UNITED STATES SECURITIES AND EXCHANGE COMMISSION Washington, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 OR 15(d) of The Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): May 3, 2010

BIOSANTE PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware	001-31812	58-2301143	
(State or other jurisdiction	(Commission File Number)	(IRS Employer Identification No.)	
of incorporation)			
111 Barclay Boulevard	l		
Lincolnshire, Illinois		60069	
(Address of principal executive offices)		(Zip Code)	
Registrant's	telephone number, including area code: (8	47) 478-0500	
	N/A		
(Former r	name or former address, if changed since l	ast report.)	
Check the appropriate box below if the Forunder any of the following provisions:	m 8-K filing is intended to simultaneously	v satisfy the filing obligation of the registrant	
o Written communications pursuant to R	ule 425 under the Securities Act (17 CFR	230.425)	
o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)			
Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))			
o Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))			

Section 8 — Other Events

Item 8.01. Other Events.

BioSante Pharmaceuticals, Inc. is filing this current report on Form 8-K to file as an exhibit the license agreement dated December 3, 2008 between BioSante Pharmaceuticals, Inc. and Azur Pharma International II, Limited, as amended.

Section 9 — Financial Statements and Exhibits

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.

Description

10.1 License Agreement dated December 3, 2008 between BioSante Pharmaceuticals, Inc. and Azur Pharma International II, Limited*

10.2 Amendment No. 1 to License Agreement and Asset Purchase Agreement dated December 7, 2009 between BioSante Pharmaceuticals, Inc. and Azur Pharma International II, Limited*

^{*} Confidential treatment has been requested with respect to designated portions of this document. Such portions have been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

BIOSANTE PHARMACEUTICALS, INC.

By: /s/ Phillip B. Donenberg Phillip B. Donenberg Chief Financial Officer, Treasurer and Secretary

Dated: May 3, 2010

BIOSANTE PHARMACEUTICALS, INC.

FORM 8-K

<u>Exhibit Index</u>

Exhibit No.	Description	Method of Filing
10.1	License Agreement dated December 3, 2008 between BioSante Pharmaceuticals, Inc. and Azur Pharma International II, Limited (*)	Filed herewith
10.2	Amendment No. 1 to License Agreement and Asset Purchase Agreement dated December 7, 2009 between BioSante Pharmaceuticals, Inc. and Azur Pharma International II, Limited (*)	Filed herewith

* Confidential treatment has been requested with respect to designated portions of this document. Such portions have been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

[Portions of this Exhibit have been omitted pursuant to a request for confidentiality under Rule 24b-2 of the Securities Exchange Act of 1934, as amended. A copy of this Exhibit with all sections intact has been filed separately with the Securities and Exchange Commission.]

LICENSE AGREEMENT

This AGREEMENT ("Agreement"), dated December 3, 2008 is made by and between BioSante Pharmaceuticals, Inc., 111 Barclay Boulevard, Lincolnshire, IL 60069 ("BPA"), and Azur Pharma International II Limited, a Bermuda limited liability company, Clarendon House, 2 Church Street, Hamilton HM 11, Bermuda and such of its Affiliates as it may designate from time to time under one or more provisions of this Agreement ("Company").

WHEREAS, BPA is the owner of know-how associated with the manufacture and distribution of Elestrin.

WHEREAS, BPA has certain rights under that certain License Agreement dated as of June 13, 2000, as amended in a series of six amendments, as follows: Amendment No. 1 dated May 20,2001; Amendment No. 2 dated July 5, 2001; Amendment No. 3 dated August 30,2001; Amendment No. 4 dated August 8,2002; Amendment No. 5 dated December 30,2002; and Amendment No. 6 dated October 10,2006 with three clarifying letters dated October 27,2006, November 6, 2006, and November 7, 2006 (the foregoing collectively the **"Antares License Agreement")** from Antares Pharma IPL AG **("Antares")**, successor in interest to Permatec Technologie, AG, such License Agreement and amendments together being attached as <u>Exhibit C</u>.

WHEREAS, Company desires to obtain a license to BPA's know-how concerning Elestrin and to obtain a sublicense under the Antares License Agreement as it concerns Elestrin.

WHEREAS, BPA desires to grant such licenses to Company, and further to grant such sublicense subject to the limitations and applicable terms of the Antares License Agreement.

NOW THEREFORE, BPA and Company (collectively, the "Parties" and each individually, a "Party") agree as follows:

1. Definitions.

(a) "<u>Affiliate</u>" shall mean any corporation or other business entity that directly or indirectly controls, is controlled by, or is under common control with a party. Control means ownership or other beneficial interest in 50% or more of the voting stock or other voting interest of a corporation or other business entity.

(b) "<u>Assigned Contracts</u>" means (i) all purchase orders for the Product received by BPA or any of its Affiliates prior to the Closing Date but not shipped prior to 11:59 p.m. (EST) on the Closing Date and (ii) those purchase orders placed by BPA and set forth on <u>Schedule 1(b)</u> hereto.

- (c) "Authorized Marks" has the meaning set forth in Section 2(c)
- (d) "Azur Parent" means Azur Pharma Limited, an Irish limited liability company.

(e) "Business" means the development, manufacture, packaging, handling, storage, distribution and transport of the Product in and outside the Territory as relates to the promotion, marketing and sale of the Product in the Territory.

(f) "Change in Control" means, with respect to BPA, (i) the current shareholders of BPA ceasing to own a majority of the outstanding voting stock of BPA (ii) BPA merging, consolidating, or otherwise combining with any other Person and, immediately following such transaction, the current shareholders of BPA cease to own a majority of the voting stock or other equity interests of the Person surviving such transaction, (iii) BPA selling or otherwise transferring or disposing of all or substantially all of its assets or business.

(g) "<u>Commercially Reasonable Efforts</u>" means efforts and resources used by a participant in the pharmaceutical industry consistent with the prudent exercise of reasonable business judgment with respect to a product owned by it or to which it has rights (exclusive or non-exclusive, as the case may be), which is of similar market potential, at a similar stage in its product life, taking into account the competitiveness of the marketplace, including generic competition, applicable regulatory impediments, and reimbursements available for the product. For clarity, with respect to the promotion, marketing, and sale of Product, it shall not be Commercially Reasonable to substantially discontinue the distribution of Product or to substantially discontinue manufacture (or purchase from DPT) of Product for sale to customers. In the case of BPA, "Commercially Reasonable Efforts" means efforts and resources used by a participant in the pharmaceutical industry consistent with the prudent exercise of reasonable business judgment with respect to a product out-licensed by it, which is of similar market potential, at a similar stage in its product life, taking into account the competitiveness of the marketplace, including generic competition, applicable regulatory impediments, and reimbursements available for the product out-licensed by it, which is of similar market potential, at a similar stage in its product life, taking into account the competitiveness of the marketplace, including generic competition, applicable regulatory impediments, and reimbursements available for the product.

(h) "<u>Competitive Product</u>" means a pharmaceutical product that (i) contains estrogen as its sole active ingredient; (ii) is delivered transdermally other than as a patch or vaginal delivery; and (iii) is marketed for the Launch Indication.

(i) "<u>Contracts</u>" means all unexpired contracts, agreements, purchase orders, licenses, or other binding arrangements with Third Parties to which BPA or any of its Affiliates is a Party, to the extent and solely to the extent related to the Intellectual Property Rights, the Business of the Product or the transactions contemplated by this Agreement. For clarity, "Contracts" does not include the Antares License Agreement. Contracts are set forth in <u>Schedule 1(i)</u>.

(j) "Dollars" and the symbol "\$" each means lawful money of the United States of America.

(k) "FDA" means the Food and Drug Administration or any successor agency hereof.

(l) "Field" shall mean all uses licensed and permissible under the Antares License Agreement for the Product, including the field of transdermal gel preparations.

(m) "<u>Force Majeure</u>" shall mean acts of God, explosion, fire, flood, tornadoes, thunderstorms, earthquake or tremor, war whether declared or not, civil strife, <u>riots</u> or embargo, or changes in applicable laws, regulations or orders by any government, governmental agency or instrumentality, strikes, shortage of labor, fuel, power or raw materials, inability to obtain supplies, or other circumstances (whether or not similar or dissimilar to the foregoing), in each case beyond the reasonable control of a party and having the effect of preventing, prohibiting or delaying such party from performing its obligations hereunder.

(n) "<u>Fundamental Rep</u>" means any of the representations and warranties set forth in Section 11(a)(viii) (Power and Authorization), Section 11(a)(ix) (Authorization of Regulatory Authorities), Section 11(a)(x) (Noncontravention), Section 11(a) (xi)(Encumbrances), Section 11(a)(xii(a)) (Title), Section 11(a)(xviii) (Taxes) and Section 11(a)(xx) (No Brokers).

(o) "Intellectual Property Rights" means, with respect to the Product, any and all intellectual property rights owned or controlled (including by means of any license or sublicense, provided that such rights can be licensed or sublicensed to a Third Party) by BPA or its Affiliates in or with respect to the Territory that are solely or primarily directed to the formulation, manufacture, packaging, promotion, distribution, marketing, sale, offering for sale, use, making, importing or exporting of the Product, as each such business has been conducted in the ordinary course, including any and all such rights constituting:
(i) Patents, invention disclosures and invention assignments; (ii) copyrights and other works including art work used in the labeling of the Product and related digital files; (iii) the Know-How; (iv) Trade Secrets; (v) all applications, registrations, or common law or unregistered rights relating to any of the foregoing; and (vi) all rights to obtain renewals, continuations, divisions and/or patent term extensions or SPCs or other extensions of legal protections pertaining to any of the foregoing.

(p) "Know How" shall mean all methods, processes, techniques, compositions, technology, information, data, results of tests, studies, statistical and other analyses and expertise, which are not generally known including, but not limited to, patent claims and related information not yet disclosed to the public, formulae, procedures, protocols, manufacturing technology relating to Product that is used by BPA or its Affiliates and is necessary for the formulation, manufacture, packaging, release testing, and stability and shelf life determination of Product in the Territory, including, but not limited to, specifications and test methods, manufacturing and packaging instructions, master formula, validation reports (process, analytical methods and cleaning), stability data and analytical methods, clinical and non-clinical safety and efficacy studies, marketing studies and absorption, excretion and metabolism studies, quality control and quality assurance processes, regulatory filings including, without limitation, NDAs, information relating to planned Phase IV trials or planned line extensions, techniques, and results of experimentation and testing, which (i) relate to the Product, and (ii) are necessary or useful to the development, marketing or manufacture of the Product in the Territory (in the case of manufacture, worldwide), all to the extent as of the Closing Date of this Agreement owned or controlled (including by means of any license or sublicense, provided that such rights can be licensed or sublicensed to a Third Party) by BPA or its Affiliates.

(q) "<u>Knowledge</u>" means, with respect to BPA and with respect to any particular matter, the actual knowledge of one or more of the employees of BPA as of the Closing Date.

(r) **"<u>Launch Indication</u>**" shall mean the treatment of hot flashes (vasomotor symptoms) in menopausal women or associated with the menopause.

(s) "Laws" means all federal, state, and local laws, statutes, ordinances, regulations and rules and published guidelines or pronouncements having the effect of law promulgated by any Regulatory Authority, including the United States Food, Drug and Cosmetic Act, as amended, and the rules and regulations promulgated thereunder, the Medicare and Medicaid Patient Act of 1987, as amended, and the rules and regulations promulgated thereunder, the Prescription Drug Marketing Act of 1987, as amended, and the rules and regulations promulgated thereunder, and including all other laws, rules and regulations governing the marketing, advertising, distribution and sale of the Product in the Territory.

(t) "Liability" means any liability (whether known or unknown, asserted or unasserted, absolute or contingent, accrued or unaccrued, liquidated or unliquidated, and due or to become due), including any liability for Taxes.

(u) "Losses" has the meaning set forth in Section 15(a) below.

(v) "<u>Material Adverse Effect</u>" means a material adverse effect on the assets, financial condition or results of operations of the Business taken as a whole, or a material adverse effect on the formulation, manufacture, packaging, promotion, distribution, marketing and sale of the Product in the Territory, provided that in no event will any of the following, individually or in the aggregate, be deemed to constitute, nor shall any of the following be taken into account in determining whether there has been, or will be, a Material Adverse Effect with respect to such Person, or with respect to a Business: (A) any change in general economic or financial market conditions, (B) any change in the general state of the industry in which such Person operates, (C) any act of terrorism or war, (D) the announcement of the execution of this Agreement or the transactions contemplated hereby, or (E) any act or omission by BPA in compliance pursuant to and in accordance with the terms of this Agreement.

(w) "<u>NDA</u>" means the New Drug Application for the Product.

(x) "<u>Net Sales</u>" shall mean the aggregate arms-length gross price invoiced by Company or its Affiliates for the sale for commercial use of Product to non-affiliated Third Parties during the relevant period, less deductions for (i) normal and customary trade and cash discounts, credits and allowances, normal and customary provisions for rejections and returns of Product, wholesaler fees, rebates or refunds incurred or granted; (ii) sales, use or excise taxes and duties, and freight and insurance, to the extent included in the gross price charged; (iii) normal credits and chargebacks consistent with customary practices in the industry; (iv) sales credits, refunds, returns and allowances actually given, paid or received, as applicable; and (vi) bad debts to the extent that the debt written off was previously included in calculating Net Sales. Such amounts shall be determined from books and records maintained by Company in accordance with GAAP, consistently applied. For clarity, sales between or among Company and/or its Affiliates shall be excluded from the computation of Net Sales, and in such case Net Sales shall be calculated based on the first sale to a non-affiliated Third Party.

In the event that Product is sold together with one or more other products by the process known as "bundling," or if discounts and rebates for Product are calculated in whole or in part based on the sales of other products, then for the purpose of calculating the applicable Net Sales, Company shall not apply any proportionately greater discount or rebate to Product than the smallest applied to any other product with which it is sold; but for the avoidance of doubt rebates and/or discounts applicable specifically to sales of the Product shall be counted as deductions in full.

(y) "<u>New Indication</u>" shall mean the development and commercialization of Product in any other indication but the Launch Indication.

(2) "<u>Party</u>" or "<u>Parties</u>" has the meaning set forth in the preamble above.

(aa) "<u>Patents</u>" shall mean those patents and patent applications that are (1) owned by BPA or (2) licensed to BPA at any time during the term of this Agreement with the right to sublicense under the Antares License Agreement and that claim (i) the Product (including methods of manufacture and/or use) in the United States; or (ii) the manufacture of Product outside of the United States. Independent claims of such Patents that embrace both the Product and other compositions that comprise hormones other than estrogen shall be deemed, together with any claims that depend therefrom, "Group One Claims." Independent claims of such Patents that embrace compositions that comprise hormones other than estrogen shall be deemed, together with any claims that depend therefrom, "Group Two Claims." The Patents are listed in <u>Schedule l(aa)</u> hereto.

(bb) **"<u>Permitted Encumbrances</u>"** means (i) encumbrances for Taxes (a) not yet due and payable and arising in the ordinary course of business or (b) being contested in good faith so long as adequate provision therefor has been made in accordance with GAAP; (ii) statutory and contractual encumbrances of landlords, carriers, warehousemen, mechanics, materialmen, suppliers and repairmen, and other like encumbrances, incurred in the ordinary course of business and not yet delinquent or being contested in good faith; and (iii) encumbrances and other matters specifically disclosed by BPA in <u>Schedule 1(bb)</u> hereto.

(cc) "**Person**" means an individual, a corporation, a general partnership, a limited partnership, a limited liability company, a limited liability partnership, an association, a trust or any other entity or organization, including a governmental authority.

(dd) "<u>Phase IV</u>" means, as applicable, a study or program designed to obtain additional safety or efficacy data, detect new uses for or abuses of the Product, or to determine effectiveness for labeled indications under conditions of widespread usage, which is commenced after regulatory approval of the Product.

(ee) "<u>Product</u>" shall mean that certain product currently known as Elestrin, together with any improvements or modifications thereto that are under the NDA and for the avoidance of doubt including such product at the sample unit size.

(ff) "Quarter" means a three-month period ending on March 31st, June 30th, September 30th or December 31st; provided, however, that (i) the initial Quarter shall begin on the Closing Date and end on December 31, 2008.

(gg) "<u>**Regulatory Authority**</u>" means any federal, state, local, foreign or international governmental regulatory body or agency with regulatory authority over pharmaceuticals or the Business, including the FDA.

(hh) "**Royalty Term**" means the period starting on the Closing Date and ending upon the later of (i) the expiration of the last to expire of the Patents with at least one Valid Claim covering the Product (including its use or manufacture) in the Territory and (ii) December 31, 2023. However, if BPA or Antares obtains a patent during the term of this Agreement that achieves exclusivity for the Product in the Territory, then the Royalty Term shall continue for the life of that patent and provided that such exclusivity is maintained.

(ii) "Taxes" (and with correlative meanings, "Tax" and "Taxable") means all taxes of any kind imposed by a federal, state, local or foreign governmental authority, including, but not limited to, those on, or measured by or referred to as, income, gross receipts, financial operation, sales, use, ad valorem, value added, franchise, profits, license, withholding, payroll (including all contributions or premiums pursuant to industry or governmental social security laws or pursuant to other laws and regulations), employment, excise, severance, stamp, occupation, premium, property, transfer or windfall profits taxes, customs, duties or similar fees, assessments or charges of any kind whatsoever, together with any interest, surcharges and penalties, additions to tax or additional amounts imposed by such governmental authority with respect to such amounts.

(jj) "<u>Territory</u>" shall mean the United States of America and those of its territories and possessions over which the FDA has regulatory authority.

(kk) "Third Party" means any Person other than any Party or any of its respective Affiliates.

(ll) "Third Party Claim" has the meaning set forth in Section 15(b) below.

(mm) "Trade Secret" means information, including technical and non-technical data, a formula, pattern, compilation, program device, method, technique, process or other information similar to any of the foregoing, that derives economic value, actual or potential, from not being generally known to, and not being readily ascertainable by other Persons who can derive economic value from its disclosure or use, which (i) relate to the Product, and (ii) are necessary or useful to the development, marketing or manufacture of the Product in the Territory (in the case of manufacture, worldwide), all to the extent as of the Closing Date of this Agreement owned or controlled (including by means of any license or sublicense, provided that such rights can be licensed or sublicensed to a Third Party) by BPA or its Affiliates.

(nn) "<u>Valid Claim</u>" means any claim of an issued and unexpired Patent that has not been held unenforceable or invalid by a court or other governmental agency of competent jurisdiction in an unappealed or unappealable decision, and that has not been disclaimed or admitted to be invalid or unenforceable through reissue or otherwise, which claim would be infringed by the manufacture, use, importation, offer for sale, or sale of Product but for the license and sublicense granted herein.

(oo) Other capitalized expressions in this Agreement have the meanings attributed to them within the Section(s) of this Agreement in which they first appear.

2. License Grant; the Antares License Agreement.

(a) BPA grants to Company and its current Affiliates* upon and subject to all the terms and conditions of this Agreement, (i) an exclusive sublicense under BPA's rights under the Intellectual Property Rights, including the Patents and an exclusive license under Know How to make, have made, use, sell, offer for sale, import, and develop Product in the Field in the Territory and (ii) a non-exclusive sublicense (limited to Canada, New Zealand, South Africa, Israel, Mexico, The People's Republic of China (including Hong Kong), and Indonesia) under BPA's rights under the Patents and a nonexclusive license under Know How to make and have made Product for importation of the Product into the Territory for sale by Company in the Field in the Territory, *provided that* Company agrees that it shall not use any such rights for any other purpose.

In order to permit Company to conduct development activities outside the Territory for the purpose of furthering Company's license rights inside the Territory, BPA additionally grants Company a non-exclusive license under the Intellectual Property Rights to conduct clinical trials and further development of Product in any country of what is defined as the "Territory" in the Antares License Agreement ("<u>Antares Territory</u>"), but only for the purpose of Company's exercise of its rights inside the Territory as granted in this Agreement, and not for the sale, marketing, registration, or other commercial exploitation of Product (or other license rights) outside the Territory.

In order to permit BPA to conduct development activities inside the Territory for the purpose of furthering its rights and interests outside the Territory, the grant of an exclusive license to Company in this Agreement shall not prohibit BPA from conducting clinical trials and further development of Product in the Territory (excluding the sale, marketing, registration, or other commercial exploitation of Product inside the Territory) for the purpose of BPA's exercise of rights and interests outside Territory.

(b) During the Royalty Term BPA (including its Affiliates) shall not (i) make, have made, sell, market, or distribute Competitive Product in the Territory, nor (ii) license any Third Party to develop, make, have made, sell, market, or distribute Competitive Product in the Territory. However, in the event that BPA is acquired by a Third Party that is developing or marketing a Competitive Product at the time of acquisition, this Section 2(b) shall not require the acquiring company to discontinue the development or sale of such product so long as the acquiring company complies in all other respects with the obligations of BPA under this Agreement.

(c) Subject to the terms and conditions of this Agreement, BPA hereby grants to Company a nonexclusive license with respect to BPA's company names and logos and other trademarks of BPA appearing in the trade dress or packaging of the Purchased Inventory **("Authorized Marks")**, limited and to the extent necessary to resell and distribute pursuant to this Agreement such items of Purchased Inventory bearing such names, logos, and other trademarks. In exercise of its rights under this Section 2(c), Company (i) shall maintain the quality of such Purchased Inventory to preserve the reputation and goodwill of the names, logos, and other trademarks, and (ii) shall not modify such names, logos, and other trademarks. All goodwill associated with such names, logos, and other trademarks shall remain the property of, and inure to the benefit of, BPA.



(d) Company shall have no liability or responsibility for any obligation or liability arising under the Antares License Agreement to the extent that such obligation or liability arose during, or relates to, the period prior to the Closing Date or to any Product sold into the distribution channel prior to the Closing Date. Company shall have no liability or responsibility for any obligation or liability arising under the Antares License Agreement to the extent that such obligation or liability arose during, or relates to, the period after the Closing Date other than those contemplated by Section 2(e). BPA shall remain responsible to Antares for all obligations of BPA and its other licensees under the Antares License Agreement, subject to and in accordance with the terms thereof, except to the extent that Company has assumed such obligations pursuant to Section 2(e) of this Agreement.

(e) Company recognizes that certain rights granted in this Agreement derive from and are subservient to the Antares License Agreement. Notwithstanding any other provision in this Agreement, this Agreement does not and shall not be read to grant to Company any rights in or to Antares' intellectual property that are not granted to BPA with the right to sublicense under the Antares License Agreement. The provisions of the Antares License Agreement that are required to be incorporated into this Agreement are hereby incorporated into this Agreement. Further, Company agrees that it shall be bound by those obligations set forth in the Antares License Agreement but only to the extent that the Antares License Agreement affirmatively imposes or requires such obligations to be imposed on sublicensees of BPA and only to the extent such obligations were in effect on the Closing Date and relate to the Product in the Territory as are set forth in Exhibit C. Without prejudice to the generality of the foregoing, Company shall have no obligation to pay any monies to Antares pursuant to the Antares License Agreement whether prior to or subsequent to the Closing Date, and any and all amounts payable thereunder shall remain the responsibility of BPA. As for any additional obligations under the Antares License Agreement binding upon sublicensees which arise after the Closing Date, by amendment of the Antares License Agreement or otherwise, Company shall be bound only to those specific additional obligations to which it has agreed to be bound in a written amendment to this Agreement duly executed by Company. BPA shall not without the Company's prior written consent agree to an amendment of the Antares License Agreement that would be binding on Company. Company shall not knowingly take any action (or refuse or omit to take any action) mat would cause a breach of the Antares License Agreement, and any termination of rights resulting from such a breach shall not be an event of a breach of this Agreement by BPA. In connection with the foregoing, Company shall reasonably cooperate with BPA in all respects (including making available relevant employees, records, papers, information, samples, specimens, and the like) to timely cure or resolve any dispute between Antares and BPA relating to the Antares License Agreement, or any alleged breach of the Antares License Agreement. Such cooperation shall be at BPA's expense unless the underlying dispute or alleged breach results from action or inaction by Company in contravention of Company's obligations and rights hereunder, in which case it shall be at Company's expense.

(f) BPA covenants with Company that during the Royalty Term (i) BPA shall not take any action (or refuse to take any action) that would cause a breach of the Antares License Agreement or termination of the rights granted under the Antares License Agreement; (ii) BPA shall take Commercially Reasonable actions to timely cure any breach of the Antares License Agreement, and (iii) if BPA becomes aware of any alleged or actual breach by BPA of the Antares License Agreement (including without limitation by receipt of a notice from Antares thereof), BPA shall promptly provide Company a detailed notice of the nature and circumstances of such breach and a copy of any notice provided by Antares to BPA. BPA further covenants that it will not during the Royalty Term terminate the Antares License Agreement that are derived from the Antares License Agreement on the same or better terms without increasing the obligations of Company under this Agreement. BPA will not agree to any amendment to the Antares License Agreement that adversely effects the Product in the Territory, the rights of Company or the obligations of Antares with respect to the Product in the Territory without Company's prior written consent, which consent shall not be unreasonably withheld, delayed or conditioned.

(g) Intentionally omitted.

(h) During the term of this Agreement, BPA shall, at Company's request, exercise Commercially Reasonable Efforts to enforce the exclusivity of the license rights granted to BPA pursuant to the Antares License Agreement with respect to Product in the Territory if such rights are violated by Antares or any Third-Party licensee of BPA. BPA agrees that it will use Commercially Reasonable Efforts to enforce its rights under the Antares License Agreement insofar as such rights pertain to the Product in the Territory on Company's behalf, for Company's benefit, and, except to the extent prohibited by the Antares License Agreement or applicable Laws, in consultation with Company. In addition, BPA shall use Commercially Reasonable Efforts in its dealings with Antares (without being required to pay any fees or amounts) to procure the benefit of the provisions of Section 16 of this Agreement for Company. Without limiting the generality thereof, the foregoing shall include keeping Company informed in a timely manner (including providing Company with copies of all correspondence and notices) of all material matters arising under the Antares License Agreement pertaining to the Product in the Territory of which BPA or its Affiliates have Knowledge.

(i) All rights and interests not expressly granted to Company are reserved by BPA.

(j) Company and its Affiliates shall not sell or otherwise distribute Product to customers outside of the Territory or to any party who the Company or BPA has reasonable grounds to believe is likely to export Product outside the Territory. All inquiries or orders received by Company for Product to be delivered outside the Territory shall be referred by Company to BPA. BPA and its Affiliates shall not sell or otherwise distribute Product to customers within the Territory or to any party who the Company or BPA has reasonable grounds to believe is likely to import Product into the Territory. BPA shall require its licensees or sublicensees who sell or otherwise distribute Product to make a covenant similar to that provided by BPA in this Section 2(j) with respect to Product. All inquiries or orders received by BPA for the Product to be delivered within the Territory shall be referred by BPA to Company.

(k) Intentionally omitted.



3. Up-Front License Fees. Royalties and Milestones.

(a) In consideration of the grant of the licenses to Know-How and the grant of a license and sublicense of the Patents, Company shall pay to BPA:

(i) an upfront payment of \$500,000 at the Closing;

(ii) subject to the provisions of subparagraph (2) below and Section 16(b) royalty payments during the Royalty Term as follows:

(1) 10% on Net Sales below \$10 million of the Product in the Territory in a calendar year;

(2) 20% on Net Sales between \$10 million and \$17.5 million of the Product in the Territory in a calendar year;

and

(3) 10% on Net Sales above \$17.5 million of the Product in the Territory in a calendar year.

(1) Single Royalty. The royalty provided in Section 3(a)(ii) shall not increase for the Product by reason of the Product being covered by more than one Valid Claim or the Product being covered both by one or more Valid Claims and by Know How.

(2) In the event that one or more generic versions of the Product that is approved under 21 U.S.C. 355(j) (or any successor legislation) or which has an "AB" rating with respect to that Product, is sold by a Third Party in the Territory, for the remainder of the Royalty Term the Royalty payable pursuant to Section 3(a)(ii) shall be reduced by xxx% of Net Sales so that the royalty payments for the remainder of the Royalty Term shall be as follows:

(a) xxx% on Net Sales below \$xxx million of the Product in the Territory in a calendar year;

and

(b) xxx% on Net Sales between \$xxx million and \$xxx million of the Product in the Territory in a calendar year;

(c) xxx% on Net Sales above \$xxx million of the Product in the Territory in a calendar year.

[Portions of this Section have been omitted pursuant to a request for confidentiality under Rule 24b-2 of the Securities Exchange Act of 1934, as amended. A copy of this Exhibit with all sections intact has been filed separately with the Securities and Exchange Commission.]

(iii) milestone payments, in each case upon the first achievement of given annual Net Sales of the Product in the territory during the Royalty Term, as follows, "Annual Net Sales" being Net Sales in an applicable calendar year:

(1) \$XXX million upon the first achievement of \$XXX million of Net Sales of the Product in the Territory in a calendar year;

(2) \$XXX million upon the first achievement of \$XXX million of Net Sales of the Product in the Territory in a calendar year;

(3) \$XXX million upon the first achievement of \$XXX million of Net Sales of the Product in the Territory in a calendar year;

(4) \$XXX million upon the first achievement of \$XXX million of Net Sales of the Product in the Territory in a calendar year;

(5) \$XXX million upon the first achievement of \$XXX million of Net Sales of the Product in the Territory in a calendar year;

(6) \$XXX million upon the first achievement of \$XXX million of Net Sales of the Product in the Territory in a calendar year; and

(7) \$XXX million upon the first achievement of \$XXX million of Net Sales of the Product in the Territory in a calendar year.

[Portions of this Section have been omitted pursuant to a request for confidentiality under Rule 24b-2 of the Securities Exchange Act of 1934, as amended. A copy of this Exhibit with all sections intact has been filed separately with the Securities and Exchange Commission.]

Company shall make each milestone payment within thirty (30) days of the occurrence of the applicable milestone. For clarity, each milestone payment will be required only once, upon the first achievement of the applicable milestone. Each milestone payment shall be made by Company into an escrow account identified to Company by BPA that is established for the benefit of both BPA and Antares. BPA agrees that each such payment by Company into the escrow account shall satisfy Company's obligation for such payment to BPA notwithstanding any dispute that may arise concerning the operation of the escrow account. Antares is a third party beneficiary of this Agreement solely with respect to this provision concerning payments into the escrow account.

(iv) Intentionally omitted.

4. Reports and Payments.

(a) On or before the end of each Quarter Company shall submit a good faith estimate of gross sales and Net Sales made by the Company and its Affiliates during such Quarter and within forty five (45) days following the end of each Quarter, the Company shall submit to BPA a written report with respect to the preceding calendar quarter (the **"Payment Report")** stating:

(i) gross sales and Net Sales made by the Company and its Affiliates to Third Parties during such Quarter, including an itemization of deductions from gross sales that separately shows the amount of each category of deduction enumerated in Section l(x).

(ii) intentionally omitted;

(iii) a calculation under Section 3 of the amounts due to BPA, making reference to the applicable subsection thereof;

and

(iv) such additional information as is required by BPA to comply with its obligation to provide a report to Antares pursuant to the Antares License Agreement.

The first Payment Report shall be due on February 15, 2009, and the first good-faith estimate shall be due January 10,2009. In addition, reports for milestone payments shall be provided together with such payment when due. For the avoidance of doubt, Company shall submit to BPA a Payment Report each Quarter even if no royalty is due for such Quarter.

(b) On the last business day of that month in which a Payment Report is due under paragraph (a) above, Company shall make payment to BPA of the amount due for the period covered by the Payment Report. Notwithstanding the foregoing, milestone payments shall be due as set forth Section 3(a)(iii) above.

(c) <u>Inspections and Audit</u>. Company or one or more of its Affiliates shall keep full, true and accurate books of account containing particulars and reasonable supporting documentation which may be necessary for the purpose of determining the Net Sales, royalties due thereon, the statements provided by Company pursuant to Section 3(a) above, and Company's compliance with Section 7(a)(i). Such records shall be kept at the principal place of business of Company, Azur Parent, or an Affiliate of Company in the United States as notified to BPA, and shall be open at all reasonable times and upon reasonable advance notice to the inspection of Antares, BPA, or an independent certified public accounting firm retained by Antares or BPA, and reasonably acceptable to Company, for the purpose of verifying any payment made under this Agreement. The party initiating the inspection and audit (Antares or BPA) shall bear the full cost of any such audit, unless the audit discloses that the amount due for the audited period exceeds the amount paid for such period by (i) ten percent (10%) or more during the first two years of this Agreement; or (ii) five percent (5%) or more thereafter, in which case Company shall bear the full cost of such audit. Any additional payment found in such audit to be due BPA shall be paid by Company within thirty (30) days after such finding.

(d) <u>Interest</u>. In the event Company fails to pay any amount due and payable under this Agreement by the due date, then it shall pay BPA interest on the total outstanding amount at the lower of (i) two percentage points above the Prime Rate publicly announced by J.P. Morgan Chase & Co. at its principal office that is prevailing on the Due Date, or (ii) the highest rate permitted by law.

5. Closing

(a) <u>Closing</u>. The closing (the "<u>Closing</u>") of licenses contemplated by Section 2 hereof shall take place on the date hereof (the "<u>Closing Date</u>") concurrently with the execution and delivery of this Agreement at the offices of Kenyon & Kenyon LLP, located at One Broadway, New York, NY 10004-1007, or at such other time or in such other location as the Parties shall mutually agree, including via facsimile and/or email. The effective time of the Closing shall be 5:00 pm, New York City on the Closing Date. At the Closing:

(i) BPA shall deliver to Company counterparts of the following documents, duly executed by BPA and/or its applicable Affiliate(s):

(1) a certificate, dated as of the Closing Date, of the Secretary or another officer of BPA certifying that BPA's and execution, delivery and performance of this Agreement has been duly authorized by all necessary corporate action on the part of BPA; and

(2) such other documents, instruments and certificates as BPA and Company reasonably agree are necessary to effect the transactions to be consummated at the Closing.

(ii) Company shall deliver to BPA:

(1) counterparts of each of the agreements referred to in Section 5(a)(i), above, duly executed by Company;

(2) a certificate, dated as of the Closing Date, of the Secretary or Assistant Secretary of Company certifying an accurate and complete copy of the resolutions of the board of directors of Company authorizing the execution, delivery and performance of this Agreement and the other agreements to which it is a party;

(3) the payments required at Closing pursuant to Section 3 above; and

(4) such other documents, instruments and certificates as BPA and Company reasonably agree are necessary to effect the transactions to be consummated at the Closing.

6. Regulatory and Related Matters and Transition.

(a) <u>New Indications</u>. Company shall have the right, in its sole discretion, to pursue a New Indication for the Product in the Territory (and to engage in development work and clinical trials outside the Territory for such purpose pursuant to the provisions of Section 2(a)), subject to and in accordance with the terms and conditions of this Agreement. If Company decides to pursue any such New Indication, Company shall be solely responsible at its own expense for accomplishing all Product development and commercialization, including without limitation (1) any pre-clinical, clinical and regulatory work, additional clinical testing or other studies and manufacturing requirements relating to the Product for such New Indication; (2) all FDA and other regulatory obligations post approval for such New Indication; and (3) any other Product and medical requirements relating to the sale or marketing of the Product for such New Indication.

(b) <u>Data Sharing</u>. BPA and Company agree to provide one another immediate, full and free access to the clinical data and results generated by or on behalf of each (including by Affiliates of such party and, in the case of BPA, information received from Antares) and regulatory and manufacturing information in each case relating to the Product, and each agrees that the other may utilize all such information directly or through permitted (sub)licensees in pursuit of product approvals in their respective geographical areas (the Territory for Company and all other areas for BPA). BPA shall use Commercially Reasonable Efforts to obtain such information from other licensees or sublicensees, but BPA shall have no obligation to share or provide any such information regarding Product with Company if despite such efforts such information is not freely available to BPA with the right to share same with Company. For the avoidance of doubt, (i) BPA shall have the absolute right to freely share all information from Company with Antares, and (ii) neither party shall be required to provide the other with information on new or other transdermal estrogen products or to modifications or improvements of the packaging or delivery system for Elestrin.

(c) <u>Transitional Assistance</u>. For the twelve month period beginning on the Closing Date, BPA shall provide Company with technical and business support for the manufacture, regulatory matters, safety matters, marketing, distribution, and sale of Product as described in this paragraph. Such support shall be in the form of making available for meetings and consultation with Company, at mutually agreeable times, such knowledgeable BPA employees as BPA may identify who have information, know-how, experience, and expertise that may reasonably assist Company in its activities with respect to the Product under this Agreement. Unless otherwise agreed to between the Parties, such employees will be made available for consultations with Company by phone or at their regular places of business, with Company to cover any out-of-pocket costs for travel if by agreement of the Parties travel is required. The time provided by BPA shall not exceed forty hours of executive time and one hundred hours of managerial or technical/scientific/clinical time

(d) <u>Nycomed and DPT Agreement</u>. To the extent reasonably required by Company, BPA shall exercise Commercially Reasonable Efforts to enforce the appropriate rights under that certain Termination, Release and Settlement Agreement with Nycomed dated as of August 6, 2008 (the "Nycomed Agreement") to procure for Company the benefit of the transitional provisions for the remainder of the term of the Nycomed Agreement (as amended).

7. Diligence; Compliance With Laws: Copromotion.

(a) The Company shall use Commercially Reasonable Efforts to market, sell and distribute Product for commercial sale and distribution in the Territory.

(i) Company shall launch the Product within 125 (one hundred and twenty five) days after the Closing Date. Company shall spend at least \$5 million on sales, marketing, and medical affairs support for the Product during each of (x) the twelve month period beginning at said launch, and (y) the twelve month period beginning on the first anniversary of said launch. During the twenty four (24) month period beginning at said launch, Company shall promote the Product using its women's health sales force. The foregoing obligations shall be suspended for the period in which commercialisation of the Product is materially adversely affected by a failure to supply outside of Company's control, Force Majeure or action by the FDA, provided that Company shall exercise Commercially Reasonable Efforts to end such period of adversity. For the avoidance of doubt, each \$5 million obligation above (i) shall include all costs relating to the sales force time spent in relation to the promotion of the Product, sample costs and related activities whether prior to or after the date of such launch, but (ii) shall not include any amounts paid to BPA under this Agreement.

(ii) During the Royalty Term the Company and its Affiliates shall not develop, make, have made, market, sell, offer for sale, or distribute Competitive Products in the Territory. However, in the event that Company, or a substantial part of the assets and business of Company including the Business, is acquired by a Third Party that is marketing a Competitive Product at the time of acquisition, this Section 7(a)(ii) shall not require the acquiring company to discontinue sales of such product so long as the acquiring company complies in all other respects with the obligations to diligently sell and where applicable promote the Product. If Company signs a definitive agreement with respect to a merger or acquisition by which it would acquire rights (other than residual financial rights) in a Competitive Product at any time during the Royalty Term, then Company (or its applicable Affiliate) shall have six (6) months from the closing of such definitive agreement to divest itself of such rights in the Competitive Product and, during such six (6) month period, the sale, marketing or distribution of such Competitive Product shall not be in violation of this Section 7(a)(ii). In the case of divestiture under the preceding sentence, such divestiture can occur by either (x) an outright sale of all rights in the Competitive Product to a Third Party or (y) a license to one or more Third Parties of the right to sell, market and distribute such Competitive Product so long as Company and its Affiliates only retain residual financial rights with respect to such Competitive Product and do not exercise or have the ability to exercise any role or influence in any manner over the conduct of the business of such Competitive Product (other than the protection of reputational, intellectual property or similar rights or interests). For the avoidance of doubt, Company shall not under any circumstances use the Patents, Know How, Trademark, Trade Secrets, BPA's Confidential Information, or any aspect of the Intellectual Property Rights in connection with or to advance or assist with the research, development, design, formulation, manufacture, sale, distribution, or marketing of a Competitive Product.

(b) Company shall at all times materially comply with and adhere to all Laws in the conduct of all of its activities under this Agreement, including without limitation in the manufacture, marketing, advertising, promotion, distribution, and sale of Product.

(c) In connection with the launch of the Product by Company, Company shall promptly provide BPA with two copies of each item of advertising, detailing, or promotional materials used by Company for marketing the Product in the Field in the Territory. Thereafter Company shall provide BPA with one copy of each advertising, detailing or promotional material at the same time as providing the annual summary report and the mid year update to that report as envisaged pursuant to this Section 7(c). The Company shall also provide BPA an annual summary report of its commercialization of the Product, including copies of the Company's actual draft sales and marketing plans, and afford BPA a reasonable opportunity to provide input into same and meet with the Company to discuss; *provided, however*, that this shall not be construed as a right of BPA to approve such sales and marketing plans. In addition, the Company shall provide BPA a mid-year update to such report summarizing any further developments in the commercialization of the Product.

(d) Company shall promptly provide BPA with copies of all correspondence and documents to and from FDA and all notices received from FDA concerning the Product, and also provide BPA with regular updates as BPA may reasonably request.

(e) For a period beginning twenty four (24) months after the launch of the Product by Company, or if earlier Company's failure to comply with Section 7(a)(i), and ending on the earlier of (A) five (5) years from the Closing Date or (B) six (6) months after closing of an event that is a Change in Control of BPA, BPA shall retain the right to commence copromoting the Product in the Territory with its own sales force (the "Copromotion Sales Force"). If BPA elects to exercise such right, the parties shall negotiate in good faith a copromotion agreement taking into account (i) the then current level of support then applied by Company to the Product and the status of the Product and (ii) otherwise on usual commercial terms for the copromotion of pharmaceutical products, with the material terms of such agreement providing that (i) BPA shall be responsible for all costs incurred by the Copromotion Sales Force, (ii) orders for Product obtained or solicited by the Copromotion Sales Force shall be directed to Company and Company shall fill such orders in a nondiscriminatory manner and on the same terms as orders obtained by Company's own sales force, (iii) Company shall be solely responsible for setting the price of Product, and for all trade, distribution, managed markets, medical, safety activities, advertising decisions and other activities and operational decisions relating to the Product, (iv) the Copromotion Sales Force shall use only those promotional materials that are developed by Company, or, if developed by BPA, are approved by Company (such approval not to be unreasonably withheld), and shall not promote to physicians or customers targeted by Company and identified to BPA, (v) Company shall make available to the Copromotion Sales Force the same promotional materials and Product specific training made available to its own sales force (with the cost of materials provided to BPA to be paid by BPA), (vi) Company shall provide to BPA all directives provided to Company's own sales force concerning compliance with laws and regulations for marketing and sale of Product, and BPA shall be responsible to ensure compliance by the Copromotion Sales Force of such directives, (vii) BPA shall be responsible and shall indemnify Company for all Losses arising out of for the actions and conduct of the Copromotion Sales Force, (viii) BPA shall obtain product liability insurance in the amount specified in Section 14(c), and (ix) the financial provisions of the co-promotion arrangements shall be negotiated (provided that the Company shall not be adversely impacted financially by the copromotion activities compared to its sales, profitability and cash flow arising from the Product in the absence of such copromotion activities so long as Company materially maintains at least the same level of sales efforts and activities as it used prior to the start of copromotion by BPA). For the avoidance of doubt, if BPA exercises its right within the time period provided in the first sentence of this paragraph, the duration of the copromotion shall not conclude at the end of that period and shall rather be part of the negotiated terms of the copromotion agreement.

8. Proprietary Rights. Company acknowledges and agrees that as between Company and BPA, BPA shall have and obtain title to and ownership in the formulation of the Product, the Patents and the Know How (as that term is defined in the Antares License Agreement), including, but not limited to, any and all improvements, developments, and inventions thereof during the Royalty Term that cover and solely relate to the Product, if any (which shall promptly be disclosed by Company to BPA) and any such improvements, developments and inventions shall constitute Intellectual Property Rights provided however that on or after December 31, 2023 no royalty shall be payable by Company where the only patent which achieves exclusivity for the Product relates to such improvements, developments and inventions developed by or on behalf of Company. For the avoidance of doubt, any inventions made by or on behalf of Company during the term of the Agreement that do not cover and solely relate to the Product shall remain the property of Company, except that to the extent that Company has the right to grant such rights, any such inventions that pertain in part to the Product are hereby licensed to BPA, its successors and assigns on a nonexclusive, nonterminable, perpetual basis with respect to Product outside the Territory (and with respect to Product inside the Territory but limited to the scope and term of BPA's rights in the Territory as otherwise provided in this Agreement). With the exception of the "except that" provision of the preceding sentence, nothing in this Agreement shall be interpreted to grant any ownership, license or other right to any party in or to any improvement, development or invention of Company arising from its research and development activities generally to the extent such activities are not directed toward the Product. Nothing in this Agreement shall be interpreted to cause any information relating to Company's research and development activities generally to the extent such activities are not directed toward the Product to be considered the Confidential Information of any party other than Company.

9. Manufacturing.

(a) During the Royalty Term Company shall use Commercially Reasonable Efforts to have the Product manufactured in sufficient quantities to supply any demand and any government or commercial requirements in the Territory, and at all times shall ensure that the manufacture of Product for sale in the Territory materially complies with applicable Laws. The conclusion by Company of an agreement with, or furnishing purchase orders to, DPT or another reputable Third Party manufacturer that is approved by the FDA to manufacture the Product (if any) shall constitute performance of its obligation under this Section 9(a). Nothing in this Agreement shall require Company to qualify a source other than DPT to manufacture the Product.

(b) At the request of Company, BPA shall reasonably assist Company with arranging for manufacture of Product by DPT, including without limitation, by facilitating introductions of Company's representatives to, and the commencement of discussions by such representatives with, such contacts within DPT as are then reasonably available to BPA, and offering assistance and consultation to Company's representatives with respect to the conduct of any such discussions with DPT. BPA shall request and authorize DPT to work collaboratively with and disclose BPA Confidential Information to Company regarding the manufacture of Product. Company shall request and authorize DPT (or such other entity that Company may engage for manufacture of Product) to work collaboratively with and disclose Company Confidential Information to BPA regarding the manufacture of Product.

(c) Company agrees that any Know How, Trade Secrets, or Confidential Information of BPA held by DPT as of and following the Closing Date shall as between Company and BPA remain the property of BPA and be governed by the license and confidentiality provisions of this Agreement.

(d) Subject to compliance with all applicable laws and regulatory requirements, Company agrees to supply BPA with Product at cost plus 7.5% for use outside the Territory and BPA shall have the right to place orders for reasonable quantities of Product for sale by BPA or BPA's licensees outside the Territory when Product is being made by or for Company; *provided*, *however*, if BPA and BPA's licensees intend to order sufficient quantities of Product to comprise a complete manufacturing batch of Product, BPA and its licensees shall place their own order for the Product independently of Company's orders. Company shall give BPA reasonable advance notice for each manufacturing run to enable BPA to exercise its rights under this Section 9(d). Product shall be packaged in the normal US packaging and Company shall not be responsible for any changes in packaging or other activities that are not part of the normal manufacturing practices of Company. BPA shall pay Company's actual out of pocket cost for such manufacture plus 7.5% of such cost (which shall only be payable if such product is purchased

from Company) including any surcharges imposed by the manufacturer for partial batches and special packaging and labeling requirements. BPA shall make payments for its orders either directly to the manufacturer or to Company, as applicable, and shall take delivery either directly from manufacturer or Company, with the details of same to be negotiated in good faith between BPA and Company (subject to the default rules of the Uniform Commercial Code if agreement on the details is not reached). In the event that the manufacturer is not able to fill the entire quantity ordered by Company and BPA, Company shall be entitled to direct DPT to satisfy the needs of Company and its customers as reasonably demonstrated by Company to BPA, and if there is sufficient capacity remaining to supply all or part of the requirement of BPA and its licensees. In no event shall Company have any responsibility for any matters relating to the supply of the Product such as failed lots, quality issues, delays in supply, or product liability or otherwise have any liability with regard to the supply of such product, and BPA hereby indemnifies and holds harmless Company with regard to any claim which may be made by any Third Party and for its part confirms that Company has no liability to BPA based on or arising out of the supply of Product under this Section 9(d) (except for Company's obligation to supply as set forth in the first sentence of this Section 9(d)).

(e) At the request of BPA, Company shall send to DPT a letter in substantially the form of <u>Exhibit B</u> to advise DPT that it is permitted to communicate with BPA as set forth herein.

10. Confidentiality.

(a) <u>Confidential Information</u>. In connection with this Agreement, the Parties may provide to each other Confidential Information, including without limitation each Party's invention disclosures, proprietary materials and/or technologies, economic information, business or research strategies, trade secrets and material embodiments thereof. As used herein, **"Confidential Information"** means any information of a confidential or proprietary nature disclosed by a party to this Agreement to the other Party, including, in the case of Company, royalty reports or development reports submitted pursuant to this Agreement. For the avoidance of doubt, any such Confidential Information related to the Intellectual Property as of and after the Closing Date shall be considered BPA's Confidential Information.

(b) <u>Confidentiality and Non-Use</u>. The recipient of the disclosing Party's Confidential Information shall use such Confidential Information solely to exercise its rights and perform its obligations under this Agreement (including, without limitation, the right to use and disclose such Confidential Information in regulatory applications and filings and for Company to use and disclose such Confidential Information to applicable Third Parties such as appointed or potential manufacturers), and in the case of BPA only under the Antares License Agreement, unless otherwise mutually agreed in writing. The recipient of a disclosing Party's Confidential Information shall maintain such Confidential Information in confidence, and shall disclose such Confidential Information only to (i) those of its employees, agents, consultants, sublicensees, attorneys, accountants, and advisors who have a reasonable need to know such Confidential Information and who are bound by obligations of confidentiality and non-use no less restrictive then those set forth herein, and (ii) in the case of BPA only, to Antares. The recipient of the other Party's Confidential Information shall take the same degree of care that it uses to protect its own confidential and proprietary information of a similar nature and importance (but in any event no less than reasonable care).

(c) <u>Exclusions</u>. Confidential Information shall not include information that; (i) is in the recipient's possession prior to receipt from the disclosing Party as demonstrated by contemporaneous documentation; (ii) is or becomes, through no fault of the recipient, publicly known; (iii) is furnished to the recipient by an unaffiliated Third Party without breach of a duty to the disclosing Party; (iv) is independently developed by the recipient without use of, application of or reference to the disclosing Party's Confidential Information as demonstrated by contemporaneous documentation.

(d) <u>Legal Disclosures</u>. It shall not be a violation of this Section 10 to disclose Confidential Information to the extent required to be disclosed under applicable law, *provided* that the recipient, to the extent possible and in accordance with applicable law, shall give the disclosing Party prior written notice of the proposed disclosure and shall cooperate fully with the disclosing Party to minimize the scope of any such required disclosure.

(e) <u>Survival</u>. All obligations of confidentiality and non-use imposed under this Section 10 shall survive for five years after the termination or expiration of this Agreement.

(f) <u>Communications with Antares</u>. Company shall not directly communicate with Antares with respect to the Product during the Royalty Term unless specifically provided for in this Agreement or expressly authorized in writing by BPA, provided that Company shall be entitled to notify Antares of its acceptance of contingent obligations of Antares to Company, in substantially the form set forth in <u>Schedule 10(f)</u>.

11. Representations. Warranties.

(a) Except as set forth on the corresponding section of the Disclosure Schedule attached hereto as <u>Schedule 11(a)</u>. BPA represents and warrants as of the Closing Date as follows:

(i) <u>Antares License Agreement</u>, (a) the Antares License Agreement is in full force and effect; (b) the copy of the Antares License Agreement that BPA has disclosed to Company on or before the Closing Date is a true and accurate copy of such agreement as in effect as of the Closing Date; (c) BPA is not in material breach of the Antares License Agreement; (d) there is no unresolved material dispute between BPA and Antares in connection with the Antares License Agreement, and in particular there is no outstanding allegation of any material breach of the Antares License Agreement by BPA or Antares; and (e) BPA has disclosed to Company in writing all material correspondence between BPA and Antares pertaining to the operation of the Antares License Agreement as it pertains to the rights sublicensed to Company in this Agreement.

(ii) <u>Other Licenses</u>. BPA has not granted any license to the Intellectual Property Rights (including the Patents or Trademark) in the Field and in the Territory that remain in effect or in force as of the Closing Date, other than to Company pursuant to this Agreement.



(iii) <u>Claims</u>, (a) there are no claims, actions, suits or proceedings commenced, pending or to BPA's Knowledge threatened against it or any of its Affiliates relating to any of the the Intellectual Property Rights or the Business that could reasonably be expected to have a Material Adverse Effect on the rights and benefits granted to Company hereunder and, to the Knowledge of BPA, no fact or circumstance exists that could reasonably be expected to validly give rise thereto; (b) BPA has not received written notice that any Third Party intends to challenge the patentability or validity of any Patent or Trademark, with the exception of the challenge to the Trademark made by Warner Chilcott and which has been resolved pursuant to the Trademark Coexistence Agreement of July 23,2008; (c) there is no lawsuit pending or to BPA's Knowledge threatened, which in any manner challenges or seeks the rescission of, or seeks to prevent, enjoin, alter or materially delay the consummation of, or otherwise relates to, this Agreement or the transactions contemplated hereby; and (d) there is no lawsuit which BPA presently intends to initiate which directly involves any of the Intellectual Property Rights or the Business and, to the Knowledge of BPA, no fact or circumstance exists that could reasonably be expected to validly give rise thereto. Since December 31,2006, BPA has not been notified in writing of any claim against it or its Affiliates or insurers relating to product liability or similar liability relating to Product and no payment or settlement of any kind has been made in response to or in anticipation of such a claim.

(iv) <u>NDA, Clinical Data and Phase IV Studies</u>, (a) BPA has made available for inspection by Company a copy of the NDA and copies of all material correspondence and documents to and from FDA regarding the Product or the NDA; (b) BPA has performed all clinical studies regarding the Product in material compliance with all applicable laws and guidelines and good clinical practice; and (c) the FDA has not imposed an obligation to conduct one or more Phase IV studies.

(v) <u>Safety and Efficacy Data</u>. BPA has disclosed to Company all material safety- and efficacy-related data and information (including without limitation toxicology, carcinogenicity and mutagenicity data and information) generated by, disclosed to and/or known to BPA regarding the Product.

(vi) <u>No Debarment</u>. In the course of developing Product, BPA has not, and to its Knowledge no other party has, engaged any person who has been debarred by the FDA or is the subject of debarment proceedings by the FDA, and BPA hereby covenants that it and its Affiliates shall not do so with respect to Product during the Royalty Term.

(vii) <u>Organization</u>. BPA is duly organized, validly existing and in good standing under the laws of its jurisdiction of formation.

(viii) <u>Power and Authorization</u>. The execution and delivery by BPA of this Agreement, and the performance of each of its respective obligations hereunder and thereunder and the consummation of the transactions contemplated hereby and thereby are within its power and have been duly authorized by all necessary action on the part thereof. This Agreement (a) has been or, when executed and delivered in accordance herewith, will be, duly executed and delivered by a duly authorized representative of BPA and (b) is or, when executed and delivered in accordance herewith, will be, the legal, valid and binding obligation thereof, enforceable against such Person in accordance with their respective terms, except as enforceability may be limited by applicable bankruptcy, insolvency, reorganization, moratorium or other similar laws now or hereafter in effect relating to or affecting creditors' rights generally.

(ix) <u>Authorization of Regulatory Authorities</u>. No action by or in respect of, or filing with, any Regulatory Authority is required by BPA or any of its Affiliates for, or in connection with, the valid and lawful (i) authorization, execution and delivery by BPA and its Affiliates of this Agreement or (ii) the consummation of the sale of the license of the Intellectual Property Rights, as contemplated hereby.

(x) Noncontravention.

(a) The execution and delivery by BPA of this Agreement, and the performance of each of its respective obligations hereunder and thereunder and the consummation of the transactions contemplated hereby and thereby does not and will not (i) violate any Laws or any decree or judgment of any court or other Regulatory Authority applicable to BPA, the Intellectual Property Rights or the Business; (ii) violate or conflict with, result in a breach of, constitute a default (or an event which, with or without notice or lapse of time or both, would constitute a default) under, permit cancellation of, or result in the creation of any encumbrance (other than Permitted Encumbrances) upon any of the Intellectual Property Rights under, any Contracts to which BPA is a party or by which any of them is bound (subject to BPA obtaining the consents set forth on <u>Schedule 11(x)</u>; or (iii) violate or conflict with any provision of the Certificate of Incorporation or By-laws or other organizational documents of any of BPA.

(b) No material consents or approvals of, or filings or registrations by BPA with, any Regulatory Authority or any other Third Party are necessary in connection with the execution, delivery and performance of this Agreement by BPA.

(xi) <u>Encumbrances</u>. Except for Permitted Encumbrances, (i) there are no encumbrances on any of the Intellectual Property Rights owned by BPA, (ii) BPA has not caused there to be any encumbrances on the Intellectual Property Rights that are licensed to BPA, and (iii) to the Knowledge of BPA, there are no encumbrances on the Intellectual Property Rights that are licensed to BPA with the exception of such encumbrances referred to in Schedule l(bb).

(xii) Title: Sufficiency.

(a) At the Closing, BPA will convey to Company a valid license to and under the Intellectual Property Rights on the terms and conditions of this Agreement.

(b) The Intellectual Property Rights constitute all of the material assets and rights that are currently used by BPA solely or primarily in connection with the conduct of the Business pertaining to the Product.

(xiii) Intellectual Property.

(a) To BPA's Knowledge, the use, sale, offer for sale, manufacture, import, promotion, marketing or distribution of the Product in the Territory (including the practice of the Intellectual Property Rights with respect to same), in a manner consistent with the manner in which the Business is conducted as of the Closing Date, does not interfere with, infringe upon, misappropriate, or otherwise conflict with any intellectual property right owned or controlled by any Third Party. BPA has not received any written charge, complaint, claim, demand, or notice within the past two (2) years alleging any such interference, infringement, misappropriation, or violation (including any claim that BPA or any of its Affiliates must license or refrain from using any of the Intellectual Property Rights). To the Knowledge of BPA, within the past two (2) years no Third Party has undertaken any activities which challenged, infringed or misappropriated, or if unabated would constitute infringement or misappropriation, of any of the Intellectual Property Rights.

(b) <u>Schedule 11(xiii)</u> identifies all current and subsisting trademark, copyright, domain and patent filings or registrations that have been made or issued to BPA or its predecessors that relate to the Intellectual Property Rights. With the exception of the rights licensed to BPA under the Antares License Agreement, BPA is the sole owner of the Intellectual Property Rights, free of any Encumbrances other than Permitted Encumbrances, and with respect to such rights as are licensed to BPA under the Antares License Agreement, BPA is the sole owner of the Intellectual Property Rights, free of BPA, valid, subsisting and in full force and effect. Each item identified in <u>Schedule 11(xiii)</u> is, to the Knowledge of BPA, valid, subsisting and in full force and effect, and BPA and Antares has taken all steps necessary to maintain such registrations, including the payment when due of all registration and maintenance fees and annuities and the filing of all necessary renewals, statements and certifications, and all necessary documents and certificates in connection with such registered Intellectual Property Rights have been filed with the relevant patent, copyright or other governmental or Regulatory Authorities for the purposes of maintaining such registered Intellectual Property Rights.

(c) The Intellectual Property Rights licensed to Company pursuant to the licenses granted in Section 2, constitute all of the intellectual property and proprietary rights owned or licensed to BPA that are necessary for Company to conduct the Business in the same manner, in all material respects, as the Business is conducted by BPA and its Affiliates immediately prior to the Closing Date, except that Company's ability to use the Authorized Marks shall be limited to the use contemplated by Section 2(c).

(xiv) Legal Compliance.

(a) Since December 31,2006, BPA and its Affiliates have conducted their operations as they pertain to the Business of the Product in material compliance, in all respects, with all applicable Laws. Neither BPA nor any of its Affiliates has received any written notice of a material violation of any applicable Laws from any Regulatory Authority relating to the Business or the promotion, distribution, marketing, use and sale of the Product in the Territory within the past twenty-four (24) months.

(b) With respect to the manufacture, labeling, packaging, promotion, distribution, marketing, use and sale of the Product in the Territory, neither BPA nor any of its Affiliates has received or been subject to, during the past twenty-four (24) months, any FDA Form 483s relating to the Product, any FDA notices of adverse findings relating to the Product, or any warning letters or other correspondence from the FDA or any other Regulatory Authority in which the FDA or such other Regulatory Authority asserted that the promotion, distribution, marketing, use or sale of any Product in the Territory was not in compliance with applicable Laws. During the past twenty-four (24) months with respect to the promotion, distribution, marketing, use and sale of the Product in the Territory, there has not been any occurrence of any product recall, market withdrawal or replacement, or post-sale warning conducted by or on behalf of BPA or its Affiliates concerning the Product or, to the Knowledge of BPA, any product recall, market withdrawal or replacement conducted by or on behalf of any Third Party as a result of any alleged defect in the Product.



(c) Since December 31, 2006, all adverse events relating to the Product known to BPA have been duly reported to the FDA to the extent required by applicable Laws.

(xv) Regulatory Approvals.

(a) <u>Schedule 11(xv)</u> includes a complete list of all of the NDAs and ANDAs held by BPA or its Affiliates with respect to the Product. BPA is the sole and exclusive owner of the NDA. The NDA in respect of the Product is in full force and effect.

(b) To BPA's Knowledge, all Product sold under the NDA have been marketed in accordance with the NDA.

(xvi) Contracts.

(a) Neither BPA or any of its Affiliates nor, to the Knowledge of BPA, any other party to any Assigned Contract, is in breach or violation of, or default under, or has repudiated any provision of, any Assigned Contract, except for such breaches, defaults, violations or repudiations as would not have a material impact on the ability of BPA or its Affiliates to conduct the Business in accordance with past practices of BPA or its Affiliates.

(xvii) <u>No Material Adverse Effect</u>. Since August 8, 2008, the Business has been conducted only in the ordinary course and to the Knowledge of BPA there has not been any change, effect, event or condition that has had, or would reasonably be expected to have, a Material Adverse Effect.

(xviii) <u>Taxes</u>.

(a) BPA has timely filed all material Tax Returns required to be filed relating to the Licensed Intellectual Property Rights (excluding any Tax Returns required to be filed as a result of the transactions contemplated herein) and such Tax Returns were correct and compete in all material respects at the time of filing.

(b) BPA has timely paid all material Taxes shown as due and owing on the material Tax Returns described in (a) above.

(c) BPA has not received from any Regulatory Authority any written notice of proposed adjustment, deficiency or underpayment of any material Taxes relating to the Licensed Intellectual Property Rights that has not been satisfied by payment or withdrawn, and no written claims related to such Taxes have been asserted or threatened against BPA.

(d) No agreement for the extension of time for the assessment of any material taxes relating to the Licensed Intellectual Property Rights is currently in effect.

(e) There are no liens for Taxes on the Intellectual Property Rights owned by BPA other than Permitted Encumbrances, BPA has not caused the creation of any lien for Taxes on any Intellectual Property Rights that are licensed to BPA and to BPA's Knowledge there are no hens for Taxes on any Intellectual Property Rights that are licensed to BPA.

(xix) <u>Generics</u>. (i) To the Knowledge of BPA, no AB Rated generic equivalent to the Product (a <u>"Generic</u>") has been Launched, (ii) to the Knowledge of BPA, no ANDA seeking approval of a Generic has been filed with the FDA and (iii) BPA has not received written notice expressly indicating that any Person intends to submit an ANDA in respect of a Generic with the FDA.

(xx) <u>No Brokers</u>. BPA and its Affiliates have no liability of any kind to, and are not subject to any claim of, any broker, finder or agent in connection with the transactions contemplated by this Agreement other than those which will be borne by BPA.

(b) Company represents and warrants to BPA as follows:

(i) Organization. Company is duly organized and validly existing under the laws of its jurisdiction of formation.

(ii) <u>Power and Authorization</u>. The execution and delivery by Company of this Agreement, and the performance of each of its respective obligations hereunder and thereunder and the consummation of the transactions contemplated hereby and thereby are within its power and have been duly authorized by all necessary action on the part thereof. This Agreement (a) has been or, when executed and delivered in accordance herewith, will be, duly executed and delivered by a duly authorized representative of Company and (b) is or, when executed and delivered in accordance herewith, will be, the legal, valid and binding obligation thereof, enforceable against such Person in accordance with their respective terms, except as enforceability may be limited by applicable bankruptcy, insolvency, reorganization, moratorium or other similar laws now or hereafter in effect relating to or affecting creditors' rights generally.

(iii) <u>Authorization of Regulatory Authorities</u>. No action by or in respect of, or filing with, any Regulatory Authority is required by Company or any of its Affiliates for, or in connection with, the valid and lawful (i) authorization, execution and delivery by Company and its Affiliates of this Agreement or (ii) the consummation of the sale of the license of the Intellectual Property Rights, as contemplated hereby.

(iv) Noncontravention.

(a) The execution and delivery by Company of this Agreement, and the performance of each of its respective obligations hereunder and thereunder and the consummation of the transactions contemplated hereby and thereby does not and will not (i) violate any Laws or any decree or judgment of any court or other Regulatory Authority applicable to Company, the Intellectual Property Rights or the Business; (ii) violate or conflict with any provision of the Certificate of Incorporation or Bylaws or other organizational documents of any of Company.

(b) No material consents or approvals of, or filings or registrations by Company with, any Regulatory Authority or any other Third Party are necessary in connection with the execution, delivery and performance of this Agreement by Company.

(v) <u>No Brokers</u>. Company and its Affiliates have no liability of any kind to, and are not subject to any claim of, any broker, finder or agent in connection with the transactions contemplated by this Agreement other than those which will be borne by Company.

(c) Other than as expressly provided in this Agreement, neither party makes any warranty and makes no representation, express or implied. IN PARTICULAR, BUT WITHOUT LIMITATION OF THE GENERALITY OF THE PRECEDING SENTENCE, EXCEPT AS EXPRESSLY SET FORTH HEREIN EACH PARTY HEREBY EXPRESSLY DISCLAIMS AND DOES NOT GIVE ANY WARRANTY AND MAKES NO REPRESENTATION WITH RESPECT TO THE PRODUCTS, PATENTS, AND TRADEMARK AND MATERIALS OR ANY CLINICAL TRIALS CONDUCTED BY EITHER PARTY REGARDING THE PRODUCT AND THE RESULTS THEREOF, INCLUDING WITHOUT LIMITATION, ANY WARRANTY OF COMPLETENESS, ACCURACY, VALIDITY, ENFORCEABILITY, NON-INFRINGEMENT, MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE THEREOF.

12. Prohibition Against Use of Names: Confidentiality of Agreement.

(a) Subject to the provisions of Section 2(c), neither Party shall use the name, insignia, or symbols of the other party, or the name of any director, officer, employee, agent or representative of such other party, for any advertising, packaging or other promotional or publicity purpose without such other party's prior written consent; *provided*, *however*, that either party may identify the other party if required by law, regulation, court order or the rules of any securities exchange on which the identifying party's stock is traded. Upon execution of this Agreement, BPA and Company may each issue a press release in the form annexed hereto as <u>Exhibit A1</u> and <u>Exhibit A2</u>. respectively. Either party may issue future press releases regarding this Agreement with the prior written approval of the other party, such approval not to be unreasonably withheld or delayed (and in any event provided within three (3) days). Once the content of a press release has been approved by the other party, a party may release future press releases that contain substantially the same content without additional approval. Upon issuing any press release, the party doing so shall simultaneously copy the other party.

(b) Subject to the provisions of this Section 12, including the exception for any public disclosures made in compliance with the terms of Section 12(a), the parties agree that the terms of this Agreement are confidential and will not be disclosed by either party to any Third Party (except to a party's professional advisor) without advance written permission of the other party, provided that either party may make any filings or disclosures of this Agreement or its terms required by law or regulation in any country so long as such party uses its reasonable efforts to obtain confidential treatment for portions of this Agreement as available. consults with the other party, and permits the other party to participate, to the extent practicable, in seeking a protective order or other confidential treatment, and further provided that either party may disclose the terms of this Agreement to a Third Party (and its professional advisors) when such disclosure is in connection with negotiation or closing of (i) a merger, acquisition, placement, investment, or other such transaction with such Third Party, (ii) the sale of securities to or other financing from such Third Party or a financing underwritten by such Third Party, in which case disclosure may be made to such Third Party (and its professional advisers), or (iii) the potential conclusion by Company of agreements in relation to the performance of its rights and obligations under this Agreement that reasonably require such disclosure, including in relation to the manufacture distribution and sale of Product. Advance written permission for disclosure will not be required when a party is ordered to disclose information concerning the Agreement by a Governmental Authority or such disclosures are required by law, regulation, or stock exchange rules, except that such party will make all reasonable efforts to limit any disclosure as may be required in the course of legal proceedings by entry of an appropriate protective and confidentiality order, and will provide the other party with as much advance notice of such circumstances as is practicable.

13. Compliance with Governmental Obligations.

(a) Each Party shall comply upon reasonable notice from the other party with all governmental requests related to the Product or this Agreement directed to either party, including without limitation by providing all information, data and assistance necessary to comply with legitimate governmental requests related to the Product or this Agreement. Each party shall promptly notify the other party of all such governmental requests.

14. Additional Covenants And Agreements.

(a) <u>Expenses</u>. Except to the extent otherwise expressly set forth in this Agreement, BPA and Company shall bear their respective expenses incurred in connection with the preparation, execution and performance of this Agreement, including, without limitation, all fees and expenses of agents, representatives, counsel and accountants.

(b) Withholding. Any and all payments made by Company (or its successors or assigns) to BPA shall be made without setoff, counterclaim or other defense, and free and clear of, and without deduction or withholding for or on account of, any withholding taxes, except to the extent such withholding taxes are required by law. In the event that due to Company's assignment of this Agreement or any rights hereunder to any other Person or Company's failure to comply with applicable tax laws, any withholding taxes are imposed and required by law to be deducted or withheld from any payment required to be made under this Agreement, then the amount of such payment shall be increased by Company (or its successors or assigns) as may be necessary such that such payment is made, after withholding or deduction for or on account of such withholding taxes, in an amount that is not less than the amount provided for herein, and Company (or its successors or assigns) shall withhold the full amount of such withholding taxes from such payment and shall pay such amount to the governmental authority imposing such withholding taxes in accordance with applicable law. In the event of any tax withholding not subject to the provisions of the preceding sentence, Company shall provide to BPA receipts, statements, or other documentation concerning such withholding, assign to BPA or its designee the right to apply for release of the withheld amounts, and execute any assignment, permission, certificate or the like reasonably required for BPA or its designee to make such application. On or prior to the Closing, and from time to time thereafter upon the reasonable request of Company for so long as accurate, BPA shall furnish to Company a duly completed and executed Form W-9 certifying that BPA is a U.S. Person. On or prior to the date on which any such form or certification expires or becomes obsolete and after the occurrence of any event requiring a change in the most recent form or certification previously delivered to Company, including the assignment by BPA of this Agreement or any rights hereunder to any other Person or the permitted assumption by any other Person of BPA's rights under this Agreement, BPA and the assignee (or assuming Person) shall provide Company duly completed copies of Internal Revenue Service Forms W-9 or W-8BEN (or any successor forms), as applicable, or any other documentation prescribed by applicable law to enable Company to determine whether or not withholding taxes are required to deducted from any payment required to be made under this Agreement.

(c) Company shall obtain and carry in full force and effect product liability insurance in respect of the applicable Product in the amount of \$10,000,000 per occurrence and in the aggregate and policies of \$10,000,000 of excess coverage in the aggregate. For three years from the Closing Date BPA shall obtain and carry in full force and effect product liability insurance in respect of the applicable Product in the amount of \$5,000,000 per occurrence and in the aggregate and policies of \$5,000,000 of excess coverage in the aggregate.

(d) Each of BPA and Company shall at all times comply with all statutory workers' compensation and employers liability requirements covering its employees with respect to activities performed under this Agreement.

15. Indemnity.

(a) Subject to the limitations set forth in this Section 15, BPA shall indemnify, hold harmless and defend Company, its Affiliates, and their respective officers, directors, employees and agents (the **"Company Indemnitees")** from and against any and all losses, damages, liabilities, judgments, fines, amounts paid in settlement, expenses and costs of defense (including without limitation reasonable attorneys' fees) resulting from any action, suits, claims, demands, or prosecutions brought or initiated by a Third Party (each a **"Third Party Claim")** (collectively "Losses") incurred or suffered by the Company Indemnitees or any of them as a result of, arising out of, or relating to:

(i) any breach of, or inaccuracy in, any representation or warranty made by BPA in this Agreement or any certificate delivered pursuant hereto (disregarding, for purposes of determining both the existence of any breach and the extent of any Losses, any qualification or exception with respect to materiality or Material Adverse Effect contained therein); or

(ii) any breach, nonperformance, or violation of any covenant or agreement of BPA (including, without limitation, under this Section 15) contained in this Agreement.



(b) Subject to the limitations set forth in this Section 15, Company will indemnify and hold BPA, its Affiliates and their respective officers, directors, employees and agents (collectively the **"BPA Indemnitees"**) harmless against any and all Losses resulting from a Third Party Claim incurred or suffered by the BPA Indemnitees or any of them as a result of, arising out of, or relating to:

(i) any breach of, or inaccuracy in, any representation or warranty made by Company in this Agreement or any certificate delivered pursuant hereto (disregarding, for purposes of determining both the existence of any breach and the extent of any Losses, any qualification or exception with respect to materiality or Material Adverse Effect contained therein); or

(ii) any breach, nonperformance, or violation of any covenant or agreement of Company (including, without limitation, under this Section 15) contained in this Agreement.

(c) Inter-Party Claims. In order for a Party to validly assert a Claim for indemnification under this Article, such Party shall deliver written notice (a "Claim Notice") to the other Party as soon as practicable but in any event no later than thirty (30) days after such Claim becomes known to the Company Indemnitee or BPA Indemnitee, as applicable (all such persons collectively, the "Indemnified Person"), specifying (to the extent known) the facts constituting the basis for, and the amount (to the extent known) of, such Claim. Failure to deliver a Claim Notice with respect to a Claim in a timely manner as specified in the preceding sentence shall not be deemed a waiver of the right of the Indemnified Person to indemnification in connection therewith except (i) to the extent the other Party (the "Indemnifying Party") is actually and materially prejudiced as a result of such failure, in which case the amount of indemnification to which the Indemnified Person is entitled shall be reduced by the amount, if any, by which the Indemnified Person's Damages would or are reasonably expected to have been lower had such Claim Notice been timely delivered and, (ii) the Indemnified Person shall be solely responsible for any expenses incurred by the Indemnified Person during such period of delayed notice and for any increased costs (such as cost of substituting counsel) resulting from such delayed notice, and there shall be a rebuttable presumption that the Indemnifying Party was actually and materially prejudiced as a result of such failure if the notice is delayed more than six (6) months. The Indemnified Person shall deliver to the Indemnifying Party, promptly following the Indemnified Person's receipt thereof, copies of all notices and documents (including court papers) received by the Indemnified Person relating to any Claim made by another Person against the Indemnified Person (a "Third Party Claim"). If the Indemnifying Party does not notify the Indemnified Person in writing within thirty (30) days from its receipt of the Claim Notice that the Indemnifying Party disputes such Claim or reserves its rights (an "Indemnity Dispute Notice"), the Indemnifying Party shall be deemed to have agreed with and accepted such Claim. The Indemnified Person may in all events take all necessary and appropriate actions to defend a Third Party Claim until defense is undertaken by the Indemnifying Party, and shall in no event concede liability except as part of a settlement that is approved by the Indemnifying Party or otherwise permitted under this Section 15 or after giving seven days' notice to the Indemnifying Party of its intention to do so in circumstances where the Indemnifying Party does not undertake such defense prior to the expiry f such notice.

(d) Third Party Claims. The Indemnifying Party may assume the defense of any Third Party Claim with counsel selected by the Indemnifying Party and reasonably acceptable to the Indemnified Person by providing written notice to the Indemnified Person within thirty (30) days after receiving the applicable Claim Notice. If the Indemnifying Party fails to assume the defense of a Third Party Claim by providing such written notice, the Indemnifying Party shall be liable for the fees and expenses of one counsel selected by the Indemnified Person and reasonably acceptable to the Indemnifying Party, except that the Indemnifying Party shall retain the right to substitute counsel of its selection and reasonably acceptable to the Indemnified Person. If the Indemnifying Party elects to assume the defense of a Third Party Claim, the Indemnified Person shall have the right to participate in the defense thereof and to employ counsel, at its own expense, separate from the counsel employed by the Indemnifying Party, it being agreed, subject to the following sentence, that the Indemnifying Party shall control such defense, and the Indemnifying Party shall not be liable to the Indemnified Person for any legal or other expenses incurred by the Indemnified Person in connection with the defense thereof. Notwithstanding the preceding sentence, if the named parties (including any impleaded parties) to an Action in connection therewith include both an Indemnified Person and the Indemnifying Party (or any of its Affiliates) and the Indemnified Person reasonably concludes that there may be legal defenses available to it which are different from or additional to those available to the Indemnifying Party (or its Affiliates), the Indemnifying Party shall be liable for the fees and expenses of one separate counsel selected by the Indemnified Person to represent the Indemnified Person in connection therewith and, if the Indemnified Person notifies the Indemnifying Party thereof in writing, the Indemnifying Party shall not have the right to assume the defense thereof. If the Indemnifying Party elects to defend or prosecute a Third Party Claim, the Indemnified Person shall fully cooperate in the defense or prosecution thereof, and such cooperation shall include the retention and (upon the Indemnifying Party's request) the provision to the Indemnifying Party of records and information that are reasonably relevant to such Third Party Claim, and making the Indemnified Person's Agents available on a mutually convenient basis to provide additional information and explanation of any such materials.

The Indemnifying Party shall not effect, without the prior written consent of the Indemnified Person, any settlement, compromise or discharge of a Third Party Claim unless the same (x) involves an unconditional release of the indemnified claim against the Indemnified Person in form reasonably satisfactory to the Indemnified Person, (y) does not include any statement or admission as to fault, culpability, or failure to act by or on behalf of any Indemnified Person and (z) is limited to the payment of monetary damages and/or to action solely undertaken by the Indemnifying Party. The Indemnifying Party shall not be liable for any settlement, compromise or discharge of a Third Party Claim effected without its prior written consent, but if settled, compromised or discharged with its written consent or if there is a final Order for the plaintiff in any such Third Party Claim, the Indemnifying Party shall indemnify the Indemnified Person in connection therewith.

(e) Intentionally omitted.

(f) Limits.

(i) BPA will have no obligation to indemnify any Company Indemnitee pursuant to Section 15(a)(i) unless (i) any individual Loss contemplated by Section 15(a)(i) exceeds Twenty Thousand Dollars (\$20,000), in which case the total amount of such Loss (the "<u>Threshold Claim Amount</u>") shall be taken into account, and (ii) the cumulative total of Threshold Claim Amounts exceeds One Hundred Thousand Dollars (\$100,000) (the <u>"Deductible Amount</u>"), whereupon the Company Indemnitees shall be entitled to indemnification in respect of all Losses including those less than the Deductible Amount and including Losses which are individually less than the Threshold Claim Amount.

(ii) BPA will have no obligation to indemnify any Company Indemnitee pursuant to Section 15(a)(i) to the extent that the aggregate amount of all such Losses incurred or suffered by such Company Indemnitees exceeds \$2,000,000, provided however that the foregoing limitation of \$2,000,000 (the **"Cap"**) shall not apply with regard to any breach of, or inaccuracy in, any representation or warranty made by BPA in Sections 11(a) subparagraphs (iv)(b), (vi) and (xv)(b) in which case the limitation shall be \$1,000,000 (the **"Alternative Cap"**) provided further, that the foregoing limitations shall not apply to any claim or suit based upon a breach or inaccuracy of a Fundamental Rep.

(iii) For the avoidance of doubt, the limitations set forth in Section 15(f)(1) and (ii) shall not apply in respect of the indemnification obligations of BPA in Section 15(a)(ii).

(iv) Notwithstanding anything in this Agreement to the contrary, BPA will have no obligation to indemnify any Company Indemnitee pursuant to Section 15(a)(i), or for damages to Company for breach of a representation or warranty other than a Fundamental Rep, unless the occurrence of a loss or damage to Company became manifest within eighteen (18) months after Closing and Company gave notice to BPA of same no more than twenty (20) months after Closing.

(g) <u>Time for Claims</u>. No claim may be made or suit instituted seeking indemnification pursuant to this Section 15 unless a written notice describing the basis for such claim or suit in reasonable detail in light of the circumstances then known to the Indemnified Party is provided to the Indemnifying Party:

(i) at any time prior to the expiration of the applicable statute of limitations, in the case of any claim or suit based upon a breach or inaccuracy of a Fundamental Rep;

(ii) at any time prior to (i) eighteen months after the end of the License Term, in the case of claims arising from a breach of a covenant to be performed or complied with during the License Term, or from an inaccurate certification made in a certificate delivered pursuant to <u>Section 5(a)(i)(1)</u> or 5(a)(i)(2) or (ii) the expiration of the applicable statute of limitations in the case of claims arising from a breach of any other provision including breach of a covenant.

The representations and warranties made by the Parties under this Agreement shall survive for a period contemporaneous with the period during which the applicable Party may assert a claim in respect of a breach thereof, as set forth above in this Section 15(g).

(h) <u>Consequential Damages</u>. IN NO EVENT WILL EITHER PARTY HAVE ANY LIABILITY TO THE OTHER FOR ANY INDIRECT (INCLUDING LOST PROFITS), SPECIAL, CONSEQUENTIAL OR PUNITIVE DAMAGES EVEN IF ADVISED OF THE POSSIBILITY THEREOF, PROVIDED THAT THE FOREGOING DOES NOT LIMIT THE PARTIES RESPECTIVE INDEMNITY OBLIGATIONS FOR THIRD PARTY CLAIMS. THE ALLOCATION OF LIABILITY IN THIS PARAGRAPH REPRESENTS THE AGREED AND BARGAINED FOR UNDERSTANDING WITH RESPECT TO THE ALLOCATION OF RISKS INHERENT IN THIS AGREEMENT.

16. Intellectual Property.

(a) Patent Prosecution.

(i) As between the parties and to the extent that BPA has the right to do so under the Antares License Agreement: (i) BPA shall be responsible for the preparation, filing, prosecution and maintenance of the Patents in the Territory; provided, however, that Company shall reimburse BPA for any such costs incurred after the Closing Date to the extent exclusively relating to the Product or requested by Company, and (ii) BPA shall reasonably cooperate with Company to seek Company's input and comments on prosecution strategy, and shall provide Company with a copy of each submission made by BPA to a patent authority in the Territory regarding a Patent. Notwithstanding anything in the foregoing, if BPA (and any Third Party with the right to prosecute or maintain any Patent under the Antares License Agreement) determines in its sole discretion to abandon or not maintain such Patent anywhere in the Territory, then BPA shall provide Company with thirty (30) days prior written notice before any relevant deadline relating to the relevant Patent and shall offer in writing to Company the transfer of the respective Patent (if owned by BPA) or transfer of the right to prosecute and maintain the relevant Patent (if in-licensed to BPA). In the event Company accepts such offer to transfer the Patent within thirty (30) days after receipt of the offer, BPA shall take all measures necessary for the transfer and assignment of the Patent to Company and shall execute all documents necessary therefore. Company shall treat such information as BPA Confidential Information. In the event Company does not accept BPA's offer within the thirty (30) days time period, BPA is free to abandon the respective Patent. Further, to the extent permissible under the Antares License Agreement, BPA agrees to use good faith efforts to persuade Antares to add independent claims that solely cover estrogen-only products to any U.S. patent applications within the Patents. The cost and expense associated therewith shall be borne and reimbursed by Company. BPA shall use Commercially Reasonable Efforts to maintain all of the Patents in common ownership, where common ownership is required by one or more terminal disclaimers in the Territory, whether the terminal disclaimer refers to patents or patent applications.

(ii) Intentionally omitted.

(iii) The Parties acknowledge that Company, as the holder of the NDA, may refer to applicable Patents in the listing for the Product in the Orange Book.

(b) Patent Enforcement.

(i) <u>Group One Claims</u>. If requested by Company, BPA shall use Commercially Reasonable Efforts (including Commercially Reasonable Efforts to persuade Antares to agree to permit BPA to enforce the Group One Claims pursuant to this paragraph, subject to the enforcement rights of the Antares License Agreement, to enforce the Group One Claims against infringement by Third Parties in the Territory, provided that Company agrees to pay all fees, costs, and expenses incurred by BPA in or as a result of undertaking such efforts to enforce the Group One Claims at Company's

request, provided further that if the proceedings relate to the Product and one or more other products, the Parties shall agree on a fair allocation of the costs to be borne by Company. If requested by Company, BPA shall also use Commercially Reasonable Efforts, subject to the enforcement rights of the Antares License Agreement, to defend the Group One Claims against any challenges in the Territory, provided that Company agrees to pay all fees, costs, and expenses incurred by BPA in or as a result of undertaking such efforts to defend the Group One Claims. If Company so elects BPA to enforce Group One Claims or defend Group One Claims, Company shall reasonably assist and cooperate in any enforcement or defense at Company's sole expense. If BPA finds it necessary or desirable to join Company as a party, Company shall execute all papers or perform any other acts as may reasonably be required by BPA, at the expense of Company. BPA shall keep Company reasonably informed concerning such Group One Claims to the extent that BPA itself has such information, including (to the extent available to BPA and permitted by a discovery confidentiality order or the like) providing copies of any communications received in connection with such litigation to Company promptly after receipt thereof. To the extent practicable, BPA shall consult with and consider any comments made by Company (including the development and implementation of a litigation strategy) and permit Company the opportunity to review and comment on any proposed written communication, filing pleadings or other documents or submissions filed with the court in the course of such proceedings. BPA will seek and reasonably consider Company's comments on strategy for dispositive motions and settlement in any action to enforce or defend the Group One Claims, and Company will reasonably assist and cooperate in any enforcement or defense; provided, however, that BPA shall retain the sole right to select counsel of its choosing reasonably acceptable to Company (it being agreed that Kenyon & Kenyon LLP is acceptable). Any recovery realized as a result of any infringement actions described in this Section 16(b) (after reimbursement of the Parties' reasonable attorneys' fees for outside counsel and litigation expenses) shall be treated as Net Sales of Product in the year of receipt in accordance with Section 3(a) with Company receiving such amounts and paying to BPA the applicable royalty under Section 3(a)(ii), but shall not be treated as Net Sales for the purpose of any milestone payments under Section 3(a)(iii). Neither Party will enter into any withdrawal, termination or settlement (including the granting of a covenant not to sue or other rights that have a material impact on the rights granted to Company pursuant to this Agreement and/or a Related Agreement) of any action brought under this Section 16(b)(i) that affects the other Party's rights or interests without the other Party's prior written consent, not to be unreasonably withheld, conditioned or delayed. BPA will notify Company of all substantive developments with respect to such enforcement or defensive actions of the Group One Claims including, but not limited to, all material filings, court papers and other related documents, substantive settlement negotiations and offers of settlement. Nothing in this Section 16(b)(i) shall prohibit BPA from independently deciding to bring such enforcement or defense action regarding the Group One Claims in the Territory at BPA's sole expense provided that, BPA shall not agree to any settlement or other compromise of any litigation or claim, demand or dispute relating to any alleged or threatened infringement of any Group One Claim in relation to any pharmaceutical product containing as its sole active ingredient the same active ingredient as the Product, or otherwise likely to adversely affect the rights granted to Company hereunder, without Company's prior written consent if such settlement or other compromise: (i) provides for a license to any intellectual property used or useful in or in respect of the product at issue other than the applicable Group One Claims; (ii) provides for any transfer of technology, know-how or other proprietary rights; or (iii) involves supply of the product in question by BPA or BPA's Affiliate. For purposes of clarification, the parties agree that BPA shall have the sole right to settle or compromise such litigation or claim, demand or dispute, including without limitation by licensing or otherwise encumbering the applicable BPA Patent(s) without the consent of Company provided the terms of such settlement do not fall within clause (i), (ii) or (iii) of the first sentence of this Section 16(a). BPA further hereby agrees that Company shall have those rights possessed by BPA vis a vis Antares as set forth in Sections 8.2.2 and 8.2.4 of the Antares License Agreement, pursuant to Section 6 of Amendment No. 6 thereto.

(ii) Group Two Claims. At its own expense, Company may, but will not be obligated to, elect to enforce Group Two Claims against any actual, alleged or threatened infringement by Third Parties in the Territory and may also elect to defend the Group Two Claims against any challenges in the Territory. If Company so elects to enforce Group Two Claims against Third Party infringement, BPA, at Company's request and sole cost and expense, will reasonably assist and cooperate in any enforcement or defense of the Group Two Claims. If Company finds it necessary or desirable to join BPA as a party, BPA will execute all papers or perform any other acts as may reasonably be required by Company, at the expense of Company. BPA agrees that BPA shall abide by any judgment resulting from such enforcement or defense of the Group Two Claims. Any recovery realized as a result of any infringement actions described in this Section 16(b)(ii) (after reimbursement of the parties' reasonable attorneys' fees for outside counsel and litigation expenses) shall be treated as Net Sales of Product in accordance with Section 3(a) with Company receiving such amounts and paying to BPA the applicable royalty under Section 3(a)(ii), but shall not be treated as Net Sales for the purpose of any milestone payments under Section 3(a)(iii). Company will seek and reasonably consider BPA's comments on strategy for dispositive motions and settlement in any action to enforce or defend the Group Two Claims (provided, however, that Company shall retain the sole right to select counsel of its choosing) and will notify BPA of all substantive developments with respect to such enforcement or defensive actions regarding the Group Two Claims including, but not limited to, all material filings, court papers and other related documents, substantive settlement negotiations, offers of settlement, and court hearings and proceedings.

(iii) Paragraph IV Proceedings.

Notwithstanding the provisions of the foregoing Sections (a) and (b) if a Paragraph IV Certification (as defined in C.F.R. Title 21) is filed referencing the Product the following provisions shall apply:

(a) in the event that either BPA or Company receives a Paragraph IV Certification (as defined in C.F.R. Title 21) it shall inform the other Party verbally and in writing (by facsimile or by e-mail) as soon as practicable and in any event not later than two (2) Business Days of receipt of the foregoing certification or notice;

(b) during the following twenty-one (21) day period, BPA shall consult with Company as to the commercial reasonableness of suing such Third Party for patent infringement within the requisite forty-five (45) day period **("Infringement Suit")**;

(c) if upon, expiration of the twenty-one (21) day period, the Parties agree to file an Infringement Suit, the following applies:

i as between BPA and Company, Company shall have sole discretion to direct the strategy of the Infringement Suit (with Company recognizing that Antares as patent owner may itself exercise such control);

ii Company shall keep BPA informed at all times of the Infringement Suit including providing copies of any communications received in connection with such litigation to BPA promptly after receipt thereof. Company shall consult with and consider any comments made by BPA (including the development and implementation of a litigation strategy) and permit BPA the opportunity to review and comment on any proposed written communication, filing pleadings or other documents or submissions filed with the court in the course of such Infringement Suit;

iii BPA shall cooperate with Company to enforce the Patents and the Know-How, including initiation or maintenance as a party to the Infringement Suit to enforce such rights;

iv Company shall be responsible for Company's own external costs and expenses, including legal fees, associated with the Infringement Suit, and shall also be responsible for such reasonable costs of BPA as BPA incurs at the request of Company if BPA joins in the suit at Company's request.

(d) if, upon expiration of the twenty-one (21) day period, Company notifies BPA in writing that Company does not want to initiate the Infringement Suit, the following applies:

i as between BPA and Company, BPA shall have, in its sole discretion, the right to file an Infringement Suit and to direct the strategy thereof;

ii BPA shall keep Company informed at all times of the Infringement Suit including providing copies of any communications received in connection with such litigation to Company promptly after receipt thereof. BPA shall consult with and consider any comments made by Company (including the development and implementation of a litigation strategy) and permit Company the opportunity to review and comment on any proposed written communication, filing pleadings or other documents or submissions filed with the court in the course of such Infringement Suit;

iii Company shall cooperate with Company to enforce the Patents and the Know-How, including initiation or maintenance as a party to the Infringement Suit to enforce such rights;

iv BPA shall be responsible for BPA own external costs and expenses, including legal fees, associated with the Infringement Suit, and shall also be responsible for such reasonable costs of Company as Company incurs at the request of BPA if Company joins in the suit at BPA's request.

(c) <u>Patent Term Restoration and Regulatory Exclusivity</u>. The Parties shall take Commercially Reasonable Efforts to cooperate with each other in obtaining patent term restoration or extension, supplementary protection certificates, regulatory data extensions or exclusivity, or their equivalents, in the Territory where applicable, with any expense for same directed at the Product to be paid by Company. For the avoidance of doubt, this paragraph imposes no obligation on BPA to conduct or fund clinical studies.

(d) <u>Patent Marking and Rights</u>. Company shall mark Product with U.S. Patent No. 7,198,801, and following the issuance of any additional Patents with the numbers of such patents, in accordance with the requirements set forth in 35 U.S.C. § 287(a), in each case subject to regulatory restrictions imposed by the FDA or any other regulatory agency with jurisdiction over approval of human pharmaceuticals in the Territory. The Company shall not challenge or contest, or assist or encourage others to challenge or contest, the validity and enforceability of the Patents.

(e) Defense of and Liability for Infringement Claims.

(i) Each Party shall promptly notify the other Party in writing of any allegation made, threatened or brought against either of them alleging infringement or other unauthorized use of the intellectual property of a Third Party arising from (i) the development, manufacture, importation, use, offer for sale, sale or other commercialization of the Product in the Territory or (ii) from the development or manufacture outside the Territory as relates to the importation, use, offer for sale, sale or other commercialization of the Product in the Territory (**"Infringement Claim'*).** The provisions of this Section 16(e) are in addition to and separate from the provisions of Section 11(a)(xiii).

(ii) If a court or judicial body finds the Parties are required to obtain a Third Party License or orders the payment of a lump sum or periodic payment (such as a royalty) to the Third Party, or the Parties agree to settle the infringement Claim by taking a Third Party License or agreeing to make payments to the Third Party, then, subject to Section 16(e)(iii) and the following sentence, BPA's aggregate cumulative liability under this Section 16(e) shall be fifty percent (50%) of any lump sum payment due to a Third Party; and fifty percent (50%) of any royalty amount due to a Third Party; plus ten per cent (10%) of the external legal fees and expenses incurred by Company in such proceedings.

(iii) Company will be entitled to recover amounts due by BPA to Company under Section 16(e)(ii) solely as a credit against on-going royalties payable by Company to BPA under this Agreement, provided however that the maximum credit which may be claimed by Company in any Quarter is limited to an amount that will not reduce royalties to BPA for that Quarter below 8% of Net Sales. In addition any deficit remaining in Company's recovery of amounts due by BPA to Company following recovery by Company within the limitations set forth in this Section 16(e)(ii) may be carried over from year to year.

(iv) BPA and Company shall consult in good faith with respect to any actions BPA or Company proposes to take in order to mitigate any loss or liability with respect to any Infringement Claim, such actions may include Company ceasing to sell the Product, DPT ceasing to manufacture and supply Company with Product, Company ceasing to supply BPA with Product (for use outside the Territory) and/or the Parties agreeing to modify the Product.

(f) Third Party Licenses and Settlements.

(i) <u>Notice</u>. If during the Royalty Term either Party reasonably believes that the making, importation, use, offer for sale or sale of the Product in the Field in the Territory would infringe the intellectual property rights of a Third Party, that Party **("the Notifying Party")** shall so inform the other Party **("Notified Party")**, which notification shall include documents supporting the Notifying Party's position. If the Notifying Party believes a Third Party License is necessary or advisable to exercise its rights and obligations under this Agreement, including to sell the Product and/or mitigate any potential liability therefore, the notice shall include reference to such Third Party License.

(ii) <u>Counter-Notice</u>. Notified Party shall have thirty (30) days to review the notice issued pursuant to Section 16(f)(i) from the Notifying Party and to agree or disagree with the Notifying Party's belief by counter-notice. If the Notified Party disagrees with the Notifying Party's belief, then the Notified Party shall provide the Notifying Party with documents or other information supporting the Notified Party's position. The Notifying Party shall have thirty (30) days from the date of receipt to review the documents or other information from the Notified Party. Failure by the Notified Party to respond to the Notifying Party's notice, or by the Notifying Party to respond to the Notified Party's counter-notice, shall be taken for the purposes of the decision as to whether to obtain a license under this Section 16(f) (but for the avoidance of doubt, not for any other purpose whatsoever) as acceptance of the position of the other Party. The Parties agree that the time periods as set forth in this Section 16(f) may be reasonably extended by the mutual written agreement of the Parties.

(iii) <u>Resolution</u>. If the Notified Party disagrees with the Notifying Party's position pursuant to the terms as set forth in Section 16(f)(ii) herein and if the Notifying Party maintains its original position after such review period, then the matter shall be referred first to the officers of BPA and Company having responsibility for the subject matter of the dispute, or their designees. Such officers, or their designees, as the case may be, shall negotiate in good faith to resolve such dispute in a mutually satisfactory manner. If such efforts do not result in a mutually satisfactory resolution of the dispute within thirty (30) days of such referral, the matter shall be referred to the chief executive officer of each Party, or their respective designees.

(iv) <u>Final Resolution</u>. If the Parties' chief executive officers or their designees do not resolve the dispute within thirty (30) days of the matter being referred to them (or such longer time periods as may be mutually agreed in writing by the Parties) under Section 16(f)(iii), an independent mutually acceptable Third Party law firm with suitable expertise in the field of intellectual property in pharmaceuticals (the **"Firm")** shall be appointed to determine whether, in its opinion, the making, importation, use, offer for sale or sale of the Products in the Field and in the Territory would infringe the intellectual property rights of a Third Party, and that such infringement arises from or relates to the subject matter described in Section 16(e)(i) and that a Third Party License is necessary or advisable as referenced in Section 16(e)(ii). Once appointed, the Firm shall not be used by either Party (or their respective Affiliates) for matters pertaining to the Licensed Intellectual Property other than subsequent disputes under this Section 16(f). The costs of the Firm shall be borne by the Party with whom the Firm disagrees.

(v) <u>Disputes Not To Be Reopened</u>, The procedures in Sections 16(f)(i) to 16(f)(iv) shall not be used more than once in relation to any particular Third Party intellectual property identified in a Third Party License of Section 16(e), absent new and relevant facts.

(vi) Negotiation, If the Parties or the Firm determine that a Third Party License under Section 16(e) should be obtained as a Final Resolution of Section 16(f)(iv), Company shall have the initial right to negotiate such license but shall not grant or obtain a license or finalize a settlement without BPA's prior written consent, which may not be unreasonably withheld, conditioned or delayed. In the event that Company is unsuccessful in obtaining a license or settlement within one hundred and twenty (120) days of its first meeting with such Third Party (provided that this one hundred and twenty (120) day time period shall not include any days attributed to waiting for BPA to consent to any license or settlement proposal referred to in the previous sentence in this Section), then BPA shall have the right to negotiate such license, provided that BPA may only offer or grant to a Third Party in negotiations or as part of any settlement arising from such a negotiation a sublicense to the license granted to Company under this Agreement in accordance with Section 2, but shall not otherwise be entitled to offer or grant any right whatsoever to the Intellectual Property Rights in such circumstances without Company's prior written consent. In all such negotiations Company and BPA, as the case may be, shall conduct the negotiations with the Third Party in good faith and shall keep the other Party informed of the negotiations and, inter alia shall furnish drafts of the agreements shared with the applicable Third Party. Should Company and BPA fail to agree on one or more terms of the proposed agreement with a Third Party, they shall submit such dispute to the procedures set forth in Section 16(f) in which case to the extent required the Firm shall make a decision on the final form of the Third Party License. The costs of the Firm shall be borne by the Party with whom the Firm disagrees.

(vii) <u>Recovery</u>. Company shall be entitled to recover from BPA a portion of any amounts due pursuant to the Third Party License from BPA in accordance with the terms of Sections 16(e)(ii) and 16(e)(iii) as are applicable to this Section 16(f). For the avoidance of doubt, any monies so recovered from BPA by Company shall be considered together with any other monies recovered under Section 16(e)(ii) in calculating and determining BPA's aggregate cumulative liability under this Agreement.

(viii) <u>Unrelated Licenses</u>. Nothing in this Clause 3.5 shall be construed as affecting Company's rights to obtain licenses wholly unrelated to the incorporation of the BPA Intellectual Property in the Product, at its own expense.

17. Term of Agreement.

(a) This Agreement shall be effective as of the date first set forth above and shall continue in full force and effect until its expiration or termination in accordance with this Section. In addition to the rights of termination provided for elsewhere in this Agreement, either Party will be entitled forthwith to terminate this Agreement by written notice to the other Party if that other Party commits a material breach of any of the provisions of this Agreement, and fails to cure the same within sixty (60) days after receipt of a written notice from a Party hereto giving full particulars of the breach and requiring it to be remedied; provided, that if the breaching Party has proposed a course of action to cure the breach and is acting diligently and in good faith to cure same but has not cured the breach by the sixtieth (60th) day, such period shall be extended by such period as is reasonably necessary to permit the breach to be cured, provided that such period shall not be extended by more than ninety (90) days, unless otherwise agreed in writing by the Parties, and further provided that in the case of a breach that is the nonpayment of money, the breaching party shall have a nonextendible period of fourteen (14) days to cure following notice. The right to terminate shall be in addition to and not in substitution for any other available remedy at law or in equity.

(b) Either party may immediately terminate this Agreement upon written notice should the other party file a petition under any bankruptcy or insolvency act or have any such petition filed against it that is not dismissed within ninety (90) days.

(c) At any time during the Royalty Term Company shall have the right to terminate this Agreement on ninety (90) days notice in which case it shall return to BPA all rights and licenses sold and granted to Company under this Agreement, and the provisions of (h) below shall apply to such return if Company exercises its option. Upon the expiry of ninety (90) days of the exercise of such termination right, Company shall not be required to make further payments under this Agreement to BPA, but shall remain obligated to BPA for all payments or other obligations based on or required by sales of Product and other events occurring prior to the termination and effective return to BPA of all such rights and licenses. For the avoidance of doubt, Company shall not be entitled to a refund of or credit for payments made (or required to be made) to BPA before such effective return of rights and BPA shall remain entitled to (i) retain in full all such payments that were made and (ii) receive all such payments that were required to be made.

(d) If Company substantially discontinues distribution of Product and such substantial discontinuation continues for a period in excess of three (3) months, BPA shall have the right to terminate unless Company presents a plan to resume distribution of Product that is reasonably acceptable to BPA, provided that BPA shall not have a right to terminate where such discontinuation is caused by Force Majeure provided that Company exercises Commercially Reasonable Efforts to eliminate or overcome said Force Majeure so as to resume distribution of Product.

(e) Upon expiration of the Royalty Term and payment to BPA by Company of all amounts due on account of sale of Product during the Royalty Term and any other amounts then due or payable, and provided that Company is not then in breach of this Agreement, the licenses granted in Section 2 shall become fully paid-up.

(f) On termination of this Agreement, the licenses granted under Section 2 shall terminate and any and all information, trademarks, documents, Patents, and Know How (as that term is defined in Section 1.6 of the Antares License Agreement) relating to the Product, including all copies in whatever form or media, shall be immediately provided to and assigned to BPA; *provided, however.* Company may maintain one copy of any such information solely for purposes of exercising its legal rights hereunder. After such transfer, Company agrees to provide BPA with copies of all correspondence and documents to and from FDA and all notices received from FDA and to also provide BPA with regular updates as BPA may reasonably request.

(g) If this Agreement terminates for any reason, Company shall have the right to sell any Product that it has in process or in inventory as of the Closing Date of notice of such termination, *provided* that Company pays all royalties and milestones due on Net Sales thereof in accordance with Section 3 and *further provided* that such sell-off period shall be limited to 90 days from termination. Upon termination of this Agreement, Company shall remain liable for any involuntary or voluntary recalls initiated by Company of Product sold by Company pursuant to this Agreement.

(h) In the event that the Antares License Agreement terminates for breach by BPA that is not caused by the action or inaction of Company, it is agreed that in accordance with Section 12 of Amendment No. 6 to the Antares License Agreement (as clarified by a letter agreement dated October 27,2006 between BPA and Antares), Company's rights shall not terminate and this Agreement together with all of BPA's rights and obligations hereunder shall be deemed to be irrevocably assigned to Antares automatically without the need for any further action by any party, and this Agreement and all future payments and performance by Company hereunder shall thereafter continue in full force and effect between Company as the direct licensee and Antares as licensor. For the avoidance of doubt, upon such assignment all obligations of Company to BPA other than confidentiality obligations shall cease to be of any further force or effect, with the exception of amounts due or payable to BPA on account of sales or other activities that occurred prior to such assignment (even if the date for actual payment of such amounts is under the terms of this Agreement after such assignment), which shall be paid to BPA when they would otherwise be due under this Agreement.

(i) In the event that the Antares License Agreement terminates for liquidation or bankruptcy of BPA, it is agreed that in accordance with Section 12 of Amendment No. 6 to the Antares License Agreement (as clarified by a letter agreement dated November 6,2006 between BPA and Antares), Company's rights shall not terminate and this Agreement together with all of BPA's rights and obligations hereunder shall be deemed to be irrevocably assigned to Antares automatically without the need for any further action by any party, and this Agreement and all future payments and performance by Company hereunder shall thereafter continue in full force and effect between Company as the direct licensee and Antares as licensor. For the avoidance of doubt, upon such assignment all obligations of Company to BPA other than confidentiality obligations shall cease to be of any further force or effect, with the exception of amounts due or payable to BPA on account of sales or other activities that occurred prior to such assignment (even if the date for actual payment of such amounts is under the terms of this Agreement after such assignment), which shall be paid to BPA when they would otherwise be due under this Agreement.

(j) <u>Bankruptcy</u>: The Parties intend that (A) the license rights granted hereunder are fundamentally in the nature of a license to "intellectual property" as defined in the Section 101 of the U.S. Bankruptcy Code, 11 U.S.C. § 101(35A), (B) Company's continued enjoyment of the License is fundamental to the basic agreement hereunder and integral to the operation of Company's business; and (C) the License should be deemed "intellectual property" that is subject to Company's rights under Section 365(n) of the Bankruptcy Code, 11 U.S.C. § 365(n).

Upon any election by Company pursuant to Section 365(n)(l)(B) of the Bankruptcy Code, Company shall be entitled to (on its own or through agents) exercise all of its rights and remedies under this Agreement with respect to the License and to reasonably inform BPA throughout the process. To the extent permitted under applicable law, Licensor shall have no option to reject or otherwise terminate this Agreement in any bankruptcy or other similar proceeding (including where a receiver, liquidator or examiner is appointed) relating to Licensor and in that instance the License shall continue in full force and effect unless terminated by Licensee.

18. <u>Notices</u>. Any notice required or permitted to be given under this Agreement shall be sufficient if sent by certified mail (return receipt requested) or recognized commercial courier that requires a signature for delivery (such as FedEx), to the attention of the Chief Executive Officer of the respective company at the address set forth below or to such other address as a party may specify by notice hereunder, with copies sent in the same manner to the following:

In the case of Company:

Azur Pharma International II Limited David J Doyle/Sandra Seymour Clarendon House 2 Church Street, Hamilton HM 11 Bermuda Facsimile: (441) 292 4720

with copies to:

Azur Pharma Limited 45 Fitzwilliam Square Dublin 2 Ireland Attn: David Brabazon Facsimile: +353 1 634 4170

Mr. Colin Sainsbury BCM Hanby Wallace 88 Harcourt Street Dublin 2 IRELAND Facsimile: +353 1 418 6805

In the case of BPA:

CEO and President BioSante Pharmaceuticals, Inc. 111 Barclay Boulevard Lincolnshire, IL 60069 USA

-with a copy to-

Charles A. Weiss, Esq. Kenyon & Kenyon LLP 1 Broadway New York, NY 10004 USA



19. <u>No Agency or Joint Venture</u>. The Company is not an agent, joint venturer or partner of BPA, and the parties do not intend to create an agency, joint venture or partner relationship. Company and BPA shall be independent contractors. Neither Company nor BPA shall have the authority to make any statements, representations or commitments of any kind, or take any action, which shall be binding on the other, without the prior consent of the party to do so, except as expressly provided for herein.

20. <u>Assignment</u>. Neither party may assign this Agreement (including rights and obligations) without the prior written consent of the other, which consent shall not be unreasonably withheld or delayed. Such consent shall not be required for any assignment to (i) an Affiliate, or (ii) to a party that succeeds to all or substantially all of the assigning party's business or assets (whether by sale, merger, operation of law or otherwise), or (iii) in the case of Company to a party that succeeds to all or substantially all of Company's business or assets (whether by sale, merger, operation of law or otherwise), or (iii) in the case of Company to a party that succeeds to all or substantially all of Company's business or assets (whether by sale, merger, operation of law or otherwise) relating to the Company's Women's Health Division, or (iv) in the case of Company on or after the second anniversary of the Closing Date relating to the Product *provided* that in each case such assignee agrees in writing to be bound by the terms and conditions of this Agreement and *further provided* that in the case of assignment to an Affiliate, the assigning Party shall remain bound. Any purported assignment in contravention of this provision shall be null and void. The provisions of this Section 20 are subject to the first sentence of Clause 7(e).

21. <u>Non-Waiver and Entirety</u>. Any failure of either party to enforce any obligations under this Agreement shall not be deemed a waiver of such obligations. This Agreement constitutes the entire agreement and understanding of the parties and supersedes all previous communication between the parties. Notwithstanding the foregoing, the parties acknowledge that certain rights granted to Company under this Agreement are derived from, and subservient to, the rights granted to BPA under the Antares License Agreement.

22. <u>Governing Law</u>. This Agreement is governed by and construed in all respects in accordance with the laws of the State of Illinois, USA and the United States of America (without regard to conflicts of laws principles), excluding the United Nations Convention on Contracts for the International Sale of Goods.

23. Dispute Resolution.

(a) <u>Conciliation</u>. The parties wish first to seek an amicable settlement of all disputes, controversies or claims arising out of or relating to this Agreement by conciliation in accordance with the UNCITRAL Conciliation Rules now in force. The conciliation shall take place in Chicago, Illinois (USA) before a conciliator. If assistance is needed in connection with the appointment of a conciliator or other administrative matters, JAMS Endispute, Inc., 222 S. Riverside Plaza, Chicago, Illinois, US (telephone 312-739-0200) shall be the institution to render such assistance. The language to be used in the conciliation proceedings shall be English.

(b) Arbitration. Subject to possible court proceedings under Section 23(d) of this Agreement, if any conciliation proceedings under Section 23(a) of this Agreement are terminated in accordance with Article 15 of the UNCITRAL Conciliation Rules or rejected in accordance with Article 2 of those Rules, without resolution of the disputes, controversies or claims, then all said disputes, controversies or claims shall be determined by arbitration in accordance with the UNCITRAL Arbitration Rules now in force, as supplemented by the IBA Rules on the Taking of Evidence in International Commercial Arbitration, as adopted June 1,1999, insofar as said IBA Rules are not inconsistent with the express provisions of this Agreement. The language to be used in the arbitral proceedings shall be English. There shall be three (3) arbitrators and the appointing authority shall be JAMS Endispute, Inc. In rendering the award, the arbitrator shall follow and apply the substantive laws of the State of Illinois (without regard to conflict or choice of laws principles). The arbitrator shall have the authority to award compensatory damages only, subject to the limitations described in this Agreement. Each party shall pay the fees of its own attorneys, expenses of witnesses and all other expenses and costs in connection with the presentation of such party's case (collectively, "Attorneys' Fees"). The remaining cost of the arbitration, including without limitation, fees of the arbitrator, costs of records or transcripts and administrative fees (collectively, "Arbitration Costs") shall be borne equally by the parties. Notwithstanding the foregoing, the arbitrator in the award may apportion said Attorneys' Fees and Arbitration Costs, pursuant to Articles 38 through 40 of the UNCITRAL Arbitration Rules. The award rendered by the arbitrator shall be final, and judgment may be entered in accordance with the applicable law by any court having jurisdiction thereof.

(c) <u>Confidentiality</u>. The existence and resolution of any conciliation and/or arbitration shall be kept confidential, and the parties, the conciliator and the arbitrator shall not disclose to any person any information about such arbitration.

(d) <u>Court Proceedings</u>. Notwithstanding the arbitration provisions in Section 23(b) of this Agreement, either party shall have the right to sue in any court of competent jurisdiction to collect from the other party funds due and owing such party hereunder. Section 23(b) of this Agreement shall not be construed to prevent either party from seeking injunctive relief against the other party from any judicial or administrative authority of competent jurisdiction to enjoin that party from breaching this Agreement pending the resolution of a dispute by arbitration, pursuant to said Section 23(b). Any action to confirm an arbitration award or any other legal action related to this Agreement between the parties may be instituted in any court of competent jurisdiction. BPA and Company each waive their right to a trial by jury in any such court proceedings.

(e) <u>Location</u> The conciliation and arbitration shall be conducted in New York, New York, unless the dispute also involves a dispute with respect to the Product between BPA and Antares pursuant to the Antares License Agreement, in which case they shall be conducted in Chicago, Illinois.

24. <u>Force Majeure</u>. No party shall be liable to the other party for delay or failure in the performance of the obligations on its part contained in this Agreement if and to the extent that such failure or delay is due to circumstances beyond its control which it could not have avoided by the exercise of reasonable diligence. The affected party shall notify the other party promptly should such circumstances arise, giving an indication of the likely extent and duration thereof, and shall use all commercially reasonable efforts to resume performance of its obligations as soon as practicable.

25. <u>Severability</u>. Each party hereby acknowledges that it does not intend to violate any public policy, statutory or common laws, rules, regulations, treaty or decision of any government agency or executive body thereof of any country or community or association of countries. Should one or more provisions of this Agreement be or become invalid, the parties agree that it is their intent that the remainder of the Agreement shall continue in effect, and shall substitute, by mutual consent, valid provisions for such invalid provisions which valid provisions in their economic effect are sufficiently similar to the invalid provisions that it can be reasonably assumed that the parties would have entered into this Agreement with such valid provisions.

26. <u>Headings</u>. Section headings contained in this Agreement are for convenience of reference only and shall not in any way affect the interpretation of this Agreement.

27. <u>Further Assurances</u>. Each party agrees to take or cause to be taken such further actions, and to execute, deliver and file or cause to be executed, delivered and filed such further documents and instruments, and to obtain such consents, as may be reasonably required or requested in order to effectuate fully the purposes, terms and conditions of this Agreement.

28. <u>Execution</u>. This Agreement may be executed in two or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.

29. <u>Guarantee</u>. Azur Parent hereby guarantees to BPA the performance by Company of all of Company's duties and obligations under this Agreement, including payment obligations, the grant of rights and licenses, defense and indemnity obligations, and payment of all damages, liability, costs, expenses and other amounts that may be payable to BPA or its Affiliates, or recoverable by BPA or its Affiliates, from Company by virtue of this Agreement. For clarity, Azur Parent agrees to pay any amounts owed to BPA or its Affiliates by Company under this Agreement in the event that Company fails to pay such amounts when due under this Agreement and to pay any amounts of liability or damages owed to BPA or its Affiliates by Company for Company's breach of the Agreement if Company fails to pay such amounts when due under this Agreement upon written request.

[signature page follows]

IN WITNESS THEREOF, BPA and the Company have caused this Agreement to be executed by their duly authorized representatives as of the day and year first written above.

BioSante Pharmaceuticals, Inc.

By: /s/ Stephen M. Simes Stephen M. Simes Chief Executive Officer and President

Azur Pharma International II Limited

By: /s/ Kevin Insley

Kevin Insley Director

[Portions of this Exhibit have been omitted pursuant to a request for confidentiality under Rule 24b-2 of the Securities Exchange Act of 1934, as amended. A copy of this Exhibit with all sections intact has been filed separately with the Securities and Exchange Commission.]

AMENDMENT NO. 1 TO LICENSE AGREEMENT AND ASSET PURCHASE AGREEMENT

This AGREEMENT ("**Amendment**"), dated November 30, 2009 (the "**Amendment Effective Date**") is made by and between BioSante Pharmaceuticals, Inc., 111 Barclay Boulevard, Lincolnshire, IL 60069 ("**BPA**"), and Azur Pharma International II Limited, a Bermuda limited liability company, Clarendon House, 2 Church Street, Hamilton HM 11, Bermuda and such of its Affiliates as it may designate from time to time under one or more provisions of this Agreement ("**Company**").

WHEREAS, BPA and Company are parties to that certain License Agreement dated as of December 3, 2008 (as amended by the Amendment, the "License Agreement").

WHEREAS, BPA and Company wish to amend certain provisions of the License Agreement as set forth below.

WHEREAS, BPA and Company are parties to that certain Asset Purchase Agreement dated as of December 3, 2008 (as amended by the Amendment, the "Asset Purchase Agreement").

WHEREAS, BPA and Company wish to amend certain provisions of the Asset Purchase Agreement as set forth below.

NOW THEREFORE, BPA and Company (collectively, the "Parties" and each individually, a "Party") agree as follows:

1. <u>Definitions</u>. Except as otherwise set forth in this Amendment, capitalized terms shall have the definitions set forth in the License Agreement or Asset Purchase Agreement, as the case may be.

2. Royalties and Milestone Payments; Amendment to License Agreement.

(a) Within seven (7) days of the Amendment Effective Date, Company shall pay BPA \$1,000,000.00 ("Payment One").

(b) Company may in its sole and absolute discretion pay BPA an additional amount of either \$525,000.00 ("**Payment Two**") or \$1,050,000 ("**Payment Two** A") no later than January 11, 2010. For clarity, the benefits to Company under this Amendment for making Payment Two shall also apply if Company makes Payment Two A.

(c) If Company has made Payment Two A, then Company may in its sole and absolute discretion pay BPA an additional amount of either \$550,000.00 ("**Payment Three**") or \$1,100,000.00 ("**Payment Three** A") no later than February 22, 2010. For clarity, the benefits to Company under this Amendment for making Payment Three shall also apply if Company makes Payment Three A.

(d) In consideration of the above payments, and depending on what payments are made, the royalty required by Section 3(a) (ii) of the License Agreement and the milestones required by Sections 3(a)(iii)(1), 3(a)(iii)(2), 3(a)(iii)(4), and 3(a)(iii)(5) of the License Agreement shall modified from the current rates and amounts to the rates and amounts shown in the attached Table 1. After Payment One, the royalties will be reduced to the rates under the heading "After Payment One." If Payment Two is made, such royalties shall be reduced to the rates shown in the Table 1 below under the heading "After Payment Two." If Payment Two A is made, such royalties and such milestones shall be reduced to the rates under the heading "After Payment Two" A." If Payment Three is made, then such royalties shall be reduced to the rates under the heading "After Payment Three." If Payment Three A is made, such royalties and such milestones shall be reduced to the rates under the heading "After Payment Three." If Payment Three A is made, such royalties and such milestones shall be reduced to the rates and amounts under the heading "After Payment Three." If Payment Three A is made, such royalties and such milestones shall be reduced to the rates and amounts under the heading "After Payment Three." If Payment Three A is made, such royalties and such milestones shall be reduced to the rates and amounts under the heading "After Payment Three." If Payment Three A is made, such royalties and such milestones shall be reduced to the rates and amounts under the heading "After Payment Three." If Payment Three A is made, such royalties and such milestones shall be reduced to the rates and amounts under the heading "After Payment Three."

For clarity, the milestones required by Sections 3(a)(iii)(3), (6), and (7) of the License Agreement are not modified by this Amendment and will still be required in accordance with the terms of the License Agreement if the specified Net Sales of those subsections are achieved.

(e) If Company pays BPA Payment Two, the second Section 3(a)(ii)(2) of the License Agreement (beginning "In the event that one of more generic versions...") is deleted in its entirety and replaced with the following:

"In the event that one or more generic versions of the Product that is approved under 21 U.S.C. 355(j) (or any successor legislation) or which has an "AB" rating with respect to that Product, is sold by a Third Party in the Territory, for the remainder of the Royalty Term the Royalty payable pursuant to Section 3(a)(ii) shall be reduced from the royalties shown in Table 1 under the heading "After Payment Two" by the same percent reduction as occurs under the Antares License Agreement as the result of such generic entry."

(f) If Company pays BPA both Payment Two and Payment Three, the second Section 3(a)(ii)(2) of the License Agreement (beginning "In the event that one of more generic versions....") is deleted in its entirety and replaced with the following:

"In the event that one or more generic versions of the Product that is approved under 21 U.S.C. 355(j) (or any successor legislation) or which has an "AB" rating with respect to that Product, is sold by a Third Party in the Territory, for the remainder of the Royalty Term the Royalty payable pursuant to Section 3(a)(ii) shall be reduced by such amount below 4.5% of Net Sales as the royalty payable by BPA to Antares is reduced."

(g) In each case, the royalties and milestones set forth in Table 1 shall take effect as of the first day of the calendar month following the month in which the payment is made.

(h) Section 3 of the License Agreement is amended by adding a new Section 3(b) as follows:

"Notwithstanding anything in this Agreement to the contrary, (i) the royalties hereunder shall never be less than the royalties required by the Antares License Agreement, which are 4.5% of Net Sales with a reduction to 3.5% of Net Sales in the case of generic competition and (ii) if Company has made Payment Three or Payment Three A, the royalties hereunder shall never be greater than the royalties required by the Antares License Agreement (which as stated above is 4.5% of Net Sales with a reduction to 3.5% of Net Sales in the case of generic competition). Further, when Company sends royalty reports to BPA it shall at the same time send a copy of those royalty reports to Antares. Additionally, if Company makes Payment Three or Payment Three A then it shall going forward remit royalty payments and send royalty reports directly to Antares (with a copy of the reports and check or payment advice to BPA), and BPA agrees that with respect to Company's royalty obligations to BPA under this License Agreement the receipt of those payments by Antares shall be deemed equivalent to their receipt by BPA."

3. Additional Modifications to License Agreement in the Event of Payment Three.

If Company pays BPA both Payment Two and Payment Three, then the License Agreement shall be further amended as follows upon receipt of Payment Three:

(a) Section 7 of the License Agreement is amended as follows: Sections 7(a) and 7(b) are retained without modification. Sections 7(c), 7(d), and 7(e) are deleted in their entirety and replaced with the following:

"(c) Company shall provide BPA an annual summary report of its commercialization of the Product, including copies of the Company's sales and marketing plans and one copy of each advertising, detailing or promotional material used during the year.

(d) With each annual summary required by Section 7(c) above, Company shall also provide BPA with copies of all material correspondence and documents to and from FDA and all notices received from FDA concerning the Product. However, any such materials concerning safety or adverse events, or matters that may interrupt manufacture or require any recall, shall promptly be provided by Company to BPA and not delayed until the annual submission."

(b) Section 16(b)(iii)(a) to (c) of the License Agreement shall be deleted in its entirety and replaced with the following:

"Notwithstanding the provisions of the foregoing Sections (a) and (b) if a Paragraph IV Certification (as defined in C.F.R. Title 21) is filed referencing the Product the following provisions shall apply:

(a) in the event that either BPA or Company receives a Paragraph IV Certification (as defined in C.F.R. Title 21) it shall inform the other Party verbally and in writing (by facsimile or by e-mail) as soon as practicable and in any event not later than two (2) Business Days of receipt of the foregoing certification or notice;

(b) during the following twenty-one (21) day period, Company shall consult with BPA as to the commercial reasonableness of suing such Third Party for patent infringement within the requisite forty-five (45) day period (**"Infringement Suit**");

(c) if upon, expiration of the twenty-one (21) day period, Company elects at its discretion to file an Infringement Suit, the following applies:

i as between BPA and Company, Company shall have sole discretion to direct the strategy of the Infringement Suit (with Company recognizing that Antares as patent owner may itself exercise such control);

ii Company shall keep BPA informed at all times of the Infringement Suit including providing copies of any communications received in connection with such litigation to BPA promptly after receipt thereof. Company shall consult with and consider any comments made by BPA (including the development and implementation of a litigation strategy) and permit BPA the opportunity to review and comment on any proposed written communication, filing pleadings or other documents or submissions filed with the court in the course of such Infringement Suit;

iii BPA shall cooperate with Company to enforce the Patents and the Know-How, including initiation or maintenance as a party to the Infringement Suit to enforce such rights;

iv Company shall be responsible for Company's own external costs and expenses, including legal fees, associated with the Infringement Suit, and shall also be responsible for such reasonable costs of BPA as BPA incurs at the request of Company if BPA joins in the suit at Company's request. Any recovery realized as a result of any infringement action described in this Section 16(b)(iii) (after reimbursement of the Parties' reasonable attorneys' fees for outside counsel and litigation expenses) shall be treated as Net Sales of Product in the year of receipt in accordance with Section 3(a) with Company receiving such amounts and paying to BPA the applicable royalty under Section 3(a)(ii), but shall not be treated as Net Sales for the purpose of any milestone payments under Section 3(a)(ii)."

(c) Section 16(e) of the License Agreement shall be deleted in its entirety and replaced with the following:

"(e)(i) Each Party shall promptly notify the other Party in writing of any allegation made, threatened or brought against either of them alleging infringement or other unauthorized use of the intellectual property of a Third Party arising from (i) the development, manufacture, importation, use, offer for sale, sale or other commercialization of the Product in the Territory or (ii) from the development or manufacture outside the Territory as relates to the importation, use, offer for sale, sale or other commercialization of the Product in the Territory ("**Infringement Claim**"). The provisions of this Section 16(e) are in addition to and separate from the provisions of Section 11(a)(xiii).

(e)(ii) BPA shall at Company's request consult with Company on the response to an Infringement Claim, and shall at Company's request cooperate with Company (at Company's expense) in Company's response and defense of such claim, but shall otherwise have no obligation in respect to an Infringement Claim.

(e)(iii) Company shall have sole discretion as to the manner in which it will defend an Infringement Claim, including with regard to any actions Company proposes to take in order to mitigate any loss or liability with respect to any Infringement Claim, such actions may include Company ceasing to sell the Product, DPT ceasing to manufacture and supply Company with Product, Company ceasing to supply BPA with Product (for use outside the Territory) and/or the Company electing to modify the Product."

(d) Section 16(f) of the License Agreement shall be deleted in its entirety and replaced with the following:

"Any licenses from Third Parties that may be required for Company's activities under this License Agreement shall be the sole responsibility of Company in its sole discretion and at its sole expense. BPA shall at Company's request consult with Company with respect to any such potential license."

(e) Section 9(d) of the License Agreement shall be deleted in its entirety and replaced with the following:

"Subject to compliance with all applicable laws and regulatory requirements, Company agrees to supply BPA with Product at cost plus 7.5% for use in Israel and Canada and BPA shall have the right to place orders for reasonable quantities of Product for sale by BPA or BPA's licensees in Israel and Canada when Product is being made by or for Company; *provided, however*, if BPA and BPA's licensees intend to order sufficient quantities of Product to comprise a complete manufacturing batch of Product, BPA and its licensees shall place their own order for the Product independently of Company's orders. Company shall give BPA reasonable advance notice for each manufacturing run to enable BPA to exercise its rights under this Section 9(d). Product shall be packaged in the normal US packaging and Company shall not be responsible for any changes in packaging or other activities that are not part of the normal manufacturing practices of Company. BPA shall pay Company's actual out of pocket cost for such manufacture plus 7.5% of such cost (which shall only be payable if such product is purchased from Company) including any surcharges imposed by the manufacturer for partial batches and special packaging and labeling requirements. BPA shall make payments for its orders either directly to the manufacturer or to Company, as applicable, and shall take delivery either directly from manufacturer or Company, with the details of same to be negotiated in good faith between BPA and Company (subject to the default rules of the Uniform Commercial Code if

agreement on the details is not reached). In the event that the manufacturer is not able to fill the entire quantity ordered by Company and BPA, Company shall be entitled to direct DPT to satisfy the needs of Company and its customers as reasonably demonstrated by Company to BPA, and if there is sufficient capacity remaining to supply all or part of the requirement of BPA and its licensees. In no event shall Company have any responsibility for any matters relating to the supply of the Product such as failed lots, quality issues, delays in supply, or product liability or otherwise have any liability with regard to the supply of such product, and BPA hereby indemnifies and holds harmless Company with regard to any claim which may be made by any Third Party and for its part confirms that Company has no liability to BPA based on or arising out of the supply of Product under this Section 9(d) (except for Company's obligation to supply as set forth in the first sentence of this Section 9(d))."

(f) Section 9 of the License Agreement is amended by adding a new Section 9(f) as follows:

"For countries outside the Territory other than Israel and Canada, Company may at its sole discretion agree that it shall supply BPA with Product for use in such countries on such terms as may be agreed including (i) to the extent applicable, the provisions set out in Section 9(d), (ii) Company shall be permitted to allocate limited manufacturing capacity or limited supply of Product to itself and its own customers ahead of any orders for Product placed by BPA for such countries, and (iii) the Parties shall in such event confer in an effort to arrange to fill BPA's orders for such countries in a way that will not disrupt manufacturing or supply for Company."

4. Modification to Asset Purchase Agreement in the Event Company Makes Payment 3 Three A.

If Company pays BPA both Payment Two A and Payment Three A, then the Asset Purchase Agreement shall be amended as follows upon receipt of Payment Three:

(a) Section 13 of the Asset Purchase Agreement shall be deleted in its entirety and replaced with the following:

"In the event that the License Agreement between BPA and the Company is terminated for material breach by Company, or Company knowingly takes any action (or refuses or omits to take any action) that would cause a breach of the Antares License Agreement likely to result in the termination of the Antares License Agreement by Antares on account of such breach, Company assigns all right, title and interest in and to the NDA, the Trademark (together with all goodwill associated therewith), and the Domain Names to BPA, shall promptly transfer all documentation related to such NDA, Trademark, and Domain Names to BPA, and agrees to take all such further action and promptly execute such further documents as may be reasonably necessary or desirable to give full effect to such assignment, including without limitation submitting a letter to the FDA

requesting transfer and any related documents with the FDA to effect such transfer, providing an assignment of the Trademark in recordable form, and providing an assignment to transfer ownership of the Domain Name with the registrar. After such transfer of the NDA to BPA, Company agrees to cooperate with BPA, at Company's own expense other than its reasonable out of pocket expenses, which shall be reimbursed by BPA upon request, for a reasonable transition period not to exceed six (6) months, regarding (i) FDA regulatory obligations for the Product, including without limitation the preparation and submission of annual reports, the reporting of adverse events, and cooperating with governmental regulatory agencies; (ii) communication with Third Parties regarding the Product, including without limitation responding to complaints and medical inquiries; (iii) investigating all complaints and adverse drug experiences related to the Product; and (iv) giving such notice as BPA may request to the FDA and to DPT or any other contract manufacturer of Product."

5. <u>Agreements otherwise remain in effect</u>. All provisions of the License Agreement and Asset Purchase Agreement that are not amended in this Agreement remain in effect, except to the extent that any provisions may have lapsed, been satisfied, or become moot without regard to this Agreement.

[signature page follows]

IN WITNESS THEREOF, BPA and the Company have caused this Agreement to be executed by their duly authorized representatives as of the day and year first written above.

BioSante Pharmaceuticals, Inc.

By /s/ Stephen M. Simes Stephen M. Simes Chief Executive Officer and President

Azur Pharma International II Limited

By: /s/ Kevin Insley Kevin Insley Director

TABLE 1

	_	After	After	After	After	After
Event	Current	Payment One	Payment Two	Payment Two A	Payment Three	Payment Three A
Net Sales of the Product in the Territory in a calendar year under \$10,000,000 or over			Royalty			
\$17,500,000	Royalty 10%	Royalty 7.25%	5.875%	Royalty 5.875%	Royalty 4.5%	Royalty 4.5%
Net Sales of the Product in the Territory in a calendar year Sales between \$10,000,000 and						209003
\$17,500,000	Royalty 20%	Royalty 12.75%	Royalty 8.625%	Royalty 8.625%	Royalty 4.5%	Royalty 4.5%
Milestone at \$XXXXXX in Net Sales of the Product in the Territory in a calendar year Milestone at \$XXXXXX in Net Sales of the Product in the Territory in a calendar year				\$XXXXXXXX		\$XXXXXXXX
calendar year Milestone at \$XXXXXX in Net Sales of the Product in the Territory in a				\$XXXXXXXX		\$XXXXXXXX
calendar year Milestone at \$XXXXXX in Net Sales of the Product in the Territory in a				\$XXXXXXXXX		\$XXXXXXXXX
calendar year	\$XXXXXXXX	\$XXXXXXXX	\$XXXXXXXX	\$XXXXXXXX	\$XXXXXXXX	\$XXXXXXXX

[Portions of this Section have been omitted pursuant to a request for confidentiality under Rule 24b-2 of the Securities Exchange Act of 1934, as amended. A copy of this Exhibit with all sections intact has been filed separately with the Securities and Exchange Commission.]