second Year	Third Year	Fourth Year & Fifth Year	Subsequent Years
Minimum	$20	75	70	70	Prior Year Minimum + CPI	Fifth Year Minimum
Maximum	$60	135	125	125	Prior Year Maximum + CPI	Fifth Year Maximum

Key EU Countries

	Pre-Launch*	First Year	Second Year	Third Year	Fourth Year & Fifth Year	Subsequent Years
Minimum	$15	40	40	40	Prior Year Minimum + CPI	Fifth Year Minimum
Maximum	$30	80	80	80	Prior Year Maximum + CPI	Fifth Year Maximum

In the event that the Parties are unable to agree upon budgeted Marketing Costs in the Global Marketing Plan or Country Marketing Plan for a particular Year, then the applicable Minimum Marketing Costs for such Year shall apply.

For the US Territory, "+CPI" means that the minimum and maximum Marketing Costs are adjusted annually, with the first such adjustment taking place for Year 4, according to changes in the Consumer Price Index for All Urban Consumers (CPI-U): U.S. city average, for the preceding Year.

For the Key EU Countries, "+CPI" means the United Kingdom, "Retail Price Index" as quoted in The Financial Times.

*Pre Launch represents all marketing activities in aggregate prior to launch, excluding the formal launch meeting. Launch meeting is included in First Year costs.

SCHEDULE 6.4

REDUCTION OF DETAILING REQUIREMENTS AND MARKETING COST OBLIGATIONS

Forecast Net Sales in Relevant Two Year Period

first Year - $250 million

second Year - $750 million

Mean Net Sales - $500 million

Actual Net Sales in Relevant Two Year Period

first Year - $125 million

second Year - $375 million

Mean Net Sales - $250 million

Marketing Cost obligations in Year following relevant two Year period: $50 million

Detail Requirement in Year following relevant two Year period: 1 million Details

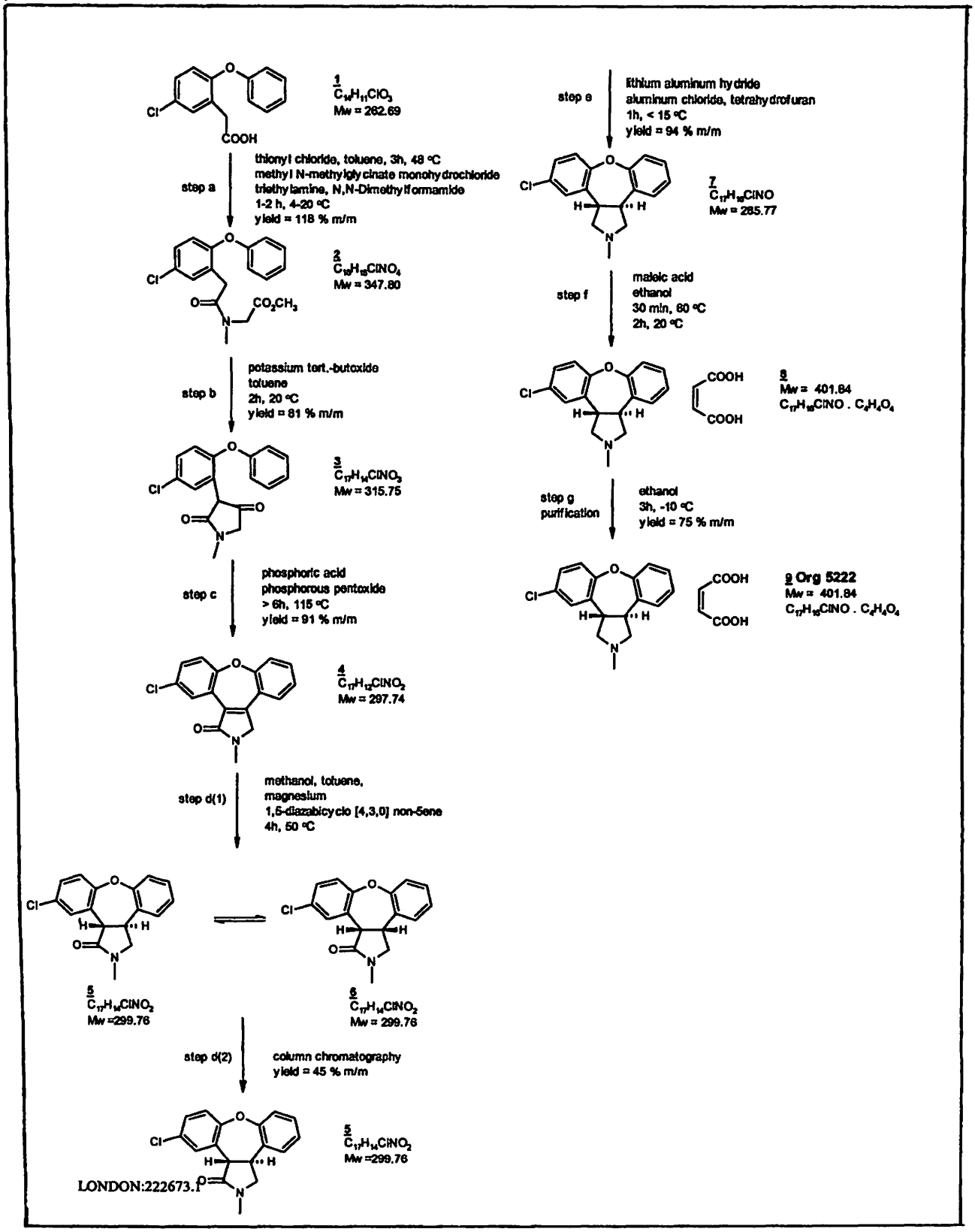
Calculation of fraction = Mean Actual Net Sales/Mean Forecast Net Sales = .5

Maximum Marketing Cost reduction in Year following relevant two Year period = $25 million

Maximum Detail reduction in the Years following relevant two Year period = 500,000 Details

SCHEDULE 9.8

CURRENT MANUFACTURING PROCESS



SCHEDULE 13.5(ii)(a)

RAT AND MOUSE CARCINOGENICITY STUDIES

Satisfaction of the endpoints for the Rat and Mouse Carcinogenicity Studies means:

1. No finding, whether statistically significant or not, that would significantly impact regulatory acceptance, time to registration, or limit the intended use for or patient population of the Product. This includes, but is not limited to any: (a) increased incidence of tumors, and (b) non-neoplastic findings.

2. Full compliance with guidelines for the design and conduct of carcinogenicity studies (specifically, ICH Guidelines S1C and S1B). This includes, but is not limited to: (a) achieving a maximum tolerated dose; (b) having an adequate number of animals per group to allow for the assessment of carcinogenic potential, and (c) absence of any protocol deviations.

SCHEDULE 16.14

JOINT PRESS RELEASE

DRAFT

For immediate release:

October XX, 2003

PFIZER AND AKZO NOBEL'S ORGANON ENTER GLOBAL COLLABORATION FOR POTENTIAL NEW PSYCHOTROPIC TREATMENT

New York, and Arnhem, THE NETHERLANDS Oct. XX -- Pfizer Inc and Organon, the human pharmaceutical business unit of Akzo Nobel, today announced they have entered into a global agreement for the exclusive worldwide development and commercialization of Organon's asenapine, a potential new psychotropic medication for the treatment of a variety of disorders that is beginning Phase III trials in schizophrenia and bipolar disorder.

Under terms of the agreement, which is subject to government approval, the companies will collaborate on the clinical development and manufacturing of asenapine, and co-promote the product in the United States, European Union, Japan and other markets. Pfizer will make an initial payment of $100 million and up to $270 million in milestone payments contingent upon regulatory approvals and launch of asenapine in the U.S., Europe and Japan as well as attainment of certain agreed-upon sales levels. Further terms of the agreement were not disclosed.

"Organon is excited about its partnership with Pfizer to develop and market asenapine. Phase II clinical trials with asenapine have shown promising results which could assist patients in treating their psychoses," said Michael Novinski, Organon International Board Member and President of Organon USA. "We believe this collaboration will provide the appropriate development and commercial resources necessary to serve the patient population who may benefit from this treatment," said Toon Wilderbeek, Member of the Akzo Nobel Board of Management.

"We are very pleased Organon chose Pfizer as its partner to advance the development of asenapine, which has the potential to help patients live more productive lives," said Karen Katen, President, Pfizer Global Pharmaceuticals. "As with most drugs in the neuroscience category, psychotropic medications work for only about 70% of individual patients so new treatments are always needed. We believe asenapine will present additional options for patients and physicians in the management of psychoses, allow us to build upon Pfizer's expertise in this area and compliment our current neuroscience portfolio."

Asenapine is a 5HT2/D2 antagonist that belongs to a class of medicines known as atypical antipsychotics. These drugs act on both the 5HT2 and D2 receptors and show superior tolerability and efficacy compared to older antipsychotic medications that act mainly on D2 receptors. In early clinical studies, asenapine was well-tolerated and showed statistically superior efficacy when compared with placebo.

Akzo Nobel's human healthcare unit Organon, headquartered in Roseland, NJ USA, is a renowned pharmaceutical company with a strong commitment to human health care. The company develops and produces innovative prescription medicines for gynecology, psychiatry, cardiovascular diseases, immunology and anesthesia. Organon products are sold in over 100 countries, more than half of which have an Organon subsidiary. The company currently employs approximately 13,000 people.

SCHEDULE 13.5(ii)(a)

RAT AND MOUSE CARCINOGENICITY STUDIES

Satisfaction of the endpoints for the Rat and Mouse Carcinogenicity Studies means:

1. No finding, whether statistically significant or not, that would significantly impact regulatory acceptance, time to registration, or limit the intended use for or patient population of the Product. This includes, but is not limited to any: (a) increased incidence of tumors, and (b) non-neoplastic findings.

2. Full compliance with guidelines for the design and conduct of carcinogenicity studies (specifically, ICH Guidelines S1C and S1B). This includes, but is not limited to: (a) achieving a maximum tolerated dose; (b) having an adequate number of animals per group to allow for the assessment of carcinogenic potential, and (c) absence of any protocol deviations.

SCHEDULE 16.14

JOINT PRESS RELEASE

DRAFT

For immediate release:

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