

UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

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FORM 8-K  
CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

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Date of Report (Date of earliest event reported):  
JUNE 13, 2000

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BIOSANTE PHARMACEUTICALS, INC.  
(Exact name of registrant as specified in its charter)

WYOMING  
(State or Other of  
Incorporation)

000-28637  
(Commission File Number)

58-2301143  
(I.R.S. Employer  
Identification Number)

175 OLDE HALF DAY ROAD  
LINCOLNSHIRE, ILLINOIS  
(Address of principal executive offices)

60069  
(Zip Code)

(847) 793-2434  
(Company's telephone number, including area code)

NOT APPLICABLE.  
(Former name or former address, if changed since last report)

## ITEM 5. OTHER EVENTS

On June 13, 2000, BioSante Pharmaceuticals, Inc., a Wyoming corporation ("BioSante"), entered into a license agreement and a supply agreement with Permateg Technologie, AG, a corporation organized under the laws of Switzerland ("Permateg"), covering four hormone products for the treatment of testosterone deficiency in men and estrogen deficiency in women. Three of the four new products licensed by BioSante are gel formulations of testosterone (the natural male hormone), estradiol (the natural female hormone) and a combination of estradiol and a progestogen (another female hormone). The fourth product is an estradiol patch.

### LICENSE AGREEMENT

Under the terms of the license agreement, Permateg has granted BioSante an exclusive license, with the right to grant sublicenses, to develop and, after receipt of all necessary approvals, market the products in the following countries: United States, Canada, Mexico, Israel, Australia, New Zealand, China, Malaysia, Indonesia and South Africa, except that BioSante's rights to market the combined estradiol and progestogen product extend only to the United States and Canada. BioSante has an option to add additional countries to the covered territories. BioSante also has an exclusive right of first offer to develop and market in the United States, Canada, Japan and any other country listed above not already licensed to third parties or subject to a third party's right of first refusal, and to enter into a respective license therefore, another proposed gel formulation product currently being developed by Permateg. In addition to this product, Permateg has agreed to license to BioSante another gel formulation product that Permateg is currently developing in the event Permateg does not previously enter into a license agreement for that product with another party.

In consideration for the license, BioSante has agreed to pay Permateg an initial license fee, a portion of which may be applied against future royalty payments and/or sublicense up front payments. In addition, BioSante must pay Permateg a royalty based on a certain percentage of the aggregate net sales for each product sold in each country, commencing with the first commercial sale of any of the products, and thereafter with respect to each such product until the later of: (1) the expiration of the last to expire patents applicable to such product in such country and (2) the tenth anniversary of the first commercial sale of such product in such country. In addition to the up-front license fee and royalty payments, BioSante must make certain milestone payments upon the attainment of certain milestones relating to the development and commercial sale of the products. In the event BioSante sublicenses any of the products in any portion of the territories, BioSante must pay Permateg a certain percentage of any up-front or sublicense or milestone payments received from such sublicensees. In the event BioSante licenses the two additional gel formulation products that Permateg is currently developing, BioSante must pay Permateg an additional license fee, milestone payments and royalties based on a certain percentage of net sales.

The term of the license agreement will expire on a country-by-country and product-by-product basis when the royalties expire, at which time BioSante will have a fully paid-up exclusive license regarding the applicable product in such country. The parties may terminate the license agreement earlier upon the occurrence of certain events.

The license agreement is attached as Exhibit 1 to this report and is incorporated by reference into this report in its entirety.

#### SUPPLY AGREEMENT

Under the terms of the supply agreement, Permaterc has agreed to manufacture or have manufactured and sell exclusively to BioSante, and BioSante has agreed to purchase exclusively from Permaterc, BioSante's total requirements for the products covered under the license agreement between the two parties. Within two years following the first commercial sale of a product, BioSante has the right to ask Permaterc to assure that a second company becomes qualified as an alternative manufacturer of the products.

The term of the supply agreement is the longer of 20 years or as long as BioSante is paying royalties on any product to Permaterc under the license agreement. The parties may terminate the supply agreement earlier upon the occurrence of certain events.

The supply agreement is attached as Exhibit 2 to this report and is incorporated by reference into this report in its entirety.

#### ITEM 7. FINANCIAL STATEMENTS AND EXHIBITS.

(a) FINANCIAL STATEMENTS OF BUSINESSES ACQUIRED.

Not applicable.

(b) PRO FORMA FINANCIAL INFORMATION.

Not applicable.

(c) EXHIBITS.

EXHIBIT NO. ---	DESCRIPTION -----
10.1*	License Agreement dated as of June 13, 2000 between Permaterc Technologie, AG and BioSante Pharmaceuticals, Inc. (filed herewith)
10.2*	Supply Agreement dated as of June 13, 2000 between BioSante Pharmaceuticals, Inc. and Permaterc Technologie, AG (filed herewith)
99.1	Press Release dated June 13, 2000 (filed herewith)

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\* Confidential treatment has been requested with respect to designated portions contained within 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.

SIGNATURES

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/ Stephen M. Simes

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Stephen M. Simes  
President and Chief Executive Officer

Dated: July 10, 2000

BIOSANTE PHARMACEUTICALS, INC.

FORM 8-K

INDEX TO EXHIBITS

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LICENSE AGREEMENT  
BETWEEN  
PERMATEC TECHNOLOGIE, AG  
AND  
BIOSANTE PHARMACEUTICALS, INC.

[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  
INTACT HAS BEEN FILED SEPARATELY WITH THE SECURITIES AND  
EXCHANGE COMMISSION.]

INDEX

[PORTIONS OF THIS INDEX 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 THIS INDEX INTACT HAS BEEN FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION.]

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## LICENSE AGREEMENT

This agreement is entered into, effective this 13th day of June, 2000, by and between PERMATEC TECHNOLOGIE, AG, a corporation of Switzerland ("PERMATEC"), and BIOSANTE PHARMACEUTICALS, INC., a Wyoming corporation ("BIOSANTE").

### BACKGROUND

WHEREAS, PERMATEC has begun formulation and development of several new pharmaceutical products based on proprietary know-how, and desires to grant BIOSANTE an exclusive license in defined geographical areas under the terms and conditions set forth hereinafter to continue the development of and to market these products;

WHEREAS, BIOSANTE desires to take from PERMATEC such a license to continue the development and to market these products;

THE PARTIES ARE HEREBY AGREED AS FOLLOWS:

#### 1. DEFINITIONS

1.1 "AFFILIATE" shall mean, with respect to either party hereto, any corporation, partnership or other entity controlled by, controlling or under common control with, such party, with "control" meaning direct or indirect beneficial ownership of more than 50% of the voting power of, or more than 50% of ownership interest in, such corporation, partnership or other entity.

1.2 "APPROVAL" shall mean the first effective date on which sales of a new drug may begin, in accordance with a new drug approval received from FDA, and any equivalent approval from the respective Regulatory Authority in any other country of the Territory.

1.3 "DEVELOP" or "DEVELOPMENT" shall mean and include to undertake any and all activities to investigate, research, conduct clinical trials, perform market research, prepare and submit applications for Approval, negotiate with government entities (including the FDA and Regulatory Authorities), or conduct any other activities ordinarily undertaken, or necessary or required or advisable to be undertaken, by the sponsor of a pharmaceutical product in the process of being prepared for marketing or being marketed and to be granted Approvals, on the same basis as if it were the owner of the Products.

1.4 "DEVELOPMENT PLAN" shall mean the Development Plan for each Product pursuant to Section 5.6 below.

1.5 "FDA" shall mean the US Food and Drug Administration.

1.6 "KNOW-HOW" shall mean all information and data, which are not generally known including, but not limited to, patent claims and related information not yet disclosed to the public, formulae, procedures, protocols, techniques and results of experimentation and testing, which (a) relate to any of the Products, and (b) are necessary or useful to the Development or Marketing of any of the Products in the Territory, all to the extent as of the effective date of this Agreement owned or otherwise controlled by and at the free disposition of PERMATEC.

1.7 "MARKET" or "MARKETING" shall mean any and all activities ordinarily associated with efforts to interest a given market in a product and to induce and further sales, including, but not limited to, sales, sales support, continuing medical education, advertising, promotion, publicity and media relations.

1.8 "NET SALES" shall mean the aggregate arms-length gross price invoiced by BIOSANTE and, if applicable, invoiced by the sublicensees of BIOSANTE, for the sale for commercial use of Products to non-affiliated third parties during the relevant period, less deductions for (i) normal and customary trade and cash discounts, credits and allowances (for rejection or return of Products), rebates or refunds incurred or granted; and (ii) sales, use or excise taxes and duties, and freight and insurance, to the extent included in the gross price charged.

1.9 "PATENTS" shall mean all patents and patent applications filed or having presently or in the future legal force in any country in the Territory owned by PERMATEC which claim any of the Products, or the process to manufacture any of the Products, including but not limited to the patents and patent applications listed in EXHIBIT A hereto, together with all patents that in the future issue therefrom in any country of the Territory, including utility, model and design patents and certificates of invention, and all divisionals, continuations, continuations-in-part, reissues, renewals, extensions, substitutions, confirmations or additions to any such patents and patent applications.

1.10 "PRODUCTS" shall mean the four pharmaceutical products developed by PERMATEC, either dermal gel or patch, for application on the skin, intended for pharmaceutical use with humans for any indication now known or known in the future, and with defined active compounds, all as listed in EXHIBIT B.

1.11 "REGULATORY AUTHORITY" shall mean any governmental authority in any country of the Territory competent to approve pharmaceutical products for manufacturing, marketing, distribution and sale in any country of the Territory and/or to approve the price for pharmaceutical products to be sold in any country of the Territory.

1.12 "SPECIFICATIONS" shall mean the specifications, recipes and manufacturing instructions for Products as known at the effective date of this Agreement and from time to time during the term of this Agreement changed, altered, amended or repealed by mutual consent of the parties.

1.13 "SUPPLY AGREEMENT" shall mean the written agreement between BIOSANTE PHARMACEUTICALS, INC. and PERMATEC TECHNOLOGIE, AG, executed by the parties at or about the same time as this License Agreement.

1.14 "TERRITORY" shall mean the United States of America and those of its territories and possessions over which the FDA has regulatory authority (the "USA"); Canada; Australia; New Zealand; South Africa; Israel; Mexico; The People's Republic of China (including Hong Kong) ("China"); Malaysia; and Indonesia. The countries are classified according to EXHIBIT C in three tiers.

1.15 "GOOD MANUFACTURING PRACTICES" or "GMP" shall mean the then-current requirements of FDA relating to the manufacture of pharmaceutical products and related activities in the United States, as set forth in applicable FDA regulations and Guidance Documents, and any and all equivalent rules and regulations applicable to such activities in any other country of the Territory.

## 2. LICENSE GRANT

2.1 LICENSE: PERMATEC hereby grants to BIOSANTE an exclusive license, with the right to grant sublicenses as provided in this Agreement, to Develop the Products in the Territory (except for the E2-XXXXX Combi Gel or any other product substituted under section 2.5 of this Agreement, the Territory for which is restricted to USA and Canada) as "applicant" and "owner" of Products, as those terms are defined in applicable regulations, for purposes of obtaining Approvals, and upon receipt of the Approvals, to Market and sell the Products, in the Territory, and to use the Patents and Know-How exclusively for that purpose, all in accordance with the provisions contained in this Agreement. It is the parties' intention that any product characterized by its marketing approval, as opposed to Products, developed by BIOSANTE and based on PERMATEC's technology will be and remain the property of BIOSANTE but BIOSANTE will not be allowed to use or market the products in case the License Agreement between PERMATEC and BIOSANTE is terminated. [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 AGREEMENT WITH THIS SECTION INTACT HAS BEEN FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION.]

2.2 SUB-LICENSES: In the event that BIOSANTE grants a sublicense under its license to any Affiliate or third party for any part of the Territory, then BIOSANTE shall be responsible for any and all acts, deeds and undertakings of its sub-licensee(s) and shall continue to be bound by all terms and provisions under this Agreement throughout its

term. BIOSANTE shall assume any and all obligations and undertakings in lieu and place of its sub-licensee(s) and shall be held responsible for these obligations, including but not limited to the confidentiality obligations set forth hereinafter. Furthermore, BIOSANTE undertakes that any and all sub-license agreements shall provide for inspection and audit provisions identical to the provisions set forth below in order to enable PERMATEC to control and audit and receive any and all payments due as provided in this Agreement. BIOSANTE shall provide PERMATEC promptly with copies of all agreements with such sub-licensee(s) (with only the commercial terms redacted).

2.3 ASSISTANCE: PERMATEC agrees during the term of this Agreement to provide technical and scientific assistance to BIOSANTE (i) without any additional charge to the extent mutually agreed upon in the Development Plan, and (ii) against reimbursement applying a rate of USD 150 per man-hour spent by PERMATEC personnel in addition to the mutually agreed upon assistance pursuant to sub-section (i) hereinabove, provided in each case that BIOSANTE undertakes and agrees to reimburse any and all reasonable out-of-pocket expenses incurred by PERMATEC in connection with any such assistance. Such assistance shall be provided by PERMATEC within a reasonable time in response to requests in connection with BIOSANTE's efforts to obtain Approvals for the Products, including, without limitation, providing the chemistry, manufacturing and control components of any application needed to obtain Approvals.

2.4 NO FURTHER OR TRADEMARK LICENSE: It is understood and acknowledged by BIOSANTE that the license granted hereunder shall under no circumstances encompass any further license grant, including without limitation any further license with respect to the Know-How or the Patents or any products other than Products, or with respect to any trademark or trade-name of PERMATEC, including without limitation its internationally registered trademark "Permatec".

2.5 E2-XXXXX COMBI GEL: BIOSANTE has ninety (90) days to exchange the E2-XXXXX Combi Gel with another progestative from the following list: XXXXX, XXXXX or XXXXX. BIOSANTE shall use its best efforts to decide on a change in a shorter period of time. Without written notice from BIOSANTE requesting a change, PERMATEC will assume that E2-XXXXX Combi Gel remains the originally selected progestative. In the meantime, the Development Plan will be established based on E2-XXXXX Combi Gel. If PERMATEC has a potential interested party for one of the mentioned Combi gels, excluding E2-XXXXX Combi Gel, with proposed commercial terms, PERMATEC shall inform BIOSANTE in writing and BIOSANTE has fifteen (15) business days to decide on a change. [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 AGREEMENT WITH THIS SECTION INTACT HAS BEEN FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION.]







3.3.5.1	Gel Testosterone	up to USD XXXXX
3.3.5.2	Gel E2	up to USD XXXXX
3.3.5.3	Patch E2	up to USD XXXXX
3.3.5.4	E2-XXXXX Combi Gel	up to USD XXXXX

The following payments shall be made:

XXXXXXXXXX: Up to USD XXXXX for Gel Testosterone, USD XXXXX for Gel E2 and USD XXXXX for Patch E2, USD XXXXX for E2-XXXXX Combi Gel, depending upon whether payments have previously been made for XXXXXXXXXXXXX as set forth below.

XXXXXXXXXXXXX: USD XXXXX XXXXXXXXXXXXXXXXXXXXX  
XXXXXXXXXXXXXXXXXXXXXXXXXXXX  
XXXXXXXXXXXXXXXXXXXXXXXXXXXX

XXXXXXXXXXXXX: USD XXXXX XXXXXXXXXXXXXXXXXXXXX  
XXXXXXXXXXXXXXXXXXXXXXXXXXXX  
XXXXXXXXXXXXXXXXXXXXXXXXXXXX

If a patent exists that prevents BIOSANTE from introducing any Product into commercial sale, notwithstanding Approval, the XXXXXXXX payments described in this subsection will be delayed until such time as the patent in issue ceases to prevent such sale.

3.3.6 XXXXXXXXXXXXXXXX: In the event that BIOSANTE fails to XXXX XXXXXXXXXXXXXXXXXXXXXXXX pursuant to Section 3.3.1 or 3.3.2 above at the time as provided in the Development Plan for the respective Product, and such failure to XXXXXXXXXXXXXXXX continues for more than thirty (30) days after BIOSANTE receives from PERMATEC the respective notice to do so, then the respective milestone payment under Section 3.3.1 and 3.3.2 above, respectively, shall nonetheless become due and payable upon the expiration of the thirty (30) day period provided for in PERMATEC's notice.

3.3.7 XXXXXXXXXXXXXXXX: In the event that BIOSANTE fails to XXXX XXXXXXXXXXXXXXXXXXXXXXXX

XX  
XX  
XX

continues for more than thirty (30) days after BIOSANTE receives from PERMATEC the respective notice to do so, then the respective milestone payment under Section 3.3.4 above shall nonetheless become due and payable upon the expiration of such thirty (30) day period provided for in PERMATEC's notice.

3.4 SUB-LICENSEE PAYMENTS: Should BIOSANTE in its sole discretion, but always in accordance with Section 2.2 above, sub-license any of the Products, in any portion of the Territory, BIOSANTE shall pay to PERMATEC XXXXX percent (XXXXX%) of any up-front or sublicense or milestone payments received from such sub-licensees, in addition to royalties, except for up-front or milestone or sublicense payments related to a sublicense in China, Hong Kong, Malaysia or Indonesia for which BIOSANTE will pay PERMATEC XXXXX percent (XXXXX%) of such payments from sub-licensees. [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 AGREEMENT WITH THIS SECTION INTACT HAS BEEN FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION.]

3.5 MODE OF PAYMENTS, RELATED REPORTS

3.5.1 INITIAL AND MILESTONE PAYMENTS: The initial payment and all milestone payments due PERMATEC under this Agreement shall be paid in U.S. Dollars (USD), within thirty (30) days of the triggering event of the initial payment and each milestone, respectively, by confirmed wire transfer to a bank account of PERMATEC reasonably notified to BIOSANTE.

3.5.2 ROYALTY PAYMENTS: All royalty payments due to PERMATEC under this Agreement shall accrue and be paid to PERMATEC quarterly, in U.S. Dollars (USD), within sixty (60) days of the end of each calendar quarter (each quarter being a period of three consecutive calendar months commencing January, April, July and October), by confirmed wire transfer to a bank account of PERMATEC reasonably notified to BIOSANTE from time to time.

3.5.2.1 WITHHOLDING: Any and all withholding taxes or similar charges assessable to BIOSANTE on royalties payable hereunder for sales outside of the United States will be deducted from such amount due, will be paid by the payer to the proper taxing authority, and proof of payment of said tax, as well as any other documents or confirmations reasonably required by PERMATEC to recover any such withholding taxes or parts thereof from the proper tax authorities, will be secured and sent to PERMATEC as evidence of such payment.

- 3.5.2.2 CALCULATION OF ROYALTIES: Any conversions into U.S. Dollars (USD) from the currency in which the corresponding Net Sales for any royalties were made, are to be made by applying an exchange rate equal to the applicable buying rate reported by The Wall Street Journal for the currency of the country in question for the last business day of the calendar quarter in question.
- 3.5.2.3 REPORTS: Each such royalty payment shall be accompanied by a statement showing on a country-by-country and Product-by-Product basis the amount of Net Sales of each Product achieved during such quarter and the amounts of royalty due on such Net Sales of Products. With respect to any calendar quarter for which no payment is due for any given Product in any given country, BIOSANTE shall nonetheless include such Product and/or country in each such quarterly statements. Each such statement shall be certified by the CFO or other authorized officer of BIOSANTE to be complete, true and accurate.
- 3.5.2.4 BOOKS AND RECORDS: BIOSANTE shall keep full, true and accurate books of account containing all particulars and reasonable supporting documentation which may be necessary for the purpose of determining the Net Sales of Products, royalties due thereon and the statements provided by BIOSANTE pursuant to Section 3.5.2.3 above. Such records shall be kept at BIOSANTE's principal place of business, and shall be open at all reasonable times and upon reasonable advance notice to the inspection of PERMATEC or an independent certified public accounting firm retained by PERMATEC, and reasonably acceptable to BIOSANTE, for the purpose of verifying any payment made under this Agreement. PERMATEC shall bear the full cost of any such audit, unless the audit discloses that the amount due during any period audited exceeds the amount paid by (i) ten percent (10%) or more during the first two (2) years following first commercial sale of a Product in any country; or (ii) five percent (5%) or more thereafter, in which case BIOSANTE shall bear the full cost of such audit. Any additional royalty found in such audit to be due PERMATEC shall be paid by BIOSANTE within thirty (30) days after such finding.

4. PERMATEC PRODUCTION OF PRODUCTS

4.1 PRODUCTION OF CLINICAL BATCHES: PERMATEC will formulate and produce and supply the Products in sufficient quantities for all purposes of Development as reasonably needed for BIOSANTE to perform its Development obligations under this Agreement, as follows:

- 4.1.1 ORDERS: PERMATEC will supply Products for clinical studies in response to written orders from BIOSANTE to be issued in accordance with the Development Plan for each Product. Any order for such clinical batch shall provide for lead times of at least one-hundred-eighty (180) days, and will allow for quantities of +/- 10% of the quantity of Product ordered. BIOSANTE agrees to purchase from PERMATEC all supplies of Products so ordered for all Development purposes hereunder.
- 4.1.2 PRODUCTION COSTS: PERMATEC shall bear the costs, up to an aggregate of XXXXX Dollars (USD XXXXX) per Product (for a potential aggregate maximum of XXXXX Dollars (USD XXXXX) for all four products), associated with the formulation and production of such clinical batches of the Products including, without limitation, the preparation of the chemistry, manufacturing and control components of any application needed to obtain Approval(s), with any additional cost of the formulation and production of such clinical batches of Products in excess of USD XXXXX per Product to be borne exclusively by BIOSANTE. [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 AGREEMENT WITH THIS SECTION INTACT HAS BEEN FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION.]
- 4.1.3 FURTHER PROVISIONS: Any and all further provisions governing the production and supply of clinical batches of Products shall be mutually agreed upon by the parties at the appropriate time and, absent such mutual agreement, the respective provisions of the Supply Agreement shall apply mutatis mutandis to such production and supply of clinical batches.
- 4.1.4 REPAYMENT OF PRODUCTION MILESTONES: In the event that PERMATEC, within the one-hundred-eighty (180) days minimum lead time for the order of any Product for clinical studies from BIOSANTE under Section 4.1.1 above, may not reasonably demonstrate its ability to produce or have produced the ordered clinical batch of the respective Product in time and in compliance with applicable GMP, then BIOSANTE may request PERMATEC to repay the respective production milestone payment paid by BIOSANTE for the production of the clinical batches of such Product under Section 3.3.1 and 3.3.2, respectively, upon receipt of which request PERMATEC shall be fully released from its obligation under Sections

4.1.1 through 4.1.3, but with respect to the affected Product only. In that case, PERMATEC shall repay to BIOSANTE 25% of USD XXXXX per product up to a total of XXXXX Dollars (USD XXXXX). [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 AGREEMENT WITH THIS SECTION INTACT HAS BEEN FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION.]

4.2 PRODUCTION OF COMMERCIAL SUPPLY: The terms and conditions governing the ordering, manufacturing and supply of any Product for commercial use shall be mutually agreed upon by the parties in a separate Supply Agreement.

5. DEVELOPMENT OBLIGATIONS OF BIOSANTE AND PERMATEC

5.1 NON-TERRITORY DEVELOPMENT: PERMATEC shall retain all rights to the Products, the Know-How and the Patents in geographical areas not included within the Territory, and PERMATEC shall have all rights, but no obligation whatsoever, to develop, market and sell or license out to a third party any Product with respect to any and all countries outside the Territory.

5.2 DATA SHARING: BIOSANTE and PERMATEC agree to provide one another immediate, full and free access to the clinical data and results generated by or on behalf of each with respect to the Products, and each agrees that the other may utilize all such data and results, directly or through permitted (sub-) licenses in pursuit of Product Approval in their respective geographical areas (the Territory for BIOSANTE, all other areas for PERAMATEC), provided that (i) BIOSANTE undertakes to include such obligation in any and all of its sub-license agreements in accordance with Section 2.2 above, and (ii) PERMATEC will use its best efforts to obtain access to such data from other licensees or sublicensees, but PERMATEC shall have no obligation to share or provide any such information and data regarding Products with BIOSANTE under this Section 5.2, if such information and data is not freely available to PERMATEC.

5.3 BIOSANTE'S DEVELOPMENT AND MARKETING OBLIGATIONS/UNITED STATES: BIOSANTE agrees and undertakes to diligently use all its commercially reasonable efforts to (1) Develop the Products in the Territory, and to (2) obtain Approval from the FDA to market the Products as applicant and owner, consistent with the Development efforts undertaken by other companies similarly situated within the industry for similar drug products used for similar indications, all in accordance with the respective Development Plan for each Product. As Approvals for each respective Product are obtained, BIOSANTE shall proceed diligently to (1) use all its commercially reasonable efforts to sell the Product[s] in the applicable jurisdictions of the Territory, (2) Market, advertise and promote the sale of and otherwise employ marketing and sales techniques

reasonably designed to develop a demand for the Product[s] in order to achieve the projected sales. Toward these ends, BIOSANTE shall take appropriate steps including but not limited to:

- (a) preparation and filing of an Investigational New Drug Application with FDA concerning each Product as applicant; and
- (b) establishing and maintaining a program reasonably designed and funded to obtain information adequate to enable BIOSANTE to file a New Drug Application or Abbreviated New Drug Application, as applicable, for each Product; and
- (c) investing and making available any and all necessary financial, Marketing, sales and human resources required to achieve in time the projected sales of each Product as provided for in the Development Plan.

5.4 BIOSANTE'S DEVELOPMENT AND MARKETING OBLIGATIONS/NON-US: In all other countries of the Territory, BIOSANTE agrees to use all its commercially reasonable efforts to Develop and Market, or have Developed and Marketed by sub-licensees in accordance with Section 2.2 above, the Products and to obtain the necessary Approvals, consistent with the Development and Marketing efforts undertaken by other companies similarly situated within the industry for similar drug products used for similar indications in any country of the Territory, all in accordance with the respective Development Plan for each Product, in order to achieve in time the projected sales of each Product as provided for in the Development Plan.

5.5 PROTOCOL REVIEW: The parties agree that before either begins a clinical trial of a Product, whether conducted by or on behalf of such party, it will give the other party the opportunity to review the protocol for such trial, along with the opportunity to provide comments. The reviewing party shall have fourteen (14) days to complete such review. Notwithstanding any such consultation, the party conducting such clinical trial shall maintain full and sole responsibility regarding any such study protocol.

#### 5.6 DEVELOPMENT PLAN

- 5.6.1 AGREED DEVELOPMENT PLAN: As soon as possible, but in any event within ninety (90) days of entering into this Agreement, BIOSANTE shall prepare and provide to PERMATEC, for each Product, a Development Plan containing sales projections, its best good faith projection of a Development timetable (including projected timetables for clinical studies and the FDA new drug application process), and projected date of launch. BIOSANTE and PERMATEC will consult and agree on this Development Plan by written acknowledgement by each party on a copy of the plan, provided to the other party.
- 5.6.2 MATERIAL DEVIATIONS: Material deviations from the Development Plans, including without limitation deviations from the timetable contained therein, shall require the prior written consent by PERMATEC, which



consent shall not be unreasonably withheld, except that in no event shall PERMATEC's approval be withheld if BIOSANTE may demonstrate that such deviation is required, due to, or caused by, any material technical, scientific or clinical reason encountered by BIOSANTE during the Development of such Product.

5.7 DEVELOPMENT REPORTING: BIOSANTE undertakes to provide PERMATEC regularly, but at least twice yearly (within sixty (60) days of the start of the calendar year and July 1, respectively), with an update reasonably detailing the steps and actions performed and results achieved or gained by BIOSANTE in pursuing the Development pursuant to the Development Plan, including without limitation information on the status of any filing for Approvals for each Product.

6. REPRESENTATIONS, WARRANTIES AND COVENANTS; INDEMNIFICATION

6.1 PERMATEC'S: PERMATEC, as an inducement to BIOSANTE to enter into this Agreement, represents, warrants and covenants to BIOSANTE as follows:

6.1.1 RIGHT TO LICENSE: PERMATEC has full right, power and authority to grant an exclusive license to BIOSANTE in the Territory pursuant to the terms of this Agreement to practice the technology covered by any and all patents listed in Exhibit A, and Know-How, and to Develop, Market and sell the Products, free and clear of any mortgage, lien, encumbrance or other third-party interest of any kind. As of the effective date of this Agreement, PERMATEC is not aware of any fact or circumstances that the Products are, in or with respect to the Territory, subject to any restrictions, covenants, licenses other than this Agreement, or judicial and administrative orders of any kind, which detract in any material respect from the value of the Products, or which could interfere with the use thereof by BIOSANTE in the Territory as contemplated by this Agreement.

6.1.2 NO INABILITY TO RECEIVE APPROVAL: As of the effective date of this Agreement, PERMATEC is aware of no facts that would reasonably lead it to conclude that any of the Products will be unable to receive the contemplated Approval from the FDA or Approval from any other Regulatory Authority upon satisfactory completion of clinical trials, and PERMATEC has no knowledge of any facts which would reasonably lead it to conclude that satisfactory completion of clinical trials is not likely.

6.1.3 CLEAR RIGHTS: As of the effective date of this Agreement, PERMATEC has not received any notice and has no knowledge that (i) the rights to Develop, Market and sell the Products have been challenged in any

judicial or administrative proceeding, or (ii) any person, entity or product has infringed or will infringe any patent rights encompassed by the Patents and applicable to the Products, or (iii) any patent rights or other intellectual property rights, including but not limited rights of trade mark, trade dress and copyright, have been infringed by PERMATEC or will be infringed by BIOSANTE by virtue of performing the activities contemplated by this Agreement.

- 6.1.4 RIGHT TO EXECUTE AND PERFORM: PERMATEC has full right, power and authority to execute and deliver this Agreement, and to perform its obligations under it, and has taken all necessary action to authorize such execution, delivery and performance. This Agreement constitutes the legal, valid and binding obligation of PERMATEC, enforceable against it in accordance with its terms.
- 6.1.5 COMPLIANCE WITH LAW: PERMATEC will comply with all applicable laws in connection with performance of its obligations under this Agreement. The execution, delivery and performance of this Agreement by PERMATEC does not violate any provision of applicable law or of any regulation, order, decree of any court, arbitration or governmental authority, or any other agreement to which PERMATEC is a party. No consents, approvals or authorizations, registrations or filings are required in connection with the execution, delivery, performance, validity or enforceability of this Agreement, except as have been obtained or set forth in this Agreement.
- 6.1.6 NO FURTHER REPRESENTATION: Except for the specific representations and warranties given by PERMATEC in this Section 6.1, PERMATEC does not give any further or other warranty and makes no other or further representation, whether express or implied. IN PARTICULAR, BUT WITHOUT LIMITATION OF THE GENERALITY OF THE PRECEDING SENTENCE, PERMATEC DOES NOT GIVE ANY WARRANTY AND MAKES NO REPRESENTATION WITH RESPECT TO THE PRODUCTS AND/OR THE KNOW-HOW, INCLUDING WITHOUT LIMITATION, ANY WARRANTY OF COMPLETENESS, ACCURACY, MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE THEREOF, IN PARTICULAR WITH RESPECT TO THE INTENDED PURPOSE OF SUCCESSFUL APPLICATION FOR APPROVAL(S) IN ANY COUNTRY OF THE TERRITORY.

6.2 BIOSANTE'S: As an inducement to PERMATEC to enter into this Agreement, BIOSANTE represents and warrants to PERMATEC as follows:

- 6.2.1 RIGHT TO EXECUTE AND PERFORM: BIOSANTE has full right, power and authority to execute and deliver this Agreement, and to perform its

obligations under it, and has taken all necessary action to authorize such execution, delivery and performance. This Agreement constitutes the legal, valid and binding obligation of BIOSANTE, enforceable against it in accordance with its terms.

- 6.2.2 COMPLIANCE WITH LAW: BIOSANTE will comply with all applicable laws in connection with performance of its obligations under this Agreement. The execution, delivery and performance of this Agreement by BIOSANTE does not and will not violate any provision of applicable law or of any regulation, order, decree of any court, arbitration or governmental authority, or any other agreement to which BIOSANTE is a party. No consents, approvals or authorizations, registrations or filings are required in connection with the execution, delivery, performance, validity or enforceability of this Agreement, except as have been obtained or set forth in this Agreement.
- 6.2.3 BEST EFFORTS: BIOSANTE represents and warrants that it will use its best efforts to perform and pursue all steps and actions required for, and apply for and pursue the Approvals for Product in accordance with the Development Plans and within the time-limits set forth therein, and, upon such granting of any such Approvals, to Market the Products throughout the Territory during the term of and in accordance with this Agreement.
- 6.2.4 COMPLIANCE WITH APPROVALS: BIOSANTE represents and warrants that in addition to complying with and respecting any and all applicable laws, rules, regulations and orders, it shall also comply with all terms and conditions of the Approvals (if any), when Developing, Marketing and selling Products in any country of the Territory.
- 6.2.5 NO FURTHER REPRESENTATION: Except for the specific representations and warranties given by BIOSANTE in this Section 6.2, BIOSANTE does not give any further or other warranty and makes no other or further representation, whether express or implied. IN PARTICULAR, BUT WITHOUT LIMITATION OF THE GENERALITY OF THE PRECEDING SENTENCE, BIOSANTE DOES NOT GIVE ANY WARRANTY AND MAKES NO REPRESENTATION WITH RESPECT TO THE PRODUCTS AND/OR THE KNOW-HOW, INCLUDING WITHOUT LIMITATION, ANY WARRANTY OF COMPLETENESS, ACCURACY, MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE THEREOF, IN PARTICULAR WITH RESPECT TO THE INTENDED PURPOSE OF SUCCESSFUL APPLICATION FOR APPROVAL(S) IN ANY COUNTRY OF THE TERRITORY.

6.3 INDEMNIFICATION BY BIOSANTE: Without affecting any other remedies available under this Agreement, BIOSANTE shall defend, indemnify and hold PERMATEC and

its directors, officers and employees, harmless from and against any and all claims, suits or demands for liability, damages, costs and expenses (including reasonable fees, costs and expenses of attorneys and other professionals and court costs, but excluding consequential damages for lost profits) arising from or relating to the negligence or willful misconduct of BIOSANTE or its Affiliates or its sub-licensees in connection with the subject matter of this Agreement.

6.4 INDEMNIFICATION BY PERMATEC: Without affecting any other remedies available under this Agreement, PERMATEC shall defend, indemnify and hold BIOSANTE and its directors, officers and employees, harmless from and against any and all claims, suits or demands for liability, damages, costs and expenses (including reasonable fees, costs and expenses of attorneys and other professionals and court costs, but excluding consequential damages for lost profits) arising from or relating to the negligence or willful misconduct of PERMATEC in connection with the subject matter of this Agreement.

## 7. CONFIDENTIALITY

7.1 OBLIGATION OF CONFIDENTIALITY: Except to the extent expressly authorized by this Agreement, or otherwise agreed in writing, the parties agree that, at all times during the term of this Agreement and for five (5) years thereafter, the receiving party shall keep completely confidential, shall not publish or otherwise disclose and shall not use directly or indirectly for any purpose, any information furnished, disclosed, delivered or otherwise made available to it by the other party pursuant to this Agreement (including without limitation Know-How), except to the extent that it can be established by the receiving party by competent proof that such information:

- (a) was already known to the receiving party, other than under an obligation of confidentiality, at the time of disclosure by the other party;
- (b) was generally available to the public or otherwise part of the public domain at the time of its disclosure to the receiving party;
- (c) became generally available to the public or otherwise part of the public domain after its disclosure, other than through any act or omission of the receiving party in breach of this Agreement; or
- (d) was disclosed to the receiving party, other than under an obligation of confidentiality, by a third party who had no obligation to the disclosing party not to disclose such information to others.

7.2 EXCEPTIONS: Each party may disclose the other's information to the extent such disclosure is reasonably necessary in filing or prosecuting patent applications, pursuing or defending litigation, or complying with applicable governmental regulations, provided that if a party intends to make any such disclosure, it shall give reasonable advance written notice to the other party of such intended disclosure, and shall take reasonable steps to restrict or limit such disclosure or require confidential treatment thereof.

7.3 WHEN CONSENT NEEDED: Except as otherwise provided in Section 7.2 above, neither party shall disclose any terms or conditions of this Agreement to any third party without the prior consent of the other party. Notwithstanding the foregoing, prior to the execution of this Agreement, the parties shall agree upon the substance of information that can be used to describe the terms of this transaction, and the parties may disclose only such information without the other party's consent.

## 8. PROPRIETARY RIGHT AND PATENTS

8.1 TITLE: PERMATEC shall retain title to and full ownership in the Products, the Patents and the Know-How including, but not limited to, any and all developments and inventions related thereto, if any (hereinafter collectively referred to as "PERMATEC IPR"). BIOSANTE does not by virtue of this Agreement, directly or indirectly through its officers, directors, employees, agent, Affiliates, customers or other controlled or associated third parties, acquire any proprietary interest in or other right to PERMATEC IPR, other than provided in this Agreement.

8.2 INFRINGEMENT BY THIRD PARTIES: PERMATEC and BIOSANTE recognize that they each have an interest in the protection of the PERMATEC IPR. Either or both may wish to take steps to protect or defend their respective interests in specific circumstances. In addition:

8.2.1 NOTICE: If either PERMATEC or BIOSANTE becomes aware of (i) any product or activity of any kind that involves or may involve an infringement or violation of PERMATEC IPR with respect to Products and/or the Territory, or (ii) any third-party action, claim or dispute (including, but not limited to, actions for declaratory judgement alleging invalidity or non-infringement) based upon or arising out of PERMATEC IPR with respect to Products and/or the Territory, then each agrees to promptly so notify the other in writing.

8.2.2 INDEPENDENT DECISIONS TO ACT: Each party shall, in its sole discretion, have the right but no obligation to determine the most commercially appropriate course of action, if any, for it to follow to enforce, or otherwise abate the infringement of, or defend third-party actions regarding, PERMATEC IPR with respect to Products and the Territory, including whether to request status as an additional party to any such action. Each party deciding to take any such course of action shall do so at its own risk, benefit, cost and expense. Notwithstanding anything contained herein, BIOSANTE shall not accept any settlement or award in any such action which has or may have a negative impact on the proprietary or other legitimate rights of PERMATEC in any of the PERMATEC IPR, without the prior written consent of PERMATEC, which consent shall not be withheld unreasonably.

8.2.3 REDUCTION IN ROYALTY: In the instance in which an A/B rated generic equivalent or substitute of a Product on sale in any part of the Territory is reasonably notified by either party under Section 8.2.1 above to infringe a Patent available for such Product in such country of the Territory, and PERMATEC takes no action against the third party, but BIOSANTE does, and BIOSANTE may give evidence that the marketing of such competitive product has led to a reduction in sales of the affected Product in such country of the Territory of more than fifteen percent (15%), then the Royalty payable by BIOSANTE to PERMATEC for that Product after such reasonable notice pursuant to Section 8.2.1 in that country of the Territory will be XXXX percent (XXXX%) for as long as (1) such competing product is on sale, and (2) BIOSANTE's Royalty obligation exists under this Agreement. [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 AGREEMENT WITH THIS SECTION INTACT HAS BEEN FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION.]

8.2.4 COOPERATION: In addition to the above, each party, regardless of whether it joins in a legal action, agrees to cooperate with the other to provide reasonable assistance in the prosecution or defense of any actions regarding PERMATEC's IPR. Each party shall keep the other regularly informed on developments in any such action in which it participates or obtains information, if the other party is not involved.

## 9. TERM AND TERMINATION

9.1 TERM: This Agreement shall be effective on the date first written above and shall expire, unless earlier terminated by either party pursuant to this Section 9, on a country-by-country and Product-by-Product basis upon the expiration of the respective Royalty Term, subject to BIOSANTE's continuing fully-paid up exclusive license pursuant to Section 3.2 above.

9.2 TERMINATION: At any time, this Agreement may be terminated by giving written notice to that effect, as follows:

- (a) by either party, if the other party is in material default or in material breach of any term or provision hereof, including without limitation to the terms and deadlines incorporated into the parties' agreed Development Plan, which termination shall apply only to the Product(s) and Country(ies) involved, or material breach of any representation or warranty in this Agreement or material breach of the confidentiality obligations hereof, and such material default or material breach continues and is not remedied within thirty (30) days upon the other party's written request to remedy such default or breach; or

- (b) by either party, if the other party goes into liquidation, voluntarily or otherwise, other than for the sole purpose of reorganisation, or goes into bankruptcy or makes an assignment for the benefit of creditors, or in the event of a receiver being appointed of a substantial part of the other party's property; or
- (c) by either party in its sole discretion, with respect only to the involved Product or Products, or country or countries of the Territory, respectively, and without prejudice to any other rights conferred on it by this Agreement and in addition to any other remedies available to it by law or in equity, if such party terminates the Supply Agreement for material breach or insolvency or other material reason caused or set by the other party as provided for in such Supply Agreement, with the effect of such being the termination of this Agreement upon the effective date of the termination of the Supply Agreement; or
- (d) by PERMATEC, with respect only to the involved Product or Products, or country or countries of the Territory, respectively, if BIOSANTE, (A) within six (6) months after the delivery of clinical supplies has not initiated with respect to each Product and for each country of the Territory reasonable steps, including sub-licensing in case BIOSANTE shall not wish to Develop and Market itself the Product in certain countries of the Territory, to Develop and thereafter Market such Product pursuant to the provisions of this Agreement, it being understood the development work done in the USA may be applicable in all countries of the Territory or (B) within three (3) months after receipt of commercial quantities after receipt of any Approval for a Product in any given country of the Territory has not launched such Product in such country of the Territory, or (C) within eighteen (18) months after receipt of the first Approval for any given Product by any Regulatory Authority, does not either (i) file a request for Approval for such Product in all countries of the Territory only if the first approval is useful for approval purposes, or (ii) sublicense such Product in such other country(ies) of the Territory, or (D) ceases the Marketing and sale of any Product in any country of the Territory after the Approval from the respective Regulatory Authority has been received, in each case with respect to the affected Product and the affected country(ies) only, and in each case only if BIOSANTE does not cure such situation within three (3) months after PERMATEC's written request to do so, subject always to Section 11.10 below; or
- (e) by BIOSANTE prior to the granting of an Approval for any given Product in any given country of the Territory, in case of material technical, scientific or regulatory problems or, if the results and data achieved and generated during the Development of any given Product in reasonable determination show that Approval for such Product will be unlikely to be granted, with respect to the affected Product only and in a specific country of the Territory, and provided that prior to such termination, the parties have discussed in all details the problems encountered and not agreed on a mutually acceptable change of the Development Plan pursuant to Section 5.6.2 above; or

- (f) by BIOSANTE, if any Regulatory Authority has finally denied the Approval (or any material part thereof) for any given Product in any country of the Territory, with respect to the affected Product and such country or countries only; or
- (g) by BIOSANTE if in its reasonable discretion it determines that it would not be economically viable to develop and market a Product in any country of the Territory, with respect to a specific product and country only. In this case, BIOSANTE shall inform PERMATEC immediately of this decision and shall provide in writing and within 30 days a detailed explanation including market research data and projections and calculation for such a decision. Following this decision and on a country-by-country basis, PERMATEC has the right to use free of charge all the development data, registration file for marketing or licensing purposes in that specific country and for that specific Product. In that case the repayment of the costs to generate data by PERMATEC to BIOSANTE as defined in paragraph 9.4 does not apply. The approvals obtained by BIOSANTE in these countries will be transferred free of charge to PERMATEC upon request.

9.3 NO PREJUDICE TO RIGHTS: The termination of this Agreement shall be without prejudice to any rights and obligations of either party accrued prior to the effective date of such termination, unless explicitly otherwise agreed. BIOSANTE shall forthwith make all payments due and outstanding to PERMATEC at the date of termination. Except as explicitly otherwise stated in this Agreement or otherwise agreed in writing, PERMATEC shall not be obliged to refund upon termination of this Agreement to BIOSANTE any payments, including without limitation the milestone payments or royalties made by BIOSANTE to PERMATEC prior to such termination pursuant to the provisions of this Agreement.

9.4 TERMINATION OF LICENSE, RETURN OF INFORMATION: In the event of termination of this Agreement for whatsoever reason, then the license granted hereunder shall immediately be terminated and BIOSANTE shall immediately refrain from using directly or indirectly in any way the Patents, Know-How and confidential information of PERMATEC. Furthermore, BIOSANTE shall return to PERMATEC all materials, documentation, information, data and other things furnished by PERMATEC in connection with this Agreement, including without limitation any and all information on PERMATEC IPR, together with all copies thereof in BIOSANTE's possession or under its control, which were achieved, produced or received hereunder, all free of any charge. Furthermore, BIOSANTE shall deliver to PERMATEC any and all studies, data, results and protocols achieved, produced or gained by BIOSANTE in performing the Development and not previously delivered to PERMATEC pursuant to Section 5.2 above. PERMATEC shall have the right, but no obligation, to use, at its sole discretion, any and all such material for its own purposes. In case PERMATEC shall use such information in applying and receiving marketing approval and launching the Product, then at launch, PERMATEC shall reimburse the costs to generate such information to BIOSANTE excluding development costs that were paid by BIOSANTE to PERMATEC under this Agreement. In case PERMATEC shall use such information to enter a license



agreement with a third party, then PERMATEC shall reimburse the costs to generate such information to BIOSANTE excluding development costs that were paid by BIOSANTE to PERMATEC under this agreement. The reimbursement to BIOSANTE will occur at the execution of the license agreement and shall not exceed the net payments (upfront, milestones and royalty payments excluding development costs) received by PERMATEC from a third party under a license agreement. BIOSANTE's costs to generate such information which is to be reimbursed by PERMATEC is to be agreed between BIOSANTE and PERMATEC at the time of termination or when the information is to be transferred to PERMATEC

9.5 PARTIAL TERMINATION: In the event that any termination hereunder is limited to one or more, but not all, countries of the Territory and/or to one Product only, but not all Products, as provided for in Sections 9.2(d), (e) and (f) above, then the effects of such termination shall only apply to such country or countries and/or the affected Product, but shall not affect in any way the validity of this Agreement with respect to any other country of the Territory with respect to the affected Product and/or any other Product.

9.6 REMEDIES NOT LIMITED: The termination of this Agreement by either party shall not limit remedies which may be otherwise available under this Agreement or in law or equity to either party.

#### 10. OPTIONS TO EXTEND TERRITORY OR PRODUCTS

10.1 OPTION TO EXTEND TERRITORY: During a period of 180 days after the effective date of this Agreement (the "Exercise Period"), BIOSANTE shall have a free option, exercisable in its sole discretion, to add any or all of the nations of XXXXX, XXXXX, XXXXX, XXXXX and XXXXX (the "Option Countries") to the Territory that is the subject of this Agreement, with respect to the Products provided and to the extent that the Products are available for license for the considered countries. The option may be exercised by BIOSANTE during the Exercise Period by giving written notice of exercise to PERMATEC as provided in this Agreement. The parties recognizing that they may or may not desire to abide by identical terms to those in this Agreement with respect to the extended portions of the Territory, upon receipt by PERMATEC of BIOSANTE's written notice of exercise, the parties agree to negotiate in good faith and determine the specific terms to apply to BIOSANTE's Development and Marketing in the extended portions of the Territory. Notwithstanding anything contained in this Section 10.1, PERMATEC, during the Exercise Period, if it has negotiated with a third party commercial terms of a license (including, without limitation license fees, milestone payments, royalties and allocation of development costs) in any Option Country, may request BIOSANTE in writing to elect whether or not to exercise its option under this Section 10.1 with respect to the same country or countries that are the subject of the terms negotiated with the third party, in which case BIOSANTE shall have thirty (30) days from such notice from PERMATEC to exercise that option. In the event that BIOSANTE does not exercise its option under this Section 10.1 within the thirty (30) day period after receipt of

PERMATEC's notice hereunder, then the option under this Section 10.1 shall lapse and fall away, irrespective of any part of the Exercise Period remaining. [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 AGREEMENT WITH THIS SECTION INTACT HAS BEEN FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION.]

10.2 RIGHT OF FIRST OFFER: During a period starting on the XXXXX (XXXXX) day after the effective date of this Agreement and ending on the XXXXX (XXXXX) anniversary of the effective date of this Agreement (the "Offering Period"), BIOSANTE shall have an exclusive right of first offer to Develop and Market in the United States, Canada, Japan, and any other country of the Territory not already licensed to third parties or subject to a third party's right of first refusal, and to enter into a respective license therefor, any non-proprietary sexual hormone product or related hormonal product, including XXXXX and its derivatives, that PERMATEC may have formulated, invented, developed, licensed or otherwise obtained rights with respect to, and which PERMATEC intends to, but has not prior to such Offering Period committed to, license out for the Territory or parts thereof. Exercise of the right of first offer shall commence with PERMATEC notifying BIOSANTE at any time during the Offering Period of its intention to license out such product, which notice shall in reasonable detail describe the product and Territory or parts thereof in question and the commercial terms of such license (including without limitation license fees, milestone payments, royalties and allocation of development cost). BIOSANTE shall have XXXXX (XXXXX) days to accept the offer on identical terms as contained in such notice, during which XXXXX (XXXXX) days PERMATEC and BIOSANTE agree to negotiate in good faith all terms of such contemplated license and development agreement on the basis of PERMATEC's notice, unless otherwise agreed by the Parties. Notice and exercise under this Section 10.2 shall be made by written notice. In the event that BIOSANTE shall not accept the commercial terms notified by PERMATEC, then PERMATEC shall be free to grant such license to any third party, irrespective of any part of the Offering Period remaining. In the event that PERMATEC has the ability to license the products described to a third party within the first XXXXX (XXXXX) days of this Agreement, PERMATEC shall immediately so notify BIOSANTE, and BIOSANTE shall have fifteen (15) business days within which to exercise its right of first offer as described elsewhere in this paragraph. [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 AGREEMENT WITH THIS SECTION INTACT HAS BEEN FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION.]

10.3 Option regarding the XXXXX Combi Gel

10.3.1 LICENSE AGREEMENT: PERMATEC will not license XXXXX Combi Gel to any company other than the one company identified by PERMATEC to BIOSANTE during negotiation of this Agreement in the first XXXXX (XXXXX) days of the effectiveness of this Agreement. If no license agreement is reached in that XXXXX (XXXXX) day period with the

company described, then during a period starting on the XXXXX (XXXXXt) day after the effective date of this Agreement and ending on the XXXXX (XXXXXt) anniversary of the effective date of this Agreement (the "Offering Period") PERMATEC will offer and BIOSANTE hereby agrees to accept an exclusive license on the XXXXX Combi Gel pursuant to the terms and conditions set forth below. . [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 AGREEMENT WITH THIS SECTION INTACT HAS BEEN FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION.]

10.3.2 TERMS: PERMATEC will license to BIOSANTE XXXXX Combi Gel in the countries of the United States of America and Canada and any other part of the Territory not already licensed to third parties except Japan on the following basic terms: for a license fee of XXXXX Dollars (USD XXXXX), which license fee is not refundable, non-recoverable and payable as set forth below, and a XXXXX percent (XXXXX%) royalty on Net Sales of XXXXX Combi Gel, calculated in the same manner as royalties for the Products under this Agreement, and BIOSANTE to bear all costs of development (including without limitation clinical study cost), and otherwise on substantially identical terms as set forth in this Agreement. The costs associated with the production of clinical batches of XXXXX Combi Gel will be borne equally by PERMATEC and BIOSANTE up to XXXXX Dollars (USD XXXXX), with any amounts in excess thereof to be borne by BIOSANTE. [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 AGREEMENT WITH THIS SECTION INTACT HAS BEEN FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION.]

10.3.3 PAYMENTS: [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 AGREEMENT WITH THIS SECTION INTACT HAS BEEN FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION.]

10.3.3.1 EXECUTION OF LICENSE AGREEMENT: Upon execution of a separate license agreement concerning XXXXX Combi Gel, BIOSANTE shall pay to PERMATEC a milestone payment of XXXXX Dollars (USD XXXXX).

10.3.3.2 XXXXXXXXXXXXXXXX: Upon XXXXXXXXXXXX XXXXXXXXXXXXXXXXXXXXXXXX, BIOSANTE shall pay to PERMATEC a milestone payment of XXXXX Dollars (USD XXXXX).



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, the place of arbitration shall be Chicago, Illinois (USA) 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 costs 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) CONFIDENTIALITY. 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) COURT PROCEEDINGS. Notwithstanding the arbitration provisions in Section 11.2(c) of this Agreement, PERMATEC shall have the right to sue in any court of competent jurisdiction to collect from BIOSANTE funds due and owing PERMATEC hereunder. Section 11.2(c) 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 11.2(c). 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. PERMATEC and BIOSANTE each waive their right to a trial by jury in any such court proceedings.

11.3 NOTICE: All notices and other communications hereunder shall be in writing and shall be deemed given if delivered personally or by facsimile transmission, mailed by registered or certified mail (return receipt requested, postage prepaid) or sent by overnight courier service to the parties at the following addresses (or at such other address for a party as shall be specified by like notice):

If to PERMATEC

Permatec Technologie, AG  
c/o Permatec Pharma AG  
Hardstrasse 18  
CH-4132 Muttenz, Switzerland  
Attn.: PRESIDENT  
Fax No: +41 61 465 92 91

WITH COPY TO: Rinderknecht Klein & Stadelhofer  
Beethovenstrasse 7  
CH-8022 Zurich, Switzerland  
Fax No: ++41 1 287 24 00

If to BIOSANTE:

Stephen M. Simes  
President and CEO  
BioSante Pharmaceuticals, Inc.  
175 Olde Half Day Road  
Lincolnshire, Illinois 60069  
Tel: (847) 793-2434  
Fax: (847) 793-2435

WITH COPY TO: Eric F. Greenberg  
Ungaretti & Harris  
3500 Three First National Plaza  
Chicago, Illinois 60602-4283  
Tel: (312) 977-4647  
Fax: (312) 977-4405

11.4 ENTIRETY: The terms and conditions of this Agreement, together with the Exhibits referred to herein, constitute the entire agreement and understanding of the parties, and supersede all previous communications whether oral or written between the parties, including any previous agreement or understanding varying or extending the same.

11.5 MODIFICATION: This Agreement may be released, discharged, abandoned, changed or modified only by an instrument in writing of equal formality, signed by the duly authorized officer or representative of each of the parties.

11.6 SEVERABILITY: 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.

11.7 WAIVER: The failure of either party at any time or from time to time to exercise any of its rights or to enforce any of the terms, conditions or provisions under this Agreement shall not be deemed to be a waiver of any such rights nor shall it prevent such party from subsequently asserting or exercising any such rights.

11.8 RELATIONSHIP OF PARTIES: Nothing in this Agreement is intended or shall be deemed to constitute a partnership, agency or joint venture relationship between the parties.

11.9 ASSIGNMENT: Neither this Agreement nor any interest hereunder shall be assignable by either party without the prior written consent of the other party (provided that this shall not restrict or prevent BIOSANTE from sublicensing its rights or responsibilities hereunder). Notwithstanding the foregoing, PERMATEC may subcontract any and all of its obligations hereunder to any third party, and the parties may assign this Agreement or any of its respective rights or obligations hereunder to any Affiliate or successor by merger or sale of substantially all of their business; provided in each case, however, that such party shall remain jointly and severally liable for the performance of all of its duties and obligations hereunder.

11.10 FORCE MAJEURE: Neither party hereto shall be held liable or responsible to the other party nor be deemed to have defaulted under or breached this Agreement for failure or delay in fulfilling or performing any term of this Agreement when such failure or delay is caused by or results from causes beyond the reasonable control of the affected party, including but not limited to fire, floods, embargos, war, acts of war (whether war be declared or not), insurrections, riots, civil commotions, strikes, lockouts or other labour disturbances, acts of God, omissions or delays in acting by any governmental authority (including the FDA and Regulatory Authorities) or the other party hereto.

11.11 INTEREST: In the event any amount due and payable under this Agreement is not paid by the due date, then the party owing such amount shall pay to the other party, without being requested by such other party, interest on the total outstanding amount at the rate equal to the U.S. Prime Rate, as reported by the Wall Street Journal on the date that such payment falls due, increased by three percent (3%), in United States Dollars and adjusted on the first day of every subsequent calendar quarter.

11.12 INTERPRETATION: The Parties will execute or have executed a Supply Agreement at or about the same time as this License Agreement, which has as its initial subject matter the same Products that are the subject of this License Agreement. It is the Parties' intent and understanding that there are no conflicts or contradictions between the two Agreements, as the License Agreement is intended to control the licensing (including supply of products for development), Development and Marketing of the Products, and the Supply Agreement is intended to control the supply of commercial quantities of

Products. In the event and to the extent any direct conflict or contradiction between the two Agreements is identified, it is the Parties' intent that the terms of the License Agreement shall govern.



IN WITNESSETH WHEREOF, the parties hereto have caused this instrument to be executed by their duly authorized officers with effect as of the date first above written.

PERMATEC TECHNOLOGIE, AG

/s/ Dr. Jacques Gonella

-----  
By: Dr. Jacques Gonella  
Its: Executive Chairman

/s/ Dr. Philippe Dro

-----  
By: Dr. Philippe Dro  
Its: President and COO

BIOSANTE PHARMACEUTICALS, INC.

/s/ Stephen M. Simes

-----  
By: Stephen M. Simes  
Its: President and CEO

## EXHIBIT A

## PATENTS

A NOVEL COMPOSITION FOR TRANSDERMAL ADMINISTRATION OF AN ESTROGEN, A PROGESTIN  
OR A MIXTURE THEREOF (COMBI GEL)

Ref. : PRE.001

COUNTRY	APPLICATION DATE	NUMBER	PATENT DATE	NUMBER	EXPIRATION DATE
Argentina	06.06.1997	P970102497			06.06.2017
Australia	05.06.1997	24729/97			05.06.2017
Canada	05.06.1997	2,207,144			05.06.2017
Europe	04.06.1997	97108989.1			04.06.2016
Italy	06.06.1996	MI96A001152	07.04.1998	1283102	06.06.2016
Japan	05.06.1997	9-185695			05.06.2017
Korea, Rep.	04.06.1997	97-236704			04.06.2017
New Zealand	05.06.1997	328021	19.03.1998	328021	05.06.2017
South Africa	05.06.1997	974981	25.03.1998	97/4981	05.06.2017
Taiwan	06.06.1997	86107807			
U.S.A	05.06.1997	08/869.982	06.04.1999	5,891,462	05.06.2017

ADMINISTRATION SYSTEM FOR ESTRADIOL (ESTRADIOL PATCH)

Ref. :                   GPH.001

COUNTRY	APPLICATION DATE	NUMBER	PATENT DATE	NUMBER	EXPIRAT. DATE
Australia	07.05.1993	38459/93	05.11.1996	670273	07.05.2013
Austria	07.05.1993	93810336.3	05.08.1998	0569338	07.05.2013
Belgium	07.05.1993	93810336.3	05.08.1998	0569338	07.05.2013
Denmark	07.05.1993	93810336.3	05.08.1999	0569338	07.05.2013
Europe	07.05.1993	93810336.3	05.08.1999	0569338	07.05.2013
Europe/It.	07.05.1993	93810336.3	05.08.1999	0569338	07.05.2013
France	07.05.1993	93810336.3	05.08.1999	0569338	07.05.2013
Germany	07.05.1993	93810336.3	05.08.1999	0569338	07.05.2013
Greece	07.05.1993	93810336.3	05.08.1999	0569338	07.05.2013
Ireland	07.05.1993	93810336.3	05.08.1999	0569338	07.05.2013
Japan	28.04.1993	102325/1993	30.07.1999	2960832	28.04.2013
Korea, Rep.	07.05.1993	93-7877			07.05.2013
Luxembourg	07.05.1993	93810336.3	05.08.1998	0569338	07.05.2013
Netherlands	07.05.1993	93810336.3	05.08.1998	0569338	07.05.2013
New Zealand	05.05.1993	247549	11.04.1996	247549	05.05.2013
Portugal	07.05.1993	93810336.3	05.08.1998	569338	07.05.2013
South Africa	06.05.1993	93/3180	31.08.1994	93/3180	06.05.2013
Spain	07.05.1993	93810336.3	05.08.1998	0569338	07.05.2013
Sweden	07.05.1993	93810336.3	05.08.1998	0569338	07.05.2013
Switzerland	07.05.1993	93810336.3	05.08.1998	0569338	07.05.2013
Taiwan	08.05.1993	82103602	27.11.1995	NI072551	07.05.2013
U.K.	07.05.1993	93810336.3	05.08.1998	569338	07.05.2013
Canada	07.05.1993	2,095,789			07.05.2013
U.S.A.	03.05.1993	08/058,517			

Ref.: GPH.001/A und /CON1

COUNTRY	APPLICATION DATE	NUMBER	PATENT DATE	NUMBER	EXPIRAT. DATE
GPH.001/A Switzerland	08.05.1992	1487/92			08.05.2012
GPH.001/CON 1 U.S.A.	19.12.1994	08/358,897	09.09.1997	5,665,377	09.09.2014

EXHIBIT B

PRODUCTS

[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 AGREEMENT WITH THIS SECTION INTACT HAS BEEN FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION.]

Gel E2 (where estradiol is the sole active ingredient, and where the gel is applied to the skin)

Gel Testosterone (where testosterone is the sole active ingredient and where the gel is applied to the skin)

Patch E2 (where estradiol is the sole active ingredient and where the patch is applied to the skin)

E2-XXXXX Combi Gel (where estradiol and XXXXX XXXXX are the two active ingredients and where the gel is applied to the skin)

Option regarding XXXXX Combi gel

XXXXX Combi Gel (where XXXXX and XXXXX are the two active ingredients and where the gel is applied to the skin)

EXHIBIT C  
COUNTRY CLASSIFICATION

First Tier:	USA
Second Tier	Canada; China
Third Tier:	All other countries of the Territory

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SUPPLY AGREEMENT

between

BIOSANTE PHARMACEUTICALS, INC.

and

PERMATEC TECHNOLOGIE, AG  
-----

[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 INTACT HAS BEEN FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION.]

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## SUPPLY AGREEMENT

This Agreement, effective the 13th day of June, 2000, is made between BioSante Pharmaceuticals, Inc., a Wyoming corporation, with an office at 175 Olde Half Day Road, Lincolnshire, Illinois (hereinafter, "BIOSANTE") and Permateg Technologie, AG, a corporation organized and existing under the laws of Switzerland and having its principal office at Grienbachstrasse 17 CH 6301 Zug Switzerland (hereinafter, "PERMATEC").

BIOSANTE and PERMATEC do hereby agree as follows:

### ARTICLE 1 - DEFINITIONS.

- 1.1 "COMPOUNDS" shall mean the respective active ingredients in any of the Products.
- 1.2 "CONTRACT MANUFACTURER" shall mean any company or companies designated by PERMATEC to Manufacture and/or Package the Products hereunder.
- 1.3 "DEA" shall mean the United States Drug Enforcement Administration.
- 1.4 "FDA" shall mean the United States Food and Drug Administration.
- 1.5 "GOOD MANUFACTURING PRACTICES" or "GMP" shall mean the then-current requirements of FDA or other relevant authority relating to the manufacture of pharmaceutical products and related activities, as set forth in applicable FDA or other relevant authority regulations and Guidance Documents.
- 1.6 "GOVERNMENT AGENCIES" shall mean the respective governmental health authorities that control or in any way regulate the manufacture, packaging, distribution, sale, export or import of the Products in any jurisdiction of the Territory. Each reference in this Agreement to "Government Agencies" shall be deemed to refer to the relevant governmental health authorities for the respective jurisdictions of the Territory into which the Products will be or were sold by BIOSANTE, its Affiliates or the sublicensees of any of them (e.g., for the United States, "Government Agencies" shall include the FDA and the DEA).
- 1.7 "GOVERNMENTAL APPROVALS" shall mean the respective approvals sought or obtained by BIOSANTE, its Affiliates or the sublicensees of any of them from the appropriate Government Agencies to market and sell the Products in each of the jurisdictions of the Territory into which BIOSANTE or such other entity chooses to market the Products. Each reference in this Agreement to "Governmental Approvals" shall be deemed to refer to the relevant approval obtained for the respective jurisdiction into which the Products will be or were sold by BIOSANTE, its Affiliates or the sublicensees of any of them (e.g., for the United States, "Governmental Approvals" shall mean the NDA, ANDA or IND).

1.8 "LICENSE AGREEMENT" shall mean the written agreement between PERMATEC TECHNOLOGIE, AG and BIOSANTE PHARMACEUTICALS, INC., executed by the parties at or about the same time as this Supply Agreement.

1.9 "MANUFACTURING" shall mean all of the following: (a) the purchasing and warehousing of raw materials, the preparation of the formulation like adding excipients, solubilizing, mixing, incoming and outgoing quality control and other procedures associated with the preparation of the formulation (the "Preparation"); or (b) incorporating of the finished Products containing the Compounds into a delivery system and other procedures associated with all of the foregoing (the "Filling"); and (c) the Preparation, Filling and final packaging and labeling of the finished Products in packaged form and other procedures associated with all of the foregoing (the "Packaging"); each of (a), (b) and (c) above all done in accordance with the Specifications and the Governmental Approvals (including, without limitation, with respect to sales of the Products into the U.S., all applicable requirements of the FDA and DEA and GMP). The terms "Manufacture", "Manufactured" and "Manufacturing" in this Agreement shall refer to the same activities.

1.10 "NDA" shall mean a New Drug Application, Abbreviated New Drug Application, or Investigational New Drug application filed by or on behalf of BIOSANTE with the FDA for any of the Products.

1.11 "PRODUCT" or "PRODUCTS" shall mean one or more of the finished, packaged products which are Manufactured by PERMATEC for sale to BIOSANTE, its Affiliates or the licensees or sublicensees of any of them pursuant to this Agreement. The products are listed in Exhibit D.

1.12 "SPECIFICATIONS" shall mean the procedures, requirements, standards and other items set forth in Exhibit A attached hereto, as the same may be supplemented and amended from time to time in accordance with Article 5.3.

1.13 "TERRITORY" shall mean the United States and those of its territories and possessions over which the FDA has regulatory authority; Canada; Australia; New Zealand; South Africa; Israel; Mexico; and The People's Republic of China (including Hong Kong); Malaysia; and Indonesia.

## ARTICLE 2 - SUPPLY OF PRODUCTS.

2.1 Subject to the terms hereof, PERMATEC agrees to Manufacture, or have Manufactured, and sell exclusively to BIOSANTE in the Territory, and BIOSANTE shall purchase exclusively from PERMATEC, BIOSANTE's total requirements for Products pursuant to purchase orders submitted by BIOSANTE to PERMATEC from time to time in accordance with Article 4.2. PERMATEC or its Contract Manufacturer shall supply all equipment, raw and packaging materials, and labor, and shall assure its own or its Contract Manufacturer's compliance, whichever is applicable, with current GMP necessary to Manufacture the Products.

2.2 Upon request from BIOSANTE, PERMATEC, with full assistance of BIOSANTE in North America, shall cause an audit to be performed at its manufacturing facilities or that of its

Contract Manufacturer for the purpose of determining whether such facilities are likely to obtain FDA or other relevant agencies' approval, and shall promptly provide BIOSANTE with a copy of such audit. If such audit indicates that the manufacturing facilities are in substantial compliance with FDA or other relevant agencies' requirements to be a Manufacturer of the Products, PERMATEC shall use all commercially reasonable efforts to provide Products to BIOSANTE as soon as possible (in response to its orders) for clinical and commercial use by BIOSANTE and in its other efforts to obtain all requisite Government Approvals. BIOSANTE shall provide full assistance to PERMATEC to select and validate an adequate Contract Manufacturer and to obtain the necessary approvals in the United States of America or such other part of the Territory where BIOSANTE may have regulatory expertise.

2.3 Notwithstanding the foregoing, PERMATEC shall not sell Products, and BIOSANTE shall not be obligated to purchase Products from PERMATEC, unless and until PERMATEC or its Contract Manufacturer shall have complied with all relevant requirements from the appropriate Government Agencies to Manufacture and sell the Products in the respective jurisdictions (e.g., for sales of Products in the United States, BIOSANTE shall have obtained FDA approval for PERMATEC or its Contract Manufacturer to be a manufacturer of the Products under the NDA).

2.4 Throughout this Agreement, all references to "PERMATEC" that relate to its rights and duties as the manufacturer and/or packager of the Products shall be deemed to include any Contract Manufacturer designated by PERMATEC to Manufacture the Products hereunder; provided, however, that such Contract Manufacturer has complied with all relevant requirements from the appropriate Government Agencies to Manufacture the Products for BIOSANTE and provided further, that notwithstanding any such designation, PERMATEC shall continue to be jointly and severally liable, along with such designee, to BIOSANTE under every provision of this Agreement.

2.5 Within two (2) years following first commercial sale of each Products in a country of the Territory, BIOSANTE may ask PERMATEC to assure that a second company (which it shall designate in addition to the then current manufacturer of the Products) becomes qualified as an alternative manufacturer of the Products and complies with all relevant requirements from the appropriate Government Agencies to Manufacture and sell the Products in certain commonly agreed jurisdictions of the Territory. PERMATEC shall use all commercially reasonable efforts whenever possible to identify and propose an alternative Contract Manufacturer to BIOSANTE.

### ARTICLE 3 - PRICE.

3.1 The price of the Products shall be determined in accordance with the pricing schedule attached hereto as Exhibit B.

3.2 The price of the Products referenced on Exhibit B shall be adjusted upward or downward on an annual basis in accordance with the terms of Exhibit B, commencing on January 1 of the year following the first full year of commercial sale of the Products in the United States. Notwithstanding the foregoing, in the event the prices of the Products increase or decrease due to

any supplement or amendment to the Specifications as provided in Article 5.3 below, whether or not such increase or decrease occurs prior to or following the first commercial sale of the Products in the United States, the price of the Products shall be adjusted by the actual change in cost to PERMATEC due to such supplement or amendment to the Specifications. Such change in price shall be effective only with respect to Products manufactured after the date of implementation of the change to the Specifications.

3.3 All Products ordered by BIOSANTE prior to the notification of any price increase will be supplied and invoiced to BIOSANTE by PERMATEC at the prices current as of the date on which the order was received by PERMATEC.

3.4 Payment for each order shall be made within forty-five (45) days following the date of invoice or delivery, whichever is later; provided, however, that BIOSANTE shall not be required to pay for nonconforming Products.

3.5 All payments required to be made pursuant to this Agreement shall be made in U.S. dollars, unless otherwise agreed in writing between the parties.

3.6 PERMATEC shall keep full, true and accurate books of account containing all particulars and reasonable supporting documentation which may be necessary for determining the costs of the Products as outlined in Exhibit B. Such records shall be kept at PERMATEC's principal place of business or at the Contract Manufacturer's place of business and shall be open at all reasonable times and upon reasonable notice to the inspection of an independent certified public accounting firm retained by BIOSANTE, and reasonably acceptable to PERMATEC, for the purpose of verifying any price charged under the Agreement. BIOSANTE shall bear the full cost of such audit, unless the audit discloses that the price charged exceeded the actual cost of the Products by (i) ten percent (10%) or more during the first two (2) years following the first commercial sale of the Products; or (ii) five percent (5%) or more thereafter, in which case PERMATEC shall bear the full cost of the audit. BIOSANTE's audit right shall be limited to the twelve (12) months preceding the last invoice. The audit cost that may be charged to PERMATEC pursuant to what is described above shall be capped at Twenty Thousand Dollars (USD 20,000).

#### ARTICLE 4 - FORECASTS; ORDERING; SHIPMENTS.

The procedures to be followed with respect to the purchase by BIOSANTE of the Products shall be as follows:

4.1 In order to permit PERMATEC to regularly supply BIOSANTE with the Products, at least three (3) months prior to the first day of January and July of each year during the term hereof, BIOSANTE shall advise PERMATEC in writing of BIOSANTE's estimated requirements for the Products for each twelve (12) month period commencing respectively on the first day of such January and July. All Products sold to BIOSANTE hereunder will be shipped to BIOSANTE no later than three (3) months after release of the finished goods by the

Quality Control Department. PERMATEC will use its best efforts to ship product within one (1) month of such release.

4.2 BIOSANTE shall order the Products by firm non-cancelable purchase order specifying a quantity, description of the Products with relevant Quality Compliance data, address of delivery, method of shipment and delivery date. Orders shall be placed on PERMATEC's standard purchase order form, a copy of which is attached hereto as Exhibit C; provided, however, that the terms of this Agreement shall prevail in the event of any inconsistency between this Agreement and the terms and conditions of PERMATEC's standard purchase order form. Firm orders will be issued by BIOSANTE at least nine (9) months prior to the requested delivery date during a 2 year launch period, thereafter firm orders will be issued at least six (6) months prior to requested delivery date. PERMATEC shall promptly acknowledge acceptance of such order in writing and shall advise BIOSANTE of the anticipated ship date of the quantity ordered. In case of material change in specifications, the orders will be issued nine months (9) before delivery time for the 3 first orders. PERMATEC agrees to make its best efforts with respect to all orders to deliver ordered goods as quickly as possible after receipt of the order.

4.3 Delivery of Products to be sold by PERMATEC under this Agreement shall be made as may be mutually agreed between the parties, and be ex factory, in all instances in which BIOSANTE has specified both the method of shipment and carrier. All shipments shall be made pursuant to instructions received from BIOSANTE or, if not specified, in a commercially reasonable manner. PERMATEC will provide shipping documentation in accordance with that requested in BIOSANTE's firm order as well as a certificate of analysis for each Production lot sent separately, but in every instance, it shall be sent so as to be received by BIOSANTE within two (2) weeks of shipment.

#### ARTICLE 5 - SPECIFICATIONS; QUALITY CONTROL; RECORDS.

5.1 Products supplied to BIOSANTE pursuant to this Agreement shall be Manufactured, stored and shipped by PERMATEC in accordance with the Specifications, in compliance with the Governmental Approvals and in conformance with all applicable requirements of the Government Agencies (including, without limitation, all applicable GMP with respect to Products sales into the U.S. or any other territories and possessions over which the FDA has jurisdiction).

5.2 Neither party may supplement or amend the Specifications without the other party's prior written approval, which shall not be unreasonably withheld; provided, however, that the Specifications will be supplemented or amended if BIOSANTE determines that such change or amendment is necessitated by applicable requirements of the FDA or other Government Agencies. The parties agree that BIOSANTE may supplement Exhibit A hereto with Specifications for Products to be sold in other countries of the Territory in addition to the United States. All such changes shall be approved in writing at least sixty (60) days in advance of their implementation. The cost of the Products will be amended according to the changes required by BIOSANTE or any governmental requirements.

5.3 PERMATEC shall perform and have sole responsibility for all quality control tests and assays on raw and packaging materials and on finished Products, all in a manner consistent with the Specifications and PERMATEC's internal quality control procedures for similar products. PERMATEC shall retain records pertaining to such testing and shall, upon written request by BIOSANTE, furnish BIOSANTE with copies thereof.

5.4 PERMATEC shall prepare and maintain batch records and a file sample, properly stored, from each lot or batch of Products. Upon any termination of this Agreement, PERMATEC shall offer copies of such batch records and file samples to BIOSANTE.

5.5 PERMATEC shall be responsible for the procurement of raw material and container materials, intermediate and final product testing and stability studies, complaint investigations and inspections by Government agencies at the manufacturing facility. PERMATEC shall make available the records pertaining to the foregoing to BIOSANTE for such lawful purpose as BIOSANTE may reasonably request.

5.6 PERMATEC shall obtain and maintain all licenses, permits and registrations necessary to Manufacture and supply Products to BIOSANTE.

5.7 Each party shall keep complete and accurate records pertaining to (a) the Manufacture, including quality control, of the Products (in the case of PERMATEC); or (b) the use, sale and other disposition of the Products (in the case of BIOSANTE) for at least three (3) years or for such longer period if and as required by law. Each party shall make available such records to the other party for such lawful purpose as such other party may reasonably request in writing.

#### ARTICLE 6 - INSPECTIONS; PRODUCT RECALLS.

6.1 PERMATEC shall promptly notify BIOSANTE of any inspections by representatives of any of the Government Agencies of the manufacturing facility and the results of any such inspections, including actions taken by PERMATEC to remedy conditions cited in such inspections.

6.2 Each party agrees to promptly (but in no event later than one (1) business day) inform the other of product quality, health or safety related complaints or inquiries that raise potentially serious quality, health or safety concerns regarding the Products. All other such information not involving the above-described situations shall be transmitted to the other party within five (5) days of receipt.

6.3 To the extent permitted by law, any decision to recall or cease distribution of Products in any jurisdiction of the Territory shall be made by BIOSANTE in its sole discretion and under its sole responsibility and shall be communicated promptly to PERMATEC. In the event of any such recall, BIOSANTE shall assume complete responsibility and bear all the costs for the recall. BIOSANTE will provide PERMATEC with any information concerning the Manufacturing of Products which may reasonably be required in connection with the recall, and will manage such

recall. Notwithstanding BIOSANTE's assumption of responsibility for the conduct of recalls, recall costs shall be borne by BIOSANTE until the respective responsibilities are established.

#### ARTICLE 7 - NONCONFORMING PRODUCTS.

7.1 BIOSANTE shall be deemed to have accepted delivery of the Products in good order and condition, unless it has given a written notice of any short delivery or nonconformity in respect of the Products within sixty (60) days after the date of delivery. Notwithstanding the foregoing, in the case of any nonconformity which is not readily discoverable within such sixty (60) day period, the claim therefor under this Article 7.1 shall not be deemed waived if made by BIOSANTE within thirty (30) days after BIOSANTE learns of such nonconformity.

7.2 All such claims by BIOSANTE shall be accompanied by a report of analysis of the allegedly nonconforming Products that shall have been prepared by BIOSANTE or its agent. If, after its own analysis of the Product sample, PERMATEC confirms such nonconformity, PERMATEC shall, at PERMATEC's election, either replace the nonconforming Products with conforming Products at PERMATEC's expense or refund to BIOSANTE the entire purchase price therefor. The nonconforming Products shall either be returned to PERMATEC, at PERMATEC's request and its expense, or destroyed, at PERMATEC's expense.

7.3 If, after its own analysis, PERMATEC does not confirm such nonconformity, the parties shall in good faith attempt to agree upon a settlement of the issue. In the event that the parties cannot resolve the issue, they shall submit the disputed Products to an independent laboratory, mutually selected by the parties, for testing and the results of such testing shall be binding upon the parties. The party whose assertion as to the conformity or nonconformity of the Products in question is not borne out by the results of testing of the independent laboratory shall bear all costs and expenses of such testing. Notwithstanding anything to the contrary in this Article 7, PERMATEC's warranties and indemnification obligations under this Agreement shall survive any failure by BIOSANTE to reject the Products in question.

#### ARTICLE 8 - CONSENTS, REPRESENTATIONS, AND WARRANTIES.

PERMATEC hereby covenants, represents and warrants to BIOSANTE, and its Affiliates as follows:

8.1 On the date of shipment, all Products sold hereunder will have been Manufactured, stored and shipped by PERMATEC or its designated Contract Manufacturer in accordance with the Specifications, in compliance with the Governmental Approvals and in conformance with all applicable requirements of the Government Agencies (including, without limitation, all applicable GMP with respect to Products sales into the U.S. or any other territories and possessions over which the FDA has jurisdiction).

8.2 PERMATEC will have good title to all Products sold hereunder, which title shall pass to BIOSANTE free and clear of any lien, encumbrance or other conflicting interest of any kind.



8.3 If PERMATEC enters into a contract with a Contract Manufacturer, it will promptly provide BIOSANTE with a complete and accurate copy of such contract (plus all amendments thereto) if any, redacted so that only BIOSANTE-related terms are revealed.

#### ARTICLE 9 - LIMITATIONS ON WARRANTY; INDEMNIFICATION.

9.1 Without affecting any other remedies available under this Agreement, PERMATEC shall defend, indemnify and hold BIOSANTE and its directors, officers and employees, harmless from and against any and all claims, suits or demands for liability, damages, costs and expenses (including the reasonable fees, costs and expenses of attorneys and other professionals and court costs) resulting from product recall, personal injury, product liability or property damage or otherwise, arising from or relating to the negligence or willful misconduct of PERMATEC or the Contract Manufacturer of PERMATEC.

9.2 Without affecting any other remedies available under this Agreement, BIOSANTE shall defend, indemnify and hold PERMATEC and its directors, officers and employees, harmless from and against any and all claims, suits or demands for liability, damages, costs and expenses (including the reasonable fees, costs and expenses of attorneys and other professionals and court costs, but excluding consequential damages for lost profits) arising from or relating to the negligence or willful misconduct of BIOSANTE or its Affiliates or its sub licensees.

#### ARTICLE 10 - TERM AND TERMINATION.

10.1 This Agreement shall commence as of the date of this Agreement and shall continue for the longer of twenty (20) years, or as long as BIOSANTE is paying royalties on any product, unless the Agreement is terminated in accordance with the terms hereof.

10.2 (a) Failure by either party to comply with any of the obligations contained in this Agreement in any material respect shall entitle the other party to give to the party in default written notice specifying the nature of the default and requiring it to cure such default. If such default is not cured within sixty (60) days after the receipt of such notice, the notifying party shall be entitled, without prejudice to any of its rights conferred on it by this Agreement, in addition to any other remedies available to it by law or in equity, to terminate this Agreement with respect only to the involved Product or Products, or country or countries of the Territory, respectively, by giving written notice. The right of either party to terminate this Agreement shall not be affected in any way by its waiver or failure to take action with respect to any previous default.

(b) Further, failure by either party to comply with any of the obligations contained in the License Agreement in any material respect (or a material breach of any representation, warranty or covenant contained therein) shall entitle the other party to give to the party in default written notice specifying the nature of the default and requiring it to cure such default. If such default is not cured within the cure period specified under said Agreement, the notifying party shall be

entitled, without prejudice to any of its rights conferred on it by this Agreement, in addition to any other remedies available to it by law or in equity, to terminate this Agreement, with respect only to the involved Product or Products, or country or countries of the Territory, respectively, by giving written notice. Further, in the event that the License Agreement is terminated by either Party in its entirety with respect to all Products in all countries of the Territory, either party shall have the right to terminate this Agreement immediately upon written notice. The right of either party to terminate this Agreement shall not be affected in any way by its waiver or failure to take action with respect to any previous default.

10.3 Either party may, in addition to any other remedies available to it by law or in equity, terminate this Agreement by written notice to the other party in the event the other party shall have become insolvent or bankrupt, or shall have made an assignment for the benefit of its creditors, or there shall have been appointed a trustee or receiver of the other party or for all or a substantial part of its property, or any case or proceeding shall have been commenced or other action taken by or against the other party in bankruptcy or seeking reorganization, liquidation, dissolution, winding-up, arrangement, composition or readjustment of its debts or any other relief under any bankruptcy, insolvency, reorganization or other similar act or law of any jurisdiction now or hereafter in effect, or there shall have been issued a warrant of attachment, execution, distraint or similar process against any substantial part of the property of the other party, and any such event shall have continued for sixty (60) days undismissed, unbonded and undischarged.

10.4 BIOSANTE may terminate this Agreement upon a determination, in its sole discretion, that there is an available alternative source of Products at a lower price than that of PERMATEC. BIOSANTE agrees to promptly notify PERMATEC of its alternative opportunity, and the parties agree to negotiate in good faith in an attempt to give PERMATEC an opportunity to match the alternative. If it is determined that this will not be possible, BIOSANTE may give notice of termination. Termination under this Article 10.4 shall not be construed as giving rise to a breach of this Agreement by PERMATEC. Termination pursuant to this Article 10.4 shall be effective upon six (6) months written notice to PERMATEC.

10.5 Notwithstanding anything in this Agreement to the contrary, BIOSANTE may terminate this Agreement at any time by written notice to PERMATEC in the event that BIOSANTE is unable to obtain the FDA approval of PERMATEC or its Contract Manufacturer as the manufacturer of the Products under the NDA.

10.6 Termination or expiration of this Agreement for any reason shall be without prejudice to any rights which shall have accrued to the benefit of either party prior to such termination or expiration. Such termination or expiration shall not relieve either party from obligations which are expressly indicated to survive termination or expiration of this Agreement.

#### ARTICLE 11 - GOVERNING LAW; CONCILIATION; ARBITRATION.

11.1 GOVERNING LAW: 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.

#### 11.2 DISPUTE RESOLUTION:

- (a) CONCILIATION. 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, USA (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 11.2(d) of this Agreement, if any conciliation proceedings under Section 11.2(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, the place of arbitration shall be Chicago, Illinois (USA) 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 costs 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) CONFIDENTIALITY. 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) COURT PROCEEDINGS. Notwithstanding the arbitration provisions in Section 11.2(b) of this Agreement, PERMATEC shall have the right to sue in any court of competent jurisdiction to collect from BIOSANTE funds due and owing PERMATEC hereunder. Section 11.2(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 11.2(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. PERMATEC and BIOSANTE each waive their right to a trial by jury in any such court proceedings.

#### ARTICLE 12 - TRADEMARKS.

12.1 BIOSANTE shall determine and own the trademarks and trade names to be used in connection with the marketing of Products in the Territory. PERMATEC shall have no right to use such trademarks and trade names other than in connection with its Manufacturing Products for sale to BIOSANTE under this Agreement. Upon termination of this Agreement, PERMATEC shall not use any of such trademarks or trade names, whether or not they have been registered in the relevant jurisdiction, or use or adopt any trademark or trade name that may be confusingly similar therewith.

12.2 PERMATEC owns certain trademarks and trade names to be used in connection with the Products in the Territory. BIOSANTE shall have no right to use such trademarks and trade names unless approved by PERMATEC. Upon termination of this Agreement, BIOSANTE shall not use any of such trademarks or trade names, whether or not they have been registered in the relevant jurisdiction, or use or adopt any trademark or trade name that may be confusingly similar therewith.

#### ARTICLE 13 - CONFIDENTIALITY.

Except to the extent expressly authorized by this Agreement or otherwise agreed in writing, the parties agree that, at all times during the term of this Agreement and for five (5) years thereafter, the receiving party shall keep completely confidential, shall not publish or otherwise disclose and shall not use directly or indirectly for any purpose any information furnished to it by the other party pursuant to this Agreement, except to the extent that it can be established by the receiving party by competent proof that such information:

(a) was already known to the receiving party, other than under an obligation of confidentiality, at the time of disclosure by the other party;

(b) was generally available to the public or otherwise part of the public domain at the time of its disclosure to the receiving party;

(c) became generally available to the public or otherwise part of the public domain after its disclosure, other than through any act or omission of the receiving party in breach of this Agreement; or

(d) was disclosed to the receiving party, other than under an obligation of confidentiality, by a third party who had no obligation to the disclosing party not to disclose such information to others.

Each party may disclose the other's information to the extent that such disclosure is reasonably necessary in complying with applicable governmental regulations, provided that if a party intends to make any such disclosure, it shall give reasonable advance written notice to the other party of such disclosure.

#### ARTICLE 14 - FORCE MAJEURE.

No failure by either party to carry out or observe any of the stipulations or conditions of this Agreement shall give rise to any claims against the party in question, or be deemed a breach of this Agreement, if such failure or omission is caused by any cause beyond the reasonable control of the party including, without limitation, strikes, acts of God, public enemy, riots, fire, flood, compliance with governmental laws, rules and regulations, delays in transit or delivery, inability to secure necessary governmental priorities for materials or any other event beyond the control and without the fault or negligence of the party in question; provided that the party affected shall give prompt notice of any such cause to the other party. The party giving such notice shall thereupon be excused from such of its obligations hereunder as it is thereby disabled from performing for so long as it is so disabled, provided however, that in the event that PERMATEC is prevented from performing its obligations hereunder for a continuous period of three (3) months or for a total period of six (6) months in any period of twelve (12) calendar months, BIOSANTE may terminate this Agreement immediately and such cause of non-performance shall not be deemed a breach by PERMATEC.

#### ARTICLE 15 - ASSIGNMENT.

Neither this Agreement nor any interest hereunder shall be assignable by either party without the prior written consent of the other party. Notwithstanding the foregoing, either party may assign this Agreement to any successor by merger or sale of substantially all of its assets. In the event that BIOSANTE sublicenses its rights under the License Agreement, BIOSANTE may also assign its rights and obligations hereunder to such sublicensee. This Agreement shall be binding upon the successors and permitted assigns of the parties and the name of a party appearing herein shall be deemed to include the names of such party's successors and permitted assigns to the extent necessary to carry out the intent of this Agreement. Any assignment not in accordance with this Article shall be null and void.

ARTICLE 16 - NOTICE.

All notices and other communications hereunder shall be in writing and shall be deemed given if delivered personally or by facsimile transmission, mailed by registered or certified mail (return receipt requested, postage prepaid) or sent by overnight courier service to the parties at the following addresses (or at such other address for a party as shall be specified by like notice):

If to BIOSANTE

Stephen M. Simes  
President and CEO  
BioSante Pharmaceuticals, Inc.  
175 Olde Half Day Road  
Lincolnshire, Illinois 60069  
Tel. +1 (847) 793-2434  
Fax +1 (847) 793-2435

WITH COPY TO: Eric F. Greenberg  
Ungaretti & Harris  
3500 Three First National Plaza  
Chicago, Illinois 60602-4283  
Tel: (312) 977-4647  
Fax: (312) 977-4405

If to PERMATEC

Dr. Philippe Dro  
President and COO  
PERMATEC TECHNOLOGIE, AG  
c/o Permatec Pharma AG  
Hardstrasse 18  
CH-4132 Muttensz, Switzerland  
Fax. +41 61 465 92-91

WITH COPY TO: Rinderknecht Klein & Stadelhofer  
Beethovenstrasse 7  
CH-8022 Zurich, Switzerland  
Fax No: ++41 1 287 24 00

ARTICLE 17 - ENTIRETY.

The terms and conditions of this Agreement, together with the License Agreement, constitute the entire agreement and understanding of the parties, supersede all previous

communications whether oral or written between the parties, including any previous agreement or understanding varying or extending the same. There are no further or other agreements or understandings, written or oral, in effect between the parties with respect to the subject matter hereof.

ARTICLE 18 - MODIFICATION.

This Agreement may be released, discharged, abandoned, changed or modified only by an instrument in writing of equal formality, signed by the duly authorized officer or representative of the parties.

ARTICLE 19 - ENFORCEABILITY.

Whenever possible, each provision of this Agreement will be interpreted in such a manner as to be effective and valid under applicable law, but in the event of a conflict between any provision of this Agreement and any applicable law, regulation, ordinance or decree, the provision of this Agreement so affected shall be curtailed and limited to the extent necessary to bring it within the legal requirements but otherwise it shall not render null and void other provisions of this Agreement, unless either of the parties, in the absence of the provision in question, would not have entered into this Agreement.

ARTICLE 20 - WAIVER.

The failure of either party at any time or from time to time to exercise any of its rights or to enforce any of the terms, conditions or provisions under this Agreement shall not be deemed to be a waiver of any such rights nor shall it prevent such party from subsequently asserting or exercising any such rights.

ARTICLE 21 - RELATIONSHIP OF PARTIES.

Nothing in this Agreement is intended or shall be deemed to constitute a partnership, agency or joint venture relationship between the parties.

ARTICLE 22 - PUBLICITY.

If either party wishes to make a public disclosure concerning this Agreement and such disclosure mentions the other party by name or description, such other party will be provided with an advance copy of the disclosure and will have three (3) business days within which to approve or disapprove such use of its name or description. Disclosures once approved do not need to be re-approved for further dissemination. The parties will provide copies of such disclosures to the other party within a reasonable time. Approval shall not be unreasonably

withheld by either party. Absent approval, no public disclosure shall use the name of or otherwise describe such party except to the extent required by law. However, the initial news release announcing the signing of this Agreement shall be approved by both parties simultaneously with signing.

IN WITNESSETH WHEREOF, the parties hereto have caused this instrument to be executed by their duly authorized officers with effect as of the date first above written.

BioSante Pharmaceuticals, Inc.

/s/ Stephen M. Simes

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By: Stephen M. Simes  
Its: President and Chief Executive Officer

Permatec Technologie, AG

/s/ Dr. Jacques Gonella

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By: Dr. Jacques Gonella  
Its: Executive Chairman

/s/ Dr. Philippe Dro

-----

By: Dr. Philippe Dro  
Its: President and COO



EXHIBIT A - PRODUCTS SPECIFICATIONS

TO BE SUPPLIED BY PERMATEC BEFORE START OF MANUFACTURING OF THE  
FIRST COMMERCIAL BATCH

EXHIBIT B - PRICING SCHEDULE

[PORTIONS OF THIS EXHIBIT B 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 INTACT HAS BEEN FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION.]

- (1) The price of the Products shall be made up of:
  - (a) Raw material: In case the raw material (compound, excipients, dispensing device, packaging material and shipment material) are to be supplied by PERMATEC, this supply will be charged to BIOSANTE at PERMATEC's actual cost plus XXXXX%.
  - (b) Primary manufacturing: A portion per unit of finished Product equivalent to PERMATEC's actual costs of synthesis of the Products (consisting of the reasonable overhead and out-of-pocket expenses attributable thereto), will be charged to BIOSANTE at PERMATEC's actual cost plus XXXXX%;
  - (c) Filling: A portion per unit of Products equivalent to PERMATEC's actual Filling costs (consisting of reasonable overhead and out-of-pocket expenses attributable thereto), will be charged to BIOSANTE at PERMATEC's actual cost plus XXXXX%;
  - (d) Packaging: A Portion per unit of Products equivalent to PERMATEC's actual Packaging costs (consisting of reasonable overhead and out-of-pocket expenses attributable thereto), will be charged to BIOSANTE at PERMATEC's actual cost plus XXXXX%;
  - (e) Quality Control and release: A portion per unit of Products equivalent to PERMATEC's actual in process and finished products quality control costs (consisting of overhead and out-of-pocket expenses and stability tests) will be charged to BIOSANTE at PERMATEC's actual cost plus XXXXX%;
  - (f) Shipment: The price is understood to be ex factory in accordance with subsection 4.3 of this Agreement. Any special shipment instructions given by BIOSANTE will be charged by PERMATEC to BIOSANTE at XXXXX;
  - (g) Financial costs: Any reasonable financial costs (consisting of working capital increase, inventory costs, leasing costs, letter of credit) related to the manufacturing and shipment of Products to BIOSANTE is to be charged at XXXXX to BIOSANTE.

- (2) Once determined, the price may only be adjusted in accordance with Article 3.2 of the Agreement.
- (3) (A) Notwithstanding the above terms of this Exhibit B, if Product or Products are Manufactured or Packaged by a third party Contract Manufacturer, the price charged BIOSANTE for all activities performed by the third party shall equal the amount invoiced for the Products to PERMATEC plus XXXXX% and shall reflect any credits, discounts, allowances or rebates given thereon. (B) When a Contract Manufacturer is utilized, to the extent that PERMATEC devotes personnel (other than administrative), e.g., QA/QC function to comply with its obligations under this Supply Agreement, PERMATEC may charge BIOSANTE for the cost of such activity related solely to BIOSANTE Products, at its actual cost plus XXXXX%.
- (4) PERMATEC shall use all commercially reasonable efforts to minimize all costs of the Products whether incurred by PERMATEC directly or by a Contract Manufacturer.
- (5) BIOSANTE shall use all commercially reasonable efforts to provide PERMATEC with timely and accurate forecasts and to inform PERMATEC about any material specifications changes as early as possible.

EXHIBIT C- FORM OF PERMATEC PURCHASE ORDER-  
TO BE PROVIDED BY PERMATEC UPON BIOSANTE REQUEST AND BEFORE THE  
FIRST COMMERCIAL ORDER

EXHIBIT D

List of Products

[PORTIONS OF THIS EXHIBIT D 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 INTACT HAS BEEN FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION.]

Gel E2 (where estradiol is the sole active ingredient, and where the gel is applied to the skin)

Gel Testosterone (where testosterone is the sole active ingredient and where the gel is applied to the skin)

Patch E2 (where estradiol is the sole active ingredient and where the patch is applied to the skin)

E2-XXXXX Combi Gel (where estradiol and XXXXX XXXXX are the two active ingredients and where the gel is applied to the skin)

Option regarding XXXXX Combi gel

XXXXX Combi Gel (where XXXXX and XXXXX are the two active ingredients and where the gel is applied to the skin)

[LOGO]

BIOSANTE PHARMACEUTICALS, INC.  
175 Olde Half Day Road  
Lincolnshire, Illinois 60069  
www.biosantepharma.com

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FOR IMMEDIATE RELEASE

BULLETIN BOARD: BTPH  
CANADIAN VENTURE EXCHANGE: BAI

BIOSANTE PHARMACEUTICALS, INC. ANNOUNCES IN-LICENSE  
OF FOUR HORMONE PRODUCTS FOR MEN'S AND WOMEN'S HEALTH

LINCOLNSHIRE, ILLINOIS, JUNE 13, 2000 - BioSante Pharmaceuticals, Inc. (OTCBB-BTPH; CDNX-BAI) today announced that it has signed an in-license agreement covering four hormone products for the treatment of testosterone deficiency in men and estrogen deficiency in women. The license agreement was signed with Permatec Technologies, AG of Switzerland.

"This agreement implements our in-licensing strategy which aims to build a robust product pipeline of late-stage innovative pharmaceutical products," said Stephen M. Simes, president and CEO of BioSante. "These products and their unique delivery systems are ideal candidates for this strategy - not only do they meet our in-licensing criteria, they also represent large market opportunities."

These products will address a variety of hormone deficiencies that affect both men and women. Symptoms of these hormone deficiencies include impotence, lack of sex drive, muscle weakness and osteoporosis in men and menopausal symptoms in women including hot flashes, vaginal atrophy, decreased libido and osteoporosis. The market for testosterone and estrogen products is well over a billion dollars in size in the U.S. alone, and that figure is expected to double over the next five years.

Three of the four new products licensed by BioSante are gel formulations of testosterone (the natural male hormone), estradiol (the natural female hormone) and a combination of estradiol and a progestogen (another female hormone). The gels are designed to be quickly absorbed through the skin after application on the arms, abdomen or thighs, delivering the required hormone to the bloodstream evenly and in a non-invasive, painless manner. The gels which should be applied once per day and will be absorbed into the skin without a trace of residue. The fourth product is an estradiol patch for application on the skin once per week with delivery of estradiol lasting seven days. BioSante expects to begin human clinical trials by the end of 2000, in order to obtain FDA approval to market as soon as possible.

LICENSE TERMS AND TERRITORY

Under terms of the license agreement signed with Permatec, BioSante acquired exclusive marketing rights, with the right to grant sub-licenses, to the three testosterone and estradiol products for all therapeutic indications in the U.S., Canada, Mexico, Israel, Australia, New Zealand, China, Malaysia, Indonesia and South Africa. BioSante acquired exclusive marketing rights, with the right to grant sub-licenses, for the combination estradiol and progestogen product in the U.S. and Canada. BioSante will make an upfront payment, expects to fund the development of the products, make milestone payments and once regulatory approval to market is received, pay royalties on sales of the products.

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ABOUT PERMATEC TECHNOLOGIE, AG

BioSante entered into the license agreement with Permateg Technologie, AG, a drug delivery company that specializes in developing transdermal systems and topical dermatological products. Permateg, a company of the Permateg Group of Muttentz (Basel), Switzerland, is a private company founded in 1995 by Dr. J. Gonella, who also was the founder of JAGO now known as SkyePharma (NASDAQ: SKYE). Permateg employs 15 people most of whom are research and development scientists involved in formulation and product development. Permateg has expertise in the formulation of patch and gel products and has granted a similar license to the estradiol/progestogen combination gel to a multi-national pharmaceutical company headquartered in Europe for marketing in other countries to which BioSante does not have the rights. Earlier this year Permateg announced its intention to merge with Medi-Ject Corporation (NASDAQ: MEDJ) of Minneapolis, Minnesota. According to Medi-Ject, it is the world's leading marketer of needle-free injectable drug delivery systems.

ABOUT BIOSANTE PHARMACEUTICALS, INC.

BioSante is an emerging pharmaceutical company, developing its nanoparticulate-based platform technology for novel vaccines, vaccine adjuvants and drug delivery systems. BioSante intends to grow through developing its platform technology and by in-licensing additional late-stage pharmaceuticals to expand its product portfolio.

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