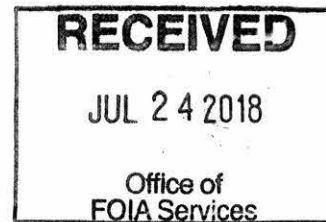




18-05371-E

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



July 24, 2018

Dear Mr. Livornese:

I request pursuant to the Freedom of Information Act (FOIA) 5 U.S.C. § 552. As Amended by Public Law No. 104-231, 110 Stat. 3048, copies of the following agreements, based on the **File No. 0-19410 - CF#21669**, and as **FOIA Request 18-02993-E**.

Exhibit 10.44 to Form 10-K filed on 02/29/2008 by Sepracor Inc /De/.

Exhibit Title: License Agreement

CIK: 877357

Sectilis will pay up to \$61 for research, copies and review fees for all of the abovementioned agreements. Please forward all releasable material for copying. My daytime telephone number is 202-558-2356. Please call me or e-mail at research@sectilis.com to discuss the total cost or estimated cost of this research/copies should the amount exceed the price indicated in this request.

Sincerely,

Stella Vasconcellos
Research Assistant
Sectilis LLC
6931 Arlington RD. # 580
Bethesda, MD 20814



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

Office of FOIA Services

August 16, 2018

Ms. Stella Vasconcellos
Sectilis LLC
6931 Arlington Rd. # 580
Bethesda, MD 20814

RE: Freedom of Information Act (FOIA), 5 U.S.C. § 552
Request No. **18-05371-E**

Dear Ms. Vasconcellos:

This letter is in response to your request, dated and received in this office on July 24, 2018, for access to Exhibit 10.44 to Form 10-K filed on February 29, 2008 by Sepracor Inc /De/.

In connection with a previous request, access was granted to the subject exhibit. Therefore, we have determined to release the same exhibit (copy enclosed) to you. No fees have been assessed in this instance.

If you have any questions, please contact me at reidk@sec.gov or (202) 551-3504. You may also contact me at foiapa@sec.gov or (202) 551-7900. You also have the right to seek assistance from Lizzette Katilius as a FOIA Public Liaison or contact the Office of Government Information Services (OGIS) for dispute resolution services. OGIS can be reached at 1-877-684-6448 or Archives.gov or via e-mail at ogis@nara.gov.

Sincerely,

Kay Reid

Kay Reid
FOIA Lead Research Specialist

Enclosures

LICENSE AGREEMENT

THIS LICENSE AGREEMENT (this "Agreement") is made and entered into as of December 31, 2007 (the "Effective Date") by and between BIAL - PORTELA & C^a, S.A., a Portuguese corporation having a principal place of business at À Av. da Siderurgia Nacional, 4745-457 S. Mamede do Coronado, Portugal (hereinafter referred to as "BIAL") and SEPRACOR INC., a Delaware corporation having a principal place of business at 84 Waterford Drive, Marlborough, MA 01752, USA (hereinafter referred to as "SEPRACOR").

WITNESSETH

WHEREAS, BIAL Controls (as defined below) the BIAL Patents and BIAL Know-How (each as defined below) relating to its proprietary compound BIA 2-093 (as defined below) and its use in the treatment of human diseases and conditions including, without limitation, epilepsy; and

WHEREAS, SEPRACOR wishes to acquire licenses under the BIAL Patents, BIAL Know-How and BIAL Trademarks (each as defined below) for the purpose of developing, commercializing, marketing, offering for sale, selling, and distributing Licensed Products (as defined below) comprised of BIA 2-093 for use within the Field and Territory (each as defined below), and BIAL is willing to grant such licenses under the terms and conditions of this Agreement; and

WHEREAS, BIAL wishes to acquire licenses under any future SEPRACOR Know-How and Development Intellectual Property (each as defined below) and SEPRACOR is willing to grant such licenses under the terms and conditions of this Agreement; and

WHEREAS, the Parties (as defined below) will execute a Supply Agreement (as defined below) under which BIAL or its Affiliates will, unless otherwise agreed in writing by the Parties, supply all of SEPRACOR's requirements of Licensed Products to SEPRACOR for sale and distribution within the Field and Territory.

NOW, THEREFORE, in reliance on the foregoing recitals and in consideration of the mutual covenants and promises set forth herein, the Parties agree as follows:

ARTICLE 1
DEFINITIONS

As used in this Agreement, the following terms have the following meanings, and the singular includes the plural and vice-versa:

1.1 “Affiliate” means any person or entity that, as of the Effective Date or at any time in the future, directly or indirectly through one or more intermediaries, controls, is controlled by, or is under common control with a Party. For purposes of this definition, “control” means (i) the ownership of at least fifty percent (50%) of the voting securities of the entity or such lesser percentage which is the maximum allowed by applicable law; (ii) ownership of at least fifty percent (50%) interest in the assets, profits, or earnings of the entity; or (iii) the ability to otherwise direct the management and operations of the entity.

1.2 “ANDA” means an abbreviated new drug application filed pursuant to 21 U.S.C. 355(j).

1.3 “Approval” means the receipt of all authorizations, including, without limitation for any labeling and indications, from all governmental entity(ies) that are required to market and sell a Licensed Product within the Field and Territory.

1.4 “BIA 2-093” means BIAL’s proprietary compound (S)-(-)-10-acetoxy-10,11-dihydro-5H-dibenz/b,f/azepine-5-carboxamide, known under the International Nonproprietary Name (INN) Eslicarbazepine Acetate.

1.5 “BIA 2-093 IND” means the IND No. 67,466 effective as of the 20th December 2006.

1.6 “BIA 2-093 Product” means BIA 2-093 in 800mg, 600mg and 400mg tablet formulations in fully finished and packaged consumer form.

1.7 “BIAL Know-How” means (i) research and development information, unpatented inventions, trade secrets, proprietary materials, or any other type of proprietary or confidential technical data or information, including, without limitation, methods, techniques, processes, specifications, recipes, formulae, designs, plans, drawings, data, protocols, or preclinical and clinical studies, which are Controlled by BIAL as of the Effective Date and (a) reasonably necessary for the development, commercialization, importation, use, sale, or offer for sale of the Licensed Products, or (b) useful for the development, commercialization, importation, use, sale, or offer for sale of the Licensed Products to the extent that BIAL has developed or uses such know-how in connection with the Licensed Products; and (ii) subject to the provisions in Section 6.7, the BIA 2-093 IND and any other regulatory filings and correspondence and all data and information submitted in support of such filings or correspondence, which are Controlled by BIAL as of the Effective Date and relate solely to BIA 2-093 and/or the Licensed Products. The term BIAL Know-How includes any items encompassed by (i) and (ii) in the preceding sentence created after the Effective Date and during the Term of this Agreement and Controlled by BIAL.

1.8 “BIAL Logo” means the logo included in Exhibit C, which BIAL may, at its own discretion, update from time to time.

1.9 “BIAL Patents” means: (i) all U.S. and Canadian patents and patent applications Controlled by BIAL as of the Effective Date, covering the manufacture, use, import, offer for sale, and sale of the Licensed Products, including, without limitation, the patents and patent applications listed in Exhibit A; (ii) any U.S. or Canadian divisional, substitution, continuation, or continuation-in-part applications based on, directly or indirectly, relying for priority on, or having identical disclosure as, any of the U.S. or Canadian patent or patent applications in (i); (iii) any patent issuing from any of the applications in (i) or (ii); and (iv) any extensions, reissues, or reexaminations of any of the patents in (i) and/or (iii). BIAL Patents also include any Development Intellectual Property created by BIAL solely or jointly with SEPRACOR or that otherwise come under BIAL’s Control during the Term of this Agreement covering the manufacture, use, import, offer for sale or sale of the Licensed Products. BIAL agrees to update Exhibit A from time to time with additional Development Intellectual Property created by BIAL solely or jointly with SEPRACOR or that otherwise come under BIAL’s Control during the

Term of this Agreement covering the manufacture, use, import, offer for sale or sale of the Licensed Products.

1.10 “BIAL Studies” has the meanings set forth in Section 6.4(a).

1.11 “BIAL Trademarks” means the marks, brand names and/or other indicators of source listed in Exhibit B for use in conjunction with the Licensed Products within the Field and Territory. Exhibit B may be updated from time to time with additional BIAL Trademarks for use with the Licensed Products within the Field and Territory, as selected pursuant to Sections 2.3(a) and 5.3(x). For the avoidance of doubt, the term “BIAL Trademarks” does not encompass the INN Eslicarbazepine Acetate, the BIAL Logo or any marks, brand names and/or other indicators of source not specifically listed in Exhibit B.

1.12 “Business Day” means 9:00 am to 5:00 pm local on a day (other than a Saturday or Sunday) on which banks are open for business in Porto, Portugal, and Boston, MA USA.

1.13 “Change of Control” means any of the following events: (i) a Third Party (or group of Third Parties acting in concert) directly or indirectly, acquires more than fifty percent (50%) of the then outstanding capital stock entitled to vote for the election of SEPRACOR’s directors; (ii) SEPRACOR consolidates with or merges into a Third Party, or a Third Party consolidates with or merges into SEPRACOR, which, in either event, more than fifty percent (50%) of the then outstanding capital stock of the surviving entity entitled to vote for the election of directors is not held by the parties holding at least fifty percent (50%) of the outstanding shares of SEPRACOR preceding such consolidation or merger; or (iii) SEPRACOR conveys, transfers or leases all or substantially all of its assets.

1.14 “Commercialization Plan” means a plan with the primary objective of (i) preparing the market for and launching Licensed Products within the Field and Territory and (ii) continuing the marketing and sale of each Licensed Product after commercial launch has occurred. The term “Commercialization Plan” includes both the Strategic Commercialization Plans and the Annual Commercialization Plans referred to in Article 7 as well as any amendments thereto.

1.15 “Commercially Reasonable Efforts” means efforts and resources that are consistent with those utilized by SEPRACOR or BIAL, as the case may be, for its own internally developed or in-licensed pharmaceutical products, which are at a similar stage in their development or product life and have similar market potential as the Licensed Products, and (ii) with those utilized by other pharmaceutical companies of similar size and resources for its own internally developed or in licensed pharmaceutical products for the same therapeutic areas as the Licensed Products and which are at a similar stage in their development or product life and have similar market potential as the Licensed Products.

1.16 “Competing Product” means any pharmaceutical product with a primary indication in the same therapeutic class as the Licensed Products, which is defined as any pharmaceutical product in the Anatomical Therapeutic Chemical Class System category of N03A, and with the same label claims that can be directly substituted for the relevant Licensed Product.

1.17 “Controlled” means, with respect to any patents, copyrights, trademarks, know-how, trade secrets, proprietary information or data (including, without limitation, any regulatory filings and related data), or any other forms of comparable property rights protected by Federal law and foreign counterparts (collectively “Intellectual Property”), the possession of the right, whether directly or indirectly, whether by ownership, license or otherwise, to disclose, assign, or grant a license, sublicense or other right to or under such Intellectual Property, as provided for in this Agreement, without violating the terms of any agreement, contract, or any other arrangement with any Third Party. For the avoidance of doubt, Third Party Intellectual Property will only be considered “Controlled” by a Party, if the Party has right to disclose, assign, or grant a license, sublicense or other right to the other Party as provided for in this Agreement, at no additional cost and without prior Third Party approval. The term “Control” or “Controls” used in this context will also have a correlative meaning.

1.18 “CMC Program” means the chemistry, manufacturing and control program relating to the BIA 2-093 Product or any other Licensed Products.

1.19 “Development Intellectual Property” means any inventions or discoveries (whether or not patentable) made solely by one Party or jointly by the Parties in the performance of this Agreement or the Supply Agreement and any patent applications or patents claiming such inventions or discoveries, but only to the extent such Development Intellectual Property relates to BIA 2-093 or any Licensed Product. The term “Development Intellectual Property” also includes, to the extent Controlled by a Party, any inventions or discoveries (whether or not patentable) made solely by its sublicensee, a contractor, or an Affiliate of a Party or jointly by a Party and its sublicensee, a contractor, or an Affiliate in the performance of this Agreement or the Supply Agreement and any patent applications or patents claiming such inventions or discoveries.

1.20 “Development Plan” has the meaning set forth in Section 6.2 below.

1.21 “Development Studies” has the meaning set forth in Section 6.2 below.

1.22 “Effective Date” means the date first written above.

1.23 “Exclusivity Rights” means a marketing or data exclusivity right conferred as a result of (i) designation as a drug for rare diseases or conditions under Sections 525 *et seq.* of the FD&C Act, (ii) approval of an NDA for a new chemical entity pursuant to 21 U.S.C. 355 and the FD&C Act or any relevant subsequent legislation, rules or regulations, (iii) the exclusive right granted by the FDA upon completion of pediatric studies requested by the FDA under Section 505A(a) of the FD&C Act, and any successor legislations thereof. The term “Exclusivity Rights” also means any marketing or data exclusivity rights that may be conferred under any applicable Canadian law.

1.24 “Executive Officer” means with respect to SEPRACOR, a Senior Vice President or higher ranking officer, and with respect to BIAL, a Director or higher ranking officer.

1.25 “FDA” means the United States Food and Drug Administration and its successor bodies.

1.26 “FD&C Act” means the U.S. Food, Drug and Cosmetic Act, the rules and regulations of the FDA promulgated thereunder and as amended from time to time.

1.27 “Field” means all human and non-human diagnostic, prophylactic and therapeutic uses of the Licensed Products for adjunctive use in Adult Partial Epileptic Seizures and any and all new indications, including but not limited to Epilepsy Monotherapy, Trigeminal Neuralgia, Diabetic Neuropathic Pain and Post-herpetic Neuralgia.

1.28 “Fully Burdened Manufacturing Cost” means all costs incurred (i.e. paid or accrued) by BIAL, its Affiliates, agents or contractors in the manufacture and supply of BIA 2-093, the BIA 2-093 Product and Licensed Products, including without limitation direct and indirect costs, including overhead. Such costs to be calculated in accordance with International Financial Reporting Standards and using the normal cost accounting and allocation methods and procedures.

1.29 “IND” means an Investigational New Drug Application filed with the FDA in support of conducting clinical development in the United States.

1.30 “JSC” has the meaning set forth in Section 5.1.

1.31 “Knowledge of BIAL” or words of like import means, with respect to the existence or absence of a fact, the actual knowledge of an officer of BIAL.

1.32 “Licensed Products” means the BIA 2-093 Product and all other products (including any current or future dosages, formulations, improvements and/or delivery modes) comprising BIA 2-093 and all possible metabolites, salts, hydrates, polymorphs, crystalline forms, solvates and prodrugs thereof, including any present and future combination products containing BIA 2-093 or a metabolite, salt, hydrate, polymorph, crystalline form, solvate or prodrug thereof, as one of the active ingredients.

1.33 “Liabilities” has the meaning set forth in Section 15.1.

1.34 “Milestone Event” has the meaning set forth in Section 3.1(b).

1.35 “Milestone Payments” has the meaning set forth in Section 3.1(b).

1.36 “Minimum Sales” has the meaning set forth in Section 7.4.

1.37 “NDA” means a New Drug Application to be filed with the FDA including all documents, data, and other information required to be included in such filing.

1.38 “Net Sales” means the gross amounts received for sales of the Licensed Products by or on behalf of SEPRACOR, its Affiliates and/or its sublicensee (the “Selling Party”) to Third Parties, less deductions actually allowed or specifically allocated to the Licensed Products by the Selling Party using U.S generally accepted accounting principals for:

(a) transportation charges to the extent that they are included in the price or otherwise paid by the purchaser, including, without limitation, insurance, for transporting Licensed Products and separately identified on the invoice or in other documentation maintained in the ordinary course of business;

(b) trade, quantity and cash discounts, or charge-backs, refunds or other rebates actually granted to the customer (including, if applicable, hospitals or private or public health insurance entities);

(c) credits, rebates and allowances to the customer on account of rejection or returns of the Licensed Products (including wholesaler and retailer returns), or on account of non-discretionary retroactive price reductions affecting such Licensed Products;

(d) sales and excise taxes, other consumption taxes, customs duties and customary compulsory payments to governmental authorities and any other governmental charges imposed upon the production, importation, use or sale of the Licensed Products actually paid by SEPRACOR and separately identified on the invoice or in other documentation maintained in the ordinary course of business (but not including taxes assessed against the income derived from the sales of Licensed Products); and

(e) any other items actually deducted from gross invoices sales amounts as reported by the Selling Party in its financial statements in accordance with the U.S generally accepted accounting principals, applied on a consistent basis.

In no event will any particular amount, identified above, be deducted more than once in calculating Net Sales (i.e., no “double counting” of reductions). Sales of the Licensed Products

between SEPRACOR and its Affiliates or sublicensee will be excluded from the computation of Net Sales, but the subsequent resale of such the Licensed Products to a Third Party will be included within the computation of Net Sales.

In the case of any sale or disposal for value, other than in an arms length transaction exclusively for money, such as barter or counter trade, Net Sales will be calculated as above on the value of the consideration received or the fair market value (if higher) of the Licensed Products in the country of sale or disposal.

Any amounts hereunder will be determined from the books and records of SEPRACOR, its Affiliates and sublicensee maintained in accordance with US generally applied accounting practices consistently applied to all products of SEPRACOR.

1.39 “Net Selling Price” means for the applicable period and for each respective Licensed Product (and, in relation to the BIA 2-093 Product, for each respective dosage) the amount corresponding to the total Net Sales of a Licensed Product divided by the actual number of units sold net of returns (for example, the total Net Sales of the BIA 2-093 Product for the applicable period divided by the total number of pills sold).

1.40 “Paper NDA” means an application filed pursuant to 21 U.S.C. 505(b)(2).

1.41 “Party” or “Parties” means SEPRACOR or BIAL when used in the singular or SEPRACOR and BIAL when used in the plural.

1.42 “Product Liability Claim” has the meaning set forth in Section 15.7(a).

1.43 “SEPRACOR Know-How” means (i) research and development information, unpatented inventions, trade secrets, proprietary materials, or any other proprietary or confidential technical data or information, including without limitation, methods, techniques, processes, specifications, recipes, formulae, designs, plans, drawings, data, protocols or preclinical and clinical studies which are Controlled by SEPRACOR during the Term of this Agreement and (i) are reasonably necessary for the manufacture, development, commercialization, importation, use, sale, or offer for sale of any Licensed Product, or (ii) useful for the manufacture, development, commercialization, importation, use, sale, or offer for sale of

the Licensed Products to the extent that SEPRACOR has developed or uses such know-how in connection with the Licensed Products, and (ii) all IND/NDA and any other regulatory filings and correspondence and all data and information submitted in support of such filings or correspondence which are Controlled by SEPRACOR during the Term of this Agreement and which relate solely to the BIA 2-093 or any Licensed Products.

1.44 “Supply Agreement” has the meaning set forth in Article 4.

1.45 “Third Party” means any person or entity who or which is neither a Party nor an Affiliate of a Party.

1.46 “Term” has the meaning set forth in Section 14.1.

1.47 “Territory” means the United States of America and Canada.

1.48 “Three Year Strategic Development Plan” means a Development Plan providing the information required in Section 6.3(b) for a period of three (3) years beginning on January 1 of the year following the date on which such Development Plan is approved. Notwithstanding the foregoing, the initial Three Year Development Plan will cover the three year period beginning on the date it is approved.

ARTICLE 2

GRANT OF RIGHTS

Notwithstanding any other provision of this Agreement, no rights or obligations hereunder will be of any force or effect until payment by SEPRACOR of the license fee set forth in Section 3.1(a).

2.1 Exclusive License: BIAL grants to SEPRACOR an exclusive (even as to BIAL) license under the BIAL Patents and BIAL Know-How to use, market, distribute, import, commercialize, offer for sale and sell the Licensed Products under the BIAL Trademarks within the Field and Territory either directly on its own and/or through its Affiliates, sublicensee and/or distributors permitted hereunder. The license granted to SEPRACOR under this Section 2.1 does

not include an exclusive right to use or practice the BIAL Patents and BIAL Know-How to develop Licensed Products or to have such Licensed Products developed on its behalf within the Field and the Territory.

(a) BIAL grants SEPRACOR the right to grant a sublicense only in Canada, provided that such sublicense conforms with the terms of this Agreement and the sublicensee expressly agrees to be subject to substantially similar obligations imposed to SEPRACOR under this Agreement, including without limitation the provisions of Sections 6.8, 7.6(b), 7.7, 8.1, 8.2 and 9.1.

(b) BIAL reserves to itself all rights in and to the Licensed Products, BIAL Patents, and BIAL Know-How for all uses outside of the Territory.

(c) SEPRACOR agrees not to use, market, commercialize, distribute, import, offer for sale or sell the Licensed Products outside of the Territory. SEPRACOR further agrees not to use, market, commercialize, distribute, import, offer for sale or sell any Licensed Products other than the BIA 2-093 Product until the Parties agree, in writing, to either (i) the terms and prices for the supply of such other Licensed Products by BIAL to SEPRACOR or (ii) absent such agreement, until such terms, supply prices and/or royalties are determined in accordance with the provisions of Section 4.3(b).

2.2 Non-Exclusive License: BIAL grants to SEPRACOR a worldwide, non-exclusive license, without any right to sub-license, under the BIAL Patents and BIAL Know-How to develop or have developed on its behalf, Licensed Products for use and sale within the Field and the Territory, subject to the limitations set forth in Article 6.

(a) BIAL will provide SEPRACOR with a draft of the protocols of any planned development study to be conducted by or on behalf of BIAL or its licensees in the Territory and will consider in good faith any comments provided by SEPRACOR within the period of thirty (30) days upon receipt of the said draft by SEPRACOR. SEPRACOR will have the right to veto any such development study (including the use of BIAL Trademarks in connection therewith) by BIAL or on behalf of BIAL in the Territory if SEPRACOR believes it will materially adversely affect the development, commercialization, marketing or sale of a Licensed Product within the

Territory. In the event of a dispute between the Parties as to whether there is a reasonable likelihood that such development study (or use of BIAL Trademarks in connection therewith) will materially adversely affect a Licensed Product within the Territory, the dispute will be submitted to one arbitrator in accordance with the provisions of Section 16.1.

2.3 Trademark License: BIAL grants SEPRACOR an exclusive (even as to BIAL), royalty-free license to use the BIAL Trademarks in connection with any Licensed Products that SEPRACOR uses, markets, promotes, distributes, imports, commercializes, offers for sale or sells within the Field and Territory either directly on its own and/or through its Affiliates, sublicensee, and/or distributors authorized under Section 2.1.

(a) The Parties will mutually agree upon the BIAL Trademarks. BIAL will own all right, title and interest in the BIAL Trademarks and the goodwill associated therewith and will be solely responsible for registering and maintaining such trademarks. If requested, SEPRACOR will assist and cooperate with BIAL in the selection, registration, and maintenance of the BIAL Trademarks.

(b) Any marketing, sale or distribution of Licensed Products by SEPRACOR, its Affiliates, sublicensee, or distributors under the license set forth in Section 2.1, will take place exclusively under the BIAL Trademarks, subject to each Party's rights set forth in Section 2.4. SEPRACOR will not file or obtain any trademark application or registration, or Internet domain name registration, comprised of or containing any BIAL Trademarks or the INN Eslicarbazepine Acetate, or any variations thereof, without BIAL's express written permission. SEPRACOR will use the BIAL Trademarks only in accordance with guidelines mutually agreed upon by the Parties.

(c) BIAL reserves to itself all rights in and to the BIAL Trademarks outside of the Territory and the right to use such marks within the Territory in conjunction with any development and/or publication activities conducted in accordance with this Agreement.

(d) BIAL agrees that it will not use outside the Territory trademarks and trade names for the Licensed Products that are the same or confusingly similar to the BIAL Trademarks used in connection with the commercialization of Licensed Products within the Territory.

(e) In the event that the Parties agree, pursuant to Sections 2.3(a) and 5.3(x), not to use one or more of the brands, trademarks or indicators of source listed in, or otherwise added to, Exhibit B, such brands, trademarks or indicators will be considered excluded from Exhibit B, provided that such brands, trademarks or indicators will not be used in the Territory by BIAL without SEPRACOR's prior written consent, except as BIAL Trademarks are permitted to be used by BIAL hereunder.

2.4 BIAL Logo License: BIAL grants SEPRACOR a non-exclusive license to use the BIAL Logo on all packaging materials, promotional materials and documents that are used by SEPRACOR either directly on its own and/or through its sublicensee, contractors or distributors in connection with the development, promotion, marketing, offer for sale, sale, import and commercialization of the Licensed Products. SEPRACOR agrees that all such packaging materials, promotional materials and documents that are used by SEPRACOR, its sublicensee, contractors or distributors in connection with the development, promotion, marketing, offer for sale, sale, import and commercialization of the Licensed Products will contain with legible letters of a reasonable size the words "under license from [BIAL Logo]", unless BIAL determines, in its sole discretion, that such reference will be "under license from BIAL". SEPRACOR will also be permitted to include SEPRACOR's trade name, trademarks and other logos on any packaging materials, promotional materials or other documents with equal prominence as the BIAL Logo.

2.5 Contracting: SEPRACOR has the right to contract with Third Parties to perform its development, marketing, and commercialization responsibilities under this Agreement in accordance with the terms of this Agreement; provided (i) that SEPRACOR uses, markets, imports, distributes, offers for sale, sells and commercializes the Licensed Products at all times in its own name, (ii) that SEPRACOR uses Commercially Reasonable Efforts to ensure that its contractors assign to SEPRACOR any inventions or discoveries (whether or not patentable) made in the performance of the subcontract or, absent such assignment, that its contractors grant to SEPRACOR rights to any inventions or discoveries (whether or not patentable) made in the performance of the subcontract consistent with SEPRACOR's obligations to BIAL hereunder, including without limitation the provisions of Sections 6.8, 8.1 (b)(c)(d), 8.2 and 9.1 (b) and that

SEPRACOR remains, at all times, solely responsible and liable to BIAL for all of the contractor activities and for any failure by a contractor to comply with the terms of this Agreement.

2.6 Manufacture of the Licensed Products: Unless otherwise agreed to by the Parties in writing or provided for in the Supply Agreement, SEPRACOR has no right to make or have made on its behalf, BIA 2-093, the BIA 2-093 Product or any other Licensed Product, and all Licensed Products will be supplied to SEPRACOR by BIAL or BIAL Affiliates in accordance with the terms of the Supply Agreement.

2.7 Ownership of BIA 2-093 IND: Within forty-five (45) days after the Effective Date, BIAL will transfer all right, title and interest in the BIA 2-093 IND to SEPRACOR, subject to the reservation set forth in Section 2.7 (a), for the Term of this Agreement and will promptly notify the FDA in writing of its transfer to SEPRACOR. SEPRACOR will simultaneously notify the FDA in writing that the BIA 2-093 IND has been transferred to SEPRACOR and that SEPRACOR accepts all rights and responsibilities thereunder.

(a) Subject to the exclusive licenses granted to SEPRACOR herein, BIAL retains all right, title and interest in all BIAL Know-How submitted in support of the BIA 2-093 IND, including but not limited to, all safety and effectiveness data, provided that SEPRACOR has the right to rely upon and utilize such BIAL Know-How during the Term to support any future regulatory applications or submissions to the FDA, Health Canada, or any other relevant regulatory bodies in the Territory related to the Licensed Products and to the extent consistent with the terms of this Agreement.

(b) BIAL reserves the right to use and refer to the BIA 2-093 IND and BIAL Know-How submitted in support of the BIA 2-093 IND, including but not limited to, all safety and effectiveness data for (i) any purpose, including without limitation, for development and regulatory activities in any country of the world, excluding the Territory (except in the event that the licenses granted by BIAL to SEPRACOR under Sections 2.1 and 2.3 convert to non-exclusive licenses pursuant to Section 7.4(b)), and (b) subject to Section 2.2(a), for the sole purpose of conducting permitted development activities within the Territory.

(c) Except as otherwise provided in Section 14.5(b), upon the expiration or the termination of this Agreement, all right, title, and interest in the BIA 2-093 IND will revert back to BIAL.

2.8 Delivery of BIAL Know-How for Use under Sections 2.1 and 2.2:

(a) Existing BIAL Know-How: BIAL will provide to SEPRACOR, as soon as reasonably practicable following the Effective Date, a copy of BIAL Know-How in existence prior to the Effective Date for use in accordance with the licenses set forth in Sections 2.1 and 2.2.

(b) New BIAL Know-How and BIAL Development Intellectual Property: BIAL will as soon as reasonably practicable provide SEPRACOR with a copy of any BIAL Know-How and Developmental Intellectual Property that comes under BIAL's Control after the Effective Date. To the extent that BIAL licenses-in know-how or patents relating to a Licensed Product after the Effective Date, which is not Controlled by BIAL because prior authorization by and/or an additional payment to the licensor is required before it can be disclosed and/or sublicensed to SEPRACOR under Sections 2.1 and 2.2, BIAL will use Commercially Reasonable Efforts to obtain such rights for SEPRACOR, provided that SEPRACOR agrees, in writing, to: (i) comply with any terms that may apply to such disclosure/sublicensing; (ii) pay a pro rated share of any milestone payments or license fees that BIAL incurs in obtaining its license, based on the value of the Parties respective territories as determined by the aggregate sales reported by a mutually agreed upon Third Party data provider such as IMS for the pharmaceutical products in Anatomical Therapeutic Chemical Class System category of N03A or, if such BIAL Know-How relates to an indication other than epilepsy, with respect to the indication for which such BIAL Know-How relates; and (iii) pay any running royalty that may be imposed by the Licensor on SEPRACOR's right to use such Third Party know-how or patents. BIAL will use Commercially Reasonable Efforts to obtain reasonable terms when negotiating SEPRACOR's sublicense.

(c) All BIAL Know-How disclosed to SEPRACOR under Section 2.8(a) and (b) above is subject to the terms and conditions of this Agreement, including without limitation, the confidentiality provisions of Article 10.

2.9 Limitation to Territory:

(a) During the Term of this Agreement, SEPRACOR agrees not to directly or indirectly register, market or sell Licensed Products and/or solicit customers for the Licensed Products and/or use the BIAL Trademarks outside the Territory. SEPRACOR will promptly notify BIAL if it has reason to believe that any Licensed Product has been or will be exported from the Territory during the Term of this Agreement.

(b) Except as expressly permitted herein, during the Term of this Agreement, BIAL agrees not to directly or indirectly market or sell Licensed Products and/or solicit customers for the Licensed Products and/or use the BIAL Trademarks within the Territory. BIAL will promptly notify SEPRACOR if it has reason to believe that any Licensed Product has been or will be exported to the Territory during the Term of this Agreement other than pursuant to the Supply Agreement.

ARTICLE 3
PAYMENTS

3.1 License Fees: SEPRACOR will make the following payments to BIAL:

(a) License Fee: Within five (5) Business Days after the Effective Date, SEPRACOR will pay BIAL Seventy-Five Million U. S. Dollars (US\$ 75,000,000), as a licensing fee. This license fee is not refundable under any circumstances and is not creditable against the transfer prices and/or royalties due under Article 4 or any other payments due by SEPRACOR under this Agreement or the Supply Agreement;

(b) Milestone Payments: SEPRACOR will make the following milestone payments (the "Milestone Payments") to BIAL upon each of the milestone events specified below (each, a "Milestone Event"):

Milestone Event

Milestone Payment

(in U.S. Dollars)

Receipt of written confirmation from the FDA following a pre-NDA meeting with the FDA that it will accept the NDA submission for the BIA 2-093 Product <u>without the need for additional Phase III clinical studies</u> prior to filing an NDA for Adjunctive Use in Adult Partial Epileptic Seizures	<u>\$10,000,000</u>
Written acceptance by the FDA of an NDA file for the BIA 2-093 Product for Adjunctive Use in Adult Partial Epileptic Seizures	<u>\$20,000,000</u>
FDA approval of the BIA 2-093 Product for Adjunctive Use in Adult Partial Epileptic Seizures	<u>\$50,000,000</u>
FDA approval of a Licensed Product for any and each additional indication (other than Adult and Pediatric Adjunct Partial Epileptic Seizures), for either adult or pediatric use, including without limitation the following indications: <u>Epilepsy Monotherapy; Trigeminal Neuralgia; Diabetic Neuropathic Pain; and Post-herpetic Neuralgia.</u> <u>For the avoidance of doubt, BIAL will receive these milestones only once for each additional indication (i.e., if any such indication is approved for adult use, BIAL will not receive an additional milestone for pediatric use, and vice versa).</u>	<u>\$20,000,000</u>
FDA grant of six months pediatric exclusivity for the BIA 2-093 Product for Adjunctive use in Partial Epileptic Seizures	<u>\$20,000,000</u>

(c) SEPRACOR will report in writing (with proper written documentation evidencing same) the occurrence of each Milestone Event to BIAL within five (5) Business Days of the date on which the Milestone Event has occurred and will pay the corresponding Milestone Fee within

thirty (30) days of the date on which the Milestone Event has occurred, regardless of whether two or more milestones occur at the same time. The Milestone Payments are not refundable under any circumstances and are not creditable against the transfer prices and/or royalties and/or other Milestone Payments due under Article 4 or any other payments due by SEPRACOR under this Agreement or the Supply Agreement.

3.2 Tax Matters:

(a) All payments under Section 3.1 will be made in accordance with the terms of the treaty between Portugal and the United States to avoid double taxation.

(b) BIAL will pay and otherwise be responsible for all value added taxes and transfer taxes in connection with any payment made to BIAL pursuant to this Agreement for all applicable sales, goods and services.

(c) Any income or other tax that one Party hereunder is required to withhold and pay on behalf of the other Party hereunder with respect to amounts payable under this Agreement will be deducted from and offset against said amounts prior to payment to the other Party; provided, however, that in regard to any tax so deducted, the Party making the withholding will give or cause to be given to the other Party all assistance reasonably necessary to enable that other Party to claim exemption therefrom or credit therefor, and in each case will promptly furnish the Party on whose behalf amounts were withheld, proper evidence of the taxes paid on its behalf and execute and provide such Party with any documents reasonably necessary in connection therewith. Each Party will comply with reasonable requests of the other Party to take any proper actions that may minimize any withholding obligation. BIAL will provide to SEPRACOR a properly completed and executed Form W8-BEN prior to any payment made to BIAL. A properly completed and executed Form W8-BEN will be completed and provided annually to SEPRACOR.

3.3 Interest: If SEPRACOR fails to make payment within any of the above stated timeframe, BIAL is entitled, without prejudice to any other right or remedy available to BIAL, to charge SEPRACOR interest (both before and after judgment) on the unpaid amount at the annual rate of 12% (twelve percent) per annum calculated on a daily basis until payment is made in full.

ARTICLE 4

SUPPLY

4.1 General: Unless otherwise agreed to by the Parties, and without prejudice to BIAL's right to decide, in its sole discretion, not to supply, directly or through a BIAL Affiliate, Licensed Products (other than the BIA 2-093 Product which BIAL will supply pursuant to the Supply Agreement) to SEPRACOR, SEPRACOR will purchase all of its requirements of BIA 2-093 Product and other Licensed Products from BIAL or BIAL's Affiliates.

4.2 Supply Agreement: Promptly after the Effective Date and within the period of one hundred and eighty (180) days thereof (or as otherwise agreed in writing by the Parties), BIAL or a BIAL Affiliate and SEPRACOR or its Affiliate will negotiate in good faith and enter into a Supply Agreement (the "Supply Agreement") for the clinical supply of BIA 2-093, the supply of physician samples of the BIA 2-093 Product and the commercial supply of the BIA 2-093 Product.

4.3 Commercial Supply – Additional Licensed Products:

(a) The Parties acknowledge and agree that transfer prices for supply to SEPRACOR of any Licensed Products, other than BIA 2-093 Products, will be negotiated in the future in good faith, and such transfer prices will have a comparable economic value to the transfer prices for the BIA 2-093 Product. The Supply Agreement will be amended as necessary to reflect such transfer prices and any other necessary changes resulting from the addition of any Licensed Products.

(b) Should BIAL or a BIAL Affiliate not agree to supply a Licensed Product (other than the BIA 2-093 Product which BIAL will supply pursuant to the Supply Agreement) to SEPRACOR, BIAL will have the right to decide, in its sole discretion, whether (i) to supply to SEPRACOR the BIA 2-093 active pharmaceutical ingredient at a reasonable transfer price to be mutually agreed in writing between the Parties and/or collect a royalty (to be agreed between the Parties) on the Net Sales of that Licensed Product in the Territory or (ii) not to supply to SEPRACOR the BIA 2-093 active pharmaceutical ingredient and only collect a royalty (to be

agreed between the Parties) on the Net Sales of that Licensed Product in the Territory. The Parties undertake to negotiate in good faith and on terms with comparable economic value to the supply of BIA 2-093 Product.

(c) In the event that, within the period of ninety (90) days of written request of either Party, the Parties do not reach an agreement on the transfer prices and/or royalties mentioned in this Section 4.3, the following procedure will apply: (i) BIAL will have the right to choose, at its sole discretion, one of the options set forth in Sections 4.3(a), 4.3(b)(i) and 4.3(b)(ii), and the transfer prices and/or royalties will be determined by one arbitrator in accordance with the provisions of Section 16.1.

4.4 Generic Entry: The Parties agree to negotiate in good faith a provision in the Supply Agreement to reflect the impact on the applicable transfer prices and/or royalties upon the entry into the market in each country within the Territory of a generic version of a Licensed Product, provided however that neither Party will be under an obligation to agree on any revised prices and/or royalties.

ARTICLE 5

JOINT STEERING COMMITTEE

5.1 Committee Formation: The Parties will form a Joint Steering Committee (the "JSC"), with general strategic oversight and decision making duties over the Parties' activities hereunder and to provide a forum for regular exchange of data (to the extent required under this Agreement) relating to the Licensed Products.

5.2 Make-up of the JSC: The JSC will consist of six members, namely, three members from each of BIAL and SEPRACOR, at least one of whom from each Party will be an Executive Officer of such Party. Each Party will designate its initial members of the JSC within the period of fifteen (15) days after the Effective Date. BIAL and SEPRACOR may each replace any or all of its representatives on the JSC at any time upon written notice to the other Party in accordance with Section 16.11 of this Agreement. Any member of the JSC may designate a substitute with due authority to temporarily attend and perform the functions of that member at any meeting of the JSC as long as an Executive Officer from each Party will always be present.

BIAL and SEPRACOR each may, in its sole discretion but subject to the written objection of the other Party (with demonstrable reason for objection), invite to attend meetings or portions of such meetings of the JSC a reasonable number of non-member representatives of such Party (including, without limitation, its employees or non-employee professional advisors), who have a reasonable purpose for attending such meeting or portion of such meeting. The chairperson of the JSC will alternate at each meeting between one of BIAL's Executive Officers and one of SEPRACOR's Executive Officers. The chairperson will establish the timing (at a mutually agreed upon time with the other Party) and agenda for all JSC meetings and will send notice of such meetings, including the agenda at least twenty (20) days prior to the meeting, to all JSC members provided, however, that either Party may request that specific items be included in the agenda provided that notice of such changes is provided to all JSC members at least five (5) days prior to the date of the meeting.

5.3 JSC Responsibilities: Responsibilities of the JSC include, without limitation, the following:

(i) Reviewing and coordinating the overall strategies for the development of the Licensed Products in accordance with this Agreement;

(ii) Reviewing and coordinating the overall strategies for the commercialization of the Licensed Products in accordance with this Agreement;

(iii) Discussing those matters relating to supply of Licensed Products that are not specifically addressed in the Supply Agreement;

(iv) Discussing and reviewing the Development Plan for the subsequent calendar year;

(v) Proposing and reviewing substantive amendments to the Development Plan;

(vi) Discussing and reviewing the Three (3) Year Strategic Development Plan;

(vii) Discussing and reviewing the Commercialization Plan for the subsequent calendar year;

(viii) Proposing and reviewing substantive amendments to the Commercialization Plan;

(ix) Coordinating efforts regarding the development and commercialization of the Licensed Products between and among all BIAL licensees of the Licensed Products pursuant to Section 8.1 hereof, including international congress and communication activities;

(x) Discussing and reviewing additional BIAL Trademarks;

(xi) Discussing and reviewing a global branding strategy for the Licensed Products;
and

(xii) Performing such other responsibilities as may be assigned to the JSC pursuant to this Agreement or as may be mutually agreed upon in writing by the Parties from time to time.

5.4 Meetings: The JSC may meet, convene or be polled in person or by video or telephone conference (where all Parties can hear and be heard). In addition, the JSC may be polled through electronic mail or correspondence. The JSC will meet within sixty (60) days of the Effective Date and at least quarterly every calendar year thereafter, where the first two (2) such meetings will be in person for all of the JSC members. The JSC will meet on such dates, and at such places and times or in such manner, as the members of the JSC will agree from time to time. Meetings of the JSC that are held in person will alternate between the offices of BIAL and SEPRACOR, or at such other place as the Parties may agree. The Party hosting the meeting will be responsible for recording minutes of the meeting in writing. Such minutes will be circulated to the Parties promptly following the meeting for review, comment and written approval.

5.5 Decision-making: The JSC may make decisions with respect to any subject matter within the JSC's functions as described above. Except as expressly provided in this Agreement, all decisions which are to be made by the JSC will be made by unanimous vote or written consent, with each Party having one vote in all decisions. The JSC will use reasonable best efforts to resolve the matters within its roles and functions or otherwise referred to it.

5.6 Right to Decide: If, with respect to a decision that is to be made by the JSC pursuant to Section 5.3, the JSC cannot reach consensus within fifteen (15) days after it has met (whether in person or by telephone or video conference) and attempted to reach such consensus or the Parties cannot reach consensus on whether the JSC has decision-making authority under Section 5.3 regarding a matter within fifteen (15) days after such matter was first raised by either

Party, the dispute in question will be referred to the Chief Executive Officer (“CEO”) of BIAL and the CEO of SEPRACOR for resolution. The CEO’s will use reasonable efforts to resolve the matter referred to them. If the CEO’s cannot resolve the matter within fifteen (15) days, then the matter will be decided:

(i) by the CEO of BIAL in good faith, giving appropriate consideration to the reasonable business and scientific concerns of SEPRACOR, for all matters relating to the disputes mentioned in Sections 5.3(i), (iii), (iv), (v), (vi), (ix), (xi), 6.3 (c), 6.3 (d), 6.3 (e) and 10.5(a); provided, however, that the CEO of BIAL will not have decision making authority with respect to (a) that portion of any Development Plan or Three (3) Year Strategic Development Plan related to (I) regulatory activities (subject to the limitation set forth in Section 5.6(iii)(a) below and Section 6.6(b)), and (II) publication plans for the Licensed Products in the Territory, and (b) Section 5.3(xi), if and to the extent that BIAL’s global branding strategy conflicts with SEPRACOR’s Commercialization Plan for the Territory.

(ii) by the CEO of SEPRACOR in good faith, giving appropriate consideration to the reasonable business and scientific concerns of BIAL, for all matters specifically mentioned in Sections 5.3(ii), (vii), (viii), 6.6(c), 10.5(b) and that portion of any Development Plans and Three (3) Year Strategic Development Plans related to regulatory activities (subject to subject to the limitation set forth in Section 5.6(iii)(a) below and Section 6.6(b)) and publication plans for the Licensed Products in the Territory.

(iii) For the avoidance of doubt, neither the CEO of BIAL nor the CEO of SEPRACOR will have decision making authority with respect to (a) the contents of the initial draft label submitted to the FDA for review and approval for each Licensed Product, (b) the contents of the initial draft of any modifications to a Licensed Product label submitted to the FDA for review and approval, solely to the extent regarding any new indications, and (c) that matter specifically mentioned in Section 5.3(x).

(iv) To the extent additional responsibilities are imposed on the JSC pursuant to Section 5.3 (xii), the Parties will mutually agree which CEO will have the right to decide any matter encompassed by that responsibility in the event that neither the JSC nor the CEO’s can reach an agreement regarding that dispute.

(v) Notwithstanding anything to the contrary contained herein or this Section 5.6, neither Party's CEO will have decision making authority over any dispute explicit reserved for arbitration pursuant to Section 16.1.

Neither Party will exercise its right to finally resolve a dispute in accordance with this Section 5.6 in a manner that (a) excuses such Party from any of its obligations specifically enumerated under this Agreement, or (b) requires the other Party to make payments or other commitments in excess of those specifically set forth herein. Notwithstanding this Section 5.6, any dispute regarding the interpretation of this Agreement or any alleged breach of this Agreement will be resolved in accordance with the terms of Section 16.1.

5.7 Alliance Managers: Promptly after the Effective Date, each Party will appoint an individual to act as the alliance manager for such Party (the "Alliance Manager"). Each Alliance Manager who is not otherwise a member of the JSC will thereafter be permitted to attend meetings of the JSC. The Alliance Managers will be the primary contact for the Parties regarding the activities contemplated by this Agreement and will facilitate all such activities hereunder. Each Party may replace its Alliance Manager with an alternative representative at any time with prior written notice to the other Party. The Alliance Managers will not, in any manner, take over the role of the JSC and will not have any rights, powers or discretion except as expressly granted to the Alliance Managers hereunder. In no event will the Alliance Managers have any power to modify or amend this Agreement. The Parties agree that the Alliance Managers will meet in July of each year so that the Parties can discuss any issues, including without limitation any responses by BIAL, that may arise during BIAL's annual scheduled shutdown for three weeks in August.

ARTICLE 6

DEVELOPMENT OF THE LICENSED PRODUCTS

IN THE FIELD AND TERRITORY

6.1 Responsibility: Except as otherwise provided for in this Agreement, SEPRACOR will be responsible for, and will bear the expenses of, the development of the Licensed Products for use, offer for sale and sale, marketing, commercialization, importation, and distribution

within the Field and Territory, including primary responsibility for all efforts required to obtain the Approvals for the use of Licensed Products within the Field and Territory.

6.2 Development Activity: SEPRACOR will use Commercially Reasonable Efforts to conduct, at its own expense (except as set forth in Section 6.4(c)), the development of the Licensed Products in accordance with the development plans for the Licensed Products within the Field and Territory (the “Development Plan”) including, but not limited to any preclinical, clinical, or post-marketing studies (the “Development Studies”) set forth in any such Development Plan, provided that such development efforts are consistent with the final decisions made by BIAL pursuant to its authority under Section 5.6(i). SEPRACOR will use Commercially Reasonable Efforts to complete the Development Studies as soon as reasonably practicable. For the avoidance of doubt, SEPRACOR does not commit to complete such Development Studies within any given period of time or to obtain any positive results.

6.3 Development Plans:

(a) Within the period of sixty (60) days after receiving the FDA minutes from a Pre-NDA meeting with respect to the BIA 2-093 Product, SEPRACOR will provide BIAL with a copy of the Three (3) Year Strategic Development Plan for 2008-2010.

(b) SEPRACOR will also submit a draft Annual Development Plan to BIAL by June 1st of each calendar year (the first being due by June 1st 2008 for calendar year 2009) and a revised Three (3) Year Strategic Development Plan by December 31st of each calendar year (the first being due by December 31st 2008 for calendar years 2009-2011) for BIAL’s review and comment. Development Plans will at a minimum and without limitation include a reasonable description of the following:

(i) Proposed Development Studies, including those considered as part of any medical marketing plan (including post marketing clinical trials), and the final draft protocol for any such Development Study;

(ii) Regulatory activities;

(iii) Plans for any new Licensed Product, improvements to a Licensed Product or any new presentations or indications within the Field and Territory;

(iv) Publication plans;

(c) BIAL will review and comment upon each Annual Development Plan and each revised Three (3) Year Strategic Development Plan within thirty (30) days of receipt thereof. If BIAL fails to provide SEPRACOR with specific comments within the respective timeframe, the Annual Development Plan or the Three (3) Year Strategic Development Plan, as the case may be, will be deemed accepted by BIAL. SEPRACOR will consider in good faith all comments by BIAL to the Development Plan. BIAL will have the right to veto that portion of any Annual Development Plan, revised Three (3) Year Strategic Development Plan (other than the portion of such plans regarding (a) regulatory activities (subject to Section 6.6(b)) , and (b) publication plans for the Licensed Products in the Territory), or a Developmental Study (including its protocol) if BIAL believes in good faith that such plan or study will materially adversely affect BIA-2093 and/or a Licensed Product outside the Territory, including without limitation the development, regulatory approval, marketing, sale and commercialization thereof. In the event of a dispute between the Parties as to whether there is a reasonable likelihood that an Annual Development Plan, revised Three (3) Year Strategic Development Plan (other than the portion of such plans regarding (a) regulatory activities (subject to Section 6.6(b)), and (b) publication plans for the Licensed Products in the Territory), or a Development Study will materially adversely affect a Licensed Product outside the Territory, the dispute will be submitted to the JSC and will be decided in accordance with the mechanism set forth in Sections 5.5 and 5.6(i).

(d) SEPRACOR will submit any amendments to the Annual Development Plans or the Three (3) Year Strategic Development Plans for BIAL's review and comment within the period mentioned in Section 6.3 (c) and under the terms of the said Section 6.3(c).

(e) If not previously submitted for BIAL's review and comment as part of an Annual Development Plan, SEPRACOR will submit any additional proposed Development Study, including the final draft protocol thereof, for review and comment by BIAL within the period and under the terms mentioned in Section 6.3(c).

(f) Before issuing final study reports on any Development Study, a first draft report must be sent to BIAL for review and comment within the period of fifteen (15) days.

(g) In addition to BIAL's rights under this Section 6.3, SEPRACOR will consider in good faith any comments provided by BIAL within the applicable time periods in relation to any Annual Development Plan, revised Three (3) Year Strategic Development Plan, Development Study, and draft protocol for any such Development Study or draft report.

(h) SEPRACOR will regularly through the JSC and promptly upon BIAL's written request, keep BIAL fully informed of the status of any Development Study. BIAL has the right to appoint one or more monitors to observe SEPRACOR's development activities related to the Licensed Product.

6.4 Ongoing and Supplemental Studies:

(a) BIAL will use Commercially Reasonable Efforts to conduct, at its own expense, the studies listed in Exhibit D (the "BIAL Studies"). All decisions regarding such studies, including the corresponding protocols (the "BIAL Protocols"), rest solely in the discretion of BIAL, provided that (i) BIAL will consider in good faith any comments provided by SEPRACOR in relation to any BIAL Study or draft BIAL Protocol and (ii) BIAL will regularly through the JSC and promptly upon SEPRACOR's written request, keep SEPRACOR fully informed of the status of any BIAL Study. SEPRACOR has the right to appoint one or more monitors to observe the BIAL Studies. All data and information resulting from such BIAL Studies and Controlled by BIAL will be promptly shared with SEPRACOR and will be considered BIAL Know-How. BIAL will use Commercially Reasonable Efforts to complete the BIAL Studies as soon as reasonably practicable. For the avoidance of doubt, BIAL does not commit to complete such BIAL Studies within any given period of time or to obtain any positive results.

(b) BIAL will provide SEPRACOR with any amendments to the BIAL Protocols for review and comment within thirty (30) days of its receipt thereof. Before issuing final study reports on any BIAL Studies, a first draft report must be sent to SEPRACOR for review and comment within the period of fifteen (15) days, and BIAL will consider in good faith any comments in relation thereto.

(c) The Parties will share equally the actual costs and expenses of conducting any studies required by the FDA to obtain the Approval of the BIA 2-093 Product for Adult Adjunct Partial Epileptic Seizures in the United States of America, provided that (i) SEPRACOR will be responsible for conducting such studies and (ii) prior to initiating any such study the Parties will mutually agree upon a budget for the study. Once approved, any modification to that study budget must also be mutually agreed upon by the Parties. The Parties acknowledge that the study budget will serve only as a good faith estimate of the study costs and expenses and will not limit the Parties obligations under this Section 6.4(c).

(d) Except as provided for in Sections 6.4(a) and 6.4(c), SEPRACOR will be solely responsible and will bear the costs and expenses of all other studies necessary or useful for the Approval of the BIA 2-093 Product and/or Licensed Products within the Field and the Territory, as well as for any marketing or post-Approval studies.

6.5 CMC Program: BIAL or a BIAL Affiliate is responsible for performing (itself or through one or more contract manufacturers) and will bear the expenses of the CMC Program for the BIA 2-093 Product. BIAL or a BIAL Affiliate will also be responsible for performing (itself or through one or more contract manufacturers) and will bear the expenses of the CMC Program for a Licensed Product other than the BIA 2-093 Product in the event that BIAL decides to be the supplier (directly or through a BIAL Affiliate) of such Licensed Product to SEPRACOR. If BIAL decides not to be the supplier of such Licensed Product to SEPRACOR, SEPRACOR will be responsible for performing (itself or through one or more contract manufacturers) and will bear the expenses of the CMC Program for such Licensed Product.

6.6 INDs/NDAs:

(a) Except in the event that the licenses granted by BIAL to SEPRACOR under Sections 2.1 and 2.3 convert to non-exclusive licenses pursuant to Section 7.4(b), SEPRACOR is responsible for the filing of and will own any and all INDs, NDAs and other regulatory filings for the Licensed Products within the Field and Territory, provided that BIAL will be responsible for maintaining and keeping the BIA 2-093 IND in good standing until it is transferred to SEPRACOR in accordance with Section 2.7.

(i) BIAL will have the right to use and refer to all INDs, Approvals, NDAs and regulatory filings for the Licensed Products within the Field and the Territory and all Know-How submitted in support thereof, including but not limited to, all safety and effectiveness data for (i) any purpose, including without limitation, for development and regulatory activities in any country of the world, excluding the Territory (except in the event that the licenses granted by BIAL to SEPRACOR under Sections 2.1 and 2.3 convert to non-exclusive licenses pursuant to Section 7.4(b)), and (ii) subject to Section 2.2(a), for the sole purpose of conducting permitted development activities within the Territory.

(ii) SEPRACOR will use Commercially Reasonable Efforts to submit an NDA for the BIA 2-093 Product for Adult Adjunct Partial Epileptic Seizures as soon as reasonably practicable but no later than sixty (60) days following the preparation, final compilation and quality control review of all the necessary data, summaries, and administrative sections required to permit a NDA filing. SEPRACOR does not guarantee acceptance or approval by the FDA (or Canadian equivalent) of any IND, NDA or other regulatory filings.

(b) SEPRACOR will provide BIAL with a proposed draft of (a) the initial label to be submitted to the FDA for review and approval for each Licensed Product, and (b) the initial draft of any modifications to a Licensed Product label to be submitted to the FDA for review and approval, solely to the extent regarding any new indications. The Parties will thereafter cooperate in good faith to agree as soon as practicable on a mutually acceptable draft label for such submission to the FDA. Any additional regulatory matters regarding any such label or modification, including without limitation, working with the FDA to obtain the final approved label, will be subject to Section 6.6(c).

(c) In addition to Section 6.6(b), SEPRACOR will provide BIAL with a draft of all proposed regulatory filings and will consider in good faith any comments by BIAL within thirty (30) days upon receipt of such draft. If BIAL fails to provide SEPRACOR with specific comments within such timeframe, the NDA or other regulatory filing will be deemed acceptable by BIAL. If BIAL considers that a proposed regulatory filing will materially adversely affect the Licensed Product outside the Territory and SEPRACOR will not amend the proposed NDA or regulatory filing in the manner requested by BIAL, the dispute will be submitted to the JSC and

will be decided in accordance with the mechanism set forth in Sections 5.5 and 5.6(ii), except as otherwise provided in Section 6.6(b).

(d) To the extent that providing a copy of a draft regulatory filing pursuant to Section 6.6(c) is not practicable, SEPRACOR will give access thereof to BIAL and provide BIAL with ten (10) days written notice prior to the date such draft may be accessed by BIAL. Notwithstanding the foregoing, BIAL will have the right, to the extent reasonably practicable, to request copies of portions of such draft regulatory filings.

(e) Notwithstanding Section 6.6(a), BIAL will have the right to participate in any meetings, interactions, or communications (“Interactions”) with the FDA or other regulatory authorities in the Territory to the extent that such Interactions relate to the DMF. BIAL may attend as an observer, or participant if so desired by the Parties, in other Interactions with the FDA or other regulatory authorities in the Territory. Prior to any such Interactions, SEPRACOR will provide BIAL with a draft of any communication, agenda and/or notice of any planned interaction and will consider in good faith any comments provided by BIAL within the period of twenty (20) days upon receipt of the said draft by BIAL.

(f) Neither Party warrants to the other Party that any Approvals will be obtained within the Field or Territory. The Parties agree that any and all costs and expenses incurred by SEPRACOR or BIAL in connection thereto are not refundable under any circumstances and are not creditable against the transfer prices and/or royalties due under Article 4 or any other payments due by SEPRACOR under this Agreement or the Supply Agreement.

(g) Except as otherwise provided in Section 14.5(b), upon the termination or expiration of the Term of this Agreement, all right, title, and interest in any and all regulatory filings and authorizations issued thereunder, including without limitation the Approvals, the IND and the NDA and its Canadian equivalents, will be assigned to BIAL.

6.7 Drug Master File: Notwithstanding Section 6.6(a), BIAL will be responsible for filing and maintaining, directly or through a Third Party appointed by BIAL, the Drug Master File (“DMF”) relating to the manufacture of the BIA 2-093 active pharmaceutical ingredient, to the extent that (i) the Parties agree that DMF submission is preferable to incorporation of the

DMF information in the applicable NDA and (ii) BIAL has obtained from its Third Party suppliers the right to file and maintain such DMF. In such an event, BIAL will file and maintain such DMF in its own name and/or in the name of its relevant suppliers and will permit SEPRACOR to cross-reference the open portion of such DMF in its regulatory filings for Licensed Products in the Territory. For the avoidance of doubt, regulatory authorities in the Territory will have the right to access the entire DMF, including the closed portion.

6.8 SEPRACOR Know-How: SEPRACOR will, as soon as reasonably practicable and promptly upon BIAL's written request, provide BIAL with a copy of all SEPRACOR Know-How created during the Term of this Agreement. SEPRACOR grants to BIAL a fully paid-up, royalty-free, perpetual, exclusive license (even to SEPRACOR), with the right to grant sublicenses to BIAL's Affiliates, Third Party licensees and distributors in any country outside the Territory, under any SEPRACOR Know-How to the extent necessary to allow BIAL, its Affiliates, Third Party licensees and distributors to use, make, have made, import, develop, register, market, offer for sale, sell, and commercialize Licensed Products or similar products outside the Territory. Subject to Section 2.2(a), SEPRACOR also grants to BIAL a fully paid-up, royalty-free, perpetual, non-exclusive license, with the right to grant sublicenses to BIAL's Affiliates and Third Party licensees, under any SEPRACOR Know-How to the extent necessary to allow BIAL and its sublicensees to develop Licensed Products or similar products within the Territory for use outside of the Territory. To the extent that SEPRACOR licenses-in know-how during the Term, which would not be encompassed by the term "SEPRACOR Know-How" because prior authorization by and/or an additional payment to the licensor of such know-how is required before it can be disclosed and sublicensed to BIAL. SEPRACOR will use Commercially Reasonable Efforts to obtain such rights for BIAL, provided that BIAL agrees, in writing, to: (i) comply with any terms that may apply to such disclosure/sublicensing; (ii) pay a pro rated share of any milestone payments or license fees that SEPRACOR incurs in obtaining its license, based on the value of the Parties respective territories as determined by the aggregate sales reported by a mutually agreed upon Third Party data provider such as IMS for the pharmaceutical products in Anatomical Therapeutic Chemical Class System category of N03A or, if such SEPRACOR Know-How relates to an indication other than epilepsy, with respect to the indication for which such SEPRACOR Know-How relates; and (iii) pay any running royalty that may be imposed by

the licensor on BIAL's right to use such Third Party know-how. SEPRACOR will use Commercially Reasonable Efforts to obtain reasonable terms when negotiating BIAL's sublicense.

ARTICLE 7

COMMERCIALIZATION OF THE LICENSED PRODUCTS

IN THE FIELD AND TERRITORY

7.1 Commercialization: SEPRACOR will use Commercially Reasonable Efforts to market and sell the BIA 2-093 Product within the Field and Territory and will initiate commercialization of the BIA 2-093 Product in the United States within six (6) months after receiving FDA Approval, provided however that failure to launch the BIA 2-093 Product within such six (6) month period will not be considered a breach of this Agreement if such failure was caused by circumstances beyond the reasonable control of SEPRACOR including, but not limited to, BIAL's failure to meet timeframes hereunder or inability to supply the BIA 2-093 Product in accordance with the terms of the Supply Agreement. Notwithstanding anything in this Agreement to the contrary, the decision whether or not to pursue the development and/or launch of Licensed Products in addition to the BIA 2-093 Product, and the timing of such launch, will be at SEPRACOR's sole discretion.

7.2 Responsibility: Except as otherwise expressly provided for in this Agreement, SEPRACOR is solely responsible for commercializing the Licensed Products within the Territory. Notwithstanding anything in this Agreement to the contrary, the decision whether or not to launch the Licensed Products in Canada and the timing of such launch will be at SEPRACOR's sole discretion.

7.3 Commercialization Plans:

(a) Within the period of sixty (60) days after the Effective Date, SEPRACOR will designate an employee to work with BIAL on the preparation of a Strategic Commercialization Plan to be used as an interim plan until the adoption of the first Annual Commercialization Plan in accordance with this Section 7.3(a). A draft annual commercialization plan will be provided to BIAL no later than November 1st of each calendar year for the following calendar year (the

first being due by November 1, 2008 for calendar year 2009) for review and comment by BIAL (each, an “Annual Commercialization Plan”). Notwithstanding the foregoing, SEPRACOR will use Commercially Reasonable Efforts to provide the Annual Commercialization Plan to BIAL by October 1st of each year. Annual Commercialization Plans will at a minimum and without limitation include a reasonable description of the following:

- (i) Plans for positioning and branding of the Licensed Products;
- (ii) Promotional campaigns for the Licensed Products and messaging by audience;
- (iii) Competitive & market analysis of the Licensed Products;
- (iv) Congress and meeting plans;
- (v) Market research plans;
- (vi) Distribution plans for the Licensed Products;
- (vii) Payer Strategies including pricing and reimbursement plans;
- (viii) High level sales and activity plans;
- (ix) Concepts for developing sales training and promotional materials;
- (x) Sales forecasts, including sampling;
- (xi) Key opinion leader development & medical affairs plans;
- (xii) Plans to ensure appropriate medical information responses with respect to the Licensed Products; and
- (xiii) Lifecycle plan.

For clarity, Commercialization Plans will not include sales force incentives and budgets.

(b) SEPRACOR will consider in good faith any comments by BIAL in relation to the draft Annual Commercialization Plan that are provided to SEPRACOR within twenty (20) days of BIAL’s receipt thereof. If BIAL fails to provide SEPRACOR specific comments within the respective timeframes, the draft Annual Commercialization Plan will be deemed acceptable to BIAL.

(c) SEPRACOR will provide BIAL with long term Strategic Commercialization Plans if and to the extent SEPRACOR adopts such practice with respect to its other products at a similar stage in their development or product life and with similar market potential as the Licensed Products.

(d) SEPRACOR will provide BIAL with any material amendments to the Annual Commercialization Plans for review and comment by BIAL and will consider in good faith any comments provided by BIAL within fifteen (15) days of receipt thereof.

7.4 Minimum Sales:

(a) The agreed minimum annual sales in Net Sales (the “Minimum Sales”) for years two and three of commercialization of Licensed Products in Territory (following launch in the U.S.) are set forth in Exhibit E. The Minimum Sales in units for any subsequent years will be agreed upon between the Parties by November 1st of each calendar year.

(b) If the Minimum Sales are not achieved in accordance with Section 7.4 (a) for reasons within SEPRACOR’s reasonable control, the licenses granted to SEPRACOR pursuant to Sections 2.1 and 2.3 will become non-exclusive upon ninety (90) days prior written notice from BIAL; provided, however that such licenses will remain exclusive if within thirty (30) days following such notification SEPRACOR agrees to pay to BIAL an amount equal to the average applicable transfer price during the year multiplied by the sum of the units that constitute the shortfall. Should SEPRACOR choose such an option, the amount of the additional payment will be added to the invoice for SEPRACOR’s new order of the Licensed Products. It is however clearly understood that SEPRACOR’s right to avoid non-exclusivity pursuant to this Section 7.4(b) is exercisable only for up to two (2) consecutive years.

(c) If the Minimum Sales are not achieved in accordance with Section 7.4 (a) for reasons within SEPRACOR’s reasonable control for three (3) consecutive years, BIAL will have the right to terminate this Agreement and the Supply Agreement with immediate effect.

(d) For the purposes of this Section 7.4, circumstances outside of SEPRACOR’s reasonable control will include, without limitation, BIAL’s failure to meet timeframes hereunder,

BIAL's inability to supply the BIA 2-093 Product in accordance with the terms of the Supply Agreement, study results outside of the Territory materially adversely impacting sales within the Territory, the entry into the market of a generic of a Licensed Product or racemic BIA 2-093, adverse regulatory decisions or other market conditions.

7.5 Resources: SEPRACOR will use Commercially Reasonable Efforts to at all times deploy the appropriate resources, including without limitation the numbers and type of field based personnel, in order to maximize the commercial value of the Licensed Products during the lifecycle. SEPRACOR will market and promote the Licensed Products in accordance with the Approvals.

7.6 Sales Information:

(a) SEPRACOR will regularly through the JSC and promptly upon BIAL's written reasonable request, keep BIAL fully informed of the status of the commercialization of the Licensed Products in the Territory. Notwithstanding the above, SEPRACOR will provide BIAL with the following information:

(i) by the fifteenth (15th) Business Day of each month, a summary of Ex-Factory Sales for the prior month. "Ex-Factory Sales" means direct sales to trade customers from SEPRACOR's finished goods inventory;

(ii) by the fifteenth (15th) Business Day of each month following the end of each calendar quarter, an audited summary of Ex-Factory Sales for the prior calendar quarter; and

(iii) by the fifteenth (15th) Business Day of each month, market dynamic/competitor information with respect to monthly prescription volume, market share, competitor market share, market trends and competitor performance, provided that BIAL enters into a third party data sharing agreement with IMS for SEPRACOR to share such information.

(b) During the Term and for a period of one (1) year thereafter, SEPRACOR and its Affiliates will keep full and accurate books of accounts and other records in sufficient detail so that the Net Selling Price and Net Sales of the Licensed Products can be properly ascertained.

SEPRACOR, its Affiliates and sublicensee, at BIAL's request with reasonable written notice, will permit an independent certified public accountant selected by BIAL and reasonably acceptable to SEPRACOR, at its sole expense, access during SEPRACOR's ordinary business hours, to such books and records as may be necessary to determine the correctness of any calculation associated with the sale of the Licensed Products under this Agreement; *provided, however*, that (i) BIAL will be permitted only one (1) such audit in any twelve (12) month period, and (ii) such accountant will only have access to that portion of SEPRACOR's books and records that relate to this Agreement and the Licensed Products. Prior to the audit, such accountant will enter into a confidentiality agreement with SEPRACOR that is no less restrictive than the confidentiality obligations set forth in Article 10 of this Agreement. SEPRACOR will use Commercially Reasonable Efforts to obtain BIAL's right to access the books and records of SEPRACOR's sublicensee in a manner and for purposes consistent with this Section 7.6(b).

7.7 Non Competing Products:

(a) During the Term of this Agreement, SEPRACOR and its Affiliates will not promote, distribute, market, commercialize, offer for sale, or sell any Competing Product within the Field and Territory. SEPRACOR will use Commercially Reasonable Efforts to cause its sublicensee not to promote, distribute, market, commercialize, offer for sale, or sell any Competing Product within the Field and Territory during the Term.

(b) During the period of seven (7) years after the first commercial sale of the BIA 2-093 Product, or, subject to Section 14.5(b)(i), during the Term if the Agreement is terminated prior to the expiration of such seven (7) year period, BIAL and its Affiliates will not promote, distribute, market, commercialize, offer for sale, or sell any Competing Product within the Field and Territory.

ARTICLE 8

REGULATORY AND CLINICAL DEVELOPMENT ISSUES

8.1 Cooperation:

(a) BIAL will keep SEPRACOR informed as to development efforts of Licensed Products in the Field outside of the Territory, and will use reasonable efforts not to, and will use

reasonable efforts to cause its licensees not to conduct any studies that will materially adversely affect the Licensed Products in the Field within the Territory. Each Party will cooperate as reasonably requested by the other Party in an effort to ensure that the development of the Licensed Products are coordinated worldwide, provided however that this will not be interpreted or construed as limiting BIAL's right to decide, at its sole discretion, on the development of Licensed Products and/or BIA 2-093 outside the Territory.

(b) Outside the JSC, cooperation will include, without limitation, and without prejudice to the provisions of Article 6 and Section 10.5:

(i) providing the other Party with a copy of each material clinical protocol synopsis, draft regulatory submission relevant to product labeling, and/or proposed publication of clinical data Controlled by such Party with respect to a Licensed Product within the Field within or outside of the Territory at least fifteen (15) days prior to its submission or publication, and considering, in good faith, all comments received within ten (10) days of the other Party's receipt of any such material for its review; and

(ii) the sharing by each Party of all clinical data that is Controlled by such Party and is available to it and which can legally be provided to the other Party within fifteen (15) days of such data becoming available.

SEPRACOR will also provide BIAL with any documents, data and information encompassed by this Section 8.1 (b)(i) and (ii) that its sublicensee or contractors may develop during the Term of this Agreement, provided that such sublicensee or contractors have agreed in writing that SEPRACOR may disclose such items to BIAL and that BIAL may use such items in the manner set forth in Section 8.1 (d). BIAL will also provide SEPRACOR with any documents, data and information encompassed by this Section 8.1 (b)(i) and (ii) that its licensees or distributors for the Licensed Products outside the Territory have or may in the future develop, provided that such licenses or contractors have agreed in writing that BIAL may disclose such items to SEPRACOR and that SEPRACOR may use such items in the manner set forth in Section 8.1 (d). Cooperation will also include discussions regarding other activities of the JSC concerning supply and commercialization of the Licensed Products.

To the extent that providing a copy of a draft regulatory filing pursuant to Section 8.1(b)(i) is not practicable, each Party will give access thereof to the other Party and provide the other Party with ten (10) days notice prior to the date such draft may be accessed by such other Party. Notwithstanding the foregoing, each Party will have the right, to the extent reasonably practicable, to request copies of portions of such draft regulatory filings.

(c) BIAL will only share SEPRACOR's documents, data and information encompassed by Section 8.1 (b)(i) and (ii) with those of its licensees or distributors for the Licensed Products outside the Territory that have agreed, in writing, to (i) provide to SEPRACOR any similar data, documents and information that they have or may develop and (ii) comply with confidentiality obligations with respect to such data, documents and information that are no less restrictive than those set forth in Article 10 of this Agreement. For clarity, access to SEPRACOR data, documents and information provided hereunder to a BIAL licensee or distributor is not contingent upon the licensee or distributor having similar data to share, but rather its willingness to issue authorization set forth in Section 8.1 (b).

(d) BIAL and its Affiliates outside the Territory will be entitled to use SEPRACOR's and SEPRACOR's Affiliates or sublicensee's documents, data and information encompassed by Section 8.1 (b)(i) and (ii) for the purposes of filing and obtaining any Approvals or marketing authorizations outside the Territory and licensing any Third Parties to distribute, promote and commercialize products under such Approvals or marketing authorizations. SEPRACOR and its Affiliates will be entitled to use BIAL data and information encompassed by Section 8.1 (b)(i) and (ii) for the purposes of filing and obtaining any Approvals or marketing authorizations within the Territory.

(e) SEPRACOR will promptly provide BIAL with copies of any correspondence received from or sent to any regulatory authority in the Territory with respect to BIA 2-093 and/or Licensed Products. BIAL will promptly provide SEPRACOR with copies of any correspondence received from or sent to the European Medicines Evaluation Agency ("EMA") with respect to BIA 2-093 and/or Licensed Products whenever BIAL considers it materially relevant to the development of the Licensed Products in the Territory.

8.2 Rights to Use and Reference SEPRACOR Data; Marketing Materials:

(a) In addition to the authorization granted in Section 8.1 (d) and the SEPRACOR Know-How license granted pursuant to Section 6.8, any data (including without limitation any preclinical and clinical data) Controlled by SEPRACOR during the Term relating to any Licensed Products in the Territory will be made fully available to BIAL at no cost whatsoever and BIAL and its Affiliates will have a fully paid up, royalty-free, perpetual, right to use and cross-reference such SEPRACOR data in seeking Approvals for such Licensed Products outside the Territory and/or in connection with commercialization of the Licensed Product outside the Territory.

(b) Such fully paid up, royalty-free, perpetual, right to use and cross-reference the SEPRACOR data may be extended by BIAL to its licensees or distributors outside the Territory so long as such licensees or distributors have agreed to grant a corresponding right to SEPRACOR. For clarity, this right to use and reference any SEPRACOR data by a BIAL licensee or distributor is not contingent upon the licensee or distributor having similar data, but rather its willingness to grant SEPRACOR rights to use and reference such data to the extent it exists.

(c) Twice per year or promptly upon the other Party's reasonable request, each Party will provide the other Party with specimens of its marketing materials for Licensed Products in the Field for informational purposes only. Neither Party, its Affiliates, licensees, distributors or other Third Parties will use the other Party's marketing materials to market, sell or offer for sale Licensed Products without such Party's prior written consent.

8.3 Adverse Events:

(a) Promptly following the Effective Date, but in no event later than two hundred and forty (240) days thereafter, the Parties will develop and agree upon safety data exchange procedures in a separate and detailed Pharmacovigilance Exchange Agreement ("PVEA"). BIAL will be responsible for all Pharmacovigilance related activities until such agreement is signed. BIAL will have all relevant Affiliates and other licensees become a party to such PVEA or to enter into similar agreement(s) with BIAL in order to ensure global regulatory compliance.

The PVEA will describe the collection, investigation, analysis, reporting, and exchange of information concerning adverse events, product safety and product complaints relating to the Licensed Products, sufficient to permit each Party, its Affiliates, sublicensees or licensees to comply with its legal or regulatory obligations, including to the extent applicable, those obligations contained in ICH guidelines.

(b) If a Licensed Product becomes subject to a pattern of Serious Adverse Reactions (as defined in the ICH Guidelines) or either Party receives notice from a regulatory authority relating to a significant concern for patient safety, the Parties will in good faith analyze and agree on risk minimization measures and other reasonable actions to be carried out, by either Party or both Parties, in relation to such Licensed Product, including without limitation, the modification of the relevant Approval

8.4 Quality Agreement. Simultaneous with the execution of the Supply Agreement, the Parties will enter into a Quality Agreement with terms appropriate for the manufacture of finished products for commercial distribution.

ARTICLE 9

INTELLECTUAL PROPERTY

9.1 Ownership of Development Intellectual Property: All Development Intellectual Property conceived solely by the employees of a Party will be owned by that Party. Development Intellectual Property conceived by employees of both Parties will be jointly owned by the Parties, each having an equal and undivided interest in such Development Intellectual Property.

(a) Any Development Intellectual Property that BIAL Controls or is jointly owned by the Parties will be encompassed by the licenses set forth in Sections 2.1 and 2.2 without additional consideration other than the payments set forth in Article 3, provided however that the Licensed Products will be subject to the transfer price and/royalty provisions of Article 4.

(b) SEPRACOR grants BIAL an exclusive (even as to SEPRACOR), royalty-free, fully paid-up, perpetual license, with the right to grant sublicenses, under any Development Intellectual Property that SEPRACOR Controls or is jointly owned by the Parties, to make, have made, use, import, develop, offer for sale and sell products (including without limitation Licensed Products) or processes outside of the Territory for as long as BIAL Controls (by license or otherwise) outside the Territory any patent, patent application, or other intellectual property right which would be infringed by the making, importation, use, development, sale or offer for sale of any product or process encompassed by such Development Intellectual Property ("Blocking BIAL IP"). After expiration of such Blocking BIAL IP, the license under this Section 9.1(b) will convert to a Semi-Exclusive, royalty-free, fully paid-up, perpetual license, with the right to grant sub-licenses under any Development Intellectual Property that SEPRACOR Controls to make, have made, use, import, develop, offer for sale and sell any products (including without limitation Licensed Products) or processes outside of the Territory. For the purposes of this Section 9.1(b), the term "Semi-Exclusive License" means that, in addition to BIAL, SEPRACOR will have the right, directly or through one licensee, to make, have made, use, import, offer for sale and sell such products (including without limitation Licensed Products) or processes outside of the Territory under the SEPRACOR Development Intellectual Property.

(c) Subject to SEPRACOR's rights set forth in Section 2.2(a), SEPRACOR also grants BIAL a royalty-free, fully paid-up, perpetual, non-exclusive license, with the right to grant sublicenses, under any Development Intellectual Property that SEPRACOR Controls to the extent necessary to allow BIAL, its Affiliates, and Third Party licensees to develop products (including without limitation Licensed Products) or processes within the Territory for use outside of the Territory.

(d) During the Term of this Agreement, SEPRACOR will use Commercially Reasonable Efforts to retain all right, title and interest in any Development Intellectual Property that is conceived solely by the SEPRACOR sublicensee or a contractor or jointly by SEPRACOR and the SEPRACOR sublicensee or a contractor. If SEPRACOR, despite such efforts, is unable to retain all right, title and interest in any such Development Intellectual Property it will use Commercially Reasonable Efforts to negotiate an exclusive, world-wide

license under such Development Intellectual Property to make, have made, use, import, develop, offer for sale and sell products (including without limitation Licensed Products) or processes, with the right to grant BIAL (a) an exclusive (even as to licensor and SEPRACOR) sublicense, with the right to grant further sublicenses, under such Development Intellectual Property to make, have made, use, import, develop, offer for sale and sell products (including without limitation Licensed Products) or processes outside the Territory and (b) a non-exclusive sublicense, with the right to grant further sublicenses, under such Development Intellectual Property to develop products (including without limitation Licensed Products) or processes within the Territory for use outside of the Territory, provided that BIAL agrees, in writing, to: (i) comply with any terms that may apply to such disclosure/sublicensing; (ii) pay a pro rated share of any milestone payments or license fees that SEPRACOR incurs in obtaining its license, based on the value of the Parties respective territories as determined by the aggregate sales reported by a mutually agreed upon Third Party data provider such as IMS for the pharmaceutical products in Anatomical Therapeutic Chemical Class System category of N03A or, if such Development Intellectual Property relates to an indication other than epilepsy, with respect to the indication for which such Development Intellectual Property relates; and (iii) pay any running royalty that may be imposed by the licensor on BIAL's right to use such Development Intellectual Property. SEPRACOR will use Commercially Reasonable Efforts to obtain reasonable terms when negotiating BIAL's sublicense.

(e) Any license granted under Sections 9.1 (b), (c) and (d) will expire upon the last to expire of the licensed patents encompassed by such license.

(f) The Parties agree that, to the extent it is required by the laws of any country, the Parties will execute necessary documentation to reflect or record any licenses under jointly owned Developmental Intellectual Property licenses or sublicenses granted in accordance with this Agreement under any Developmental Intellectual Property.

9.2 Prosecution of Development Intellectual Property:

(a) Each Party may, at its own expense, file, prosecute, maintain, defend and enforce the patents and patent applications relating to Development Intellectual Property which are owned solely by that Party.

(b) Notwithstanding Section 9.2(a), SEPRACOR will have the first opportunity to file U.S. and foreign patent applications on any Development Intellectual Property Controlled solely by SEPRACOR or jointly owned by SEPRACOR and its sublicensee or a contractor. SEPRACOR will cause a copy of any such patent application and all communications between its agents and any patent office regarding each such patent application and/or patent to be provided to BIAL or its agent for comment, within a reasonable deadline prior to submitting such communications to the patent office. Provided that BIAL responds within the specified deadline, SEPRACOR will consider or cause its agents to consider, in good faith, any comments BIAL may have regarding that application or communication, provided that all final prosecution decisions will rest solely with SEPRACOR. BIAL will be responsible for any expenses that it may incur in providing such comments. SEPRACOR (or its sublicensee or a contractor) will pay all official taxes, annuities, renewal and maintenance fees required to keep in force all issued patents for Development Intellectual Property solely Controlled by the SEPRACOR or jointly owned by SEPRACOR and its sublicense or any of its contractors.

(c) BIAL has the right to file a patent application for Development Intellectual Property Controlled by SEPRACOR in any country in which SEPRACOR decides not to file. SEPRACOR will notify BIAL of the decision not to file a patent application in a particular country within three (3) months of making that decision, but not later than sixty (60) days prior to the time when any statutory bar might foreclose filing of a patent application in that country. Upon receipt of such notification, BIAL has the option to assume full responsibility, at its own discretion and expense, to file a patent application in any such country, in which event SEPRACOR will reasonably cooperate and assist BIAL, at BIAL's expense, in executing a written assignment of the Development Intellectual Property to BIAL in that country and provide any other conveyance instruments, documents or assistance as may be necessary or desirable to

establish ownership or to support of the prosecution of the application. In the event that such patent application becomes the subject of an opposition or related proceeding, or if any patent(s) to issue becomes involved in any adversary proceeding (e.g. litigation, nullity or revocation proceedings), BIAL will provide SEPRACOR notice of such proceeding and BIAL will provide SEPRACOR reasonable opportunity to comment and advise to BIAL.

(d) SEPRACOR will advise BIAL if it no longer desires to continue prosecution or pay maintenance fees, on any patent application or patent either in the United States or any foreign country for Development Intellectual Property Controlled by SEPRACOR. Such notification will be in writing and will be provided not less than forty-five (45) days before the expiration of a response period or the payment due date for a maintenance fee. Upon receipt of such notification, BIAL has the option, exercisable upon written notification to SEPRACOR, to assume the prosecution and/or maintenance of the patent application or patent, in which event SEPRACOR will reasonably cooperate with and assist BIAL, at BIAL's expense, in executing a written assignment of the patent application or patent to BIAL and provide any other conveyance instruments, documents, or assistance as may be necessary or desirable to establish ownership of the patent or patent application or to support of the prosecution of the application.

(e) BIAL will use Commercially Reasonable Efforts to file, prosecute and maintain patents and patent applications filed inside and outside the Territory on all Development Intellectual Property jointly-owned by the Parties. All costs including legal fees, official taxes, annuities, renewal, and maintenance fees required to prosecute all such applications and keep in force all issued patents that are jointly owned by the Parties, will be shared equally by the Parties with respect to patents and patent applications in the Territory and by BIAL with respect to patents and patent applications outside the Territory. If BIAL desires to discontinue its participation in the prosecution of any jointly-owned patent application or maintenance fee of an issued patent, it will notify SEPRACOR in writing not less than forty five (45) days before the expiration of a response period or the payment due date for a maintenance fee. Upon receipt of such notification, SEPRACOR has the option to assume full responsibility, at its discretion and expense, for the prosecution and maintenance of the affected patent application(s) or patent(s) in or outside the Territory, in which event BIAL will reasonably cooperate with and assist SEPRACOR, at SEPRACOR's expense, in executing a written assignment of the patent

application or patent to other Party and provide any other conveyance instruments, documents, or assistance as may be necessary or desirable to establish ownership of the patent or patent application or to support the prosecution of the application. Except as otherwise provided in Section 2.1(a), neither Party may grant a license under a patent or patent application filed in the Territory on jointly-owned Development Intellectual Property without the express written consent of the other Party.

ARTICLE 10

CONFIDENTIALITY, PUBLICITY AND PRESS RELEASES

10.1 Confidential Information: As used in this Agreement, the term "Confidential Information" means all technology, formulations, materials, samples, prototypes, processes, data, know-how and all other information or data, whether written or oral, technical or non-technical, including, without limitation, BIAL Know-How, SEPRACOR Know-How, Commercialization Plans, Development Plans, BIAL Protocols, financial statements, reports, pricing, trade secrets, secret processes, formulas, customer data (including customer lists), business information, business methods, business plans, and pricing, cost, supplier and manufacturing information, that is disclosed by or on behalf of either Party (including by or on behalf of or through a parent, subsidiary, Affiliate, contractor, licensee or sublicensee) to or for the benefit of the other Party (including by or on behalf of or through a parent, subsidiary, Affiliate, contractor, licensee or sublicensee) in the performance of this Agreement or the Supply Agreement. The term "Confidential Information" does not include any such items for which the receiving Party can show by competent written proof or other reasonable support that such item:

- (a) was known to and existed in documentary or other physical form in the possession of the receiving Party at the time of disclosure;
- (b) subsequent to the receipt hereunder, is made available to the receiving Party by a Third Party which is legally entitled to make such information available;
- (c) was or becomes publicly known through no fault of the receiving Party; or

(d) is independently developed by the receiving Party without access to Confidential Information disclosed hereunder.

10.2 Obligations of Confidentiality: During the Term of this Agreement and for a period equal to the last to expire of the BIAL Patents or five (5) years after the termination or expiration of this Agreement, whichever is longer, each Party agrees to:

(a) to preserve the confidentiality of all Confidential Information received from the other Party, and not to disclose any such Confidential Information to a Third Party without first obtaining the written consent of the disclosing Party, except as may be otherwise provided herein;

(b) to take all necessary steps to ensure that Confidential Information received from the other Party is securely maintained and to inform those who are authorized to receive such Confidential Information of their obligations under this Agreement; and

(c) to use any and all Confidential Information received from the other Party solely in connection with, or as permitted by, this Agreement and the Supply Agreement and for no other use.

All Confidential Information will remain the property of the disclosing Party.

10.3 Right to Disclose:

(a) Nothing herein will be construed as preventing either Party from disclosing any Confidential Information received from the other Party to its employees, Affiliates, distributors, licensees, sublicensees, consultants, agents and contractors, in each case where such person or entity has a reasonable need to know such Confidential Information, provided that, with respect to Affiliates, distributors, licensees, sublicensees consultants, agents and contractors, such entities have undertaken similar obligations of confidentiality with respect to the Confidential Information.

(b) Nothing contained in this Article restricts the Parties from disclosing Confidential Information as reasonably required for: (i) seeking any Approval or other authorization required under or for the purposes of this Agreement, including without limitation the approval of the

Agreement itself by AICEP – Agência para o Investimento e Comércio Externo de Portugal, E.P.E., (ii) regulatory, tax or customs reasons, (iii) audit purposes, (iv) the development, manufacture, use, sale, external testing or marketing trials of products in a manner consistent with the terms of this Agreement, the Supply Agreement, the PVEA and Quality Agreement, (v) the filing or prosecuting patent applications contemplated by this Agreement, without violating the above secrecy provision; it being understood that publication of such applications within eighteen (18) months of filing will not violate such secrecy provisions, or (vi) by court order or other government order or request. With respect to disclosing Confidential Information pursuant to a court order or other government order or request, prompt notice of such order or request will be provided to the disclosing Party and the disclosure will not occur until the disclosing Party either approves the disclosure or has had the opportunity to seek a protective order or other appropriate remedy to curtail such disclosure. In the event that the disclosing Party is unsuccessful in preventing the disclosure of Confidential Information to the court or government, the other Party will take reasonable efforts to protect the confidentiality of the Confidential Information and will disclose only that portion of Confidential Information which it is legally required to disclose.

10.4 Disclosure of Financial and Other Terms: Except as required by applicable laws, treaties or agreements (including securities laws), the Parties agree that the terms of this Agreement, the Supply Agreement, the PVEA and Quality Agreement will be considered Confidential Information of both Parties. Notwithstanding the foregoing, (a) either Party may disclose such terms as are required to be disclosed in its publicly-filed financial statements or other public statements, pursuant to applicable laws, regulations or stock exchange rules (*e.g.*, U.S. Securities and Exchange Commission, NASDAQ, NYSE or any other stock exchange on which securities issued by either Party may be listed); *provided*, to the extent possible, such Party will provide the other Party with a copy of the proposed text of such statements or disclosure (including any exhibits containing this Agreement or the Supply Agreement) sufficiently in advance of the scheduled release or publication thereof to afford such other Party a reasonable opportunity to review and comment upon the proposed text (including redacted versions of this Agreement or the Supply Agreement), (b) either Party has the right to disclose this Agreement under a confidentiality obligation no less protective than that set forth in this Agreement, to any potential acquirer, merger partner, providers of financing, or potential

providers of financing and their advisors, (c) upon the execution of this Agreement, the Parties will be permitted to issue the joint press release attached hereto as Exhibit F, and (d) after the Effective Date, each Party has the right to disclose the existence and execution of this Agreement and the Supply Agreement and the general nature of its terms, provided that the specifics of such terms are not disclosed including, without limitation, the financial terms set forth herein. Neither Party will make any other statement to the public regarding the execution and/or any other aspect of the subject matter of this Agreement or the Supply Agreement, except: (i) where a Party reasonably believes disclosure is required under applicable laws or ethical commercial practice; and (ii) either Party may use the text of a statement previously approved by the other Party.

10.5 Publications:

(a) SEPRACOR will submit to BIAL drafts of all proposed publications related to SEPRACOR's development or commercialization activities in the Territory with respect to the Licensed Products no later than fifteen (15) days, prior to the intended submission date for publication, for review and approval by BIAL, provided however that BIAL's approval will not be unreasonably withheld or delayed. For the purposes of this Section 10.5(a), BIAL's approval will only be considered reasonably withheld in the event that (i) the publication contains Confidential Information disclosed by BIAL or on BIAL's behalf, (ii) information that creates potential statutory bars to filing a U.S., Canadian or foreign patent application, or (iii) the proposed publication will materially adversely affect a Licensed Product outside the Territory, including without limitation the development, regulatory approval, marketing and commercialization thereof. In the event of a dispute between the Parties as to whether a publication proposed by SEPRACOR will materially adversely affect a Licensed Product outside the Territory, the dispute will be submitted to the JSC and will be decided in accordance with the mechanism set forth in Sections 5.5 and 5.6(i).

(b) BIAL will submit to SEPRACOR drafts of all proposed publications related to BIAL's and its licensees development activities in the Territory with respect to the Licensed Products no later than fifteen (15) days, prior to the intended submission date for publication, for review and approval by SEPRACOR, provided however that SEPRACOR's approval will not be unreasonably withheld or delayed. For the purposes of this Section 10.5(b), SEPRACOR's

approval will only be considered reasonably withheld in the event that (i) the publication contains Confidential Information disclosed by SEPRACOR or on SEPRACOR's behalf, (ii) information that creates potential statutory bars to filing a U.S. or Canadian patent application, or (iii) the proposed publication will materially adversely affect a Licensed Product within the Territory, including without limitation the development, regulatory approval, marketing and commercialization thereof. In the event of a dispute between the Parties as to whether a publication proposed by BIAL will materially adversely affect a Licensed Product in the Territory, the dispute will be submitted to the JSC and will be decided in accordance with the mechanism set forth in Sections 5.5 and 5.6(ii).

(c) Notwithstanding anything to the contrary contained herein, neither Party can withhold approval of a publication of the other Party if legally obligated to make such publication.

(d) For the avoidance of doubt, the provisions of Section 10.5(b) apply solely to publications related to BIAL's development activities in the Territory and are not applicable with respect to any of BIAL's activities, including without limitation development activities, outside the Territory. SEPRACOR acknowledges that publications relating to such BIAL activities outside the Territory may, by their own nature, be made available on a worldwide basis, including in the Territory.

10.6 Consequences of Breach: The Parties understand that monetary damages may be inadequate or insufficient to protect any breach of any of the provisions of this Article 10 by either Party or employees, Affiliates, distributors, licensees, sublicensees and contractors, or any other person or entity acting in concert with it or on its behalf. Accordingly, the non-breaching Party will be able to seek all remedies available at law or in equity, including the right to request injunctive relief, specific performance of the provisions of this Article 10 and/or to claim damages in a court of competent jurisdiction.

ARTICLE 11
PATENT PROSECUTION AND MAINTENANCE

11.1 Duty to Prosecute and Maintain BIAL Patents Controlled Solely by BIAL: BIAL will, at BIAL's expense, use its reasonable efforts to prosecute or cause to be prosecuted or continue to prosecute to allowance in the Territory all of the patent applications included in the BIAL Patents Controlled solely by BIAL. BIAL will pay all official taxes, annuities, renewal and maintenance fees required to keep in force all issued patents included in the BIAL Patents in the Territory. If BIAL desires to discontinue the prosecution or payment of a maintenance fee on any patent application or patent included in the BIAL Patents, it will notify SEPRACOR in writing not less than forty-five (45) days before the expiration of a response period or the payment due date for a maintenance fee. Upon receipt of such notification, SEPRACOR has the option to assume full responsibility, at its discretion and expense, for the prosecution and maintenance of the affected patent application(s) or patent(s) in the Territory, in which event BIAL will reasonably cooperate with and assist SEPRACOR, at SEPRACOR's expense, in executing a written assignment of the patent application or patent to SEPRACOR and provide any other conveyance instruments, documents, or assistance as may be necessary or desirable to establish ownership of the patent or patent application or to support of the prosecution of the application. Any expenses incurred by SEPRACOR for the prosecution and maintenance of the affected patent application(s) or patent(s) are not refundable under any circumstances and are not creditable against the transfer prices and/or royalties due under Article 4 or any other payments due by SEPRACOR under this Agreement or the Supply Agreement.

11.2 SEPRACOR's Right to Consult: SEPRACOR has the right to review and comment upon the content of all patent applications included in the BIAL Patents Controlled solely by BIAL, prior to filing by BIAL in the Territory. BIAL will cause a copy of the patent application and all communications between BIAL's agents and any patent office in the Territory regarding that patent application and/or patent to be provided to SEPRACOR or its agent for comment, within a reasonable deadline prior to submitting such communications to the patent office. Provided that SEPRACOR responds within the specified deadline, BIAL will consider or cause its agents to consider, in good faith, any comments SEPRACOR may have regarding that application or communication, provided that all final prosecution decisions will rest solely with

BIAL. SEPRACOR will be responsible for any expenses that it may incur in providing such comments. BIAL will pay all official taxes, annuities, renewal and maintenance fees required to keep in force all issued BIAL Patents. The above notwithstanding, BIAL is under no obligation to disclose any patent application or related correspondence that contains Third Party confidential information to SEPRACOR until such information is published as part of the application. In the event such patent application contains Third Party confidential information, BIAL will make reasonable efforts to obtain the Third Party's consent to disclose the confidential information to SEPRACOR.

11.3 Abandonment of Opposition Contest: BIAL will provide SEPRACOR with advance written notice of any decision by BIAL not to defend a priority, opposition or reexamination in any patent office within the Territory relating to a BIAL Patent. SEPRACOR will have a reasonable time period from receipt of such notice to elect to continue prosecuting and defending such patent or patent applications. If SEPRACOR elects to continue, SEPRACOR will bear the cost of such a contest and will control that contest. BIAL will, at SEPRACOR's request and expense, provide SEPRACOR with reasonable assistance including, but not limited to, providing available documents and making witnesses available reasonably requested or required by SEPRACOR to continue prosecuting and defending such patent or patent applications, including cooperation of any consultants of BIAL, at SEPRACOR's expense. BIAL, at its own expense, will have the right to participate in such contest, or designate its own counsel to so participate, throughout each step of the contest. Any expenses or fees paid by SEPRACOR in defending such a contest are not refundable under any circumstances and are not creditable against the transfer prices and/or royalties due under Article 4 or any other payments due by SEPRACOR under this Agreement or the Supply Agreement. If SEPRACOR elects to continue prosecuting and defending any patent or patent application pursuant to this Section 11.3, BIAL will reasonably cooperate with and assist SEPRACOR, at SEPRACOR's expense, in executing a written assignment of the patent application or patent to SEPRACOR and provide any other conveyance instruments, documents, or assistance as may be necessary or desirable to establish ownership of the patent or patent application or to support of the prosecution of the application.

11.4 Notices of Issued Patent: BIAL will notify SEPRACOR within ten (10) Business Days of: (a) the issuance of each U.S. patent included among the BIAL Patents along with the date of issuance and the patent number for each such patent; and (b) communications pertaining to any patent included among the BIAL Patents, which BIAL receives as patent owner pursuant to the Drug Price Competition and Patent Term Restoration Act of 1984, including without limitation any notice pursuant to Sections 101 and 103 of that act from persons who have filed an ANDA or a Paper NDA.

11.5 Authorization Relating to Patent Term Extension: In the event that applicable law in any country within the Territory provides for the extension of the term of any patent included among the BIAL Patents, BIAL will apply for and use its reasonable efforts to obtain such an extension. SEPRACOR agrees to cooperate with BIAL in obtaining such extension. Should the law require SEPRACOR to apply for such an extension directly, BIAL will cooperate with SEPRACOR in obtaining such an extension and will execute such documents and take such additional actions as SEPRACOR may reasonably request in connection therewith. Should applicable law in a country within the Territory require that any such authorization be held in the name of SEPRACOR, such authorization will be held by SEPRACOR solely for the benefit of and in trust for BIAL and, upon termination or expiration of the Term of this Agreement, SEPRACOR agrees to assign such authorization to BIAL, its Affiliate or nominee and to provide any other conveyance, instruments, documents or assistance as may be necessary or desirable to establish ownership of such authorization in BIAL. Notwithstanding anything to the contrary contained herein, the Parties will, 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 issue, a BIAL Patent will be extended if either Party elects to extend such patent.

11.6 Patent Certifications:

(a) Each Party will immediately give written notice to the other of any certification of which it becomes aware that has been filed pursuant to 21 U.S.C. § 355(b)(2)(A)(iv), or § 355(j)(2)(A)(vii)(IV) (or any amendment or successor statute thereto or Canadian equivalent statute) claiming that the BIAL Patents covering the Licensed Product are

invalid, unenforceable, and/or that infringement will not arise from the manufacture, use, sale or offer for sale, of such Third Party product by a Third Party. If BIAL decides not to bring infringement proceedings against the Third Party making such a certification with respect to any Licensed Product, BIAL will give notice to SEPRACOR of its decision not to bring suit within ten (10) Business Days after receipt of notice of such certification (or, if the time period permitted by law is less than twenty (20) Business Days, within half of the time period permitted by law for SEPRACOR to commence such action). SEPRACOR may then, but is not required to, bring suit against the Third Party that filed the certification. Any suit by either Party may be in the name of either or both Parties, as may be required by law. For this purpose, the Party not bringing suit will execute such legal papers necessary for the prosecution of such suit and will provide assistance at the other Party's expense as may be reasonably requested by the Party bringing suit.

(b) If BIAL commences infringement proceedings against the Third Party, BIAL will be solely responsible for the expenses and costs of prosecuting that lawsuit, even if BIAL names SEPRACOR as a co-plaintiff or otherwise brings SEPRACOR into the lawsuit. BIAL will seek the advice of and consult with SEPRACOR regarding the strategy and prosecution of the lawsuit. BIAL will seek SEPRACOR's approval of counsel selected to prosecute the lawsuit. In no event will BIAL dismiss or otherwise resolve such lawsuit without the participation of and express written consent of SEPRACOR.

(c) If SEPRACOR commences infringement proceedings against the Third Party, SEPRACOR will be solely responsible for the expenses and costs of prosecuting that lawsuit, even if SEPRACOR names BIAL as a co-plaintiff or otherwise brings BIAL into the lawsuit. SEPRACOR will seek the advice of and consult with BIAL regarding the strategy and prosecution of the lawsuit. SEPRACOR will seek BIAL's approval of counsel selected to prosecute the lawsuit. In no event will SEPRACOR dismiss or otherwise resolve such lawsuit without the participation of and express written consent of BIAL.

ARTICLE 12

INFRINGEMENT

12.1 Infringement of the BIAL Patents:

(a) If either Party identifies a Third Party infringement of an issued BIAL Patent (including any BIAL Patent that is jointly owned by the Parties) in the Territory it will promptly notify the other Party of the alleged infringement. BIAL will have five (5) months, from the date that BIAL either receives a notice of alleged infringement from SEPRACOR or provides such a notice to SEPRACOR, to: (i) secure cessation of the infringement; (ii) enter suit against the infringer; or (iii) provide SEPRACOR with evidence of a bone fide negotiation for the acceptance by the infringer of a sublicense under the BIAL Patent. If BIAL initiates a suit against the infringer, SEPRACOR will cooperate fully with BIAL, at BIAL's expense, including joining in the action as a party to the extent necessary to permit BIAL to pursue the action. BIAL will assume all costs of asserting a claim of infringement against the Third Party, and will reimburse SEPRACOR for its costs (excluding attorney fees) of assisting in the action.

(b) If BIAL does not complete one of the three actions describe in Section 12.1 (a) within five (5) months after the notice, SEPRACOR may initiate the action against the infringer and BIAL will cooperate fully with SEPRACOR, at SEPRACOR's expense, including joining the action to the extent necessary to permit SEPRACOR to pursue the action. SEPRACOR will assume all costs of asserting a claim of infringement against the Third Party, and will reimburse BIAL for its costs (excluding attorney fees) of assisting in the action.

(c) Any damages or other monetary awards recovered in any action brought by one of the Parties against an infringer of a BIAL Patent will be applied to the reimbursement of the Parties for their respective out-of-pocket expenses (including reasonable attorneys' fees and expenses) incurred in prosecuting such infringement action on a pro rata basis based upon their respective out-of-pocket expenses until all such expenses have been recovered, and any remaining balance, if any, will be divided seventy percent (70%) to SEPRACOR and thirty percent (30%) to BIAL. Both Parties must agree to the terms of any sublicense granted under Section 12.1 (a) or the settlement of any law suit initiated by one of the Parties.

12.2 Alleged Infringement of Third Party Patents:

(a) If either Party learns that the making, packing, labeling, handling, storage, importation, transportation, use, distribution, promotion, offer for sale, marketing or sale of a Licensed Product within Field and Territory infringes or is alleged to infringe a Third Party patent, it will promptly notify the other Party. The Parties will thereafter attempt to agree upon a course of action which may include, without limitation: (i) obtaining a license or assignment from said Third Party; (ii) defending to final judgment any suit against either or both Parties, (iii) resolving any suit against either or both Parties, (iv) filing a declaratory judgment action against such Third Party; (v) filing for re-examination of the Third Party patent; or (vi) obtaining a competent opinion of counsel regarding non-infringement, invalidity or unenforceability of the Third Party patent.

(b) In the event the Parties do not agree upon a course of action, SEPRACOR will decide the course of action to take, except with respect to (i) the action mentioned under 12.2(a)(iii) which always requires BIAL's previous consent and to (ii) the actions mentioned under 12.2(a)(i), (ii), (iv) and (v) which require BIAL's previous consent if the Third Party alleging infringement is the owner of similar patents or patent applications outside the Territory which could allegedly be infringed by BIAL, its Affiliates, licensees or distributors, in which event BIAL will have the right to negotiate a license or assignment from such Third Party. BIAL's consent pursuant to this Section 12.2(b) shall not be unreasonably withheld.

(c) Subject to SEPRACOR's indemnity obligations of Section 15.1(d), BIAL agrees to pay to SEPRACOR fifteen percent (15%) of any license fees, settlement payments, milestone payments, and royalties due by SEPRACOR to a Third Party, to enable SEPRACOR to use, import, offer for sale and sell the BIA 2-093 Product for the treatment of epilepsy (and not for any other indication or use) in the Territory, provided, however (i) that BIAL's obligation under this Section 12.2 (c) is contingent on the Parties agreement as to obtaining such a license or resolution. Any amounts payable by BIAL under this Section 12.2 (c) will never exceed, per calendar year, three percent (3%) of the invoiced commercial supply of the BIA 2-093 Product purchased by SEPRACOR for commercial sale in the Territory in said calendar year (the "3% Annual Payment Cap"). Should the amount payable by BIAL under this Section 12.2 (c) exceed

the 3% Annual Payment Cap in any given calendar year, the amount by which the cap is exceeded will be carried over each of the subsequent calendar years until such amount is paid in full, provided that the 3% Annual Payment Cap will not be exceeded in any calendar year. For the avoidance of doubt, BIAL's obligation hereunder applies only to future sales of the BIA 2-093 Product for the treatment of epilepsy and not to any past damages that may be awarded to any Third Parties in any legal proceedings or otherwise agreed upon in settlement. Nothing in this Section 12.2 (c) expressly or implicitly relieves SEPRACOR of its obligation to indemnify BIAL under Section 15.1(e).

(d) Except as expressly provided in Section 12.2 (c), any costs incurred by SEPRACOR in connection with the actions that it may take pursuant to this Section 12.2, or any license fees, milestones, royalties or other payments due to a Third Party as consideration for a license of intellectual property rights used to develop, import, distribute, sell or offer for sale any Licensed Products in the Territory will be borne solely by SEPRACOR and are not creditable against the transfer prices and/or royalties due under Article 4 or any other payments due by SEPRACOR to BIAL under this Agreement or the Supply Agreement.

ARTICLE 13

REPRESENTATIONS AND ACKNOWLEDGEMENTS

13.1 Representations and Warranties by BIAL:

(a) As of the Effective Date, BIAL represents and warrants that: (i) BIAL has and will continue to have the legal power and authority to grant the licenses set forth in Sections 2.1-2.4 of this Agreement and that it has not made and will not make any commitments to any Third Party inconsistent with or in derogation of such rights; (ii) the patents and patent applications set forth on Exhibit A are all the patents and patent applications in the Territory as of the Effective Date that relate to the Licensed Products; and (iii) BIAL exclusively Controls all right, title and interest to the BIAL Patents listed in Exhibit A and that any issued patent listed in Exhibit A is in full force and effect and in good standing in the Territory and have been maintained and/or prosecuted in good faith.

(b) As of the Effective Date, BIAL represents that, to the Knowledge of BIAL, it knows of no material deficiencies with respect to the BIAL Know-How which could materially impact the rights granted to SEPRACOR hereunder.

(c) As of the Effective Date, BIAL represents and warrants that, to the Knowledge of BIAL, it has complied in all material respects with all applicable laws, permits, governmental licenses, registrations, approvals, concessions, authorizations, orders, injunctions and decrees with respect to the development and/or manufacture of the Licensed Products.

(d) As of the Effective Date, BIAL represents and warrants that it has not received any communications from a regulatory authority which would reasonably be expected to adversely impact the development, manufacture, use, import, offer for sale, sale, or marketing of any Licensed Product.

(e) As of the Effective Date, BIAL represents that, to the Knowledge of BIAL, the development, use, sale or offer for sale, or import of the BIA 2-093 Product for use in the treatment of Epilepsy in the Territory, does not infringe nor will infringe any Third Party's valid patents issued prior to the Effective Date or constitutes a misappropriation of a Third Party's trade secrets or other intellectual property rights in BIAL's possession as of the Effective Date.

(f) As of the Effective Date, BIAL represents and warrants that, to the Knowledge of BIAL, there is no Third Party infringing any of the BIAL Patents or misappropriating BIAL Know-How in derogation of the rights granted to SEPRACOR in this Agreement with respect to the Licensed Products.

(g) BIAL represents and warrants that, to the Knowledge of BIAL, it is the exclusive owner of all right, title and interest in the BIAL Trademarks and that the aforementioned trademarks are subject to pending applications for registration in the Territory.

(h) Except for Third Party patentability challenges filed by BIAL with the U.S. Patent and Trademark Office and currently pending with the U.S. Patent and Trademark Office, BIAL represents, to the Knowledge of BIAL, that there are no filed, pending, threatened, anticipated, or alleged actions, suits, claims, interference proceedings (including agency or patent office proceedings) or governmental investigations in the Territory as of the Effective Date involving

the Licensed Products, BIAL Patents, BIAL Know-How or the BIAL Trademarks by or against BIAL, or any of its Affiliates.

(i) As of the Effective Date, BIAL represents and warrants that to the Knowledge of BIAL, there is no actual, pending, alleged or threatened product liability action with respect to any Licensed Product or BIA 2-093 anywhere in the world and BIAL is not aware of any facts or circumstances that would cause BIAL to believe that there is a basis for such a product liability claim.

(j) As of the Effective Date, BIAL represents that, to the Knowledge of BIAL, it has not failed to furnish SEPRACOR with any information requested by SEPRACOR, or intentionally concealed from SEPRACOR any information requested by SEPRACOR and in its possession which BIAL reasonably believes would be material to SEPRACOR's decision to enter into this Agreement and undertake the commitments and obligations set forth herein.

(k) As of the Effective Date, BIAL represents and warrants that (i) there are no Competing Products Controlled by or on behalf of BIAL or its Affiliates, and (ii) no products are under development or currently being considered for development by or on behalf of BIAL or its Affiliates that are aimed to result in a pharmaceutical product for the treatment of epilepsy.

13.2 Representation and Warranties by SEPRACOR:

(a) SEPRACOR represents and warrants that it will use its Commercially Reasonable Efforts to ensure that all promotional labeling and post-marketing Licensed Products communications, complaint handling and reports of Adverse Events known to SEPRACOR will be in full compliance with all material laws and regulations of countries within the Territory.

(b) As of the Effective Date, SEPRACOR represents and warrants that it has the financial resources and capability to meet its obligations under this Agreement.

(c) As of the Effective Date, SEPRACOR represents and warrants that (i) there are no Competing Products Controlled by or on behalf of SEPRACOR or its Affiliates, and (ii) no products are under development or currently being considered for development by or on behalf

of SEPRACOR or its Affiliates that are aimed to result in a pharmaceutical product for the treatment of epilepsy.

13.3 Mutual Representations: Each Party hereby represents to the other Party as of the Effective Date, that:

(a) Such Party will at all times in connection with its obligation hereunder and pursuant to the Supply Agreement, Safety and Pharmacovigilance Agreement and Quality Agreement be in compliance with all material laws and regulations applicable to such Party.

(b) Such Party is a corporation duly organized, validly existing and in good standing under the laws of its place of incorporation.

(c) The execution and delivery of this Agreement by such Party has been duly authorized by all necessary corporate actions on the part of such Party. Such Party has full power, authority and legal right to execute and deliver this Agreement and to perform its obligations hereunder. This Agreement has been duly executed and delivered by such Party, is a legal and valid obligation binding upon such Party and enforceable against such Party in accordance with its terms, except as such enforceability may be limited by applicable insolvency and other laws affecting creditors rights generally or by the availability of equitable remedies.

(d) The execution, delivery and performance of this Agreement does not and will not violate (i) the organizational documents or by-laws of such Party, or (ii) any provision of any agreement or other instrument or document to which such Party is a party or by which any of its assets or properties is bound or affected.

13.4 Prior Knowledge: No liability for any breach of any warranty or representation given by a Party under this Article 13 will arise to the extent the other Party has knowledge at the Effective Date that such representation or warranty is untrue or inaccurate.

13.5 Negation of Implications: Except as expressly stated herein, nothing in this Agreement will be construed as:

(a) An obligation on the part of either Party to bring or prosecute actions or suits against Third Parties for infringement of any of the BIAL Patents or other intellectual property rights of the Parties;

(b) Conferring on either Party a right to use in advertising, publicity, or otherwise any trademark, service mark, or trade name of the other Party;

(c) Granting by implication, estoppel, or otherwise, any licenses or rights under patents or other intellectual property of a Party other than those rights expressly granted herein;
or

13.6 Non Reliance; Disclaimer:

(a) The representations of each Party set forth in this Agreement are intended for the sole and exclusive benefit of the other Party hereto, and may not be relied upon by any Third Party.

(b) EXCEPT AS OTHERWISE SPECIFICALLY PROVIDED IN THIS AGREEMENT, NEITHER PARTY MAKES ANY REPRESENTATIONS OR WARRANTIES, EXPRESS, IMPLIED, STATUTORY OR OTHERWISE, CONCERNING THE LICENSED PRODUCTS OR ANY PATENTS, KNOW-HOW, TRADEMARKS OR OTHER INTELLECTUAL PROPERTY DISCLOSED, DEVELOPED, OR LICENSED UNDER THIS AGREEMENT. EXCEPT TO THE EXTENT EXPRESSLY SET FORTH HEREIN, EACH PARTY EXPRESSLY DISCLAIMS REPRESENTATIONS OR WARRANTIES, EXPRESS, IMPLIED, STATUTORY OR OTHERWISE, CONCERNING THE LICENSED PRODUCTS OR ANY PATENTS, KNOW-HOW, TRADEMARKS OR OTHER INTELLECTUAL PROPERTY DISCLOSED, DEVELOPED, OR LICENSED UNDER THIS AGREEMENT, INCLUDING WITHOUT LIMITATION ANY WARRANTY OR REPRESENTATION OF NON-INFRINGEMENT, MERCHANTABILITY, AND FITNESS FOR A PARTICULAR PURPOSE.

ARTICLE 14
TERM AND TERMINATION

14.1 Term:

(a) This Agreement commences as of the Effective Date and will remain in force in each country within the Territory, unless otherwise terminated in accordance with any of the provisions of this Article 14, until the later of: (i) ten (10) years after the first commercial sale following Approval of any Licensed Products in such country; (ii) expiry of the last to expire of the BIAL Patents in the respective country; or (iii) expiry of the last to expire of the Exclusivity Rights in the relevant country (the "Term").

(b) The Parties have the right to extend the Term of this Agreement on the following terms and conditions:

(i) either Party notifies the other in writing at least six (6) months prior to the anticipated expiration of the Term of this Agreement that it desires to extend the Term, and will include a term sheet with its proposal for the terms of such extension, including the length of the extended term, which may include conditions of supply of Licensed Products.

(ii) upon receipt of such notice, the Parties will enter into good faith negotiations regarding the terms of such extension. If the Parties reach an agreement on such terms at any time prior to the expiration of the original Term, the Parties will execute an amendment to this Agreement reflecting such terms.

14.2 Termination: Prior to expiration of the Term as set forth in Section 14.1, this Agreement may be terminated, without prejudice to any other remedies available to it at law or in equity, upon the occurrence of any of the following events ("Termination Events");

(a) by either Party, upon sixty (60) days written notice to the other Party, if the other Party materially breaches or defaults in the performance of any of its obligations hereunder (with the exception of payment obligations) and fails to cure such breach within sixty (60) days following receipt of such notice or, if such default cannot be cured within such 60-day period, if

the other Party does not commence and diligently continue actions to cure such default during such 60-day period;

(i) Upon any notice under this Section 14.2(a), the Parties will in good-faith meet and discuss if a plan to remedy the alleged breach or default within a period exceeding the 60-day period, or to commence actions towards the remedy within such an extended period, can be mutually agreed.

(b) by BIAL, upon thirty (30) days written notice to SEPRACOR, if SEPRACOR materially breaches or defaults in the performance of any payment obligation hereunder and fails to cure such breach within the said thirty (30) days following receipt of such notice;

(c) by either Party if the other Party commits an act of bankruptcy, is declared bankrupt, voluntarily files or has filed against it a petition for bankruptcy or reorganization, enters into a procedure of winding up to dissolution, or should a trustee or receiver be appointed for its business assets or operations;

(d) In the event that SEPRACOR has undergone a Change of Control involving any of the following circumstances (i) to (iii), BIAL will have the right to terminate this Agreement, at BIAL's sole discretion, upon thirty (30) days written advance notice to SEPRACOR within twelve months of becoming aware of such Change of Control if: (i) the Third Party involved in the Change of Control, whether by absorption of, absorption by, acquisition of, acquisition by, consolidation or merger with, SEPRACOR or otherwise (the "Change of Control Entity") is selling, offering for sale, importing, promoting or commercializing a Competing Product in and/or outside the Territory and such Change of Control Entity does not (A) provide notice to BIAL within thirty (30) days of the Change of Control of its intention to divest itself of such Competing Product; (B) having provided such notice to BIAL does not use Commercially Reasonable Efforts to divest itself of such Competing Product within six (6) months of such Change of Control; or (C) having provided such notice to BIAL does not actually divest itself of such Competing Product within one (1) year of such acquisition; or (ii) the Change of Control Entity has infringed or is infringing any BIAL Patent, BIAL Trademarks or other intellectual property right of BIAL or its Affiliates, relating to the Licensed Products, in and/or outside the

Territory; or (iii) the Change of Control Entity does not have the financial capability to meet SEPRACOR's obligations under this Agreement.

(e) by either Party, with immediate effect, if the Approvals for a Licensed Product covered by this Agreement is permanently revoked or cancelled by the FDA or Health Canada due to patient safety reasons;

(f) If, following good-faith discussions with BIAL, including without limitation those set forth in Section 8.3(b), SEPRACOR determines, in its reasonable judgment, that the Licensed Products have become subject to a pattern of Serious Adverse Reactions (as defined in the ICH Guidelines) and, in good faith, reasonably believes that it would significantly impact the long-term viability of the Licensed Products, SEPRACOR will have the right to terminate this Agreement upon ten (10) days' prior written notice to BIAL setting forth the reasons therefore in reasonable detail;

(g) by BIAL, with immediate effect, in the event of termination of the Supply Agreement (i) by SEPRACOR, other than as a result of a material breach by BIAL, or (ii) by BIAL as a result of a material breach by SEPRACOR;

(h) SEPRACOR will have the right to terminate this Agreement at will on written notice to BIAL at any time after the Effective Date: (i) prior to the receipt of the first Approval for a BIA 2-093 Product in the Territory, provided that BIAL is given at least six (6) months' prior written notice, or (ii) anytime thereafter, provided that BIAL is given at least twelve (12) months' prior written notice.

(i) by either Party, in accordance with Section 16.3.

(j) by SEPRACOR, within ninety (90) days of its receipt of written notice from BIAL pursuant to 7.4(c) that the licenses granted to SEPRACOR pursuant to Section 2.1 and 2.3 will become non-exclusive.

(k) by either Party, immediately upon a generic version of the Licensed Products exceeding ten percent (10%) of the total Net Sales of Licensed Products in the Territory, if (i) pursuant to the mechanism set forth in the Supply Agreement as contemplated in Section 4.4, the

Parties are unable to negotiate in good faith a new transfer price reflecting the impact of the applicable transfer price as a result of such generic entry, and (ii) following such generic entry, SEPRACOR is unwilling to pay the floor price (as set forth in the Supply Agreement) for commercial supply of the BIA 2-093 Product.

- (l) by BIAL, pursuant to 7.4(c).

14.3 Waiver of Termination Event; Termination Disputes. The right of either Party to terminate this Agreement as provided in Section 14.2 will not be affected in any way by such Party's waiver or failure to take action upon the occurrence of a previous Termination Event. Any dispute as to whether a Party is entitled to terminate under Section 14.2 will be resolved as provided in Section 16.1 hereof.

14.4 Rights and obligations upon Expiration of Term or Termination (other than termination for breach or termination at will under Section 14.2(h)): Unless the Agreement is terminated for breach by the other Party, the following rights and obligations will survive the expiration and termination of this Agreement:

- (a) All licenses granted by BIAL under this Agreement or the Supply Agreement will terminate upon expiration or termination of this Agreement and SEPRACOR will have the right to sell-off over the six (6) months immediately following such termination, any Licensed Products then in its inventory or on order from BIAL, under the BIAL Trademarks, provided SEPRACOR complies with all relevant provisions of this Agreement.

- (b) SEPRACOR will promptly assign to BIAL, or to its Affiliate or nominee, all right, title and interest in the BIA 2-093 IND, and SEPRACOR will notify the FDA and other applicable regulatory bodies in writing that ownership of the BIA 2-093 IND has been assigned to BIAL or its Affiliate or nominee.

- (c) SEPRACOR will promptly assign to BIAL or its Affiliate or nominee, any Approval(s), and any pending or approved NDAs and INDs, relating to BIA 2-093 and/or Licensed Products in the Territory.

(d) Any authorizations relating to patent term extensions that, in accordance with Section 11.5 are held in SEPRACOR's name, will be immediately assigned to BIAL, its Affiliate or nominee as soon as reasonably practicable.

(e) The licenses granted to BIAL by SEPRACOR under this Agreement will continue in effect as fully paid-up, royalty-free, and perpetual.

(f) The following terms and provisions will survive the expiration or termination of the Agreement under Section 14.4: Articles 10, 14, 15 and Sections 2.5, 2.7(c), 6.6(g), 6.8, 7.6(b), 8.1(c)(d); 8.2(a)(b), 8.3(a), 9.1, 9.1(b)(c)(d)(e)(f), 9.2, 11.5, 13.4, 13.5, 13.6, 16.1, 16.6, 16.7, 16.8, 16.10, 16.11 and 16.12.

(g) Expiration or termination of this Agreement will not relieve the Parties of any obligations or liability accruing prior to such termination or expiration, including, without limitation, the payment obligations set forth in Article 3.

14.5 Rights and obligations upon Termination of the Agreement for Breach or at will:

(a) If the Agreement is terminated by BIAL for breach by SEPRACOR, or by SEPRACOR at will:

(i) All licenses granted by BIAL under this Agreement or the Supply Agreement will terminate and SEPRACOR will have the right to sell-off over the six (6) months immediately following such termination, any Licensed Products then in its inventory or on order from BIAL, under the BIAL Trademarks, provided SEPRACOR complies with all relevant provisions of this Agreement.

(ii) SEPRACOR and its Affiliates will not promote, distribute, market, commercialize, offer for sale or sell within the Field and Territory, any Competing Product for the period of one (1) year after the date of termination;

(iii) SEPRACOR will promptly assign to BIAL, or to its Affiliate or nominee, all right, title and interest in the BIA 2-093 IND and SEPRACOR will notify the FDA and other applicable regulatory bodies in writing that ownership of the BIA 2-093 IND has been assigned to BIAL or its Affiliate or nominee.

(iv) SEPRACOR will promptly assign to BIAL or its Affiliate or nominee, any Approval(s), and any pending or approved NDAs and INDs (or Canadian equivalents), relating to BIA 2-093 and/or Licensed Products in the Territory.

(v) Any authorizations relating to patent term extensions that, in accordance with Section 11.5 are held in SEPRACOR's name, will be immediately assigned to BIAL, its Affiliate or nominee as soon as reasonably practicable;

(vi) The licenses and sublicenses granted to BIAL by SEPRACOR under this Agreement will continue in effect as fully paid-up, royalty-free, and perpetual, and will convert to worldwide licenses;

(vii) SEPRACOR will promptly assign and deliver to BIAL or its Affiliate all right, title and interest in any Development Intellectual Property owned solely by SEPRACOR or jointly by the Parties, in and outside the Territory, as well as all SEPRACOR Know-How, including without limitation, documents, material, data, reports, health authority or development correspondence, rights and information, Controlled by SEPRACOR, directly relating to or concerning the relevant Licensed Products; and

(viii) In the event of termination by SEPRACOR at will, SEPRACOR will, during the period between the notice of termination and the effective date of termination, use Commercially Reasonable Efforts with respect to SEPRACOR's activities under this Agreement, including without limitation development and commercialization activities; provided, however, SEPRACOR will not be obligated to pay any additional milestone and expense payments pursuant to Section 3.1(b). SEPRACOR will also diligently cooperate with BIAL or its nominee in good faith to effect a smooth and orderly transition in the development, sale and marketing, promotion and commercialization of the Licensed Products in the Territory and, at BIAL's written request, SEPRACOR will use its Commercially Reasonable Efforts to (1) complete any ongoing SEPRACOR Development Studies or, to the extent so requested by BIAL, to promptly transfer of such Development Studies or portions thereof to BIAL or its nominee and (2) to comply with SEPRACOR's obligations under Sections 14.5(a)(iii), (iv), (v) and (vii) prior to the effective date of termination and soon as reasonably practicable upon BIAL's written request.

(b) If the Agreement is terminated by SEPRACOR for breach by BIAL:

(i) BIAL and its Affiliates will not promote, distribute, market, commercialize or sell within the Field and Territory, any Licensed Products for the period of one (1) year after the date of termination;

(ii) The licenses granted to SEPRACOR by BIAL pursuant to Section 2 will be fully paid-up, royalty-free, and perpetual and all right, title and interest to all Approval(s), any NDAs and INDs (or Canadian equivalents), relating to BIA 2-093 and/or Licensed Products in the Territory will vest with SEPRACOR; *provided, however*, that SEPRACOR will pay BIAL a trade mark royalty of six and one half percent (6.5%) of Net Sales of Licensed Products for as long as they are sold in the Territory. Notwithstanding anything to the contrary contained herein, the rights granted to SEPRACOR pursuant to this Section 14.5(b)(i) and (ii) will become effective if and only if the arbitral tribunal, pursuant to Section 16.1, determines such remedy is reasonable in light of the magnitude of BIAL's breach or willful misconduct and of the payments made by SEPRACOR to BIAL under this Agreement in consideration for the rights granted to SEPRACOR by BIAL.

(c) Termination of this Agreement will not relieve the Parties of any obligation or liability accruing prior to such termination or expiration, including, without limitation, the payment obligations set forth in Article 3.

(d) The following terms and provisions will survive the termination of the Agreement under Section 14.5: Articles 10, 14, 15 and Sections 2.5, 2.7(c), 6.6(g), 6.8, 7.6(b), 8.1(c)(d); 8.2(a)(b), 8.3(a), 9.1(b)(c)(d)(e)(f), 9.2, 11.5, 13.4, 13.5, 13.6, 16.1, 16.6, 16.7, 16.8, 16.10, 16.11 and 16.12 and, if terminated by SEPRACOR pursuant to 14.5(b), Article 11 and Sections 12.1 and 12.2 (a)(b)(d).

ARTICLE 15
INDEMNIFICATION

15.1 Indemnity by SEPRACOR: Except as otherwise provided in Sections 15.2 and 15.3, SEPRACOR will indemnify, defend, and hold harmless, BIAL, its Affiliates, directors, officers, shareholders, employees, representatives, agents, successors and assigns from and against any and all liabilities, claims, suits, demands, assessments, fines, damages, losses, costs and expenses (including, without limitation, the reasonable costs and expenses of attorneys and other professionals) (collectively, “Liabilities”) arising in connection with Third Party claims or suits or demands based on (a) alleged or actual bodily injury or property damage resulting from the manufacturing, packing, labeling, handling, storage, transportation, use, distribution, promotion, marketing, offer for sale or sale of the Licensed Products by or on behalf of SEPRACOR, its Affiliates, sublicensee or contractors including any Product liability Claim (in accordance with Section 15.7); (b) liabilities arising from clinical trials conducted by or on behalf of SEPRACOR in connection with any Licensed Products and/or the filing and processing of the NDA (including, without limitation, the studies mentioned in Section 6.4 (c)); (c) the gross negligence or willful misconduct of SEPRACOR or its Affiliates, sublicensee, contractors, or any of its agents, directors, officers or employees; and (d) subject only to BIAL’s obligations under Section 12.2(c), any claim of infringement or misappropriation of any patent, trade secret, copyright, or trademark or other proprietary right arising out of the packing, labeling, handling, storage, importation, transportation, use, distribution, promotion, marketing, offer for sale or sale of the Licensed Products.

15.2 Indemnity by BIAL: Except as otherwise provided in Section 15.1 and 15.3, BIAL will indemnify, defend, and hold harmless, SEPRACOR, its Affiliates, directors, officers shareholders, employees, representatives, agents, successors and assigns, harmless from and against any and all Liabilities arising in connection with Third Party claims or suits or demands based on (a) alleged or actual bodily injury or property damage resulting from the manufacturing, packing, labeling, handling, storage, transportation, use, distribution of Licensed products by or on behalf of BIAL, its licensees (other than SEPRACOR) or Affiliates, including any Product liability Claim (in accordance with Section 15.7); (b) liabilities arising from clinical trials conducted by or on behalf of BIAL in connection with any Licensed Products; and (c) the

gross negligence or willful misconduct of BIAL or its Affiliates, sublicensees, or any of its agents, directors, officers or employees. Subject to the conditions set forth in Section 12.2 (c), BIAL agrees to reimburse SEPRACOR for a portion of any license fees, settlement payments, milestone payments and royalties due by SEPRACOR for a license, under a Third Party patent, to use, import, offer for sale, and sell the BIA 2-093 Product for the treatment of epilepsy within the Territory.

15.3 Mutual Indemnity: In addition to Sections 15.1 and 15.2, each Party (“Indemnifying Party”) will indemnify, defend, and hold harmless, the other Party and its Affiliates, directors, officers, shareholders, employees, representatives, agents, successors and assigns (the “Indemnitees”) from and against any and all Liabilities arising in connection with Third Party claims or suits or demands to the extent arising out of or resulting from a false representation or the breach by the Indemnifying Party of any warranty, covenant or obligation contained in this Agreement.

15.4 Conditions of Indemnification: If a Party hereunder seeks indemnification under this Article 15, such Party must: (a) promptly inform the Indemnifying Party of any claim, suit or demand threatened or filed, (b) permit the Indemnifying Party to assume direction and control of the defense of claims resulting therefrom (including the right to settle such claims at the sole discretion of the Indemnifying Party, but subject to the approval of the other Party, not to be unreasonably withheld, if such settlement provides for injunctive or other non-monetary relief affecting the Indemnitees or any admission of liability), and (c) cooperate as requested (at the expense of the Indemnifying Party) in the defense of such claims. Notwithstanding anything to the contrary contained herein, a Party’s failure to promptly notify the Indemnifying Party of a claim for which it is seeking indemnification, will only relieve the Indemnifying Party of its obligations under this Section 15 if and to the extent the Indemnifying Party is actually prejudiced thereby.

15.5 Limits of Indemnity: An Indemnifying Party’s (including sublicensee’s) obligations under this Article 15 will not extend to any Liabilities to the extent (a) arising from the Indemnified Party’s failure to comply with the terms and conditions of this Agreement, (b) arising from the negligence or willful misconduct of the Indemnitee, its agents or employees or

(c) such claim falls within the scope of the indemnification obligations of the Indemnitee. No Party will be liable under any provision of this Agreement for any punitive, exemplary, multiplied or consequential damages.

15.6 Recalls.

(a) Voluntary and Mandatory Recalls: Decision-Making. To the extent that: (i) any regulatory authority in the Territory issues a directive or order or requests that a Licensed Product be recalled or withdrawn, (ii) a court of competent jurisdiction orders a recall or withdrawal of a Licensed Product in the Territory, or (iii) SEPRACOR determines that an event, incident or circumstance has occurred that warrants a Licensed Product should be recalled or withdrawn voluntarily in the Territory, the Parties will recall or withdraw the Licensed Product as set forth in this Section 15.6. As between the Parties, SEPRACOR will control and coordinate all activities that SEPRACOR deems reasonably necessary in connection with such recall or withdrawal of the Licensed Product in the Territory, including making all contact with relevant regulatory authorities; provided, however, that SEPRACOR will not take any action with respect to any such recall without first notifying BIAL in writing, and to the extent practical, consulting in good faith with BIAL. SEPRACOR will consider in good faith any comments of BIAL in connection with any aspect of the management of any such recall. For clarity, all matters relating to a withdrawal or recall of a Licensed Product outside of the Territory will be determined, controlled and coordinated solely by BIAL.

(b) Costs of Recall. All actual direct and documented out-of-pocket expenses for the execution of any recall or withdrawal of a Licensed Product supplied to SEPRACOR by BIAL ("Recall Costs") pursuant to Section 15.6(a) above, will initially be shared equally between the Parties, provided that (i) in each case, responsibility for the Recall Costs will be subject to the final allocation between the Parties as set out in paragraphs (i) and (ii) below, and (ii) BIAL will reimburse SEPRACOR for all amounts paid by SEPRACOR for the recalled products in excess of BIAL's Fully Burdened Manufacturing Costs. For clarity, Recall Costs do not include any lost or refunded sales. In the event that it is finally determined, or agreed between the Parties, that such recall or withdrawal:

(i) is caused by breach of BIAL's representations or warranties as set forth in this Agreement or the Supply Agreement, including failure to supply Licensed Product conforming to the specifications set forth in the Supply Agreement or Quality Agreement, or the gross negligence or willful misconduct of BIAL or BIAL's failure to comply with applicable laws and regulations including cGMP (to be defined in the Quality Agreement) (collectively, the "Fault of BIAL"), BIAL will be responsible for all Recall Costs; and

(ii) is caused by breach of SEPRACOR's representations or warranties as set forth in this Agreement or the Supply Agreement, including failure of SEPRACOR, or its Affiliates, its sublicensee or contractors, to handle, store, transport, market, promote, distribute, sell or use the Licensed Product in accordance with applicable laws and regulations or the terms of the applicable Approval, the Supply Agreement, the Quality Agreement or the gross negligence or willful misconduct of SEPRACOR, its Affiliates, sublicensee or contractors (collectively, "Fault of SEPRACOR"), SEPRACOR will be responsible for all Recall Costs.

15.7 Product Liability Claims.

(a) Notification to the Other. Each Party will notify the other Party as promptly as practicable if any Third Party claim is commenced or threatened against such Party alleging product liability, product defect, design, packaging or labeling defect, failure to warn or any similar action relating to the use or safety of any Licensed Product sold by or under authority of SEPRACOR, its Affiliates or sublicensee in the Territory (a "Product Liability Claim"). BIAL will notify SEPRACOR as promptly as practicable of any Product Liability Claim with respect to any Licensed Product sold by or under authority of BIAL outside of the Territory.

(b) Cooperation, Counsel and Control. Each Party will cooperate with the other Party in connection with any such Product Liability Claim that is commenced or threatened against the other Party. If a Product Liability Claim is asserted against both Parties, each Party will have the right to designate counsel to defend itself in the Product Liability Claim. If a Product Liability Claim is brought against one Party but not the other Party, the named Party will control the defense and/or settlement thereof at its own expense with counsel of its choice, subject to this Section 15.7. In such case, the other Party may participate in the

defense and/or settlement thereof at its own expense with counsel of its choice. In any event, the Party that is subject to a Product Liability Claim (if not asserted against both Parties) agrees to keep the other Party hereto informed of all material developments in connection with any such Product Liability Claim.

(c) Settlement, Admissions and Asserting Positions. Neither Party will settle any Product Liability Claim, or make any admissions or assert any position in such Product Liability Claim, in a manner that would adversely affect the other Party, the Licensed Product or the development, manufacture, use or sale thereof without the prior written consent of the other Party, which will not be unreasonably withheld or delayed.

(d) Bearing the Liabilities. To the extent a Product Liability Claim is caused by: (i) the Fault of BIAL, BIAL will bear all Liabilities from such Product Liability Claim to the extent of its fault, (ii) the Fault of SEPRACOR, SEPRACOR will bear all Liabilities from such a Product Liability Claim to the extent of its fault, or (iii) circumstances other than those described in Sub-section (i) or (ii), above, SEPRACOR will be solely responsible for the Liabilities from such Product Liability Claim.

ARTICLE 16

MISCELLANEOUS

16.1 Dispute Resolution:

(a) Any dispute, controversy or claim arising out of or relating to the alleged breach, termination, or invalidity of this Agreement will be submitted in the first instance to the Chief Executive Officer ("CEO") of BIAL, or such person's designee of equivalent or superior position, and the CEO of SEPRACOR, or such person's designee of equivalent or superior position.

(b) If the CEO's cannot resolve the dispute within thirty (30) days of receipt by the CEO's, the Parties agree that either Party may submit the dispute for arbitration in accordance

with the Rules of the International Chamber of Commerce ("ICC") in effect on the date of filing of the arbitration (the "Rules"), except as modified herein.

(c) If the amount in controversy, including claims and counterclaims, is less than five million dollars (US\$5,000,000) or if only injunctive relief is requested, there will be one arbitrator, who will be selected jointly by SEPRACOR and BIAL within twenty (20) days of receipt by respondent of a copy of the demand for arbitration. Such arbitrator will have sixty (60) days from the date of appointment to render a decision. If the amount in controversy may be five million dollars (US\$5,000,000) or more, or if the dispute involves the termination of this Agreement, there will be three neutral and impartial arbitrators, one appointed by SEPRACOR and one appointed by BIAL within twenty (20) days of receipt by respondent of a copy of the demand for arbitration, and the third arbitrator, who will serve as chair of the arbitral tribunal, will be appointed by agreement of the Party-appointed arbitrators within thirty (30) days of the appointment of the second arbitrator.

(d) Any arbitrator appointed in accordance with Section 16.1(c) will have significant experience with the arbitration of similar large, complex, commercial disputes between pharmaceutical companies. All arbitration proceedings will be conducted in the English language. The arbitration proceeding will be held and the award issued in London, England although the Parties may agree in writing to conduct the arbitration proceedings in a different location. The Parties agree that only documents directly relevant to the issues in dispute must be produced in any such arbitration. The arbitration will be conducted as expeditiously as practicable, and the Parties and the arbitrators will use their best efforts to hold the hearing on the merits no later than one hundred twenty (120) days after the appointment of the arbitration tribunal and the arbitrators will use their best efforts to issue a final award within twenty (20) days after the close of the hearing.

(e) In addition to damages, the arbitration tribunal may award any remedy provided for under applicable law and the terms of this Agreement, including, without limitation, specific performance or other forms of injunctive relief. The arbitration tribunal is not empowered to award damages in excess of compensatory damages, and each Party hereby irrevocably waives any right to recover punitive, exemplary, multiplied (including without limitation treble),

consequential or similar damages with respect to any dispute. The arbitration award must be in writing and will state, in English and in reasonable detail, the findings of fact and conclusions of law on which it is based. The arbitration award will be final and binding on the parties and will not be appealable except as otherwise provided for by applicable treaty or law and may be entered and enforced in any court having competent jurisdiction.

(f) Each Party will pay its own expenses of arbitration and the expenses of the arbitration tribunal and the ICC will be equally shared, except that if, in the opinion of the arbitration tribunal, any claim by a Party hereto or any defense or objection thereto by the other Party was unreasonable, the arbitration tribunal may in their discretion assess as part of the award all or any part of the arbitration expenses of the other Party (including reasonable attorneys' fees) and the fees and expenses of the arbitration tribunal and the ICC against the Party raising such unreasonable claim, defense or objection.

16.2 Either Party may, without inconsistency with this agreement to arbitrate, apply to a court to seek pre-arbitral provisional injunctive relief to maintain the status quo or prevent irreparable harm, pre-arbitral attachment, or any other relief or order in aid of arbitration proceedings and the enforcement of any award. Without prejudice to such provisional remedies as may be available under the jurisdiction of a court, the arbitration tribunal will have full authority to grant provisional remedies and to direct the Parties to request that any court modify or vacate any temporary or preliminary relief issued by such court, and to award damages for the failure of any Party to respect the arbitrator(s)' orders to that effect.

16.3 Force Majeure: If any circumstance beyond the reasonable control of either Party occurs which delays or renders impossible the performance of that Party's obligations under this Agreement on the dates herein provided (a "Force Majeure"), such obligation will be postponed for such time as the event of Force Majeure exists, provided such Party notifies the other Party in writing as soon as practicable, but in no event more than ten (10) Business Days after the inception of such event of Force Majeure. The Party so affected will give to the other Party a good faith estimate of the continuing effect of the Force Majeure condition and the anticipated duration of the affected Party's non-performance. Notwithstanding the foregoing, if the period of any previous actual non-performance of a Party because of Force Majeure conditions plus the

anticipated future period of non-performance because of such conditions will exceed an aggregate of one hundred eighty (180) days, then the Party unaffected by such event may terminate this Agreement by not less than sixty (60) days written notice of termination to the other Party; provided that, if the Force Majeure event ceases within such sixty (60) day period, this Agreement will remain in full force and effect. Events of Force Majeure will include, without limitation, war, revolution, invasion, insurrection, riots, mob violence, sabotage or other civil disorders, acts of God, limitations imposed by exchange control regulations or foreign investment regulations or similar regulations, laws, regulations or rules of any government or governmental agency, any inordinate delays in the regulatory review or governmental approval process that are within the sole control of such government or governmental agency. A Party will be considered affected by an event of Force Majeure to the extent that any of its suppliers or contractors is affected by such an event.

16.4 Assignment: Except as set forth in Section 14.2(d), neither Party may assign, transfer or otherwise dispose of this Agreement or any rights or obligation with respect thereto, to any other party without the prior written consent of the other Party, provided however that BIAL may assign or transfer this Agreement, or any part or right or obligation thereof, to any Affiliate, or in connection with the transfer or sale of all or substantially all of its assets related to the Licensed Products or the business to which this Agreement relates, without SEPRACOR's consent. Any attempted or purported assignment or transfer of rights or obligations other than provided herein will be void.

16.5 Performance by Affiliates: Either Party may exercise any of its respective rights and perform any of its respective obligations hereunder through any of its Affiliates.

16.6 No Third Party Beneficiaries: This Agreement does not confer any rights or remedies upon any person or entity other than SEPRACOR and BIAL and their respective successors and permitted assigns and sublicensees.

16.7 Waiver: The waiver by a Party, whether express or implied, of any provisions of this Agreement, or of any breach or default of a Party, will not be construed to be a continuing waiver of such provision, or of any succeeding breach or default, or a waiver of any other provisions of this Agreement.

16.8 Governing Law: All matters affecting the interpretation, validity, and performance of this Agreement will be governed by the laws of New York, U.S.A. without regard to its choice or conflict of law principles.

16.9 Unenforceable Provisions: Any provision hereof that is prohibited or unenforceable in any jurisdiction will, as to such jurisdiction, be ineffective only to the extent of such prohibition or unenforceability without invalidating the remaining provisions hereof or affecting the validity or enforceability of such provision in any other jurisdiction. The Parties will replace such ineffective provision for such jurisdiction with a valid and enforceable provision which most closely approaches the idea, intent, and purpose of this Agreement, and in particular, the provision to be replaced.

16.10 Relationship Between the Parties: BIAL and SEPRACOR are independent contractors and will not be deemed to be partners, joint venturers or each other's agents, and neither will have the right to act on behalf of the other except as may be expressly agreed to in writing.

16.11 Entire Agreement: It is the mutual desire and intent of the Parties to provide certainty as to their future rights and remedies against each other by defining the extent of their mutual undertakings as provided herein. The Parties have in this Agreement incorporated all representations, warranties, covenants, commitments and understandings on which they have relied in entering into this Agreement and, except as provided for herein, neither Party has made any covenant or other commitment to the other concerning its future action. Accordingly, this Agreement, the Supply Agreement, the PVEA and Quality Agreement and the exhibits attached hereto and thereto (i) constitute the entire agreement and understanding between the Parties with respect to the matters contained herein, and there are no promises, representations, conditions, provisions or terms related thereto other than those set forth in this Agreement, and (ii) supersedes all previous understandings, agreements and representations between the Parties, written or oral relating to the subject matter hereof. The Parties hereto may from time to time during the continuance of this Agreement modify, vary or alter any of the provisions of this Agreement, but only by written agreement of all Parties hereto.

16.12 Notices: All communications, reports, payments, and notices required by this Agreement will be addressed to the Parties at their respective addresses set forth below or to such other address as requested by a Party by notice in writing to the other Party.

If to BIAL:

BIAL

Attention: Dr. Luis Portela, President and Chief Executive
Officer

BIAL

Avenida da Siderurgia Nacional
4745-457 S. Mamede do Coronado
Portugal

Fax: +351 229 866 199

With a copy to:

Ricardo Chorão

Director, Legal Department

BIAL

Avenida da Siderurgia Nacional
4745-457 S. Mamede do Coronado
Portugal

Fax: +351 229 866 190

If to SEPRACOR:

SEPRACOR INC.

Attention: Adrian Adams, President and Chief Executive Officer
SEPRACOR INC.

84 Waterford Drive

Marlborough, MA 01752

USA

Fax: 508-357-7492

With a copy to:

Andrew I. Koven, Executive Vice President, General Counsel &
Corporate Secretary

SEPRACOR INC.

84 Waterford Drive

Marlborough, MA 01752

USA

Fax: 508-357-7511

All such notices, reports, payments, and communications will be made by First Class mail, postage prepaid, or by reputable overnight courier providing evidence of receipt, or by facsimile (and promptly confirm by mail or overnight courier), and will be considered made as of the date of confirmed receipt.

16.13 Headings: All headings in this Agreement are for convenience only and will not affect the meaning of any provision hereof.

16.14 Counterparts: This Agreement may be executed simultaneously in any number of counterparts, but all such counterparts taken together will constitute one and the same agreement. This Agreement, to the extent signed (and initialed in all pages) and delivered by means of a facsimile machine, will be treated in all manner and respects and for all purposes as an original agreement or instrument and will be considered to have the same binding legal effect as if it were the original signed version thereof delivered in person.

[Signature Page Follows]

IN WITNESS WHEREOF, and intending to be legally bound, the parties hereto have caused this Agreement to be executed by their duly authorized representatives as of the Effective Date.

BIAL - PORTELA & C^a, S.A

SEPRACOR INC.

By: /s/ Isabel Morgado

By: /s/ Adrian Adams

Its: Member of the Board

Its: President and CEO

Date: December 31, 2007

Date: December 31, 2007

By: /s/ José Redondo

Its: Member of the Board

Date: December 31, 2007

EXHIBIT A

BIAL PATENTS

1. US patent no 5,753,646
CA patent no 2180301
2. US patent no 7,119,197
US patent application no 11/525,811
CA patent application no 2447980
3. US patent no 7,241,886
CA patent application no 2448094
4. US patent no 7,189,846
CA patent application no 2525419
5. US patent application no 11/719,478
CA patent application no 2587726
6. US patent application no 11/572,077
CA patent application no 2574002
7. US patent application no 11/813,938
CA patent application no 2594869
8. PCT publication nos WO2006/120501
US patent application publication no US20060252745
US patent application publication no US20060252746
CA patent application no - awaiting filing receipt
9. PCT publication no WO2007/012793*

10. PCT publication no WO2007/094694*

11. PCT publication no WO2007/117166*

12. British Patent Application no 0700773.5*

13. US patent application No 60/982,790

* All U.S. and Canadian patents and patent applications based upon these applications will be deemed Bial Patents pursuant to Section 1.9 of the Agreement.

EXHIBIT B

BIAL TRADEMARKS

1. United States:

1.1. trademark application No. 78/775034 “ERELIB”;

1.2 trademark application No. 78/774997 “PAZZUL”.

2. Canada:

2.1. trademark application No. 1283186 “ERELIB”;

2.2 trademark application No. 1283185 “PAZZUL”.

EXHIBIT C

BIAL LOGO

Bial

EXHIBIT D

BIAL STUDIES

BIAL ONGOING OR PLANNED STUDIES

Non-Clinical:

Effects of 2-093, 195, 194 & OXC on neurodegeneration in mouse corneal kindling model

Brain PK of 194,195- impact of multidrug transporter inhibition

Effect of 2-093 on seizures and neurotransmitter amino acid concentrations after intrahippocampal microperfusion of latrunculin A in mice

99840 Functional assessment of effects of of BIA 2-093, BIA 2-194, BIA 2-195, Oxcarbazepine on Nav 1.9 (dorsal root ganglion typical sodium channels, "TTX-resistant") in transiently transfected mammalian cells

99839 Functional assessment of effects of BIA 2-093, BIA 2-194, BIA 2-195, Oxcarbazepine on Nav 1.8 in transiently transfected mammalian cells

ZNA11516 Experimental model: neuropathic pain in mice

83933 Effect of BIA 2-059 on the Ames test

783949 Effect of BIA 2-059 on the chromosomal aberration assay in Human peripheral lymphocytes

ZNA14666 A Mechanistic Study of BIA 2-093 and Related Compounds in a Mouse Hippocampal Slice Model of Epileptic Firing

ZNA14193.001 The Disposition of Total Radioactivity in the Mouse Following Single Oral and Single Intravenous Administration of [¹⁴C] BIA 2-093

ZNA14193.002 The Tissue Distribution of Total Radioactivity in the Mouse Following Single Oral Administration of [¹⁴C] BIA 2-093

ZNA15523 Investigation of Milk Transfer in the Mouse Following Single Oral Administration of [¹⁴C] BIA 2-093

ZNA17945 CSF Pharmacokinetic Study with BIA 2-093 in cynomolgus monkey

Juvenile toxicity study in the dog - planned

Mouse dependence study - planned

Clinical:

Study BIA 2-093 123 - Exploratory cognition & behavioural effects

Study BIA 2-093 124 - Confirmatory cognition & behavioural effects

Study BIA 2-093 125 - Drug-Drug interaction with Metformin

Study BIA 2-093 126 - Drug-Drug interaction with Gliclazide

Study BIA 2-093 127 - CSF vs plasma PK correlation

Study BIA 2-093 128 - Drug Drug Interaction with oral contraceptives at 800mg

Study BIA 2-093 206 – Efficacy & safety study in painful diabetic neuropathy

Study BIA 2-093 207 – Efficacy & safety in post herpetic neuralgia

Study BIA 2-093 208 - Cognitive and neuropsychological effects of ESL in Paediatrics

Study BIA 2-093 209 - Exploratory safety & efficacy in Migraine

Study BIA 2-093 210 - Exploratory safety & efficacy in Fibromyalgia

Study BIA 2-093 211 - Exploratory safety & efficacy in Familial Amyloidotic Polyneuropathy

Study BIA 2-093 304 - Non US phase IIIb to involve additional countries and investigators

Study BIA 2-093 305 – Phase III in children – Europe & others (non US)

Others

Drug Product Process Validation Control

EXHIBIT E

MINIMUM SALES

The agreed minimum annual sales in Net Sales (the "Minimum Sales") for years two and three of commercialization of Licensed Products in Territory following launch in the U.S. are:

YEAR TWO: \$20,000,000
YEAR THREE: \$40,000,000

EXHIBIT F

PRESS RELEASE

Sepracor Inc. and Bial Announce Exclusive Licensing Agreement for Development and Commercialization of Anti-Epileptic Compound in United States and Canada

BIA 2-093, Eslicarbazepine Acetate, has Completed Large-Scale Phase III Clinical Studies

Submission of U.S. New Drug Application (NDA) Anticipated Late 2008 or Early 2009

U.S. Anti-Epileptic Market Estimated at Approximately \$4 Billion in 2006

MARLBOROUGH, Mass. & S. MAMEDE DO CORONADO, Portugal--(BUSINESS WIRE)--Jan. 2, 2008--Sepracor Inc. (Nasdaq: SEPR) and Bial today announced an exclusive licensing agreement for the development and commercialization of Bial's anti-epileptic compound BIA 2-093 in the United States and Canada. Under the terms of the agreement, Sepracor will be responsible for filing the U.S. NDA and seeking marketing approval from the U.S. Food and Drug Administration (FDA), and contingent on obtaining regulatory approval, commercialization of the product in the U.S. Sepracor anticipates that the NDA will be submitted to the FDA in late 2008 or early 2009 with a potential product launch in late 2009 or early 2010, subject to FDA approval. In exchange, Bial is entitled to receive an upfront payment of \$75 million and subsequent payments upon accomplishment of various development and regulatory milestones, which could include up to an additional \$100 million if all milestones are met. Bial will also receive compensation for providing finished product and milestone payments upon FDA approval of additional indications, if any.

"We are very pleased with the addition of this late-stage asset to our growing product pipeline," said Adrian Adams, President and Chief Executive Officer of Sepracor. "Strategically, BIA 2-093 further strengthens our existing central nervous system portfolio, which includes LUNESTA(R) brand eszopiclone for the treatment of insomnia, as well as earlier-stage candidates for various central nervous system disorders. This milestone in-licensing event is reflective of our overall global corporate strategy to fully leverage our product franchises and commercial infrastructure while driving enhanced research and development productivity and successfully pursuing aligned and value-enhancing corporate development and licensing initiatives."

"In Sepracor we have found a partner who truly shares our vision and commitment to this compound and a company with a proven commercial track record in the U.S. market. This is a landmark event for BIAL and represents the first result of our R & D work within the CNS area. I am very proud of the people within BIAL who have helped to make this happen through their hard work and dedication" said Luis Portela, President and Chief Executive Officer of Bial.

BIA 2-093 (eslicarbazepine acetate) is a new chemical entity which has been designed to offer patients suffering with partial epilepsy additional control of their seizures and improved quality of life. Bial is currently completing clinical evaluation of BIA 2-093 for the adjunctive use in partial seizures in adults with epilepsy.

Eslicarbazepine acetate has been shown in clinical studies to be safe and effective in the control of seizures as adjunctive therapy in adults. Bial has tested the compound in three Phase III trials in 22 countries with over one thousand patients randomized to an 18-week acute double-blind therapy and subsequently followed in a one year, open label extension study. The potential for once-daily administration could be an important clinical advantage for patients with epilepsy in the U.S. and Canada. In addition, there may be benefits to patients such as reduced drug-drug interactions, which may distinguish this drug from commonly used compounds such as carbamazepine.

According to the National Institute of Neurological Disorders and Stroke, epilepsy is a brain disorder in which clusters of nerve cells, or neurons, in the brain sometimes signal abnormally. In epilepsy, the normal pattern of neuronal activity becomes disturbed, causing strange sensations, emotions, and behavior or sometimes convulsions, muscle spasms, and loss of consciousness. Epilepsy is a disorder with many possible causes. Anything that disturbs the normal pattern of neuron activity - from illness to brain damage to abnormal brain development - can lead to seizures. Epilepsy may develop because of an abnormality in brain wiring, an imbalance of nerve signaling chemicals called neurotransmitters, or some combination of

these factors.

About Sepracor

Sepracor Inc. is a research-based pharmaceutical company dedicated to treating and preventing human disease by discovering, developing and commercializing innovative pharmaceutical products that are directed toward serving unmet medical needs. Sepracor's drug development program has yielded a portfolio of pharmaceutical products and candidates with a focus on respiratory and central nervous system disorders. Currently marketed products include LUNESTA brand eszopiclone, XOPENEX(R) brand levalbuterol HCl Inhalation Solution, XOPENEX HFA(R) brand levalbuterol tartrate Inhalation Aerosol and BROVANA(R) brand arformoterol tartrate Inhalation Solution. Sepracor's corporate headquarters are located in Marlborough, Massachusetts.

About Bial

Bial is a Portuguese research-based pharmaceutical company headquartered in S. Mamede do Coronado, Portugal, whose goal is to improve health and wellbeing. Bial was founded in 1924 and is the largest Portuguese pharmaceutical company with an international presence in over 30 countries. It is the partner of choice for many global companies wishing to commercialize products within the Iberian Peninsula, Latin America and Africa. Research and development is focused on the central nervous and cardiovascular systems and Bial currently has several other innovative programs under development, which the company expects to bring to the market within the next years.

Sepracor Forward-Looking Statement

This news release contains forward-looking statements that involve risks and uncertainties, including statements with respect to the safety, efficacy and potential benefits of BIA 2-093; the timing and success of regulatory events relating to BIA 2-093, including the possible submission of an NDA late 2008 or early 2009 and potential commercialization in late 2009 or early 2010; and future payments by Sepracor to Bial. Among the factors that could cause actual results to differ materially from those indicated by such forward-looking statements are: clinical benefits, efficacy and safety of BIA 2-093; the timing and success of submission, acceptance, and approval of regulatory filings for BIA 2-093; unexpected delays in commercial introduction of, and the commercial success of, BIA 2-093; the success of Sepracor's alliance with Bial; Sepracor's ability to obtain favorable reimbursement approval levels, or obtain reimbursement approval at all, for BIA 2-093, if approved for commercialization; the scope of Bial's and/or Sepracor's patents and the patents of others; the ability of Sepracor and Bial to attract and retain qualified personnel; and certain other factors that may affect future operating results that are detailed in Sepracor's quarterly report on Form 10-Q for the quarter ended September 30, 2007 filed with the Securities and Exchange Commission.

In addition, the statements in this press release represent Sepracor's expectations and beliefs as of the date of this press release. Sepracor anticipates that subsequent events and developments may cause these expectations and beliefs to change. However, while Sepracor may elect to update these forward-looking statements at some point in the future, it specifically disclaims any obligation to do so. These forward-looking statements should not be relied upon as representing Sepracor's expectations or beliefs as of any date subsequent to the date of this press release.

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"Safe Harbor" Statement under the Private Securities Litigation Reform Act of 1995: Statements in this press

release regarding Sepracor Inc.'s business which are not historical facts are "forward-looking statements" that involve risks and uncertainties. For a discussion of such risks and uncertainties, which could cause actual results to differ from those contained in the forward-looking statements, see "Risk Factors" in the Company's Annual Report or Form 10-K for the most recently ended fiscal year.